

START

9513358.2464

0041595

PNL-MA-70

UC-900

PNL Administrative/Technical Procedures

Procedures for Quality Assurance Program

May 1995

Prepared for the U.S. Department of Energy
under Contract DE-AC06-76RLO 1830

Pacific Northwest Laboratory
Operated for the U.S. Department of Energy
by Battelle Memorial Institute



PNL-MA-70

THIS PAGE INTENTIONALLY
LEFT BLANK



PNL Administrative/Technical Procedures

**Procedures for Quality
Assurance Program**

J. E. McGarrah

May 1995

**Pacific Northwest Laboratory
Richland, Washington 99352**

DISCLAIMER

This document was prepared in support of Battelle's activities for the United States Government under Contract No. DE-AC06-76RLO 1830. Accordingly, neither the United States Government nor any agency thereof, nor Battelle Memorial Institute, nor any of their employees, makes **any warranty, expressed or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights.** Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government of any agency thereof, or Battelle Memorial Institute. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.

PACIFIC NORTHWEST LABORATORY
operated by
BATTELLE MEMORIAL INSTITUTE
for the
UNITED STATES DEPARTMENT OF ENERGY
under Contract DE-AC06-76RLO 1830

Printed in the United States of America

Available to DOE and DOE contractors from the
Office of Scientific and Technical Information, P.O. Box 62, Oak Ridge, TN 37831;
prices available from (615) 576-8401. FTS 626-8401.

Available to the public from the National Technical Information Service,
U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161.

NTIS Price Codes, Microfiche A01

Printed Copy

Price Code	Page Range	Price Code	Page Range
A02	1- 10	A15	326-350
A03	11- 50	A16	351-375
A04	51- 75	A17	376-400
A05	76-100	A18	401-425
A06	101-125	A19	426-450
A07	126-150	A20	451-475
A08	151-175	A21	476-500
A09	176-200	A22	501-525
A10	201-225	A23	526-550
A11	226-250	A24	551-575
A12	251-275	A25	576-600
A13	276-300	A99	601-Up
A14	301-325		

CONTROLLED DOCUMENT LIST
PNL-MA-70 PROCEDURES

February 10, 1995

DOCUMENT NUMBER	REV NUM	NO. OF ICNS ISSUED	TITLE	EFFECTIVE DATE
**CAP CAP-70-401	1	0	PREPARATION OF REQUEST FOR PROPOSALS AND AWARD OF CONTRACTS/AGREEMENTS	08/31/94
CAP-70-701	1	0	PROPOSAL EVALUATION, SUPPLIER/SUBCONTRACTOR SELECTION, AND CONTRACT/AGREEMENT ADMINISTRATION (POST AWARD)	08/31/94
**PAP PAP-70-101	1	0	COMMUNICATION AND COMMITMENT (INTER-FACE) CONTROL	08/31/94
PAP-70-201	3	0	INDOCTRINATION AND TRAINING	08/31/94
PAP-70-203	3	0	QUALIFICATION AND CERTIFICATION OF INSPECTION AND TEST PERSONNEL	08/31/94
PAP-70-205	3	0	QUALITY ASSURANCE PLANS	08/31/94
PAP-70-206	1	1	CONTROLLING WORK RECEIVED FROM HANFORD CONTRACTORS	08/31/94
PAP-70-207	0	0	QUALITY PROGRAM REQUIREMENTS FOR SAFETY CLASS SYSTEMS, STRUCTURES, AND COMPONENTS	08/31/94
PAP-70-208	3	0	IMPACT LEVELS	08/31/94
PAP-70-301	1	0	HAND CALCULATIONS, GENERAL	08/31/94
PAP-70-302	3	0	ASSURANCE AND CONTROL OF ENGINEERING DESIGN	08/31/94
PAP-70-401	2	0	PURCHASE REQUISITIONS	08/31/94
PAP-70-402	1	0	CONTROL OF SUSPECT/COUNTERFEIT ITEMS	08/31/94
PAP-70-404	2	0	OBTAINING SERVICES	08/31/94
PAP-70-501	3	0	PREPARATION AND APPROVAL OF ADMINISTRATIVE PROCEDURES	08/31/94
PAP-70-601	3	0	DOCUMENT CONTROL	08/31/94

DOCUMENT NUMBER	REV NUM	NO. OF ICNS ISSUED	TITLE	EFFECTIVE DATE
PAP-70-602	3	0	PROCEDURE AND INSTRUCTION CHANGE CONTROL AND CHANGE REQUEST	08/31/94
PAP-70-604	1	0	INDEPENDENT TECHNICAL REVIEW	08/31/94
PAP-70-605	1	0	DOCUMENT CONTROL - FURNISHED DOCUMENTS	08/31/94
PAP-70-606	1	0	PEER REVIEW	08/31/94
PAP-70-702	3	0	PREPARATION AND USE OF INSPECTION/TEST INSTRUCTIONS	08/31/94
PAP-70-704	3	0	SOURCE INSPECTIONS, TESTS, AND SURVEILLANCES	08/31/94
PAP-70-706	4	0	RECEIVING INSPECTION	08/31/94
PAP-70-801	2	0	IDENTIFICATION AND CONTROL OF TEST MATERIALS (TESTING AND ANALYSIS)	08/31/94
PAP-70-803	2	0	ITEM IDENTIFICATION AND CONTROL	08/31/94
PAP-70-901	1	0	CONTROL OF PROCESSES	08/31/94
PAP-70-902	1	0	CONTROL OF SPECIAL PROCESSES	08/31/94
PAP-70-1001	2	0	INDEPENDENT INSPECTION	08/31/94
PAP-70-1101	1	0	TEST PLANNING, PERFORMANCE, AND EVALUATION	08/31/94
PAP-70-1201	3	1	CALIBRATION CONTROL SYSTEM	08/31/94
PAP-70-1202	1	0	CALIBRATION CONTROL SYSTEM FOR RADIATION DETECTION EQUIPMENT	02/10/95
PAP-70-1301	2	0	HANDLING, STORAGE, AND SHIPPING	08/31/94
PAP-70-1401	2	0	INSPECTION AND TESTING STATUS AND TAGGING	08/31/94
PAP-70-1501	2	0	NONCONFORMANCE REPORTS	08/31/94
PAP-70-1502	2	0	DEFICIENCY REPORTS	08/31/94
PAP-70-1602	2	0	CORRECTIVE ACTION	08/31/94
PAP-70-1701	4	0	RECORDS SYSTEM	08/31/94

9513358.2467

DOCUMENT NUMBER	REV NUM	NO. OF ICNS ISSUED	TITLE	EFFECTIVE DATE
**SCP SCP-70-312	3	0	DETERMINATION OF SOFTWARE REQUIREMENTS	08/31/94
SCP-70-313	1	0	FINAL INTERNAL DEVELOPMENT REVIEW OF SOFTWARE AND DOCUMENTATION	08/31/94
SCP-70-314	2	0	SOFTWARE CONFIGURATION MANAGEMENT	08/31/94
SCP-70-315	1	0	CONVERSION TESTING, VERIFICATION, AND/OR VALIDATION OF SOFTWARE	08/31/94
SCP-70-316	2	0	SOFTWARE APPLICATION CONTROL	08/31/94
SCP-70-317	1	0	TRANSFER OF SOFTWARE, DATA, AND/OR DOCUMENTATION	08/31/94
SCP-70-318	1	0	CONTROL OF DATABASES	08/31/94

John M. Sarral

Documentation Systems Department Manager

1/20/95

Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

CONTRACTS ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: CAP-70-401

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 5

TITLE: CAP-70-401, PREPARATION OF REQUEST FOR PROPOSALS AND AWARD OF CONTRACTS/AGREEMENTS

PURPOSE

Describe uniform methods for the processing of approved purchase requisitions (PRs), preparation and control of request for proposals (RFPs), and award of purchase orders (POs), subcontracts, interlaboratory authorizations (ILAs), and memorandum purchase orders (MPOs).

APPLICABILITY

This procedure applies to the processing of all approved PRs, RFPs, and award of POs, subcontracts, ILAs, and MPOs.

Procedures applicable to other phases of the procurement process are covered under CAP-70-701, Proposal Evaluation, Supplier/Subcontractor Selection, and Purchase Order/Subcontract Administration (Post Award).

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Contract Assistant
- Contract Specialist
- Procurement Section Manager
- Requisition Control Clerk (RCC)
- Subcontract Section Manager.

DEFINITIONS

Contract - A mutual agreement between two parties where offer and acceptance have resulted from a Request for Proposal issued from the PNL Contract Specialist.

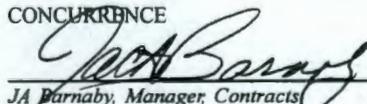
Contract Assistant - An employee of Battelle-Northwest who provides clerical and administrative assistance to Contract Specialists.

Contract Specialist - An employee of Battelle-Northwest who issues RFPs and negotiates and executes contracts and agreements that are within the limits of a written delegation of authority from the Director, PNL. This definition includes PNL Buyers/Subcontract Specialists.

Interlaboratory Authorization (ILA) - An agreement for the acquisition of materials or services from other Battelle components. (ILAs are not contracts.)

CONCURRENCE

DATE


JA Barnaby, Manager, Contracts 6/16/94

APPROVAL AUTHORITY

DATE


GH Cunningham, Director, Legal and Contracts 6/20/94

PREPARED BY

DATE


KE Harrison 6/16/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


JE McGarrah, Manager 6/20/94

CONTRACTS ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: CAP-70-401

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 2 OF 5

Memorandum Purchase Order (MPO) - An agreement for the delivery of material and/or the performance of services by a DOE integrated cost-reimbursement contractor not located at the Hanford site. (MPOs are not contracts.)

Quality Programs (QP) - The Quality Programs Directorate, consisting of the Documentation Systems Department, Process Quality Department, Quality Planning and Assessment Department, and support staff for continuous improvement.

Request for Proposal - A solicitation document issued to prospective offerors.

Requisition Control Clerk (RCC) - An employee of Battelle-Northwest who receives and screens all PRs.

Standard Quality Assurance Clauses - The contract clauses, RFP provisions and notes contained in PNL Administrative Procedure PAP-70-401, Purchase Requisitions.

Statement of Work (SOW) - The technical requirements which may include drawings, specifications, QA requirements, item description, etc., on the PR/RFP.

Technical Administrator - The individual technically knowledgeable in the requirements for the items or services requested who is responsible for overseeing the technical aspects of the contract.

IMPLEMENTATION

1.0 Processing of Approved PRs

1.1 The Requisition Control Clerk (RCC) shall receive and screen PRs to ensure that:

- an Impact Level (I, II, or III) or a Safety Class or Non-Safety Class has been specified
- the PR contains a dated QP Representative signature when Impact Level I or II or Safety Class is specified or Impact Level III or Non-Safety Class and QA requirements are specified.

1.2 Written PRs not specifying an impact level, safety classification, or, when required, a dated QP Representative signature, shall be returned by the RCC to the Technical Administrator.

1.3 Each PR package shall show evidence of RCC screening.

1.4 The Contract Specialist shall review each PR to ensure that all drawings, specifications, and/or statements of work, and any revisions thereto, are accurately specified in the PR.

1.5 The Contract Specialist shall resolve with the Technical Administrator any inconsistencies or ambiguities found in the PR package. The Contract Specialist shall not proceed with RFP preparation until the Technical Administrator has resolved, with the organizations affected, any inconsistencies or ambiguities.

2.0 Preparation and Control of RFPs

2.1 Request For Proposals

2.1.1 The Contract Specialist shall prepare a written RFP (may be sent via FAX) when the PR indicates that QA requirements apply. Such RFP shall specify accurately the technical and QA requirements of the PR, original or amended. A written RFP is not required when: (1) the PR specifies PAP-70-401 Standard Quality Assurance notes to the Contract Specialist, (2) contract

CONTRACTS ADMINISTRATIVE PROCEDURE

clauses requiring delivery of only seller As-built drawings, reports or certifications (the QA requirements shall be transmitted, e.g., FAX), or (3) the Contract Specialist selects an offeror that is being considered for analytical or calibration services and is on a current Process Quality Department Evaluated Supplier's Listing noting the same quality assurance program referenced on the PR with similar **analytical** or **calibration** services to those being requested. The Contract Specialist shall obtain the offeror's current QA Manual/Plan revision number and advise the Procurement Quality Assurance Administrator (PQA Administrator).

2.1.2 A Procurement or Subcontracts Section Manager shall ensure that RFPs containing QA requirements have been independently reviewed for accurate transfer of technical and QA requirements from the PR to the RFP.

2.1.3 When issuing RFPs, the Contract Assistant shall send a copy of RFPs containing QA requirements to the PQA Administrator.

2.2 Evaluation Criteria

When an RFP containing QA requirements specifies an evaluation criteria that is not limited to price, such evaluation criteria shall expressly exclude QA requirements.

3.0 Changes

3.1 If a change to the Statement of Work (SOW) or QA requirements of an RFP is made before the proposal due date, the Contract Specialist shall:

- obtain and process an authorizing document fully approved by the affected organizations
- obtain an independent review of the RFP change in the same manner as the original document.

3.2 If a change to correct a clerical error in an original RFP SOW or QA requirements is made before the proposal due date, no additional authorizing document or review is required.

3.3 The Contract Specialist shall obtain: (1) review of changes to the SOW or QA requirements specified in an RFP after initial proposals have been received by the Technical Administrator and QP Representative; (2) review of changes to Standard Quality Assurance Clauses by the Legal Office and Lead Procurement Quality Engineer (Lead PQE).

4.0 Contract Preparation

4.1 After agreement with an offeror has been reached, and after receiving a document from the PQA Administrator for the offeror having an acceptable QA program/practice (e.g., QA Clauses 160/168), the Contract Specialist shall prepare a contract containing all technical and QA requirements specified by the PR or resulting from contract negotiations.

4.2 Upon completion of the contract document, the Contract Assistant shall ensure that contracts containing QA requirements have been reviewed to ensure that all technical and QA requirements specified by the PR or resulting from contract negotiations are accurately specified in the contract. The Contract Specialist shall sign the contract attesting that technical and QA requirements have been accurately specified.

4.3 When distributing contracts, the Contract Assistant shall send a copy of the contracts containing QA requirements to the PQA Administrator.

5.0 Preparation and Issuance of ILAs, and MPOs

CONTRACTS ADMINISTRATIVE PROCEDURE

- 5.1 Once the technical and cost estimate has been received from the Battelle component for ILAs or the DOE integrated contractor for MPOs, the Contract Specialist shall prepare the ILA or MPO. QA requirements, if any, shall be specified. Standard Quality Assurance clauses shall be modified, as appropriate, and modified wording for Standard QA Clauses 160 and 140a are as follows:

PREAWARD SURVEY BEFORE WORK AUTHORIZATION

When deemed necessary by Battelle, a preaward survey will be conducted of the Agency's production, laboratory, and/or quality assurance capabilities. Evaluation of documented quality assurance program(s)/system(s) applicable to materials to be produced or services to be performed by the agency or its subcontractor(s) may include but shall not be limited to inspection/test controls, software controls, calibration of measuring and test equipment, special process controls, material storage and handling, drawing change controls, and analytical QA/QC controls.

SUBMITTAL(S) REQUIRED BEFORE WORK AUTHORIZATION

The Agency shall submit, prior to any Preaward Survey, a complete description of its quality program/system. Such description may consist of a copy of the Agency's approved QA/QC Manual, a QA/QC plan, or a combination thereof, and shall specify the standard(s) upon which the system is based. Alternately, if a QA/QC manual/plan has been previously submitted, the Agency may, (provided its manual/plan has not since been revised), specify in its proposal the date and/or revision of its current QA/QC manual/plan.

In addition to the above, the Agency shall submit (1) a signed document attesting that the proposed SOW/QA requirements document has been reviewed by the Agency's Quality Assurance Representative and (2) a listing of client's names and QA representative's phone numbers who have evaluated its quality assurance program/plan within the past two years.

- 5.2 If a change to the (SOW) or QA requirements of an ILA or MPO is made before issuance, the Contract Specialist shall obtain and process an authorizing document fully approved by the affected organizations.
- 5.3 When distributing signed ILAs or MPOs, the Contract Assistant shall send a copy of ILAs, or MPOs containing QA requirements to the PQA Administrator.
- 5.4 The Contract Specialist shall withhold issuance of an ILA or MPO until receipt of a written or cc:Mail evaluation (QA Clause 160) of the agency's QA program and/or special process capabilities from a PQA Administrator.

6.0 PNL Receiving Inspection

- 6.1 When the PR specifies that receiving inspection is to be performed by a Process Quality Representative, the Contract Specialist shall ensure that the items being procured and the required accompanying documentation are routed to the Process Quality inspection facility or other specifically designated inspection location. NOTE: The requirement for PNL independent receiving inspection will usually be indicated on the PR with a check in the "QC" and "REC" boxes under the "INSPECTION BY:" heading at the bottom of the PR form; however, this requirement may also be transmitted by separate memo or other means.
- 6.2 All material or items shall be considered to be in a "HOLD" condition until receiving Inspection is completed per the requirements specified in PAP-70-706, Receiving Inspection. These materials or items may not be used until the receiving inspection is complete.

CONTRACTS ADMINISTRATIVE PROCEDURE

7515558.270

PROCEDURE NO.: CAP-70-401

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 5 OF 5

REQUIRED RECORDS

None. (Documents mentioned in this procedure that are required records are identified as such in other procedures).

**THIS PAGE INTENTIONALLY
LEFT BLANK**

CONTRACTS ADMINISTRATIVE PROCEDURE

9515998-2471

PROCEDURE NO.: CAP-70-701

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: CAP-70-701, PROPOSAL EVALUATION, SUPPLIER/SUBCONTRACTOR SELECTION, AND CONTRACT/AGREEMENT ADMINISTRATION (POST AWARD)

PURPOSE

Describe the methods to ensure that quality assurance requirements are properly addressed by offerors, evaluated by Battelle, and included in contracts such that satisfactory administration leads to complete performance of work.

APPLICABILITY

This procedure applies to proposals resulting from requests for proposals (RFPs) containing quality assurance requirements and to changes in the technical or quality assurance requirements of a contract/agreement.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Contract Specialist
- Source Selection Official.

DEFINITIONS

Contract - A mutual agreement between two parties where offer and acceptance have resulted from a Request for Proposal issued from the PNL Contract Specialist.

Contract Specialist - An employee of Battelle-Northwest who issues RFPs and negotiates and executes contracts and agreements that are within the limits of a written delegation of authority from the Director, PNL. This definition includes PNL Buyers/Subcontract Specialists.

Formal Source Selection - Proposal evaluation by an appointed group who recommends, to a source selection official at a management level above that of Contract Specialist, the selection of a source for contract award.

Informal Source Selection - Proposal evaluation and source selection by a Contract Specialist, if authorized to execute the contract(s). If a Contract Specialist is not authorized to execute the contract, proposal evaluation and source selection is made by a person who is so authorized.

Interlaboratory Authorization (ILA) - An agreement for the acquisition of materials or services from other Battelle components. (ILAs are not contracts.)

Memorandum Purchase Order (MPO) - An agreement for the delivery of material and/or the performance of services by a DOE integrated cost-reimbursement contractor not located at the Hanford site. (MPOs are not contracts.)

CONCURRENCE

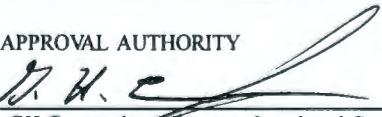
DATE


JA Barnaby, Manager, Contracts

6/16/94

APPROVAL AUTHORITY

DATE


GH Cunningham, Director, Legal and Contracts

6/23/94

PREPARED BY

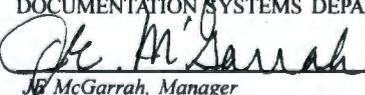
DATE


KE Harrison

6/16/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


JM McGarrah, Manager

6/20/94

CONTRACTS ADMINISTRATIVE PROCEDURE

Quality Programs (QP) - The Quality Programs Directorate, consisting of the Documentation Systems Department, Process Quality Department, Quality Planning and Assessment, and support staff for continuous improvement Development Program.

Request for Proposal - A solicitation document issued to prospective offerors.

Technical Administrator - The individual technically knowledgeable in the requirements for the items or services requested who is responsible for overseeing the technical aspects of the contract.

IMPLEMENTATION

1.0 Informal Source Selection

1.1 Selection Based on Price Only

- 1.1.1 When required by the Purchase Requisition (PR) or when it is not clear that all proposals conform to the technical requirements of the RFP, the Contract Specialist shall send a copy of the technical portion of timely proposals resulting from RFPs containing Quality Assurance (QA) requirements to the technical administrator for a written evaluation.
- 1.1.2 After selection of prospective contractor(s) has been made, the Contract Specialist shall send a copy of the QA submittals of each prospective contractor to the Procurement Quality Assurance (PQA) Administrator for a written evaluation of the prospective contractor's quality program and/or special process capabilities.
- 1.1.3 The Contract Specialist shall obtain from each prospective contractor any additional information requested by the PQA Administrator.
- 1.1.4 When an onsite preaward survey is required, the Contract Specialist shall coordinate the necessary arrangements.
- 1.1.5 The Contract Specialist shall withhold award until the written or cc:Mail evaluation (QA Clause 160) of each prospective contractor's quality program and/or special process capabilities has been received from the PQA Administrator.

1.2 Selection Based on Price and Other Factors

- 1.2.1 The Contract Specialist shall send a copy of timely proposals resulting from RFPs containing QA requirements to the technical administrator for a written evaluation in accordance with the factors specified in the RFP.
 - 1.2.2 After selection of prospective contractor(s) has been made, the Contract Specialist shall send a copy of the QA submittals of each selected prospective contractor to the PQA Administrator for a written evaluation of the prospective contractor's quality program and/or special process capabilities.
 - 1.2.3 The Contract Specialist shall obtain from each selected prospective contractor any additional information requested by the PQA Administrator.
 - 1.2.4 When an onsite preaward survey is required, the Contract Specialist shall coordinate the necessary arrangements.
-

CONTRACTS ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: CAP-70-701

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

1.2.5 The Contract Specialist shall withhold award until the written or cc:Mail evaluation (QA Clause 160) of each prospective contractor's quality program and/or special process capabilities has been received from the PQA Administrator.

2.0 Formal Source Selection

- 2.1 The Contract Specialist shall send a copy of timely proposals resulting from RFPs containing QA requirements to the evaluation group for a written evaluation in accordance with the factors specified in the RFP.
- 2.2 After receipt of the evaluation group's recommendations, the Contract Specialist shall send a copy of the QA submittals of each offeror recommended for selection to the PQA Administrator for a written evaluation (QA Clause 160) of the prospective contractor's quality program and/or special process capabilities.
- 2.3 The Source Selection Official shall obtain from each of the recommended offerors any additional information requested by the PQA Administrator.
- 2.4 When an onsite preaward survey is required, the Contract Specialist shall coordinate the necessary arrangements.
- 2.5 The Contract Specialist shall withhold award until the written or cc:Mail evaluation (QA Clause 160) of each prospective contractor's quality program and/or special process capabilities has been received from the PQA Administrator.

3.0 Contract/Agreement Administration

- 3.1 The Contract Specialist shall interface with contractors to ensure receipt of deliverable QA documentation. The Contract Specialist shall transmit the originals or reproducible copies of all QA documentation to the PQA Administrator for review.
- 3.2 If specified by the contract/agreement, the Contract Specialist shall not provide final invoice approval until all deliverable QA documentation has been delivered and accepted/approved.
- 3.3 When source surveillances, audits of suppliers with ongoing contracts, source inspections, or source reviews are to be performed, the Contract Specialist shall coordinate the necessary arrangements and contact the PQA Administrator accordingly.
- 3.4 When a Contract Specialist receives a copy of a nonconformance report (NCR), appropriate action shall be taken.
- 3.5 If a change is made to the technical or QA requirements of a contract/agreement, the Contract Specialist shall obtain and process an authorizing document fully approved by the affected organizations.
- 3.6 If a change is made to correct a clerical error in a statement of work or QA requirement, no additional authorizing document or review is required.

REQUIRED RECORDS

None. (Documents mentioned in this procedure that are required records are identified as such in other procedures).

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-101

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: PAP-70-101, COMMUNICATION AND COMMITMENT (INTERFACE) CONTROL

PURPOSE

Define the lines of communications between PNL and its clients to ensure that these communications are controlled and documented in accordance with Battelle policy and the requirements of the client agreement.

APPLICABILITY

This procedure applies to both written and oral communications on technical and quality assurance matters between PNL and its clients. It also applies to commitments made by PNL to its clients, and vice versa.

This procedure applies to both multi-project programs and to single projects or activities. When this procedure is used on a single 1830 project, those requirements described for the Program Manager are the responsibility of the Cognizant Manager.

Communications with PNL suppliers and Hanford Contractors are described and controlled through the procurement document control series of procedures (PAPs 70-401 through 70-404, and CAPs 70-401 and 70-701) and through the series for control of purchased items and services (PAPs 70-702 through 70-706).

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Contract Associate
- Cognizant Manager
- Contract Administrator
- Program Manager.

IMPLEMENTATION

1.0 The Cognizant Manager shall identify those items in contracts, contract modifications, correspondence or other documents to be transmitted to the client that either establish new commitments to the client or satisfy previous ones. For Impact Level I projects or Safety Class systems, structures, and components (SSCs), these commitments shall be registered in a Commitment Control Log (EXHIBIT 1) or in a computer data base that provides the same information as EXHIBIT 1. The commitment Control Log may also be used to register commitments by the client to PNL.

For Impact Level II projects, the commitments shall be documented and tracked, but use of the Commitment Control Log is not required.

1.1 The Cognizant Manager shall ensure that all communications between PNL and clients are controlled and documented in accordance with Battelle policy and the requirements of the client agreement.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE


RL Shaub

6/16/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

-
- 1.2 The Cognizant Manager shall ensure that project files contain documentation sufficient to constitute a full history and permit ready reconstruction of all actions for the purpose of:
- providing a complete background to ensure informed decisions at each step
 - providing information for reviews/audits
 - furnishing essential facts in the event of inquiries/challenges by third parties (government agencies/auditors, litigation, etc.).
- 1.3 The Cognizant Manager shall ensure that no 1830 work or 1831 Government or Industrial contract work is performed prior to the issue of an approved work authorization.
- 1.4 The Cognizant Manager shall:
- for 1830 Programmatic/Related Services, ensure that all commitments created subsequent to work authorization issue are documented before activity is initiated to execute the commitment.
 - for 1830 Work for Non-Federal Entities, ensure that no work in addition to or different from that specified in the client agreement is performed prior to the modification of the client agreement in accordance with the requirements of such agreement.
 - for 1831 Government and Industrial Contracts, ensure that no work in addition to or different from that specified in the client contract is performed prior to the modification of the client contract in accordance with the requirements of such agreement.
- 1.5 The Cognizant Manager shall provide to the Cognizant Program Manager all documentation required to be delivered to the client.
- 2.0 The Program Manager shall obtain all required technical and quality assurance reviews/approvals of the deliverable documentation.
- 2.1 The Program Manager shall ensure that any noneditorial changes made to documentation to be delivered to the client after the completion of initial technical and quality assurance review/approvals are resubmitted to the affected organizations.
- 2.2 The Program Manager shall provide a reproducible copy of the documentation delivered to the client, as finally approved, to the Cognizant Manager for processing as a project record.
- 3.0 The Program Manager shall periodically, but not less frequently than monthly, review the status of commitments to the clients and take action as required. He/she shall also review the status of actions required of the client (approvals, clearances, authorizations) and
- for 1830 Programmatic/Related Services, take action as necessary
 - for 1831 Work for Non-Federal Entities, notify the contract Services Contract Administrator of any problems
 - for 1831 Government and Industrial contracts, notify the Cognizant Contract Associate of any problems.
- 4.0 When notified of problems by a Program Manager, the Cognizant Contract Associate for 1830 Work for Non-Federal Entities, or for 1831 Government and Industrial Contracts, shall take any necessary action, notify the Program Manager of the action and provide appropriate records for the project files.
-

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-101

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- Commitment Control Log
 - all documentation delivered to a client.
-

**THIS PAGE INTENTIONALLY
LEFT BLANK**

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-201

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 7

TITLE: PAP-70-201, INDOCTRINATION AND TRAINING

PURPOSE

Provide a uniform method for identifying, performing, and documenting the required indoctrination and training of PNL staff. Indoctrination and training are required to ensure that PNL staff members achieve and maintain technical and quality assurance level of knowledge needed to accomplish assigned work.

APPLICABILITY

This procedure applies to the training of all staff members who perform or manage activities that affect the quality of work at PNL. Indoctrination and training needs are determined and initiated when:

- a new project or activity begins (evaluate annually thereafter)
- new personnel are assigned to the project or activity
- there is a significant change in the project or activity; e.g., scope of work, quality assurance requirements, etc.
- the responsible manager determines that training should be performed, documented, and entered into the staff member's training file
- training is specified by PNL clients.

Additional qualification requirements for inspection, test, and non-destructive testing personnel and QA Lead Auditors and auditors are provided in PAP-70-203, Qualification and Certification of Inspection and Test Personnel, and PNL-MA-531, Quality Programs Instructions.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Instructor
- Line, Service Activity, or Project Manager (i.e., Responsible Manager)
- Trainee.

DEFINITIONS

Briefing - An informal overview of a topic rather than detailed instruction; e.g., a modification of a procedure with which the trainees are familiar.

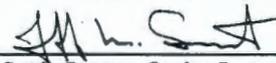
CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

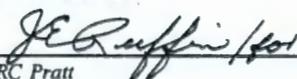
DATE


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE


RC Pratt

6/20/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-201

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 2 OF 7

Core Business Training - Applicable to an employee's customary work activity(s); normally this training is a function of line management to provide.

Formal Classroom Training - Training presented by an instructor in accordance with an approved lesson plan, relying primarily on a lecture format, with little or no "hands-on" involvement by the trainees.

Generic Training - Training required of all PNL employees which is independent of the work assignment or job title of the employee.

Group Training Documentation Form - A form to identify and document training of one or more subjects to a group of individuals, using any of the four training methods (EXHIBIT 2).

Individual Training Assignment Form - A form to document assignment and completion of required training of one or more subjects for an individual, using any of the four training methods (EXHIBIT 1).

On-the-Job Training (OJT) - Training through performance of a specific job function under the supervision of an instructor or mentor who is familiar with the job, in accordance with an approved OJT plan (EXHIBIT 3).

Project-Specific Training - Training apart from an employee's core business activity(s) that is related to a specific piece of work (project/activity).

Qualifications - The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function (ASME NQA-1).

Reading Assignments - A training method utilizing reading/study of the current and subsequent revision(s) of applicable codes, standards, technical procedures, administrative procedures, etc.

GENERAL

The Laboratory Training Coordinator (LTC) maintains a centralized training records system. These records are maintained for the purpose of providing responsible managers with information on current and prior training of staff members.

The LTC also supports responsible managers in identifying the need for retraining by:

- preparing a report identifying individual staff members requiring retraining, when requested by management
- forwarding the report to responsible managers for scheduling attendance at the next available training session
- issuing a schedule of formal training offered at PNL.

The LTC maintains a master file of the approved lesson plans, the PNL Training Course Catalog, the PNL Training Questionnaire, and associated training records including the Laboratory Training Database System. In order to keep this information current, the LTC:

- assigns course codes and revision numbers to lesson plans
- reviews lesson plans for completeness, e.g., retrain cycle, references, audience, objectives, description
- checks for duplication of lesson plan content
- supersedes and cancels lesson plans as required.

The LTC is available to:

- assist in course development
- discuss and recommend appropriate training methods
- provide guidance on revision and update of lesson plans.

IMPLEMENTATION

1.0 Evaluation and Documentation of Education, Previous Experience, and Competency

1.1 Prior to allowing staff members to perform activities affecting quality, the Line Manager shall obtain documentation showing that staff members have the appropriate education and experience for the work they are to perform. Documentation shall provide the following information:

- education completed (e.g., degree and major)
- work experience (employer and major responsibilities)
- licenses and certifications
- related training and qualifications
- applicable dates associated with the above information.

NOTE: Much of the information may be documented in a current resume. All such documentation must be maintained in non-sensitive files (i.e., separate from personnel or business sensitive files) and be available for review.

1.2 The Line Manager shall provide documented (e.g., memo to file or on the job training documentation) evidence that personnel operating equipment and systems that could affect the safety of operations (e.g., hot cell operations or hazardous material containment systems) have demonstrated their capability to correctly and safely operate the equipment and systems.

1.3 The Line Manager shall ensure that documentation referenced in paragraphs 1.1 and 1.2 is maintained in non-sensitive files and is readily retrievable. Copies of all training assignment and attendance forms shall be forwarded to the LTC. Copies should be retained by the Line Manager if required by a client or at the manager's discretion. Other competency documentation (e.g., current resumes, certifications, memos to file, qualification records) shall be maintained by the Line Manager in staff files.

2.0 Training Categories

2.1 Generic Training: Generic training is non-job specific and is mandated by regulation, DOE directive, or overall PNL management policy. It applies to everyone at PNL, regardless of the work they do. Examples of this kind of training are:

- New Hire Orientation
- Lab Safety and Security Indoctrination
- Portable Fire Extinguisher Use.

See note in 2.2.

2.2 Core Business Training: Core business training is job specific and is mandated by regulation, DOE Directive or overall PNL management policy. It applies to everyone at PNL who customarily performs a specific job or activity. Examples of this kind of training are:

- Radiation Protection
- Lead Auditor Certification
- 40 Hour Hazardous Material Worker Training.

NOTE: Generic and Core Business Training assignments are documented using the PNL Training Questionnaire which is maintained and available through the LTC in the Human Resources Directorate.

2.3 Project Specific Training: Project specific training applies to those kinds of activities required by a particular piece of work or project. Normally, the work is of a known duration, and falls outside the staff member's customary (core) business activities. Examples of this kind of training are:

PNL ADMINISTRATIVE PROCEDURE

- Quality Assurance Plans
- Project Management Plans
- Technical or Administrative Procedures.

NOTE: Training responsibilities between line management and project management will vary, according to specific demands of the project and their relationship to the core business training requirements of staff assigned to the project.

3.0 Identification and Assignment of Training

3.1 The Line or Service Activity Manager shall:

- ensure personnel are qualified, indoctrinated, and trained prior to and commensurate with the work to be performed
- review each staff member's previous training records at time of hire and at a minimum, annually thereafter
- identify all generic training required for new personnel, and retraining needs for existing personnel
- identify all required training or retraining applicable to each staff member's assigned work activities (i.e., core business) using the PNL Training Questionnaire available from the LTC
- assign identified generic and core business training using the PNL Training Questionnaire available from the LTC. Additional training deemed appropriate may be assigned by preparing an Individual Training Assignment Form (EXHIBIT 1) for each staff member, or a Group Training Documentation Form (EXHIBIT 2), as appropriate
- verify that the trainee has an understanding of the training substance or material commensurate with the work to be performed
- ensure that personnel who need further training for a particular job perform work only with qualified supervision until training is completed
- assign new training or retraining as required training materials are revised or the nature/scope of work changes
- forward completed training records (originals or reproducible copies) to the LTC
- retain copies in staff files, if desired.

NOTE: Assignment and completion of training may be documented on forms equivalent to those included in this procedure.

Alert staff that trainees who receive required training external to PNL are responsible to provide their manager with copies of documentation (e.g., certificates) verifying satisfactory completion of the course.

3.2 The Project Manager shall:

- verify each staff member's training is commensurate with the work to be performed
 - identify any required training that is project specific
 - assign project-specific training identified by preparing an Individual Training Assignment Form (EXHIBIT 1) for each staff member or a Group Training Documentation Form (EXHIBIT 2), as appropriate
-

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-201

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 5 OF 7

- verify that the trainee has an understanding of the training substance or material commensurate to the applicable work
- assign retraining or new training as applicable training materials/requirements are revised or the nature/scope of work changes
- forward completed training records (originals or reproducible copies) to the LTC
- retain copies in project files if required by client, or if desired.

NOTE: Assignment and completion of training may be documented on forms equivalent to those included in this procedure.

Alert staff that trainees who receive required training external to PNL are responsible to provide their manager and the LTC with copies of documentation (e.g., certificates) verifying satisfactory completion of the course.

4.0 Formal Classroom Training

4.1 Application: Formal classroom training is appropriate when:

- large amounts of detailed information must be presented
- feedback in the form of discussion or examination is desired
- the material is complex and unfamiliar to the trainees.

4.2 Responsibilities: The Responsible Manager or Instructor shall:

- use as-is or modify an existing lesson plan on file with the LTC, if available, in accordance with the training, or
- develop an original lesson plan in accordance with the training (forms available from LTC)
- obtain all required approval/concurrence signatures for the lesson plan, as necessary
- coordinate with the LTC to schedule training, if appropriate (e.g., presentation of classes required by a significant number of PNL staff)
- present training in accordance with the lesson plan
- document all training sessions on a Group Training Documentation Form (EXHIBIT 2) or an alternative form which contains all required information
- forward all completed training records (originals or reproducible copies), including a copy of the lesson plan used, to the LTC
- retain a copy of all lesson plans and other training records in staff files, if required by a client, or if desired.

NOTE: Guidelines for lesson plan preparation are available from the LTC.

5.0 On-the-Job Training

5.1 Application: On-the Job Training (OJT) is appropriate when:

- The trainee is required to demonstrate proficiency in a process or skill.

PNL ADMINISTRATIVE PROCEDURE

- Supervised experience or mentoring is necessary prior to allowing the individual to work independently; e.g., training which concerns the use of specialized test equipment.

5.2 Responsibilities: The Responsible Manager or Instructor/Mentor shall:

- use as-is or modify an existing OJT Plan on file with the LTC, if available, in accordance with the training, or
- develop an original OJT Plan in accordance with the training (see EXHIBIT 3 for guidelines)
- obtain all approval/concurrence signatures required on the OJT Plan (see EXHIBIT 3)
- conduct training in accordance with the OJT Plan
- document the training on an Individual Training Assignment Form (EXHIBIT 1), a Group Training Documentation Form (EXHIBIT 2), or an alternative form which contains all required information
- forward all completed training records (originals or reproducible copies), including the OJT Plan, to the LTC
- retain a copy of all OJT Plans and other training records in staff files, if required by a client, or if desired.

6.0 Briefing Sessions

6.1 Application: Briefing sessions are appropriate when:

- Training is meant to be an overview of a topic rather than detailed instruction.
- Training is to an Interim Change Notice or a revision of a procedure with which the trainees are familiar.
- The amount of material to be presented is not large or complex in nature, but does require instructor input to ensure that the trainees adequately understand the subject.

6.2 Responsibilities: The Responsible Manager or Instructor shall:

- document all briefing sessions on an Individual Training Assignment Form (EXHIBIT 1), a Group Training Documentation Form (EXHIBIT 2), or an alternative form which contains all required information
- forward all completed training records (originals or reproducible copies) to the LTC
- retain a copy of all training records in staff files, if required by a client, or if desired.

7.0 Reading Assignments

7.1 Application: Reading assignments are appropriate when:

- the topic is adequately addressed in a document
- no instructor input is required to clarify the material
- the trainee is familiar with the basic concepts presented.

7.2 Responsibilities: The Responsible Manager shall:

- document all reading assignments on an Individual Training Assignment Form (EXHIBIT 1), a Group Training Documentation Form (EXHIBIT 2), or an alternative form which contains all required information
-

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-201

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 7 OF 7

- forward all completed training records (originals or reproducible copies) to the LTC
- retain a copy of all lesson plans and other training records in staff files, if required by a client, or if desired.

8.0 Personnel Certification

- 8.1 Whenever personnel certification is required (e.g., Lead Auditors and Inspectors), an examination shall be developed to evaluate the employee's comprehension of and the ability to apply the body of knowledge presented in the training.
- 8.2 The requirement for an examination shall be specified in the administrative procedure developed for and applicable to a specific discipline or skill.
- 8.3 If the responsible manager or instructor desires feedback on the adequacy of the training, Training Assessment Forms are available from the LTC.

9.0 Training Waivers

- 9.1 Formal training may be waived in specific areas where the staff member has an acceptable level of proficiency based on previous experience or training, as determined by the Responsible Manager.
- 9.2 The Responsible Manager shall:
 - complete the Training Waiver (EXHIBIT 4), and
 - attach or reference documented evidence of equivalent training or previous experience to the Training Waiver Form (e.g., certificate of completion, attendance sheet, resume, etc.)
 - obtain approval signature of the next level manager (one-over-one)
 - obtain concurrence of the Cognizant Quality Engineer if Impact Level I or II or Safety Class related training
 - obtain concurrence by affected organization's representative if safety or security related training
 - forward the Training Waiver to the LTC for review and entry into individual training records.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- documentation of education and experience
- completed training assignment forms
- evidence of completion of formalized training
- evidence of competency or certification
- lesson plans
- training waivers.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

OJT PLAN INSTRUCTIONS

Training Plans are used for on-the-job training sessions. The Responsible Manager or Instructor has the option of using the sample plan shown on Page 2 of this Exhibit, or designing an alternative form. If an alternative form is used, it must contain the following information:

1. Project, activity, line identification.
2. Training Plan Number (this number should be unique to each individual Training Plan, and prefixed by project number or by organization acronym).
3. Lesson title and revision number.
4. Objectives - describe what the trainee should be able to do or know upon completion of the training.
5. Presentation - identify within the training plan the information to be presented and any materials used which will achieve the course objective.
6. Examination - examinations are at the discretion of the Instructor. Indicate if an examination is required, and attach any testing or examination documents to the training plan.
7. Time Allocation - indicate when the training should be completed.
8. Retraining Period - indicate when retraining is required, if applicable.
9. Obtain all required signatures.
10. Prepare an Individual Training Assignment Form (Exhibit 1) or a Group Training Documentation Form (Exhibit 2).
11. Forward a copy of the plan and any associated training records (originals or reproducible copies) to the Laboratory Training Coordinator.

[Empty rectangular box]

Pacific Northwest Laboratories	ON-THE-JOB TRAINING PLAN	Page _____ of _____ Date Issued: _____
Project/Activity: _____		
Training Plan No.: _____ Rev. No.: _____		
Lesson Title: _____ _____		

TRAINING PLAN OUTLINE

I. OBJECTIVES:

II. PRESENTATION:

III. EXAMINATION: (optional)

IV. TIME ALLOCATION:

V. RETRAINING PERIOD:

Prepared By: _____
 Instructor

_____ Date

Concurred With: _____
 Cognizant Quality Engineer

_____ Date

Approved By: _____
 Responsible Manager

_____ Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-203

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 5

TITLE: PAP-70-203, QUALIFICATION AND CERTIFICATION OF INSPECTION AND TEST PERSONNEL

PURPOSE

Define requirements and responsibilities for the qualification and certification of inspection and test personnel. The qualification and certification process established by this procedure implements the requirements of Supplement 2S-1 and Appendix 2A-1 of ASME NQA-1.

APPLICABILITY

This procedure applies to qualifying and certifying personnel who inspect or test physical items to determine if they are acceptable for use. It does not apply to qualifying personnel who test or analyze items to collect data or verify designs, or who perform surveillance (unless the surveillance results are used to accept an item).

This procedure addresses obtaining qualified inspection personnel from Hanford Contractors or from outside suppliers, up to the initiation of the Work Order or Purchase Requisition.

The qualification and certification of personnel performing nondestructive examinations (NDE) using Magnetic Particle (MT), Liquid Penetrant (PT), Leak Testing (LT), Eddy Current (ET), Radiography (RT), and Ultrasonic (UT) methods is addressed in PNL-MA-531, Quality Programs Instructions.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Manager
- Lead Procurement Quality Engineer (Lead PQE)
- Level III Examiner
- QP Representative.

IMPLEMENTATION

1.0 Decision to Use Inspection or Test

- 1.1 The Cognizant Manager with the QP Representative shall designate those activities that will require independent inspections or tests to determine the acceptability of physical items for use. When such inspections or tests are required, personnel shall be qualified and certified in accordance with this procedure.
- 1.2 The determination of the need for independent inspections or tests shall be made no later than during the preparation and review of the Purchase Requisition or other ordering document.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

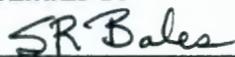
DATE


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

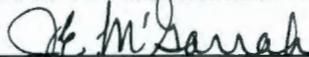
DATE


SR Bales

6/16/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

If these requirements are apparent when the QA plan is prepared, they should be included in the plan. Examples of such activities include:

- receiving inspection that involves the use of precision measuring and test equipment
- weld inspection
- source inspection or surveillance.

2.0 Inspection Personnel Selection

2.1 The Lead PQE shall arrange for the required inspection personnel. Sources for such personnel may include:

- Process Quality Department
- other Hanford Contractors with inspector qualification programs that have been evaluated by the Lead PQE (obtained in accordance with PAP-70-404, Obtaining Services)
- the services of subcontractors who have been evaluated by the Lead PQE (obtained in accordance with PAP-70-401, Purchase Requisitions)
- PNL personnel possessing expertise in singular or unusual applications.

2.2 The Lead PQE or Level III Examiner shall select inspection personnel to receive training, qualification, and certification in accordance with this procedure. Those selected shall have the education, experience, or training commensurate with the scope, complexity, or special nature of the activities to be inspected.

2.3 The Lead PQE or the Level III Examiner shall verify the relevant education and work experience of candidates for certification. The verification can be achieved by utilizing the PNL Personnel Security investigations, see EXHIBIT 4, Verification of Education and Experience, or by contacting previous employers and educational institutes. This must be documented on EXHIBIT 5, Verification of Experience and Education, by recording who was contacted, association with the candidate (supervisor, co-worker, instructor, etc.), level of certification and time held, and education or training received. EXHIBIT 4 or 5, as applicable, must be kept on file with the candidates' certification records.

2.4 When an inspection requires specialized expertise in a state-of-the-art technology or for a singular application, the Lead PQE may select individuals who are qualified by virtue of their expertise but may not be certified. Such inspections shall be authorized on a case-by-case basis and a documented statement of qualification shall be provided by the Lead PQE.

3.0 Qualification Levels

3.1 Level I Personnel

The Level I person shall be capable of performing and documenting the results of inspections or tests in accordance with approved procedures, acceptance standards, and/or industry practices. The Level I person shall receive guidance from a Level II or III on the complexity and/or nature of the inspection to be performed.

3.2 Level II Personnel

The Level II person shall have all the capabilities of a Level I. In addition, the Level II shall be able to perform the following:

- plan inspections/tests
-

- set up inspections/tests, including the preparation and set up of related equipment as appropriate
- supervise or maintain surveillance over the inspections/tests
- supervise lower level personnel
- evaluate the validity and acceptability of inspection/test results.

3.3 Level III Personnel

The Level III person shall have all the capabilities of the Level II. In addition the Level III shall be able to perform the following:

- evaluate the adequacy of specific programs used to train and certify inspection and test personnel
- administer certification tests
- develop and administer training programs for Level I and Level II candidates.

4.0 Education and Experience

4.1 Level I

- 4.1.1 Two years of related experience in equivalent inspection or testing activities; or
- 4.1.2 High school graduation and six months of related experience in equivalent inspection or testing activities; or
- 4.1.3 Completion of college level work leading to an associate degree in a related discipline plus three months of experience in equivalent inspection or test activities.

4.2 Level II

- 4.2.1 One year of satisfactory performance as a certified Level I in the corresponding inspection or test category; or
- 4.2.2 High school graduation plus three years of related experience in equivalent inspection or test activities; or
- 4.2.3 Completion of college level work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspection or test activities; or
- 4.2.4 Graduation from a four year college plus six months of related experience in equivalent inspection or test activities.

4.3 Level III

- 4.3.1 Six years of satisfactory performance as a certified Level II in the corresponding inspection or test category; or
- 4.3.2 High school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus eight years of experience with at least two years as a certified Level II and at least two years associated with research or nuclear facilities; or
- 4.3.3 Completion of college level work leading to an associate degree, and seven years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with research or nuclear facilities; or

PNL ADMINISTRATIVE PROCEDURE

- 4.3.4 Graduation from a four year college plus five years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with research or nuclear facilities.

5.0 Indoctrination and Training of Inspection Personnel

5.1 The Lead PQE or Level III Examiner shall determine the need for and provide indoctrination and training to candidates for inspector certification in the following areas, in accordance with PAP-70-201, Indoctrination and Training:

- technical objectives
- applicable codes
- standards used
- Quality Assurance Program elements that apply.

5.2 This indoctrination and training shall include the candidate's reading of the Technical Procedure for the applicable inspection discipline. The Lead PQE or Level III Examiner shall administer a written or oral test to verify the candidate's comprehension of the procedure.

6.0 Initial Qualification and Certification of Inspection Personnel

The Lead PQE shall assess the qualifications of and certify inspection personnel. Such personnel shall be certified to the appropriate Level as determined by the Lead PQE or Level III Examiner utilizing the qualification requirements specified in Section 4.0.

6.1 The candidate's capability shall be determined by one of the following methods:

- a comprehensive test
- a demonstration of capability in the intended area of qualification, such as visual weld inspection or receiving dimensional inspection
- an evaluation of records which provides objective evidence of experience, training and testing, or capability from the candidate's previous employer, if the following conditions are met:
 - a. The candidate's certification was in accordance with NQA-1 Supplement 2S-1 and was current at the time of termination.
 - b. The certification of the candidate by PNL is within a year of the candidate's actual performance in the capacity being certified.
 - c. The candidate's previous employer is another DOE contractor.
 - d. The previous employer's certification program has been evaluated as acceptable by a PNL Lead Auditor.

6.2 The candidate shall have passed the test required by Paragraph 5.2.

6.3 Candidates for welding and dimensional inspection shall be examined for their ability to read Jaeger Chart J-1 letters at a 12 inch distance in at least one eye, either uncorrected or with corrective lenses. The examination shall be documented on EXHIBIT 2, QA/QC Eye Examination Record. Candidates shall also be examined for any other physical capabilities that are required for the successful performance of their work, and the results of these examinations shall be documented.

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-203

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 5 OF 5

6.4 Upon completion of a certifiable candidate's assessment, the Lead PQE shall complete EXHIBIT 1, Certification/Qualification/Evaluation Record of Inspection and Test Personnel, blocks 1 through 5 and 7, and shall sign and date the form in block 8. Block 4 shall clearly designate the kinds of inspection that the candidate is certified to do.

7.0 Initial Qualification and Certification of Test Personnel

The Cognizant Manager shall assess the qualification of and certify personnel to perform testing. The method shall be the same as delineated in Section 6.0 for inspection personnel, except that Paragraph 6.1, third bullet is not applicable. The Cognizant Manager shall assume the responsibilities of the Lead PQE.

8.0 Reevaluation of Performance of Inspection and Test Personnel

- 8.1 The Lead PQE or Cognizant Manager, as applicable, shall ensure that inspection or test personnel are reevaluated annually. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability as described in Paragraphs 6.0 and 7.0. When a vision test is required for certification (see Paragraph 6.3), this test shall be performed at least annually.
- 8.2 The Lead PQE or Cognizant Manager, as applicable, shall document the results of the periodic evaluations in blocks 6, 7, and 9 of the certification form (EXHIBIT 1), and on the Certification of Inspection/Test Personnel Maintenance Log form (EXHIBIT 3).
- 8.3 If during the evaluation required by Paragraph 8.1, or at any other time, it is determined by the Lead PQE or the Cognizant Manager that an individual's capabilities are not in accordance with the qualification requirements specified for that work, this shall be noted on both the certification form and on the log. The person shall not perform such work until his capability has been demonstrated.
- 8.4 The Lead PQE or Cognizant Manager shall ensure that anyone who has not performed inspection or testing activities in his qualified area for one year is reevaluated in accordance with Paragraph 6.0 and 7.0 before being allowed to perform further inspection or testing in this area.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- Certification/Qualification/Evaluation Record of Inspection and Test Personnel
- QA/QC Eye Examination Record
- Certification of Inspection/Test Personnel Maintenance Log
- Verification of Education and Experience
- records documenting test results, capability demonstrations, and training pertinent to certification.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

**THIS PAGE INTENTIONALLY
LEFT BLANK**

EXAMPLE ONLY

QA/QC EYE EXAMINATION RECORD					
Employee			Employee No.		
Employer			Department		
ACTUAL RESULTS OF EXAMINATION					
Vision	DISTANCE		NEAR		Both Eyes Together
	Right	Left	Right	Left	
With Lenses					
Without Lenses					
Depth Perception					
Color Vision (Ishihara)					
Color Vision (Primary Colors)					
HEHF Examiner _____ <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Signature Title Date </div> <p>I authorize Hanford Environmental Health Foundation (HEHF) to furnish the above eye examination results to my employer.</p> Employee _____ <div style="display: flex; justify-content: space-between; margin-top: 5px;"> (To be signed at the time of examination) Date </div>					
EVALUATION OF EXAMINATION RESULTS					
Near vision acuity is such that the candidate is qualified to perform work in accordance with RDT standards, ASME Section III and XI which requires the ability to read Jaeger No. 1 letters in at least one eye using natural or corrected vision at a distance of at least 12 inches or equivalent ability. <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A </div>					
Near vision acuity is such that the candidate is qualified to perform work in accordance with ASNT SNT-TC-1A and ASME NQA-1 which require the ability to read a minimum of Jaeger No. 2 letters in at least one eye using natural or corrected vision at a distance of at least 12 inches or equivalent ability. <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A </div>					
Distance vision acuity is such that the candidate is qualified to perform work in accordance with ASME Section XI which requires the ability to achieve a Snellen Notation of 20/30 or better in at least one eye using natural or corrected vision. <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A </div>					
Stereo acuity (depth perception) as required by RDT standards is acceptable Color vision is normal as indicated by identifying at least 19 out of 25 Ishihara color plates. <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A </div>					
The employer's written practice or procedure number used for inspection personnel certification is: _____					
Corrective lenses required:		For near vision?		For distance vision?	
		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Employer Representative _____ <div style="display: flex; justify-content: space-between; margin-top: 5px;"> Signature Title Date </div>					

**THIS PAGE INTENTIONALLY
LEFT BLANK**

**THIS PAGE INTENTIONALLY
LEFT BLANK**

VERIFICATION OF EDUCATION AND EXPERIENCE

Date: _____

The Resume of _____ is attached.

The education and work experience as described in the attached resume has been verified by the PNL Personnel Security group of the Safeguards and Security Department.

Supervisor, Personnel Security
Safeguards and Security Department
Battelle, Pacific Northwest Laboratories

**THIS PAGE INTENTIONALLY
LEFT BLANK**

VERIFICATION OF EXPERIENCE AND EDUCATION

NDE Candidate Name: _____ Date: _____

Considered for Certification in: _____

EDUCATION/TRAINING

Institute/Training Facility	Dates Attended	Degree/Diploma Certificate	Contact

WORK EXPERIENCE

Employer	Dates From - To	Method	Contact/Title

Person Verifying: _____

Title: _____ Date: _____

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-205

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 6

TITLE: PAP-70-205, QUALITY ASSURANCE PLANS

PURPOSE

Establish methods of documenting Quality Assurance Plans to ensure that appropriate quality program requirements have been identified, documented, and agreed upon prior to beginning work.

APPLICABILITY

This procedure applies to Impact Level I & II projects, technical service activities, and construction projects including Safety Class systems, structures, and components (SSCs).

This procedure may also apply to activities or services provided by support organizations (e.g. Craft Services, Laboratory Training, Laboratory Safety, etc.) when required by governing documents or considered appropriate by the cognizant management.

The methods for determining impact levels are in PAP-70-208, Impact Levels. Methods for determining safety class are in PNL-MA-44, Safety Analysis. PAP-70-207, Quality Program Requirements for Safety Class Systems, Structures, and Components, describes the method for determining quality program requirements for safety class SSCs.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Author
- Cognizant Staff (staff associated with or working on the project, activity, etc.)
- Lead Quality Engineer
- Line Manager
- Project/Cognizant Manager (manager responsible for the project, activity, facility, etc.)
- Quality Engineer.

DEFINITIONS

Management Plan - As used in this procedure, the term "Management Plan" is a generic term and may refer to a Project Management Plan, Service Activity Management Plan, Facility Management Plan, etc.

QA Plan - As used in this procedure, the term "QA Plan" refers to either the quality program requirements appearing in the Management Plan or the separate QA Plan prepared as an individual document.

CONCURRENCE _____ DATE _____
 _____ N/A _____

APPROVAL AUTHORITY _____ DATE 6/20/94
 JW Smith, Director, Quality Programs

PREPARED BY _____ DATE 6/20/94
 RL Shaub

DOCUMENTATION SYSTEMS DEPARTMENT _____ DATE 6/20/94
 JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

GENERAL

This procedure contains both requirements and guidance for the preparation of QA Plans.

The impact level shall be equal to the highest impact level of any of the work elements, within the Work Breakdown Structure (WBS) or Work Packages as appropriate. Impact Level I and II projects/activities and Safety Class systems, structures, and components (SSCs) require QA Plans. Impact Level III projects/activities and Non-Safety Class SSCs shall comply with the requirements of PNL-MA-70, Part 2, Good Practices Standard. Additional instructions in the preparation of Management Plans will be found in PNL-MA-91, Construction Project Management, PNL-MA-95, Research Project Management System, PNL-MA-96, Project Management System for Complex Projects, or PNL-MA-98, General System Description for PNL's Cost and Schedule Management System.

Safety classes are assigned to systems, structures, and components (SSCs). These SSCs can either be "Safety Class" or "Non-Safety Class". Criteria and guidance for selecting the safety class SSCs is located in PNL-MA-44, Safety Analysis. Safety Class SSCs are hardware oriented and the required quality program requirements apply to the hardware item and activities associated with that item.

Safety Class SSCs are involved with the prevention and mitigation of consequences of design basis accidents as described in PNL-MA-44, Section 7.0, Safety Class. If the project/activity, in question, does not fall within these limitations for a Hanford site activity, the requirement for documenting safety class may be disregarded.

IMPLEMENTATION

1.0 Preparation

1.1 The Cognizant Manager, with assistance from the Quality Engineer, shall document quality program requirements in a QA planning document (QA Plan). The QA Plan shall be:

- included in the Management Plan, or
- a separate QA Plan.

1.2 The QA Plan may be presented in a number of format options. Following are QA Plan options:

- EXHIBIT 1, Management Plan, QA Plan Section (and Instructions for Management Plan, QA Plan Section Preparation)

The QA Plan format presented in this exhibit is intended for use on R&D projects and services activities. This recommended format is designed for inclusion into the project/activity management plan.

- EXHIBIT 2, QA Plan (and Instructions for QA Plan Preparation)

The QA Plan format presented in this exhibit is intended for use on R&D projects and service activities. This recommended format is designed as a stand alone QA Plan where it has been decided not to include the QA Plan into the project/activity management plan. It should also be used on R&D Projects that require a QA Plan but do not have a management plan.

- EXHIBIT 3, QA Section of Construction Project Management Plan (and Instructions for Management Plan, QA Section Preparation)

The QA Plan format presented in this exhibit is intended for use on construction projects. This recommended format is designed for inclusion into the construction management plan.

- EXHIBIT 4, QA Plan for Construction Project (and Instructions for QA Plan for Construction Projects)

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-205

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 6

The QA Plan format presented in this exhibit is intended for use on construction projects. This recommended format is designed as a stand alone QA Plan where it has been decided not to include the QA Plan into the construction management plan. It should also be used on construction projects that require a QA Plan but do not have a management plan.

EXHIBIT 5, Facility QA Plan (and instructions for Facility QA Plan Preparation)

The QA Plan format presented in this exhibit is intended for use on facilities that have Safety Class SSCs. This QA Plan format is used for documenting the administrative procedures that have been identified in PAP-70-207, Quality Program Requirements for Safety Class Systems, Structures, and Components.

- QAMS-005/80, Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans

The format presented in this document should be used on all projects and activities that require QAMS-005/80.

- alternate QA Plan instructions and format as specified by the client. Prior approval by a Lead Quality Engineer is required when using alternate QA Plan formats.

1.3 QA Plans may make exclusions or specify limitations; e.g., certain phases of work may be excluded from some of the QA Plan's requirements or limits may be put on the applicability. Provisions for such exclusions or limitations are made in EXHIBITS 1, 2, 3, 4, and 5.

1.4 When it is appropriate to establish different impact levels for some work elements, procurements or deliverables, the impact level of each item should be identified and documented as part of the QA Plan. EXHIBIT 6, WBS Impact Level Matrix, EXHIBIT 7, Impact Level Breakdown for Construction Projects, or other appropriate format may be used.

- The project/activity impact level shall reflect the highest work element impact level.
- The project/activity management task work element impact level shall reflect the project/activity impact level.
- Work activities and records for each work element shall be in accordance with that work element impact level.

1.5 EXHIBIT 8, Information to be Considered for QA Plans, shall be used in preparing all Management Plans/QA Plans.

2.0 Review and Approval

2.1 The Author shall obtain a documented review of the draft QA Plan by the:

- Cognizant Manager
- Process Quality (the assigned Quality Engineer)
- Records Management.

The Cognizant Manager should obtain sufficient staff reviews to ensure that practices described in the QA Plan are appropriate.

2.2 The QA Plan Author shall resolve any comments and circulate the QA Plan for concurrence and approval.

PNL ADMINISTRATIVE PROCEDURE

- a. Approval of the Management Plan, QA Plan Section shall be concurrent with the approval of the Management Plan. Process Quality acceptance of the QA Plan provisions shall be evidenced by Process Quality signature and date on the Management Plan.
- b. Cognizant Manager and Process Quality concurrence, and Line Manager approval of separate QA Plans shall be documented by signature and date on the QA Plan.

2.3 Process Quality concurrence shall be provided by a Lead Quality Engineer.

3.0 Distribution

3.1 The Cognizant Manager shall prepare a Management Plan or QA Plan distribution list which shall include at a minimum:

- the Cognizant Manager
- Line Manager
- appropriate project or activity personnel
- Quality Engineer
- Lead Quality Engineer
- Records Management.

3.2 Management Plans and QA Plans shall be distributed as follows:

- a. The Cognizant Manager for Impact Level I projects, activities, etc., shall transmit the Management Plan/QA Plan and distribution list to Document Control for issue as a controlled document.
- b. The Cognizant Manager for Impact Level II projects, activities, etc., shall transmit the Management Plan/QA Plan to those on the distribution list. As an option, the Cognizant Manager may have Document Control assume the responsibility for distribution as in "a." above.
- c. The Cognizant Manager for facilities with Safety Class SSCs shall transmit the Management Plan/QA Plan to those on the distribution list. As an option, the Cognizant Manager may have Document Control assume the responsibility for distribution as in "a." above.

4.0 QA Requirements Implementation

- 4.1 On receipt of the Management/QA Plan the Cognizant Manager shall ensure that affected personnel are aware of the quality program requirements. Training requirements are identified in PAP-70-201, Indoctrination and Training.
- 4.2 Cognizant Staff shall ensure that work performed is accomplished in accordance with the requirements of the Management/QA Plan.
- 4.3 Cognizant Staff who are reassigned and no longer need the Management/QA Plan shall return the plan to the cognizant manager or designated document distribution control.

5.0 Revisions and Interim Changes

- 5.1 Cognizant Managers, with QE assistance, shall by a memo to file document an annual review of their Impact Level I Management/QA Plans, normally during the first quarter of the fiscal year, and revise them as necessary.
- 5.2 Cognizant Managers shall notify the QE and shall revise Impact Level I and II Management/QA Plans when one of the following occurs:

- a change in scope that affects the assigned impact level or changes or adds QA related requirements
- a major change in organization, e.g., cognizant manager change.

- 5.3 The Cognizant Manager shall revise Facility QA Plans when the safety class of a facility SSC changes.
- 5.4 The Cognizant Manager, with Process Quality assistance, shall determine whether the change is to be processed as an interim change or as a revision.
- 5.5 The Cognizant Staff may use the Document Change Request form (see PAP-70-602, Procedure and Instruction Change Control and Change Request) to request a change in the QA Plan.
- 5.6 The Cognizant Manager shall initiate the required revisions or interim changes when necessary.
- a. Revisions are recommended when three (3) ICN have been approved and issued since the last revision. Interim changes shall be made using the ICN form (see PAP-70-602).
 - b. Revisions shall require a Management/QA Plan rewrite. Revised text shall be clearly identified in the document. Example methods include background shading, vertical lines in right margin, or italicizing the change.
 - c. Revisions and major interim changes shall be prepared, reviewed, approved, and issued in accordance with sections 1.0, 2.0, and 3.0.
 - d. Minor changes require the concurrence of the Quality Engineer and shall be distributed in accordance with Subsection 3.0. Minor changes are those that do not change the scope, impact level assignments, or requirements of the Management/QA Plan. Examples include:
 - correction of typographical/grammatical errors
 - addition of missing information to ensure that the document is interpreted correctly
 - wording changes to improve understanding
 - correction of obviously incorrect information.

6.0 Project Completion

- 6.1 The Cognizant Manager shall upon completion of work or superseding the Management/QA Plan, and prior to Management/QA Plan closeout:
- resolve any outstanding action items, such as open NonConformance Reports (NCRs), Audit/Surveillance/Assessment Corrective Actions, or Deficiency Reports
 - complete the project, activity, or facility records in accordance with the requirements of PAP-70-1701, Records System
 - ship or otherwise dispose of leftover or archival test materials and samples in accordance with the requirements of PAP-70-801, Identification and Control of Test Materials (Testing and Analysis), and PAP-70-803, Item Identification and Control.
- 6.2 For Impact Level I QA Plans, the Cognizant Manager shall issue a memo, with QE concurrence, to Document Control requesting closure of the QA Plan. For Impact Level II QA Plans, the Cognizant Manager shall issue a memo, with QE concurrence, to Document Control requesting closure of the QA Plan or issue a memo to all copy holders, stating that the QA Plan is closed, and the date of closure.

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-205

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 6 OF 6

NOTE: If records or materials are to be retained for an extended period after other activities are complete, the "closure" memo may leave the requirements and procedures for these records and materials in effect by specific statement in the closure.

REQUIRED RECORDS

The Quality Assurance (QA) Plan created as a result of this procedure is a record.

MANAGEMENT PLAN, QA PLAN SECTION

EXAMPLE

X.0 QUALITY ASSURANCE PLAN NO. _____

X.1 QA Program

X.1.1 The PNL Quality Assurance Program conforms to the requirements of ASME NQA-1 as delineated by the PNL Quality Assurance Manual PNL-MA-70, Parts 1 and 3. The requirements of Parts 1 and 3 of PNL-MA-70 apply to this project as dictated by the project Work Breakdown Structure (WBS) element impact levels and the activities being performed.

OR

X.1.1 The PNL Quality Assurance Program conforms to the requirements of DOE 5700.6C as delineated by the PNL Quality Assurance Manual PNL-MA-70, Part 1 and 3, and this QA Plan. The requirements of Parts 1 and 3 of PNL-MA-70 apply to this project as dictated by the project Work Breakdown Structure (WBS) element impact levels and the activities being performed.

X.1.2 The project organization is shown in Exhibit X.1 of this project management plan. Change to the organizational structure or individual assignments that do not reflect a change in project scope or a change in QA requirements will not require a management plan revision, but will be included in the next revision of the management plan.

X.2 Impact Level

X.2.1 Project Impact Level I

X.2.2 The project impact level assignment is shown in Exhibit X.3, Project Impact Level. Exhibit X.3 provides the impact level for each of the project WBS elements and these levels in turn dictate the level of the QA Program applied to the individual WBS elements of the project.

X.3 Safety Class SSCs

X.3.1 Safety Class

X.3.2 When performing work associated with Safety Class systems, structures, and components (SSCs), that work shall comply with the applicable requirements of Parts 1 and 3 of PNL-MA-70. Work associated with Non-Safety Class SSCs shall comply with the Good Practices Standard located in Part 2 of PNL-MA-70. This QA Plan identifies the applicable PNL-MA-70, Part 3, Administrative Procedures for SSCs and work being performed.

X.4 Requirements

X.4.1 This QA Plan applies only to the project Impact Level I and II WBS elements, as designated in Exhibit X.3. Impact Level I and II activities shall comply with the applicable requirements, as appropriate for the work being performed, in Parts 1 and 3 of PNL-MA-70. Impact Level III activities shall comply with the Good Practice Standards (GPS) located in Part 2 of PNL-MA-70.

MANAGEMENT PLAN, QA PLAN SECTION (cont'd)

X.4.2 Special Client Requirements

- A. (List the individual client requirements and the PNL-MA-70 Section or the Administrative Procedure that satisfies this requirement.)
- B. (List the individual client requirements not covered by the PNL-MA-70 Manual, Part 1 or 3 and document the method by which the project will comply with the requirement.)
- C. Client required exclusions or limitations of applicability.

(Document any specific exclusions, exceptions or limitations to PNL-MA-70 requirements on the applicability of Parts 1 and/or 3 of PNL-MA-70 to any part of the project required by the client.)

X.4.3 Other Requirements, Limitations, Directions, or Planning

(Provide information required by the instructions and document any additional special requirements.)

Instructions for Management Plan, QA Plan Section Preparation

When the QA Plan is incorporated into the Management Plan, the QA Plan shall normally consist of four subsections. These subsections shall contain the information on how the QA Program applies to the applicable project. Obtain the QA Plan Number from Process Quality.

Subsection

1. QA Program - This subsection shall contain a statement about the PNL QA Program and its applicability to the project. The subsection should identify the project organization and any critical interfaces. (See example above.)
2. Impact Level - This subsection shall contain the impact level documentation and rationale:
 - Document the project, activity, etc., impact level. (Guidance on determining impact level is located in PAP-70-208, Impact Levels.)
 - Provide a brief summary of the rationale for the assigned impact level.
 - Provide a matrix of the individual WBS element impact levels as an exhibit/figure to the management plan. Follow the direction and guidance in Exhibit 3, WBS Impact Level Matrix.
3. Safety class - Only documented if it is determined that the project/activity has a safety class SSC. The designation of Safety Class is assigned to systems, structures, and components that are used to prevent or mitigate a design basis accident. Methods for determining the safety class of SSCs are documented in Section 7 of PNL-MA-44, Safety Analysis.
4. Requirements - for Impact Level I and II projects, the QA requirements are contained in Parts 1 and 3 of PNL-MA-70. The individual WBS element impact levels and work to be performed determine which of those requirements apply to the individual WBS elements, and the degree to which they apply. In addition to the PNL QA Program requirements,

MANAGEMENT PLAN, QA PLAN SECTION (cont'd)

the client may impose QA requirements. For special reasons, exclusions or limitations may be taken to the QA Program requirements. These shall be documented in this subsection as follows:

- Describe the extent of the QA Plan coverage and where to find the project impact levels (e.g., the WBS Impact Level Matrix) and discuss Impact Level I and II requirements as opposed to Impact Level III requirements (Example in subsection X.4.1 of Exhibit 1).
- Special Client Requirements:
 - Quote any special client requirements that are satisfied through provisions in Parts 1 or 3 of PNL-MA-70. Identify the section(s) in PNL-MA-70, Part 1, or the subsection(s) or paragraphs(s) in the Part 3 Administrative Procedures that satisfy the requirement.
 - Quote any special client requirements that are not satisfied through provisions in Parts 1 or 3 of PNL-MA-70. Identify the method by which these requirements will be accomplished.
 - Record any specific exclusions, exceptions, or limitations from PNL-MA-70 requirements mandated as a result of special client requirements.
- Other Requirements, Limitations, Directions, or Planning
 - See Exhibit 8 of this procedure.

This section may also be used by the cognizant manager to provide any other appropriate direction.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

QA PLAN FORMAT

QA Plan No.: _____

Impact Level: I II III

Safety Class SSCs:

or

Non-Safety Class SSCs:

QA Plan for (Project Title)

Plan Effective Date: _____

CONCURRENCES AND APPROVAL:

Cognizant Manager (Concurrence)

Date

Process Quality (Concurrence)

Date

Line Manager (Approval)

Date

QA PLAN FORMAT (cont'd)

SCOPE:

CLIENT:

AUTHORIZING DOCUMENT:

QA REQUIREMENT SPECIFICATION(S):

PNL-MA-70, PNL Quality Assurance Manual

Other: _____

Impact Level I and II WBS element activities shall comply with the applicable requirements, as appropriate for the work being performed, in Parts 1 and 3 of PNL-MA-70. Impact Level III activities shall comply with the GPS Standards located in Part 2 of PNL-MA-70.

When performing work associated with Safety Class systems, structures, and components (SSCs), that work shall comply with the applicable requirements of Parts 1 and 3 of PNL-MA-70. Work associated with Non-Safety Class SSCs shall comply with the Good Practices Standard located in Part 2 of PNL-MA-70. This QA Plan identifies the applicable PNL-MA-70, Part 3, Administrative Procedures for SSCs and work being performed.

This QA Plan also identifies client QA requirements, if applicable, and any client imposed exclusions or limitations to PNL procedure requirements. If other quality-related activities are later performed, the appropriate PNL-MA-70 requirements and procedures shall be applied, unless specifically excluded.

QA PROGRAM/ORGANIZATION:

IMPACT LEVEL RATIONALE:

SPECIAL CLIENT REQUIREMENTS:

A. Covered by Part(s) 1 and/or 3 of PNL-MA-70

Client Requirement

Where Covered

B. Not covered by Part(s) 1 and/or 3 of PNL-MA-70

C. Client required exclusions or limitations of procedure applicability

QA PLAN FORMAT (cont'd)**OTHER REQUIREMENTS, LIMITATIONS, DIRECTIONS, OR PLANNING:****Instructions for QA Plan Preparation****TITLE PAGE**

QA PLAN NUMBER: Supplied by Process Quality (and QA Plan Revision Number)

IMPACT LEVEL: The highest impact level of any WBS element (Exhibit 5, WBS Impact Level Matrix) covered by the QA Plan. See PAP-70-208, Impact Levels, for criteria and method of determining impact levels.

SAFETY CLASS: Only documented if it is determined that the project/activity has a safety class SSC, check as appropriate, Safety Class or Non-Safety Class. The designation of Safety Class is assigned to systems, structures, and components that are used to prevent or mitigate a design basis accident. Methods for determining the safety class of SSCs are documented in Section 7 of PNL-MA-44, Safety Analysis.

TITLE: The project title or a descriptive title for the type of work to which this plan applies, e.g., "X-Ray Diffraction Analysis".

EFFECTIVE DATE: Date the QA Plan takes effect.

CONCURRENCES AND APPROVAL: Others may be added when appropriate.

TEXT PAGES

SCOPE: Identify the program, project(s), activity, facility, or organizational component to which this plan applies. Provide a brief description of the purpose/intent of the project.

CLIENT: Identify the client.

AUTHORIZING DOCUMENT: Identify the project funding document. If not applicable, enter "NA", "Activity", or "Facility".

QA REQUIREMENT SPECIFICATION(S): Check either or both boxes. Make an entry in "Other" when the client has specified QA requirements in addition to those contained in PNL-MA-70.

QA PLAN FORMAT (cont'd)

QA PROGRAM/ORGANIZATION: Provide a brief statement (as in the following example) describing the PNL QA Program and the location in the QA Plan of an organization chart (project, activity, facility, etc.), if applicable. Also, a critical interface chart if applicable. (Use continuation sheets as necessary.)

EXAMPLE: "The PNL Quality Assurance Program conforms to the requirements of ASME NQA-1 as interpreted by Parts 1 and 3 of PNL-MA-70, Quality Assurance Manual. This QA Plan applies only to the project Impact Level I and II WBS elements, as designated by Exhibit 1. The project organization with key personnel identified is located in Exhibit 2, Project Organization, with key organizational interfaces shown in Exhibit 3, Project Interfaces." WBS elements identified as Impact Level III shall comply with the requirements of PNL-MA-70, Part 2.

IMPACT LEVEL RATIONALE: Provide rationale for the designated impact level and instructions for applying to the project, activity, etc., WBS element impact levels (reference to the Impact Level Matrix should be sufficient). The Impact Level Matrix shall be prepared on the form and in accordance with the instructions given in Exhibit 6, WBS Impact Level Matrix.

SPECIAL CLIENT REQUIREMENTS: Special client requirements is subdivided into three parts and addressed as follows:

- A. Quote any special client requirements that are satisfied through provisions in Parts 1 or 3 of PNL-MA-70. Identify the section(s) in PNL-MA-70, Part 1, or the subsection(s) or paragraph(s) in the Part 3 Administrative Procedures that satisfy each requirement.
- B. Quote any special client requirements that are not satisfied through provisions in Parts 1 or 3 of PNL-MA-70. Identify the method by which these requirements shall be accomplished.
- C. Record any specific exclusions, exceptions or limitations from PNL-MA-70 requirements mandated as a result of special client requirements. Identify alternative controls and/or procedures.

(Use continuation sheets as necessary.)

OTHER REQUIREMENTS, LIMITATIONS, DIRECTIONS, OR PLANNING: See Exhibit 8 of this procedure.

This section may also be used by the cognizant manager to provide any other appropriate direction.

CONSTRUCTION PROJECT MANAGEMENT PLAN, QA PLANS SECTION

EXAMPLE

X.0 QUALITY ASSURANCE PLAN NO. _____

X.1 QA Program

X.1.1 The PNL Quality Assurance Program conforms to the requirements of ASME NQA-1 as delineated by the PNL Quality Assurance Manual PNL-MA-70, Parts 1 and 3. The requirements of Parts 1 and 3 of PNL-MA-70 apply to this project as dictated by the project Work Breakdown Structure (WBS) element impact levels and the activities being performed.

OR

X.1.1 The PNL Quality Assurance Program conforms to the requirements of DOE 5700.6C as delineated by the PNL Quality Assurance Manual PNL-MA-70, Part 1 and 3, and this QA Plan. The requirements of Parts 1 and 3 of PNL-MA-70 apply to this project as dictated by the project Work Breakdown Structure (WBS) element impact levels and the activities being performed.

X.1.2 The project organization is shown in Exhibit X.1 of this management plan. Changes to the organizational structure or individual assignments that do not reflect a change in project scope or a change in QA requirements will not require a management plan revision.

X.1.3 Applicable project interfaces with DOE, Kaiser Engineers Hanford (KEH), the off-site Architect-Engineer, the construction contractor, other DOE contractors, and other organizations are shown in Exhibit X.2.

X.2 Impact Level

X.2.1 Impact Level ___ has been assigned to this project. Documentation of impact level assignment and rationale are provided by the project impact level approval form, Exhibit X.3.

X.2.2 Impact level assignments for individual elements of this project are shown in the project impact level breakdown of Exhibit X.4. These individual element impact level assignments define the required application of the QA program to the specific elements.

X.3 Safety Class SSCs

X.3.1 Safety Class/Non-Safety Class

X.3.2 When performing work associated with Safety Class systems, structures, and components (SSCs) that work shall comply with the applicable requirements, of Parts 1 and 3 of PNL-MA-70. Work associated with Non-Safety Class SSCs shall comply with the Good Practices Standard located in Part 2 of PNL-MA-70. This QA Plan identifies the applicable PNL-MA-70, Part 3, Administrative Procedures for SSCs and work being performed.

X.4 Requirements

X.4.1 The applicable provisions of Parts 1 and 3 of PNL-MA-70 that are appropriate for specific activities shall be required for Impact Level I and II elements of this project.

CONSTRUCTION PROJECT MANAGEMENT PLAN, QA PLAN SECTION (cont'd)

- X.4.2 The applicable provisions of the Good Practices Standard (GPS) contained in Part 2 of PNL-MA-70 that are appropriate for specific activities shall be required for Impact Level III (or lower) elements of this project.
- X.4.3 Special Project QA Requirements
- A. (List the individual project special QA requirements and the PNL-MA-70 Section or the Administrative Procedure that satisfies each requirements)
- B. (List the individual project QA requirements not covered by the PNL-MA-70 Manual, Part 1 or 3 and document the method by which the project will comply with each requirement.)
- C. Required exclusions or limitations of applicability
- (Document any specific exclusions, exceptions or limitations to PNL-MA-70 requirements on the applicability of Parts 1 and/or 3 of PNL-MA-70 to any part of the project.)
- X.4.4 Other QA Requirements, Directions, or Planning
- (Provide information required to document any additional QA requirements as required by the instructions.)

Instructions for Management Plan, QA Section Preparation

When the QA requirements are covered in a Management Plan, the QA Section shall consist of four subsections. These subsections shall contain the information on how the QA Program applies to the project.

Subsection

1. QA Program - This subsection shall contain a statement about the PNL QA Program and its applicability to the project. The subsection should identify the project organization and any critical interfaces. (see example above)
2. Impact Level - This subsection shall contain or reference the impact level documentation and rationale:
 - Document the project, activity, facility, etc., impact level. (Guidance on determining impact level is located in PAP-70-208, Impact Levels)
 - Provide a breakdown of the individual project element impact levels as an exhibit/figure to the management plan. Follow the direction and guidance in Exhibit 6, Impact Level Breakdown for Construction Projects.
3. Safety class - Only documented if it is determine that the project/activity has a safety class SSC. The designation of safety class is assigned to systems, structures, and components that are used to prevent or mitigate a design basis accident. Methods for determining the safety class of SSCs are documented in Section 7 of PNL-MA-744, Safety Analysis
4. Requirements - for Impact Level I and II projects, the QA requirements are contained in Parts 1 and 3 of PNL-MA-70. The individual project element impact levels and work to be performed determine which of those requirements apply to the individual elements and the degree to which they apply. In addition to the PNL QA Program requirements, the client may impose QA requirements. For special reasons, exclusions or limitations may be taken to the QA Program requirements. These shall be documented in this subsection as follows:

CONSTRUCTION PROJECT MANAGEMENT PLAN, QA PLAN SECTION (cont'd)

- describe the extent of the QA Plan coverage and where to find the project impact levels (e.g., the Impact Level Breakdown) and discuss Impact Level I and II requirements as opposed to Impact Level III requirements (example in X.4.1 and X.4.2 of Exhibit 1).
- Special Project QA Requirements:
 - Quote any special project QA requirements that are satisfied through provisions of Parts 1 or 3 of PNL-MA-70. Identify the section(s) in PNL-MA-70, Part 1, or the subsection(s) or paragraph(s) in the Part 3 Administrative Procedures that satisfy the requirements.
 - Quote any special project QA requirements that are not satisfied by provisions of Parts 1 or 3 of PNL-MA-70. Identify the method by which these requirements will be met.
 - Record any specific exclusions, exceptions, or limitations from PNL-MA-70 requirements.
- Other QA Requirements, Directions, or Planning
 - See Exhibit 8 of this procedure.
 - This section may also be used by the cognizant manager to provide any other appropriate direction.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

QA PLAN FORMAT (CONSTRUCTION PROJECT)

QA Plan No. _____

Impact Level: [] I [] II [] III

Safety Class SSCs: []

or

Non-Safety Class SSCs: []

QA Plan for Construction Project
(Project Title/Description)

Plan Effective Date: _____

CONCURRENCES AND APPROVAL:

Cognizant Manager (Concurrence)

Date

Process Quality (Concurrence)

Date

Line Manager (Approval)

Date

QA PLAN FORMAT (CONSTRUCTION PROJECT) (cont'd)

PROJECT SCOPE:

QA REQUIREMENT SPECIFICATION(S):

PNL-MA-70, PNL Quality Assurance Manual

Other: _____

Impact Level I and II WBS element activities shall comply with the applicable requirements, as appropriate for the work being performed, in Parts 1 and 3 of PNL-MA-70. Impact Level III activities shall comply with the GPS Standards located in Part 2 of PNL-MA-70.

When performing work associated with Safety Class systems, structures, and components (SSCs), that work shall comply with the applicable requirements of Parts 1 and 3 of PNL-MA-70. Work associated the Non-Safety Class SSCs shall comply with the Good Practices Standard located in Part 2 of PNL-MA-70. This QA Plan identifies the applicable PNL-MA-70, Part 3, Administrative Procedures for SSCs and work being performed.

This QA Plan also identifies client QA requirements, if applicable, and any client imposed exclusions or limitations to PNL procedure requirements. If other quality-related activities are later performed, the appropriate PNL-MA-70 requirements and procedures shall be applied, unless specifically excluded.

QA PROGRAM/ORGANIZATION:

IMPACT LEVEL RATIONALE:

SPECIAL CLIENT REQUIREMENTS:

A. Covered by Part(s) 1 and/or 3 of PNL-MA-70

Client Requirement

Where Covered

B. Not covered by Part(s) 1 and/or 3 of PNL-MA-70

C. Client required exclusions or limitations of procedure applicability

OTHER REQUIREMENTS, LIMITATIONS, DIRECTIONS, OR PLANNING:

QA PLAN FORMAT (CONSTRUCTION PROJECT) (cont'd)**Instructions for QA Plan Preparation****TITLE PAGE**

QA PLAN NUMBER: Supplied by Process Quality (and QA Plan Revision Number)

IMPACT LEVEL: The highest impact level of any WBS element (Exhibit 5, WBS Impact Level Matrix) covered by the QA Plan. See PAP-70-208, Impact Levels, for criteria and method of determining impact levels.

SAFETY CLASS: Only documented if it is determined that the project/activity has a safety class SSC, check as appropriate, Safety Class or Non-Safety Class. The designation of Safety Class is assigned to systems, structures, and components that are used to prevent or mitigate a design basis accident. Methods for determining the safety class of SSCs are documented in Section 7 of PNL-MA-44, Safety Analysis.

PROJECT TITLE/DESCRIPTION: The project title and/or description.

EFFECTIVE DATE: Date the QA Plan takes effect.

CONCURRENCES AND APPROVAL: Others may be added when appropriate.

TEXT PAGES

PROJECT SCOPE: Identify the program, project(s), activity, facility, or organizational component to which this plan applies. Provide a brief description of the purpose/intent of the project.

QA REQUIREMENT SPECIFICATION(S): Check applicable box(es). Make an entry in "Other" when the client has specified QA requirements in addition to those contained in PNL-MA-70.

QA PROGRAM/ORGANIZATION: Provide a brief statement (as in the following example) describing the PNL QA Program and the location in the QA Plan of an organization chart (project, activity, facility, etc.), if applicable. Also, a critical interface chart if applicable. (Use continuation sheets as necessary.)

EXAMPLE: "The PNL Quality Assurance Program conforms to the requirements of ASME NQA-1 as interpreted by Parts 1 and 3 of PNL-MA-70, Quality Assurance Manual. This QA Plan applies only to the project Impact Level I and II WBS elements, as designated by Exhibit 1. The project organization with key personnel identified is located in Exhibit 2, Project Organization, with key organizational interfaces shown in Exhibit 3, Project Interfaces." WBS elements identified as Impact Level III shall comply with the requirements of PNL-MA-70, Part 2.

QA PLAN FORMAT (CONSTRUCTION PROJECT) (cont'd)

IMPACT LEVEL RATIONALE: Provide rationale for the designated impact level and instructions for applying to the project, activity, etc., WBS element impact levels (reference to the Impact Level Matrix should be sufficient). The Impact Level Matrix shall be prepared on the form and in accordance with the instructions given in Exhibit 6, Impact Level Matrix.

SPECIAL CLIENT REQUIREMENTS: Special client requirements is subdivided in three parts and addressed as follows:

- A. Quote any special client requirements that are satisfied through provisions in Parts 1 or 3 of PNL-MA-70. Identify the section(s) in PNL-MA-70, Part 1, or the subsection(s) or paragraph(s) in the Part 3 Administrative Procedures that satisfy each requirement.
- B. Quote any special client requirements that are not satisfied through provision in Parts 1 or 3 of PNL-MA-70. Identify the method by which these requirements shall be accomplished.
- C. Record any specific exclusions, exceptions or limitations from PNL-MA-70 requirements mandated as a result of special client requirements. Identify alternative controls and/or procedures.

(Use continuation sheets as necessary.)

OTHER REQUIREMENTS, LIMITATIONS, DIRECTIONS, OR PLANNING: See Exhibit 8 of this procedure.

This section may also be used by the cognizant manager to provide any other appropriate direction.

FACILITY QA PLAN FORMAT

QA Plan No. _____

Safety Class SSCs: []

or

Non-Safety Calss SSCs: []

Facility QA Plan

(Facility/Building)

Plan Effective Date: _____

CONCURRENCES AND APPROVAL:

_____	_____
Cognizant Manager (Concurrence)	Date

_____	_____
Process Quality (Concurrence)	Date

_____	_____
Line Manager (Approval)	Date

FACILITY QA PLAN FORMAT (cont'd)

SCOPE:

QA REQUIREMENT SPECIFICATION(S):

- DOE 5700.6C as delineated in PNL-MA-70 and this QA Plan (see Other Requirements, Limitations, Directions, or Planning Section below)
- ASME NQA-1 as delineated in PNL-MA-70
- Other

When performing work associated with Safety Class systems, structures, and components (SSCs), that work shall comply with the applicable requirements of Parts 1 and 3 of PNL-MA-70. Work associated with Non-Safety Class SSCs shall comply with the Good Practices Standard located in Part 2 of PNL-MA-70. This QA Plan identifies the applicable PNL-MA-70, Part 3, Administrative Procedures for work being performed. If other quality-related activities are later performed, the appropriate PNL-MA-70 requirements and procedures shall be applied, unless specifically excluded.

APPLICABLE ADMINISTRATIVE PROCEDURES

Administrative procedures applicable to Safety Class SSCs are identified in PAP-70-207, Quality Program Requirements for Safety Classified Systems, Structures, and Components. Each Safety Class SSC is assigned required administrative procedures based on the task being performed. The requirements of the Good Practices Standard apply to Non-Safety Class SSCs.

<u>SSC</u>	<u>TASK</u>	<u>PROCEDURE</u>
------------	-------------	------------------

OTHER REQUIREMENTS, LIMITATIONS, DIRECTIONS, OR PLANNING:

Instructions for QA Plan Preparation

QA PLAN NUMBER: Supplied by Process Quality (and QA Plan Revision Number)

SAFETY CLASS: Check either "Safety Class" or "Non-Safety Class". The safety class of an SSC is determined in accordance with PNL-MA-44, Safety Analysis, manual. An SSC will be classified either "Safety Class" or "Non-Safety Class". Normally a QA Plan will only be written for SSCs that are classified as "Safety Class".

SCOPE: Identify the scope of the QA Plan. To what SSCs does it apply and for the applicable SSCs what actions does it apply.

FACILITY: Identify the facility in which the SSCs covered by this QA Plan are located.

FACILITY QA PLAN FORMAT (cont'd)

QA REQUIREMENTS SPECIFICATION(S): Check the appropriate box. Where Hanford site DOE Facilities are involved, the correct box would be DOE 5700.6C. When "Other" is checked, an additional entry identifying the specification is required.

CONCURRENCES AND APPROVAL: Others may be added when appropriate.

APPLICABLE ADMINISTRATIVE PROCEDURES: Identify the Safety Class SSCs and the action or task to be performed. For each SSC and action there will be a number of applicable administrative procedures as determined by PAP-70-207. Enter those procedures on the chart for the appropriate SSC/action.

OTHER REQUIREMENTS, LIMITATIONS, DIRECTIONS, OR PLANNING: See Exhibit 8 of this procedure.

This section may also be used by the cognizant manager to provide any other appropriate direction.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

WBS IMPACT LEVEL MATRIX (cont'd)

Instructions for WBS Impact Level Matrix

The WBS Impact Level Matrix shall be used to identify the impact levels of each WBS element of a given project. It may also be used to identify various other aspects or requirements of a project. This instruction provides direction on those items that the matrix shall be used for and guidance on those items/activities where it may be used.

The following information shall be entered on the WBS Impact Level Matrix shown on Page 1 of this Exhibit.

PAGE ___ OF ___: Enter the QA Plan Exhibit page number(s).

PROGRAM: Enter the program, project, activity, etc., title.

DATE: Enter current date.

REV. NO: Enter the WBS Impact Level Matrix revision number.

INDEX NO: Enter sequential number for each WBS element.

WBS LEVEL: Enter an X in the WBS Level column that indicates the appropriate WBS level for each element.

WBS ELEMENT TITLE: Enter the title of each individual WBS element.

GUIDANCE: Several PNL-MA-70, Part 3, procedures require that various items/activities be identified in the QA Plan (see Exhibit 8). This may be accomplished using this matrix. The item/activity that is to be identified (i.e., major procurements, requirement for certified inspection personnel, controlled processes, etc.) may be entered following the WBS element.

EXAMPLE: A major procurement to be acquired as part of a specific WBS element may be added after that WBS element and the impact level of the procurement assigned with subsequent approval by QA Plan approval. Hence, at the time of the procurement the impact level will have been preapproved and delays in procurement impact level approval avoided.

WBS ELEMENT CODE: Enter the appropriate WBS element number.

GUIDANCE: The WBS Element Code identifier for the items/activities listed may be shown by the use of an alpha modifier on the WBS element number or by the work package number, when available.

EXAMPLE: If there are two procurements under WBS element number 010202, the procurements may be identified as 010202A and 010202B.

Note: The information contained in the Index No. through WBS Element Code columns should be the same information that appears on the project WBS Index with the exception of the guidance items.

IMPACT LEVEL: Enter an "X" under the appropriate impact level for each WBS element.

GUIDANCE: Assign the item/activity impact level by entering an "X" in the appropriate column. The item/activity impact level shall not be higher than the WBS element impact level.

REMARKS: Provide rationale for impact levels selected, as appropriate, to assist in the interpretation of the QA Plan and impact levels selected.

IMPACT LEVEL BREAKDOWN FOR CONSTRUCTION PROJECTS

Project Designation: _____ Project Impact Level: _____

Project Title/Description: _____

Projects Elements	Element Impact Levels		
Element Designation/Title/Description	I	II	III

Notes:

IMPACT LEVEL BREAKDOWN FOR CONSTRUCTION PROJECTS (cont'd)

INSTRUCTIONS FOR USE

The Impact Level Breakdown for Construction Projects form shown on page 1 of this Exhibit or equivalent documentation shall be used to identify the impact levels of the elements that constitute a construction project. These elements will normally consist of the facility or equipment items included within the scope of the project. The breakdown may also be used to identify various other aspects or requirements of the project when it is necessary to identify impact levels for them. If all elements of a project are known to be the same impact level, this form may be omitted; however, a statement that the project impact level applies to all elements of the project must then be included in the QA section of the management plan.

The following information shall be entered on the Impact Level Breakdown Form:

PROJECT DESIGNATION: For Line Items and General Plant Projects, enter the DOE project number. For Miscellaneous Capital Work Orders, Expense Projects, etc., enter the project or other designation used by the cognizant project organization.

PROJECT IMPACT LEVEL: Enter the impact level for the project. Note that no element of a project can have a higher impact level than the project.

PROJECT TITLE/DESCRIPTION: Enter the project title and/or description itself used by the cognizant project organization.

PROJECT ELEMENTS

ELEMENT DESIGNATION/TITLE/DESCRIPTION: Use this portion of the form to provide a clear breakdown of the project into its elements. This may be done by assigning numerical designations such as 1.0, 1.1, 1.1.1, 1.1.2, etc. with appropriate titles/descriptions for each, or a simple indented title/description listing may be used. It is not necessary to do a further breakdown of Impact Level III elements; thus, the degree of breakdown may vary depending upon impact level.

ELEMENT IMPACT LEVELS: Use these columns to identify the applicable impact level for each element by entering an "X" in the appropriate column. Footnotes to be explained below may also be entered.

NOTES: Use this space to list applicable references or to provide further explanation for other entries on the form.

PAGE OF : Enter the appropriate page numbers for the form.

GENERAL INSTRUCTIONS

Use the Breakdown to clearly show the application of impact levels to the project elements. When necessary include or reference appropriate supporting evidence for the rationale used to arrive at particular impact level assignments.

If certain impact level decisions cannot be made when the QA section of the Management Plan is being prepared, enter "To Be Determined" or "TBD" in the appropriate places on the form. However, these decisions must be made and the impact levels assigned prior to performance of the affected design, engineering, or construction activities.

INFORMATION TO BE CONSIDERED FOR QA PLANS

This exhibit should be used in preparing all QA Plans. Not all items listed below need to be addressed, only those that are applicable and provide useful and relevant information to project/activity/facility staff. If the information requested is already or will be provided in another document, references to those documents shall be made in the QA Plan.

When the requested information is the result of other QA Program documents, the appropriate references are provided below. If no information is provided in response to these requests, the defaults specified by the QA Program will be imposed.

If information requested below is not available when the QA Plan is prepared, provide the best information available at that time. Do not unreasonably hold up issuance of the QA Plan waiting on more complete information. Interim Changes Notices can be used to update the QA Plan.

The cognizant manager may implement additional requirements of the QA Program that were not specifically addressed in the QA Plan. Further, it is not necessary for the QA Plan to be revised to reflect all requirements implemented unless this is the only way of identifying exactly what was done and why.

1. Where more than one organization is to be involved in activities covered by a QA Plan, the responsibility and authority of each organization shall be clearly identified. The intent of this requirement is to address key interfaces between organizations that are external to the project/activity/facility. This is usually addressed via an organization chart.
2. Identify internal interfaces between organizational units that are supporting the project/activity/facility. Usually addressed via an organization chart.
3. Identify any activities that will require qualified and certified inspection personnel (reference PAP-70-203).
4. Identify any controlled processes to be performed (reference PAP-70-901).
5. Identify any special processes to be performed (reference PAP-70-902).
6. Identify any special records generation requirements. Normally records generation is addressed via the RIDS but special attention or client emphasis may be warranted and documented in the QA Plan.
7. Identify the need for Quality Engineer concurrence on RIDS (reference PAP-70-1701).
8. Identify the need for dual storage of records (reference PAP-70-1701). There are two options (a & b shown below) and it must be clearly specified which option is acceptable. Option b is recommended when the client requires a strict interpretation of Basic Requirement 17 of ASME NQA-1.
 - a. Dual storage where one copy is sent to the PNWD Records Center and the second copy is maintained with the project in the field, or
 - b. Dual storage where two copies are sent to the PNWD Records Center which maintains one in the Record Center and forwards the second to the DOE Records Holding area of the 712 Building.
9. Identify the records turnover requirements (reference PAP-70-1701).
10. Identify the requirements and frequency for record reviews, including Laboratory Record Book (LRB) reviews.

INFORMATION TO BE CONSIDERED FOR QA PLANS (cont'd)

11. Identify those activities that will require an Engineering Design Plan (EDP) (reference PAP-70-302).
12. Identify the degree of independence required for the verification of engineering/scientific software prior to its use to generate data or information (reference SCP-70-312).
13. Identify the need and degree of validation required for engineering/scientific software (reference SCP-70-315).
14. Identify database steward(s).
15. Identify the review and approval requirements for test plans (reference PAP-70-1101 and PNL-MA-50).
16. Identify the need for independent in-process or final inspection (reference PAP-70-1001).
17. Identify the approval authority for making changes to permanently installed programmatic instrumentation and alarms associated with the project/activity/facility that is covered by the QA Plan.
18. Identify any major procurements and significant or special procurement controls.
19. Identify quality assurance requirements associated with sampling and analytical procedures, data processing, and reporting for activities associated with environmental protection, safety, and health protection.
20. When applicable to the scope of the project, identify production tests, construction tests, pre-operational tests and/or operational tests, and the required controls.
21. Identify the disposition or archival of test materials, specimens, and samples.
22. Identify software to be used, developed, or transferred.
23. Identify any special controls that are required to attain the required quality of products or services. Also consider and identify special controls necessary for the verification of that quality.
24. Identify any activities that will require a Peer Review in accordance with PAP-70-606.
25. Identify any activities that will require an Independent Technical Review in accordance with PAP-70-604.
26. For construction projects, review DOE Order 6430.1A, Section 0140, QUALITY ASSURANCE, for additional information that may need to be included in the QA Plan.

9513358.2508

INTERIM CHANGE NOTICE
(ICN)

A. Document No: PAP-70-206	Revision No: 1	Effective Date of ICN: 12/14 /94
Document Title: Controlling Work Received from Other Hanford Contractors		Change Requested By: JE McGarrah
Document's Original Author: RL Shaub		

B. Action:

Replace existing EXHIBIT 3 with attached EXHIBIT 3.

C. Effect of Change: N/A

THIS PAGE INTENTIONALLY LEFT BLANK

D. Reason for Change/Description of Change:

Reason for Change:

EXHIBIT 3 WHC Mail Stop was incorrect.

Description of Change:

Changed EXHIBIT 3, Page 1 of 1, WHC Related Work Mail Stop from MSIN R2-56 to MSIN N1-71

E. Approval Signatures (Please Sign and Date)	Type of Change:	{Check (✓) one}
	<input checked="" type="checkbox"/> Minor Change	<input type="checkbox"/> Major Change
DS Concurrence: JE Ruffin <i>JE Ruffin</i>	_____	Date: 11 / 22 / 94
Approval Authority: JE McGarrah <i>JE McGarrah</i>	_____	Date: 11 / 22 / 94
Other Approvals: _____	_____	Date: / /
_____	_____	Date: / /

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE
9515556.2509

TITLE: PAP-70-206, CONTROLLING WORK RECEIVED FROM HANFORD CONTRACTORS

PURPOSE

Ensure that appropriate quality assurance requirements have been identified and agreed upon prior to beginning work for Hanford Contractors.

APPLICABILITY

This procedure applies to all technical work conducted in support of Hanford Contractors.

This procedure does not apply to administrative or other nontechnical support services. Specifically excluded from the applicability of this procedure are services provided by the Technical Library and walk-in services such as duplicating, text processing, etc.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Recipient (Person receiving the Work Authorization and responsible for performing requested work).

GENERAL

All staff involved with work for Hanford Contractors are encouraged to include a discussion of QA requirements with their technical contact when considering new work. Process Quality Representatives (QEs) are available to assist with these discussions.

The work authorizing document utilized between the Hanford Contractors is the Work Order (EXHIBIT 1). A Work Order is required for all new work except walk-in services.

Often the Work Order serves primarily as the vehicle to establish funding and usually does not provide a detailed description of the work to be performed. The description of the work to be performed is often provided in a stand-alone document (e.g., Letter of Instruction, Statement of Work, memos, etc.) that should reference the Work Order in some way. These stand-alone documents can be considered work authorizing documents from the technical viewpoint.

Each Hanford Contractor has a system (e.g., Impact Levels, QA Levels, etc.) that helps determine the appropriate QA requirements. However, for the following reasons, PNL staff should not rely exclusively on the client's QA numerical designator (e.g., QA Level 1) to determine the appropriate QA requirements for a piece of work:

- These systems are not consistent among the Hanford Contractors.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


RL Shaub

6/16/94


JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

- Simply stating "QA Level 1" or "similar" does not provide useful information for PNL to determine what specific QA requirements are appropriate for the scope of work.
- PNL may increase the QA requirements above that specified by the client, when PNL determines this is appropriate.

The flow for processing Hanford Contractors authorized work is shown in EXHIBIT 2, Work Control Process for Work Authorized by Hanford Contractors.

IMPLEMENTATION

1.0 Evaluating QA Requirements

The Recipient shall evaluate the QA requirements provided with all requests for work. QA requirements received can usually be placed into one of four groups. These groups and the required actions associated with each of these groups are discussed below. The cognizant Process Quality Representative can be contacted to assist in evaluating the appropriate QA requirements for work authorizations received.

1.1 Group 1 - Work Authorizations Which Do Not Contain QA Related Information

If the client has authorized work (either in writing or verbally) and the QA requirements are not identified, the Recipient shall complete Part A of EXHIBIT 3 and send it to the technical contact within the client's organization. Work shall not progress beyond the planning stages until the client responds.

1.2 Group 2 - Work Authorizations Which Contains Only a QA Designator

If the client has authorized work and a QA Level has been specified but no additional information on QA requirements has been provided, the Recipient shall complete Part B of EXHIBIT 3 and send it to the technical contact within the client's organization. Work may proceed when the required PNL controls are in place (i.e. PMP, QA Plan, etc.).

1.3 Group 3 - Work Authorization Identifies Requirements that PNL is Unable to Implement

If the client has authorized work and specified QA requirements that PNL is unable to implement, the Recipient shall complete Part C of EXHIBIT 3 and send it to the technical contact within the client's organization. An explanation of why PNL is unable to implement the specified requirements shall be attached to the transmittal. PNL will not proceed until resolution is obtained.

1.4 Group 4 - Work Authorizations with Adequately Identified QA Requirements

If the client has authorized work and QA requirements are adequately specified, the Recipient is responsible for assuring that the following appropriate actions take place.

- 1.4.1 For work that is to be conducted under an existing QA Plan, the Recipient shall assure that deliverables are traceable to the QA requirements governing the work and the work authorizing document.
- 1.4.2 For all other work, the Recipient shall assign an Impact Level in accordance with PAP-70-208, Impact Levels and:
 - prepare a QA plan in accordance with PAP-70-205, Quality Assurance Plans, or
 - conduct the work in accordance with GPS.

PNL ADMINISTRATIVE PROCEDURE
9515358.2510

PROCEDURE NO.: PAP-70-206

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

2.0 Special Cases

When the client requests PNL to conform to the client's own QA policies and procedures while acting as a consultant or performing technical support work, the Recipient shall complete Part D of EXHIBIT 3 if this request has not already been documented.

REQUIRED RECORDS

None.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

HANFORD SITE WORK ORDER

EXAMPLE

BA2959
WORK ORDER

54-306 JB (01 89)

*SERVICING/ COST CENTER	*CUSTOMER/ SUPPORT CODE	SUB-ACCOUNT/ ACCT. CLASS	REF. NO. WO	AUTH. FUNDS	AREA	BLOG	(1)
START DATE	TERM DATE	OVERHEAD CODES		PROJECT NO			
RESPONSIBLE ORG.	QA LEVEL	QA REVIEW	FY FUNDS	PR NO.	SYSTEM		
DESCRIPTION		FACILITIES CHANGE NOTICE - <input type="checkbox"/> YES <input type="checkbox"/> NO		ASSIGNED TO	FM NO		
				ESTIMATED COST (INCLUDES REFERRAL ORDERS)			
				HOURS			
				LABOR & TIME			
				MATERIAL			
				OTHER			
				TOTAL			
BUDGET APPROVAL	DATE			LINE OR COST ACCOUNT			
ISSUED BY	DATE	PHONE	ACCEPTED BY			ASSIGNED SERV	
APPROVED BY	DATE	COMPLETED - FMN		DATE	ISSUING ORGAN		

SERVICING FINANCIAL

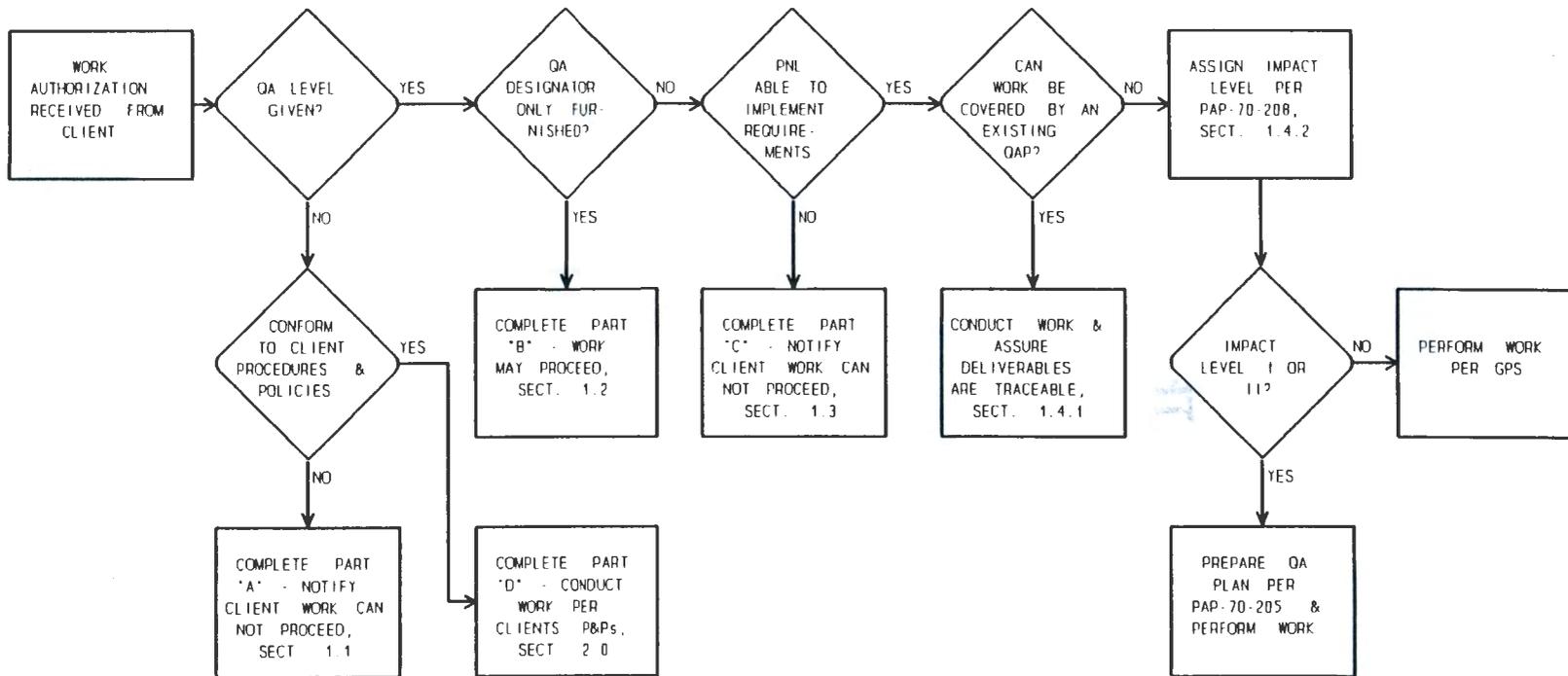
* FIRST DIGIT COMPANY INDICATOR

D - PNL R - KEH M - HEHF W - WMC 9 - DOE

(1) FOR INTERNAL CONTRACTOR USE ONLY

**THIS PAGE INTENTIONALLY
LEFT BLANK**

WORK CONTROL PROCESS FOR WORK AUTHORIZED BY HANFORD CONTRACTORS



9513501.2512

**THIS PAGE INTENTIONALLY
LEFT BLANK**

QA REQUIREMENTS EVALUATION SHEET

Date: _____

To: (Client's Primary Technical Contact) _____

From: (PNL Recipient) _____

Subject: _____

Applicable Work Order Number: _____

- A. PNL has been requested to perform the subject work for your organization. To date, PNL has not been informed of the QA requirements applicable to this work. Until PNL is notified of the appropriate requirements, work will not proceed beyond the initial planning phase.
- B. PNL has been requested to perform the subject work for your organization. PNL has been informed that this work is identified as QA Level _____. No additional QA requirements have been identified, therefore, the work will be conducted in accordance with the Impact Level _____ requirements of PNL's QA Program, PNL-MA-70.
 - A QA plan will be prepared prior to progressing beyond the planning stages of this work.
 - A QA Plan _____ already exists that adequately covers this type of work and will be used accordingly.
 - The work will be conducted in accordance with PNL's Good Practices Standard and a specific QA Plan will not be prepared.
- C. PNL has been requested to perform the subject work for your organization. Your work authorizing document identifies requirements that cannot be implemented by PNL at this time. PNL will proceed following resolution of this issue.
- D. PNL has been requested to perform the subject work for your organization. It is PNL's understanding that this work will be governed solely by your policies and procedures and, therefore, PNL's QA program does not apply.

Attach copy of subject work order.

Required Distribution:

Copy Appropriate Organization

PNL Process Quality (P7-72)
Project/Activity File

WHC Related Work: WHC QA, MSIN N1-71
KEH Related Work: KEH QA, MSIN E3-11
HEHF Related Work: HEHF QA, _____

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE
95133501.2514

PROCEDURE NO.: PAP-70-207

REVISION NO.: 0

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: PAP-70-207, QUALITY PROGRAM REQUIREMENTS FOR SAFETY CLASS SYSTEMS, STRUCTURES, AND COMPONENTS

BACKGROUND/INTRODUCTION

The methods and requirements contained in this procedure for applying Quality Program requirements to safety class systems, structures, and components supersede those described in ICN-PAP-70-208-R2-1 (PAP-70-208). The ICN provided interim instructions for the application of Quality Program administrative control requirements to safety class systems, structures, and components.

PURPOSE

Provide a uniform method of ensuring the appropriate Quality Program requirements are applied to Safety Class and Non-Safety Class systems, structures, and components (SSCs).

APPLICABILITY

This procedure applies to PNL designed, constructed, maintained, owned and/or operated systems, structures, and components. Safety class is limited to facility SSCs.

Methods for the application of impact levels to programs, projects, and activities are contained in PAP-70-208, Impact Levels.

REFERENCES

PNL-MA-44, Safety Analysis

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Building Manager
- Cognizant Staff (individual responsible for initiating or accomplishing work)
- Cognizant Manager (manager responsible for ensuring work correctly accomplished)
- Facilities Engineer
- Project Manager.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

RL Shaub

6/17/94

RL Shaub

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah

6/20/94

JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

GENERAL

Safety class is assigned to systems, structures, and components (SSCs) in accordance with the guidance found in Section 7.0, Safety Classification, of PNL-MA-44, Safety Analysis. PNL-MA-44 establishes a Safety Classification committee to ensure consistent interpretation of the safety class criteria. PNL-MA-44, Safety Analysis, also provides guidance for the interim assignment of safety class to currently existing facility SSCs assigned impact levels.

IMPLEMENTATION

1.0 Quality Program Administrative Control Selection

- 1.1 Quality assurance administrative controls are applied to work based on the task being performed and the safety class of the SSCs.
- 1.2 Cognizant Staff shall determine the PNL-MA-70, administrative procedures that apply to the work being performed by use of EXHIBIT 1, Safety Class Procedure Applications Guide.

NOTE: EXHIBIT 1, Page 2, provides the information of EXHIBIT 1 in a flowchart form.

The guide, EXHIBIT 1, references procedure groups for specific activities, based on who is to perform the activity and the safety class of the impacted SSCs. Refer to EXHIBIT 2, Safety Class Procedure Group Listings, to determine required procedures that correspond to the activity performed, the performer, and the safety class the impacted/involved SSC.

- 1.3 Cognizant Staff shall ensure that SSCs that generate and/or collect reportable data required by regulation, code, or statute shall, as a minimum, be controlled as Impact Level II items even if the SSCs are Non-Safety class SSCs. Affected SSCs include, but are not limited to:

- stack monitoring systems
- effluent monitoring systems

that generate and/or collect reportable data required by regulation, code, or statute.

- 1.4 Cognizant Staff shall ensure that activities related to SSCs that could have an impact on PNL's mission, programs, and business shall, as a minimum, be controlled as Impact Level II items even if the SSCs are Non-Safety class. These include:

- critical path activities in major client programs or line items, e.g., designs or analysis, or acquisitions of long time materials and equipment
- activities whose deliverables will be critical to major decisions in such areas as business, economics, or technology applications
- activities where documentation of how the product or result was generated is required as part of the deliverable and/or establish the acceptability or validity of the product or results
- any activity designated by the cognizant director as being of sufficient potential concern as to warrant special management attention. Typical bases for such concern might include prior client evaluations, Operations Directive commitments, public or scientific image, future market potential, and client requests.

2.0 Work Performance

2.1 New Design or Construction

- 2.1.1 For new design or construction the assigned Project Manager shall ensure safety class is assigned to SSCs in accordance with PNL-MA-44, Safety Analysis.
- 2.1.2 The Cognizant Staff shall determine the PNL-MA-70 administrative controls that apply to the SSCs in accordance with Section 1.0 above.
- 2.1.3 The Cognizant Manager shall ensure that the procedures required by EXHIBIT 2, Safety Class Procedure Group Listings are applied when activities are performed that affect Safety Class SSCs.

2.2 Design/Modification

- 2.2.1 The Facilities Engineer shall ascertain the safety class of the SSC.

NOTE: If the SSC has not yet been assigned a safety class the Facilities Engineer shall refer to PNL-MA-44, Safety Analysis, Section 7.0, for guidance.

- 2.2.2 The Cognizant Staff shall determine the PNL-MA-70 administrative controls that apply to the SSCs in accordance with Section 1.0 above.
- 2.2.3 The Cognizant Manager shall ensure that the procedures required by EXHIBIT 2 are applied when activities are performed that affect Safety Class SSCs.

2.3 Maintenance and Operation

- 2.3.1 The Building Manager shall ascertain the Safety Class SSCs.

NOTE: Requirements for the management of SSCs during corrective and preventive maintenance, operations, etc will be found in PNL-MA-595, Management Plan - MP-FO-1 for PNL Facility Systems, Structures, and Components. Guidelines for SSCs not assigned a safety class will also be found in this document.

- 2.3.2 The Cognizant Staff shall determine the PNL-MA-70 administrative controls that apply to the SSCs in accordance with Section 1.0 above.
- 2.3.3 The Cognizant Manager shall ensure that the procedures shown in EXHIBIT 2 are applied when activities are performed that affect Safety Class SSCs.

REQUIRED RECORDS

None.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

**SAFETY CLASS
PROCEDURE APPLICATIONS GUIDE**

By responding to the following questions, the user will generate a list of applicable Administrative Procedures. This list of procedures furnishes the necessary Quality Program administrative controls for those Safety Class (SCCs) and the activities that affect Safety Class SCCs.

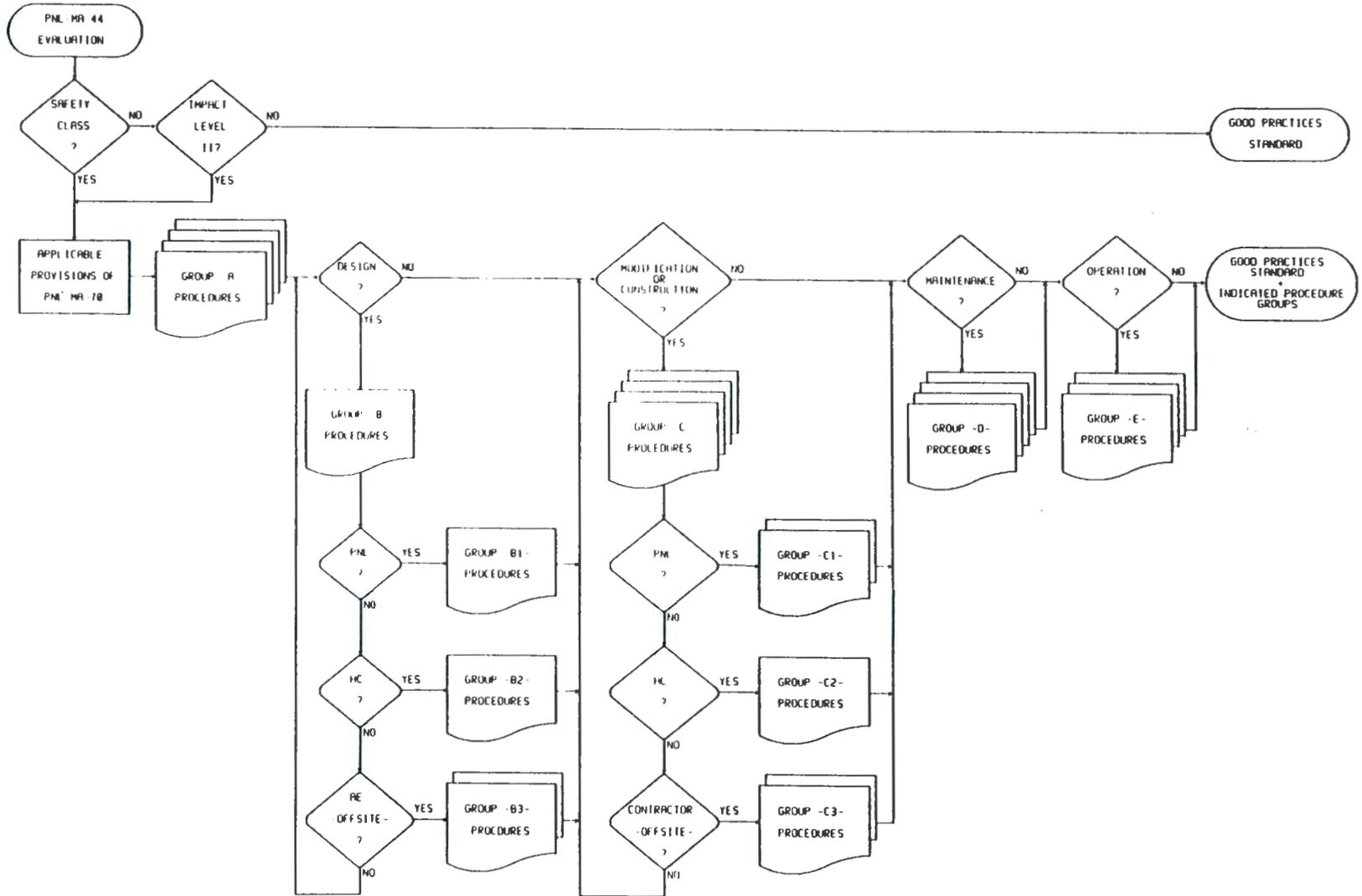
Determine Administrative Procedure Applicability

- 1.0 Use the safety class assigned when the facility systems, structures, or components (SCCs) were evaluated per Section 7.0, Safety Classification, of Laboratory Safety Manual PNL-MA-44, Safety Analysis. Determine the administrative control requirements by responding to the following questions. The procedure groups below apply only to the SCCs affected for the activities indicated.
- 2.0 **Is the SSC Non-Safety Class?** If 'Yes', proceed to 3.0. If 'No', proceed to 4.0.
- 3.0 **Is the SSC Impact Level II (refer to paragraphs 1.3 & 1.4 of the procedure)?** If 'Yes', proceed to 4.0. If 'No', the Good Practices Standard of PNL-MA-70, Part 2, applies.
- 4.0 **Group A procedures apply, proceed to 4.1.**
 - 4.1 **Are any Design activities involved?** If 'Yes', Group B procedures apply, proceed to 4.1.1. If 'No', proceed to 4.2.
 - 4.1.1 **Are the Design activities being performed by PNL?** If 'Yes', Group B1 procedures apply, proceed to 4.2. If 'No', proceed to 4.1.2.

NOTE: It is possible that the design activities may be split between PNL and a Hanford Contractor (HC) or Architect Engineer (AE). If this occurs, the controls for that type activity apply where applicable.
 - 4.1.2 **Are the Design activities being performed or subcontracted by another Hanford contractor?** If 'Yes', Group B2 procedures apply, proceed to 4.2. If 'No', proceed to 4.1.3.
 - 4.1.3 **Are the Design activities being performed by an off-site AE?** If 'Yes', Group B3 procedures apply, proceed to 4.2. If 'No', proceed to 4.2.
 - 4.2 **Are any Construction or Modification activities involved?** If 'Yes', Group C procedures apply, proceed to 4.2.1. If 'No', proceed to 4.3.
 - 4.2.1 **Are the Construction or Modification activities being performed by PNL?** If 'Yes', Group C1 procedures apply, proceed to 4.3. If not, proceed to 4.2.2.

NOTE: It is possible that the construction or modification activities may be split between PNL and an HC or off-site contractor. If this occurs the controls for that type activity apply where applicable.
 - 4.2.2 **Are the Construction or Modification activities being performed or subcontracted by another Hanford contractor?** If 'Yes', Group C2 procedures apply, proceed to 4.3. If 'No', proceed to 4.2.3.
 - 4.2.3 **Are the Construction or Modification activities being performed by an off-site contractor?** If 'Yes', Group C3 procedures apply, proceed to 4.3. If 'No', proceed to 4.3.
 - 4.3 **Are any Maintenance activities involved?** If 'Yes', Group D procedures apply. Proceed to 4.4.
 - 4.4 **Are Operational activities involved?** If 'Yes', Group E procedures apply.

SAFETY CLASS ANALYSIS



**SAFETY CLASS
PROCEDURE GROUP LISTINGS**

Each facility system, structure, or component (SSC) has a safety class assigned. The safety class indicates the safety significance of the SSC. As a result, a graded approach to the application of Quality Program administrative controls is required.

Following are the procedures that provide the necessary Quality Program administrative controls to Safety Class facility SSCs. This exhibit may be used in conjunction with the checklist provided in Exhibit 1 or as a stand alone reference listing for Safety Class SSCs. The Good Practices Standard applies, as a minimum, to SSCs that are classified as Non-Safety Class.

Group A Procedures

Group A procedures always apply to the activities performed in support of a Safety Class system, structure, or component.

PNL-MA-531	QUALITY PROGRAMS INSTRUCTIONS (Planning and Performing Surveillance) (Quality Trend Analysis of Reported Data) (Internal Audits)	(QP Staff activities)
PAP-70-201	INDOCTRINATION AND TRAINING	
PAP-70-207	QUALITY PROGRAM REQUIREMENTS FOR SAFETY CLASS SYSTEMS, STRUCTURES, AND COMPONENTS	
PAP-70-301	HAND CALCULATIONS, GENERAL	
PAP-70-501	PREPARATION AND APPROVAL OF ADMINISTRATIVE PROCEDURES	
PAP-70-601	DOCUMENT CONTROL	
PAP-70-602	PROCEDURE AND INSTRUCTION CHANGE CONTROL AND CHANGE REQUEST	
PAP-70-605	DOCUMENT CONTROL - FURNISHED DOCUMENTS	
PAP-70-1502	DEFICIENCY REPORTS	
PAP-70-1701	RECORDS SYSTEM	

Group B Procedures

Group B procedures apply to Design activities performed on Safety Class SSC. **Group B** procedures contain those procedures that always apply plus additional procedures that apply under limited conditions.

Always Apply (Group B):

PAP-70-302 ASSURANCE AND CONTROL OF ENGINEERING DESIGN

PNL Doing the Design Work (Group B1) apply:

PAP-70-404 OBTAINING SERVICES

Hanford Contractor (HC) Doing or Contracting for the Design Work (Group B2) apply:

PNL-MA-531	QUALITY PROGRAMS INSTRUCTIONS (Supplier and Other Hanford Contractor Audits)	(QP Staff activities)
PAP-70-101	COMMUNICATION AND COMMITMENT (INTERFACE) CONTROL	
PAP-70-404	OBTAINING SERVICES	

**SAFETY CLASS
PROCEDURE GROUP LISTINGS**

Off-Site AE Doing the Design Work (Group B3) apply:

CAP-70-401	PREPARATION OF RFPS AND AWARD OF PURCHASE ORDERS/SUB CONTRACTS
CAP-70-701	PROPOSAL EVALUATION, SUPPLIER/SUBCONTRACTOR SELECTION AND PURCHASE ORDER/SUBCONTRACTOR ADMINISTRATION (POST AWARD)
PAP-70-101	COMMUNICATION AND COMMITMENT (INTERFACE) CONTROL
PAP-70-401	PURCHASE REQUISITIONS
PAP-70-704	SOURCE INSPECTIONS, TESTS, AND SURVEILLANCES
PAP-70-1602	CORRECTIVE ACTION

Group C Procedures

Group C procedures apply to Modification or Construction activities performed on a Safety Class SSC. Group C procedures contain procedures that always apply plus additional procedures that apply under limited conditions.

Always Apply (Group C):

PAP-70-203	QUALIFICATION AND CERTIFICATION OF INSPECTION TEST PERSONNEL
PAP-70-302	ASSURANCE AND CONTROL OF ENGINEERING DESIGN
PAP-70-402	CONTROL OF SUSPECT/COUNTERFEIT ITEMS
PAP-70-702	PREPARATION AND USE OF INSPECTION/TEST INSTRUCTIONS
PAP-70-704	SOURCE INSPECTION, TESTS, AND SURVEILLANCES
PAP-70-706	RECEIVING INSPECTION
PAP-70-803	ITEM IDENTIFICATION AND CONTROL
PAP-70-902	CONTROL OF SPECIAL PROCESSES
PAP-70-1001	INDEPENDENT INSPECTION
PAP-70-1201	CALIBRATION CONTROL SYSTEM
PAP-70-1301	HANDLING, STORING, AND SHIPPING
PAP-70-1401	INSPECTION AND TESTING STATUS AND TAGGING
PAP-70-1501	NONCONFORMANCE REPORTS

PNL doing Modification or Construction Work (Group C1) apply:

CAP-70-401	PREPARATION OF RFPS AND AWARD OF PURCHASE ORDERS/SUBCONTRACTS
CAP-70-701	PROPOSAL EVALUATION, SUPPLIER/SUBCONTRACTOR SELECTION AND PURCHASE ORDER/SUBCONTRACT ADMINISTRATION (POST AWARD)
PAP-70-401	PURCHASE REQUISITIONS
PAP-70-404	OBTAINING SERVICES

Hanford Contractor (HC) doing or Contracting for Modification or Construction Work (Group C2) apply:

PAP-70-101	COMMUNICATION AND COMMITMENT (INTERFACE) CONTROL
PAP-70-404	OBTAINING SERVICES

Off-Site Contractor doing Modification or Construction Work (Group C3) apply:

CAP-70-401	PREPARATION OF RFPS AND AWARD OF PURCHASE ORDERS/SUB CONTRACTS
CAP-70-701	PROPOSAL EVALUATION, SUPPLIER/SUBCONTRACTOR SELECTION AND PURCHASE ORDER/SUBCONTRACTOR ADMINISTRATION (POST AWARD)
PAP-70-101	COMMUNICATION AND COMMITMENT (INTERFACE) CONTROL
PAP-70-401	PURCHASE REQUISITIONS
PAP-70-1602	CORRECTIVE ACTION

**SAFETY CLASS
PROCEDURE GROUP LISTINGS****Group D Procedures**

Group D procedures always apply to Maintenance activities performed on a Safety Class SSC.

CAP-70-401	PREPARATION OF RFPS AND AWARD OF PURCHASE ORDERS/SUBCONTRACTS
CAP-70-701	PROPOSAL EVALUATION, SUPPLIER/SUBCONTRACTOR SELECTION AND PURCHASE ORDER/SUBCONTRACT ADMINISTRATION (POST AWARD)
PAP-70-203	QUALIFICATION AND CERTIFICATION OF INSPECTION AND TEST PERSONNEL
PAP-70-302	ASSURANCE AND CONTROL OF ENGINEERING DESIGN
PAP-70-401	PURCHASE REQUISITIONS
PAP-70-402	CONTROL OF SUSPECT/COUNTERFEIT ITEMS
PAP-70-404	OBTAINING SERVICES
PAP-70-604	INDEPENDENT TECHNICAL REVIEW
PAP-70-702	PREPARATION AND USE OF INSPECTION/TEST INSTRUCTIONS
PAP-70-704	SOURCE INSPECTION, TESTS, AND SURVEILLANCES
PAP-70-706	RECEIVING INSPECTION
PAP-70-803	ITEM IDENTIFICATION AND CONTROL
PAP-70-902	CONTROL OF SPECIAL PROCESSES
PAP-70-1001	INDEPENDENT INSPECTION
PAP-70-1201	CALIBRATION CONTROL SYSTEM
PAP-70-1301	HANDLING, STORING, AND SHIPPING
PAP-70-1401	INSPECTION AND TESTING STATUS AND TAGGING
PAP-70-1501	NONCONFORMANCE REPORTS

Group E Procedures

Group E procedures always apply to Operational activities performed on a Safety Class SSC.

PAP-70-604	INDEPENDENT TECHNICAL REVIEW
PAP-70-803	ITEM IDENTIFICATION AND CONTROL
PAP-70-901	CONTROL OF PROCESSES
PAP-70-1101	TEST PLANNING, PERFORMANCE, AND EVALUATION
PAP-70-1201	CALIBRATION CONTROL SYSTEM
PAP-70-1301	HANDLING, STORING, AND SHIPPING
PAP-70-1401	INSPECTION AND TESTING STATUS AND TAGGING
PAP-70-1501	NONCONFORMANCE REPORTS

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-208, IMPACT LEVELS

PURPOSE

Describe the method of determining and applying impact levels to projects, service activities, and work orders.

APPLICABILITY

PNL projects, service activities, and work orders shall be assigned impact levels according to the potential safety and/or technical consequences of a failure to accomplish goals. The type and degree of safety, management, and administrative controls applied to, and resource requirements for, the project, task, activity, or item are determined or guided by the assigned impact level.

Tasks and items within an Impact Level I or II project or activity may be assigned a lower impact level than the project or activity. Criteria and requirements for the assignment of impact levels are provided in this procedure.

Methods for ensuring that appropriate Quality Program requirements are applied to safety class systems, structures, and components are described in PAP-70-207, Quality Program Requirements for Safety Class Systems, Structures, and Components. Safety class items are limited to PNL facility systems, structures, and components (SSCs).

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Line Manager
- Project/Cognizant Manager
- Quality Programs (QP) Representative
- Safety Representative
- Staff Members
- Technical Representatives.

IMPLEMENTATION

1.0 Impact Level Assignment

1.1 If the client has specified the Battelle impact level to be applied to the project, the Project Manager shall not assign an impact level lower than that specified level. However, a higher impact level shall be assigned if required by the criteria in Exhibit 1, Impact Level Criteria.

1.2 The Cognizant Manager shall review and process work orders received from Hanford Contractors in accordance with PAP-70-206, Controlling Work Received from Hanford Contractors, unless the work order covers activities that, based on client concerns, are obviously Impact Level III (see Exhibit 1, Impact Level

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

6/17/94

6/20/94

RL Shaub

JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

Criteria). Contact information shall be documented and retained as part of the project/activity records.

- 1.3 The Cognizant Manager shall determine the impact level for all service activities using the criteria in Exhibit 1, Impact Level Criteria. Documentation of the applicable impact level with the rationale and approval/concurrence signatures shall be retained as part of the activity records.

2.0 Documentation of Impact Level

- 2.1 The Cognizant Manager shall document the impact level in the project/activity management plan or, when there is no management plan required, in the project/activity QA Plan. Documentation and content requirements for QA Plans are provided in PAP-70-205, QA Plans.
- 2.2 The Cognizant Manager shall not assign an impact level to a subtier task/activity that is higher than the impact level assigned to the project activity.
- 2.3 The Cognizant Manager may assign an impact level to subtier task/activities that is lower than the impact level assigned to the project/activity, provided that the consequences of a potential failure of the particular item/activity was not a factor in assigning the specific impact level to the project as a whole. In such cases, the subtier item/activity shall be assigned that same impact level.
 - a. The Cognizant Manager shall determine, or have determined, the impact level for any task, subtask, procurement, work order fabrication or service, item or activity to be specifically identified in the QA Plan.
 - b. In determining subtier impact levels, Exhibit 1, Impact Level Criteria, shall be used.
 - c. More than one impact level criteria may be applicable to a given project/activity.

3.0 Impact Levels Not in the QA Plan

- 3.1 Staff Members may assign Impact Level III to any item/activity that is to be used exclusively on a project/activity previously classified as a Impact Level III project/activity. The Cognizant Manager's signature on the purchase requisition, work order, drawing, etc., is adequate documentation of determination.
- 3.2 If items/activities have not been assigned an impact level in an approved QA Plan, the Cognizant Manager shall determine the impact level, using the criteria in Exhibit 1, Impact Level Criteria. When the impact level assigned to a specific item/activity is lower than the impact level assigned to the project/activity as a whole, the rationale, approval, and concurrence for such levels shall be documented and included in the project/activity file.
- 3.3 For any documents that include, or should include an impact level, the Cognizant Managers, Line Managers, Technical Representatives, Safety Representatives, and QP Representatives shall include in their review of the document a review of the impact level assigned.

4.0 Use of Impact Levels

4.1 Staff Members should note that:

- Impact levels are one of the factors used in the determination of quality assurance requirements.
- Impact Level I and II items and activities are required to meet the requirements of the PNL-MA-70 Manual and its associated administrative procedures.
- Some administrative procedures apply additional requirements to Impact Level I items and activities that are not applied to Impact Level II.

9513550.2520
PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-208

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

- Quality assurance requirements for Impact Level III items and activities are provided in the Good Practices Standard, Part 2 of PNL-MA-70.
 - Impact levels are also used to determine the applicability of other, non-QA specific, management control requirements.
- 4.2 QP Representatives shall review documents specifying QA requirements to determine if the QA requirements are appropriate for the assigned impact level and for the functions to be performed.
- 4.3 The Cognizant Manager shall review the project/activity impact level when a change in project/activity scope occurs.

REQUIRED RECORDS

Documentation of the impact level is a record. Therefore, documents where the impact level is recorded such as:

- activity/management plans
- activity/project QA plans
- Proposal Preparation and Risk Assessment forms

are records.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

IMPACT LEVEL CRITERIA

Impact Level I (IL-I)

Applies to projects, tasks, activities, or items whose failure could:

- A. Result in (or increase the severity of) a release of radioactive, hazardous or toxic material to the public or environs beyond established limits.
- B. Inhibit the detection of such release.
- C. Prevent control, including safe shutdown, which would reduce the magnitude or consequence of such release.

A project, task, activity, or item is IL-I if it or its end product is:

1. Equipment, a system, or a facility (or design, analysis or operation thereof) relied upon to prevent, detect or control an off-site release of radioactive or toxic materials exceeding established limits.
2. A peripheral component, procedure, or test which, through its presence or performance, could prevent the proper functioning of IL-I equipment or systems.
3. Any activity where the activity itself, its deliverable, or its application will be directly relied on for establishing licensing or regulatory requirements.
4. An off-site deliverable that will be required to meet licensing requirements.

Impact Level II (IL-II)

Applies to projects, tasks, activities, or items whose failure could:

- A. Expose on-site personnel to radioactive, hazardous, or toxic material beyond established limits.
- B. Cause a major impact in achievement of facility or program objective (test, operations, production).

A project, task, activity, or item is IL-II if any of the following apply:

1. It or its end product is:
 - a. equipment, a system or a facility (or design, analysis or operation thereof) relied upon to prevent, detect, or control an on-site release of radioactive or toxic materials exceeding established limits, or
 - b. a peripheral component, procedure, or test which through its presence or performance could prevent the proper functioning of the IL-II equipment.
2. It will be required to meet statutory requirements but will be used on-site only.
3. It includes activities where error or failure could cause a major impact in achievement of facility or program objectives. These include:

- a. critical path activities in major client programs or line items, e.g., designs or analysis, or acquisitions of long lead time materials and equipment
 - b. activities whose deliverables will be critical to major decisions in such areas as business, economics, or technology applications
 - c. activities where documentation of how the product or result was generated is required as part of the deliverable and/or to establish the acceptability or validity of the product or results
 - d. any activity designated by the cognizant director as being of sufficient potential concern as to warrant special management attention. Typical bases for such concern might include prior client evaluations, Operations Directive commitments, public or scientific image, future market potential, and client requests.
4. The proposed work involves a client that requires adherence to a recognized QA Program (e.g., NQA-1, MIL-Q-9858A, QAMS-005, NQA-2 Part 2.7) or a client that requires adherence to controls in addition to those in GPS (e.g., an existing QA Plan, IEEE-Std, regulatory/statutory requirements).

Impact Level III (IL-III)

A project, task, activity, or item is IL-III if it does not meet the criteria for either IL-I or IL-II.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-301, HAND CALCULATIONS, GENERAL

PURPOSE

Describe the requirements for the performance, documentation, and review of hand calculations to ensure accuracy and completeness.

APPLICABILITY

This procedure applies to the performance, documentation, and review of hand calculations when compliance with this procedure is specifically required by a QA Plan, Statement of Work, or other governing document.

The requirements of this procedure for documentation and records are not applicable to hand calculations that are documented in a Laboratory Record Book (LRB) and reviewed as part of the review of the LRB.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Project Managers.

IMPLEMENTATION

1.0 Bases for Hand Calculations

- 1.1 Client or other requirements or constraints on the bases for hand calculations shall be described or referenced in calculation reports.
- 1.2 Except for terms, values, and methods commonly known and accepted in the applicable technical discipline, calculation reports shall define the following items with sufficient detail so that a competent third party familiar with the discipline involved may readily review the calculations:
 - assumptions and references
 - algorithms, models, and calculation procedures
 - input data and sources, except for those constants, coefficients, etc., which have been published in the literature and are generally accepted in the discipline involved.
- 1.3 Calculation reports shall also include sample calculations whenever necessary to permit review or reconstruction by a third party.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE



6/20/94

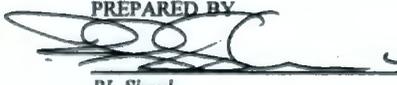
JW Smith, Director, Quality Programs

PREPARED BY

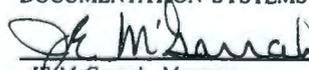
DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE



6/17/94



6/20/94

RL Shaub

JE McGarran, Manager

PNL ADMINISTRATIVE PROCEDURE

- 1.4 If a programmable or preprogrammed calculator or computer is used for any portion of a calculation, the calculator/computer shall be identified and the program identified and/or described.

2.0 Performance and Documentation of Hand Calculations

- 2.1 The Project Manager shall ensure that staff members and others who perform hand calculations are qualified in the appropriate technical disciplines and are familiar with the subject of the calculations.
- 2.2 Hand calculations shall be performed in a logical, straightforward manner, and shall be presented in a form which can be understood and reviewed by others who are qualified in the applicable discipline.
- 2.3 The Project Manager may designate or allow any appropriate media to be used to perform and document calculations provided that the following requirements are met:

- Calculations shall be clear, legible, and reproducible by photocopying.
- Errors or deletions of record originals of hand calculations shall be suitably marked, initialed, and dated by the person making the correction. The marking shall clearly and unambiguously identify deletions and corrections.
- Permanent black ink is preferred for record originals. Red or other color ink which has been shown to be reproducible may be used.
- Pencil drafts and working papers may be used provided that record originals, if required, are prepared by photocopying and meet all applicable requirements of this procedure.

- 2.4 Except as noted in 2.8 below, the first page or cover page of each hand calculations report shall include the following information:

- the title, subject, or description of the calculations or other traceable reference
- program/project designation, if applicable
- a completed, accurate "Page 1 of" entry, together with an accurate and correct listing of any appendices or attachments
- name of each person preparing the calculations and date of preparation.

Any appropriate format which includes the above items may be used when approved by the Project Manager.

- 2.5 Subsequent pages of hand calculations and also any appendices, attachments, or other supporting documentation shall be page numbered and shall be identified with the reference shown on the first page or cover page.
- 2.6 Final results of hand calculations shall be clearly identified by suitable marking or description. Such data may be presented in graphic form or may be tabulated provided that an adequate descriptive title is used.
- 2.7 Hand calculations may be presented in their original hand written form or may be typed or printed. Any calculations which are transposed from their original form shall be checked against the original to ensure that errors in transposing or copying are not introduced.
- 2.8 Hand calculations may be documented as a portion of a larger report, provided that all applicable requirements of this procedure are met. In such cases page identification, etc., shall comply with

requirements for the report; however, documentation of the preparation and review process for the calculations shall be maintained as required by this procedure.

3.0 Review of Hand Calculations

- 3.1 Hand calculations shall be checked as a primary verification of accuracy and completeness. Checking shall be performed by qualified persons who did not participate in performing the calculations. Checking shall be documented, preferably by signature and date on the calculations. Separate documentation is acceptable, provided that traceable records are maintained.
- 3.2 When required by a client or by a QA Plan or other governing document, the Project Manager shall ensure that other independent reviews are performed and documented as specified. The Project Manager may also require that additional reviews be performed and documented of all or any portion of the calculations.
- 3.3 Partial or limited scope checking and reviews shall be clearly identified as such when they are documented.

4.0 Errors in Hand Calculations Reports

If errors are found in reports of hand calculations which have been published, distributed, or delivered to a sponsor, the Project Manager shall:

- evaluate the significance and effect of the errors
- take and document appropriate corrective action
- inform the client and other report recipients, as required by the applicable QA Plan or other governing document.

REQUIRED RECORDS

The calculation reports created as a result of this procedure are records.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-302, ASSURANCE AND CONTROL OF ENGINEERING DESIGN

PURPOSE

Provide a uniform method to ensure the proper identification, definition, documentation, and control of applicable requirements for engineering design activities.

APPLICABILITY

This procedure is applicable to engineering design activities. Also, this procedure requires compliance with PNL-MA-90, Design: Preparation, Control, and Implementation, which provides detailed requirements and procedures, including methods and formats for engineering design drawings and documents.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Manager (As used in this procedure can be a line or project manager).
- Project Manager.

DEFINITIONS

Engineering Design (Design) - Engineering drawings and specifications or other documents that provide a detailed description of components, equipment, systems, or facilities; the act of conceiving, planning, and preparing engineering drawings, specifications, and related documents.

IMPLEMENTATION

1.0 Identification of Client Requirements

1.1 The Project Manager shall ensure that client design requirements for which PNL will be responsible are identified, reviewed for feasibility and acceptability, and documented by qualified personnel. These requirements should be identified as early as possible, preferably in the proposal or pre-proposal stages of a project or program, but, in any event, before agreement to perform design or to obtain design services.

Applicable client requirements include:

- requirements that are to be incorporated in design drawings, specifications, or other documents
- requirements for the conduct of design activities
- quality assurance and quality control requirements applicable to design.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY



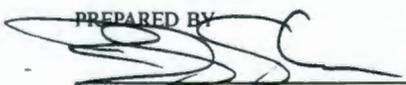
JW Smith, Director, Quality Programs

DATE

6/20/94

PREPARED BY

DATE

 6/16/94

RL Shaub

DOCUMENTATION SYSTEMS DEPARTMENT



JE McGarrah, Manager

DATE

6/20/94

PNL ADMINISTRATIVE PROCEDURE

- 1.2 The Project Manager shall ensure that client documents transmitted to PNL specifying requirements for design are handled as controlled documents. (It shall be acceptable to extract from client documents those portions that apply to design and handle them as controlled documents, provided that traceability to the basic document is maintained.)
- 1.3 When necessary to clarify a client's requirements, the Project Manager shall further define and document such requirements in sufficient detail so they are clearly described for use by design organizations.
- 1.4 Client requirements which cannot be met in their entirety or which include areas of uncertainty shall be referred to cognizant PNL management for resolution and appropriate action.
- 1.5 In dealing with client requirements, the Cognizant Manager shall ensure that all written communications between PNL and clients are handled by authorized PNL organizations/personnel so the communications may be controlled and documented in accordance with PNL policy and agreements with the client.
- 1.6 When information is received orally or by other informal means, the transmittal shall be followed promptly by a controlled document.
- 1.7 Except as specifically provided by prior agreement with the client, all changes to client requirements, such as functional design criteria, shall be identified, approved, documented, and controlled in the same manner as the original requirements. Such agreement with the client or approved procedures may authorize less stringent controls for specified types, classes, or categories of design changes.

2.0 Documentation and Implementation of Design Requirements

- 2.1 The Project Manager shall ensure that requirements for design and for the performance of design activities are noted in the applicable Project Management Plan (PMP) and/or Quality Assurance Plan, are specifically defined in an Engineering Design Plan (EDP), and are implemented as described in PNL-MA-90, Design: Preparation, Control, and Implementation.

NOTE: When design activities are to be subcontracted (either on or off the Hanford Site), information equivalent to an EDP shall be documented by the Project Manager and included in the Statement of Work.

- 2.1.1 The EDP shall identify the impact level(s) and/or safety classification(s) applicable for design.
 - 2.1.2 The EDP shall identify design requirements, such as:
 - design bases
 - performance requirements
 - regulatory requirements
 - codes
 - standards.
 - 2.1.3 Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.
 - 2.1.4 Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be followed promptly by a controlled document.
 - 2.2 The Project Manager shall ensure the applicable EDP is transmitted to other PNL organizations/personnel who are to perform design activities, including analyses and calculations. The EDP shall not be used to transmit requirements to organizations outside of PNL.
-

- 2.3 The Project Manager shall ensure that data presented on design drawings and specifications are shown in a clear, logical, and straightforward manner. Ambiguous notes, callouts, and dimensioning practices shall be avoided.
- 2.3.1 Callouts for parts and materials shall include appropriate specifications, including applicable classes, grades, types, etc. The currently effective revision of each specification shall be called out except when specifically stated otherwise in the EDP.
- 2.3.2 When specifically required by the EDP, the assigned impact levels or safety classifications for items shall be identified on the drawings and in specifications and other documents.
- 2.3.3 Design analysis shall be performed by individuals who have demonstrated competence in the discipline and area of analysis. Documentation of design analysis shall include:
- identification of the subject of the analysis
 - definition of the objective of the analysis
 - definition of design inputs and their sources
 - results of literature searches or other applicable background data
 - identification of assumptions and indication of those that must be verified as the design proceeds
 - identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, program verification, and the bases (or reference thereto) supporting application of the computer program to the specific problem
 - identification of individual performing analysis
 - date and evidence of review and approval.
- 2.4 Computer Aided Design (CAD) systems, word processing systems, and other computer applications are acceptable design and analysis tools. The Project Manager shall ensure that the controls applied to their use are comparable to the controls applied to noncomputer design work.
- 2.4.1 Computer system hardware and software shall be suitable for the application.
- 2.4.2 Drawing and document originals prepared using CAD or other computer systems shall be approved by dated signatures. Revisions may have previous approvals printed or typed, provided that a record copy or microfilm of the signed original of each previous revision is retained.
- 2.4.3 Adequate logs or other records shall be maintained so computer hardware and software configurations used to produce design drawings and documents are identifiable and traceable.
- 2.4.4 Computer programs shall be controlled to ensure that changes are documented and approved by authorized personnel.
- 2.4.5 Computer programs may be utilized for design analysis without individual verification of the program for each application provided:
- the computer program has been verified to show that it produces correct solutions for each encoded mathematical model within defined limits for each parameter employed; and

PNL ADMINISTRATIVE PROCEDURE

- the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

2.4.6 Where changes to previously verified computer programs are made, verification shall be required for the changes, including evaluation of the effects of these changes on the capability of producing correct and valid solutions as noted in Subsection 2.4.5 above.

2.5 Supporting design documents include documents and reference material generated and used during the design process, such as feasibility studies, conceptual design reports, calculations, layouts, catalog information, and vendor supplied drawing; they do not include specifications, codes, standards, or other documents controlled separately from the design process.

2.5.1 The Project Manager shall ensure that any such supporting design documents which are classified as project records are processed in accordance with project records requirements.

2.5.2 When there is a requirement to reproduce copies of supporting design documents, they shall be controlled in accordance with PNL-MA-90, Design: Preparation, Control, and Implementation and specified Engineering Design Plan (EDP) requirements.

2.6 The Project Manager shall ensure that required interface controls for design activities and for design drawings and documents are defined and maintained.

2.6.1 When more than one organization is involved in a design effort, the Project Manager shall ensure that information on design criteria and design decisions is documented and distributed uniformly to the affected participating design organization. This shall include the interface between those organizations or personnel performing analyses and calculations, as well as those performing design or document preparation.

2.6.2 The Project Manager shall ensure that interface control measures, such as a drawing index and/or interface control drawings, are defined by the EDP and are prepared and maintained.

2.7 Drawings, and other design documents shall be prepared in accordance with the applicable requirements of the EDP and shall be legible, reproducible by photocopying, and suitable for filing and retrieval as permanent records.

3.0 Design Verification

3.1 The Project Manager shall ensure that the EDP includes appropriate requirements for design verification commensurate with the importance to safety, the complexity of the design, the uniqueness of the design, the state of the art, and the similarity with previous proven design. The EDP shall define the specific application of methods of verification to design items and shall specify or reference appropriate procedures or other supporting documents. Design verification methods shall include one or more of the following:

- performance of design reviews
- use of alternate calculations
- performance of qualification tests.

3.1.1 Verification of design data shall be performed by individuals or organizations other than those who performed the original design function; however, individuals may be from the same organization as the originator. Verification may be performed by the originator's supervisor (or manager) provided that:

- the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or
-

- the supervisor is the only individual in the organization competent to perform the verification.
- 3.1.2 Verification shall be performed by individuals who are competent in the applicable technical disciplines and are familiar with the criteria and requirements for the design.
- 3.1.3 Verification shall be performed at an appropriate level of detail which will ensure that the function, discipline, or organization represented by the verifier is adequately covered. cursory supervisory reviews do not meet the intent of this procedure and shall not be performed or offered in lieu of required verification actions.
- 3.1.4 Design verification reports shall clearly document the results of the verification and identify the reviewer(s). Design verification reports and support documentation shall be placed in the project or activity record files.
- 3.1.5 Complex designs that require a large amount of design effort shall be verified at critical stages of development to ensure timely correction of deficient conditions.
- 3.1.6 Design verification shall be accomplished on items prior to release for:
- procurement
 - manufacture
 - construction
 - release to other organizations for use.

If the schedule dictates that the above be initiated prior to verification, provisions shall be made to identify those items or activities released for the above prior to verification.

- 3.1.7 In all cases, the design verification shall be completed prior to relying upon the component, system, or structure to perform its function.
- 3.1.8 Where a design has been previously verified in accordance with this Procedure or an equivalent approved procedure, the design verification procedure need not be duplicated for identical designs.
- a) The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each different application or when different performance criteria are applicable.
 - b) Any known problems affecting the standard or previously proven designs and their effects on other features shall be considered.
 - c) Traceability to the previous design and verification shall be provided in any subsequent application of the design.
 - d) When changes to a previously verified design are made, the changes shall be verified and overall design analysis shall be reviewed for any effect.
- 3.2 The Project Manager shall ensure that requirements for design reviews and checking are defined in the EDP, in accordance with PNL-MA-90, Design: Preparation, Control, and Implementation, and implemented.
- 3.2.1 Design review shall ensure that the design documents relate to and meet design input requirements. In addition:
- were design inputs correctly selected

PNL ADMINISTRATIVE PROCEDURE

- are assumptions described, reasonable, and sufficiently identified to permit subsequent reverification when detailed design activities are complete
 - was an appropriate design method used
 - were design inputs correctly incorporated into the design
 - is the final design reasonable when compared to design inputs
 - were the necessary design and verification requirements for interfacing organizations documented in some design requirements document?
- 3.2.2 Design review shall ensure that all items comprising the design are properly identified.
- 3.2.3 Design review shall ensure that all commercial items that are modified or undergo special testing are uniquely identified with either a Hanford or Battelle part number.
- 3.3 The Project Manager shall ensure that EDP entries for verification by use of alternate calculations or analyses define applicability and address the following items:
- appropriateness of assumptions
 - input data used
 - computer programs or other calculation methods.
- 3.3.1 When specified by the EDP, alternate calculations or analyses that are made with alternate methods to verify the correctness of the original calculations or analyses shall be used as a means of verification.
- 3.3.2 When this method of verification is used, the appropriateness of assumptions, the input data used, and the computer program or other calculation methods used shall also be reviewed.
- 3.3.3 Alternate calculations or analyses used for verification shall be documented in a manner similar to that used for the original calculations or analyses and shall comply with EDP requirements.
- 3.4 When design adequacy is to be verified by qualification testing, the Project Manager shall ensure that tests are identified in the EDP and that the test configuration is clearly defined and documented. The documentation that will be used to plan, define, control, and document the qualification testing shall be identified in the EDP.
- 3.4.1 When specified by the Engineering Design Plan (EDP), qualification testing shall be used to verify the adequacy of design.
- 3.4.2 Qualification testing used for design verification shall be planned and conducted in accordance with documented procedures specified by the EDP.
- 3.4.3 The test configuration shall be clearly defined and documented.
- 3.4.4 Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions which have been determined by considering the operating modes and environmental conditions in which the item must perform satisfactorily.
- 3.4.5 Testing should include, as appropriate, bench and proof tests before installation, preoperational tests, post-maintenance tests, post-modification tests, and operational tests.
-

- 3.4.6 Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.
- 3.4.7 If test results indicate that modifications to the item are necessary to obtain acceptable performance, the modifications shall be documented and the item modified and retested and otherwise verified to ensure satisfactory performance.
- 3.4.8 When tests are to be performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.
- 3.4.9 Testing should be structured so that proving tests are not confused with proofing the adequacy of work.
- 3.4.10 Test results shall be reviewed by the responsible design organization to ensure that test requirements have been met.
- 3.4.11 The conduct of qualification testing and the test results shall be documented in accordance with EDP requirements.
- 3.5 All design analyses and calculations shall be reviewed by an independent individual or group also having comparable knowledge of design standards and their application to the scope of work. The design engineer and independent reviewer shall reconcile all reviewer comments and the reviewer shall approve the corrected analyses and calculation documents.

Independent reviewers of design analyses and calculations for Impact Level 1 activities and/or Safety Class structures, systems, and components shall be fully qualified in the engineering discipline(s) involved. Such reviews shall be formally planned, executed, and documented (including reviewer qualification) to provide documented evidence of the review and acceptable disposition of comments. These documents shall be placed in the project or activity record files.

4.0 Change Control

Changes to final designs, field changes, modifications to operating facilities, and non-conforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design.

- 4.1 Control measure for changes shall include assurance that the design analysis for the structure, system, or component are still valid.
- 4.2 Changes that occur during design implementation by PNL shall be controlled in accordance with the applicable requirements of PNL-MA-90, Design: Preparation, Control, and Implementation.
- 4.3 Changes that occur on Construction Projects (General Plant Projects, Line Items, or larger) shall be controlled in accordance with the applicable requirements of PNL-MA-91, Construction Project Management System.
- 4.4 Nonconforming items processed by PNL staff shall be controlled in accordance with PAP-70-1501, Nonconformance Reports.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-302

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 8 OF 8

- design requirements documents including the EDP and Functional Design Criteria
 - permanent and temporary engineering drawings
 - specifications
 - supporting design documents
 - design verification reports.
-

TITLE: PAP-70-401, PURCHASE REQUISITIONS

PURPOSE

Provide a uniform method for processing purchase requisitions and provides methods to ensure that procured items or services satisfy the technical and quality requirements of the user.

APPLICABILITY

This procedure applies to purchase requisitions initiated for items or services.

The procedure for obtaining services from Hanford Contractors or service groups within PNL is described in PAP-70-404, Obtaining Services.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Contract Specialist
- Lead Procurement Quality Engineer (Lead PQE)
- Procurement Quality Engineer (PQE)
- Purchase Requisition (PR) Author
- Quality Programs (QP) Representative.

DEFINITIONS

Fastener - Public Law 101-592, Fastener Quality Act, defines fasteners as:

- 1) A screw, nut, bolt, or stud with:
 - a) internal or external threads or a load indicating washer of metal,
 - b) nominal 1/4 inch or M5 (5mm) and larger diameter, and
 - c) through-hardening to meet a standard or specification requirement.
- 2) A screw, nut, bolt, or stud having internal or external threads bearing a grade identification marking required by a standard or specification.
- 3) A washer when it is subject to a standard or specification applicable to the product included with the definition of 2) above.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

KE Harrison

6/17/94

KE Harrison

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah

6/20/94

JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

IMPLEMENTATION

1.0 Preliminary Assembly of Data

- 1.1 To help identify any technical and quality requirements for procurements, the Purchase Requisition (PR) Author shall review applicable documents including:
 - Client's Statement of Work
 - Project Management Plan
 - Quality Assurance (QA) Plan.
- 1.2 The PR Author shall ensure that the Purchase Requisition (PR) and attachments contain all technical and quality information, descriptions, drawings, specifications, or requirements necessary to specify completely the required supplies or services.
- 1.3 The PR Author shall ensure that commercial grade items related to safety specified on the PR include the applicable technical and quality assurance requirements.
 - 1.3.1 Commercial Grade Items are those items satisfying all of the following conditions:
 - not subject to design or specification requirements that are unique to nuclear applications
 - normally used in applications other than nuclear applications
 - are to be ordered from the manufacturers published product description (for example, catalog).

NOTE: The commercial grade designation is intended for items, components, or basic raw materials that can be commercially ordered from a supplier's catalog without any modification for nuclear application.

Within the context of this procedure commercial grade items are those items that are commercially available and have not been designed for nuclear application but are being procured for use in a nuclear application.
 - 1.3.2 When a commercial grade item is specifically identified in an approved design document, the PR Author shall ensure that the specific item is procured. An alternate commercial grade item may be substituted provided the approval of a cognizant design engineer is noted on the PR and documentation is on file with the original design organization approval signatures, justifying the alternate item.
- 1.4 When the PR involves a HEPA filter intended to be used in a safety-related system, the instructions and requirements of EXHIBIT 3, Procuring HEPA Filters, shall be followed.
- 1.5 Before completing the PR, the PR Author shall review PAP-70-402, Control of Suspect/Counterfeit Items, for fasteners, electrical components, or piping components.

2.0 Preparation of the PR

- 2.1 The PR Author shall complete the description block of the PR by identifying or including the following, as appropriate:
 - the scope of work or description of the item(s)
 - manufacturer and catalog number
 - Category 1, 2, or 3 for Measuring and Test Equipment
 - technical requirements including applicable codes and standards
 - necessary spare or replacement parts.
-

2.2 The PR Author shall include the correct impact level (IL, I, II, or III) or the safety class (Safety Class or Non-Safety Class) for each line item on the PR (safety class only applies to facility systems, structures, and components). The safety class may be indicated by adding "Safety Class" or "Non-Safety Class" in the Impact Level block on the PR.

2.3 If attachments are needed, the PR Author shall ensure that attached documents are referenced on the PR, in the Description block, and include:

- document title or number (the PR number may be used)
- date and revision number
- pagination.

2.4 The PR Author shall identify any applicable Standard Quality Assurance (QA) clauses, in the QA Clauses block, by reviewing the selection criteria in Sections 3.0 through 8.0 of this procedure and the Standard QA Clauses, Use Guide (EXHIBIT 1).

3.0 Supplier Capabilities/QA Program (QA Clause 160)

3.1 The PR Author shall require the Supplier to have a PNL Process Quality Department (PQD) Evaluated QA program, system, or special process whenever any of the following conditions apply:

- suppliers who must have appropriate technical and QA capabilities to ensure the integrity of the items or services to be provided (e.g., calibration/analytical services, pressure vessels, HEPA filters) (apply one of the 120 or 130 series QA Clauses)

NOTE: Pressure relief valves may be procured using only QA Clauses 130 and 167. Upon receipt, the valve will be inspected by a PQE to verify the valve is code stamped by a current ASME approved manufacturer.

- ASME B31.1 Power Piping Code requirements, AWS D1.1, AWS D1.3, AWS D9.1, etc., where failure of the item is likely to jeopardize data validity or safety conditions, disrupt the continuity of operations, or cause significant cost impact (apply QA Clause 137)
- special process (i.e., nondestructive examination, plating, etc.) requirements where failure of the item is likely to jeopardize data validity or safety conditions, disrupt the continuity of operations, or cause significant cost impact (apply 120 series QA Clause)
- suppliers who will receive Hazardous Materials (See PNL-MA-81 Glossary) from PNL for analytical work (or other designated purposes) and must have qualified personnel to package and ship Hazardous Materials in accordance with DOT regulations (apply QA Clause 127).

NOTE: This is a precautionary requirement in the event that further handling and shipping of PNL Hazardous Material is required.

- an item procured to a drawing or specification for which acceptability cannot be determined by inspecting the item upon receipt, or, at the source (apply QA Clause 163 and specify witness/hold points).

NOTE: A Request for Proposal may specify the post award development of a QA Program when the Lead PQE determines that extraordinary technical and/or QA requirements necessitate it. In such cases, the resulting contract shall contain a clause stating that:

- the contractor's QA Program be approved before any other work is performed
- disapproval of the QA Program will result in specified contractual consequences.

PNL ADMINISTRATIVE PROCEDURE

Preaward evaluation by a PQE is required (apply QA Clause 160).

3.2 The Contract Specialist shall ensure that a copy of the Contractor Nonconformance Request (EXHIBIT 4) is sent with the RFP/PO when QA Clause 201 has been imposed.

4.0 Receiving Inspection (QA Clause 167)

4.1 The PR Author shall require an independent receiving inspection (see EXHIBIT 2, Independent Receiving Inspection for examples) when source inspection or surveillance will not be performed (or is insufficient) and the item to be received is:

- fabricated to a client, PNL, or Hanford-Contractor specification or drawing that specifies:
 - dimensions and tolerances that can only be verified by using precision inspection equipment
- NOTE: Normally this involves the use of inspection equipment such as surface plates, height gages, optical comparators, etc. to measure characteristics such as true position, concentricity, angularity, perpendicularity, straightness, flatness, etc. As a general rule, it involves measuring the location of features to tolerances of ± 0.010 inch or more stringent and feature size to tolerances of ± 0.003 inch or more stringent.
- visual weld inspection or NDE
 - electronic workmanship of equipment built to ANSI/IPC specifications or other nationally recognized standards
 - other characteristics that need a certified inspector's discipline to verify acceptability.
- designated as a Safety Class system, structure, or component (SSC)
 - a safety-related HEPA filter (functional acceptance by WHC Filter Test Facility), pressure vessel, radioactive material shipping container, hoisting and rigging equipment, or other significant safety-related item
 - measuring and test equipment (M&TE) that is considered to be Calibration Category 1 (See PAP-70-1201, Calibration Control System and PAP-70-1202, Calibration Control System for Radiation Detection Equipment.)

NOTE: An "as-found" calibration performed by WHC, PNL Technical Services, PNL Instrumentation and External Dosimetry Section, or another PQD evaluated metrology facility (before the M&TE is used) will normally satisfy this requirement for independent receiving inspection.

- a suspect item as identified in PAP-70-402, Control of Suspect/Counterfeit Items.
- 4.2 Acceptance may be based solely on independent receiving inspection when the items or services are:
- relatively simple or standard in design, manufacture, and test
 - adaptable to standard or automated inspections and/or tests of the end product to verify quality characteristics after delivery.
- 4.3 When a receiving inspection is to be performed, the Purchase Requisition (PR) Author shall check the appropriate "Rec" box to indicate the organization responsible for performing the receiving inspection. When Independent Inspection is required, the PR Author shall:

- specify QA Clause 167 (number of days to withhold payment)
- refer to EXHIBIT 2, Independent Receiving Inspection, to determine the applicable independent inspection organization and its location
- indicate in the "Deliver To" block the location of the independent inspection organization.

NOTE: If assistance is needed in determining the independent inspection location, contact the Cognizant QE or PQE. The PQE will be responsible for ensuring that inspected/accepted items are routed to their final destination.

- 4.4 QA documents (i.e., certifications, test reports, etc.) required to be submitted in response to QA Clauses shall be reviewed and accepted by a PQE.

NOTE: When the PQE lacks the technical expertise to perform an adequate submittal review, he/she shall transmit the documents to the PR Author, Technical Representative, or cognizant Quality Engineer for review and approval.

If QA documents are required, the PR Author shall indicate the QA Clauses associated with the documentation in the "QA Clauses" block of the PR.

- 4.5 Independent receiving inspections are coordinated through PQ.
- 4.6 When independent receiving inspections are required, the items to be inspected will be routed to the designated inspection facility. The PQE shall tag acceptable/unacceptable items in accordance with PAP-70-1401, Inspection and Testing Status and Tagging. Acceptable items with complete and acceptable documentation shall be released to the PR author or designated recipient. Unacceptable, questionable, or incomplete items/documentation shall be segregated and placed on **HOLD** status until their disposition is resolved.

5.0 Source Inspection or Surveillance (QA Clause 163)

- 5.1 The PR Author shall require a source inspection or source surveillance when an independent receiving inspection (see EXHIBIT 2, for examples) will not be performed (or is insufficient) and the item to be received meets the criteria specified in Paragraph 4.1 above.

Source inspection is the witnessing or inspection of particular characteristics of an item or activity at some point before delivery. Source inspections typically involve a single hold point. Source surveillance is the nearly constant surveillance or monitoring of complex items or processes.

- 5.2 Source inspection shall be used when one or more of the following is true:
- cost or schedule would be considerably impacted if the item does not conform to specification or if costly special packaging had to be replaced
 - inspection at any other point would require uneconomical disassembly or destructive testing
 - special instruments, gages, or facilities required for inspection are available only at the source and Paragraph 4.1 criteria must be met
 - drop shipment to an off-site destination is specified and receiving inspection requirements (Para. 4.1) cannot be adequately performed.

- 5.3 Source surveillance should be used when:

PNL ADMINISTRATIVE PROCEDURE

- complex items have quality characteristics that are not wholly inspectable in the finished product. Therefore, contractual conformance must be established progressively through precise measurements, tests, and controls applied during purchasing, manufacturing, performance, assembly, and functional operation. Source surveillance may be performed on an individual item or on integrated items.
- items, processes, or operations cannot be adequately verified by preaward evaluation, source inspection, or receiving inspection.

5.4 When a source inspection or surveillance is required, the PR Author shall ~~impose QA Clause 163~~ in the "QA Clauses" block of the PR and indicate the organization responsible for performing the inspection or surveillance in the "Inspection By" block.

NOTE: Source inspections shall be performed by individuals who are qualified and certified to perform inspections or tests. These individuals are certified by the Lead PQE. Source surveillances do not require certified personnel.

6.0 Post-Installation Testing

6.1 The PR Author shall consider specifying post-installation testing in the following cases:

- quality characteristics are difficult to verify without installation of an item
- verification of quality characteristics requires an integrated system checkout or test with other items
- the ability to perform an intended function cannot be demonstrated except during use
- a representative of the supplier is required to be available to install, adjust, calibrate, or provide modifications (as necessary) to meet final acceptance criteria.

6.2 When post-installation testing is to be performed, the PR Author shall specify the following information on the PR:

- post-installation test(s) to be performed
- criteria to be used to determine the acceptability of the test(s)
- who will perform the test(s)
- time within which the test(s) must be performed and form and content of the test report if the test(s) is to be performed by the seller.

NOTE: There is no QA Clause associated with post-installation testing. However, QA Clause 167 should be used when delayed payment, until after testing is performed, is desired.

6.3 When post-installation testing is required, the PR Author shall notify the Lead PQE to arrange for witnessing of the testing.

7.0 Acceptance Criteria for Services

7.1 Standard QA Clauses should be used as acceptance criteria for services to the extent possible. See note in Section 9.2, on modifications to Standard QA Clauses.

7.2 The PR Author shall accept services based on one or more of the following:

- technical evaluation of data or service produced

- source inspection/surveillance and/or audit of the activity
- review by the PQE of objective evidence for conformance to the procurement document requirements (e.g., certifications, test reports, etc.)
- post-installation testing.

8.0 Other QA Clauses

The PR Author shall apply other QA Clauses, as necessary, to ensure the integrity of the item(s) or service. QA clauses may also be used to obtain necessary information or supporting documentation. Examples of additional QA Clauses are as follows:

- seller reports or certifications (170 or 180 series QA Clauses)
- identification or marking requirements (190 series QA Clauses)
- design drawings/specifications (QA Clauses 156, 157, 158, and/or 159)
- seller inspections (QA Clause 162)
- first article testing when the procurement involves a large quantity of complex items with multiple delivery dates (QA Clause 164).

9.0 Identification of QA Clauses on the PR

9.1 If no QA requirements apply, the PR Author shall check "No" in the "QA Requirement" block on the PR and go to Section 10.0.

9.2 If QA requirements apply, check "Yes" in the "QA Requirements" block on the PR. To identify standard QA Clauses on the PR, the PR Author shall write the clause number(s) in the "QA Clauses" block. If there is insufficient space to clearly communicate the clauses with inserts in the "QA Clause" block, EXHIBIT 5, Standard QA Clauses for PR, should be used. When EXHIBIT 5 is used, indicate it as an attachment in the "QA Clauses" block.

9.2.1 Certain Standard QA Clauses require inserted information such as identification of industry codes, standards, processes, hold points, etc. The PR Author shall review the Standard QA Clauses, Use Guide (EXHIBIT 1) to identify these clauses.

9.2.2 Certain Standard QA Clauses are designed to work as part of a cluster and require that all clauses in the cluster be used. The PR Author shall review the Standard QA Clauses, Use Guide (EXHIBIT 1) or QA Clauses Use Guide (EXHIBIT 6) to identify these clauses.

NOTE: If Standard QA Clauses must be modified in order to satisfy requirements, write in "Other" in the "QA Clauses" block and identify such requirements on the PR or referenced attachments. Any needed modifications should be coordinated with the Lead PQE and Legal Office.

9.3 The PR Author should contact the QP Representative, if there are questions about the appropriate application of QA Clauses.

10.0 Required Reviews

10.1 Before review by the QP Representative, the PR Author shall ensure that the PR is reviewed and approved by the following staff:

PNL ADMINISTRATIVE PROCEDURE

-
- 10.1.1 Technical Representative - initials or signs and dates the "Technical Representative" block. The PR Author may sign as Technical Representative, if technically responsible.
- 10.1.2 Level 4 or above Manager - verifies correct application of Impact Level(s), signs and dates "Authorized Req'd. Approvals" block.
- 10.1.3 The Pressure Systems Engineer, Facilities Engineering, is required to sign and date in the "Description" block when a procurement is planned for:
- vessels within the scope of the ASME Boiler and Pressure Vessel Code
 - noncode vessels with a design over 15 psig
 - vessels containing positive pressure for use with chemicals toxic to personnel, materials corrosive to the vessel, or flammable or nuclear materials
 - hydraulic piping systems operating above 300 psig
 - gas or steam systems operating above 125 psig
 - systems operating above 15 psig for service involving chemicals toxic to personnel, materials corrosive to the piping, or for flammable or nuclear materials (**except when the piping containing nuclear material is used in a cell**)
 - purchase of compressed gas cylinders (rented cylinders do not require review).
- NOTE: Review by the Pressure Systems Engineer is not required for DOT approved compressed gas cylinders unless the cylinders are being purchased.
- 10.1.4 A Radiation Protection Radiological Engineer signs and dates, in the "Description" block for safety-related HEPA filters and radioactive materials (i.e., radiography sources, radioisotopes, radio-labeled chemicals).
- PRs for radioactive material shall be clearly marked Radioactive Material and the following information included:
 - type of radionuclide
 - specific or concentration activity (e.g., Ci/g or Ci/mL)
 - physical and chemical forms (e.g., solutions, powders, sealed sources, etc.)
 - correct units of activity [e.g., becquerel with appropriate SI prefixes (kBq), curie (Ci), millicurie (mCi), or microcurie (μ Ci)].
 - A valid radiological work permit (RWP) must be in place prior to the receipt of any radioactive material for storage or use.
- 10.1.5 The Hazardous Material Transportation Officer, Laboratory Safety, signs and dates in the "Description" block for containers for the transporting of radioactive or other hazardous materials.
- 10.1.6 When there are biohazards, a Health and Safety representative should sign and date in the "Description" block.
-

10.2 The QP Representative shall review, sign, and date, in the "QP Representative" block, of each PR to ensure that:

- an impact level is designated
- technical and quality requirements have been specified and are apparently complete
- drawings and specifications have been properly approved
- the acceptability of the item or service can be adequately verified
- the need for source inspection, source surveillance or test, receiving inspection, certificate of conformance, or post-installation testing has been addressed
- the organization to perform receiving inspection or source verifications is correctly identified and that the "Deliver To" block identifies the proper location of the inspection organization
- reviews by others (e.g., Laboratory Safety, Pressure Systems Engineer, etc.) have been performed if required and are indicated by signature and date.

10.3 When assigned QA requirements involve QA documents, a QA program, PQD Evaluated Suppliers, or verification of the deliverable, the QP Representative shall send a copy of the PR with attachments to the PQE.

11.0 Changes to the PR and Subsequent Documents Before Award

- 11.1 Before submitting a completed PR to Procurement or Subcontracts, anyone making changes to the technical or QA content shall ensure that changes are reviewed, signed, and dated by all affected organizations who reviewed the original PR.
- 11.2 After submitting a completed PR to Procurement or to Subcontracts, the person who initiates a change to the technical or QA requirements on subsequent documents, such as the RFP or PO before award, shall obtain authorization from organization(s) affected by the change.
- 11.3 The Contract Specialist shall not issue a change or authorize an exception to the technical or QA requirements of the procurement document without authorization from the PR Author or Technical Representative and other individuals affected by the change.
- 11.4 All changes and authorizations shall be documented.

NOTE: Obvious clerical and editorial corrections are exempt from this requirement.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- completed purchase requisitions with QA requirements
- appropriate attachments to the PR (e.g., drawings, statement of work, specifications)
- completed POs/RFPs requested/received from Procurement/Subcontracts.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

STANDARD QUALITY ASSURANCE CLAUSES AND USE GUIDE (REV.10)

I. **HOW TO SPECIFY QA CLAUSES** - The Standard QA Clauses identified below should be selectively and judiciously applied. To require a clause in a PO/subcontract, specify standard clauses on the PR as follows: (1) specify the clause number; (2) specify the subclause letter (identified below within brackets, such as [a]); (3) specify within parentheses () the applicable asterisk and the required information to be inserted. [For example, 180a (*all stainless steel material), 170g(* Item 2)(** radiographic)]; and (4) if the applicability of a clause is not clearly defined, identify the item or equipment to which it applies (e.g., QA Clauses 129, 140c, and 160 apply to all calibration of M&TE). All alphabetic letters, instructions, and notes between brackets

[] of the clauses printed below will not be printed on the RFP or PO.

II. The exact wording of the Standard QA Clauses and corresponding notes may be changed when agreed upon by Legal, Procurement, Subcontracts, and the L&C Lead Quality Engineer (Lead PQE), without requiring a new revision to the QA Manual.

QA CLAUSES

APPLICATION AND EXPLANATORY NOTES

110 QA DOCUMENTATION DELIVERY

Unless otherwise specified, Contractor shall mail all documents required by this contract to be delivered to Battelle to * , Battelle Pacific Northwest Laboratories, P.O. Box 999, Richland, Washington, 99352. A document is not delivered until it is received by Battelle.

Battelle shall have the right to reject, as not in conformity with the requirements of this contract, any supplies or services for which all required reports, procedures or certifications are not delivered. Contractor's failure to deliver such documents, or delivery of deficient documents, shall be deemed a failure to make delivery within the meaning of the Default clause of this contract.

120 QUALITY PROGRAM/SYSTEM REQUIREMENTS

The Contractor shall provide and maintain a quality program/system that complies with:

[a] Any recognized U. S. Quality Program/System Standard in effect on the contract date (e.g., MIL-I-45208; NE (RDT) F2-4 Standard; ASME Boiler and Pressure Vessel Code, Section VIII, Appendix 10; or ANSI N45.2).

[b] MIL-I-45208, "Inspection System Requirements," in effect on the contract date.

[c] ASME NQA-1 - * Edition (incl. Addenda *) "Quality Assurance Program Requirements for Nuclear Facilities," Basic Requirements and Supplements: **

[d] 21 CFR 58, "Good Laboratory Practice for Non-clinical Laboratory Studies", in effect on the contract date.

[e] ***

[f] EPA Contract Laboratory Program (CLP) directed by the National Program Office (NPO), in EPA Headquarter's Analytical Operations Branch (AOB), Hazardous Site Evaluation Division (HSED), Office of Solid Waste and Emergency Response (OSWER).

110 The PNL Contract Specialist will specify his/her name on the purchase order or contract and send the received documents to the PQA Administrator for review and acceptance or disposition.

This clause is required whenever any QA documents specified by QA Clauses or QA requirements are required to be submitted (e.g., QA Clauses 150a, 150b, 150e, 150f, 156, 157, 159, 163, 170 series, 180 series, and 200).

120 Mandatory to specify QA clauses 140a, 160, 168, and 201 when any 120a-120g clauses are used.

120a Preferred for most applications when design controls, audits, and other complex QA Program elements are not needed and the specific QA/QC system needed is not significant. Has advantages in allowing more companies to bid and making preaward surveys easier.

120b May be used in lieu of 120a when an inspection system without design controls and audits is adequate and a strong calibration system (MIL-STD-45662) is needed.

120c Mandatory to:

- (1) *specify the applicable Edition, year, and Addenda Number and
- (2) **specify which Basic NQA-1 Requirements and Supplements apply when this clause is used.

Applicable to complex, safety related items in which basic element(s) and/or supplement(s) of NQA-1 apply in their entirety.

120d Not usually for NQA-1 related programs.

120e ***Usually specify other QA Program Number, Title, and Revision. May extend lead in statement and add selected elements of a QA Program/System.

120f Mandatory to use when the client imposes EPA Contract Laboratory Program.

[g] EPA-600/4-83-004, Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans, QAMS-005/80.

120g Mandatory to use when the client imposes QAMS-005/80.

The Contractor shall require, in writing, subcontractors of all tiers to comply with all applicable quality program/system requirements. The quality system and control of "Special Processes" of the Contractor and subcontractors of all tiers shall be subject to audit by Battelle to the extent practicable at all times and places.

The Contractor shall tender for acceptance only those supplies or services that have been inspected and tested in accordance with its quality program/system and have been found to conform with contract requirements.

127 HAZARDOUS MATERIAL SHIPPING REQUIREMENTS
The Contractor shall comply with the applicable Code of Federal Regulations, Title 49, Parts 107, and 171 through 178 when required to handle, package, mark, and ship any Hazardous Material received from Battelle on this contract.

127 Mandatory to specify QA Clauses 140e, 160 and 168 when this clause is used.

Specify this clause when suppliers will receive Hazardous Materials (See PNL-MA-81 Glossary) from PNL for analytical work (or other designated purposes) and must have qualified personnel to package and ship Hazardous Materials in accordance with DOT regulations. This clause is mandated by DOE as a precautionary requirement in the event that further handling and shipping of PNL Hazardous Material is required by PNL suppliers.

128 QA SYSTEM REQUIREMENTS FOR SHIPPING CONTAINERS/PACKAGES

128 Mandatory to specify QA Clauses 140b, 160, 168, 201, and this clause when "fissile" or "Type B" shipping containers for radioactive materials are ordered.

The Contractor shall provide and maintain a quality system complying with 10 CFR 71, Subpart H, "Quality Assurance," which has been approved by the NRC. The Contractor shall require, in writing, subcontractors of all tiers to comply with all applicable quality program/system requirements. The quality system and control of "Special Processes" of the Contractor and subcontractors of all tiers shall be subject to audit by Battelle to the extent practicable at all times and places.

Consider imposing QA Clause 163 when rejection of the item at PNL would have significant cost impact.

The Contractor shall tender for acceptance only those supplies or services that have been inspected and tested in accordance with its quality program/system and have been found to conform with contract requirements.

129 CALIBRATION SYSTEM REQUIREMENTS

129 Mandatory to specify QA Clauses 140c, 160, 168, and 201 when this clause is used. In addition, specify 170e when procuring calibration services.

The Contractor shall use a calibration system that complies with MIL-STD-45662, NE (RDT) F3-2 or IEEE Std 498 in effect on the contract date. The Contractor shall require, in writing, subcontractors of all tiers to comply with all applicable calibration requirements. The calibration system of the Contractor and subcontractors of all tiers shall be subject to audit by Battelle to the extent practicable at all times and places.

Specify this clause for the procurement of calibration services and for ordering new equipment that will be calibrated by suppliers other than WHC Standards, PNL CS, or PNL I&ED.

The Contractor shall tender for acceptance only equipment that has been calibrated in accordance with its calibration system and has been found to conform with contract requirements.

130 ASME B&PV CODE REQUIREMENTS

* shall be fabricated, inspected, and stamped in accordance with Section ** of the ASME Boiler and Pressure Vessel Code, in effect on the contract date. Contractor shall have a current ASME Certificate of Authorization to use the *** symbol stamp. The Contractor shall require, in writing, subcontractors of all tiers to comply with all applicable quality program/system requirements. The quality system and control of "Special Processes" of the Contractor and subcontractors of all tiers shall be subject to audit by Battelle to the extent practicable at all times and places.

- [a] Contractor shall submit to Battelle the ASME Manufacturers' Data Report or the ASME Manufacturers' Partial Data Report, as applicable.

137 WELDING CODE REQUIREMENTS

* shall be fabricated by qualified personnel and inspected by certified personnel in accordance with ** in effect on the contract date. Contractor's quality/program system shall require maintenance of certified records of qualified welding/NDE procedures, welders, welding operators, and qualified/certified NDE personnel.

140 SUBMITTAL(S) REQUIRED BEFORE CONTRACT AWARD

When deemed necessary by Battelle, the prospective Contractors shall submit, prior to any Preaward Survey

- [a] a complete description of its quality program/system. Such description may consist of a copy of the Offeror's approved QA/QC Manual, a QA/QC plan, or a combination thereof, and shall specify the standard(s) upon which the system is based. Alternately, if a QA/QC manual/plan has been previously submitted, an Offeror may, provided its manual/plan has not since been revised, specify in its proposal the date and/or revision of its current QA/QC manual/plan
- [b] a copy of its NRC QA Program Approval for Radioactive Material Packages (Form 311)
- [c] a complete description of its calibration system. The description may be extracted from the Offeror's documented quality program/system
- [d] a copy of its ASME "Certificate of Authorization."
- [e] qualification records of the person(s) who is knowledgeable in Department of Transportation (DOT) Hazardous Material regulations and will be designated the responsibility for any handling and shipping of Hazardous Material received from Battelle (reference contract clause titled "HAZARDOUS MATERIAL SHIPPING REQUIREMENTS") The qualification records shall include (1) the person(s)' name, (2) a summary statement of the person(s)' qualifications, (3) copies of training certificates, and (4) any other documented evidence of the person(s)' training, experience, and knowledge of DOT Hazardous Material regulations.

130 Specify Clause 130 for pressure relief valves. Specify Clause or 130a for pressure vessels and subassemblies which fall within the scope of the code. Clause 130a will print out all of Clause 130 (prefix) and 130a.

Mandatory to:

- (1) specify QA Clause 163 or 167 and F&PQ (formerly QC) as the independent inspection organization (check appropriate "Source/Rec" block on the PR).
- (2) *specify which items or equipment, if less than all, are subject to code
- (3) **specify the applicable section and division (when applicable)
- (4) ***specify the applicable symbol.

When clause 130a is specified it is also mandatory to specify QA clauses 140d, 160, and 168.

137 Mandatory to:

- (1) specify QA Clauses 120a, 140a, 140f, 150a, 150b, 150e, 160, 168, 201, 210b and
- (2) *specify which items or supplies, if less than all are subject to code.
- (3) **specify the applicable welding codes (e.g. ANSI/ASME B31.1 Power Piping Code, AWS D1.1, AWS D1.3, AWS D9.1, etc.).

140 The 140 series clauses are not contractual clauses but are used at the RFP stage of the procurement cycle to obtain information pertaining to the Offeror's capability to perform (responsibility). The submittals obtained are made contractual by use of the applicable 120, 130, and 210 series clauses.

- 140a Use in conjunction with Clauses 120a through 120g, 160, 168, and 201.
- 140b Use in conjunction with Clauses 128, 160, 168, and 201.
- 140c Use in conjunction with Clauses 129, 160, 168, and 201.
- 140d Use in conjunction with Clauses 130 or 130a, 160, 168, and 201.
- 140e Use in conjunction with Clauses 127, 160, and 168.

- [f] **a detailed Welding and NDE Plan.** The plan shall include, but not be limited to:
- (1) the Offeror's Plan for controlling the welding and NDE (As used herein, NDE includes visual weld examinations)
 - (2) the name(s) and address(es) of proposed subcontractors who will perform welding or NDE or a statement indicating that no subcontractors are proposed for performing the welding or NDE
 - (3) a list of welding procedures for each type of weld and each characteristically different welding joint (with identification of any procedures that require qualification prior to work), including welding codes/standards/specifications on which the procedures are based
 - (4) a list of NDE procedure(s) for each NDE method (including visual examination) to be used, and the codes/standards/specifications upon which such procedures are based
 - (5) a list of welders and NDE personnel that will perform or verify the welding or NDE, including identification of any certifications that will have to be completed prior to such work being performed.
 - (6) at least one representative example of a qualified welding procedure, an NDE procedure, and a Certified Record of Qualified Personnel that will be used for this work.

140f Mandatory to specify at least one 120 or 130 series clause, 150a, 150b, 150e, 160, 168, 201, and 210b when this clause is used.

Use this clause when welding and NDE controls must be performed in accordance with nationally recognized codes, standards, and specifications. Not applicable to B&PV code stamped items.

- [g] **Certified Records of all Qualified Personnel** who will perform or verify the special processes/operations listed below and all Subcontractor's name(s) and address(es).
- (1) * in accordance with *
 - (2) * in accordance with *

140g When this clause is used, it is mandatory to:

- (1) specify Clauses 168 and 210d.
- (2) *specify the special processes and the documents to which personnel are to be qualified/certified. If more than one process and document are specific, identify each process as a, b., etc; (e.g., a. Soldering MIL-S-45743, b. Painting, ANSI 101.4), etc.

- [h] **An Inspection and Test Plan.** The plan shall specify, as a minimum: (1) what is to be inspected/tested (e.g., components, sub assemblies, and assemblies), (2) the inspections/tests to be performed, and (3) the inspection/test methods or procedures to be used.

140h Mandatory to specify Clauses 168 and 210a when this clause is used.

Consider using this clause to help:

- (1) determine applicable witness points for source inspection/surveillance when clause 163 or 165 is specified.
- (2) evaluate an offeror's inspection/test process and methods.

150 SUBMITTAL(S) REQUIRED AFTER CONTRACT DATE

Prior to the performance of any operations involving the following, but in no event later than * calendar days after the contract date, the Contractor shall deliver for Battelle's review and written approval:

150 When any 150 series clauses are used, it is mandatory to:

- (1) *specify no less than 21 calendar days for Contractor to provide submittals.
- (2) **specify no less than 14 calendar days for Battelle to approve or disapprove submittals.

[a] Certified Records of Qualified Personnel who will perform or verify the welding or NDE as specified in response to the RFP which resulted in the award of this contract.

[b] **Qualified Welding Procedures (QWPs) and Certified Procedure Qualification Records (PQRs)** for each type of weld and each characteristically different welding joint listed in the plan for welding and NDE controls that was submitted in response to the RFP which resulted in the award of this contract.

[c] Reserved

[d] Reserved

[e] **Nondestructive examination (NDE) procedures** for each NDE method (including, when required, visual examination).

[f] ******* procedures.

Battelle will notify the Contractor of its approval or disapproval within ****** calendar days; provided, however, that if notice is not issued within such time, the Contractor's procedure shall be deemed approved. For the purposes of this clause, an approval or disapproval notice is issued when it is mailed.

156 DESIGN DRAWINGS AND SPECIFICATIONS SUBMITTAL (for Battelle's review and comment)

Contractor shall deliver three copies of design drawings and specifications for ***** within ****** calendar days from the contract date for Battelle's review. All such documents shall be approved by Contractor's designated engineering representative and contain all details necessary for Battelle's complete analysis of Contractor's design and its compliance with contract requirements. Battelle may, but is not required to, respond. Contractor's failure to deliver required design drawings and specifications, or the delivery of design drawings and specifications that are deficient, shall be deemed a failure to make delivery within the meaning of the Default clause of this contract.

157 DESIGN DRAWINGS AND SPECIFICATIONS SUBMITTAL (for Battelle's review and approval)

(a) Contractor shall deliver three copies of design drawings and specifications for ***** within ****** calendar days from the contract date for Battelle's review. All such documents shall be approved by Contractor's designated engineering representative and contain all details necessary for Battelle's complete analysis of Contractor's design and its compliance with contract requirements.

150a Mandatory to specify Clauses 110, 140f, and 210b when this clause is used.

See Clause 140f for application notes. Use of this clause requires the Contractor to submit the certified records of qualified personnel that were listed during the RFP stage of the procurement process.

150b Mandatory to specify Clauses 110, 140f and 210b when this clause is used.

See Clause 140f for application notes. Use of this clause requires the Contractor to submit the Qualified Weld Procedures (QWPs) and Procedure Qualification Records (PQRs) that were listed at the RFP stage of the procurement process.

150c Mandatory to specify Clauses 110 and 210b when this clause is used.

This clause may be used in conjunction with Clause 137 or when NDE is to be performed to nationally recognized standards.

150f When this clause is used, it is mandatory to:

- (1) specify Clause 110 and 210c.
- (2) ******* specify which procedures are required to be submitted after contract date.

156 When this clause is used, it is mandatory to:

- (1) specify QA Clauses 110 and 159
- (2) *****specify which item(s) or equipment
- (3) ******specify number of calendar days for Contractor to provide submittals

Specify Clause 158 when identification and marking requirements need to be included as part of the design document requirements.

This clause does not establish a design hold point. The PR author or cognizant technical staff shall perform a design review as soon as practicable and ensure that any requests for additional information from the Contractor do not imply PNL's approval of Contractor's design. Any concerns/comments for transmittal to the Contractor shall be sent to the Contract Specialist, in writing, with instructions as to the intent of such comments (e.g., for information only, request for stop work on design, for termination, or to negotiate changes, etc.)

157 When this clause is used, it is mandatory to:

- (1) specify Clauses 110 and 159.
- (2) *****specify which item(s) or equipment.
- (3) ******specify number of calendar days for Contractor to provide submittals.
- (4) *******specify the number of calendar days for Battelle's approval or disapproval.

Specify Clause 158 when identification and marking requirements need to be included as part of the design document requirements.

- (b) Within *** calendar days after Battelle receives Contractor's design drawings and specifications, Battelle shall notify Contractor, in writing, of its approval or disapproval. Notice of approval shall not relieve Contractor from complying with all requirements of this contract. A notice of disapproval shall cite the reasons of disapproval.
- (c) If the Contractor's design drawings and specifications are disapproved, the Contractor, upon Battelle's written demand, shall submit revised design drawings and specifications for Battelle's review. Upon receipt of each demand, Contractor shall make any necessary changes, modifications or additions to its design drawings and specifications. All costs related to the preparation and submission of revised design drawings and specifications following a disapproval shall be borne by Contractor. The Contractor shall submit revised design drawings and specifications in accordance with the terms and conditions and within the time specified by Battelle. Battelle shall act on any revised design drawings and specifications within the time limit specified in Paragraph (b) above. Battelle reserves the right to require an equitable adjustment of the contract price for any extension of the delivery schedule or for any additional costs to Battelle arising out of Contractor's failure to deliver complete design drawings and specifications conforming to the requirements of this contract.
- (d) If Contractor fails to deliver complete design drawings and specifications on time or Battelle disapproves any design drawing or specification submitted for its review, Contractor shall be deemed to have failed to make delivery within the meaning of the Default clause of this contract.
- (e) If Battelle does not act within the time specified in Paragraph (b) or (c) above, Battelle shall, upon timely written request from Contractor, equitably adjust under the Changes clause of this contract the delivery or performance dates and/or the contract price, and any other contractual term affected by the delay.
- (f) Before approval of Contractor's design drawings and specifications, the acquisition of material or components for, or the commencement of production of the supplies specified in Paragraph (a) above, is at the sole risk of Contractor and the costs thereof shall not be allocable to this contract for (1) progress payments, or (2) termination settlements if this contract is terminated for convenience.
- (g) All supplies specified in Paragraph (a) above, which are produced and tendered for acceptance under this contract, shall conform to Contractor's approved design drawings and specifications.
- (h) No changes to Contractor's approved design drawings and specifications shall be made without Battelle's prior written approval. Battelle's approval will be evidenced only by a modification to this contract signed by both parties.

This clause provides for a design hold point and must be used in its entirety (i.e., all subparagraphs apply). The PR Author or cognizant technical staff must approve or disapprove the design within the time specified and should realize that by approving the design they may have committed PNL to assume some responsibility for design adequacy.

158 DESIGN DRAWINGS AND SPECIFICATIONS

All Contractor design drawings and specifications delivered pursuant to the clause of this contract entitled "Design Drawings and Specifications Submittal" shall clearly specify how each * will be marked and identified including, but not limited to: (1) physical location of each identification mark, (2) method by which each mark is affixed, and (3) the data content of each mark, such as complete part number or drawing number (and revisions), and serial number (if applicable).

159 DELIVERY OF "AS-BUILT" DRAWINGS AND SPECIFICATIONS

Prior to submission of its final payment invoice, the Contractor shall deliver to Battelle * revised copies of all Battelle furnished or Contractor generated design drawings and specifications necessary to depict accurately all delivered supplies; provided, however, that if the supplies delivered conform exactly to all such design drawings and specifications, the Contractor shall instead so certify in writing. Such certification shall clearly specify all applicable design drawings and specifications (Red-line drawings ** acceptable). Contractor's failure to deliver all required "As-Built" design drawings and specifications, or the delivery of "As-Built" design drawings and specifications that are deficient, shall be deemed a failure to make delivery within the meaning of the Default clause of this contract.

160 PREAWARD SURVEY OF PROSPECTIVE SUPPLIER/SUBCONTRACTOR

When deemed necessary by Battelle, a Preaward Survey will be conducted of a prospective Contractor's technical, quality assurance, production, or financial capability. Evaluation of documented quality assurance program(s)/system(s) applicable to materials to be produced or services to be performed by the prospective Contractor or subcontractor(s) may include but shall not be limited to inspection and test controls, calibration of measuring and test equipment, special process controls, material storage and handling, and drawing change controls. If Government property will be furnished or handling and shipping of Hazardous Material received from Battelle is required, the prospective Contractor's property control system and/or capabilities to package and ship Hazardous Material may also be evaluated.

162 CONTRACTOR INSPECTION REQUIREMENTS

The Contractor shall perform or have performed all inspections and tests necessary to substantiate that the supplies tendered for acceptance conform to contract requirements. Such inspections and tests shall include, but not be limited to *.

158 Mandatory to: * specify part, component, subassembly, assembly, end item or other equipment description when this clause is used.

Use this clause in conjunction with Clauses 156 or 157, when the design drawings and specifications to be delivered must define the marking requirements for the hardware design.

159 When this clause is used, it is mandatory to:

- (1) specify Clauses 110 and 200.
- (2) *specify number of copies needed.
- (3) **specify "are" or "are not" for acceptability of red-line drawings.

This clause provides a record in the form of "As-Built" drawings or specifications of Battelle furnished or Contractor generated design changes.

Use this clause when:

- (1) the item may be built again.
- (2) the as-built condition is needed for maintenance/repair.
- (3) the as-built condition affects the project results.
- (4) the item interfaces must be known but will not be obvious in the final hardware.

160 This clause is used to establish a "PQD Evaluated Supplier" as related to its capability to perform (responsibility). When used, it is mandatory:

- (1) to specify one or more 120 or 130 series clauses (or equivalent quality program/system and/or special process requirement(s)).
- (2) to specify one or more 140 series clauses (or equivalent).
- (3) to specify Clause 168.
- (4) to specify Clause 201.
- (5) for the contract specialist to advise the PQA Administrator of low bidder and hold award of the PO/subcontract until notified of the evaluation results.

162 Mandatory to: specify the inspections and tests Contractor is required to perform (e.g., all dimensions with a tolerance of \pm .001 inches or less, hardness, acceptance test per procedure number XXX). Be specific in defining the inspection/test requirements to prevent an ambiguous meaning (e.g., the requirement "functional test" is ambiguous and may not be legally enforceable).

Use this clause in conjunction with specific 170 series clauses (when applicable) or when it is desirable to contractually require the Contractor to perform specific inspections/tests.

Generically, the Contractor is required to perform inspection/tests for compliance with the PO requirements prior to tendering for acceptance when QA Clauses 120.a-120e, 128, 129, or 162 have been specified.

163 BATTELLE'S SOURCE VERIFICATION

Contractor shall give Battelle ten (10) calendar days advance written notice of the date, time, and place * is scheduled to be performed. Contractor shall in no event perform any such operation, inspection, or test prior to the date specified in its notice or change the date, time, or place specified therein without Battelle's prior written approval. Battelle's authorized representative may, but is not required to, be present. In the event said representative witnesses an operation, inspection, or test performed by Contractor or conducts an inspection, surveillance, or test on Battelle's behalf, Contractor shall be provided documentary evidence to such effect.

164 FIRST ARTICLE TEST

(a) The Contractor shall deliver * units of ** within *** calendar days from the contract date to Battelle at **** for first article tests. The shipping documents shall specify this contract number and identify the lot, item, or other contract designation. The performance or other characteristics which the first article must meet and the tests to which it will be subjected are specified elsewhere in this contract.

(b) Within ***** calendar days after Battelle received the first article, Battelle shall notify Contractor, in writing, of the approval or disapproval of the first article. Notice of approval shall not relieve Contractor from complying with all requirements of the specifications or drawings, and all other terms and conditions of this contract. A notice of disapproval shall cite the reasons for the disapproval.

(c) If the first article is disapproved, the Contractor, upon Battelle's written demand, shall submit an additional first article for testing. Upon receipt of each demand, the Contractor shall make any necessary changes, modifications, or repairs to the first article or select another first article for testing. All costs related to these tests shall be borne by Contractor, including any and all costs for additional test following a disapproval. The Contractor shall furnish any additional first article to Battelle under the terms and conditions and within the time specified by Battelle. Battelle shall act on any additional first article within the time limit specified in Paragraph (b) above. Battelle reserves the right to require any equitable adjustment of the contract price for any extension of the delivery schedule or for any additional costs to Battelle related to these tests.

(d) If Contractor fails to deliver any first article on time, or Battelle disapproves any first article, Contractor shall be deemed to have failed to make delivery within the meaning of the Default clause of this contract.

(e) Unless otherwise provided in this contract, Contractor (1) may deliver the approved first article as a part of the contract quantity, provided it meets all contract requirements for acceptance and was not consumed or destroyed in testing; and (2) shall remove and dispose of any first article from Battelle's test facility at Contractor's expense.

163 When this clause is used, it is mandatory to:

- (1) specify Clause 110.
- (2) *specify witness/inspection/surveillance points; e.g., final test, final inspection prior to packaging, final analysis, plating operation, pressure test, shipping inspection etc.

Upon receipt of notice from Contractor, the contract specialist shall immediately notify the organization (as indicated on the PR) of the forthcoming verification (normally PNL PQA Administrator formerly F&PQ). Failure of the inspection organization to be present at the Contractor's conduct of an inspection/test/operation waives the right to witness that inspection/test/operation.

Do not use this clause to provide PNL the right to inspection because the PO Supplement Terms and Conditions already provide this right.

164 When this clause is used, it is mandatory to specify as follows:

- (1) *number of units
- (2) **PR item number or equipment description
- (3) ***number of calendar days from contract date the First Articles are required to be delivered.
- (4) ****for Richland locations, insert the words "(see shipping instructions)," and for other locations, insert the complete address
- (5) *****the number of calendar days for Battelle's approval or disapproval.

Example: 164 (* 2) (** Item 1) (** 180) (**** see shipping instructions) (***** 30).

Consider this clause when the procurement is for complex, high quantity items which have multiple delivery dates and approval of First Article(s) prior to authorization of production is important. This clause must be used in its entirety (i.e., all subparagraphs apply).

- (f) If Battelle does not act within the time specified in Paragraph (b) or (c) above, Battelle shall, upon timely written request from Contractor, equitably adjust under the Changes clause of this contract the delivery or performance dates and/or the contract price, and any other contractual term affected by the delay.
- (g) Contractor shall provide operating and maintenance instructions, all spare parts support, and all repairs of the first article during any first article test.
- (h) Before first article approval, the acquisition of materials or components for, or the commencement of production of, the balance of the contract quantity is at the sole risk of Contractor. Before first article approval, the costs thereof shall not be allocable to this contract for (1) progress payments, or (2) termination settlements if this contract is terminated for convenience.
- (i) Unless otherwise authorized in writing by Battelle, Contractor shall produce all first articles and the production quantity at the same facility.

165 Reserved**166 CONTRACTOR QA RECORDS REQUIREMENTS**

The Contractor shall maintain quality assurance records for *
Disposition of subject records shall be performed by ** or
at any date thereafter, at the Contractor's discretion.

167 RECEIVING INSPECTION NOTE TO BUYER/SUBCONTRACT SPECIALIST

Withhold payment to Contractor for up to * days after receipt of items in order to provide time for performing verification, inspection and/or functional test (Receiving Inspection) and to provide invoice approval. When appropriate, equivalent action may be taken, provided that basis for not including a provision in the contract allowing for delayed payment is documented. Send a copy of all POs to F&PQ to use as the base requirement for inspection.

168 DOCUMENTED PROPOSAL EVALUATION NOTE TO BUYER/SUBCONTRACT SPECIALIST

A documented evaluation which includes technical and PQD personnel (indicated by comments, signatures and dates) of all proposals is required for this order. The evaluation shall determine the Offeror's responsiveness (technical compliance or exceptions) and responsibility. The responsibility determination shall include, but not necessarily be limited to, quality assurance programs/systems, personnel, facilities, and past performance. Alternative proposals shall also be considered. The PNL buyer/subcontract specialist shall obtain resolution of any unacceptable technical and quality conditions prior to award of contract.

169 Reserved

166 When using QA Clause 166, it is mandatory to:

- (1) *specify the retention time of the QA records (e.g., 6 months, 6 years, etc...)
- (2) **specify the date when the records require disposition (e.g., 7/7/93)

167 It is mandatory to use this clause when:

- (1) an independent receiving inspection is required, or
- (2) a 170 or 180 series clause is specified.

* Mandatory to specify applicable days (usually less than 31 days).

This clause will not be transferred to the PO. Procurement/ Subcontracts will specify a special clause to the Contractor, and Accounts Payable will proceed to pay Contractor when they obtain invoice approval or when the withhold date has been exceeded and they have not been advised otherwise.

168 Mandatory to use this clause when QA Clause 160 is specified.

Use this clause for other situations when PQD needs to be involved in the review of proposals.

This clause will not be transferred to the PO.

170 CONTRACTOR REPORT(S)

Contractor shall submit for:

- [a] *, **Chemical Analytical Report(s)** (or Certificate of Analysis) containing the actual results of a chemical analysis performed on the specific chemicals or supplies tendered for acceptance. Such analysis shall be reported on a batch, heat, or lot basis.
- [b] *, **Mechanical/Physical Properties Test Report(s)** containing the actual results of all tests required by the Standard specification(s). Such analysis shall be reported on a batch, heat, or lot basis.
- [c] *, **Mechanical/Physical Properties Test Report(s)** containing the actual results of ** tests required by this contract. Such analysis shall be reported on a batch, heat, or lot basis.
- [d] * **Reference or Standard Materials Report(s)** specifying (1) the measurements made; (2) the results of such measurements; (3) an estimate of the uncertainties of each measurement recorded (such as random and systematic errors) and (4) the basis for the validity of each measurement recorded, consisting of either a description of the methods and sources used to make the measurements or a certification that the measurements are traceable to a nationally recognized standard or derived from accepted values of natural physical constants.
- [e] * **Calibration Report(s)** containing the parameters calibrated, acceptance criteria and the actual calibration results. Contractor shall certify that the supplies tendered for acceptance have been calibrated using standards whose calibration is (1) traceable to the National Institute for Standards and Technology (or other nationally recognized standards acceptable to Battelle), (2) derived from accepted values of natural physical constants, or (3) derived by the ratio type of self-calibration techniques. When this contract is for recalibration of Battelle's equipment, the Calibration Report shall contain the results of a pre-calibration check of the "as-found" condition recording any "out-of-tolerance" parameters.
- [f] * **Pressure and/or Leak Test Report(s)** containing the testing requirements, acceptance criteria, and actual results of all pressure and/or leak tests required by this contract.

170 All 170 series clauses require the Contractor to submit a report for a specific type of test, inspection, analysis, examination, etc.

Consider using a 120/130 series clause in conjunction with 170 series clauses when obtaining a report for critical information.

When a 170 series clause is used, it is mandatory to:

- (1) specify Clauses 110, 167, 200, and (when applicable) 162.
- (2) *specify which item(s) or other descriptive nomenclature for each 170 clause specified (e.g., Items 1 and 3, all stainless steel, all pressure retaining components, all drawing dimensions with a tolerance of $\pm .001$ inches or less, etc.).

170a Use for either a chemical analysis report on raw material (e.g., alloys) or for a certificate of analysis on high purity chemicals.

170b Use when ordering material to MIL-Specs. or other nationally recognized specifications, see Application Note for Clause 170j, when ordering ASTM material.

170c Mandatory to ** specify contractually required tests, such as tensile strength, density, or hardness when this clause is used.

Use when a test report to a specific physical property is needed and the material is NOT being ordered to a standard specification.

170d Use this clause for chemical standards, radioactive sources, Standard Reference Materials, etc. It is not necessary to specify this clause when ordering from NIST because the report is provided automatically.

170e Use this clause when the calibration data is actually needed if ordering new M&TE or for obtaining the "as-found" data and "final" data when M&TE is to be calibrated by a supplier.

Usually, this clause is not applicable to new M&TE (Category 1) which will be receiving inspected for the "as-found" condition by WHC Standards Lab or PNL CS. Consider using this clause in conjunction with Clause 129.

170f Use when hydro test, pneumatic leak test, etc. is required in the specification, drawing, or body of PR.

[g] *, **Nondestructive Examination Report(s)** containing the actual results of ** examinations required by this contract. The reports shall identify what was examined by specific section, joints, views, or serial numbers, and reference the qualified procedures used and specific acceptance criteria (e.g., AWS D1.1, Paragraph 8.15.1). The report shall contain information as required by the governing code or specification. When radiographic examinations are performed, the x-ray film shall be submitted with the report and identified by cross-reference to each film exposure. Reports shall be signed by the NDE Level II or III who either performed the examinations or interpreted the results.

170g Mandatory to ** specify visual, radiographic, magnetic particle, helium leak test, liquid penetrant, etc. when this clause is used.

Use when NDE reports are required or needed. Mandatory to use QA Clauses 120 or 130 series, 140f, 150a, 150b, 150c, 160, 168, 201, and 210b.

[h] *, **Inspection Data Report(s)** of actual inspection results, specifying what was inspected, the characteristics inspected, and the acceptance criteria, all as required by this contract.

170h When either clause is used, it is mandatory to:
or

170i (1) specify Clause 162

OR

[i] *, **Functional Test Report(s)** of the actual test results, specifying what was tested, the requirements/parameters tested, and the acceptance criteria, all as required by this contract.

(2) have otherwise specified inspection or test requirements in the procurement document.

Consider these clauses when the characteristics to be inspected or tested are of critical or major importance.

[j] *, **ASTM Manufacturers' Certification and Test Report**, certifying the actual results of all tests and inspections required by ASTM Standard Specification(s) **.

170j Mandatory to ** specify the applicable ASTM specification number(s) (e.g., B165, B670, etc.).

Use of this clause takes advantage of the certified material test reports that ASTM material manufacturers are required to perform in order to meet the applicable ASTM specifications. When ordering material to ASTM Standard Specifications, it will normally be more effective from a cost and delivery viewpoint to specify this clause in lieu of the 170a, 170b, 170c, or 180a clauses when the standard ASTM reports will suffice.

180 CONTRACTOR CERTIFICATIONS

Contractor shall submit for:

180 All 180 series clauses require the Contractor to submit a certification. When used, it is mandatory to:

- (1) specify Clauses 110, 167, and 200.
- (2) *specify which item(s) or other descriptive nomenclature for each 180 clause specified.

[a] *, **Material Certification(s)**, listing all specification numbers (including revision status) to which the material is required to conform. Each certification shall contain the substance of the following statement: "It is hereby certified that the material identified herein conforms to the listed specifications."

180a Not usually for Impact Level I or II applications. Do not use this clause as the sole basis to support material characteristics for a critical application. Consider a 170 series clause.

[b] Reserved

[c] *, **Special Process Certification(s)**, listing for ** processes, all special process specification number(s) (including revision status) to which the process is required to conform. Each certification shall contain the substance of the following statement: "It is hereby certified that the material identified herein conforms to the listed specifications."

180c Mandatory to ** specify the special processes such as heat treating, anodizing, and chrome plating in which the drawings, PRs, etc. require performance to a nationally recognized standard.

[d] *, **Direct Material Utilization Certification(s)**, specifying by nomenclature, type and/or quantity, all Battelle furnished direct materials from which the supplies tendered for acceptance were produced or which have had such direct materials incorporated or attached. Each certification shall contain the substance of the following statement: "It is hereby certified that the suppliers identified herein were produced from, contain, or have attached the direct materials listed in Battelle's Return Order # **."

180d Use this clause when PNL has furnished material with important and verified properties to the Contractor for incorporation into items to be delivered to PNL and traceability of the material must be maintained.

** When known, specify the PNL return order number.

[e] Reserved

[f] *, **a Certificate of Conformance**, listing (1) nomenclature and part number(s) and (2) contract requirements met, including reference to codes, standards, specifications (including revision status), written change orders and Battelle-approved Contractor Nonconformance Request. The Certificate of Conformance shall describe the quality assurance function and position of the person attesting its accuracy, unless the Contractor has submitted with its proposal, in response to the RFP which resulted in the award of this contract, its QA/QC Manual or a QA/QC Plan which includes such information.

180f This clause invokes a strong certificate of conformance (C of C) for NQA-1 applications or when the C of C will be used as the only basis for acceptance. When used, it is mandatory to specify one or more 120 or 130 series clauses, one or more 140 clauses, 160, 168, and 201.

Recommended for use on complex items which cannot be readily accepted by source verification, receiving inspection, or post-installation testing.

190 IDENTIFICATION/MARKING REQUIREMENTS

190 All 190 series clauses require the Contractor to identify or mark specific items listed on the Purchase Order. When used, it is mandatory to * specify what has to be marked (e.g., each end item, assembly, subassembly, part, container, bag or envelope, etc.) and any additional requirements needed.

Contractor shall mark * with the:

[a] **complete part (or catalog) number**, including any applicable revision letter/number or serial number.

190a Use when identification of material is needed.

[b] **specification and heat number** (mill identification). Marking shall be by indelible ink (or other method approved in writing by Battelle) applied to each piece along its entire length. Sheet material shall be marked in parallel strips no farther than eighteen (18) inches apart.

190b For raw material control applications. Do not use for nuclear, stainless steel or other applications where ink could cause deleterious effects (see 190c).

[c] **specification and heat number** (mill identification). Marking shall be by vibrating marking tool, nuclear grade electrochemical etch, or low chloride marking ink (or other method approved in writing by Battelle) applied to each piece along its entire length. Sheet material shall be marked in parallel strips no farther than eighteen (18) inches apart.

190c Use for nuclear or stainless steel raw material control applications.

[d] **shelf life, cure date, or expiration date**. Each piece, package or container of material shall be marked. Temperature, humidity, and other environmental storage conditions required shall be displayed in a conspicuous manner.

190d Use for age control of critical items having limited shelf life (e.g., certain chemical, rubber, biological specimens).

[e] **

190e Mandatory to ** specify special identification/marketing requirements needed when this clause is used.

Use this clause when special identification/marketing is needed and the common 190 series prefix and suffix apply.

- [f] (1) Manufacturer's name, (2) part (or catalog) number, and (3) its maximum operating temperature and maximum operating pressure. In the event that such data cannot be affixed directly thereon, it may be affixed by means of a tag.

All markings shall be legible, without any deleterious effect on the supplies to which it is applied. Unless otherwise specified, permanency of the marking shall be sufficient for the life expectancy and use, including any cleaning processes, for which the supplies are designed.

200 FORMATS OF REPORTS AND CERTIFICATIONS

Each report and/or certification shall be legible, reproducible, and contain, in addition to any other requirements as specified by this contract, the following:

- (1) The contract number
- (2) A clear identification of the supplies covered, including, but not limited to, the use of serial, lot, batch, heat, or mill numbers
- (3) The date and title of the person signing.

Each report and certification shall be signed personally by Contractor's QA/QC Manager or a representative of Contractor authorized to enter into legally binding commitments on its behalf. By submission of a report, Contractor expressly represents that the contents are accurate and complete and that all inspections, tests, analyses, processes, calibrations, and other operations required by this contract have been performed.

Submission of a certification constitutes Contractor's express warranty that the identified supplies conform to all of the requirements of this contract.

The Contractor shall, prior to or concurrently with each shipment of supplies, mail separately to Battelle three (3) copies of all required reports and certifications

201 CONTRACTOR NONCONFORMANCE REQUESTS

The Contractor may request approval to tender for acceptance (1) nonconforming supplies or (2) services at variance with the requirements of this contract. Such request shall be submitted utilizing the Battelle form entitled "Contractor Nonconformance Request" (CNR). A CNR may be submitted when

- (1) a technical, QA/QC, regulatory, or material requirement is violated
- (2) a requirement in a Contractor submittal, which has been approved by Battelle, is violated
- (3) a nonconformance cannot be corrected by continuation of the original manufacturing process or by rework, or
- (4) a nonconformance can be repaired such that form, fit, function, or safety is not impaired

Battelle's approval of Contractor's request shall be evidenced only by a modification to this contract signed by both parties

210 QA SUBMITTAL COMPLIANCE REQUIREMENTS

The Contractor shall:

- [a] comply with the inspection and test plan submitted with its proposal in response to the RFP which resulted in award of this contract.

- 190f Use this clause for pressure retaining items which fall outside the boundaries of the code where failure could cause a hazard.

- 200 Mandatory to use this clause in conjunction with Clauses 110, 167, and any 170 or 180 clause(s).

- 201 Mandatory to use this clause when Clause 180f has been specified.

This clause is for suppliers/subcontractors which have a known quality program/system (PQD Evaluated Suppliers). Contact the PQA Administrator prior to using this clause when QA Clause 160 is not specified. (See EXHIBIT 4, Contractor Nonconformance Request)

- 210 All 210 series clauses are used to obtain compliance to procedures and plans submitted at the proposal stage of procurement or after award.

- 210a Mandatory to use this clause in conjunction with Clause 140h.

- [b] comply with the Welding and NDE Plan submitted in response to the RFP which resulted in award of this contract, comply with all qualified welding and NDE procedures approved by Battelle after the contract date, and use only qualified/certified personnel whose certification records have been approved by Battelle.
- [c] comply with * procedures.
- [d] utilize, except as authorized by the Battelle in writing, only those qualified personnel to perform or verify the special processes/operations for whom certified records were submitted with its proposal in response to the RFP which resulted in award of this contract.
- 210b** Mandatory to use this clause in conjunction with Clause 140f, 150a, 150b, and 150e.
- 210c** When this clause is used, it is mandatory to:
- (1) *specify the same procedures as noted in Clause 150f.
 - (2) specify Clause 150f.
- 210d** Mandatory to use this clause in conjunction with Clause 140g.

INDEPENDENT RECEIVING INSPECTION

ITEM TO BE INSPECTED	RESPONSIBLE ORGANIZATION	INSPECT/TEST INSTRUCTION (ITI) REQUIRED	LOCATION *	REMARKS
Hardware fabricated to drawing or specification	PNL Lead Procurement Engineer (Lead PQE)	Yes	(1) 306W (2) 337/North Dock	(1) For items that require precision inspection equipment. (2) For other items.
Safety-Related HEPA Filter	(1) Hanford Filter Testing Facility (HFTF) (Test/Inspection) (2) PNL Lead PQE (Documentation/Overcheck)	(1) No (2) Yes	(1) N/A (2) At HFTF (preferred) or PNL PQD Receiving 337/North dock	(1) EXHIBIT 3 provides requirements that get HEPA Filters routed from WHC Receiving to HFTF.
Pressure Vessel/Rupture Disks	PNL Lead PQE	Yes	337/North Dock	
Radioactive Material Shipping Container	PNL Lead PQE	Yes	337/North Dock	Containers may need special routing (see * below).
Measuring and Test Equipment (Calibration Category I)	(1) WHC Standards Lab, or (2) PNL Craft Services or (3) PNL Instrumentation and External Dosimetry Section	No	(1) 337/North Dock (2) 337/North Dock (3) 318	Calibration Label and Record indicates acceptance in lieu of ITI.
QA Document Submittals	PNL Lead PQE	ITI or RPR	337/North Dock	Acceptance may be indicated on RPR or transmittal form in lieu of ITI.
Hoisting and Rigging Equipment	PNL Lead PQE	Yes	337/North Dock	
Safety Class and selected Non-Safety Class SSCs or items to be installed in such SSCs	PNL Lead PQE	Yes	337/North Dock	(1) Some items may be very large or require Post Installation Testing (see * below). (2) This Table does not apply to SSCs inspected by KEH, fixed-price contractors, or off-site AE firms as part of their WO/Contract.

* NOTE: For very large items/SSCs or Post Installation Testing, the Requisitioner should: (1) specify delivery of the item/SSC to the installation/use site and (2) notify PNL Lead PQE to perform inspection upon receipt or witness Post Installation Testing. For assistance in specifying the inspection location, contact the Cognizant QE or Lead PQE.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PROCURING HEPA FILTERS

- 1.0 When the PR involves a HEPA filter intended for use in a safety-related system, the following steps shall be performed.
- 1.1 When possible, HEPA filters should be procured in accordance with the applicable Hanford Plant Standard (HPS) which specifies purchasing instructions. The purchasing instructions in the HPS specify information required to be listed on the PR to provide a complete description of the requested filters. The following list is taken from a representative HPS.
- a. Quantity and name of item
 - b. Size, nominal airflow rating and maximum resistance at nominal airflow rating (e.g., 12" x 12" x 5-7/8" OD, 125 cfm at 1.3" wg)
 - c. Case material (e.g., plywood)
 - d. Filter pack material and type (e.g., pleated fiberglass with separators)
 - e. Separator style and material (e.g., corrugated aluminum separators)
 - f. Filter/mounting frame seal (e.g., neoprene strip gasket, downstream end)
 - g. Face guard material (e.g., galvanized wire cloth)
 - h. Applicable HPS specification including revision
 - i. Exceptions to the HPS specification if any
 - j. Specify that **Hanford Filter Test Facility (HFTF)** filter testing is required
 - k. Shipping instructions
- NOTE: The typical HPS specifications are HPS-157-M through HPS-163M. A Facilities Engineering representative can provide assistance in determining the appropriate specification.
- 1.2 If the HPS specifications do not apply to the type of filter being requested, the PR Author shall specify the applicable information from 1.1 a-k and the following information as a minimum:
- a. nuclear grade
 - b. maximum allowable pressure drop (ΔP)
 - c. efficiency (e.g., 99.97% of 0.3 micron size particles)
 - d. applicable standards such as MIL-F-51068 and MIL-F-51079
 - e. vendor model number.
- 1.3 The PR Author shall obtain the review and approval signature of a Laboratory Safety Department representative.
- 1.4 The PR Author shall apply the following QA clauses to the PR:
- a. For vacuum cleaner filters apply QA clauses 170i, and 167 (30) specifying **HFTF** receiving inspection. A Process Quality Department (PQD) evaluated supplier via QA clause 160 is not required

PROCURING HEPA FILTERS.

- b. For other filters to be used for environmental protection and those filters governed by a HPS specification apply QA clauses 110, 120a, 140a, 160, 167(30), 168, 170i, 190a, and 200. Exception to these QA clauses should be approved by the Lead Procurement Quality Engineer (Lead PQE). Apply additional QA clauses as appropriate.

1.5 HEPA filter testing.

- a. **HFTF** filter testing shall be performed for procurements of filters, or for relatively portable systems such as a vacuum cleaner. A Procurement Quality Engineer (PQE) shall perform receiving inspection to verify **HFTF** filter testing was performed and that the item conforms to the purchase order specifications

NOTE: **HFTF** may perform in-place filter testing at PNL facilities upon special request

- b. For procurements involving systems that require in-place testing (e.g., glove box that requires hard wiring and plumbing), Utility Operations performs in-place filter testing rather than **HFTF**.

1.6 The PR Author shall:

- write a statement on the PR, in the Description Block, similar to the following - "**HFTF** Filter Testing Required" - if applicable as described in 1.5 above
- specify "**HFTF**" in the "Deliver To" block and Note 747 (Building) Dock.

1.7 Check receiving inspection on the PR and indicate:

- receiving inspection by "other" and write in "**HFTF**", and
- receiving inspection by a PQE.

NOTE: **HFTF** will test and inspect filters in accordance with the "QA REQUIREMENTS FOR DOE APPROVED RECEIVING AND TESTING FACILITY" as shown in this Exhibit. A PQE will review supplier and **HFTF** documentation and may perform overchecks of the characteristics, if deemed necessary.

- 1.8 Attach to the PR a copy of Page 4 of this Exhibit, "QA Requirements For DOE Approved Receiving and Testing Facility" if **HFTF** will perform the receiving inspection and acceptance testing. If the HPS specifications do not apply, attach a copy of the alternate standard and/or specifications.

2.0 When the PR involves a HEPA Filter intended for non-safety related applications (e.g., for experimental purposes) the following steps apply:

- 2.1 Any filter that meets the technical requirements of the project may be procured.
- 2.2 The PR Author shall provide a written notice similar to the following: "Upon receipt of the filters ordered by PR No. _____, mark the filters 'FOR EXPERIMENTAL USE ONLY' and store the filters in a manner that will preclude the use of these filters in a system where the failure of the filters could have an adverse effect upon the safety of the public or on-site personnel."
- 2.3 The PR Author shall obtain reviews by a Laboratory Safety representative before PQD QE approval of the PR.
- 2.4 The following QA clauses should be applied to the PR as appropriate: 110, 167(30), 170i, 190a, and 200.

PROCURING HEPA FILTERS

Date: _____

QA REQUIREMENTS FOR DOE APPROVED RECEIVING AND TESTING FACILITY

1. Inspection and testing of Battelle procured HEPA filters shall be performed in accordance with the purchase order and the applicable specification requirements. As a minimum, the following shall be performed:
 - a. Visually check and conduct efficiency (penetration) and air flow resistance tests, including frame integrity when appropriate, in accordance with the applicable specification. Tests shall be performed at the minimum initial rated flow of the applicable specification.
 - b. Inspect each package and filter for physical damage and for the outside dimensions of the filter as designated by the applicable specification or as modified by the purchase order.
 - c. Inspect each filter for the marking requirements, including an authorized UL Label, in accordance with the applicable specification. If UL Label is not present, notify the Contract Specialist in writing. If the Contract Specialist does not provide disposition within 10 working days, the testing facility may reject the filters and/or dispose of the filters in accordance with the requirements of the purchase order.
 - d. All testing shall be performed using measuring and test equipment whose calibration is documented using standards whose calibration is:
 - (1) traceable to the U.S. National Institute of Standards & Technology (NIST) (or other nationally recognized standards acceptable to the Contract Specialist),
 - (2) derived from accepted values of natural physical constants, or
 - (3) derived by the ratio type of self-calibration techniques.
 - e. Record inspection/test results and provide copies to the Contract Specialist.
 - f. Show status of all inspected/tested filters by identifying them with either an "ACCEPTED" tag or a "REJECTED" tag, as appropriate.
2. Other:

**THIS PAGE INTENTIONALLY
LEFT BLANK**

CONTRACTOR NONCONFORMANCE REQUEST		CNR _____ Serial No.
To be completed by contractor (please type or print) the contractor accepts full responsibility for the accuracy and completeness of the information below:		
(1) TO:	(2) FROM:	
BATTELLE PACIFIC NORTHWEST LABORATORIES P.O. Box 999 Richland, Washington 99352	(3) SUBCONTRACT/P.O./W.O. NO.:	
	(4) DWG. NO. and REV.:	(7) PREVIOUS CNR'S:
	(5) NONCONFORMING ITEM(S):	(8) QUANTITY:
	(6) PRODUCT/SERVICE/PROCESS IDENTIFICATION:	
(9) DESCRIPTION OF DEFICIENT CONDITION, SPECIFICATION REQUIREMENT NOT MET, OR INTERPRETATION REQUIRED:		
(11) SUPPLIERS REQUESTED DISPOSITION:	(10) CAUSE, CORRECTIVE ACTION BEING TAKEN, and EFFECTIVITY	
(11a) JUSTIFICATION:	(10a) VERIFIED BY:	
	_____	_____
	PNL Representative	Date
	(12) LIST ATTACHMENTS:	
(13) SIGNATURE OF CONTRACTOR'S AUTHORIZED REPRESENTATIVE:	_____	
	Date	
TO BE COMPLETED BY BATTELLE PACIFIC NORTHWEST LABORATORIES		
(14) DISPOSITION:	(14a) TECHNICAL JUSTIFICATION:	
{ } Approved as Requested { } Disapproved or { } As Below		
(15) THIS REQUEST AFFECTS INSPECTION OR INSTALLATION AT SITE: { } { } NO		
(16) DISPOSITION APPROVALS		
_____	_____	_____
Project	Date	Procurement
_____	_____	_____
Process Quality Department (PQD)	Date	Customer
_____	_____	_____
(17) CNR CLOSEOUT		
REINSPECTION ACCEPTABLE [] CNR SUPERSEDED BY [] CORRECTIVE ACTION VERIFIED [] CNR CLOSED OUT []		
_____	_____	
PQD	Date	
The issuance and acceptance of this request in no way limits or affects the warranty provisions of the order. This request shall not establish a precedent or obligation to accept similar conditions in the future.		CNR -

**INSTRUCTIONS FOR FILLING OUT THE
CONTRACTOR NONCONFORMANCE REQUEST**

Contractor completes Blocks 1 through 13 excluding 10a.

- (1) Name of PNL Contract Specialist.
- (2) Contractor's name and address.
- (3) contract Number, Subcontract Number, or Purchase Order Number.
- (4) Drawing number/revision that relates to the subject item.
- (5) Description of item(s).
- (6) Unique identification directly related to the item/process/service.
- (7) Indicate previous CNRs (if any).
- (8) State how many items.
- (9) Describe the reason for this CNR.
- (10) What is the root cause, corrective action being taken to correct the condition, and the affectivity date when corrective action will be complete.
- (11) State the requested disposition (i.e., accept as is, repair, etc.).
 - (11a) Give justification on why the requested disposition should be taken.
- (12) Identify any attachments to this CNR (i.e., drawing, spec., etc.).
- (13) Signature of authorized representative and the date.

PNL completes Blocks 10a through 17 excluding Customer signature/date in Block 16.

- (10a) Signature and date of PNL Representative (usually during a source test/inspection/surveillance activity).
- (14) Usually completed by PNL Management or staff.
- (15) Check the appropriate block.
- (16) Project
PQD Representative
Procurement or
Subcontracts or
Technical Staff
Customer Representative
- (17) CNR closeout made by the PQD Representative.

STANDARD QA CLAUSES FOR PR _____ Date: _____ Page 1 of 2

I. NOTES TO CONTRACT SPECIALIST: THE FOLLOWING CLAUSES ARE FOR "PNL USE ONLY", DO NOT INCORPORATE INTO THE RFP/PO.

- 167 Rec. Insp. * _____ days (usually less than 31 days) Inspection by: Author PQE Other _____
- 168 Documented Proposal Evaluation

II. RFP CLAUSES: THE FOLLOWING CLAUSES ARE FOR INCORPORATION INTO THE RFP ONLY, NOT THE RESULTANT PO.

PQD EVALUATED SUPPLIER

- 160 Preaward survey of Prospective Supplier/Subcontractor (Check Clause 168 NOTE TO BUYER above)

SUBMITTALS REQUIRED BEFORE CONTRACT AWARD

- 140a QA Program Description
- 140c Calibration System Description
- 140e Qual. Records - DOT Hazardous Material Staff
- 140g Certified Records of Qualified Personnel * _____ in accordance with * _____
- 140h Inspection/Test Plan
- 140b NRC Prog. App. for Radioactive Mat. Packages
- 140d ASME Certificate of Authorization
- 140f Welding/NDE Plan

III. RFP/PO CLAUSES: THE FOLLOWING CLAUSES SHALL BE INCORPORATED INTO BOTH THE RFP AND RESULTANT PO.

DOCUMENTATION REQUIREMENTS

- 110 QA Documentation Delivery * Contract Specialist's name
- 200 Formats of Reports/Certifications
- 201 Contractor Nonconformance Requests

QA PROGRAM/SYSTEM REQUIREMENTS

- 120a any Nationally recognized Quality Program/System
- 120c ASME NQA-1 * _____ Edition (incl. Addenda * _____) Basic Requirements/Supplements ** _____
- 120b MIL-I-45208

- 120d 21CFR58, GLP
- 120e ***
- 120f EPA Contract Laboratory Program
- 127 Hazardous Material Shipping
- 129 Calibration System Requirements
- 120g EPA-600/4-83-004 & QAMS-005/80
- 128 QA System -Shipping Containers/Packages
- 130 B&PV Code (PR Valves) * _____ ** _____ *** _____
- 130a B&PV Code (Pressure Vessels) * _____ ** _____ *** _____
- 137 Welding Code Requirements * _____ ** _____

SUBMITTAL(S) AFTER CONTRACT DATE

- 150a Certified Welders/NDE Personnel* _____ cal. days after contract app/disapproval within ** _____ calendar days
- 150b QWPs & PQRs * _____ cal. days after contract app/disapproval within ** _____ calendar days
- 150e NDE Procedures * _____ cal. days after contract app/disapproval within ** _____ calendar days
- 150f *** _____ * _____ cal. days after contract app/disapproval within ** _____ calendar days
- 156 Design Dwgs (PNL com.) for * _____ within *** _____ calendar days
- 157 Design Dwgs (PNL app.) for * _____ within ** _____ cal. days *** _____ calendar days
- 158 Design Dwgs, Hardware Marking * _____
- 159 As Built Drawings/Specifications * _____ revised copies Red-line drawings ** _____ are _____ are not _____ acceptable

COMMENTS: _____

STANDARD QA CLAUSES FOR PR _____ Date: _____ Page 2 of 2

INSPECTIONS/VERIFICATIONS

- 162 Contractor Inspection Requirements * _____

- 163 Source Verif. * _____ days Inspection by: Author PQE Other _____
- 164 1st Article Test * _____ ** _____ *** _____ **** _____
- 167 Rec. Insp. (Fill in top of Page 1 - "NOTES TO CONTRACT SPECIALIST")

RECORDS

- 166 Contractor QA Records Requirements * _____ ** _____
- Other _____

CONTRACTOR REPORTS

- 170a Chemical Analytical * _____ 170b Mech./Physical Properties * _____
- 170c Mech./Physical Prop. * _____ ** _____
- 170d Ref./Std. Material * _____ 170e Calibration Report * _____
- 170f Pressure/Leak Test * _____
- 170g NDE Report(s) * _____ ** _____
- 170h Insp. Data Report * _____ 170i Functional Test * _____
- 170j ASTM CMTR * _____ ** _____

CONTRACTOR CERTIFICATIONS

- 180a Material Certification * _____ 180f C of C * _____
- 180c Special Process Certs * _____ ** _____
- 180d PNL Furnished Mat. * _____ ** _____

IDENTIFICATION/MARKING

- 190a Part/Catalog Number * _____ 190b Spec/Heat # (indelible ink) * _____
- 190c Spec/Heat # (Nuclear) * _____ 190d Shelf Life, cure/exp. date * _____
- 190e * _____ ** _____
- 190f Manufacturer's name, part #, maximum operating temp/pressure * _____

QA SUBMITTAL COMPLIANCE REQUIREMENTS

- 210a Comply with Inspection/Test Plan 210b Comply with Welding/NDE Plan
- 210c Comply with * _____ procedures 210d Utilize qualified/certified personnel

COMMENTS: _____

QA CLAUSES USE GUIDE

CLAUSE	MANDATORY ADDITIONAL CLAUSES	CLAUSES TO CONSIDER
120a-g	140a, 160, 168, 201	
127	140e, 160, 168	
128	140b, 160, 168, 201	163
129	140c, 160, 168, 201 (170e when procuring calibration services)	170e or 180f
130	163 or 167 and Lead PQE as inspection Organization	
130a	140d, 160, (163 or 167 and Lead PQE as inspection Organization), 168	
137	120a, 140a, 140f, 150a, 150b, 150e, 160, 168, 201, 210b	
140f	any 120 or 130 series, 150a, 150b, 150e, 160, 168, 201, 210b	
140g	168, 210d	
140h	168, 210a	
150a,b	110, 140f, 210b	
150e	110, 210b	137
150f	110, 210c	
156	110, 159	158
157	110, 159	158
159	110, 200	
160	any 120 or 130 series, any 140 clause, 168, 201	
163	110	
170a-f, j	110, 167, 200, 162 (if applicable)	any 120 or 130 series (129 for 170e), 162
170g	110, any 120 or 130 series, 140f, 150a, 150b, 150e, 160, 168, 201, 210b	162
170h,i	110, 167, 200, (162 or specify insp/test req)	any 120 or 130 series
180a-e	110, 167, 200	
180f	110, any 120 or 130 series, any 140 clause, 160, 167, 168, 200, 201	

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-402, CONTROL OF SUSPECT/COUNTERFEIT ITEMS

INTRODUCTION/BACKGROUND

The Nuclear Regulatory Commission, Department of Commerce, and other government agencies have identified a number of Suspect/Counterfeit items as being supplied to government and private contractors. To prevent the purchase of graded fasteners, electrical components, and piping components (suspect items) from suspected suppliers, it is important to notify the Contract Specialist and requisitioners of the types of items that have been determined to be suspect.

This procedure prescribes basic requirements and precautions that should be followed when procuring and receiving items that may fall under the Suspect Item category.

PURPOSE

Provide a method of identifying items that have been recognized as suspect by the Nuclear Regulatory Commission, Department of Energy, Department of Commerce, or other US Government entities and to prevent inadvertent procurement or use of such items.

APPLICABILITY

This procedure applies to the procurement and receipt of specifically identified fasteners (as defined by Public Law 101-592), electrical components, and piping components procured by the Pacific Northwest Laboratory (PNL). The procedure is applied as directed by other procedures.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Procurement Quality Engineer (PQE)
- Requisitioner (PR Author).

DEFINITIONS

Fastener - Public Law 101-592, Fastener Quality Act, defines fasteners as:

- 1) A screw, nut, bolt, or stud with:
 - a) internal or external threads or a load indicating washer of metal,
 - b) nominal 1/4 inch or M5 (5mm) and larger diameter, and
 - c) through-hardening to meet a standard or specification requirement.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

Fred M Newcomer 6/16/94

F.M. Newcomer

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah

6/20/94

JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

- 2) A screw, nut, bolt, or stud having internal or external threads bearing a grade identification marking required by a standard or specification.
- 3) A washer when it is subject to a standard or specification applicable to the product included with the definition of 2) above.

Suspect/Counterfeit Item(s) - An item that potentially or actually does not meet National Consensus Standards or is a copy or modification of an item that does meet such standards without the authority or right to do so.

Supplier Quality Information Group - A Department of Energy (DOE) and contractor group representing all DOE sites organized to develop a common Evaluated Supplier List and joint audit procedures.

GENERAL

This procedure provides a reference source of suspect items that have been identified by various U.S. Government entities. This procedure will be amended as additional information becomes available.

IMPLEMENTATION

1.0 Ordering

When the Purchase Requisition (PR) requests the same or similar type of fasteners as noted in EXHIBIT 1, electrical components (noted in EXHIBIT 2), or piping components (noted in EXHIBIT 3); the following conditions apply.

- 1.1 The Requisitioner shall specify the following minimum Standard QA Clauses (see PAP-70-401, Purchase Requisitions) and additional requirements as delineated below:

1.1.1 Graded Fasteners:

QA Clauses 110, 167 (30), 170a (*=item number), 170c (*=item number, **=type of tests), 190e (*= container of fasteners [with the] **=Part Number [or Catalog Number], Purchase Order Number, and Lot Number), and 200.

1.1.2 ASTM certified fasteners:

- QA Clauses 110, 167 (30), 170j (*=item number), **=ASTM Standard Specification Number) instead of 170a or 170c, 190e (*= container of fasteners [with the] **=Part Number [or Catalog Number], Purchase Order Number, and Lot Number), and 200
- each lot be individually certified by the manufacturer
- applicable Society of Automotive Engineers (SAE) standards (e.g., J429, etc.) in the description portion of the Purchase Requisition.

1.1.3 Electrical components: Specify QA Clauses 167 (30) and 190e (*=containers of electrical components [with the] **=complete part [or catalog] number, including any applicable revision letter/number or serial number and the Purchase Order Number).

1.1.4 Piping components: Specify QA Clause 167 (30) and 190e (*= containers of piping components [with the] **=complete part [or catalog] number, including any applicable revision letter/number or serial number and the Purchase Order Number).

1.2 For items described in 1.1, the Requisitioner shall:

- note in the DELIVER TO block "337/North Dock"
- check "QC" and "REC" in the INSPECTED BY block.

1.3 The Requisitioner shall not request electrical and piping components (identified in EXHIBITS 2 and 3) from a suspect supplier (EXHIBITS 2 & 3) unless that supplier has received an acceptable evaluation by either a PQE (QA Clause 160), or a member of the Supplier Quality Information Group.

NOTE: Evaluation information can be received by contacting a PQE.

1.4 The Requisitioner shall process the PR as described in PAP-70-401, Purchase Requisitions.

2.0 Receiving

2.1 The PQE shall inspect fasteners, electrical components, and piping components in accordance with the information contained in the exhibits to this procedure.

2.2 The PQE shall document any nonconformances in accordance with PAP-70-1501, Nonconformance Reports. Suspect/counterfeit items are required to be reported through the Off-Normal Event Reporting System. Contact an occurrence classifier (see PNL-MA-7, Off-Normal Event Reporting System).

REQUIRED RECORDS

None.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

Notice of Disclaimer

Exhibit 1 is a suspect/counterfeit Headmark List that was prepared by the United States Customs Service after extensive testing of many samples of bolts from around the nation. The headmarks on this list are those of manufacturers that have often been found to have sold bolts that did not meet the indicated consensus standards. Sufficient testing has been done on the bolts on this list to presume them defective without further testing.

ENVIRONMENT, SAFETY & HEALTH *BULLETIN*
DOE/EH-0266 August 1992

The purpose of the Notice of Disclaimer is to indicate the source for the information contained in this exhibit.

Suspect Fastener Headmark List

All Grade 5 and Grade 8 Fasteners of Foreign Origin Which Do Not Bear Any Manufacturers' Headmarks:



Grade 5



Grade 8

Grade 5 Fasteners with the Following Manufacturers' Headmarks:



Mark Manufacturer
 J Jinn



Mark Manufacturer
 KS Kosaka Kogyo (JP)

Grade 8 Fasteners with the Following Manufacturers' Headmarks:



Mark Manufacturer
 A Asahi Mfg (JP)



Mark Manufacturer
 KS Kosaka Kogyo (JP)



NF Nippon Fasteners (JP)



RT Takai Ltd (JP)



H Hinomoto Metal (JP)



FM Fastener Co of Japan (JP)



M Minamida Sieybo (JP)



KY Kyohei Mfg (JP)



MS Minato Kogyo (JP)



J Jinn Her (JP)



Hollow Triangle Infasco (CA TW JP YU) (Greater than 1/2 inch dia)



E Daiei (JP)



UNY Unytite (JP)

Grade 8.2 Fasteners with the Following Headmarks:

Mark Manufacturer



KS Kosaka Kogyo (JP)

Grade A325 Fasteners (Bennett Denver Target Only) with the Following Headmarks:

Mark Manufacturer

Type 1



A325 KS Kosaka Kogyo (JP)

Type 2



Type 3



Key: CA - Canada, JP - Japan, TW - Taiwan, YU - Yugoslavia

Notice of Disclaimer

The information contained in this Exhibit was taken from Nuclear Regulatory Commission Bulletins 90-57, 89-45, 89-45 Supp 1 and 2 and 88-46 Supp 2-4.

The purpose of the Notice of Disclaimer is to indicate the source for the information contained in this exhibit.

ELECTRICAL SUSPECT MATERIALS LIST

<u>Type of Equipment</u>	<u>Manufacturer</u>	<u>Part No.</u>	<u>Information Source</u>
Circuit Breakers	GE	THEF 136050	NRC 88-46 Supp 3 06/08/89

SUPPLIER: Bob Ferguson's
Industrial Control & Supply
Whittier, CA / Lake Forest, CA

Lakeland Engineering-
Equipment Company
Minneapolis, MN

<u>Type of Equipment</u>	<u>Manufacturer</u>	<u>Part No.</u>	<u>Information Source</u>
Shunt Trip Coil	Westinghouse	2609D39624	NRC 88-46 Supp 4 09/11/89
Frames	"	LA2600F	"
	"	LA3600F	"
	"	MA2800F	"

<u>Type of Equipment</u>	<u>Manufacturer</u>	<u>Part No.</u>	<u>Information Source</u>
Trip Units	Westinghouse	HLA 21250TM	NRC 88-46 Supp 4 09/11/89
	"	HLA 2400TM	
	"	HLA 3600T	
	"	HLB 3200T	
	"	HMA 3600T	
	"	HMA 3700T	
	"	HKA 3225T	
	"	HNB 2700T	

SUPPLIER: Molded Case Circuit Breakers Co.
Temple City, CA

ELECTRICAL SUSPECT MATERIALS LIST

<u>TYPE OF EQUIPMENT</u>	<u>MANUFACTURER</u>	<u>PART NUMBER</u>	<u>SUPPLIER</u>
Circuit Breaker	GE	AK2A25	ROSEN
Circuit Breaker	SD	KA 36200	CAL BKR
Circuit Breaker	ITE	QJ2B200	CAL BKR
Circuit Breaker	GE	TEC 360S0	GEN BKR
Circuit Breaker	GE	THED 136100WL	GEN BKR
Circuit Breaker	GE	THED 136050WL	GEN BKR
Circuit Breaker with Shunt Trip	GE	THED 136045WL	GEN BKR
Circuit Breaker	GE	THFK 236070WL	CAL BKR
Circuit Breaker	ITE	EF 3B070	ATS
Circuit Breaker	W	EH 2020	HLC Elec
Circuit Breaker	W	FA 3035	HLC Elec
Circuit Breaker	W	EH 2050	HLC Elec
Circuit Breaker	W	EH 2070	GEN BKR
Circuit Breaker	W	EH 2070	HLC Elec
Circuit Breaker	W	EH 2050	HLC Elec
Circuit Breaker	W	Unknown	MCCB
Circuit Breaker	W	FA 2100	HCL Elec
Circuit Breaker	W	FA 2050	HLC Elec
Circuit Breaker	CH	10177H13	AAKER*
Heaters	CH	10177H21	AAKER
Heaters	CH	10177H32	AAKER
Heaters	CH	10177H1036	N/A
Heaters	CH	10177H1049	N/A
Circuit Breaker	FED Pacific	2P125	MIDWEST
Starters	W	A200MICAC	HLC Elec

ELECTRICAL SUSPECT MATERIALS LIST

<u>TYPE OF EQUIPMENT</u>	<u>MANUFACTURER</u>	<u>PART NUMBER</u>	<u>SUPPLIER</u>
Circuit Breaker	W	HFB3050	HLC Elec
Circuit Breaker	GE	TE122070	AAKER
Circuit Breaker	ITE	EH 313015	GEN BKR
Circuit Breaker	W	JA 2225	MCCB
Circuit Breaker	ITE	JL3B070	MCCB
Starters	W	626B187G17 626B187G13	ROMAC*
Circuit Breaker	ITE	JL3B150	GEN BKR
Circuit Breaker	ITE	E43B015	GEN BKR
Circuit Breaker	GE THED	136150WL	CAL BKR
Circuit Breaker	GE	THED 136150	MCCB
Circuit Breaker	GE THED	124015WL	CAL BKR
Circuit Breaker	GE	TF136090	VOYTEN*
Circuit Breaker	Unknown	50DHP250	VOYTEN
Circuit Breaker	GE	AK-3A-25	NSSS*
Circuit Breaker	W	JL3-B125 JL3-8070 JL3-B150 JL3-B200 JL3-B090 JL3-B100	NSSS
Circuit Breaker	W	HFA,HFB&FA	SPECTRUM TECH
Motor	Sieman Allis	INP 143T	ROSEN*
Motor	Sieman Allis	10 HP 215T	ROSEN
Transformer	Jefferson	75KVA XFMR	ROSEN
Gauge Glasses	Siemen Allis	PN 00-737-637-118	ROSEN
Circuit Breaker	W	HLM3800T	MCCB
Circuit Breaker	ITE	1193 60 amp	PANELBD*

ELECTRICAL SUSPECT MATERIALS LIST

<u>TYPE OF EQUIPMENT</u>	<u>MANUFACTURER</u>	<u>PART NUMBER</u>	<u>SUPPLIER</u>
Circuit Breaker	W	F3100N	PANELBD
Circuit Breaker	ITE	EF2-B030	ROSEN
Circuit Breaker	W	MA3500	ROSEN
Circuit Breaker	W	EH2015	LUCKOW*
Circuit Breaker	W	EH2015	LUCKOW
Circuit Breaker	Superior 246U-3	N/A	ROSEN
Contact Block	ITE	N/A	ROSEN
Circuit Breaker	ITE	EF2-B030	ROSEN
Circuit Breaker	GE	TF361050WL	ROSEN
Circuit Breaker	W	LA3200 WL	MCCB
Circuit Breaker	W	HLA3200T	MCCB
Shunt Trip	W	2602D58U9	MCCB
Circuit Breaker	W	HLB3200T	MCCB
Shunt Trip	W	2602156G19	MCCB
Circuit Breaker	GE	TED 113020	MCCB
Aux Contact	W	EHB2100	N/A
Circuit Breaker	W	EHB2100	MCCB
Aux Contact	W	N/A	N/A
Circuit Breaker	W	HL3800T	MCCB
Circuit Breaker	GE	TED 1360 OWL	MCCB
Circuit Breaker	SD	999330	MCCB

ABBREVIATIONS EXPLAINED:

- AC BKR - AC Circuit Breaker - Electrical Supply
- ATS - ATS Circuit Breakers, Inc.
- CAL BKR - California Breakers, Inc.
- ECD - Electro Components Distributors
- GEN BKR - General Circuit Breakers and Electrical Supply, Inc.
- GEN MAG - General Magnetics/Electric Wholesale
- HLC - HLC Electric Supply, Co.
- MCCBS - Molded Case Circuit Breakers Co.

* = Name not defined

Notice of Disclaimer

The information contained in this Exhibit was taken from Nuclear Regulatory Commission Bulletins 88-05 Supp 2, 88-48 and 88-97.

The purpose of the Notice of Disclaimer is to indicate the source for the information contained in this exhibit.

RESULTS OF PNL REVIEW OF NRC BULLETINS CONCERNING PIPING

Three NRC Bulletins were reviewed to identify items/suppliers that may have provided bogus piping components/valves/internal parts fraudulently to Pacific Northwest Laboratories.

<u>Type of Equipment</u>	<u>Manufacturer</u>	<u>Information Source</u>
ASME & ASTM	Piping Supply, Inc.	NRC 88-05 Supp. 02: NRC 88-05 and supplement 01 specified testing and reporting requirements for fittings and flanges supplied by Piping Supply, Inc. NUREG 1402 and NRC 88-05 Supplement 02 suspended those activities related to fittings and flanges provided by Piping Supply, Inc. Forms other than flanges of fittings supplied by Piping Supply, Inc., are to have the location noted and their use in safety related applications evaluated.

<u>Type of Equipment</u>	<u>Manufacturer</u>	<u>Information Source</u>
Different types, brands, and sizes of valves	CMA International (See attached Supplier List for additional names and locations.)	NRC-88-48

<u>Type of Equipment</u>	<u>Manufacturer</u>	<u>Information Source</u>
Internal Valve Parts	Masoneilan-Dresser Industries	NRC-88-97

LIST OF POSSIBLE CUSTOMERS OF CMA THROUGH WHOM LICENSEES MAY HAVE PURCHASED VALVES SUPPLIED BY CMA INTERNATIONAL. THE INCLUSION OF A COMPANY ON THE LIST DOES NOT MEAN THAT THE COMPANY KNOWINGLY SUPPLIED COUNTERFEIT OR FRAUDULENT PRODUCTS.

PURCHASER/SUPPLIERADDRESS

AJ Zinda	Portland, Oregon
A I C I	Tualatin, Oregon
Action Group	Alburg, Vermont
W F Amane	Cerritos, California
American Forest Products	Martell, California
Ameron Pipe Products	Portland, Oregon
Am Fac Supply Co.	Pascaquola, Mississippi
ARA Explorations, Inc.	San Francisco, California
Advanced Fluid Controls	Dickinson, Maryland
Arby Jay Valve Co.	St. Louis, Missouri
A & B Stainless	Califon, New Jersey
Barbee Valve, Inc.	San Diego, California
Burgsoe Metal Corp.	St. Helens, Oregon
Basic Controls & Valves	Portland, Oregon
Crown Industrial Supply	Vancouver, Washington
C & A Supply	Houston, Texas
C G M Valve Co.	Houston, Texas
Can West Valve Limited	Misku, Alberta, Canada
City of Portland	Portland, Oregon
Clover Supply, Inc.	Houston, Texas
U.S. Coast Guard ISF	Seattle, Washington
Columbia Marine Construction	Vancouver, Washington
Confederated Tribes	Warm Springs, Oregon
Consolidated Supply	Portland, Oregon
Consolidated Pipe/Supply	Decatur, Alabama
Crowley Maritime Corp.	Seattle, Washington
Crown Zellerbach	Camas, Washington
Coffeyville Valve Co.	Coffeyville, Kansas
Combined Energy Equip., Inc.	Martinsville, New Jersey
D & B Valve & Fitting Co.	Provo, Utah
Dante Valve Co.	Bellflower, California
J A Davies Co.	Houston, Texas
Department of the Army	Portland, Oregon
Donaldson, Pynch & Hume	Burnaby, British Columbia, Canada
Downey Valve Co.	Long Beach, California
Dummco Corp.	Paramount, California
Eder Farms	<i>No address provided</i>
Empire Machinery & Supply	Norfolk, Virginia
Energy Valve	Houston, Texas
Familian Northwest	Portland, Oregon
Force & Motion Industries	Portland, Oregon
Fred McCoy & Company	Billings, Montana
G & S Valve, Inc.	Shreveport, Louisiana
Gat X Terminals Corp.	Vancouver, Washington
General Construction Co.	Seattle, Washington
Global Supply Co.	Hallandale, Florida
Great Western Malting Co.	Vancouver, Washington
Grinnel Corp.	Portland, Oregon
Hahn Supply	Lewiston, Idaho

PURCHASER/SUPPLIER

ADDRESS

Hammond Valve Corp.	Vancouver, Washington
Harbor Dil	Portland, Oregon
J M Harder Mechanical	Portland, Oregon
Hawaii Pipe & Supply	Honolulu, Hawaii
Houston Valve (J J Valve)	Lynwood, California
Industrial Valve of Oregon	Portland, Oregon
Imperial Valve	Port Moody, British Columbia, Canada
Industrial Commodities	Tulsa, Oklahoma
Industrial Essentials, Inc.	Birmingham, Michigan
Industrial Valve Service	Mobile, Alabama
Industrial Valve/Fitting	Tacoma, Washington
J & L Petroleum	Portland, Oregon
Jackson-Markus Supply Co.	Los Angeles, California
J & J Valve	Nowata, Oklahoma
Keenan Pipe & Supply	Eugene, Oregon
Kiewit	Portland, Oregon
Liberty Equipment & Supply Co.	Vancouver, Washington
Lowe Parker Corp.	Seattle, Washington
M & N Pipe & Supply Co.	Los Angeles, California
Mar Industrial Sales, Inc.	Portland, Oregon
Marine Piping & Supply	Commerce, California
Marine and Valve Supply	Santa Fe Spring, California
Material Distributors	Lewiston, Idaho
Material Sales & Distribution	Lake Oswego, Oregon
Meier & Grank	Portland, Oregon
McCullough Steel, Inc.	Tupelo, Mississippi
Metro East Industrial Supply	Granite City, Illinois
M-CO Northwest	Vancouver, Washington
Morton Supply, Inc.	Yakima, Washington
Mid-West Valve & Fitting	Detroit, Michigan
Madison Supply Co., Inc.	Los Angeles, California
M & S Valve & Fitting Co.	Chicago, Illinois
North American Valve Co.	Vancouver, Washington
N W Pipeline	Battleground, Washington
Nielson Valve & Supply	Murray, Utah
Northwest Controls	Seattle, Washington
NW Marine Iron Works	Portland, Oregon
Northwest Pipe	Billings, Montana
Newmans	Milwaukee, Oregon
Naval Air Station/Adak Ala Base	Pearl Harbor, Hawaii
Oregon Steel	Portland, Oregon
Parks Industrial Valve, Inc.	Alpine, Alabama
Pacific Pipeline Products	San Rafael, California
Paramount Supply	Portland, Oregon
Park Rose Water District	Portland, Oregon
Penwalt Corp.	Portland, Oregon
Precision Cast Parts	<i>No address provided</i>

PNL ADMINISTRATIVE PROCEDURE
9513553.2554

PROCEDURE NO.: PAP-70-404

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 6

TITLE: PAP-70-404, OBTAINING SERVICES

PURPOSE

Provide uniform methods for obtaining services to ensure that the services will satisfy the technical and quality requirements of the requestor.

APPLICABILITY

This procedure applies when obtaining services from within PNL or from one of the Hanford Contractors.

This procedure does not apply when the person(s) or organization(s) providing the service is governed by the requestor's Quality Assurance (QA) Plan.

The methods for obtaining services from non-Hanford subcontractors are described in PAP-70-401, Purchase Requisitions.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Scientist/Engineer (or designee)
- Lead Procurement Quality Engineer (Lead PQE)
- Procurement Quality Engineer (PQE)
- Quality Programs (QP) Representative
- Recipient (person or organization performing the service).

DEFINITIONS

Work authorizing document - the primary form used to obtain a given service. Refer to the list of work authorizing documents shown in EXHIBIT 1, MA-70 Service Requirements.

GENERAL

This procedure utilizes established methods for obtaining services rather than requiring the generation of additional documents. In addition, referencing QA requirements and obtaining a QP Representative concurrence are not required for financial documents such as work packages. QA requirements and reviews are to be recorded on the working level document(s) whenever possible.

When obtaining services from a Hanford Contractor the PNL impact level or the safety class of systems, structures, and components (SSCs) must be specified in the work authorizing documents, and appropriate requirements must be specified. It is insufficient to specify the impact level or safety class as the indicator of QA requirements.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


RL Shaub

6/17/94


JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

Existing work authorizing documents may be utilized until they are revised; at that time, they shall be revised to comply with the requirements of this procedure.

IMPLEMENTATION

1.0 General Procedures (always apply)

- 1.1 The Cognizant Scientist/Engineer shall determine the impact level ~~or the SCC safety class~~ of the service to be obtained.
 - 1.2 The Cognizant Scientist/Engineer shall specify the:
 - impact level ~~or safety class~~ in the work authorizing document for internal PNL work
 - impact level ~~or safety class~~ and specific QA requirements in the work authorizing document for services to be obtained from a Hanford Contractor
 - independent inspection requirements when PAP-70-1001, Independent Inspection, requires such inspections.
 - 1.3 The Cognizant Scientist/Engineer shall obtain services in accordance with the requirements specified in EXHIBIT 1, MA-70 Service Requirements. This Exhibit identifies the primary work authorizing documents and the minimum approvals for the type of service to be obtained.
 - 1.4 The Cognizant Scientist/Engineer shall select the person or organization to provide the service based on the supplier's capability to perform the work.
 - 1.5 QP Representative review and approval of financial documents (e.g., work orders, supplemental work orders, and work packages) is not required.
 - 1.6 Work authorizing documents may be issued by a cognizant manager or the cognizant QP manager to standardize the requirements passed on to organizations providing services to more than one organization (e.g., WHC Standards Lab).
 - 1.7 Work authorizing documents, such as Statements of Work (SOWs), may be issued when PNL has technical cognizance over another Hanford Contractor's work but does not control funding.
 - 1.8 EXHIBIT 1, MA-70 Service Requirements, identifies the work authorizing document(s) used to obtain each type of service. The Cognizant Scientist/Engineer uses attachments if necessary to describe the requested service and quality requirements. These attachments may be drawings, memos, worksheets, etc., and shall be referenced on the work authorizing document.
 - 1.9 When reviewing work authorizing documents (see EXHIBIT 1), the QP Representative shall evaluate the adequacy of QA requirements and determines the need for surveillance, preaward survey, or other verification activities prior to and/or during the performance of the work. This determination is made considering:
 - the impact level ~~or safety class of SSCs~~ (consequence of error or failure of the service to be provided)
 - client requirements
 - the quantity, extent, and type of service to be provided
-

- performance history of the service organization (consideration should be given to existence of an activity QA Plan and results of surveillances or audits)
- whether independent inspections need to be performed.

If a preaward survey or surveillance is performed before the service begins and deficiencies are identified, the deficiencies will be resolved or commitments obtained to resolve the deficiencies before the work starts.

Preaward surveys, source surveillances, and source verification activities are coordinated through the Lead PQE for suppliers and Hanford Contractors.

- 1.10 The Cognizant Scientist/Engineer shall enter the work authorizing document in the Service Log, EXHIBIT 2. When a pre-existing SOW is referenced by a new work request/order, the service log shall provide a cross reference between the existing SOW and the new work request/order.
- 1.11 The Cognizant Scientist/Engineer shall ensure that changes to work authorizing documents receive the same level of approval as the original documents unless the change is:
 - correction of typographical or grammatical errors
 - clarification of existing procedural requirements
 - correction of obviously incorrect information.
- 1.12 Work authorizing documents and documents associated with a completed service are QA records. The Cognizant Scientist/Engineer shall ensure that a copy of all such documentation is maintained.
- 1.13 The Cognizant Scientist/Engineer shall require a preaward survey of Hanford Contractors when:
 - appropriate technical and QA capabilities are needed to ensure the integrity of the items or services to be provided such as analytical/calibration services
 - where failure of the item is likely to jeopardize data validity or safety conditions, disrupt the continuity of operations, or cause significant cost impact
 - special processes (i.e., nondestructive examination, plating, welding, etc.) are required
 - an item is to be obtained to a drawing or specification for which acceptability cannot be determined by inspecting the item upon receipt or at the source.

2.0 PNL Craft Services Fabrication

- 2.1 Fabrication-related activities requested from Crafts Services are obtained in accordance with EXHIBIT 1 and PNL-MA-90, Design: Preparation, Control, and Implementation.
 - 2.1.1 A Craft Services' Quality Control Requirements (QCR) form (EXHIBIT 5) is used to identify and define requirements for welding, NDE, inspections, material control, etc. A QCR form shall be attached to a work request issued to Craft Services when any of the items or services identified on the form are to be required.
 - 2.1.2 The responsible scientist/engineer requesting work from Craft Services shall check the block on the work request form indicating whether or not a QCR form is required. When the QCR form is required by the scientist/engineer (as indicated on the work request form) the Quality Programs (QP) representative must review the QCR form.
- 2.2 After approval, the (QP) Representative shall forward a copy of the QCR to the Lead PQE for notification/retention purposes.

PNL ADMINISTRATIVE PROCEDURE

2.3 The record copy of the QCR shall be maintained in the project/activity/facility files.

3.0 PNL Crafts Services Calibration

Calibration services are obtained from Crafts Services in accordance with EXHIBIT 1, MA-70 Service Requirements, using a work request.

NOTE: A standardized statement of work (CSD-85-1) has been approved by PNL Management and applies to all calibration services performed by Craft Services. It is not necessary to reference the SOW on the work request or work package or to obtain a QP Representative's review.

4.0 PNL Analytical Services

4.1 PNL chemical or physical analytical services are obtained in accordance with EXHIBIT 1, MA-70 Service Requirements, using an Analytical Request Form (ARF), EXHIBIT 3.

4.1.1 An ARF is used for each analysis requested.

4.1.2 Each ARF is uniquely numbered. For example, the work package number may be used and the third ARF used on work package M16843 could be numbered M16843-3.

4.2 A QP Representative (representing the PNL organization initiating the ARF) shall review and approve (see 1.9) the first ARF issued by a Project to a service organization. Subsequent ARFs issued by the Project to the same service organization for the same service do not require review by a QP Representative.

4.3 Revised ARFs that change the impact level or safety class or type of analysis originally requested may be issued if reviewed, signed, and dated by a QP Representative and the revised ARF is issued to the same service organization.

4.4 The ARF number, sample number, or client identifier shall be placed on the final document (Analytical Report) for data traceability.

5.0 PNL Design and Drafting Services

Design and Drafting Services are obtained using an Engineering Design Plan (EDP) in accordance with PNL-MA-90, Design: Preparation, Control, and Implementation. Approval and preparation requirements are specified in PNL-MA-90.

6.0 PNL Facilities Engineering Services

The Cognizant Scientist/Engineer contacts the Cognizant Building Manager for all services to be requested from Facilities Engineering.

6.1 Services are typically obtained using an Engineering Request approved by the Building Manager and the Cognizant Facilities Engineering Representative.

6.2 Services requested from Facilities Engineering that involve detailed work instructions may be acquired using an SOW in accordance with Section 10.0 of this procedure or a Letter of Instruction in accordance with PNL-MA-90, Design: Preparation, Control, and Implementation.

7.0 Analytical Services From Hanford Contractors

Chemical or physical analytical services requested from Hanford Contractors are obtained using an SOW in accordance with EXHIBIT 1 and Section 10.0.

- 7.1 An ARF (EXHIBIT 3) is used to accompany each transmittal of samples and, if necessary, to specify specific analysis parameters to supplement the SOW.
- 7.2 A QP Representative reviews and approves the SOW. Because a QP Representative approves the SOW, a QP Representative's review of each ARF is not required.
- 7.3 ARFs must not change the requirements of the SOW.

8.0 WHC Standards Lab Calibration Services

Calibration services from the WHC Standards Lab are obtained in accordance with EXHIBIT 1, MA-70 Service Requirements, using a work order. The Cognizant Scientist/Engineer shall ensure the impact level or safety class is recorded on the work order.

NOTE: A standardized statement of work (WHC-85-1) has been approved by PNL and WHC management for all calibration services performed by WHC for PNL. It is not necessary to reference the SOW on the work order or to obtain a QP Representative's review of the work order.

9.0 KEH Engineering or Construction Services

Services requested from Kaiser Engineers Hanford (KEH) (the onsite Engineer/Constructor Contractor) are obtained in accordance with PNL-MA-90, Design: Preparation, Control, and Implementation, using a Letter of Instruction or a Statement of Work. Minimum approvals and other requirements for obtaining services from KEH are defined in PNL-MA-90.

10.0 Preparing and Approving Statements of Work

10.1 For other types of services not addressed in the previous paragraphs, an SOW is required. The Cognizant Scientist/Engineer shall prepare the SOW.

10.1.1 EXHIBIT 4, Statement of Work, shows a recommended format of the SOW. Content may vary depending upon the scope of work (also see PNL-MA-90, Design: Preparation, Control, and Implementation, EXHIBIT 12.5).

10.1.2 SOWs shall have a unique number for identification and may use the same number as the corresponding work order or work package. Revision numbers of the SOW must be identified.

10.1.3 SOWs prepared for Hanford Contractors specify QA requirements consistent with the requested services. When appropriate, basic requirements and supplements of ASME NQA-1 are specified. The SOW may include other provisions such as:

- requirements for reviewing and approving technical procedures
- right-of-access for PNL representatives to surveil or audit to verify compliance to the SOW
- record requirements
- other requirements imposed upon the requestor by PNL's client.

10.2 The Cognizant Scientist/Engineer shall ensure that the SOW is reviewed by the QP Representative and is approved before work begins.

11.0 Issuing Work Authorizing Documents (always apply)

PNL ADMINISTRATIVE PROCEDURE

11.1 When the Work Authorizing Document is approved, the Cognizant Scientist/Engineer shall issue the document to the recipient and maintain a record copy.

11.2 The Cognizant Scientist/Engineer shall distribute a copy of all Work Authorizing Documents that require QP Representative verification action to the QP Representative. A copy of all SOWs shall be distributed to the QP Representative.

12.0 Requirements for Work Performance (always apply)

12.1 The Recipient shall perform the requested work in accordance with the technical and QA requirements of the work authorizing document and the designated impact level or safety class.

12.2 The Recipient shall not perform unauthorized work or subcontract the requested work without prior documented approval by the cognizant engineer and a QP Representative. This approval may be documented, for example, in the work authorizing documents or in a memo.

13.0 Verifying and Closing Work (always apply)

13.1 The PNL Recipient (e.g., Craft Services) shall notify the Cognizant PNL PQE when PNL inspection by Process Quality is required.

13.2 A PQE shall perform or obtain inspections or other verifications when specified in the work authorizing documents.

13.3 The PQE shall provide documented evidence detailing the result of the inspections or verifications to the cognizant scientist/engineer.

13.4 After the requested work has been completed and the required deliverable has been received, the Cognizant Scientist/Engineer shall:

- review the item or documentation for compliance with requirements
- obtain corrective action from the person(s) or organization(s) performing the service for any discrepancies detected

NOTE: A nonconformance report per PAP-70-1501, Nonconformance Reports, or a deficiency report per PAP-70-1502, Deficiency Reports, may be required.

- ensure that item or documentation acceptance is documented by dating and initially the service log entry, calibration report, analytical report, or other appropriate document
- process all documentation associated with the requested service as QA records.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- work authorizing documents
 - documents associated with a completed service.
-

MA-70 SERVICE REQUIREMENTS

TYPE OF SERVICE	WORK AUTH DOC.	SCI/ENGR	APPROVALS QP REP.	RECIPIENT	REFERENCED SECTION
PNL Crafts Fabrication	WR*/QCR**	X	X		2.0
PNL Crafts Calibration	WR	X			3.0
PNL Crafts Other (a)	SOW/WR	X	X	X	10.0 other
PNL Analytical	ARF	X	(1st One Only) X		4.0
PNL Design & Drafting	EDP		see PNL-MA-90		5.0
PNL Facilities Engineering	ER	X	see Section 6.0		6.0
PNL Other (b)	SOW	X	X	X	10.0
External Analytical	SOW/ARF	X	(SOW only) X	X	7.0
WHC Calibration	WO	X			8.0
Kaiser	LOI/SOW form	X	X		9.0
External (c)	SOW	X	X	X	10.0 other

(a) All other services provided by Crafts not covered in sections 2.0 or 3.0.

(b) All other PNL services not covered in sections 4.0 through 6.0.

(c) All other services from Hanford Contractors not covered in sections 7.0 through 9.0.

KEY

QCR: Crafts Services QC Requirements Form
 WR: Crafts Services Work Request
 SOW: Statement of Work
 ARF: Analytical Request Form
 EDP: Engineering Design Plan
 ER: PNL Facilities Engineering Request
 WO: Work Order or Supplemental Work Order
 LOI: Letter of Instruction per PNL-MA-90
 Sci/Engr: Cognizant Scientist or Engineer requesting the work
 Recipient: Person or Organization to perform the work

* The responsible Scientist/Engineer must check either "Yes" or "No" in the QCR block on the Work Request

** Only when required on the Work Request form

**THIS PAGE INTENTIONALLY
LEFT BLANK**

**THIS PAGE INTENTIONALLY
LEFT BLANK**

ANALYTICAL REQUEST FORM

To:	Date:	WP/WO Number:
Requested By:	Phone No.:	MSIN:
Requestor's Signature		
Analysis Requested:		
Identification Numbers:		
Material Description:		
Special Storage or Handling Requirements: <input type="checkbox"/> None <input type="checkbox"/> Other:		
Disposal of Samples: <input type="checkbox"/> Discard <input type="checkbox"/> Return <input type="checkbox"/> Other:		
Requested Reports/Additional Instructions:		
QA Requirements: Impact Level: <input type="checkbox"/> I, <input type="checkbox"/> II, <input type="checkbox"/> Safety Class, <input type="checkbox"/> SOW Number, <input type="checkbox"/> Other:		
Results must be signed and dated by the analyst and reviewer, identifying the measuring and test equipment and the procedure used (including revision).		
PNL QP Representative approval required only for the first WP/WO in a series for internal work. Approval not required for external work.		
By: _____ PNL QP Representative Date		
To the best of my knowledge, this work was accomplished in accordance with the requirements of this Analytical Request Form: *		
By: _____ Responsible Analyst or Group Manager Date		
* This Certification not required if work done by PNL.		
(Return this form or a copy to the requestor).		
The report/data furnished has been reviewed and to the best of my knowledge complies with the above request.		
By: _____ Requestor Date		

**THIS PAGE INTENTIONALLY
LEFT BLANK**

1. Define what is to be reported and/or provided and by what date.
2. State that reported results are to be in writing and provided to the individual requesting the work.
3. State that the reported results are to reference the SOW number and are to include the dated signature of the person responsible for the work.

D. Records

1. For work performed by PNL organizations, identify what supporting records are to be submitted to the person requesting the work. Alternately, the organization performing the work may maintain the supporting records in accordance with PAP-70-1701. In either case, specify what records will be maintained and by whom. Examples of supporting records may include:
 - indoctrination and training records
 - calibration records
 - technical procedures
 - raw data including instrument printout
 - other documents required by the applicable PNL-MA-70 Administrative Procedures (unless included as part of the reported results)
 - nonconformance or deficiency reports.
2. For SOWs for Hanford contractors, identify the records and the retention requirements that apply to the person or organization providing the service. As an alternate, specify the records to be transferred to the requestor at the completion of the work.

PNL CRAFT SERVICES	QUALITY CONTROL REQUIREMENTS	WR#:
		Date:
Fabrication Title:	Drawing/Specification #:	IL/SC:
<p>1. Fabrication/Inspection Documentation</p> <p>a. <input type="checkbox"/> Fabrication/Inspection Traveler</p> <p>b. <input type="checkbox"/> Inspection Reports</p> <p>c. <input type="checkbox"/> Print and Specification Control</p> <p>d. <input type="checkbox"/> As-Built Red Line Drawings/Sketches</p> <p>e. <input type="checkbox"/> Other (Specify) _____</p>		
<p>2. Special Process Qualifications</p> <p>a. <input type="checkbox"/> Welder and Weld Procedure Qualifications per _____</p> <p>b. <input type="checkbox"/> NDE Examiner and Procedure Qualifications per _____</p> <p>c. <input type="checkbox"/> Other (Specify) _____</p>		
<p>3. Material Documentation</p> <p>a. <input type="checkbox"/> Actual Chemical/Physical Properties Reports (Specify) _____</p> <p>b. <input type="checkbox"/> Material Certification (Specify) _____</p> <p>c. <input type="checkbox"/> Material Supplied by Customer (Specify) _____</p> <p>d. <input type="checkbox"/> Other (Specify) _____</p>		
<p>4. Material Traceability</p> <p>a. <input type="checkbox"/> Material Identification Control Documentation</p> <p>b. <input type="checkbox"/> Individual Heat Number Marking of Parts</p> <p>c. <input type="checkbox"/> Other Methods (Specify) _____</p>		
<p>5. Handling, Storage, and Shipping Control</p> <p>a. <input type="checkbox"/> As specified in Statement of Work/Specifications</p> <p>b. <input type="checkbox"/> As Specified in Part 7, Additional Instructions</p>		
<p>6. Independent Inspection</p> <p>a. <input type="checkbox"/> As specified on Drawing/Statement of Work</p> <p>b. <input type="checkbox"/> Visual Inspection per _____</p> <p>c. <input type="checkbox"/> NDE (Specify) _____</p> <p>d. <input type="checkbox"/> Dimensional Inspection (Specify) _____</p> <p>e. <input type="checkbox"/> Witness (Specify) _____</p> <p>f. <input type="checkbox"/> Other (Specify) _____</p>		
<p>7. Additional Instructions:</p> 		
<p>Approvals:</p> 		
_____	_____	_____
Cognizant Manager/Engineer	Date	Quality Engineer
		Date

OCR INSTRUCTIONS

1. FABRICATION/INSPECTION DOCUMENTATION: QA record copies to be included by Craft Services in the completed Work Request/Documentation Package for transfer to the cognizant manager/engineer for retention or submittal to the client.

- 1a. Fabrication/Inspection Traveler - A step by step integrated fabrication/ inspection procedure which provides documented control of each important action performed during the assembly of an item. A traveler is prepared in accordance with GP-46, Preparation and Approval of Fabrication/Inspection Travelers.
- 1b. Inspection Reports - A report on the results of the inspections performed. Identify inspections in Part 6.
- 1c. Print and Specification Control - A controlled document transmittal system which ensures that the correct version of a drawing/specification is used during fabrication.
- 1d. As-Built Red Line Drawings/Sketches - Drawings/sketches which show the final condition actually achieved of a fabricated item.

2. SPECIAL PROCESS QUALIFICATIONS:

If special processes are indicated, check item 1a. and/or 1b. above. Include a requirement for identifying special process personnel and procedures. This establishes traceability to the personnel and procedure qualification records associated with the job

- 2a. Welder and Weld Procedure Qualifications - PNL Craft Services welding personnel and procedures are qualified to ASME Section IX.
- 2b. NDE Examiner and Procedure Qualifications - Specify the desired code for personnel (e.g., SNT-TC-1A) and procedure (e.g., ASME Section V) qualifications

3. MATERIAL DOCUMENTATION: (QA record copies to be included by Craft Services in Completed Work Request/Documentation Package and given to the cognizant manager/engineer for retention or submittal to client)

If material documentation is specified, check item 1b. above

- 3a. Actual Chemical/Physical Properties Reports -Specify the material and the applicable standard or specification
- 3b. Material Certification - Specify the material and the applicable standard or specification.
- 3c. Material Supplied by Customer - Specify which materials will be supplied to Craft Services.

4. MATERIAL TRACEABILITY: (QA record copies to be included by Craft Services in the completed Work Request/Documentation Package for transfer to the cognizant manager/engineer for retention or submittal to client.)

- 4a. Material Identification Control Documentation - In addition to the individual marking of parts (see 4b), a record of each cutoff, subdivision, etc., will be maintained.

4b. Individual Heat Number Marking of Parts - Heat number will be transferred to all cutoffs, subdivisions, etc.

5. HANDLING, STORAGE, AND SHIPPING CONTROL:

If special handling, storage, or shipping controls apply, indicate where the controls are documented. i.e., either in the:

- 5a. Scope of work, or
- 5b. under Item 7.

6. INDEPENDENT INSPECTION: (Inspection/witness reports are provided to Craft Services by Process Quality for inclusion in completed Work Request/Documentation Package for transfer to the cognizant manager/engineer for retention or submittal to client.)

If independent inspection is specified, also check item 1b. above.

- 6a. As specified on Drawing/Statement of Work - Check if applicable.
- 6b. Visual Inspection- Specify acceptance criteria. Visual weld inspection will be performed by a PNL Procurement Quality Engineer (PQE).
- 6c. NDE - Specify type (e.g., mag particle) and the acceptance criteria to be used. NDE will be performed by a PNL PQE.
- 6d. Dimensional Inspection - Specify dimensions and tolerances or reference drawing. Dimensional Inspection will be performed by a PNL PQE.
- 6e. Witness - Specify test to be witnessed. Test will be witnessed by a PNL PQE.

7. ADDITIONAL INSTRUCTIONS:

Specify any additional instructions or reference the Statement of Work or specification.

NOTE: QA Record copies of personnel and procedure qualifications are retained by qualifying organizations, ordinarily Craft Services for welding and Process Quality for NDE and independent inspection. Information copies will be provided to the cognizant manager/engineer upon request.

PNL ADMINISTRATIVE PROCEDURE
9513553.2562

TITLE: PAP-70-501, PREPARATION AND APPROVAL OF ADMINISTRATIVE PROCEDURES

PURPOSE

Provide a uniform method for the preparation, review, and approval (and to a limited extent, the content) of PNL-MA-70 QA program Administrative Procedures. Formal approved procedures are needed to prescribe the correct and uniform performance of quality-related administrative tasks.

APPLICABILITY

This procedure applies to the preparation of new, or revisions to, Administrative Procedures. Administrative Procedures include PNL Administrative Procedures (PAPs), Contract Administrative Procedures (CAPs), and Software Control Procedures (SCPs).

Instructions for preparing, reviewing, and approving Technical Procedures are included in PAP-70-1101, Test Planning, Performance, and Evaluation.

RESPONSIBILITIES

Staff responsibilities for implementing this procedure are:

- Approval Authority
- Author (the procedure author)
- Cognizant Line Manager
- Documentation Systems Department (DS) Manager
- DS Engineer.

IMPLEMENTATION

1.0 Preparation of Administrative Procedures

1.1 The Approval Authority designated below, or the Cognizant Line Manager, shall select procedure authors who are technically competent in the proceduralized area.

ADMINISTRATIVE PROCEDURES	APPROVAL AUTHORITY
PNL Administrative (PAPs)	Director, Quality Programs
Contracts Administrative (CAPs)	Director, Legal and Contracts
Software Control (SCPs)	Director, Quality Programs

1.2 The Author assigned to develop or revise an Administrative Procedure shall:

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

VC Thompson
VC Thompson 6/17/94

JE McGarran
JE McGarran, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

- follow the procedure format specified in EXHIBIT 1. Administrative Procedures contain five required sections and may include up to four additional sections to clarify the procedure's intent. Guidance on the content and the preferred order of the required and optional procedure sections is outlined in EXHIBIT 1
- verify that requirements from governing documents such as PNL-MA-70 Quality Assurance Manual, ASME NQA-1, or DOE 5700.6C (Quality Assurance) are addressed in the procedure
- consider outstanding changes for incorporation, as appropriate, such as approved and issued Interim Change Notices and unissued requests for change (PAP-70-602, Procedure and Instruction Change Control and Change Request). Unissued requests for change are maintained by the DS Procedure Coordinator.
- submit the draft procedure to the DS Engineer for initiation of the review and approval process.

2.0 Review and Approval of Administrative Procedures

2.1 The DS Manager, based on input from Center or Operations Managers, shall select PNL staff members to review new procedures or procedure revisions. Reviewers shall have access to pertinent background information on which to base their review comments.

2.2 The DS Engineer shall ensure that:

- new or revised procedures are distributed to the selected reviewers and others as directed by the Quality Programs Director
- instructions are provided with the distribution requesting that comments be documented on a Document Review Record (PAP-70-604, Independent Technical Review) provided with the procedure.

2.3 The DS Engineer shall evaluate each reviewer's comments for incorporation and provide resolution in the space provided or shall request the author to provide resolution. Reviewer concurrence is not required.

2.3.1 When a reviewer provides a "Do Not Concur" disposition, the DS Engineer or, if requested, the Author shall resolve the comment and obtain the reviewer's concurrence with the resolution.

Note: Unresolved comments are referred to the DS Manager for resolution.

2.3.2 After comment resolution, the DS Engineer or Author, as appropriate, shall sign the "Comments Resolved By" block on the Document Review Record.

2.4 The DS Engineer shall perform the following for each procedure:

2.4.1 Incorporate appropriate review comments.

2.4.2 Obtain the required signatures:

- the Author's -- indicating acceptance of the completed procedure
 - the DS Manager's -- indicating approval of the Author's qualifications and concurrence with the content of the procedure
 - the Approval Authority's -- for approval
 - concurrence -- indicating concurrence with the procedure content by a functional organization whose operations are tied closely with the procedures content. The requirement for this
-

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-501

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

concurrency shall be determined by the DS Manager or the Approval Authority on an individual procedure basis.

- 2.4.3 Determine the recommended effective date. This effective date is established by determining the estimated time required for training and the process time required by Document Control and Reproduction. These times and any further time required by the Documentation Systems Department for processing are added to the current date to obtain the effective date.
- 2.4.4 Transmit the signed and approved procedure, recommended effective date, and description of changes to Document Control for distribution in accordance with PAP-70-601, Document Control.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- Contracts Administrative Procedure (CAP)
- Document Review Record (DRR)
- PNL Administrative Procedure (PAP)
- Software Control Procedure (SCP).

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDUREPROCEDURE NO.: **PAP-70-XXX**REVISION NO.: **X**

EFFECTIVE DATE:

PAGE **1** OF **X**

TITLE: PAP-70-XXX, TITLE OF PROCEDURE

INTRODUCTION/BACKGROUND (Optional)

The "Introduction/Background" section provides the procedure user with information that is helpful, but not essential, to the special circumstances that exist.

PURPOSE (Required)

The "Purpose" section provides a concise description of why the procedure exists and the desired results of the procedure.

APPLICABILITY (Required)

The "Applicability" section provides a readily available and easily understood description of when the procedure needs to be implemented.

RESPONSIBILITIES (Required)

The "Responsibilities" section includes all staff who are assigned an action in the body of the procedure.

Example: Coordinator (appointed by the Cognizant Manager)

DEFINITIONS (Optional)

In general, the procedure should be written in terms that the user can understand without the need for a special definitions section. If terms have a special meaning in the context of the procedure, they should be defined either in the "Definitions" section or in the text.

GENERAL (Optional)

This section may be used to identify general information, alternatives to implementing the procedure, or the minimum requirements which are contained in the "Implementation" section.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-XXX

REVISION NO.: X

EFFECTIVE DATE:

PAGE 2 OF X

IMPLEMENTATION (Required)

- 1.1 The instructions in this section should be given in a logical sequence - chronological order is recommended.
- 1.2 If an action must be performed and documented, make this clear. If an action needs to be performed but does not need to be documented, also make this clear.
- 1.3 If equivalent controls are acceptable, define the minimum requirements which must be met. Make it clear if an equivalent control method must be approved, and by whom.
- 1.4 Do not assign actions to staff who are not required to follow the Administrative Procedure. For example, a statement such as "The client shall approve the documentation," should not be included in an Administrative Procedure. Instead, use a statement such as, "The Project Manager shall obtain the concurrence of the client".

REQUIRED RECORDS (Required)

List records that are created as a result of the procedure.

EXHIBITS (Optional)

Exhibits can be:

- examples of forms (and the instructions for those forms) used for/during the procedure
 - flow chart diagrams illustrating processes
 - examples of documents generated during the course of the procedure.
-

PNL ADMINISTRATIVE PROCEDURE
9513554.2565

PROCEDURE NO.: PAP-70-601

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: PAP-70-601, DOCUMENT CONTROL

PURPOSE

Provide a uniform method for the distribution of controlled procedures, instructions, and QA Manual sections. Distribution is controlled to ensure that documents in use are current.

APPLICABILITY

This procedure applies to the control and distribution of Administrative Procedures, Technical Procedures, and QA Manual sections. This procedure may be applied to the control and distribution of other documents and procedures.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Manager
- Coordinator (designated by the Cognizant Manager; or, may be Document Control).

GENERAL

Copyholders of controlled documents shall perform the actions as instructed on the Controlled Document Transmittal/Receipt, including signing, dating, and returning the transmittal/receipt to the issue point within the time specified.

IMPLEMENTATION

1.0 Planning

The Cognizant Manager shall:

- designate a Coordinator to implement the requirements of this procedure (usually the document's author), or
- request that Document Control perform the control and distribution function. Impact Level I projects are required to use Document Control.

NOTE: For the remainder of this procedure, the term "Coordinator" is interchangeable with Document Control staff, as applicable.

2.0 Distribution

CONCURRENCE

DATE

PK Schuette 6/16/94
PK Schuette, Manager, Records Management and Document Control

APPROVAL AUTHORITY

DATE

JW Smith 6/20/94
JW Smith, Director, Quality Programs

PREPARED BY

DATE

VC Thompson 6/15/94
VC Thompson

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah 6/20/94
JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

2.1 The Coordinator shall:

- develop a distribution list for new documents based on input from the Cognizant Manager
- obtain and review existing distribution lists when existing documents are revised, updating them based on input from the Cognizant Managers

NOTE: The Documentation Systems Department (DS) Manager's approval is required for all requests for PNL-MA-70.

- develop a transmittal. The Controlled Document Transmittal/Receipt, EXHIBIT 1, is the preferred format. However, an alternate format may be used provided the following information is included:
 - document number and revision
 - document title
 - transmittal number or letter number and date
 - Coordinator's or Cognizant Manager's signature
 - specific instructions concerning the document(s) being transmitted
 - disposition of obsolete documents
 - receipt acknowledgement requirement.

2.2 When a new or revised document is issued to a set of controlled procedures or to the QA Manual, the Coordinator shall prepare (or update) a Controlled Document List or a Table of Contents (see EXHIBIT 2 for examples of formats). As a minimum, the Controlled Document List or Table of Contents shall contain the following information:

- document number
- correct revision number
- changes issued
- document title
- effective date.

2.3 Prior to distribution the Coordinator shall indicate in red ink on the signature page or on the title page of:

- all documents for distribution (excluding the transmittal):

CONTROLLED DOCUMENT
COPY NO. _____

NOTE: The copy number is not required on the signature or title page of individual procedures that are included in a controlled manual that has a copy number. These procedures are only required to have CONTROLLED DOCUMENT in red ink on the signature or title page.

- unapproved Technical Procedures:

"UNAPPROVED PROCEDURE"
Identify Data Taken While
Using This Procedure

NOTE: Documents on which the above information is not in red ink shall be considered uncontrolled.

3.0 Workplace Copy

- 3.1 The Cognizant Manager shall determine when a current procedure or instruction is needed at the location where work is performed (e.g., field testing, analytical laboratory work, etc.). A current controlled copy of

PNL ADMINISTRATIVE PROCEDURE
9513553.2566

PROCEDURE NO.: PAP-70-601

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

the document or a copy of the current controlled document shall be made and "WORKPLACE COPY" stamped or written, in red ink, on the cover or first page of the copied document. The controlled document or workplace copy shall be maintained at the work place.

3.2 The Cognizant Manager shall control workplace copies. Minimum controls include:

- maintaining a list of current workplace copy numbers and locations
- replacing workplace copies when the documents are revised or become obsolete.

4.0 Status Control

4.1 The Coordinator shall distribute, in accordance with the distribution list, the document package which includes a transmittal (EXHIBIT 1), a controlled document list or a table of contents (EXHIBIT 2), and the documents being issued. If receipt acknowledgement is required and not received within 30 days, delinquency notification shall be sent to all delinquent copyholders. Delinquency notification may be submitted as follows to delinquent copyholders:

- 30 days - to the copyholder (PNL and Non-PNL)
- 45 days - to the PNL copyholder's Manager
- 60 days - to the PNL Center Manager or Director or Non-PNL copyholders.

4.2 If the Coordinator does not receive a response within 10 working days after the 60 day notice is sent, the PNL copyholder's manual or procedure shall be recalled. The Coordinator shall notify the PNL copyholder's Manager of this action. Non-PNL copyholders, who have not responded to the 60 day request, will be sent notification stating that they have been removed from the distribution list. The Coordinator will be responsible for implementation of the notice with concurrence from the Records Management and Document Control Manager and from the DS Manager for PNL-MA-70, Quality Assurance Manual.

REQUIRED RECORDS

The Controlled Document List or Table of Contents created by this procedure is a record and is retained by Document Control or the independent document distribution organization.

THIS PAGE INTENTIONALLY
LEFT BLANK

TRANSMITTAL EXAMPLE

Controlled Document Transmittal/Receipt (CDT/R)		Page ____ of ____
Distribution Authority Signature	Transmittal Date	Transmittal No.
From Document Control Pacific Northwest Laboratory ESB/3000, K3-70 P.O. Box 999 Richland, WA 99352	To	
Please follow instructions below: <input type="checkbox"/> See special instructions below. <input type="checkbox"/> Mark/destroy obsolete document(s). <input type="checkbox"/> Insert Interim Change Notice(s) in front of the affected document. <input type="checkbox"/> Insert Controlled Document List (CDL) _____; destroy CDL issue dated _____. If you have a change of address or questions please contact Document Control on 375-2509.		
Document No.	Document Title	
Special Instructions		
Receipt Acknowledgement: Please sign and date below and return this form within ten (10) working days to: DOCUMENT CONTROL – K3-70 I am verifying my receipt of the listed documents, and that I have incorporated the transmitted documents in accordance with the instructions.		
Signature _____		Date _____

**THIS PAGE INTENTIONALLY
LEFT BLANK**

**TABLE OF CONTENTS AND
CONTROLLED DOCUMENT LIST
EXAMPLES**

<u>EXAMPLE</u>		Section: T of C
Issued: 06/29/90 Supersedes: Draft, 06/15/94 PNL-MA-70		Page 1 of 1
PNL-MA-70 QUALITY ASSURANCE MANUAL		
CONTENTS	ISSUE DATE	
MESSAGE FROM THE DIRECTOR	07/28/89	
INTRODUCTION	07/28/89	
<u>1. ORGANIZATION</u>		
1.1 Organization	07/28/89	
<u>2. QUALITY ASSURANCE PROGRAM</u>		
2.1 Quality Assurance Program	06/29/90	
Appendix I, PNL-MA-70 Procedures	07/28/89	
Appendix II, QA Planning Flowchart	06/29/90	
Appendix III, Quality System Description Documents	06/29/90	
2.2 Indoctrination and Training	07/28/89	
<u>3. DESIGN CONTROL</u>		
3.1 Design Control	07/28/89	
3.2 Computer Software	07/28/89	
<u>4. PROCUREMENT DOCUMENT CONTROL</u>		
4.1 Procurement Document Control	07/28/89	
4.2 Work Package Control	07/28/89	
<u>5. INSTRUCTION, PROCEDURES, AND DRAWINGS</u>		
5.1 Instructions, Procedures, and Drawings	07/28/89	
<u>6. DOCUMENT CONTROL</u>		
6.1 Document Control	07/28/89	
<u>7. CONTROL OF PURCHASED ITEMS AND SERVICES</u>		
7.1 Control of Purchased Items and Services	07/28/89	
7.2 Control of Work Package Items and Services	07/28/89	
<u>8. IDENTIFICATION AND CONTROL OF ITEMS</u>		
8.1 Identification and Control of Items	07/28/89	

Page No. 1		<u>EXAMPLE</u>			
CONTROLLED DOCUMENT LIST					
LIST OF DOCUMENTS ISSUED					
DOCUMENT NUMBER	REV NUM	NO. OF ICNS ISSUED	TITLE	EFFECTIVE DATE	
** CAP					
CAP-70-401	0	0	PREPARATION OF RFPs AND AWARD OF PURCHASE ORDERS/SUBCONTRACTS	10/01/86	
CAP-70-701	0	0	PROPOSAL EVALUATION, SUPPLIER/SUBCONTRACTOR SELECTION AND PURCHASE ORDER/SUBCONTRACT ADMINISTRATION (POST AWARD)	10/01/86	
** PAP					
PAP-70-101	0	0	COMMUNICATION AND COMMITMENT (INTERFACE) CONTROL	10/01/86	
PAP-70-201	1	1	INDOCTRINATION AND TRAINING	09/01/89	
PAP-70-202	1	0	MANAGEMENT ASSESSMENT OF QA PROGRAM EFFECTIVENESS	09/01/89	
PAP-70-203	0	0	QUALIFICATION AND CERTIFICATION OF INSPECTION/TEST AND NDT PERSONNEL	10/01/86	
PAP-70-204	0	0	QUALIFICATION AND CERTIFICATION OF AUDIT/APPRaisal PERSONNEL	06/20/90	
PAP-70-205	1	2	QUALITY ASSURANCE PLANS	05/29/87	
PAP-70-208	2	0	IMPACT LEVELS	12/29/89	
PAP-70-301	0	0	HAND CALCULATIONS, GENERAL	10/01/86	
PAP-70-302	1	1	ASSURANCE AND CONTROL OF ENGINEERING DESIGN	10/28/87	
PAP-70-401	0	4	PREPARATION, REVIEW, AND APPROVAL OF PURCHASE REQUISITIONS	10/01/86	
PAP-70-404	1	0	OBTAINING SERVICES	02/28/90	
PAP-70-501	1	1	PREPARATION AND APPROVAL OF ADMINISTRATIVE PROCEDURES	10/07/88	
PAP-70-601	1	1	DOCUMENT CONTROL	10/07/88	

**THIS PAGE INTENTIONALLY
LEFT BLANK**

9513353.2569

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-602

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 4

TITLE: PAP-70-602, PROCEDURE AND INSTRUCTION CHANGE CONTROL AND CHANGE REQUEST

PURPOSE

Provide a method for any PNL staff member to request changes to controlled procedures or instructions; and identify the process of incorporating interim changes to controlled procedures and instructions.

APPLICABILITY

This procedure applies to changes to Administrative Procedures, Technical Procedures, and QA Manual sections. This procedure may be applied to changes to other documents and procedures.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Manager (manager responsible for the procedure or instruction)
- Coordinator (designated by the Cognizant Manager)
- PNL Staff.

IMPLEMENTATION

1.0 Planning

The Cognizant Manager shall:

- designate a Coordinator to be responsible for the processing of Document Change Requests (DCRs) and Interim Change Notices (ICNs)
- designate staff to review revisions to requirements and source reference documents, evaluate procedures and instructions for compliance, and recommend appropriate changes
- ensure that staff designated to evaluate, author, and coordinate changes to procedures and instructions are aware of the requirements for processing changes as described in this procedure and have access to pertinent background information on which to base their evaluations.

2.0 Document Change Requests (DCRs)

2.1 Staff Members who identify outdated, inaccurate procedures that may be contrary to new governing requirements shall initiate a DCR.

2.1.1 Complete a DCR form in accordance with instructions provided in EXHIBIT 1.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

VC Thompson
VC Thompson

6/17/94

JE McGarrah
JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

- 2.1.2 Submit the DCR to the appropriate Coordinator or the Cognizant Manager if a Coordinator has not been appointed.

NOTE: For Administrative Procedures, DCRs shall be submitted to the Documentation Systems Department (DS) Procedure Coordinator. For other controlled procedures, when it is not clear who the Coordinator or Cognizant Manager is, DCRs shall be submitted to the document's Author.

2.2 The Coordinator shall:

- a. assign a number to the DCR for traceability purposes
- b. retain a file copy of the DCR (the information may also be entered into a DCR log)
- c. forward the DCR to the Cognizant Manager for evaluation

2.3 The Cognizant Manager shall:

- a. determine whether the change should be incorporated

NOTE: This may include contacting the DCR originator for clarification and resolution of comments and, if necessary, soliciting other evaluations.

- b. determine whether the change should be processed without delay as an ICN, based on the nature or extent of change, or whether it should be held for incorporating in the next scheduled revision

NOTE: Multiple ICNs can make a procedure difficult to implement. Similarly, a single ICN with extensive changes can also be confusing to the user. Therefore, it is recommended that a procedure be revised when the change is extensive or when there are already three (3) ICNs outstanding against the procedure.

- c. document the results of the evaluation (comments, comment resolution, and final disposition) on the DCR
- d. forward the DCR (including the evaluation results) to the Coordinator for processing.

2.4 The Coordinator shall document the DCR disposition and shall notify the DCR originator of the disposition.

- 2.4.1 If the requested change is considered acceptable and processing is to continue, the Coordinator shall process the change as one of the following:

- a revision
- an ICN
- a pen-and-ink mark-up (for **Test Instructions** only - see 5.0 below).

NOTE: Cognizant Managers or Coordinators may initiate an ICN without the completion of a formal DCR when circumstances warrant.

- 2.4.2 If the change is dispositioned "to be considered or incorporated at the next revision", the Coordinator shall retain the DCR. Such DCRs are subject to periodic review by the Coordinator to access the:

- need for current revision of the procedure or instruction
 - continued retention for possible future incorporation
 - possibility of repositioning the request as no longer viable.
-

3.0 Revisions

Revisions shall be prepared, reviewed, and approved for specific procedure types in accordance with the guiding documents listed as follows:

Procedure Type	Guiding Document for Revisions
Administrative	PAP-70-501, Preparation and Approval of Administrative Procedures
Technical	PAP-70-1101, Test Planning, Performance, and Evaluation
Calibration	PAP-70-1201, Calibration Control System

4.0 Interim Change Notices (ICNs)

4.1 The Coordinator, in conjunction with the Cognizant Manager, shall determine whether the change is major or minor. A minor change is defined as:

- correction of typographical or grammatical errors
- clarification of existing procedural requirements
- correction of obviously incorrect information.

All other changes are classified as major.

4.2 The Cognizant Manager shall:

- a. incorporate the accepted DCRs into the ICN (editing as necessary)
- b. complete the entire ICN form with the exception of the ICN number, effective date, and approvals
- c. return the completed ICN to the Coordinator.

4.3 The Coordinator shall review ICNs to ensure that:

- major ICNs are reviewed and approved in the same manner and by the same organizations that performed the original review and approval (unless other organizations are specifically designated)
- minor ICNs are reviewed and approved in accordance with the requirements established by the Cognizant Manager; minor ICNs for Administrative Procedures are approved by the DS Manager
- ICNs are assigned a number and an effective date

NOTE: When the document is being reproduced and issued through Document Control, the effective date should be assigned by Document Control based upon the processing time required.

- instructions for updating the procedure or instruction are developed and distributed with or included on the ICN (e.g., page replacement or pen-and-ink markup)
- ICNs are issued and distributed in the same manner as the original procedure or instruction, in accordance with PAP-70-601, Document Control.

5.0 Markups to Test Instructions

For Test Instructions only, changes may be incorporated with pen-and-ink markups (red ink is recommended to assist users in identifying changes). The Cognizant Manager shall ensure that the following minimum requirements are met:

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-602

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 4 OF 4

- major changes receive the same level of review and approval as the original instruction and by the same organizations that performed the original review and approval (unless other organizations are specifically designated)
- minor changes are reviewed and approved by the Cognizant Manager
- approvals are either documented on, or traceable to, the Test Instruction
- all controlled copies of the instruction are updated
- markups to the workplace copy are initialed and dated by the Cognizant Manager (initialing and dating of the workplace copy signifies that the changes have been approved as required)
- superseded wording is lined out but not obscured.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- Document Change Request (DCR)
 - Interim Change Notice (ICN).
-

PACIFIC NORTHWEST LABORATORIES		<i>DOCUMENT CHANGE REQUEST</i>		<u>DCR NO. ASSIGNED:</u> DCR - _____	
Document Number:	Document Title: _____		Rev. No.	Effective Date:	
Requestor, please provide information within the double lined areas.					
<u>Requested Changes(s):</u> 					
<u>Reason/Justification, and When Changes Should Be Implemented:</u> 					
Requestors Name:	Date Sent:	Department:	Phone No.:	Manager's Name:	Phone No.:
Evaluation/Disposition by assigned DS Engineer: (For DS use only; sign & date) 					

INSTRUCTIONS FOR DCR FORMS

1. The DCR Originator shall furnish the following information in the specified blocks.

Document Number: - number of the DCR subject document.

Document Title: - title of the DCR subject document.

Rev. No.: - latest revision number of the DCR subject document.

Effective Date: - latest revision effective date of subject document.

Requested Changes: - requested change including eh paragraphs affected and any suggested wording of the change.

Reason/Justification, and When Changes Should Be Implemented: - reason for the change and the date the change is needed. Be specific enough for the evaluator and coordinator to evaluate and assign a priority to the change.

Requestors Name: - originator print name and sign.

Date Sent: - self explanatory.

Department: - self explanatory.

Phone No.: - self explanatory.

Manager's Name: - self explanatory (managers signature is not required).

Phone No.: - manager's phone number.

2. The DCR Coordinator shall assign and enter the DCR number.
3. The DCR Evaluator shall enter evaluation comments, comment resolution, and DCR disposition.

INTERIM CHANGE NOTICE
 (ICN)

ICN-
 Page 1 of 1

A. Document No.: _____	Revision No.: _____	Effective
Document Title: _____		Change Requested By: _____
Document's Original Author: _____		
B. Action: _____		
C. Effect of Change: _____		
D. Reason for Change/Description of Change:		
<u>Reason for Change:</u> _____		
<u>Description of Change:</u> _____		
E. Approval Signatures (Please Sign and Date)	Type of Change: {Check (✓) one}	
_____	<input type="checkbox"/> Minor Change <input type="checkbox"/> Major Change	
DS Concurrence: _____	Date: ____ / ____ / ____	
Approval Authority: _____	Date: ____ / ____ / ____	
Other Approvals: _____	Date: ____ / ____ / ____	
_____	Date: ____ / ____ / ____	

INSTRUCTIONS FOR ICN FORM

SECTION A. Self explanatory.

SECTION B. Include all actions that the document holder must take to update the procedure or instruction. Possible actions include: replacing pages of the document with pages which are distributed with the ICN and marking up the document (in ink) to reflect the changes identified on the ICN.

SECTION C. Identify, by title, all personnel whose job functions will be affected by the change and include a brief description of the effect. If there is no effect on personnel (e.g., the change was made to clarify the intent of the procedure or to correct a typographical error) this block should be marked "N/A".

SECTION D. State the reason for the change followed by a description of the change (including the affected paragraph, information which is deleted, and the actual wording of any replacement text) for each change included on the ICN.

SECTION E. Identify type of change and document required approvals.

PNL ADMINISTRATIVE PROCEDURE
9515553.2575

TITLE: PAP-70-604, INDEPENDENT TECHNICAL REVIEW

PURPOSE

Provide requirements and methods for performing Independent Technical Reviews to ensure that technical documents are technically adequate, complete, and correct.

APPLICABILITY

This procedure is applicable when a documented critical review by independent, qualified personnel is required to ensure the technical adequacy, completeness, and correctness of technical documents because the normal clearance review procedures (Clearance of Reports, Speeches and Articles for Use Outside BNW) will not provide adequate assessment of the material.

Independent Technical Reviews (ITRs) are required on deliverables of Impact Level I scientific or technical information such as letter and topical reports, and final research reports. In addition, an ITR shall be performed when specified by an administrative procedure, a QA Plan, or by a manager responsible for approving the technical document prior to its use of delivery.

Technical documents prepared and clearly identified as "preliminary drafts," "working papers," or "for information only" do not require an ITR unless specified by the Project Manager or the Approval Authority.

The design and peer review processes are also independent technical reviews, but of a different type, and are described in administrative procedures for these activities.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Approval Authority (Cognizant Manager responsible for PNL approval of document)
- Cognizant Manager
- Designee (appointed by the Approval Authority)
- Independent Technical Reviewer.

IMPLEMENTATION

1.0 General

- 1.1 The Cognizant Manager responsible for PNL approval of the technical document, hereinafter referred to as the Approval Authority, shall ensure that required Independent Technical Reviews (ITRs) are accomplished in accordance with this procedure prior to document approval for release/issue.

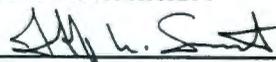
CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

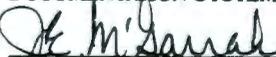
DATE

RL Shaub

6/16/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

- 1.2 The Approval Authority shall designate, hereafter referred to as the Designee, an individual (usually the author, author's manager or task/technical leader) to resolve the ITR comments and correct the document.
- 1.3 When formal clearance is required, the ITR may be used in conjunction with or prior to and independent of the PNL clearance process. The PNL clearance process should be performed on the final draft of the document which results from the ITR process.

2.0 Selection of Reviewers

- 2.1 The Approval Authority shall select Independent Technical Reviewers, hereafter referred to as Reviewers, who will be able to ensure that the document is technically adequate, complete, and correct.

2.2 The document reviewers shall include:

- Technical Representative(s)
- Quality Programs Representative (all technical procedures and when required by a governing document, the Approval Authority, or Quality Programs management)
- specialists, as applicable, in such functions as:
 - health
 - safety
 - environmental safeguards
 - licensing.

2.3 Qualifications of reviewers (resume on file with Project or traceable to the project) will be based on:

- technologies and disciplines represented in the document
 - proven competence in the subject matter of the document
 - adequate understanding of the requirements for and objectives of the technical document.
 - reviewer independence. Those selected shall be independent of the original work performed.
- 2.4 Personnel outside the Approval Authority's organization may be appointed as Reviewers with the concurrence of their manager. Such concurrence need not be documented.

3.0 Preparation of Document Review Record

- 3.1 The Approval Authority shall complete the top portion of the Document Review Record (DRR), EXHIBIT 1, and include the following additional information as appropriate and relevant to the ITR:

- project name and number
- intended use of the document
- applicable requirements and references to be considered in evaluating technical quality:
 - client requirements
 - research data
 - design inputs
 - drawings and specifications
 - procedures and instructions
 - laboratory record books
 - software documentation
 - software verification documents
 - calculations

- codes and standards
 - special instructions needed by reviewer(s) including:
 - specific criteria or requirements to be met
 - information indicating importance of the document
 - other documents or requirements affected
 - potential problems requiring consideration
 - identification of the scope of each Reviewer's review (i.e., limited to a section, topic, etc., or unlimited).
- 3.2 The Approval Authority shall clearly identify the DRR as an "ITR" and forward a copy of the DRR, with a copy of the document to be reviewed, to each Reviewer and the Designee.

4.0 Performance of Review

- 4.1 Reviewers shall review documents within their scope of review responsibility in accordance with DRR instructions. They shall either verify that the documents are adequate, complete and correct, or shall identify and document any deficiency that requires a change to the technical document.
- 4.2 Reviewers shall verify that scientific reports or other deliverable meet the following criteria, as applicable:
- reported results are traceable to and consistent with recorded data
 - data reduction has been accomplished correctly
 - data are traceable to their origin and to reported analytical results
 - the deliverable is consistent internally and with other reports
 - inferences and conclusions are soundly based
 - the deliverable satisfies program objectives.
- 4.3 Reviewers shall record the comments on the DRR and mark it to indicate that the Reviewer:
- "Concurs" indicates concurrence with the document as written. Typographical and grammatical errors may be noted.
 - "Concurs, but with comments" indicates concurrence with the document, subject to resolution of comments.
 - The Designee shall consider these comments, and either assure that they are incorporated into the document or record the reason for not doing so.
 - The Designee shall document the resolution comments on the DRR.
 - The Designee shall be advise orally or provide an information copy of the closed-out DRR to the Reviewer prior to document approval.
 - "Do Not Concur" indicates that the Reviewer has identified problems regarding concept, practice, implementation or responsibilities that render the document unacceptable. Comments reflecting these problems shall be identified with an asterisk.
 - Resolution of these comments is mandatory, and the Reviewer's written concurrence with the resolution is required.

PNL ADMINISTRATIVE PROCEDURE

- If the Designee, Reviewer and/or author cannot resolve the comments, the disagreement shall be referred to the Approval Authority for final disposition and documentation on the DRR.

- 4.4 Comments that, in the Reviewer's judgement, require documented resolution (as a minimum, those that are the basis for a "concur, but with comment" or "do not concur" disposition) shall be written on the DRR. Other comments may be either written on the DRR or noted on the document.
- 4.5 When other data or information outside of the furnished review material is used to substantiate a comment, the reference material shall be documented and/or attached to the DRR.
- 4.6 On completion of the review, the Reviewer shall sign the DRR and forward it to the Designee.

5.0 Comment Resolution

- 5.1 The Designee shall upon receipt of Reviewer comments, review and resolve the comments. The resolutions and Reviewer's, of the "Do Not Concur" comments, acceptance of the resolutions shall be recorded on the DRR.
- 5.2 Major changes resulting from resolution of one Reviewer's comments shall necessitate a followup ITR if changes affect another Reviewer's concurrence. The followup ITR may be limited to the affected section of the document.
- 5.3 When all DRR comments are resolved and required corrections to the document have been incorporated, the Designee shall prepare an ITR Report containing:
 - a statement that all required reviews have been received, comments have been satisfactorily resolved, and, in the Designee's opinion, the document fulfills its requirements and objectives
 - a statement summarizing details of any controversial resolutions or minority opinions of which the Approval Authority should be cognizant
 - a list of Reviewers with attached, closed-out DRRs, all signed by the Designee, and by the Reviewers when required
 - a copy of the document prior to review and a copy of the document resulting from the ITR resolutions.
- 5.4 The Designee shall sign and date the ITR Report and shall obtain the concurrence signature of the cognizant QP Representative that all comments are resolved and document corrections incorporated.
- 5.5 The Designee shall route the ITR Report and attachments to the Approval Authority.
- 5.6 The Approval Authority shall indicate acceptance of the report by signature and date.

REQUIRED RECORDS

The Independent Technical Review Report created as a result of this procedure is a record.

DOCUMENT REVIEW RECORD

PACIFIC NORTHWEST LABORATORIES DOCUMENT REVIEW RECORD	DOCUMENT NO.: _____ _____	Page _ of _
The referenced document is submitted for your review. Instructions for completing this form are attached. Please return the completed form to: _____ . If you have any questions, please call _____ . Comments Due: ____/____/____.		
Organization/Department	OPC/Designated Reviewer	Signature/Date
CONCUR []	CONCUR, WITH COMMENTS []	DO NOT CONCUR []
NOT REVIEWED []		
Comt. No.	Comments and Recommendations:	Resolution:
Concur with Resolution	Date	Comments Resolved By
		Date

INSTRUCTIONS FOR USING THE
DOCUMENT REVIEW RECORD (DRR)

The Document Review Record provides a consistent format for recording comments and recommendations to procedures, instructions, and other documents submitted for review.

Please include "comments and recommendations" on Page 1 in the appropriate section. Clearly identify any attachments to the DRR such as, marked text, inserts, additional pages.

The type of concurrence you select is for the entire procedure. The four selections are defined as follows:

Concur - indicates concurrence with the submitted document. The "Concur" selection is appropriate if typographical or grammatical errors are noted. However, if these types of errors impact the meaning or intent of the procedure, "Concur, with Comment" or "Do Not Concur" should be considered.

Concur, with Comment - indicates concurrence with the submitted document, subject to the disposition of comments.

Do Not Concur - indicates a concern regarding the concept, practice, implementation, or responsibilities addressed in the procedure.

Note: The "Do Not Concur" comments should be identified with an asterisk (*).

Not Reviewed - indicates no review of the submitted document.

Sign and date in the "Signature and Date" block.

Return the DRR as instructed.

TITLE: PAP-70-605, DOCUMENT CONTROL - FURNISHED DOCUMENTS

PURPOSE

Describe the methods of controlling the distribution and/or usage of documents furnished to PNL by a client or supplier to ensure that the users have the correct versions.

APPLICABILITY

Documents designated as controlled documents by the client or the applicable PNL program/Project Manager are subject to the requirements of this procedure.

This procedure is applicable to numerous documents from both clients and suppliers/subcontractors. These documents may include:

- Statements of Work (SOW)
- drawings
- specifications
- procedures
- other forms of direction and/or submittals.

Hereafter all of the above shall be referred to as documents.

This procedure does not include the contract (1830 related service and 1831) nor any documents that are part of the approved project management plan (PMP) for the project.

The review and concurrence of supplier furnished documents is accomplished in accordance with PNL-MA-531, Quality Programs Instructions.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Manager
- Document Control Designee (appointed by the Cognizant Manager)
- Staff Member (Recipient).

IMPLEMENTATION

1.0 Document Receipt

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

RL Shaub
RL Shaub 6/16/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah
JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-605

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 2 OF 2

- 1.1 The applicable Program/Project Cognizant Manager, or the client, shall make the determination as to document control requirements. Control of documents shall be required if they include:
 - baseline information
 - design criteria
 - design bases
 - acceptance criteria.
- 1.2 Upon receiving a document, the Recipient shall transmit the document to the Cognizant Manager.
- 1.3 The Cognizant Manager shall review the document to determine if control is required.
- 1.4 The Cognizant Manager or the Program/Project Document Control Designee shall be responsible for the control of the Program/Project documents.
- 1.5 If the document is to be controlled, the Cognizant Manager shall transmit to the Document Control Designee with distribution instructions for processing.
- 1.6 The Document Control Designee shall maintain a controlled documents list (CDL) for all controlled documents for which the designee has responsibility. The CDL shall include such information as:
 - document identification (title and/or number)
 - document revision
 - document date
 - document source (client/supplier)
 - distribution.
- 1.7 The Document Control Designee shall prepare a transmittal containing any required processing or special information and transmit with the document to the required staff member(s).

2.0 Staff Responsibilities

- 2.1 On receiving the document, the Staff Member shall:
 - comply with any instructions furnished and update any related material
 - ensure that personnel performing activities governed by the controlled document have immediate access to the information provided
 - mark "SUPERSEDED" or similar in red ink on any superseded documents that need to be retained for reference purposes.
- 2.2 The Staff Member shall ensure that work being performed is accomplished in accordance with the latest revision of the controlled document, unless the transmittal, QA Plan, or Statement of Work permits or requires otherwise.

REQUIRED RECORDS

A copy of all controlled documents shall be retained as a record.

TITLE: PAP-70-606, PEER REVIEW

PURPOSE

Provide requirements and methods for performing documented Peer Reviews to verify or validate project documents, material, or data.

APPLICABILITY

This procedure is applicable when indepth, critical reviews and evaluations of project documents, material, or data require interpretation or judgement to verify and/or validate.

Peer Reviews may be required at the direction of the Project Manager and on deliverables of scientific or technical information such as letter and topical reports, and final research reports when the conclusions, material, or data goes beyond existing state-of-the-art.

Documents prepared and clearly identified as "preliminary drafts," "working papers" or "for information only" do not require a Peer Review unless specified by the Project Manager or the Approval Authority.

Required technical reviews are conducted in accordance with PAP-70-604, Independent Technical Review.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Approval Authority (Cognizant Manager responsible for approval of document)
- Cognizant Manager
- Peer Review Designee (appointed by the Approval Authority)
- Peer Reviewer.

IMPLEMENTATION

1.0 General

- 1.1 The Cognizant Manager responsible for approval of the technical document shall hereinafter be referred to as the Approval Authority.
- 1.2 The Approval Authority shall designate, hereinafter to be referred to as the Peer Review Designee, a staff member to coordinate the peer review and resolve comments.
- 1.3 The Approval Authority, with client input, shall determine when a Peer Review is required for a specific document.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

RL Shaub

6/16/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah

6/20/94

JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

1.3.1 A Peer Review shall be required when:

- technical reviews, including Independent Technical Reviews, would not provide adequate assurance that all technical issues had been reviewed in sufficient detail, and
- performing the review requires interpretation or judgement because the planned or completed work includes the use of untried testing, analysis procedures, or methods; or where detailed technical criteria and requirements do not exist or are being developed.

1.3.2 The types of documents that could meet the criteria of Paragraph 1.3.1 and that may require Peer Review include but are not limited to:

- Technical (Test) Procedures that significantly advance the state-of-the-art
- reports containing analytical results or conclusions/recommendations based upon analytical results that require interpretations or judgement by a highly qualified individual.

2.0 Peer Review Request

2.1 When it has been determined that a Peer Review is required, the Approval Authority shall select a Peer Review Designee or outside organization (e.g., consultant) to coordinate/perform the Peer Review and prepare the Peer Review Request.

2.1.1 EXHIBIT 1 shall be used for the format and content of the Peer Review Request.

2.1.2 Copies of EXHIBIT 2, Peer Reviewer Qualifications; EXHIBIT 3, Peer Review Checklist; and EXHIBIT 4, Peer Review Record, of this procedure shall be attached to the Peer Review Request.

2.2 When an organization outside of PNL is selected to perform the Peer Review, that organization shall be instructed to appoint a Peer Review Manager and to obtain the PNL Approval Authority's concurrence to the review participants before initiation of the Peer Review.

3.0 Peer Review Performance

3.1 The Peer Review Designee shall select the review participants and obtain documentation of each participant's qualifications for participating in the Peer Review.

3.1.1 The number of participants will depend on the technical disciplines involved.

3.1.2 Reviewer qualifications shall be equal to, or greater than, the level of training and experience required to prepare the information being reviewed.

3.1.3 The cognizant Quality Programs Representative shall be a Peer Reviewer on Impact Level I projects (optional on Impact Level II), of deliverable technical reports and also reviews other documents as required by a governing document or considered necessary by the Project Manager or Approval Authority.

3.1.4 Reviewers qualifications shall be documented. EXHIBIT 2, Peer Reviewer Qualifications, or a current resume which addressed the same requirements may be used.

3.1.5 Copies of Peer Reviewer qualifications shall be submitted to the Approval Authority for concurrence before beginning of the Peer Review.

- 3.2 The Peer Review Designee shall document the Peer Review activities on the Peer Review Checklist, EXHIBIT 3.
- 3.3 Peer Reviewers shall review the entire document(s) with special emphasis on their area of expertise record their comments on EXHIBIT 4, Peer Review Record (PRR), and forward the completed PRRs to the Peer Review Designee.
- The Peer Review Designee may convene the Peer Reviewers as a group to resolve issues between reviewers. Minutes of the meeting(s) shall be recorded.
- 3.4 The Peer Review Designee shall provide a written summary on the PRR of the Peer Review comments and the individual reviewers shall initial and date each appropriate entry.
- 3.5 Upon resolution of any differences between reviewers, the Peer Review Designee shall sign and date the PRR and transmit with comment summary to the approval authority.
- 3.6 The Approval Authority, with the assistance of appropriate PNL staff, shall determine a proposed resolution for each comment on the PRR. The proposed resolution shall be documented in the column provided on the PRR adjacent to the subject comment.
- 3.7 The Approval Authority shall sign Part B of the PRR when satisfied that all comments have been adequately resolved and return the PRR to the Peer Reviewer Designee for concurrence.
- 3.8 Each Reviewer shall review the proposed resolution and initial and date the item when satisfied that the resolution is acceptable.
- 3.9 The Peer Review Designee shall arbitrate unresolved issues and sign Part C of the PRR when all comment resolutions have been accepted by the reviewers. In the event a comment cannot be resolved, it shall be so noted and the Approval Authority's position shall prevail.
- 3.10 The Peer Review Designee shall obtain the concurrence signature of the cognizant Quality Programs Representative that all comments are resolved and document corrections incorporated.
- 3.11 The Peer Review Designee shall transmit the completed PRR and other Peer Review Records to the Approval Authority.
- 3.12 The Approval Authority shall ensure that the document(s) reviewed are revised in accordance with the completed PRR.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- Peer Review Request
- Peer Reviewer Qualifications
- Peer Review Checklist
- Peer Review meeting minutes, if applicable
- Peer Review Peer Review Record (PRR) and attachments
- documents reviewed.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PEER REVIEW REQUEST

TO (Peer Review Designee):

ORGANIZATION (Company or PNL):

SUBJECT OF REVIEW:

QA PLAN #:

Please find attached copies of the Peer Reviewer Qualifications, Peer Review Checklists, and Peer Review Record forms required for the Peer Review of the following documents for the subject review. Please contact the undersigned should you have any questions on the use of these forms.

Peer Reviewer Qualifications (including designee) shall be submitted to the PNL Project Manager for concurrence prior to initiation of the Peer Review.

DOCUMENTS TO BE REVIEWED		
DOCUMENT TITLE	DOCUMENT NO.	REV. NO./DATE

SCOPE OF PEER REVIEW: (Describe the purpose, scope, and objectives applicable to the peer review being requested.)

PEER REVIEW REQUIREMENTS (Require that the peer review be performed and documented using the attached forms and include any other applicable requirements to help assure compliance to this procedure.)

PEER REVIEW GUIDELINES DOCUMENTS: (Reference any document that should be used for technical administrative guidance for performing the review.)

TECHNICAL DISCIPLINES INVOLVED: (List the technical disciplines to be involved in the peer review.)

 Project Manager/Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PEER REVIEWER QUALIFICATIONS

NAME OF REVIEWER:

POSITION:

ORGANIZATION:

NAME:

ADDRESS:

PHONE NO.:

EDUCATION:

MEMBERSHIP IN RELATED COMMITTEES:

SCIENTIFIC PUBLICATIONS AND PROFESSIONAL LICENSES:

RELATED EXPERIENCE, INCLUDING WORK ON SIMILAR PROJECTS/PROGRAMS (IF APPLICABLE):

Prepared By: _____
Reviewer/Date

Concurrence: _____
PNL Project Manager/Date

Reviewed By: _____
Designee/Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PEER REVIEW CHECKLIST

Project Title:

Project Manager:

Document Title:

Document No.:

Rev. No.

PEER REVIEW CHAIRPERSON SHALL INITIAL AND DATE EACH OF THE FOLLOWING ITEMS WHEN COMPLETED:

	<u>Initial</u>	<u>Date</u>
1. Review scope, purpose, objectives, schedule, and reviewers assigned	_____	_____
2. Review documented personnel qualifications	_____	_____
3. PNL Project Manager Concurrence to the Peer Review participants received and documented	_____	_____
4. All reference material and data available for review	_____	_____
5. All reviewer comments have been received	_____	_____
6. Review comments have been resolved (internal to review committee)	_____	_____
7. Peer review report prepared and sent to the PNL Project Manager	_____	_____
8. Peer review report comments resolved with the review staff and PNL Project Manager	_____	_____
9. Peer Review completed and all records to the PNL Project Manager	_____	_____

The above peer review was completed in accordance with the requirements of the above reference Peer Review Request.

Peer Review Chairman/Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PEER REVIEW RECORD

SUBJECT OF REVIEW:

PROJECT MANAGER:

A. COMMENTS

The attached comment/resolution pages provide the peer review participant's comments and the Project Manager shall provide resolution for each comment in the resolution column.

Designee/Date

B. RESOLUTION

The subject project has provided the required comment resolutions on the attached comment/resolution pages.

Project Manager/Date

C. RESOLUTION ACCEPTANCE

The subject Project Manager's resolution of the Peer Review comments have been reviewed by the Peer Reviewers and have been determined to be acceptable.

Designee/Date

QP Representative/Date

PEER REVIEW RECORD

DOCUMENT NO.:

DOCUMENT TITLE:

Comment Number	Document No. Page/Para.	Comments & Rationale ^(*)	Reviewer Initials and Date	Resolution	Concurrence: Reviewer Initials/Date

^(*) Any additional material used to substantiate comments shall be fully referenced. Copies of references not readily available to PNL shall be attached.

TITLE: PAP-70-702, PREPARATION AND USE OF INSPECTION/TEST INSTRUCTIONS

PURPOSE

Establish requirements, responsibilities, and methods for the preparation and use of Inspection/Test Instructions (ITIs) to determine acceptability of an item.

APPLICABILITY

This procedure applies to the preparation, review, and use of Inspection/Test Instructions (ITIs).

Nondestructive examinations (NDE) may be conducted using NDE inspection forms approved by the Lead Procurement Quality Engineer (Lead PQE) or the Level III NDE Examiner.

When to use an ITI during source verification activities is specified in PAP-70-704, Source Inspections, Tests, and Surveillances.

The use of an ITI for receiving inspection is specified in PAP-70-706, Receiving Inspection, and for independent inspections in PAP-70-1001, Independent Inspection.

Qualification of inspection/test personnel is discussed in PAP-70-203, Qualification and Certification of Inspection and Test Personnel. Qualification and certification of personnel performing nondestructive examination (NDE) is discussed in PNL-MA-531, Quality Programs Instructions.

PAP-70-1101, Test Planning, Performance, and Evaluation is the administrative procedure that is used to determine the acceptability of a process or for proving the adequacy of the design of an item.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Managers
- Cognizant Quality Engineer (QE)
- Cognizant Staff
- Inspection/Test Personnel.

DEFINITIONS

Inspection/Test Instructions - Specific written instructions for performing inspection or testing that are prepared, reviewed, and approved using the instructions in EXHIBIT 1 as a guideline.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

C.W. Cable 6/17/94
CW Cable

J.E. McGarr
JE McGarr, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

IMPLEMENTATION

1.0 Preparation, Review, and Approval of the ITI

- 1.1 As part of the planning process, several factors shall be considered relative to inspection or test of a quality related item.
- a. Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices.
 - b. Prerequisites to inspection or testing shall include, as applicable:
 - calibrated instrumentation
 - appropriate equipment (documented on the ITI)
 - trained inspection/test personnel
 - suitable environmental conditions
 - provisions for data acquisition.
 - c. Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.
 - d. Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements. If not previously examined, quality records shall be examined for adequacy and completeness.
 - e. Inspection results shall be documented and evaluated, and their acceptability determined by a responsible individual.
 - f. The impact level or safety class of the item should have been determined at an earlier date by the Cognizant Manager.
 - g. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to ensure quality.
- 1.2 The Cognizant Staff, with assistance of the Cognizant QE, shall prepare an ITI or equivalent using EXHIBIT 1, Inspection/Test Instruction, as a guideline when inspection or test is to be performed, including those to be performed by independent agencies. If there are questions about the capability of an independent agency to perform a required inspection, the Cognizant Staff or Cognizant QE should contact the Lead PQE.

NOTE: When the proposed inspection/testing organization is another Hanford Contractor or an off-site firm that is not governed by PNL procedures, additional detailed instructions may be necessary.

2.0 Use of the ITI

- 2.1 Cognizant Staff shall issue approved ITIs with supporting documentation directly to the PNL inspection/test organizations who are to perform the inspection/testing. When the inspection/testing is to be performed by a Hanford Contractor or another organization that has been evaluated by Quality Programs, ITIs and supporting documentation shall be submitted to the Lead PQE for concurrence and transmittal to the inspection/testing organization.
- 2.2 Inspection/Test Personnel shall:

PNL ADMINISTRATIVE PROCEDURE

9515558.2584

PROCEDURE NO.: PAP-70-702

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

- perform the prescribed inspection(s) and/or test(s)
- record on the ITI (or separate data sheet) the serial number (or other identification number) of measuring and test equipment used
- evaluate the actual results against acceptance criteria to determine acceptability. Sign and date the ITI and indicate the results of the evaluation.
- attach status indicator tags to inspected items per PAP-70-1401, Inspection and Testing Status and Tagging
- report any nonconformances by indicating "reject" for that step on the ITI and generate a nonconformance report in accordance with PAP-70-1501, Nonconformance Reports (Hanford Contractor personnel shall report as required by the Work Order/Statement of Work).

2.3 The Cognizant Manager shall ensure that completed ITIs are placed in the appropriate file such as:

- project QA files
- facilities QA files.

REQUIRED RECORDS

The completed ITI and any separate data sheets created as a result of this procedure are records.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PO/WP/WO No.: (1) Identifier: (2) Quantity: (3)	<h2 style="margin: 0;">Battelle</h2> <p style="margin: 0;">Pacific Northwest Laboratories INSPECTION / TEST INSTRUCTION</p>	Date: (4) Page (5) of Impact level: (6) Safety class: (6)				
Item Name: (7)		Item/DWG No. & Revision: (8)				
Prepared By/Date: (9)	Approved By/Date: (10)	Cognizant QE Concurrence/Date: (11)				
Responsible Inspection/Test Organization(s): (12)	Supplier Name & Address: (13)	References: (14)				
Step	Characteristic	Insp./Test Method (Procedure No.)	Acceptance Criteria	M&TE Used	Accept/Reject NCR No.	Performed By/Date
(15)	(16)	(17)	(18)	(19)	(20)	(21)
Remarks: (22)						
Reviewed and Concurred: (Signature / Date) (23)						

9513358 2580

INSTRUCTIONS FOR COMPLETING THE INSPECTION/TEST INSTRUCTION FORM

ITEMS 1 - 18 TO BE COMPLETED BEFORE AN ITI IS ISSUED FOR IMPLEMENTATION. ITEM 22 MAY ALSO BE NEEDED.

1. Purchase Order, Work Package, or Work Order Number.
2. Optional item, ~~enter model number, serial number, type, grade, etc if applicable.~~ If not used enter N/A.
3. Quantity of item to be inspected/or tested.
4. Date ITI preparation began.
5. Page 1 of 1, 1 of 2 etc.
6. Enter impact level ~~or safety class~~ of item being inspected/tested.
7. Name or description of item.
8. Item/part number, and/or drawing number, with revision. ~~When the inspection is not a final inspection of an item, note the configuration of the item at the time it is to be inspected.~~
9. Preparer signature and date ITI is ready for review and approval.
10. Signature of authorized individual and date of approval (usually the technical representative that ordered the item.)
11. Signature of Cognizant QE assigned to support the requesting organization and date of concurrence.
12. Name of organization responsible for performance of the inspection/test.
13. Supplier's name and address.
14. Reference those documents that are pertinent to the inspection/test.
15. Indicate each step of the inspection/test process (i.e., 1,2,3,4 etc.).
16. Characteristics of the item to be inspected/tested (e.g., 4.025 ± .001, Zone c-1).
17. Inspection/test method used to determine acceptance (e.g., Standard Measuring Equipment (SME); Magnetic Particle Examination).
18. Acceptance criteria for each inspection/test step(may refer to drawing or specification notes, paragraphs, etc).

DATA ENTRIES 19 - 21 ARE TO BE COMPLETED BY THE PERSONNEL PERFORMING THE INSPECTION/TEST FUNCTION. ITEM 22 MAY ALSO BE USED.

19. ~~Serial number or identification number of the~~ Measuring and Test Equipment (M&TE) used by the inspection/test personnel.
20. Results of the inspection/test accept or reject (Nonconformance Report number must be entered when reject).
21. Signature, initials, or stamp and date when inspection/test was performed.
22. For additional remarks relative to the task to be performed, who to contact in the event further direction or information is required, etc. ~~The inspection/test organization may use this block for remarks on the inspection/test.~~
23. Signature/date of individual reviewing the completed ITI to determine that the inspection was performed ~~as requested~~ and that the form is complete, usually the technical representative or Cognizant Manager.

PNL ADMINISTRATIVE PROCEDURE
9513558.2586

PROCEDURE NO.: PAP-70-704

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: PAP-70-704, SOURCE INSPECTIONS, TESTS, AND SURVEILLANCES

PURPOSE

Establish requirements and responsibilities and prescribe methods for witnessing/performing source inspections, tests, and surveillances at the facilities of suppliers or Hanford Contractors by designated PNL personnel.

APPLICABILITY

This procedure applies to the planning, witnessing/performing, and documenting of source inspections, tests, and surveillances at the facilities of suppliers or Hanford Contractors.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Contract Specialist
- Lead Procurement Quality Engineer (Lead PQE)
- PNL Representative (selected or concurred with by the Lead PQE)

DEFINITIONS

Condition - A (1) statement of fact relating to noncompliance to an agreed upon requirement, code or standard or (2) it may or may not relate to specific noncompliance at the time it was identified, but has the potential to do so if left unattended.

IMPLEMENTATION

1.0 General Comments on Source Verification (Inspection, Test, or Surveillance)

- 1.1 The PNL Contract Specialist shall arrange source verification activities at a supplier's facility.
- 1.2 The Lead PQE shall administer source verification activities at a Hanford Contractor's facility.
- 1.3 Impact levels/safety class shall be documented in the completed record for each source verification.

2.0 Performance of Source Inspection/Test

- 2.1 The Lead PQE shall concur with the selection of the PNL Representative responsible for witness/performance of the source inspection/test.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

KE Harrison
KE Harrison 6/16/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah
JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

2.2 Source inspections/tests shall be witnessed/performed by a PNL Representative:

- certified to perform inspections or tests or
- qualified to witness inspections or tests.

2.3 Each source inspection/test shall be conducted in accordance with an inspection (ITI) per PAP-70-702, Preparation and Use of Inspection/Test Instruction, or equivalent.

2.4 The PNL Representative shall document indications (typically used in Nondestructive Examination) on the ITI form. Indications that prove to be nonconformances shall be documented on a nonconformance report (NCR) per PAP-70-1501, Nonconformance Reports.

NOTE: Indications identified by the PNL Representative are weaknesses in a system or item that, if not corrected, could result in a nonconformance. In themselves, indications do not justify an NCR.

2.5 The PNL Representative shall process all correspondence, resolutions, and communications involving a supplier through the PNL Contract Specialist.

2.6 The PNL Representative shall direct all correspondence, resolutions, and communications involving a Hanford Contractor through the Lead PQE and, when applicable, the author of the work order or the individual technically knowledgeable in the requirements for the items or services requested.

2.7 The PNL Representative shall verify that resolution has been accomplished.

2.8 Inspection results shall be noted on the ITI and the Source Verification Report (EXHIBIT 1).

2.9 The PNL Representative shall provide a copy of the completed ITI to the supplier or Hanford Contractor, and request the supplier to mail three copies to the PNL Contract Specialist.

2.10 When the inspection is accomplished by a subcontracted independent inspection service, the Source Verification Report shall be reviewed and approved by the PNL Representative before release.

3.0 Source Surveillance

3.1 The Lead PQE shall select a qualified PNL Representative to be responsible for performance of each source surveillance. The Lead PQE shall ensure that the PNL Representative has been trained in the use of the Priority Planning Grid (PPG) Rating System before performing a Hanford Contractor surveillance.

3.2 Before performing a source surveillance, the PNL Representative shall appraise the supplier's or Hanford Contractor's quality performance history as a factor in determining the extent of the source surveillance.

3.3 The PNL Representative shall perform source surveillances at intervals consistent with the importance and complexity of the item or service, and such surveillances may include monitoring, witnessing, or observing activities.

3.4 The PNL Representative shall prepare a written checklist of the items or services to be reviewed, monitored, witnessed, or observed.

3.5 For Hanford Contractor surveillances, the PNL Representative shall assign a preliminary Priority Planning Grid (PPG) value to each identified Condition in accordance with Appendix A in Part 2 of PNL-MA-41, PNL ES&H Self-Assessment Management Program, and shall:

- a. "prefilter" each Condition for a PPG value
- b. as applicable, perform a second prefilter

PNL ADMINISTRATIVE PROCEDURE

9515558.2587

NOTE: If the second prefilter results in a preliminary PPG value of less than ten (10), the PNL Representative must then determine the PPG value using the entire Priority Planning Grid.

c. document the PPG value on the Condition Sheet.

3.6 For Hanford Contractor surveillances, the PNL representative shall prescribe required corrective actions in accordance with the Graded Approach to Deficiency Tracking and Corrective Action matrix in Part 2 of PNL-MA-41, PNL ES&H Self-Assessment Management Program, with the following exceptions:

3.6.1 Conditions with PPG values which are less than six (6) DO NOT require a:

- root cause determination
- corrective action plan.

3.6.2 For PPG values which are less than eleven (11) but equal to, or greater than six (6), a corrective action plan is required from the condition owner which is internally reviewed/concurred and remains with the condition owner.

3.7 All changes, correspondence, resolutions, and communications shall be administered by the same method as specified in paragraphs 2.5 and 2.6 of this procedure.

4.0 Documentation of Each Source Verification

4.1 The PNL Representative shall document each source verification on a Source Verification Report in accordance with the directions on the back of the form or equivalent. When a source surveillance is (conducted formally) similar to an audit, it may be more appropriate to document the source surveillance, including a cover letter, similar to reporting a Hanford Contractor or supplier audit.

4.2 The Lead PQE shall forward copies of the Source Verification Report or equivalent to the:

- Cognizant Manager - record file
- Contract Specialist - contract file
- receiving destination, as applicable
- supplier/Hanford Contractor when a source surveillance is performed
- PQD Supplier's History File.

REQUIRED RECORDS

The Source Verification Report and associated documentation created as a result of this procedure are records.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

SOURCE VERIFICATION REPORT

TYPE: INSPECTION [] SURVEILLANCE [] TEST []

Page 1 of 1

PO/WO NUMBER: _____ IMPACT LEVEL/SAFETY CLASS: _____

1. PURPOSE/SCOPE:

2. ACTIVITIES:

3. RESULTS:

DATE: _____

4. DOCUMENTATION:

5. CONTACTS:

6. PERFORMED BY: _____
(PNL REPRESENTATIVE SIGNATURE AND DATE)

SOURCE VERIFICATION CLOSURE:

7. CLOSED BY: _____
(PNL REPRESENTATIVE SIGNATURE AND DATE)

8. DISTRIBUTION:

INSTRUCTIONS FOR USE OF THE SOURCE VERIFICATION REPORT

1. Describe the purpose and scope of the verification activity (e.g., vacuum test 1X10 torr for each chamber, inspect widgit dimensions as indicated on DWG. # 12345-7, Rev. 2 except for A1 and A9).
2. Explain the activities taken including the description of the item or process (e.g. performed a surveillance of the tritium analysis process (real-time) to Tritium Procedure TR 846, Rev. 1).
3. Give the results of the verification activity (e.g., acceptable, unacceptable). Include the date the verification was accomplished. Unacceptable conditions require a nonconformance report by the PNL representative or equivalent document initiated by the supplier.
4. Record the governing documents (e.g., PO, WO, DWG#, Procedure #, Specification, NCR#, etc...).
5. Note the names and titles of key personnel contacted during the verification activity.
6. Name and signature of person performing the verification activity, including the date report was written.
7. Name and signature of person closing the source verification, including the date all source verification activities and corrective actions are complete.
8. Distribution:

Cognizant Manager
Cognizant Quality Engineer
Cognizant Contract Specialist
Supplier's History File
File/LB

TITLE: PAP-70-706, RECEIVING INSPECTION

PURPOSE

Establish requirements and responsibilities for receiving inspection of quality related items obtained by purchase order, subcontract, or work order.

APPLICABILITY

This procedure applies to planning, performing, and documenting PNL receiving inspection activities.

Receiving inspection of QA documentation will be addressed in PNL-MA-531, Quality Program Instructions. The use of an Inspection/Test Instruction (ITI) form is described in PAP-70-702, Preparation and Use of Inspection/Test Instructions (ITIs). Direction for when independent receiving inspection is required is discussed in PAP-70-401, Purchase Requisitions, and PAP-70-404, Obtaining Services. Information regarding suspect/counterfeit items is addressed in PAP-70-402, Control of Suspect/Counterfeit Items.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Quality Engineer (QE)
- Contract Specialist
- Procurement Quality Engineer (PQE)
- Requisitioner (e.g., Project, Activity, or Building Managers and technical representatives who purchase or request work on items including systems, structures, and components).

IMPLEMENTATION

1.0 Planning Receiving Inspection

1.1 During the preparation and review of Purchase Requisitions (PAP-70-401, Purchase Requisitions) or Work Orders (PAP-70-404, Obtaining Services), the Requisitioner and the Cognizant Quality Engineer (QE) have determined which items required receiving inspection, whether an independent inspection was required, and the organization responsible for performing the receiving inspection.

1.2 Purchased items shall be inspected, as necessary, to verify conformance to requirements specified in the procurement documents, taking into consideration:

- source verification
- audit activities
- demonstrated quality performance of the supplier

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

KE Harrison

6/16/94

KE Harrison

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah

6/20/94

JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

- consequences of failure
- intended use.

1.3 When independent receiving inspection is not required, the Requisitioner shall determine that the item:

- was not damaged during shipment
- received was the item ordered.

1.4 The Requisitioner, with assistance from the Cognizant QE, shall prepare an ITI in accordance with PAP-70-702, Preparation and Use of Inspection/Test Instructions, or equivalent when receiving inspection (independent or otherwise) is to be performed on items, except for Category 1 Measurement and Test Equipment (M&TE).

1.4.1 When receiving inspection includes supplier submittals, the ITI shall:

- reference the PQ Supplier Submittal Review Record as a step/characteristic for acceptance of such submittals, or
- include the equivalent information as steps/characteristics to be inspected on the ITI.

1.4.2 When a sample is used to verify acceptability of a group of items, the sampling procedure/plan shall be based on recognized standard practices and referenced on the ITI.

1.4.3 When independent receiving inspection is required, the ITI shall show evidence of approval (signature/date) by the:

- Requisitioner
- Cognizant QE
- PQE.

1.4.4 When graded fasteners, electrical components, or piping components are ordered, or the order is for items which contain these, the order shall be inspected in accordance with the requirements of PAP-70-402, Control of Suspect/Counterfeit Items. The inspection for suspect/counterfeit items shall be documented on an ITI prepared in accordance with PAP-70-702, Preparation and Use of Inspection/Test Instructions.

1.5 When post-installation testing is to be performed by the Requisitioner and an independent inspection hold or witness point has been established, the Cognizant QE shall review the ITI (signature/date) and then route a copy of the ITI to the Lead PQE. **The Requisitioner shall notify the Lead Procurement Quality Engineer (Lead PQE) at least one full working day before an inspection hold or witness point is reached.**

2.0 Routing of Items/QA Documentation Submittals for Independent Receiving Inspection

2.1 Required PNL independent receiving inspections will be performed by a PQE at the designated PNL Process Quality Inspection Facility or by an organization evaluated/approved by a PQE at another designated inspection location (e.g., "As found" calibration of radiological measuring equipment performed by the PNL Instrumentation and External Dosimetry Section).

2.2 The Contract Specialist shall forward supplier QA documentation submittals to a PQE for review in accordance with CAP-70-701, Proposal Evaluation, Supplier/Subcontractor Selection and Purchase Order/Subcontract Administration (Post Award).

2.3 When QA documentation submittals have been incorrectly sent to the field, the Requisitioner shall forward the submittals to the Lead PQE for review or further disposition.

3.0 Performing and Documenting Receiving Inspection

3.1 When applicable, independent receiving inspections shall be performed to verify, by objective evidence, such features as:

- freedom from shipping damage
- cleanliness
- completeness/configuration
- markings/identifications
- no suspect/counterfeit items
- calibration, including evidence of traceability to nationally recognized standards, when applicable
- dimensions
- workmanship to nationally recognized specifications and standards (e.g., visual weld inspection, electronic soldering inspection, etc.)
- NDE requirements
- physical and chemical properties
- specific drawing note requirements
- records

NOTE: This may include the review of calibration reports, certifications, test reports, NDE reports, etc. that provide objective evidence that characteristics meet specified requirements.

- other characteristics, as required, to verify the quality and conformance of the item to contractual requirements.

3.2 Independent receiving inspection activities shall be coordinated through a PQE who is responsible for:

- ensuring that each inspection package is complete and that accepted items have been tagged with an acceptance tag
- coordinating communication between PNL staff and the receiving inspection organization
- follow-up action to ensure completion of the ITI.

3.3 When only supplier document submittals are required, the receiving inspection of these documents shall be performed by a PQE. The PQE shall ensure, in coordination with the Requisitioner, that items are placed on HOLD status until required supplier submittals have been received and accepted.

3.4 The performance of receiving inspection by other than PNL shall be covered by a purchase order or a work order with a statement of work/letter of instruction.

3.5 A nonconformance discovered during the Requisitioner's or PQE's receiving inspection process shall be documented and dispositioned on a nonconformance report (NCR) in accordance with PAP-70-1501,

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-706

REVISION NO.: 4

EFFECTIVE DATE: 08/31/94

PAGE 4 OF 4

Nonconformance Reports. Status indicators shall be applied to items in accordance with PAP-70-1401, Inspection and Testing Status and Tagging.

3.6 Nonconforming items shall not be released for use until disposition is completed on the NCR and the NCR number is noted on the ITI. The ITI may be closed out provided that documentation control (traceability) is maintained through an NCR.

4.0 Receiving Inspection Records

4.1 Independent receiving inspection records shall be transmitted by the PQE to the Requisitioner.

4.2 When other than independent receiving inspection is performed, the Requisitioner performing the inspection shall be responsible for transmitting the record to the appropriate files.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- Inspection/Test Instructions (ITI)
 - Nonconformance Report (NCR)
 - PQ Supplier Submittal Review Record.
-

TITLE: PAP-70-801, IDENTIFICATION AND CONTROL OF TEST MATERIALS (TESTING AND ANALYSIS)

PURPOSE

Provide requirements, responsibility, and methods to ensure that only correct and accepted test materials are used, and identification is maintained on test materials or in documents traceable to them.

APPLICABILITY

This procedure applies to test materials.

Stock test materials (i.e., off-the-shelf materials) that are adequately identified and labeled by the supplier are exempt from this procedure provided the test materials are utilized in a manner by which the identification and status are maintained.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Staff (including analytical services personnel)
- Process Quality (PQ) Representative (Quality Engineer).
- Project Manager.

DEFINITIONS

Test Material - material (e.g., specimens or samples) that will be tested or analyzed for the purpose of obtaining (or directly supporting) data to be reported to a client.

GENERAL

The Project Manager (or his designee) shall identify and document the project's test materials in a memo (or equivalent document of record). Also, the Project Manager shall document any special requirements related to limited shelf-life or maintenance of the test materials. Cognizant Staff shall ensure that test materials are uniquely identified and traceable to source documents. Any special requirements are included with the test material when test material is transferred to others.

IMPLEMENTATION

1.0 Test Material Identification

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A

JW Smith
JW Smith, Director, Quality Programs

8/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

RL Shaub
RL Shaub 6/16/94

JE McGarr
JE McGarr, Manager 6/20/94

PNL ADMINISTRATIVE PROCEDURE

- 1.1 Test material is uniquely identified upon receipt, collection, or fabrication (if made internally) until the material is used. The identification provides traceability of the material to pertinent supporting documentation.
- 1.2 Identification is maintained either on the material or in documents traceable to the material. Identification is accomplished by using one of the following methods:
 - physical identification (e.g., mark or stamp) whenever possible
 - tagged or labeled material or container (e.g., for liquid or gaseous materials)
 - physical separation or procedural control (e.g., for radioactive materials in a glovebox or hot cell).
- 1.3 Test material identification is accomplished using materials and methods which:
 - provide for clear and legible identification
 - do not detrimentally affect the function or service life of the item
 - subsequent surface treatments do not obliterate or hide the identification unless another means of identification is substituted.
- 1.4 Identification is transferred to each part of a test material (or to documents traceable to the test material) if it is subdivided. A suffix may be added to the original identification or a new numbering method may be employed as long as the subdivided portions are traceable to their origin.

2.0 Test Material Acceptability and Traceability

- 2.1 Test material is verified as acceptable based on one or more of the following:
 - analytical results of physical or chemical properties to confirm material acceptability
 - document review by a PQ Representative to confirm requirements are met

NOTE: A PQ Representative usually verifies acceptability of supplier document submittals in accordance with PNL-MA-531, Quality Programs Instructions.

- inspection by a PQ Representative to confirm requirements are met
 - verification of traceability to the appropriate technical or quality documentation (such as drawings, specifications, material or chemical certifications, field records, analytical or test reports, inspection reports, nonconformance or deficiency reports); traceability may also be maintained through documentation in laboratory record books or data sheets.
- 2.2 Verification activities (see 2.1) that are performed to confirm material acceptability are documented.
 - 2.3 Test material that is nonconforming is identified with a "hold" tag and controlled in accordance with PAP-70-1501, Nonconformance Reports.

3.0 Limited Life Test Materials

- 3.1 The Project Manager shall identify and document the test materials having limited shelf-life.
- 3.2 Cognizant Staff shall ensure that the expiration date is identified on or with the material to prevent the inadvertent use of test material that has expired.
- 3.3 Cognizant staff may use test material when the shelf-life date has been exceeded if:

- material acceptability has been verified by physical or chemical analysis and the verification is documented, or
- justification for using the material beyond the shelf-life date is documented, or
- a new shelf-life date is assigned to the material.

4.0 Test Material Maintenance

4.1 The Project Manager shall document any special requirements and instructions by which test materials are to be maintained. Cognizant Staff shall maintain test materials in accordance with the requirements and instructions provided by the Project Manager.

4.1.1 The Project Manager shall ensure that, when necessary, a controlled environment (e.g., temperature and humidity) is provided.

4.1.2 The Project Manager shall ensure provision is made for the control of test material identification based on the conditions of storage (such as damage due to handling, contamination or aging).

4.2 Unless otherwise specified, test materials submitted for analysis are considered disposable.

REQUIRED RECORDS

None.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-803, ITEM IDENTIFICATION AND CONTROL

PURPOSE

Provide requirements, responsibilities, and methods to ensure that only correct and accepted items are used, and that identification is maintained on the items or in documents traceable to them.

APPLICABILITY

This procedure applies to the identification and control of items as defined herein.

The identification and control of test materials are established in PAP-70-801, Identification and Control of Test Materials (Testing and Analysis).

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Managers
- Process Quality (PQ) Representative (Quality Engineer).

DEFINITIONS

Controlled Items - Materials, parts, and components that receive verification of conformance to specified requirements in order to be considered acceptable for use. Examples include assemblies, subassemblies, equipment, modules, subsystems, and units.

GENERAL

The Cognizant Manager whose organization is in possession of controlled items shall use the following measures, as applicable, to ensure the use of correct and accepted controlled items and to maintain their identification.

IMPLEMENTATION

1.0 Identify Controlled Items

- 1.1 Identify controlled items with labels or tags, either attached to the item or in its immediate proximity.
- 1.2 When specified by codes, standards, or specifications; identify the applicable specification, grade of material, heat, batch, lot, part, or serial number.

CONCURRENCE _____ DATE _____
 N/A

APPROVAL AUTHORITY _____ DATE 6/20/94
 JW Smith, Director, Quality Programs

PREPARED BY _____ DATE 6/16/94
 RL Shaub

DOCUMENTATION SYSTEMS DEPARTMENT _____ DATE 6/20/94
 JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

1.3 Maintain identification on the items or in documents traceable to the items throughout fabrication, installation, and use of the item, as applicable, by one of the following methods:

- mark or stamp on the item whenever possible, but only in accordance with an approved drawing, specification, or procedure
- apply tag or label on item or container
- segregate out-of-date or damaged items from accepted items in a location that is appropriately marked
- replace identification marking if it becomes illegible from any cause (e.g., handling, aging, or environmental effects).

1.4 Use identification materials and methods which:

- provide for clear and legible identification
- do not detrimentally affect the function or service life of the item
- ensure that the identification is not obliterated if subsequent surface treatments are applied unless another means of identification is substituted.

1.5 Transfer identification to each part and subpart when items are subdivided so that both the subdivided and remaining pieces are marked.

1.6 Maintain and update project/facility records pertaining to the location and disposition of items.

2.0 Verify Controlled Item Acceptability and Traceability

2.1 Verify acceptability and traceability of controlled items by one of the following methods:

- receiving inspection to procurement specifications by a PQ Representative for manufactured items (documented in the ITI package)
- inspection of fabricated items to design documents by a PQ Representative for Craft Services fabricated items
- physical testing of an item for the function for which it was designed with a PQ Representative present to witness.

2.2 Document verification activities that are performed to confirm item acceptability.

2.3 Document unacceptability of an item on a Nonconformance Report (NCR) in accordance with PAP-70-1501, Nonconformance Reports.

3.0 Maintain Shelf-Life Items

3.1 Provide appropriate environmental conditions for the preservation of the item as specified (e.g., temperature, humidity, atmospheric pressure, etc.) to prevent deterioration.

3.2 Maintain controlled item shelf-life documentation where specified so that items exceeding expiration dates will be removed, marked, segregated, or disposed of as appropriate.

3.3 Post expiration dates that are clear and legible.

9513558.2594
PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: **PAP-70-803**

REVISION NO.: **2**

EFFECTIVE DATE: **08/31/94**

PAGE **3** OF **3**

- 3.4 Where the quality of controlled items is indeterminate or defective, document and process the item(s) in accordance with PAP-70-1501, Nonconformance Reports.

REQUIRED RECORDS

None.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-901, CONTROL OF PROCESSES

PURPOSE

Describe requirements for procedures, personnel, equipment, performance, verification, and monitoring of processes to ensure that the end results of the processes will be satisfactory.

APPLICABILITY

This procedure applies to the control of analytical procedures and other PNL processes as specified in the individual project QA Plans. The processes to which this procedure shall apply are those which, if improperly performed, could result in errors that could affect data or other deliverables, safety, cost, or schedule.

The control of special processes, generally fabrication processes such as welding, heat treating, and nondestructive examination, are addressed in PAP-70-902, Control of Special Processes.

The identification of processes performed by Hanford Contractors or outside suppliers/subcontractors is also addressed in this procedure. Guidance for subsequent actions is found in the 400 and 700 Series Administrative Procedures.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- (Cognizant) Line Manager
- (Cognizant) Project Manager
- Staff Member (who performs the process).

GENERAL

Subsection 1.0 of the Implementation Section applies to the identification of processes to be performed by PNL, suppliers/subcontractors, and Hanford Contractors. The other subsections of this procedure only apply to process performed by PNL.

IMPLEMENTATION

1.0 Controlled Process Identification

The Project or Line Manager shall ensure that the controlled processes to be performed for his or her project or function are recognized and shall determine whether or not specific qualification of each is required. This shall be accomplished as follows:

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

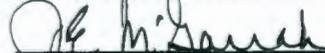
DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


RL Shaub

6/17/94


JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

- Controlled processes to be performed within the project organization shall be identified in the QA Plan if they are known at the time the Plan is prepared or revised. Identification may be through the name or number of the process procedure.
- Controlled processes to be performed by PNL analytical centers or service groups outside the project organization shall be identified in the Work Package Statement of Work.
- Controlled processes to be performed by suppliers/subcontractors or Hanford Contractors shall be identified in the Purchase Requisition or Work Order package. The requirements that the supplier/subcontractor or Hanford Contractor must meet to adequately control the process shall be specified.

2.0 Procedures and Drawings

2.1 The Line or Project Manager who is responsible for implementing the controlled process shall provide a Technical Procedure for it. In addition to meeting the requirements of PAP-70-1101, Test Planning, Performance, and Evaluation, the procedure:

- shall include a section entitled "Specific Qualification". This section shall either indicate "none required" or shall delineate the actions necessary to demonstrate that the procedure will produce acceptable results. When qualification by demonstration is required, data showing that the qualification was successful shall be provided for the Technical Review of the procedure.
- may include attachments such as instructions, drawings, checklists, or travelers as appropriate and necessary
- shall provide for conditions that are necessary for the satisfactory accomplishment of the process. As applicable, such conditions may include the use of accepted materials (PAP-70-400 & 700 series); material controls (PAP-70-801 & 803); inspection hold points (PAP-70-1001); acceptance testing (PAP-70-1101); calibration controls (PAP-70-1201); handling, storage, shipping, environmental and cleanliness controls (PAP-70-1301; and identification (PAP-70-1401). Special process controls will also be necessary if the process (such as a fabrication) includes a special process (such as welding) as one of its steps.
- shall provide for the proper sequencing of process steps
- shall include provisions for recording the performance of the process, including the performer and the date
- shall also include provisions for the performance of any necessary inspections or other verifications of correct performance.

2.2 As an alternative to 2.1, the Line or Project Manager may use drawings prepared and approved in accordance with PAP-70-302, Assurance and Control of Engineering Design, provided that the drawing contains all applicable information that would be required of a Technical Procedure.

3.0 Qualification of Processes

Controlled processes that are based on standard, well understood methods or that are self-qualifying due to their dependence on analytical standards may be considered as qualified through the Independent Technical Review of the Technical Procedure. Other processes, for which there is uncertainty as to whether they will yield reliable results, shall be qualified by demonstration.

4.0 Personnel Capability

The Cognizant Line or Project Manager shall ensure that personnel assigned to perform controlled processes are capable of performing them correctly. A listing shall be maintained of who is qualified for each procedure, including the basis for qualification. The basis shall be one or more of the following:

- the person wrote or qualified the procedure
- the manager or his designee has observed the person's satisfactory performance of the procedure
- the person has achieved acceptable results in performing the procedure.

Training records that meet the above may be utilized in lieu of the listing.

5.0 Equipment and Material Controls

The Cognizant Line or Project Manager shall ensure that adequate controls are exercised over the equipment, material, and supplies that affect process results.

6.0 Performance

The Staff Member shall perform the process in accordance with the Technical Procedure or drawing and shall document the performance as required.

7.0 Verification

The Cognizant Line or Project Manager shall notify Quality Programs of any surveillances or QA hold points that are required by the procedure.

8.0 Monitoring

The Cognizant Line or Project Manager shall ensure that the performance of the process is monitored. The level of monitoring shall be such as to provide reasonable assurance that acceptable results are being consistently achieved. Monitoring results shall be recorded on the process record sheets or traceable to the process.

REQUIRED RECORDS

Technical Procedures created as a result of this procedure are records.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE
9513558.2597

PROCEDURE NO.: PAP-70-902

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: PAP-70-902, CONTROL OF SPECIAL PROCESSES

PURPOSE

Describe requirements for identifying and performing special processes to ensure that the processes will comply with any applicable codes and standards and the end results of the processes will be satisfactory.

APPLICABILITY

This procedure applies to the control of PNL special processes, generally fabrication processes such as welding, heat treating, and nondestructive examination, that are used to determine the acceptability of or that change or determine the properties of items.

The identification of special processes performed by Hanford Contractors or suppliers/subcontractors is also addressed in this procedure. Guidance for subsequent actions is found in the 400 and 700 Series Administrative Procedures.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Manager (manager whose organization will perform the special process)
- Line Manager (non-Project Manager whose function requires the performance of special processes)
- Project Manager
- Quality Engineer
- Staff Member (who performs the special process).

GENERAL

Subsection 1.0 of the Implementation Section applies to the identification of special processes to be performed by PNL, suppliers/subcontractors, and Hanford Contractors. The other subsections of this procedure only apply to special processes performed by PNL.

IMPLEMENTATION

1.0 Special Process Identification

The Project or Line Manager shall ensure that the special processes to be performed for his or her project or function are identified. The criteria for special processes are contained in the Glossary definition. Typical ones include welding, heat treating, nondestructive examination, and painting, plating, coating or bonding, as applicable.

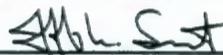
CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

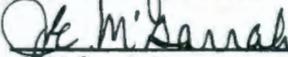
DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

RL Shaub

6/17/94


JB McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

Identification shall be in the QA Plan, if known when the QA Plan is prepared, and in the Work Package Statement of Work issued to the PNL performing organization. Any applicable codes, standards, technical requirements, and QA requirements shall be included.

When a supplier/subcontractor or Hanford Contractor is to perform the special process, it shall be identified in the procurement documents or Work Order Package. The requirements that the supplier or Hanford Contractor must meet to adequately control the special process shall also be included.

2.0 Procedures for Special Processes

The Cognizant Manager shall provide a procedure for performing the special process. Except when a prequalified procedure is available (such as certain AWS procedures), this shall be a Technical Procedure prepared in accordance with PAP-70-1101, Test Planning, Performance, and Evaluation. It shall include instructions, drawings, checklists, or travelers as necessary. These documents shall accomplish the following:

- ensure that process parameters are controlled and that any specified environmental conditions are maintained
- specify conditions necessary for accomplishing the special process, including proper equipment, process parameters, calibration requirements, and acceptance criteria
- incorporate the requirements of any applicable codes or standards, either directly or by reference
- delineate process qualification requirements as required (see 3.0)
- provide for recording evidence of the acceptable accomplishment of the special process, using qualified procedures, equipment, and personnel.

3.0 Qualification of Special Processes

The Cognizant Manager shall ensure that the procedure, equipment, and personnel to be used in performing the special process are qualified in conformance with any applicable codes, standards, and technical and QA requirements.

- 3.1 For special processes not covered by existing codes or standards, or where quality requirements exceed those of existing codes or standards, the necessary requirements for qualification shall be specified or referenced in the Technical Procedure.
- 3.2 Procedures and any equipment that can affect the outcome of the process shall be qualified by demonstration that, when performed as specified, the process yields required results.
- 3.3 Personnel shall be qualified by training (where appropriate) and demonstration that they can perform the process with the required results.
- 3.4 The Quality Engineer shall be notified of and witness key steps in qualification tests to help ensure that they are properly performed.
- 3.5 Evidence of successful qualification of the process shall be submitted with the procedure for its Independent Technical Review.

4.0 Performance of Special Processes

The Staff Member who performs the special process shall perform it in accordance with the approved Technical Procedure using qualified equipment. All data required on process performance shall be recorded. Quality Programs shall be notified for the witnessing of any specified Hold Points.

5.0 Qualification Records

The Cognizant Manager shall ensure that qualification records of procedures, equipment, and personnel are established and maintained current.

REQUIRED RECORDS

The required records are identified in section 5.0 above.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE
9515558.2599

PROCEDURE NO.: PAP-70-1001

REVISION NO.: 2

EFFECTIVE DATE:

08/31/94

PAGE 1 OF 5

TITLE: PAP-70-1001, INDEPENDENT INSPECTION

PURPOSE

Establish uniform methods for planning and performing independent inspections. These inspections help ensure that facilities, equipment, and the safety of personnel are not compromised by the use of unacceptable or unreliable items.

APPLICABILITY

This procedure applies to independent inspection of items and associated documentation for programs, projects, and activities. For this procedure, Safety-Class systems, structures, and components (SSCs) are included in the definition of items. This procedure applies to nondestructive examinations (NDE) and independent inspections that are required by Craft Services Departments's (CSD) Preventive Maintenance Procedures (PMs).

In-service maintenance of SSCs is addressed by the CSD Preventive Maintenance (PM) Program. Independent surveillances of the PM Program and processing methods will be performed by Quality Programs in accordance with PNL-MA-531, Quality Programs Instructions.

Source verifications, receiving inspections, and post-installation tests of procured items/services are also addressed in PAP-70-401, Purchase Requisitions, PAP-70-704, Source Inspections, Test, and Surveillance, and PAP-70-706, Receiving Inspection.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Quality Engineer (QE supporting the staff requesting inspection services)
- Cognizant Staff (who are responsible for performing the work)
- Lead Procurement Quality Engineer (Lead PQE)
- Process Quality Department (PQ) Representative
- Procurement Quality Engineer (PQE)
- Requesters (staff that determine the need for or request independent inspections).

DEFINITIONS

Independent Inspection - Examinations or measurements performed by qualified and certified PQD personnel or other personnel approved by the Lead PQE to verify whether an item conforms to specified requirements. Independent inspections shall be performed by persons other than those who performed or directly supervised the work being inspected. It is intended that such personnel be certified in accordance with PAP-70-203, Qualification and Certification of Inspection and Test Personnel and/or other criteria established by the Lead PQE.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

C.W. Cable
CW Cable 6/16/94

J.E. McGarran
J.E. McGarran, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

There are occasions when state-of-the-art technology, singular applications, and program considerations require inspections to be performed by individuals who are not certified in accordance with PAP-70-203, Qualification and Certification of Inspection and Test Personnel and/or do not report to the PQ Manager or Lead PQE (see Paragraph 2.0 for implementation of these exceptions).

Item - For the purpose of this procedure, the word "item" does not include research data and is intended to be limited to hardware type items (e.g., appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, etc.) including facility systems, structures, and components and associated documentation.

IMPLEMENTATION

1.0 Planning for Independent Inspection

1.1 Requesters shall:

- determine the need for independent inspections based on the requirements and guidelines as noted in this procedure (including EXHIBIT 1, Independent Inspection Guide)
- obtain the review and concurrence of the Cognizant Quality Engineer with the determinations for independent inspection.

These determinations should occur during the design or planning process before work begins. Planning may be reflected on work authorizing or sub-tier documents (e.g., drawings, work requests, QA plans, statements-of-work, PRs, etc).

1.1.1 Independent in-process inspection shall be performed when characteristics that significantly affect the item cannot be verified by a final inspection or when final inspection would be less cost effective. Plans for inspection of items that are in-process or under construction shall be developed for work activities, where necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel (surveillance) shall be planned. Both inspection and process monitoring (surveillance) shall be planned when control is inadequate without both.

1.1.2 Independent receiving and/or final inspections shall be performed prior to acceptance or use of the item when there are significant consequences of failure. These inspections may include a review to determine that required documentation, such as material certifications and prior inspection and tests reports, has been received and is acceptable. Final inspections shall be planned to provide information needed to arrive at a conclusion regarding conformance of the item to specified requirements. Inspection plans should address inspection of completed items to verify characteristics that significantly affect the item such as:

- freedom from transportation/shipping damage
 - cleanliness
 - completeness/configuration
 - markings/identifications
 - calibration or adjustments, including evidence of traceability to nationally recognized standards
 - dimensions
-

- workmanship to nationally recognized specifications and standards (e.g., visual weld inspection, electronic soldering inspection, etc.)
- NDE requirements of applicable codes, standards, and specifications
- physical and chemical properties
- specific drawing note requirements
- records required by procurement documents and applicable codes, standards, and specifications

NOTE: This may include the review of calibration reports, certifications, test reports, NDE reports, etc. that provide objective evidence that characteristics meet specified requirements.

- protection from damage
- other characteristics, as required, to verify the quality and conformance of the item to specified requirements.

1.1.3 Independent inspections shall be planned, performed, and documented when:

- A procured item requires independent receiving/source inspection (see PAP-70-401, Purchase Requisitions).
- Failure of the item is likely to jeopardize safety conditions or data validity, or cause significant cost or schedule impact.
- Inspection is required by an applicable code, standard, of specification.
- An item is fabricated to a client, PNL, or Hanford specification or drawing that specifies:

- dimensions and tolerances that can only be verified by using precision inspection equipment

NOTE: Normally this involves the use of inspection equipment such as surface plates, height gages, optical comparators, profilometers, etc. to measure characteristics such as true position, concentricity, angularity, perpendicularity, straightness, surface finish, etc. As a general rule, it involves measuring the location of features to tolerances of ± 0.010 inch or more stringent and feature size to tolerances of ± 0.003 inch or more stringent.

- visual weld inspection or NDE
- electronic workmanship of equipment built to ANSI/IPC specifications or other nationally recognized standards
- other characteristics that need a certified inspector's discipline to verify acceptability.
- Safety Class systems, structures, or components have been fabricated, installed, modified, disassembled, reworked, or repaired
- An independent inspection is deemed necessary by the Requisitioner and Cognizant QE.

PNL ADMINISTRATIVE PROCEDURE

1.1.4 Requirements for independent inspections may be increased, modified, or reduced with the concurrence of the Cognizant Quality Engineer. In addition, the rationale for any reductions shall be justified in writing.

1.2 Requesters with Cognizant Quality Engineers concurrence shall determine the specific independent inspection characteristics, hold points, and accept/reject criteria and shall identify these inspection requirements in the work authorizing or sub-tier documents.

1.2.1 Witness or hold points for independent inspections shall be established when national code requirements for inspection are imposed or when deemed necessary. Required mandatory inspection hold points shall be clearly indicated in the ITI or other applicable documents.

1.2.2 A Craft Services Department Quality Control Requirements (QCR) form (see PAP-70-404, Obtaining Services) shall be prepared to identify independent inspection requirements in accordance with the applicable drawings, specifications, codes, and standards when Craft Services is to perform the work.

1.2.3 An Inspection Test Instruction (ITI), or equivalent, shall be prepared in accordance with PAP-70-702, Preparation and Use of Inspection/Test Instructions, for all independent inspections of more than one characteristic per hold point.

1.2.4 Other work authorizing documents and inspection documents may be used when organizations other than PNL Craft Services or a PQE are responsible for performing the work or inspections.

1.2.5 When a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices and referenced on the inspection documents.

1.2.6 ~~When the inspection is not a final inspection of an item, the configuration of the item at the time of the inspection shall be documented.~~

1.3 During planning, Requesters who have identified the need for an independent inspection shall forward one copy of the document(s) identifying this need (e.g., ITI, QCR, QA Plan, PR) to the Lead PQE.

2.0 Independent Inspection Personnel

2.1 Upon request, the PNL Lead PQE shall provide and schedule independent inspection personnel to perform inspections.

2.2 Requesters shall request from the Lead PQE, in writing, any exceptions taken to use independent inspectors who are not certified in accordance with PAP-70-203, Qualification and Certification of Inspection and Test Personnel, and/or do not report to the PQ Manager.

2.3 The Lead PQE shall approve, in writing, any exceptions made to use non-certified and/or non-PQ personnel to perform independent inspections and shall maintain such documentation as a generic record of the Process Quality Department.

3.0 Independent Inspection Performance

3.1 Whenever possible, the Cognizant Staff responsible for performing the work shall notify the a PQE or the designated inspection agency at least one full working day before an inspection hold or witness point is reached.

3.2 The PQ Representative or other designated inspector shall:

- perform the prescribed inspection(s)
-

NOTE: If an inspection hold point can not be honored, consent to waive the hold point shall be obtained from the Requisitioner and Cognizant QE and recorded on the inspection document prior to continuation of work beyond the hold point.

- identify on the inspection document the measuring and test equipment used
- evaluate the actual result(s) against acceptance criteria to determine acceptability and indicate the result of the evaluation on the inspection document
- report any nonconformances on the inspection document and initiate a nonconformance report per PAP-70-1501, Nonconformance Reports
- ensure that all characteristics requiring inspection have been inspected and any required NCRs are initiated before signing and dating the inspection document
- attach status indicators to the item(s), when applicable.

3.3 The PQ Representative (or other designated inspector) shall ensure that the inspection documents (Paragraph 1.2) are completed and transmitted to:

- Requester (record copy)
- Cognizant Quality Engineer (information copy)
- PQ's supplier history file (for supplier items).

4.0 Final Acceptance

When independent inspections are used for final acceptance, the PQ Representative shall ensure that the records of any prior inspections have been reviewed and that any nonconformances have been identified and resolved.

5.0 Activities After Final Acceptance

Requesters and PQ Representatives shall ensure that appropriate re-inspections are required and performed, if modifications, repairs, or replacements of items occur after final independent inspection is completed and before delivery or turnover of the items.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- approvals for use of non-certified or non-PQ personnel to perform independent inspections
- completed inspection documents.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

INDEPENDENT INSPECTION GUIDE

ACTIVITY	INSPECTION MODE	FREQUENCY	PLANNING	METHOD
R&D system/equipment repair, rework, installation, or modification	In-process Inspection	As required on work authorizing or engineering documents or determined by Requester/QE (see Paragraph 1.1)	Determined during preparation or work authorizing or engineering documents by staff with review by QE	Performed to an ITI or equivalent per PAP-70-702
	Final Inspection	Before acceptance or use of the item		
Craft Services preventive maintenance that requires NDE or Independent Inspection	In-service Inspection	As required by the PM Procedure or determined by Requester/QE (see Paragraph 1.1)	Determined during preparation of work authorizing documents by staff with review by QE	Performed to NDE Procedure/Report, ITI, or equivalent per PAP-70-702
SSCs, fabrication, installation, repair, rework, replacement, modification, etc.	In-process Inspection	As required on work authorizing or engineering documents or determined by Requester/QE (see Paragraph 1.1)	Determined during preparation of work authorizing or engineering documents by staff with review by QE	Witness on governing document inspection performed to an ITI or equivalent per PAP-70-702
	Final Inspection	Before acceptance or use of the item		
Production of items requiring inspection by PNL for clients	In-process Inspection	As required by the governing procedure or work authorizing or engineering document	Determined during preparation of work authorizing or engineering documents by staff with QE review	Performed to an ITI or equivalent per PAP-70-702
	Final Inspection	Before acceptance or use of the item		

NOTE: Receiving/Source Inspection shall be applied, when appropriate. Minimum requirements are defined in PAP-70-401.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-1101, TEST PLANNING, PERFORMANCE, AND EVALUATION

PURPOSE

Describe the methods for planning tests; preparing Technical Procedures and Test Instructions; and performing, documenting, and evaluating the tests and resulting data (including data acquisition test) to provide a high level of confidence in the test results.

APPLICABILITY

This procedure shall apply to testing of materials or processes (other than receiving inspection of items) to verify conformance to specified requirements, to demonstrate that items will perform satisfactorily, or to acquire data.

The method for preparation, review, and use of Inspection/Test Instructions (ITIs) for inspection of material and/or testing of items is covered in PAP-70-702, Preparation and Use of Inspection/Test Instructions.

Independent Technical Reviews are performed in accordance with PAP-70-604, Independent Technical Review. The method of performing Peer Reviews is covered in PAP-70-606, Peer Review.

The method for preparing calibration procedures is described in PAP-70-1201, Calibration Control System.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Author
- Cognizant Quality Engineer
- Cognizant Staff Member
- Evaluator
- Project Manager.

IMPLEMENTATION

1.0 Project Planning

1.1 The Project Manager or designee shall include in the research project or service planning document (PMP, TPP, SOW, etc.) a description of the planned testing efforts.

1.2 The Project Manager shall evaluate the elements of the test program required and determine if the testing will be an individually planned and executed test(s) or a series of repetitive tests with variation in parameters. EXHIBIT 1, Test Flow, is provided as an assistance in the test planning.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah
JE McGarrah 6/16/94

JE McGarrah
JE McGarrah, Manager 6/20/94

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-1101

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 2 OF 4

1.2.1 When an individually planned and executed test(s) is to be conducted, an individual test plan(s) may be utilized. The test plan(s) shall contain all the required test procedure and parameter requirements. Existing technical procedures may be referenced.

1.2.2 When a repetitive series of tests is required, technical procedures shall be used with individual parameters identified by test instructions, as applicable.

1.3 The Cognizant Quality Engineer shall review all research project planning documents to ensure that the appropriate QA Program requirements are included.

2.0 Test Plans

2.1 The Project Manager shall designate an author to write the Test Plan when one is to be utilized. The content of each Test Plan will depend on the scope of the test. EXHIBIT 2, Test Plan Content, provides a description of the required content of a Test Plan.

2.2 Specific requirements for the review, including, if appropriate, an Independent Technical Review, and approval of Test Plans should be given in the Project QA Plan. An Independent Technical Review in accordance with PAP-70-604 should be used when a multi-disciplinary review is needed (e.g., chemical and physical effect of material compatibility to be used). If no approval requirements are given, the Project Manager shall approve the Test Plan. Depending upon project requirements, concurrence by Facilities Engineering, Health and Safety, Radiation Protection, Quality Programs, and/or others may be required.

2.3 Test Plans shall be approved prior to the beginning of the test and shall be available at the test location throughout the performance of the test.

3.0 Technical Procedures and Instructions

3.1 The Project Manager shall ensure that the required Technical Procedures are identified, that authors assigned to prepare procedures are technically competent in area covered by the procedures, and that the procedures define the methods of gathering information. Technical Procedures are prepared and approved in accordance with EXHIBIT 3, Preparation, Review, and Approval of Technical Procedures.

3.2 The Project Manager shall ensure that, when required, Test Instructions are prepared, approved and revised in accordance with the applicable Technical Procedure. Test Instructions shall:

- define and document specific tests
- include specific instructions (parameters to be measured, variable requirements, etc.)
- remain at the work location throughout the performance of the test
- be complete to the extent that another qualified individual may, at a later date, reproduce the test results
- define the required documentation of results
- not circumvent the requirements of the Technical Procedures.

3.3 When adequate instructions are provided to ensure the quality of the work, appropriate sections of related documents such as:

- ASTM methods
- supplier manuals
- equipment maintenance instructions
- approved drawings
- travelers with acceptance criteria

may be used in lieu of specially written test instructions. A complete reference to the appropriate documents shall be made in the supporting documentation (e.g., Laboratory Record Books [LRBs], Test Plans, Test Procedures).

4.0 Performance of Tests

4.1 Cognizant Staff Members shall:

- perform tests in accordance with the requirements and methods contained in the Test Plan, Technical Procedures, and applicable Test Instructions
- notify the Project Manager when the tests can not be conducted as specified in the Test Plan, Technical Procedures, Test Instructions, and other test specific manuals, procedures, and instructions (including when material substitutions are required). When possible, the testing shall be stopped prior to deviating from the specified instructions. Once stopped, the test shall not be restarted until the condition causing the test stoppage is resolved or the instructions modified. If the test cannot be stopped, a Deficiency Report (DR) shall be written identifying the deviation from the instructions. No future tests shall be initiated until the condition causing the DR to be generated is resolved or the instructions modified.
- document the test results, or acquisition of data generated, in the manner specified in the Test Plan and/or Technical Procedure/Test Instructions
- when applicable, use a Test In Progress Tag as described in PAP-70-1401, Inspection and Testing Status and Tagging, to identify systems and components undergoing unattended tests where inadvertent operation could jeopardize test results, and on the back of the tag record the type of test, reason for the tag, and who to contact in an emergency.
- document on a Deficiency Report tests that are nonconforming in regard to:
 - the procedure followed
 - test results outside established limits
 - equipment malfunction or out of calibration.

4.2 The following shall be included in or traceable to the test results documentation (usually by entry in the LRB, Test Instruction, or Data Sheet):

- identification of standards used
- identification of M&TE (measuring and test equipment) used
- identification of procedures used
- identification of the material, item, or process tested
- test date
- type of observation(s)
- test results acceptability
- action taken with respect to any identified unexpected results, discrepancies, and nonconformances
- signature and date of the person evaluating the data or results for conformance to acceptance criteria
- signature and date of person who performed the work/recorded the data.

5.0 Test Result Evaluation

5.1 The Project Manager shall ensure that the test results and data are evaluated.

5.1.1 In addition to evaluations performed by the researcher, evaluation shall be performed by an Evaluator who has the technical expertise to perform the evaluation, but was not the principal investigator associated with the test or the documentation being reviewed.

5.1.2 The Evaluator shall document the evaluation by dated signature on the test results documentation.

5.2 If no deficiencies or unexpected results are observed, the test results documentation shall be transmitted to the Project Manager for final action in accordance with Subsection 6.0.

PNL ADMINISTRATIVE PROCEDURE

- 5.3 In the event deficiencies are found in the data, records, or methods, or unexpected results occur, the Cognizant Staff Member shall investigate to determine the cause.
- 5.3.1 When the cause is failure to follow the test plan or technical procedure or the cause (after investigation) is unassignable, the Cognizant Staff Member shall initiate a Deficiency Report and transmit it to the Project Manager for disposition.
- 5.3.2 When the cause is traceable to a nonconforming item or sample, the Cognizant Staff Member shall initiate a Nonconformance Report and transmit it to the Project Manager for disposition.
- 5.4 The Project Manager upon notification of testing deficiencies or unexpected results, using as a basis the overall objectives of the project and when possible the Statement of Work, shall make a determination as to the usability of the test results and/or data.
- 5.4.1 If the data are determined to be usable in existing form, pertinent individuals, including the client when appropriate, shall be notified in writing noting that the data were questioned but found to be usable.
- 5.4.2 If the data are not usable, the Project Manager shall determine appropriate action to be taken, (e.g., design a new test, revise the existing procedure, repeat the test, report the test as it exists with appropriate disclaimers).

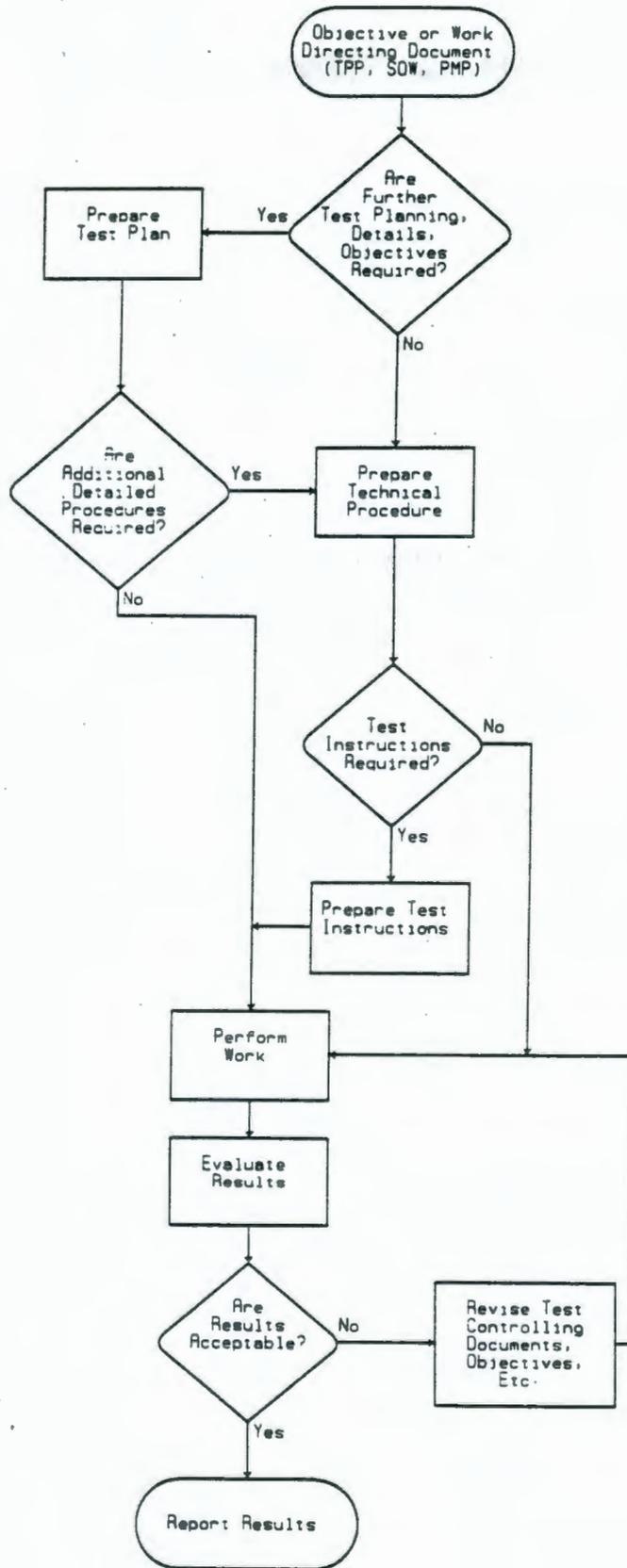
6.0 Reporting Results

- 6.1 The Project Manager or designee shall prepare a formal report when required, incorporating the data resulting from performance of the test, and conclusions drawn from evaluation of the test data.
- 6.2 The Project Manager is responsible for ensuring that adequate technical reviews are conducted of delivered products. Technical reviews on scientific or technical information, such as letter and topical reports, and final research reports are accomplished as follows:
- Independent Technical Reviews (ITRs) in accordance with PAP-70-604 are required for Impact Level I deliverables.
 - Less formal technical reviews, documented via the normal clearance process, by approval signature on transmittal letter, or other documented and traceable means, are required for Impact Level II deliverables.
 - At the direction of the Project Manager a Peer Review (PAP-70-606) may be required instead of either of the reviews described above.
- 6.3 The Project Manager shall process all records that provide objective evidence of test planning, performance, and evaluation as Project Records.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- Data Sheets
 - Formal Reports
 - Technical (Test) Procedures
 - Test Instructions
 - Test Plan (run plans).
-



Example Only. Other test planning configurations may be used.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TEST PLAN CONTENT

1.0 INTRODUCTION

This exhibit is intended to provide a brief description of the content of a Test Plan.

2.0 RESPONSIBILITIES

The Project Manager shall assign personnel to conduct the required testing and provide the necessary plans and procedures.

3.0 PROCEDURE

3.1 Each Test Plan shall contain:

- a title and/or number including date or revision
- signatures and date of the preparer and approval authority
- sufficient information to provide traceability to the project or task authorizing the test
- individual page identification that includes:
 - title or number
 - date or revision
 - page ___ of ___.

3.2 The content of each Test Plan will depend on the scope of the test. The following are items to be considered in the preparation of a Test Plan:

- Objective - Provide a short narrative on the purpose of the experiment/test/activity.
- Scope - Provide information either as a narrative or in graphic form to identify the experimental constraints and the information to be collected.
- Prerequisites of the test:
 - Personnel Qualifications - Do the participants need special training?
 - Safety - What items are safety related and what precautions should be taken?
 - Measuring & Test Equipment (M&TE) - What measurements are critical to the test and what specific M&TE will be used to make the measurements. Include the accuracy and precision required for each instrument.
 - Pretest Verification - Evaluate the need to verify certain items of a test prior to their use and indicate how the verification will be done.
- Expected Results/Acceptance Criteria - Summarize the expected results of the test and provide some criteria to use in judging the acceptability of the data. It is not necessary that these always be specific values, for some tests general trends or indications are all that is necessary.
- Documentation - Describe where the data collected during the test should be documented.
- Test Modifications - Describe how modifications to the Test Plan are to be documented and who has the authority to make modifications.

- Data Review - Describe when the data will be reviewed and who is responsible for data review.
- Provide instructions in enough detail that one familiar with the techniques and equipment would be able to repeat the work.
- Consider referencing other procedures and manuals at the appropriate steps in the test.

PREPARATION, REVIEW, AND APPROVAL OF TECHNICAL PROCEDURES

1.0 Preparation

The Author is responsible for:

- developing the Technical Procedure (TP) using the format and content guidance provided on pages 3 and 4 of this exhibit
- ensuring that the TP satisfies applicable requirements from governing documents

NOTE: When a procedural provision would be contrary to a governing document, but the Project Manager agrees that the provision is needed, the Author is responsible for obtaining or preparing corresponding changes to the governing document. The procedure shall not be issued until the governing document has been changed.

- ensuring that procedures are sufficiently detailed so an individual experienced in the technology, involved in the procedure, can perform the required functions without direct supervision
- ensuring that prerequisites (e.g., operational, testing, training, etc.) that need to be verified are identified and completion sign-offs required
- ensuring that TPs include or reference appropriate qualitative or quantitative acceptance criteria for determining that the prescribed activities have been satisfactorily accomplished
- ensuring that revisions incorporate all outstanding changes that are still applicable. These include both approved and issued Interim Change Notices (ICNs) and any accumulated unissued requests for change. Changes are identified by redlining or by a vertical line in the right margin, of the procedure, next to the change(s).

2.0 Review

- 2.1 The Author may obtain preliminary reviews of draft TPs as necessary and incorporate the comments as appropriate before entering the formal review process.
- 2.2 The Author is responsible for ensuring:
 - that the TP has been qualified in accordance with PAP-70-901, Control of Processes, or PAP-70-902, Control of Special Processes, when required by these procedures
 - that the procedure is submitted for client review and approval, when required by the client, in accordance with PAP-70-101, Communication and Commitment (Interface) Control. Resolutions to comments provided by the client are documented.
- 2.3 The formal review process differs for Impact Level I and II TPs as described below:
 - The Author is responsible for obtaining an Independent Technical Review (ITR) in accordance with PAP-70-604, Independent Technical Reviews, for Impact Level I TPs and, when the need is identified by the Project Manager, for Impact Level II or Safety Class systems, structures or components TPs.
 - The Author is responsible for obtaining a review by one or more technically competent persons and by the Cognizant Quality Engineer for Impact Level II and Safety Class systems, structures, and components TPs.

- For Impact Level I and II and Safety Class systems, structures, or components the Author is responsible for revising the procedures in accordance with accepted comments. When the author and reviewer fail to agree on comment resolution, the Author is responsible for obtaining direction on the matter from the Cognizant Manager.

3.0 Approval and Distribution

3.1 All TPs require document approval signatures on the cover page. Approvals (obtained by the Author) are as follows:

- the Author - for content and adequacy of TP
- the Cognizant Line Manager - for ensuring adequate resources needed to implement the TP are available.
- the Technical Reviewer - for technical adequacy of TP
- the QP Representative - for verifying that the TP was prepared in accordance with QA requirements and that it includes appropriate QA requirements.

3.2 The Author is responsible for:

- assigning the effective date of the TP (on or before the start of work). If it becomes necessary to release a TP for use before the reviews and approvals have been completed, the Project Manager authorizes the release by a memo attached to the TP.

NOTE: Direction to clearly identify that a TP is **unapproved shall be provided to the agency or individual responsible** for control of the documents.

When such a document is approved the Project Manager or Author notifies Document Control (DC) and an approved copy is submitted.

- ensuring the TP is distributed in accordance with PAP-70-601, Document Control.

4.0 Changes to Technical Procedures

The Author assures that:

- interim changes to TPs are processed in accordance with PAP-70-602, Procedure and Instruction Change Control and Change Request
- revisions to TPs are processed in accordance with this exhibit.

PROCEDURE FORM AND FORMAT REQUIREMENTS (First Page)

(TYPE OF PROCEDURE)			
TITLE: (INCLUDE UNIQUE NUMBER)			
<u>DESCRIPTION OF PROCEDURE SECTION CONTENT</u>			
<p>Technical Procedures issued by PNL shall consist of a minimum of four sections. Each of the four sections listed below shall be addressed in the procedure. Other sections may be added as appropriate.</p>			
<u>APPLICABILITY</u>			
<p>Start the first paragraph of this section with a statement such as:</p> <p>"This procedure applies to..." or "This procedure describes..." or "This procedure provides..."</p> <p>The remainder of the above statement should be a description of the activities and types of analyses to which the procedure is addressed.</p> <p>Describe any limitations on the use of the procedure in clear enough terms that an experienced staff member can easily determine when the procedure is required for implementation.</p>			
<u>DEFINITIONS</u>			
<p>Define words or phrases that have special meaning.</p>			
<u>RESPONSIBLE STAFF</u>			
<p>List the positions that have responsibilities within this procedure. Do not list the details for each position.</p>			
<u>PROCEDURE</u>			
<p>Provide step-by-step instructions in the sequence necessary to achieve the objective(s) of the procedure. Each step should be as simple as possible but with sufficient detail so as to be clear to an individual experienced in the technology involved in the procedure. When applicable, this section shall include:</p> <p>a. prerequisites (e.g., operational, testing, training) that need to be verified and have completion sign-offs</p> <p>b. applicable standard methods of analysis, industrial standards, and specifications (may be by reference)</p>			
Author	Date	Project Mgr.	QP Representative
			Date
Technical	Date	Line Mgr.	Other
			Date
Procedure No.	Revision No.	Effective Date	Page of

This form is the preferred method for documenting information. However, alternate methods may be used provided that the content and method of processing is consistent with this procedure.

PROCEDURE FORM AND FORMAT REQUIREMENTS (Second Page)

(TYPE OF PROCEDURE)

- c. step-by-step instructions (List in required sequence, using one instruction per step. Identify any alternate sequences that can be allowed. Capitalize and underline the title of the person who has responsibility for the action.)
- d. references to other procedures at the procedural step to which they apply
- e. references to operating manual(s) for instruments/equipment at the procedural step for which they apply
- f. description of tolerance for measured values (e.g., weight, volume, temperature, pressure, etc.)
- g. methods for controlling the handling, storage, cleaning, packaging, shipping, and preservation of items such as samples, geologic specimens, and magnetic media in order to prevent damage, loss, or deterioration
- h. description of the methods of recording data and test results. When a data sheet is used, include an exhibit in the procedure. Data sheets and other methods of recording data and test results shall identify the following as applicable:
 - test article configuration
 - test material used and their source (if known)
 - test or analysis performed
 - date of test or analysis
 - measuring and test equipment and data recorders used
 - test procedure used
 - type of observations (i.e., direct measurement, computer analyzed data, description of results based upon visual scrutiny, etc.)
 - results of the test or analysis and the acceptability of the results
 - action taken in connection with any deviations noted
 - person(s) performing the analysis
 - person evaluating the test or analytical results.
- i. description of the methods for analyzing results, and calculations to be used
- j. quantitative and qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished (limits for control values, etc.), or other means by which the validity of the data may be determined
- k. calibration requirements applicable to the data acquisition systems or operation which are followed
- l. holdpoints and witness points.

Procedure No.	Revision No.	Effective Date	Page	of
---------------	--------------	----------------	------	----

This form is the preferred method for documenting information. However, alternate methods may be used provided that the content and method of processing is consistent with this procedure.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-1201, CALIBRATION CONTROL SYSTEM

PURPOSE

Establish a uniform method for ensuring that measurements are not compromised by the use of defective or out-of-tolerance measuring and test equipment (M&TE).

APPLICABILITY

This procedure applies to M&TE (see Definitions section) with the following exceptions and limitations:

- radiation detection M&TE calibrated by the Instrument Calibration and Evaluation Section is covered by PAP-70-1202, Calibration Control System For Radiation Detection Equipment.
- devices such as watches, rulers, tape measures, and levels are not covered by the procedure if normal commercial practices provide adequate accuracy for the application
- M&TE used for indication only, shop aids, or trouble-shooting (Category 3) is only covered by the requirements related to assigning a category and labeling. This type of M&TE is either labeled with a Category 3 label or not labeled at all.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Calibrator (of M&TE)
- Cognizant Manager (see definitions)
- Cognizant Quality Engineer (QE)
- Cognizant Staff (normally the Calibrator or User of M&TE)
- Lead Procurement Quality Engineer (Lead PQE)
- M&TE Custodian (appointed by Cognizant Manager)
- Task Leader
- User (of M&TE).

DEFINITIONS

Accuracy - The closeness of agreement between an observed or measured value and an accepted reference value. (Ref. Recommended practice, Medical Products and Pharmaceutical Industry Calibration Control System)

Category 1, 2, and 3 - The three tiers used to classify M&TE. Category 1 M&TE is calibrated by a Process Quality Department (PQD) evaluated metrology facility; Category 2 is calibrated by the using organization; and Category 3 does not require calibration.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

LM Worden 6/17/94

LM Worden

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JW McGarran

6/20/94

JW McGarran, Manager

PNL ADMINISTRATIVE PROCEDURE

Cognizant Manager - For this procedure, he or she is a management representative of Battelle, Pacific Northwest Laboratories (i.e., for research projects-the project manager, for calibration services-the line manager, for facilities-the facility manager, etc...). When the Cognizant Manager is unavailable, responsibility reverts to the written delegated representative.

Measuring and Test Equipment (M&TE) - Devices or systems used to calibrate, measure, gauge, test, inspect, or control in order to acquire research, development, test, or operational data or to determine compliance with design specifications or other technical requirements. M&TE includes installed process measuring or monitoring gauges and instrumentation used for non-data purposes.

Precision - The degree of mutual agreement between repeated independent measurements of a single quantity under specified conditions. (Ref. IEEE Std 498-1990)

Resolution - The quality of an instrument scale or readout being exactly or sharply defined or stated. (Ref. IEEE Std 498-1990)

Tolerance - The allowable deviation from a specified or true value. (Ref. IEEE Std 498-1990)

GENERAL

The only requirements in the procedure that apply to Category 3 M&TE are presented in paragraphs 1.2 and 4.3. All requirements apply to Category 1 and Category 2 M&TE unless noted before the requirement.

Calibration Labels, CDT Forms, and Waiver of Calibration Forms may be obtained from the Cognizant QE or the Lead PQE.

IMPLEMENTATION

1.0 M&TE Selection and Category Assignment

- 1.1 The Cognizant Manager shall ensure that each unit or system of M&TE used by his/her organization is of the proper type, range, accuracy, tolerance, precision, resolution, and reliability to accomplish its intended function.
- 1.2 The Cognizant Manager shall ensure that each unit or system of M&TE used by his/her organization is correctly assigned one of the three categories described below:
 - Category 1: M&TE that is or will be calibrated by a PQD evaluated metrology facility, such as Westinghouse Hanford Corporation (WHC) Standards Laboratory, PNL Craft Services, original equipment manufacturer, etc. (see EXHIBIT 1, Recommended Calibration Intervals, for examples)
 - Category 2: M&TE that is or will be calibrated by the User. This category is limited to the types of M&TE that are normally calibrated by the User over a limited range for a particular application. This equipment often requires (1) calibration or performance check before use and (2) a performance check after use, when equipment stability or other factors merit it appropriate. Examples of Category 2 M&TE include:
 - gas chromatographs
 - hydrogen analyzers
 - mass spectrometers
 - spectrophotometers
 - pH meters
 - ICP systems.

- Category 3: M&TE that does not require calibration because the M&TE will be used for indication only, as a shop aid, or for trouble-shooting.

2.0 Calibration Intervals, M&TE Control Listing, and Preventive Maintenance

2.1 The Cognizant Manager shall establish a calibration interval for each M&TE unit or system. The following factors should be considered for use in the determination of the calibration interval:

- type of equipment
- calibration history
- the manufacturer's recommendations
- stability characteristics, purpose, degree of usage, accuracy, and other conditions that could affect a measurement
- Category 1: the recommended calibration interval listing in EXHIBIT 1, Recommended Calibration Intervals
- Category 1: recommendations from WHC Standards Laboratory.

2.2 The Cognizant Manager shall assign an M&TE Custodian to prepare an M&TE Control Listing in accordance with EXHIBIT 2.

NOTE: The purpose of this listing is to help ensure that the appropriate M&TE is properly controlled and to provide a basis for scheduling or recalling such equipment for maintenance/calibration based on the calibration intervals established in the previous paragraph. Thus, the complete listing may consist of recall listings provided by the WHC Standards Laboratory, Craft Services, and/or other PQD Evaluated Suppliers, provided they meet the intent of EXHIBIT 2.

Listing of Category 2 M&TE is not required for equipment that is calibrated or performance checked before use and performance checked after each use in order to perform the analysis or experiment and use of the M&TE is adequately controlled by procedures or the QA Plan.

2.3 The Cognizant Manager or Task Leader shall approve the M&TE Control Listing and have it distributed to:

- appropriate project or activity files
- users of the listed M&TE
- the line manager (facility related M&TE only).

2.4 The Cognizant Manager shall ensure that the M&TE Control Listing is kept current (e.g., changes are red-lined, initialed, and dated) and, as a minimum, updated on an annual basis.

2.5 Before a planned departure from calibration control requirements (e.g., an extended calibration interval), Cognizant Staff shall initiate a Waiver of Calibration (EXHIBIT 3) form and shall obtain approval of the Cognizant Manager and the Cognizant QE or Lead Procurement Quality Engineer (Lead PQE). A label (or note) should be placed adjacent to the calibration label (or similar method used) which refers to any outstanding calibration waiver(s). The Cognizant QE shall close out the waiver when corrective action is completed (or a new waiver issued) and distribute the waiver to the Project/Activity Files.

2.6 For M&TE used for environmental related work, the Cognizant Manager shall determine the need to apply preventive maintenance techniques (e.g., availability of critical spare parts) to M&TE that would otherwise

PNL ADMINISTRATIVE PROCEDURE

be subject to breakdowns that could lead to safety hazards, environmental contamination, or loss of completeness and accuracy in environmental data.

3.0 Calibration

3.1 Category 1: The Cognizant Manager shall obtain calibration services for M&TE from:

- PNL Craft Services, PNL Instrumentation Calibration and Evaluation Section, WHC Standards Laboratory, or other PQD-evaluated PNL or Hanford Contractor calibrating agency (see PAP-70-404, Obtaining Services)
- A PQD-evaluated supplier or subcontractor (see PAP-70-401, Purchase Requisitions).

3.2 The Cognizant Manager shall ensure that equipment is calibrated when the M&TE is used:

- to collect data that is reportable, affects the experimental results, or affects the quality of the design of engineered items/systems
- to control or monitor any process parameter(s) which (1) influences the quality of an item's characteristics (e.g., heat treatment) or 2) sets off safety-related alarms
- to determine conformance to specified requirements (e.g., for receiving, in-process, final inspection/test, or acceptance/rejection of an item)
- as a standard for calibration of other M&TE.

3.3 Category 1: The Calibrator shall calibrate* the M&TE as specified below, or shall document exceptions on a limitations statement:

- over the entire range
- to accuracy limits established by the manufacturer
- under controlled environmental conditions, considering such factors as temperature, humidity, vibration, radio frequency interference, electromagnetic interference, dust, cleanliness, fumes, and voltage stability. When inaccuracy due to environmental effects cannot be avoided, compensating corrections shall be determined, recorded, and applied to the calibration made.

* NOTE: The Calibrator shall perform a precalibration "as-found" check and record the results before any required adjustments or repairs are made.

3.4 Category 1: The Calibrator shall use standards that have:

- ranges, precisions, and accuracies such that the M&TE can be calibrated and maintained within the required tolerances
 - accuracies as high as reasonably achievable and consistent with national standards. As a minimum, such standards shall have accuracies that are at least four times better than those of the M&TE being calibrated unless limited by state-of-the-art. When the accuracy is not four times better, the rationale for deviating from this requirement must be justified and documented.
 - an established history of stability
 - known valid and documented relationships to nationally recognized standards (National Institute of Standards and Technology or equivalent) or accepted values of natural physical constants. **If no**
-

nationally recognized standards exist, the acceptability of the calibration standard used shall be documented.

- been stored to prevent inadvertent use or exposure to hostile environments
- calibration records which include (1) a statement describing the measurement uncertainties or (2) a statement that the measurements are traceable to nationally recognized standards or accepted values of natural physical constants
- calibration records which are consistent with those of other M&TE, when the calibration standard is another M&TE (e.g., a digital voltmeter used for a standard must have calibration records consistent with the Category 1 record requirements of Section 5.0).

NOTE: Do not use Category 2 M&TE to calibrate Category 1 M&TE.

- 3.5 Category 1: To ensure calibration technique uniformity, the Calibrator shall use written calibration methods or procedures with documented approval by the manager of the calibration organization. The methods/procedures shall include, as a minimum, the following information:
- revision number or effective date
 - identity of the unit or system to be calibrated
 - calibration equipment and standards
 - sequence of operations
 - checks, tests, and measurements (including acceptance tolerances)
 - special instructions when necessary.
- 3.6 Category 1: If the "as-found" condition of the M&TE exceeds the calibration tolerance, the Calibrator shall initiate a Calibration Discrepancy Tag (CDT), and shall process the CDT as described in EXHIBIT 4. Unless otherwise directed by the M&TE Custodian, the Calibrator shall provide maintenance of M&TE, such as repairing, adjusting, and re-calibrating any M&TE found out of calibration.
- 3.7 Category 1: The Calibrator shall label the M&TE as described in Section 4.1 and shall provide the M&TE Custodian a copy of calibration records meeting the requirements of Section 5.2.
- 3.8 Category 2: The User normally calibrates M&TE, as follows:
- over a limited range
 - under environmental conditions suitable for the needed accuracy
 - using reference standards such as a standard gas or chemical
 - to a manufacturer's procedure or a documented scientific method.

4.0 Labels

- 4.1 Category 1: The Calibrator shall label the M&TE (see EXHIBIT 5, Calibration Labels for Use on Category 1 M&TE) to indicate:
- when calibrated
 - when next calibration is due
 - traceability to calibration records (control number)
 - responsible calibrator and organization (i.e., PNL)

PNL ADMINISTRATIVE PROCEDURE

- if a limited calibration (e.g., not fully calibrated to manufacturer's tolerances, not calibrated on all ranges) was or was not made

NOTE: WHC uses a separate label for limited calibrations.

- when a correction factor is applicable. The Calibrator shall describe the correction factor on a separate label and shall sign, date, and apply the label.

NOTE: When equipment is calibrated by the original equipment manufacturer or other off-site supplier, the M&TE Custodian shall transfer the applicable information from the M&TE Calibration Report and the supplier's label to a PNL Category 1 Label and apply the label to the equipment before it is put into use. The supplier's label may be left on the equipment provided PNL's label is adjacent to it.

- 4.2 Category 2: The Calibrator shall list the M&TE control/serial number (e.g., PNL Property #, manufacturer's serial #, or unique identifier) on a PNL Category 2 Label (EXHIBIT 6, Other PNL Calibration Labels) and shall apply the label to the M&TE. When a correction factor is applicable, the Calibrator shall describe the correction factor on a separate label (or reference a note) and sign and date it.
- 4.3 Category 3: Cognizant Staff may label Category 3 M&TE with a green label (see EXHIBIT 6, Other PNL Calibration Labels) or choose not to use a label.

NOTE: Category 1 and Category 2: One label (not including WHC's limited calibration label or a correction factor label) may be used to indicate the calibration status for M&TE calibrated as a complete system (e.g., counting systems, temperature measuring systems, etc.) provided:

- the label indicates that it represents a system
- the system is recalibrated whenever any equipment is reworked or replaced that affects system calibration.

5.0 Records

- 5.1 Category 1: The Cognizant Manager shall assign an M&TE Custodian to maintain M&TE documentation consistent with this procedure.

NOTE: PNL Craft Services is the M&TE Custodian for facility-related M&TE records identified on the M&TE Control Listing for each facility. Craft Services maintains these records and issues copies to the Cognizant Building Manager and other identified personnel.

- 5.2 Category 1: The M&TE Custodian shall ensure that, as a minimum, the documentation includes:

- identification of calibrating agency
- identification of M&TE calibrated (name, manufacturer, serial number, and, when applicable, the range)
- calibration tolerances
- date of calibration; next calibration due
- identification of calibration standard
- as-found readings*
- as completed (final) readings*

*NOTE: Ability to report as-found and final readings is dependent on the type of M&TE being calibrated and the method of calibration. Provide an explanation on the calibration record when "as-found" and "final" readings are not recorded.

- indication of acceptance or rejection
- calibration points that were verified

- signature, initials, or stamp impression of the person performing the calibration
- traceable path to nationally recognized standards. If no known standards exist, describe the basis for calibration
- procedure used, with the revision number or effective date
- compensating corrections for environmental effects (when applicable)
- limitations statement (when applicable)
- signature or stamp and date of a calibrating organization representative who was not directly involved in the actual calibration. This person shall evaluate the calibration results and verify, through review, that the calibration record accurately and completely identifies the items listed above.

5.3 Category 2: The User shall record Category 2 M&TE calibration information in a Laboratory Record Book, on a log sheet or a PNL Calibration Record (EXHIBIT 7), or by other methods traceable to the equipment and the data collected.

If the M&TE is calibrated each time it is used and the method of calibration is specified in the M&TE's operational technical procedure, the User shall:

- record calibration results with the corresponding data
- identify the standards used with the corresponding data
- maintain supporting documentation which identifies the accuracy of the standards and the traceability of the standards to nationally recognized standards (National Institute of Standards and Technology or equivalent) or accepted values of natural physical constants. **If no nationally recognized standards exist, the acceptability of the standards used shall be documented.**

If the M&TE is not calibrated each time it is used, the User shall maintain calibration documentation that includes the following:

- calibrator's name
- date calibration was performed
- date next calibration is due
- standards used
- accuracy of standards
- traceability of the standards to nationally recognized standards (National Institute of Standards and Technology or equivalent) or accepted values of natural physical constants. **If no nationally recognized standards exist, the acceptability of the standards used shall be documented.**
- as-found and final readings.

6.0 Use of M&TE

6.1 Before using M&TE, the User shall ensure that the M&TE:

- is properly labeled

PNL ADMINISTRATIVE PROCEDURE

- is within its calibration period
- has not been damaged or degraded
- is properly suited for the intended purpose.

6.2 The User should make performance checks (e.g., checking a balance with one weight) between calibrations to provide an assessment of the M&TE performance capability but not to take the place of calibration. The User should document performance checks using one or more of the following:

- Laboratory Records Books
- log sheets
- PNL Calibration Record Cards (EXHIBIT 7)
- other methods traceable to the equipment.

6.3 Cognizant Staff shall identify any calibration discrepancies on Category 1 M&TE and shall disposition them as described in Section 7.1. Cognizant Staff shall identify any calibration discrepancies on Category 2 M&TE and shall disposition them as described in Section 7.8. A calibration discrepancy exists when:

- The User notices that the M&TE is malfunctioning in a manner that could affect data accuracy.
- The M&TE is dropped, over-stressed, abused, or potentially damaged.
- The M&TE is used on a project or activity after it was due for calibration.
- The M&TE is modified or repaired and the M&TE has not been evaluated by the calibrator.
- The calibration date is past due on M&TE included in a process control system that affects the safe operation of a facility.
- The M&TE is found to be out-of-tolerance during a performance check.
- The calibration is suspect for any other reason.

6.4 The User shall ensure that an "as-found" calibration is performed after completion of a project or activity when:

- it is necessary to confirm that M&TE is still in calibration
- there has been a significant out-of-tolerance history with the subject M&TE
- directed by the client or another authorizing agency.

6.5 Cognizant Staff shall properly handle and store M&TE to maintain accuracy.

6.6 The Calibrator shall note out-of-tolerance conditions on the calibration report, but no calibration discrepancy tag needs to be written when this is the initial calibration on:

- newly purchased M&TE
- M&TE that has been formally suspended from service by PNL technical staff
- M&TE obtained from the loan pool.

7.0 Documenting and Processing Calibration Discrepancies

7.1 Category 1: Cognizant Staff that identifies a calibration discrepancy shall prevent further use of the M&TE until the condition has been resolved by initiating a Calibration Discrepancy Tag (CDT) and processing the CDT as described in EXHIBIT 4.

- 7.2 Category 1: When the M&TE Custodian receives a CDT that requires the M&TE to be sent for calibration, he/she shall:
- initiate the action required to have calibration of the M&TE validated (i.e., an as-found performed and the M&TE recalibrated if necessary)
 - document an evaluation of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested
 - follow up to ensure that the M&TE calibration is validated/recalibrated in a timely manner.

- 7.3 Category 1: The M&TE Custodian shall request the User(s) to evaluate the impact on data acquired from measurements made during the calibration period when he/she receives a report of an as-found calibration outside of specified tolerances.

NOTE: As-found discrepancies may be reported on a CDT, a Notice of Discrepancy from WHC, or a calibration report (normally through PNL's Lead PQE) from a subcontractor.

- 7.4 The User shall address "impact on data" where the data may be suspect and it is either impossible or impracticable to have as-found readings performed by a calibration agency.
- 7.5 Category 1: The User(s) shall evaluate the calibration discrepancy to determine if there was an impact on the data.

7.5.1 Category 1: When there is no impact on the data, the User shall:

- note on the form or the note that notified him/her of the discrepancy "no impact on data from ___ * ___ to ___ * ___" (* calibration period)
- sign and date the form or note
- send a copy to the M&TE custodian.

7.5.2 Category 1: When impact on the data has been determined or is suspect, the M&TE User shall:

- initiate a Deficiency Report (DR) (PAP-70-1502)
- note the DR number on the form or the note that notified him/her of the discrepancy
- sign and date the form or note and send a copy to the M&TE custodian.

One or more of the following should be considered as recommended corrective action when there has been an impact on data:

- downgrading the data as appropriate
- repeating the inspection or test on items previously inspected or tested
- qualifying the data in a manner acceptable to the client.

NOTE: Documented performance checks made by the User during a calibration period may be used as objective evidence to show that measurements were valid and to narrow the period of uncertainty during which suspect measurements were made.

- 7.6 Category 1: When the M&TE Custodian has received evaluation results from all Users, he/she shall send a copy of the completed forms or notes to the Lead PQE. If all evaluations are not received within 30 calendar days, the M&TE Custodian shall notify the Cognizant Manager.

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-1201

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 10 OF 10

7.7 Category 1: The Lead PQE shall compile a history of as-found data on each unit of M&TE that has an as-found calibration that is out of a specified tolerance. The Lead PQE shall evaluate the M&TE on a continual basis for optimization of calibration intervals. The User shall be contacted when there is a need for action.

7.8 Category 2: The User of discrepant M&TE shall initiate action to:

- correct the discrepancy
- keep the M&TE from being used until the discrepancy is corrected. If there are other users of the M&TE and the discrepancy cannot be resolved immediately, the User shall tag the M&TE to notify other Users (the hard copy of a CDT may be used) and shall notify the M&TE Custodian.
- determine if there has been any impact on previously taken data. Initiate a Deficiency Report (DR) in accordance with PAP-70-1502 if the data may have been impacted.
- note in the appropriate record (e.g., Laboratory Record Book) if there has been no impact on data
- notify the Cognizant Manager(s) if the data of the other Users may have been impacted.

7.9 Cognizant Managers shall ensure that:

- M&TE consistently found to be out-of-tolerance is evaluated for appropriate corrective action, such as repairing/replacing the M&TE or shortening the calibration interval. In limited situations, it may be appropriate to re-evaluate and loosen the original tolerance(s) set for the M&TE.
- A calibration is performed when the accuracy of M&TE is suspect.
- Users of discrepant M&TE evaluate the impact on their data and document the results of the evaluation as described in this procedure.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- M&TE Control Listing
 - Waiver of Calibration
 - Calibration procedures/methods
 - Equipment calibration
 - Records of calibration standards
 - PNL Calibration Record Card
 - Calibration Discrepancy Tag
 - WHC Standards Lab Notice of Discrepancy
 - Deficiency Report
 - Other documents that provide traceability (e.g., log sheets, logbooks, manufacturers' test reports).
-

RECOMMENDED CALIBRATION INTERVALS

M&TE	INTERVALS	M&TE	INTERVALS
Amplifiers	6-12 Months	Multimeter	12 Months
Anemometer, Set	12 Months	Multimeter, Digital	6-12 Months
Attenuator, Set	12 Months	Oscillator, Test	12 Months
Balances (Beam, Torsion, etc.)	1-12 Months (a)	Oscilloscope	6-12 Months
Barometers	12 Months	Oxygen Indicator	6 Months
Bar, Sine	12 Months	Photo Tachometer	12 Months
Bridges	12 Months	Plate, Sine Angle	12 Months
Calibrator, Pneumatic	6 Months	Plug-in (Scope)	12 Months
Caliper (Combination, Dial)	12 Months	Potentiometer	12 Months
Capacitors	12 Months	Power Supplies	6 Months
Controllers, Temperature	6 Months	Pyrometer, Heat-Probe Indicator	6-12 Months
Counter (Frequency, Preset, Stobotac)	12 Months	Pyrometer, Optical	6-12 Months
Dividers, Voltage	12 Months	Recorder, Volt/Amp	12 Months
Dynamometer	6 Months	Recorders (General)	6-12 Months
Electrometer	12 Months	Recorders (Oscillograph)	6-12 Months
End Measuring Rod	12 Months	Resistors Decade	6-12 Months
End Standards	12 Months	Resistors, (Fixed and Standard)	12 Months
Flow Meter	12 Months	Resistors, (Shunt)	24 Months
Force Measuring Device (Compression, Tension, Torque)	12 Months	Rotameter	12 Months
Gage Blocks	12 Months	Rotary Table	24 Months
Gage (Depth, Dial, Height, Pressure, Radius, Vacuum, Wire)	12 Months	Scale, Platform	12 Months
Gage, Plug (Multiple or Repeated Applications)	30 Days	Squares and Parallels	24 Months
Gage, Plug (Occasional or Exploratory Applications)	6 Months	Square (Precision, Steel)	12 Months
Gage, (thickness, Coating, Flaw Detector)	6 Months	Standard Cells	12 Months
Gaussmeter	6 Months	Surface Plates	12-24 Months
Generator (Pulse, Signal, Sine, Time Mark)	12 Months	Tester, Capacitance	12 Months
Hardness Checkers	12 Months	Tester, Insulation	12 Months
Hygrometer	6 Months	Tester, Tube	12 Months
Hygrothermograph	12 Months	Theodolite	12 Months
Indicator, Dial	12 Months	Thermometers	24 Months
Indicator, Temperature	6 Months	Thermometer, Digital	12 Months
Inductors	12 Months	Thread Wires	12-24 Months
Length (masters, Standard)	12 Months	Timer, General	12 Months
Level, Precision	12 Months	Velometer	12 Months
Manometer	12 Months	Vibration Analyzers, Meters	6-12 Months
Meter, Electronic/Electrical	6-12 Months	Voltmeter (AC/DC, Digital)	12 Months
Megger	12 Months	Weight, Metric	12-24 Months
Micrometer (Depth, In/Outside, Thread, Tube, V-Anvil)	1-12 Months (a)	Wrench, Torque	6-12 Months
Milliammeter, DC	12 Months		

(a) Interval depends on use rate.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

INSTRUCTIONS FOR USING THE M&TE CONTROL LISTING FORM

The following information is provided to clarify what is required for each column on the M&TE control Listing.

1. Control/Serial Number - For WHC calibrated M&TE, use the WHC Code #. For PNL calibrated M&TE use, in order of preference, property number, manufacturer's serial number, or assign a unique identifier.
2. Description including manufacturer's name and model number (e.g., TEK, 2225 Oscilloscope).
3. Location (where M&TE is used or stored - list the room number, building , and area).
4. Calibration Interval (e.g., 3 months, 12 months, 2 years, during use, etc...).
5. Custodian (e.g., individual responsible for controlling or maintaining the M&TE).
6. Calibration Agency (e.g., WHC, Craft Services, User).
7. Category
8. The Listing shall be considered complete after signature/date by the preparer and the appropriate Cognizant Manager or Task Leader.
9. Project/Activity Number (or the title if not numbered).
10. QA Plan Number (when applicable).

Battelle Pacific Northwest Laboratories	WAIVER OF CALIBRATION		
Initiator: _____ Signature	_____ Date	QA Plan Number:	
M&TE Nomenclature:			
M&TE Control Number:		Calibration Category:	
Location:			
Reason for Waiver:			
THIS PAGE INTENTIONALLY LEFT BLANK			
Period of Waiver:			
Remarks:			
QP Representative: _____			
Signature		Date	
Cognizant Mgr./Task Leader: _____			
Signature		Date	
Close out of Waiver:			
QP Representative: _____			
Signature		Date	
Distribution:	Project/Activity File	Cognizant QE	Other

This form is the preferred method for documenting information. However, alternate methods may be used provided that the content and method of processing is consistent with this procedure.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

**CALIBRATION DISCREPANCY TAG
EXAMPLE**

NOTE: The CDT originator may be the User, M&TE Custodian, or Calibrator.

No. <u>00000</u>
CALIBRATION DISCREPANCY
EQUIPMENT <u> 1 </u>
CONTROL NO. <u> 2 </u>
LOCATION <u> 3 </u>
DISCREPANCY <u> 4 </u>
By <u> 5 </u> Date <u> 6 </u>
Corrective Action <u> 7 </u>
By <u> 8 </u> Date <u> 9 </u>
BT-1060-050 (5-78)

ITEM	COPY	COMPLETED BY:	MAKE ENTRY as FOLLOWS:
1	Both	Originator	<u>EQUIPMENT</u> - Enter manufacturer, model number, and description of discrepant M&TE.
2	Both	Originator	<u>CONTROL NUMBER</u> - Enter property control number or manufacturer's serial number or <u>unique identifier</u> .
3	Both	Originator	<u>LOCATION</u> - Give location of M&TE; (e.g., BLDG., 324, Rm. 125).
4	Both	Originator	<u>DISCREPANCY</u> - Provide concise explanation of discrepancy, including actual out-of-calibration values when appropriate and date calibration was due if calibration has elapsed.
5	Both	Originator	<u>BY</u> - Signature of Originator
6	Both	Originator	<u>DATE</u> - Enter date tag is initiated.

If the CDT is being prepared (normally by Craft Services) because the as-found is out-of-calibration tolerances, the Calibrator:

- a. Attaches the hard copy to the M&TE.
- b. Routes the original to the M&TE Custodian.
- c. Routes a copy of the original to the Process Quality Lead Procurement Quality Engineer (Lead PQE)
- d. Completes 7, 8, and 9 on the hard copy as described below when corrective action is completed. (The hard copy may be retained by the calibrating organization).

<u>Item</u>	<u>Copy</u>	<u>Completed By</u>	<u>Make Entry as Follows:</u>
7	Hard	Calibrator	<u>CORRECTIVE ACTION</u> - Enter action taken to correct or validate discrepancy of M&TE; e.g., "Intermittent verified, defective solder joint repaired, and recalibrated."
8	Hard	Calibrator	<u>BY</u> - Signature of calibrator.
9	Hard	Calibrator	<u>DATE</u> - Enter date corrective action completed.

If the CDT is being prepared for reasons other than the as-found being out-of-calibration tolerances, the Originator:

- a. Attaches the hard copy to the M&TE.
- b. Completes 7,8, and 9 as described below, or if he/she is not the appropriate person to determine corrective action, has the appropriate person complete 7, 8, and 9.
- c. Routes the original to the M&TE Custodian.
- d. If the M&TE will not be sent to calibration, routes a copy of the original to the Process Quality Lead PQE.

<u>Item</u>	<u>Copy</u>	<u>Completed By</u>	<u>Make Entry as Follows:</u>
7	Both	Originator	<u>CORRECTIVE ACTION</u> - Enter action to be taken. Normally this will be: "Have the M&TE calibrated".
8	Both	Originator	<u>BY</u> - Signature of originator (or person determining corrective action).
9	Both	Originator	<u>DATE</u> - Date corrective action determined.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

EXAMPLES OF
CALIBRATION LABELS FOR USE ON CATEGORY 1 M&TE

WHC STANDARDS LAB	PNL
-------------------	-----

(White with Black letters)

CALIBRATION	
Code _____	
Date _____	By _____
Expires _____	
WHC Hartford Standards Laboratory 54-7310-036 (11/87)	

(Yellow with Black letters)
(Form BD-1060-034)

CALIB - PNL

EXPIRES _____

S/N _____

BY _____

DATE _____

LIMITATIONS:

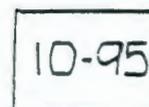
(Orange with Black letters)



1. Date that calibration expires (month and year).
2. Control/Serial Number (S/N) - use the property number or the manufacturer's serial number, or assign a unique identifier (choices are listed in order of preference).
3. Signature or initials of individual performing or responsible for calibration.
4. Date that calibration was performed (month and year).
5. Describe limitations (if any). If sufficient room is not provided to describe the limitation(s), reference the document (should be the calibration record) that describes the limitation).

Apply the label directly on the equipment and, when practical, in a visible location.

When it is not feasible to place a calibration label directly on the unit of M&TE, indicate the calibration status by affixing a 1/4" by 1/4" yellow square to the equipment and affixing the appropriate label to the box or other container where the equipment is stored. For example:



Color dots (1/4") are used on equipment when it is not feasible to use a label. The color of the dot will indicate the year in which calibration is due, and a number (1 through 12) typed in the dot will indicate the month of the year.

<u>YEAR</u>	<u>COLOR</u>
1993	Light Green
1994	Yellow
1995	White
1996	Red
1997	Light Green

Yellow - Indicates Category 1 M&TE that has calibration expiring in October 1995.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

INSTRUCTIONS FOR USE OF
OTHER PNL CALIBRATION LABELS

CATEGORY 2 M&TE CALIBRATION LABEL	CATEGORY 3 M&TE CALIBRATION LABEL
-----------------------------------	-----------------------------------

(White with Light Blue lettering)
(Form BL-1060-054)

(White with Green lettering)
(Form BL-1060-037)



Control/Serial Number (S/N) - use property number, manufacturer's serial identifier, or assign a unique identifier (choices listed in order of preference).

Apply the label in a visible location on the M&TE that is designated as Category 3. Category 3 M&TE will either have this label attached or have no label.

Apply the label in a visible location on the M&TE that is calibrated by the User. The use of Category 2 label identified above is required.

If Category 3 M&TE is labeled (labeling optional), use of the Category 3 label identified above is required. Alternate labels are not acceptable.

NOTE: When it is not feasible to place a calibration label directly on the unit of M&TE, indicate the calibration status by affixing a 1/4" by 1/4" **light blue** square to the equipment and the appropriate label to the box or other container where the equipment is stored.



Light Blue indicates Category 2 M&TE with calibration by User.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

CALIBRATION RECORD
EXAMPLE

		CALIBRATION RECORD			Calibration Control Number (S/N) [1]	
Description/Type [2]		Manufacturer [3]		Model No. [4]		Mfg. S/N [5]
Interval [6]		Significant Specification(s)/Accuracy [7]		Procedure/Method [8]		Custodian/Location [9]
Category	Date Calib.	Date Expires	Standards Used/Control or Traceability No.		Remarks - As Found-CDT No.	Calibrator
[10]	[11]	[12]	[13]		[14]	[15]

BD-1060-047 (5-78)

The PNL CALIBRATION RECORD SHALL BE PREPARED AS FOLLOWS:

ITEM MAKE ENTRY AS FOLLOWS:

- 1 CALIBRATION CONTROL NUMBER (S/N) - Enter calibration control number for the M&TE. Use property numbers, manufacturer's serial number, or assign a unique number (choices are listed in order of preference).
- 2 DESCRIPTION/TYPE - Enter type or description of M&TE, e.g., oscilloscope.
- 3 MANUFACTURER - Enter name of M&TE manufacturer.
- 4 MODEL NO. - Enter manufacturer's model number or designation.
- 5 MFG. S/N - Enter manufacturer's serial number.
- 6 INTERVAL - Enter established periodic calibration interval.
- 7 SIGNIFICANT SPECIFICATIONS/ACCURACY - enter the significant specification(s) and accuracy the M&TE is calibrated to (normally the manufacturer's specs.); e.g., voltage: $\pm 1\%$, current: $\pm 2\%$, resistance: $\pm 1.25\%$.
- 8 PROCEDURE/METHOD - Enter procedure number or method by which M&TE was calibrated. If manufacturer's manual is used, state "Manual".
- 9 CUSTODIAN/LOCATION - Enter name of person responsible for M&TE (the User) and/or the location of the M&TE.
- 10 CATEGORY - enter the assigned calibration category. Note the calibration category may change based on the application and use of the M&TE.
- 11 DATE CALIBRATED - Enter date calibration is completed.
- 12 DATE EXPIRES - Enter date calibration expires.
- 13 STANDARDS USED/CONTROL OR TRACEABILITY NO. - List standards used to perform calibration and control, serial or code numbers to provide traceability. (Normally WHC's Standards Code Number if standard is calibrated by WHC or PNL Calibration Control No. if standard is calibrated by PNL or others.)
- 14 REMARKS - AS FOUND - CDT NO. - State condition of M&TE "As Found". If M&TE is found within specified tolerances. It may be indicated by a check (\checkmark). If the M&TE is found out of tolerance, the number of the CDT that contains actual out of tolerance results shall be referenced. When used as a calibration report for each calibration - reviewer sigh/date.
- 15 CALIBRATOR - Signature of initials of the person performing and the person responsible for the calibration.

The card is one method of recording the required information. However, alternate methods are acceptable provided the information recorded is consistent with this procedure.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE

- Measuring and Test Equipment Standards - Devices or systems used as the reference standard during the calibration process. These M&TE are controlled in accordance with PAP-70-1201.
- Radiation Detection Measuring and Test Equipment (M&TE) - Radiation detection instruments that are calibrated by IC&E for use by Hanford staff to measure contamination levels or radiation fields for radiological control purposes.

GENERAL

All radiation detection M&TE calibrated by IC&E are considered Category 1 M&TE.

IMPLEMENTATION

1.0 Calibration Intervals and M&TE Database

- 1.1 The Manager, IC&E shall ensure that a calibration interval is established for each type of radiation detection M&TE unit or system. The following factors should be considered for use in the determination of the calibration interval:
 - type of equipment
 - calibration history
 - the manufacturer's recommendations
 - stability characteristics, purpose, degree of usage, accuracy, battery lifetime, and other conditions that could affect a measurement.
- 1.2 The Manager, IC&E shall ensure maintenance of a database of the radiation detection M&TE for which IC&E has the calibration responsibility. See Section 4.1 for minimum database and program record content. The database shall include the standards used by IC&E.
- 1.3 The Manager, IC&E shall ensure that the M&TE database is updated daily for each unit of M&TE calibrated during the day.
- 1.4 The Manager, IC&E shall ensure that users of the radiation detection M&TE are notified when their M&TE is past due for recalibration or maintenance.
- 1.5 Before a planned departure from calibration control requirements (e.g., an extended calibration interval), the Manager, IC&E shall initiate a Waiver of Calibration (EXHIBIT 1) form and shall obtain concurrence from the Cognizant QE. A label (or note) should be placed adjacent to the calibration label (or similar method used) which refers to any outstanding calibration waiver(s). The Cognizant QE shall close out the waiver when corrective action is completed (or a new waiver issued) and distribute the waiver to IC&E Record Files with a copy to the Lead Procurement Quality Engineer (Lead PQE).

2.0 Calibration

- 2.1 The Calibrator shall calibrate the M&TE as specified below, or shall document exceptions on a limitations statement:
 - over the entire range

- to accuracy limits established by the manufacturer or regulatory agencies
- under controlled environmental conditions, considering such factors as temperature, humidity, vibration, dust, cleanliness, fumes, voltage stability, and radio frequency/electromagnetic interference. Special care shall be applied to sources of radiation interference, such as backscatter and non-ionizing radiation to ensure they are minimized. When inaccuracy due to environmental effects cannot be avoided, compensating corrections shall be determined, recorded, and applied to the calibration made.

NOTE: If the instrument is in useable condition, the Calibrator shall perform a precalibration "as-found" check and record the results before any required adjustments or repairs are made.

2.2 The Calibrator shall use standards that have:

- sufficient range, accuracy, precision, resolution, reliability, and stability to ensure that the radiation detection M&TE can be properly calibrated and maintained within the required tolerances
- accuracies as high as reasonably achievable and consistent with national standards. Radiological calibration standards shall normally have accuracies that are at least four times better than those of the M&TE being calibrated (i.e., a 4:1 ratio). However, standard accuracies of less than a 4:1 ratio are acceptable if limited by state-of-the-art or supported by Measurement Assurance Programs. Such rationale for deviating from the 4:1 ratio shall be documented.
- known valid and documented relationships to nationally recognized standards (National Institute of Standards and Technology or equivalent) or accepted values of natural physical constants. **If no nationally recognized standards exist, the acceptability of the calibration standard used shall be documented.**
- been stored to prevent inadvertent and unsafe use or exposure to hostile environments
- records which include (1) a statement describing the measurement uncertainties or (2) a statement that the measurements are traceable to nationally recognized standards or accepted values of natural physical constants.

2.3 To ensure calibration technique uniformity, the Calibrator shall use the calibration procedures for portable instruments that are written, approved, and controlled by IC&E. The procedures shall include, as a minimum, the following information:

- revision number or effective date
- identity of the unit or system to be calibrated
- calibration frequency
- calibration equipment and standards
- sequence of operations
- checks, test, and measurements (including acceptance tolerances)
- special instructions when necessary.

2.4 When it is necessary to calibrate a type of instrument not currently covered by an established IC&E calibration procedure, the Calibrator shall use written calibration methods or procedures, manufacturer's written procedures, or shall document the calibration procedure in a PNL Laboratory Record Book (LRB). These alternative methods shall have documented approval by the Manager, IC&E.

2.5 The Calibrator shall label the M&TE as described in Section 3.0.

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-1202

REVISION NO.: 1

EFFECTIVE DATE: 02/10/95

PAGE 4 OF 6

- 2.6 If the "as-found" condition of the M&TE is found to be out of tolerance, the Calibrator shall implement the steps in Section 6.0.
- 2.7 The Calibrator shall send to Craft Services any M&TE that requires a battery change, maintenance, or repair. This should occur after the Calibrator has determined and recorded the "as-found" condition of the M&TE. Discrepant M&TE shall be handled in accordance with Section 6.0.
- 2.8 The Calibrator shall calibrate prior to use any M&TE that has received a battery change, preventative or corrective maintenance, or any adjustment other than zero adjustment.

3.0 Labels

The Calibrator shall label the M&TE (see Exhibit 2, Calibration Labels for Use on Category 1 M&TE) to indicate:

- when calibrated
- when next calibration is due
- traceability to calibration records (unique identifying number)
- responsible calibrator
- if a limited calibration (e.g., not fully calibrated to manufacturer's tolerances, not calibrated on all ranges) was or was not made
- when a correction factor is applicable, the Calibrator shall describe the correction factor on a separate label and shall sign, date, and apply the label to the M&TE.

NOTE: When special calibrations of M&TE (e.g., because the M&TE will be used for applications or circumstances that are other than that envisioned by the manufacturer) are performed, the Calibrator shall clearly label the M&TE to identify the special conditions under which it may be used.

4.0 Records

4.1 The Manager, IC&E shall ensure that records of the calibration for radiation detection M&TE are maintained as part of the IC&E program records, and as a minimum, includes the following information:

- identification of M&TE calibrated (name, manufacturer, model number, and serial number)
- calibration tolerances
- date of calibration; next calibration due
- identification of calibration standard(s)
- traceable path to nationally recognized standard(s). (If no known standard(s) exist, describe the basis for calibration.)
- as-found and final (as-left) readings

NOTE: Ability to report as-found and final readings is dependent on the type of M&TE being calibrated and the method of calibration. Provide an explanation on the calibration record when "as-found" and "as-left" readings are recorded as "zero". Explanation of "as-found" and "as-left"

readings for the instruments are available in the individual calibration procedures maintained by IC&E.

- indication of acceptance or rejection
- calibration points that were verified
- identification of the person performing the calibration
- procedure or method used, with the revision number or effective date
- compensating corrections for environmental effects (when applicable)
- maintenance and repair performed
- limitations statement (when applicable).

4.2 The Manager, IC&E, shall ensure that records are maintained for:

- additional tests and checks of instruments in conjunction with a suspected overexposure, questionable indication, or unusual occurrence
- special instrument calibrations as described in 3.0 NOTE.

5.0 Use of M&TE

5.1 Before using radiation and radioactive detection M&TE, the User shall ensure that the M&TE:

- is properly labeled
- is within its calibration period
- has not been damaged or degraded
- is properly suited for the intended purpose
- is suitable for the background and environmental conditions in the area used.

5.2 The User should make performance checks (e.g., checking against a radioactive source provided near or with the M&TE) between calibrations to provide an assessment of the M&TE performance capability but not to take the place of calibration. The User should document performance checks using one or more of the following:

- log sheets
- other methods traceable to the equipment.

5.3 The User shall identify any calibration discrepancies on radiation detection M&TE and shall disposition them as described in Section 6.0. A calibration discrepancy exists when:

- the User notices that the M&TE is malfunctioning (e.g., low battery condition)
- the M&TE is dropped, over-stressed, abused, or potentially damaged
- the M&TE is used after it was due for calibration
- the M&TE is modified or repaired and the M&TE has not been evaluated by the calibrator
- the calibration date is past due on M&TE included in a process control system that affects the safe operation of a facility
- the M&TE is found to be out-of-tolerance during a performance check
- the calibration is suspect for any other reason.

5.4 The User shall properly handle and store M&TE to maintain accuracy.

PNL ADMINISTRATIVE PROCEDURE

6.0 Documenting and Processing Calibration Discrepancies

- 6.1 The User of radiation detection M&TE shall return any discrepant M&TE to IC&E with an attached note describing the discrepancy. The hard copy of a Calibration Discrepancy Tag (CDT), see Exhibit 4 in PAP-70-1201, or the service tags shown in EXHIBIT 3 are the preferred methods.
- 6.2 The Manager, IC&E, shall ensure that the following steps are used in recording and reporting out-of-tolerance radiation monitoring M&TE.
 - 6.2.1 Determine if the out-of-tolerance condition is due to causes obvious to the user such as dead batteries, broken parts, moisture damage, etc.
 - 6.2.2 If the cause of the discrepant condition would not have been obvious to the user, determine if the as-found condition is within the range of $\pm 20\%$ of the expected value.
 - 6.2.3 If the M&TE calibration is found to be outside the $\pm 20\%$ range, record the as-found data, inform the organization that last used the M&TE by telephone, and send a follow-up letter with a copy to the cognizant Radiological Control and QA organizations. The User shall determine the impact.
 - 6.2.4 If the out-of-tolerance condition is inside the $\pm 20\%$ range or the cause of the out-of-tolerance condition would have been obvious to the User, record the results of the calibration in the M&TE database.
 - 6.2.5 M&TE that is repeatedly returned to IC&E in an out-of-tolerance condition shall be:
 - sent to Craft Services for refurbishment, or
 - replaced, or
 - assigned a shortened calibration interval.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- radiation detection M&TE database and program records
 - radiological calibration procedures
 - records of the calibration
 - records of calibration standards, including any documents that provide a traceability path to nationally recognized standards
 - waivers of calibration.
-

**THIS PAGE INTENTIONALLY
LEFT BLANK**

EXAMPLE

CALIBRATION LABEL FOR USE ON CATEGORY 1 M&TE CALIBRATED BY IC&E

YELLOW WITH BLACK LETTERING

(Form # BD-1060-034)

CALIB. - PNL	
EXPIRES	____ (1) ____
S/N	____ (2) ____
BY	____ (3) ____
DATE	____ (4) ____
LIMITATIONS:	
____ (5) ____	
BD-1060-034	

Make entry as follows:

1. Date that calibration expires (month and year).
2. A unique number assigned by the calibrating agency - e.g., use the equipment piece (EP) number, Property number, or the manufacturer's serial number.
3. Signature or initials of the individual performing or responsible for the calibration.
4. Date that the calibration was performed (month and year).
5. Describe limitations (if any). If sufficient room is not provided to describe the limitation(s), reference the document (should be the calibration record) that describes the limitation.

Apply the label directly on the equipment and, when practical, in a visible location.

When it is not feasible to place a calibration label directly on the unit of M&TE, indicate the calibration status by affixing a 1/4 in. by 1/4 in. yellow square to the equipment and affixing the appropriate label to the box or other container where the equipment is stored. FOR EXAMPLE:

10/95

YELLOW - Indicates Category 1 M&TE that has calibration expiring at the end of October 1995.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

EXAMPLES OF THE RADIATION DETECTION M&TE SERVICE TAGS

INSTRUMENT SERVICE TAG	
Inst. Number	Area/Bldg
REASONS INSTRUMENTS ARE TAGGED OUT (Circle Appropriate Reasons) <u>Malfunction or Failure</u>	
Will not go full scale close to source	Position sensitive
Will not zero	Intermittent response
Erratic needle	High response
No response	Battery check
Low batteries	Mechanical zero
Pins full scale	Reads without source
Switching transient	Alarm failure
Pins down scale	Low response beta
Low response	High response beta
Will not hold zero	Low response alpha
	High response alpha
<u>Damaged</u>	
Torn screen	Loose parts
Detector damage	Missing or broken ring (CP)
Case damage	Shield damage
Control damage	Disassembled for decontamination
Cord damage	
Comments	
[] Scheduled Calibration	
RADIATION RELEASE	
[] Conditional	[] Unconditional
RPT _____	
PR No. _____	Date _____

CAM SERVICE TAG	
Inst. Number	Area/Bldg
REASONS INSTRUMENTS ARE TAGGED OUT (Circle Appropriate Reasons) <u>Malfunction or Failure</u>	
Alarm Problem	Intermittent Response
Bell/Ceacon Problem	Low Response
Dead On Arrival	Needle Sticks
Erratic	No Response
Fail Circuit Problem	Recorder Problem
False Alarm	Requested Changes
Fullscale During Test	Spiking
High Response	Unknown
<u>Damaged</u>	
Broken Detector	Burned Out Light
Broken Needle	Disassembled for Decon
Broken Parts	Missing Parts
Comments	
[] Scheduled Calibration	
RADIATION RELEASE	
[] Limited	[] Unconditional
RPT _____	
PR No. _____	Date _____

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-1301, HANDLING, STORING, AND SHIPPING

PURPOSE

Establish procedures for handling, storing, and shipping to effectively protect items against damage or deterioration.

APPLICABILITY

This procedure applies to items, equipment, and materials that are subject to handling, storing, and shipping, including onsite transfers. This procedure is in addition to other procedures and manuals that provide for item security or for protection against radioactive or other hazardous materials.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Managers (as used in this procedure could be line or project manager, i.e., the responsible manager)
- Process Quality (PQ) Representatives (Quality Engineer).

GENERAL

When required, special equipment and special protective environments shall be provided. Directions shall provide for protection against such conditions as temperature extremes, humidity, dirt, dust, shock, and oxidation. Provisions for special protective environments shall be identified.

No special or unique written instructions are necessary when normal, routine handling, storing, and shipping methods are adequate.

Written instructions are required when factors such as fragility, cleanliness requirements, or susceptibility to temperature extremes or humidity may cause damage or deterioration to the item. Such instructions shall be included in procurement documents, drawings, or technical procedures. Storage instructions for items of limited shelf life, such as gaskets and latex gloves, shall provide for using the oldest items first.

Special technical procedures shall be provided for critical, sensitive, perishable, or high-value items, as applicable. Examples of when such procedures may be needed are:

- when handling operations or preparations for shipping or storing are complex and must be accomplished correctly and in sequence
- when periodic monitoring of storage conditions is required
- when verification by the PQ Representative is necessary.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

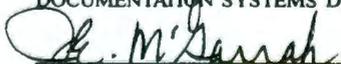
DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


RL Shaub

6/16/94


JE McGarran, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

When other manuals or procedures provide handling, storing, and shipping requirements and apply to an item or activity, they shall be incorporated by reference in the technical procedure or be supplemented as necessary. No technical procedure is required when the other manual or procedure is adequate by itself.

When special handling, storing, and shipping procedures are considered necessary for purchased items, the supplier shall be required by the procurement documents to provide these procedures for PNL's information or approval, as appropriate.

IMPLEMENTATION

1.0 Type of Directions Required

1.1 The Cognizant Manager shall determine what direction is required for the handling, storing, and shipping of individual items.

1.2 When special procedures are required, the Cognizant Manager shall have them prepared as Technical Procedures per PAP-70-1101, Test Planning, Performance, and Evaluation, and controlled per PAP-70-601, Document Control, and PAP-70-602, Procedure and Instruction Change Control and Change Request.

a. For special handling procedures:

- include requirements for any special handling tools and equipment. Inspect and test special handling tools and equipment at specified intervals to ensure proper functioning.
- require that operators of special handling equipment be experienced and trained in its use.

b. For special storing procedures, include appropriate requirements for special containers, protective environments, coatings, packing, and similar measures, as appropriate.

c. For special shipping procedures, include appropriate requirements for shipping containers, shock absorbers, load indicators, accelerometers, packing, desiccants, transport vehicles, and similar measures.

d. For all procedures, include requirements for any necessary marking, labeling, and verification of items to ensure proper handling, storing, or shipping.

1.3 The Cognizant Manager shall approve all special handling, storing, and shipping procedures.

2.0 Training and Performance of Work

2.1 The Cognizant Manager shall ensure procedure compliance by personnel performing the work. Special procedures shall be provided to the organization providing the services prior to the performance of the service.

2.2 Where no procedures are considered necessary for normal practices of handling, storing, or shipping; the Cognizant Manager shall provide verbal direction to personnel.

2.3 The Cognizant Manager shall provide training for operators of special handling tools and equipment and shall document the training. For experienced equipment operators, the Cognizant Manager shall document the qualifying experience in the training records.

3.0 Equipment Maintenance and Identification

9515558.2629
PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-1301

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

- 3.1 The Cognizant Manager shall ensure that special handling tools and equipment are maintained using a preventive maintenance schedule as appropriate. Tools and equipment shall be tested and inspected within specified intervals.
- 3.2 The Cognizant Manager shall ensure that items being stored or shipped, and equipment used in this process are marked or labeled as required by instructions or special procedures.

4.0 Verification

When requested, the Cognizant PO Representative shall provide documented, independent verification that requirements of special procedures are being implemented correctly, as applicable, and that requirements for special equipment and protective environments are provided and are being maintained.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- training records
 - documented qualifying experience.
-

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE
9513558-2630

PROCEDURE NO.: PAP-70-1401

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: PAP-70-1401, INSPECTION AND TESTING STATUS AND TAGGING

PURPOSE

Provide uniform methods for identifying the inspection, test, or operational status of items. Such identification methods are used to prevent the inadvertent installation, use, or operation of items that have not passed required inspection/test. Also, to provide methods to prevent inadvertent operation or shutdown of equipment that could jeopardize test results.

APPLICABILITY

This procedure applies to:

- purchased items requiring receiving inspection/test per PAP-70-706, Receiving Inspection
- items fabricated by PNL and inspected per PAP-70-1001, Independent Inspection
- facility installed or other items affecting operations or testing identified as nonconforming and for which PNL has responsibility
- items related to testing where inadvertent operation or shutdown of the equipment could jeopardize reportable test results.

Calibration labels and calibration discrepancy tags, which also indicate status, are addressed separately in PAP-70-1201, Calibration Control System.

Inspection or test status of items at supplier facilities is addressed in PAP-70-704, Source Inspections, Tests, and Surveillances.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- PNL Staff Members (PNL staff members, other than Process Quality personnel, who have a responsibility for the activities)
- Process Quality Department (PQ) Representative
- Procurement Quality Engineer (PQE).

DEFINITIONS

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

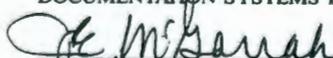
DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


RL Shaub

6/17/94


JE McGarrah, Manager

6/20/94

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-1401

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 2 OF 3

Item - For this procedure, the word "item" is limited to hardware (e.g., appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, units, etc.) and associated QA documentation.

GENERAL

Status indication or tagging is used to alert staff that:

- an item has not been inspected or tested, as required, and therefore, its quality is indeterminate
- an item is nonconforming
- the operation, shutdown, or use of an item may adversely affect in-process testing or operations
- an item has been inspected/tested as required and is acceptable for use.

Related PNL administrative procedures addressing identification of nonconforming conditions and proper indication of status are:

- PAP-70-706, Receiving Inspection
- PAP-70-1001, Independent Inspection
- PAP-70-1101, Test Planning, Performance, and Evaluation
- PAP-70-1501, Nonconformance Reports.

IMPLEMENTATION

1.0 Authority to Apply and Remove Status Tags

The person initiating the tag shall be responsible for completing the required information on the tag.

- 1.1 Any PNL Staff Member or PO Representative may apply Accept, Hold, Reject, or Test in Process tags and may remove Accept, Hold, or Reject tags after the release of the item or satisfactory completion of required action or a Test in Process Tag when the test is completed.
- 1.2 Only a PO Representative or an approved designee may apply and remove Conditionally Accept tags.

NOTE: Status tags can be obtained from the Cognizant Quality Engineer or through the PNL PQ Department.

2.0 Receipt of Purchased Items

- 2.1 Upon receipt of items requiring independent receiving inspection in accordance with PAP-70-706, Receiving Inspection, a PQE or PNL Staff Member shall either place the item(s) in a hold area or apply a yellow Hold Tag(s) (EXHIBIT 1) to the item(s) until inspected.
- 2.2 A PQE or PNL Staff Member shall apply a Hold Tag when:

- items must be transferred to other departments for acceptance testing
- there will be post-installation testing.

Upon completion of acceptance testing a PQE or PNL Staff Member shall remove the Hold Tag and apply another status tag, as appropriate.

3.0 Acceptance and Nonconformance Tagging

The following paragraphs describe the appropriate tagging for items subsequent to inspection/test.

3.1 Acceptable Items

A POE shall tag acceptable items requiring independent inspection with a green Accept Tag (EXHIBIT 2). For items being fabricated by PNL, acceptance may be indicated on the associated traveler or work instruction where required, instead of using a green Accept Tag. The Accept Tag may be removed when the item is installed or put to use.

3.2 Nonconforming Items - Prior to Disposition

Either a POE or PNL Staff Member shall tag the item with a yellow Hold Tag when an item is nonconforming. Also, initiate, or request the initiation of, a nonconformance report in accordance with PAP-70-1501, Nonconformance Reports.

3.3 Nonconforming Items - After Disposition

Accept-As-Is: Items dispositioned accept-as-is shall be tagged with a green Accept Tag.

Reject: Items to be scrapped or returned to the supplier shall be tagged with a red Reject Tag (EXHIBIT 3). Either "Scrap" or "Return to Supplier" shall be indicated on the tag.

Rework or Repair: Items to be reworked or repaired by PNL shall be tagged with a yellow Hold Tag with either "Rework" or "Repair" indicated on the tag. This tag shall accompany the item until the rework/repair is completed and the item passes reinspection.

Conditional Acceptance: Items released for use or installation on a conditional basis shall be tagged with a blue Conditional Acceptance Tag (EXHIBIT 4). The conditions or limitations applying to its use shall be noted on the tag. The tag shall be applied to, or accompany, the item until the nonconforming condition is resolved.

4.0 Operational Status Tagging

PNL Staff Members shall use Test In Process Tags (EXHIBIT 5), markings, or area postings to identify systems and components undergoing unattended tests where inadvertent operation or shutdown of equipment could jeopardize test results. The Test In Process Tag or other appropriate status indicator shall indicate the following:

- type of test
- reason for the tag or indicator, and
- who to contact in an emergency.

Note: When knowledge of status is required at locations remote from the test or operating activity, tags, status boards, or other suitable administrative controls shall be used.

REQUIRED RECORDS

None.

10/23/88 12:00

**THIS PAGE INTENTIONALLY
LEFT BLANK**

HOLD TAG
(Yellow)

**HOLD
DO NOT USE**

(FRONT)

Hold For:	<input type="checkbox"/> Inspection	<input type="checkbox"/> Disposition	<input type="checkbox"/> Other _____
	<input type="checkbox"/> Rework	<input type="checkbox"/> Repair	_____
PO No.:	Item No.:	Rework/Repair WO No.:	
NCR No.:			
Quantity:		Dwg. & Rev./Part No.:	
Project:			
Description of Item:			
Signature/Date:			

(BACK)

**THIS PAGE INTENTIONALLY
LEFT BLANK**

ACCEPT TAG
(Green)

ACCEPT

(FRONT)

PO No.:	Item No.:
WO No.:	Dwg. & Rev./Part No.:
Quantity Accepted:	
Project:	
Description of Item:	
Signature/Date:	
Remarks:	

(BACK)

**THIS PAGE INTENTIONALLY
LEFT BLANK**

**THIS PAGE INTENTIONALLY
LEFT BLANK**

CONDITIONAL ACCEPTANCE TAG
(Blue)

**CONDITIONALLY
ACCEPTED**

(FRONT)

PO No.:

Item No.:

WO No.:

NCR No.:

Project:

Dwg. & Rev./Part No.:

Quantity:

Description of Item:

Conditions/Limitations:

Signature/Date:

(BACK)

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TEST IN-PROCESS TAG
(White and Red)

<p>TEST IN PROCESS</p>

(FRONT)

<p>Description of Test:</p>
<p>Reason for Tag:</p>
<p>In Emergency, Contact:</p>

(BACK)

**THIS PAGE INTENTIONALLY
LEFT BLANK**

TITLE: PAP-70-1501, NONCONFORMANCE REPORTS

PURPOSE

Establish a uniform method for identifying, documenting, segregating, evaluating, and dispositioning of nonconforming items. Also, it provides for the notification of affected organizations and the closing of the Nonconformance Report. The reason for these controls is to prevent the inadvertent use of nonconforming items.

APPLICABILITY

This procedure applies when an item or associated documentation does not meet one or more specified requirements.

PAP-70-1502, Deficiency Reports, applies when the quality of reportable data is indeterminate.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Contract Specialist
- Cognizant Manager
- Cognizant Staff (any PNL employee)
- Designated Organization(s)
- Quality Information Management (QIM) Clerk (in Quality Planning and Assessment Department)
- Quality Programs (QP) Representative
- Technical Representative.

IMPLEMENTATION

1.0 Identification and Documentation of Nonconforming Items

- 1.1 When nonconforming items or associated documentation are found, Cognizant Staff shall either initiate a Nonconformance Report (NCR) or contact the assigned QP Representative to initiate one. Cognizant staff are responsible for completing Blocks 1 through 11 of the NCR form (EXHIBIT 1) in accordance with EXHIBIT 2, Instructions for Using the Nonconformance Report.
- 1.2 Cognizant Staff shall identify the nonconforming items by completing and attaching yellow Hold Tags (Form No. BT-1060-071, see PAP-70-1401, Inspection and Testing Status and Tagging). This identification is to be legible and easily recognizable. Record the NCR number on the Hold Tag(s).

NOTE: If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, is identified with a hold tag.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE



6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE



6/17/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE



6/20/94

RL Shaub

J. McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

2.0 Segregation of Nonconforming Items

- 2.1 Cognizant Staff shall segregate nonconforming items by placing them in a clearly identified hold area until properly dispositioned, if such action is needed to preclude inadvertent use of a nonconforming item.

NOTE: When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions are to be used to prevent inadvertent use.

- 2.2 Nonconforming items are not to be used until authorized personnel have completed an evaluation and the items are considered acceptable for use.

3.0 Evaluation and Disposition of Nonconforming Items

- 3.1 After completing Blocks 1 through 11 of the NCR form, the Cognizant Staff shall forward the NCR to a Technical Representative designated by the Cognizant Manager. The Technical Representative must have:

- demonstrated competence in the specific area to be evaluated
- adequate understanding of the requirements
- access to pertinent background information.

- 3.2 The Technical Representative shall furnish a copy of the preliminary NCR to the QP Representative.

- 3.3 The QP Representative shall furnish a copy of the preliminary NCR to the QIM Clerk.

- 3.4 If the Technical Representative and the QP Representative see indications that a supplier knowingly supplied items of substandard quality, the QP Representative shall report this information to the Lead Procurement Quality Engineer (Lead PQE). (This information is required to be reported to the Inspector General and the Lead Procurement Quality Engineer is responsible for contacting the PNL Legal Office and Safeguards and Security.)

- 3.5 The Technical Representative and the QP Representative shall coordinate the evaluation to determine the disposition of the nonconforming item(s) and the inspection/tests required after any rework/repair to determine that the item(s) meet the acceptance criteria. The inspection/tests requirements should be specified by the organization responsible for the original design.

- 3.5.1 Complete Blocks 12 through 16 of the NCR in accordance with the instructions in EXHIBIT 2.

- 3.5.2 On procured items determine if corrective action to preclude recurrence is necessary. Indicate determination in Block 13. If "yes" contact the Lead PQE. If the Lead PQE and Contract Specialist determine a Corrective Action Request (CAR) is warranted, indicate that determination in Block 13a. If it is determined that the nonconformance does not warrant a CAR, the Contract Specialist shall take the lead in obtaining corrective action. Corrective Action Requests for suppliers are initiated and processed in accordance with PAP-70-1602, Corrective Action.

- 3.5.3 For nonconforming items from Crafts Services or a Hanford Contractor, the Technical Representative and QP Representative shall determine if the nonconformance is a significant condition adverse to quality. Significant conditions may include:

- nonconformance from the same source where prior corrective actions to prevent the problem have not been effective
- nonconformances, where if the conditions creating the problem were not immediately corrected, that would result in a major adverse impact on the environment, health or safety, mission, cost, or reputation of PNL or the PNL Client.

If the determination is made that the nonconformance is a significant condition (Block 14), the QP Representative should use the methods included in PAP-70-704, Source Inspections, Tests, and Surveillances (for Hanford Contractors) or in QP-07, Internal Surveillances, of PNL-MA-531, Quality Programs Instructions, (for Craft Services) for evaluating the condition and obtaining corrective action.

If the nonconformance is not a significant condition, but corrective action to prevent recurrence is needed, the QP Representative or Technical Representative should provide the supplying organization a copy of the NCR and request corrective action.

- 3.6 The Designated Organization shall take the approved action as specified in Block 12 of the NCR form. Any desired changes, in this action, are to be coordinated with and approved by the individuals who approved the original NCR.
- 3.7 For procured items, the Contract Specialist shall keep the Technical Representative apprised of the action taken by the affected supplier. The Contract Specialist shall transmit the NCR directly to the supplier, or transmit equivalent information through other means and document the action taken.
- 4.0 Close-out of the Nonconformance Report
- 4.1 Upon completion of the approved action, the Technical Representative is notified by the Designated Organization or Contract Specialist. The Technical Representative shall verify that the disposition was performed as described in the NCR.
- 4.2 The QP Representative shall review the completed form, sign and date for approval, and distribute the document.
- 4.3 As-Builts, if such records are required, shall reflect any design deviations accepted.
- 5.0 Tracking, Status Reporting, and Records
- 5.1 The QIM Clerk shall maintain a copy of NCRs issued and a log that indicates the following:
- NCR number
 - date
 - QA plan or department or project manager
 - the originator and cognizant manager
 - nonconforming item
 - QP representative
 - date NCR closed.
- 5.2 The Cognizant Manager shall maintain a copy of the completed NCR(s) and associated documents as project/activity/facility records.
- 6.0 Forms

The EXHIBIT 1, Nonconformance Report Form, is current with the issue of this procedure but is only an example. Any subsequent revisions to the actual form will be incorporated in the next revision of this procedure.

REQUIRED RECORDS

The completed Nonconformance Report and associated documents created as a result of this procedure are records.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

NONCONFORMANCE REPORT		Page 1 of	1. NCR # PNL-
Instructions - see attachments (each block will be addressed)			
2. P.O., W.P., or Authorization No.:	3. Item Name:	4. DWG./Spec./Other No.: Rev.:	
5. Affected Organization's Title:		Project No.:	Org. Code:
7. Supplier Name:		8. QA Plan No.:	
Address:		Impact Level:	
		Safety Classification:	
9. Item	10. Description of Nonconformance (As-Required vs. As-Found)	12. Disposition, Justification, and Instructions	
11. Originator's Signature		Date	
		13. Supplier Corrective Action Required? No [] Yes []	
		13 a. CAR Required? No [] Yes [] Number: ____	
14. Significant Condition? No [] Yes []		15. Design Document Change Required? No [] Yes []	
(PNL or Hanford Contractor furnished item)		If Yes, Document No.:	
16. Technical Representative	Date	Signature	Date
QP Representative	Date	Signature	Date
17. Disposition Completed as Directed			
Alternate Disposition Completed (see Blk 12)			
		Verification (Technical Rep.)	Date
		Close-Out (QP Rep.)	Date
18. Distribution:			
QIM Clerk File:		Tech. Rep.:	
Lead PQE:		Originator:	
Cognizant Mgr.:		Others:	
QP Rep.:			

NONCONFORMANCE REPORT (Continuation Sheet)		Page of	1. NCR No.: PNL-
9. Item	10. Description of Nonconformance (As-Required vs. As-Found)	12. Disposition, Justification, and Instructions.	

INSTRUCTIONS FOR USING THE NONCONFORMANCE REPORT

NOTE: Mark N/A in each block if not applicable

TO BE COMPLETED BY THE NCR ORIGINATOR:

- BLOCK**
1. Enter nonconformance report number - obtained from the Quality Information Management (QIM) Clerk (376-8866).
 2. Identify the purchase order, work package, or Authorization number.
 3. Give the item name or description.
 4. Identify the drawing, specification, or other document containing the acceptance criteria.
 5. Identify the project name, project number, or activity title and organization code directly affected by the nonconformance.
 6. Describe where the item(s) are being held, the Hold Tag number if other than the NCR number, and record the number of hold tags used.
 7. State the name/address of the organization providing the item(s). This includes Westinghouse Hanford Company (WHC) Stores and sources within PNL (e.g., PNL Dept/Section/Group). When the item is from WHC Stores, obtain the WHC supplier's name and address.
 8. Enter the QA Plan number and the impact level and/or safety classification of the item as specified on the governing document (purchase order, work package, drawing).

NOTE: Safety classification entry will be either SC (for Safety Class) or NSC (for Non-Safety Class).
 9. If there is more than one item, assign sequential numbers for each nonconformance documented in Block 10.
 10. State the acceptance criteria of the nonconforming item(s) and the actual nonconforming condition ("as required" condition vs. the "as found" condition). Provide the quantity and (when practical) the serial numbers or other method of identification if more than one item is covered by the NCR. Include the lot or heat number when appropriate.
 11. Sign and date the NCR.

TO BE COMPLETED BY THE TECHNICAL REPRESENTATIVE WITH QP REPRESENTATIVE ASSISTANCE:

12. Disposition, justification, and instructions.
 - a. If necessary, provide one of the following preliminary dispositions:
 - Rework - to bring the item into conformance with original requirements.

NOTE: Rework shall be inspected with the inspection results, with either acceptance or further nonconformance, documented in this block.
 - Repair - to bring the item into conformance with alternate requirements. Instructions for the repair, including acceptance criteria, will be provided with this disposition. **A repair**

INSTRUCTIONS FOR USING THE NONCONFORMANCE REPORT

disposition is subject to review and approval methods commensurate with those applied to the original design.

NOTE: Repair shall be inspected with the inspection results documented in this block

- Conditional Accept - releases a nonconforming item to be tested or checked further to determine acceptability. Limitations of the release will be stated with the disposition. A conditional accept disposition is subject to review and approval methods commensurate with those applied to the original design.

NOTE: Using these dispositions requires a documented reexamination by the same organization that originally identified the nonconforming item. Include in block 12 the inspections/tests required after any rework/repair to determine that the item(s) meet the acceptance criteria. The inspection/test requirements should be specified by the organization responsible for the original design.

- b. NCRs will have one of the following final dispositions before closure:
 - Reject - item is to be scrapped, returned, or replaced.
 - Accept-As-Is/Use-As-Is - accepts the material as it was originally or in its corrected state. **Accept-as-is dispositions to design requirements are subject to review and approval methods commensurate with those applied to the original design.**
 - c. All dispositions, except rework and reject, shall include a technical justification for accepting the item.
 - d. When necessary, provide instructions for performing the disposition.
 - e. When the NCR disposition involves action to be taken with a supplier, contact the Cognizant Contract Specialist and provide a copy of the NCR so appropriate action can be taken to coordinate the disposition. Final dispositions cannot be made until coordination has been accomplished and documented.
 - f. When the NCR disposition involves action to be taken by PNL personnel, contact the Cognizant Manager(s) to coordinate the disposition and to verify their capability to perform the required disposition.
 - g. When the NCR disposition involves action to be taken by WHC Stores, contact the Lead Procurement Quality Engineer (Lead PQE) for assistance. The nonconformance shall be written against requirements (which can often be found in the status catalog). A copy of the NCR shall be forwarded to WHC-Manager, Procurement Quality Support.
 - h. If it becomes necessary to modify the original disposition the alternate disposition and justification shall be entered in this block. Review and approval commensurate that of the original shall occur. Signatures approving the revised or alternate disposition shall be affixed following this revised disposition.
13. When supplier corrective action is required to preclude recurrence of nonconformances, check "yes" in block 13, and contact the Lead PQE. If not required check "no". **This block only applies to purchased items and not to items from a PNL organization or a Hanford Contractor.**
 - 13.a. **If the Lead PQE and the Contract Specialist determine that a Corrective Action Request is required check "yes", and enter the CAR number.**

INSTRUCTIONS FOR USING THE NONCONFORMANCE REPORT

14. If it has been determined that a nonconformance from a PNL organization or a Hanford Contractor is a significant condition adverse to quality enter "Yes". If not, enter "No". See paragraph 3.5.3 of PAP-70-1501 for guidance on determining if there is a significant condition and required actions.
15. When applicable, write in the design document number (usually associated with an "accept-as-is" or "repair" justification statements).
16. Technical and QP Representatives sign and date to show approval of the NCR and disposition. Additional blocks are provided for other signatures as appropriate (e.g., weld engineer, design engineer, safety representative). After completion of all required reviews, the Technical Representative or QP Representative shall:
 - verify that all reviewers have signed and dated the NCR,
 - retain the original of the NCR for follow-up,
 - transmit necessary copies of the NCR to ensure that disposition is accomplished. If the NCR disposition involves a purchased item, send a copy of the NCR to the Cognizant Contract Specialist for procurement files and action as required
 - ensure that the item(s) is available so the disposition can be accomplished.
17. When satisfied that all necessary action has been performed, the Technical Representative shall:
 - ensure removal of the hold tag(s),
 - sign and date the NCR (Verification).
 - list the individuals or organizations who need a copy of the NCR (in block 18). At a minimum, the block will include: QIM Clerk, Lead Procurement Quality Engineer, Cognizant Manager, Originator, Technical Representative, and QP Representative.The QP Representative shall:
 - ensure that the NCR has been processed in accordance with above requirements, including one of three final dispositions (see Block 15.b. instructions),
 - sign and date the NCR (Close-out),
 - distribute copies of the NCR.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

9513358-2642

PNL ADMINISTRATIVE PROCEDURE

TITLE: PAP-70-1502, DEFICIENCY REPORTS

PURPOSE

Provide a method for addressing deficiencies from PNL or client procedural, QA, or contractual requirements to ensure that deficiencies are properly documented, their effect on results evaluated, and that corrective action is taken to preclude recurrence; and provide a method for addressing actions necessary when results have been impacted by a deficiency.

APPLICABILITY

This procedure applies to the documentation, evaluation, and correction of a deficiency from PNL procedural or client requirements when the deficiency is identified by PNL and the method for documenting, evaluating, and correcting the deficiency is not covered by another PNL-MA-70 procedure. This procedure also applies when the quality of reportable data is indeterminate (i.e., no objective evidence is available to substantiate data quality or to indicate that established procedures were met). This procedure does not apply to the documentation, evaluation, and correction of a deficiency identified in an Audit or Surveillance Report.

This procedure also applies to documenting and resolving:

- Measuring and Test Equipment (M&TE) calibration discrepancies when required by PAP-70-1201, Calibration Control System
- computer software related deficiencies when required by the Software Control Procedures (SCPs).

The evaluation and disposition of nonconforming hardware is covered in PAP-70-1501, Nonconformance Reports.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Cognizant Manager (within this procedure the Cognizant Manager is the responsible manager of the organization, activity, project, facility, etc. in which the deficient operation was located)
- Deficiency Report (DR) Originator
- Process Quality Department (PQ) Representative (usually QE)
- Quality Information Management Program (QIM) Clerk. (in Quality Planning and Assessment Department)

DEFINITIONS

Deficiency - For this procedure, a deficiency is defined as:

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

RL Shaub

6/17/94

RL Shaub

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JR McGarrah

6/20/94

JR McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

PROCEDURE NO.: PAP-70-1502

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 2 OF 3

- a) a failure to develop, document, or implement any applicable element of the QA program or activity established by mutual agreement with the client, or
- b) a failure to follow established procedures, or
- c) a situation in which the quality of an activity or document is indeterminate. For example, where the stated or implied purpose has not been met or where insufficient information exists to support the results that have been produced.

Impacted - The consequences of the deficiency negatively affect the results, data, or product or render its quality indeterminate.

IMPLEMENTATION

1.0 Originating a Deficiency Report (DR)

1.1 The QIM Clerk shall assign Deficiency Report (DR) numbers and maintain a log of DRs issued.

1.2 The DR Originator shall:

- promptly notify the Cognizant Manager of the deficiency (usually within one working day)
- contact the QIM Clerk for a DR number
- complete Blocks 1 through 11 of the DR form (EXHIBIT 1, PNL Deficiency Report) according to the EXHIBIT 1 instructions
- send the original DR to the Cognizant Manager and copies as shown in Block 14.

2.0 Evaluation of Impact of Deficiency and Corrective Action

2.1 The Cognizant Manager shall:

- complete Block 12 of the DR form according to the instructions in EXHIBIT 1, PNL Deficiency Report.
- when impact has been determined, attach a copy of the DR to the subject data sheet, laboratory record book, or other documents used to transcribe the information or data
- reference the DR number on the impacted data sheets, laboratory record book or other documents used to transcribe the data, and
- forward the original DR to the PQ Representative for review and concurrence.

2.2 If the determination is made that the deficiency is a significant condition adverse to quality (Block 12e of EXHIBIT 1, PNL Deficiency Report), the PQ Representative shall use the methods described in QP-07, Internal Surveillances, of PNL-MA-531, Quality Programs Instructions, for documenting and obtaining corrective action to prevent recurrence if the source of the deficiency is within PNL. If the source is a Hanford Contractor, use the surveillance methods described in PAP-70-704, Source Inspections, Tests, and Surveillances.

3.0 Corrective Action Completion, Verification, and Closeout

3.1 The Cognizant Manager shall ensure completion of corrective action by the expected completion date specified in the DR and shall notify the PQ Representative of its completion.

3.2 When satisfied that the corrective action has been completed, the PQ Representative shall complete Block 13 of the original DR, send copies to the QIM Clerk, the DR Originator, and the Project/Activity Manager, and return the original to the Cognizant Manager.

4.0 Notification of Client

If the investigation of the deficiency's effect on the product, results, or data indicates there was some effect, significant effect, or unknown effect and the product, results, or data have already been reported, the client and any other impacted organizations shall be notified. Inclusion of the impacted organization(s) on the distribution of the Deficiency Report is considered a suitable means of notification.

5.0 Tracking, Status Reporting, and Records

5.1 The QIM Clerk shall maintain a copy of DRs issued and a log that indicates the following:

- DR number
- date
- QA plan or department or Project Manager
- the DR Originator and Cognizant Manager
- subject
- PQ Representative
- corrective action date
- date DR closed.

5.2 The Cognizant Manager shall retain the original DR as an activity, project, facility, etc., record. A closed copy of the DR shall be permanently affixed to the data sheet, laboratory record book, or any other document used to transcribe the data containing the results in question, without obscuring any previously recorded information.

6.0 Forms

The EXHIBIT 1, PNL Deficiency Report, form is current with the issue of this procedure, but is only an example. Any subsequent revisions to the actual form will be incorporated in the next revision of this procedure.

REQUIRED RECORDS

The completed Deficiency Report created as a result of this procedure is a record.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

9513358.2644

PNL DEFICIENCY REPORT

1. DR Number:	2. Date:	3. QA Plan Number:	4. Impact Level:	5. Project/Activity Number:	6. Org. Code:
7. PROJECT/ACTIVITY TITLE:					7a. CLIENT NAME:
8. REQUIREMENT AND SOURCE OF REQUIREMENT (Document No., Revision, and Title):					
9. DESCRIPTION OF DEFICIENCY:					
9a. CORRECTIVE ACTION RESPONSE DUE:					
10. NCR Required? No <input type="checkbox"/> Yes <input type="checkbox"/> Number:		10a. Referenced Reporting Document:		11. _____ Originator's Signature and Date	
12a. EVALUATION AND CAUSE OF DEFICIENCY:					
12b. Effect of Deficiency on Validity and Integrity of Results: <input type="checkbox"/> None <input type="checkbox"/> Unknown <input type="checkbox"/> Some <input type="checkbox"/> Significant Explain:			12c. If Unknown, Some, or Significant effect, (Identify results affected or potentially affected):		
12d. ACTION TO CORRECT DEFICIENCY:					
12e. SIGNIFICANT CONDITION ADVERSE TO QUALITY? <input type="checkbox"/> No <input type="checkbox"/> Yes PQ Representative Notified <input type="checkbox"/>					
12f. ACTION TO PRECLUDE RECURRENCE: Expected Completion Date:					
12g. CONTACT CLIENT? <input type="checkbox"/> No <input type="checkbox"/> Yes Contacted (Name and date), Contacted by (Name and Date): Explain:					
12h. _____ Cognizant Manager Signature and Date			12i. _____ PQ Representative Signature and Date		
13. Corrective Action Complete/Comments: Closeout: _____ PQ Representative Signature/Date			14. Distribution: Cognizant Mgr.: _____ Project/Activity Mgr.: _____ Originator: _____ QIM Clerk: _____ PQ Rep.: _____		

INSTRUCTIONS FOR USING THE DEFICIENCY REPORT (DR) FORM

TO BE COMPLETED BY THE DR ORIGINATOR:

BLOCK

1. Enter the Deficiency Report (DR) number - obtained from the Quality Information Management Program (QIM) Clerk (376-8866).
2. Enter the date the DR was initiated.
3. Enter the QA Plan number of the project or the activity where the deficiency was identified. For Impact Level III projects or activities where the PNL Good Practices Standard serves as the QA Plan state "GPS".
4. Enter the impact level of the activity or the area where the deficiency was identified if an impact level specific to the activity/area exists. Otherwise, use the overall project impact level as identified on the Project Impact Level Approval form. If a safety classification has been assigned, enter "SC" (Safety Class) or "NSC" (Non-Safety Class) in this Block.
5. Enter the project number/work order/etc., of the project or activity where the deficiency was found.
6. Identify the organization number (e.g., D7H00) responsible for the activity affected by the deficiency. This may be different from the originating project organization number.
7. Enter the title of the project or the activity where the deficiency was identified.
- 7a. Enter the Client's name.
8. Enter the requirement and the source of the requirement for the activity affected by the deficiency. Include the document number, title, and revision when available.
9. Provide a description of the deficiency. Deficiencies must be based on failure to meet the stated or the implied purpose, the written requirements, or when the quality of data is indeterminate.
- 9a. Provide the date by which a corrective action response is due.
10. If the deficiency affects a hardware item, check if an NCR is required and, if so, record the NCR number (see PAP-70-1501).
- 10a. If the DR is generated based on a condition that was reported on another document, reference that document.
11. Sign and date in this Block, complete Block 14, and forward the original DR to the Cognizant Manager for evaluation, with copies as shown in Block 14.

TO BE COMPLETED BY THE COGNIZANT MANAGER WITH PQ REPRESENTATIVE ASSISTANCE AS NEEDED:

- 12a. Provide the cause of the deficiency by reviewing items 1 through 11, background information, and discussing the deficiency with appropriate staff.
- 12b. Provide the effect on validity and integrity of project results. Check the appropriate box and provide an explanation. Project results are to be considered impacted if there was some effect, significant effect, or unknown effect.

- 12c. If "unknown", "some", or "significant" is checked in 12b., identify the location of the results affected. Reference the DR number on these affected results.
- 12d. Provide a detailed description of the action planned to correct the deficiency.
- 12e. Determine if the deficiency is a significant condition adverse to quality. Significant conditions may include:

- * deficiencies from the same source where prior corrective actions to prevent the problem have not been effective

- * deficiencies, where if the conditions creating the deficiency were not immediately corrected, that would result in a major adverse impact on the environment, health or safety, mission, cost, or reputation of PNL or the PNL client.

If yes, check the "yes" box, notify the PQ Representative, and check the "PQ Representative Notified" block. If no, check the "no" box. (The PQ Representative will use the methods in the surveillance procedure to document and obtain corrective action to prevent recurrence for significant conditions adverse to quality.)

- 12f. If the deficiency was not identified as a significant condition adverse to quality in Block 12e, describe the action planned to prevent recurrence and the expected action completion date for all corrective actions. If identified in Block 12e as a significant condition, note that the surveillance reporting methods will be used to obtain and document corrective action to prevent recurrence.
- 12g. If results were impacted (see Item 12b. above) and they have already been reported, the client must be notified of the deficiency. Indicate whether the client was contacted. If so, indicate who was contacted, when, and by whom, as well as any client response.

This can also be used when there is a client requirement for deficiency notification and disposition concurrence by the client.
- 12h. Sign and date the original DR and forward it to the PQ Representative for concurrence with the responses to Items 12a. through 12e.

TO BE COMPLETED BY THE PQ REPRESENTATIVE:

- 12i. When satisfied with the responses to 12a. through 12e., sign and date this line and return the original DR to the Cognizant Manager.
13. Following the expected completion date or notification of completion by the Cognizant Manager, perform follow-up action to verify proper implementation of corrective action and completion of the DR in a timely manner. Once satisfied, sign and date this line on the original, provide any necessary comments, distribute copies as shown in Block 14, and return the completed DR to the Cognizant Manager.

PNL ADMINISTRATIVE PROCEDURE

9513358-2645

PROCEDURE NO.: PAP-70-1602

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: PAP-70-1602, CORRECTIVE ACTION

PURPOSE

Establish requirements and responsibilities for corrective action on supplier-related significant conditions adverse to quality.

APPLICABILITY

This procedure applies to the identification of significant conditions adverse to quality that are supplier related, the root cause of the conditions, and the corrective action taken to preclude recurrence. These conditions are documented on a Corrective Action Request (CAR).

The identification and corrective action for significant conditions adverse to quality that are not supplier related are addressed through the application of the Priority Planning Grid system to conditions identified through audits and surveillance of PNL and Hanford Contractors.

Other conditions adverse to quality and their corrective actions are addressed in Nonconformance Reports (NCRs), Deficiency Reports (DRs), Calibration Discrepancy Tags (CDTs), Surveillance Reports, and Audit Reports, as appropriate.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Contract Specialist
- Lead Procurement Quality Engineer (Lead PQE)
- Process Quality Department (PQ) Manager
- Quality Information Management Program (QIM) Clerk.

DEFINITIONS

Significant Condition Adverse to Quality - A condition which, if uncorrected, could have a serious effect on safety, operability, or product quality.

Supplier-related condition - A condition that is caused by a supplier usually during the course of a contract or during the warranty clause time limit.

IMPLEMENTATION

1.0 Identification of Significant Conditions Adverse to Quality

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

KE Harrison

6/17/94

KE Harrison

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JE McGarrah

6/20/94

JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

- 1.1 The Lead POE shall periodically review supplier-related NCRs, for significant conditions adverse to quality. Significant conditions adverse to quality may include:
- conditions that are not corrected in a timely manner
 - conditions where prior corrective action has not been effective
 - recurrent or continuing conditions based on reviews and analyses
 - conditions which, if not immediately corrected, would result in acceptance of work being withheld; a stop work request; or a major adverse impact on the environment, health and safety, mission, cost, or reputation of PNL or the PNL client.

NOTE: The Procurement Quality Assurance Administrator is responsible for reviewing during preaward evaluations the NCRs, audit reports, and source verifications in the supplier's history file for significant conditions adverse to quality. The Audit Team Leader performs the same review before performing an audit of a specific supplier.

- 1.2 The Lead POE shall initiate a CAR (EXHIBIT 1) in conjunction with the Contract Specialist when a supplier-related significant condition adverse to quality exists.
- 1.3 The Lead POE shall obtain a CAR number from the QIM Clerk and forward the CAR to the PQ Manager.
- 1.4 The PQ Manager shall review the CAR, establish a response date and, if acceptable, approve and issue the CAR.
- 1.5 The PQ Manager shall route the CAR through the Contract Specialist for action with the supplier.

2.0 Response and Corrective Action for Corrective Action Requests

- 2.1 The Contract Specialist shall coordinate CARs with suppliers and obtain an appropriate response and commitment to corrective action. The CAR, or appropriate document, shall be forwarded to the supplier for recording the root cause, corrective action, and signature/date by the supplier's management representative.
- 2.2 The Contract Specialist shall forward the supplier's response to the CAR to the PQ Manager.
- 2.3 The PQ Manager shall review the supplier's response to the CAR within one (1) week of receipt and determine and indicate the acceptability of the response/corrective action plan for supplier CARs, as follows:
- If acceptable, sign the QP concurrence block on the CAR and return the CAR to the Contract Specialist.
 - If unacceptable, go to Step 3.3.
- 2.4 The supplier shall sign/date the CAR verifying completion.

3.0 Follow-up and Close-out of Corrective Action Requests

- 3.1 The Lead POE shall review status of open CARs periodically. If response or corrective action is overdue, go to Step 3.3.
- 3.2 The Lead POE shall verify implementation and completion of the corrective action plan.
- 3.2.1 If satisfactory, the Lead POE shall sign the "Corrective Action Verified" block on the CAR, and forward the CAR to the PQ Manager's office for distribution. Have copies of the completed CAR forwarded to the original distribution.

PNL ADMINISTRATIVE PROCEDURE

9513558.2696

3.2.2 If unsatisfactory, go to Step 3.3.

3.3 The Lead POE shall discuss overdue or unsatisfactory response/action with the Contract Specialist and the PQ Manager.

3.3.1 If the CAR is to be escalated, go to Step 3.4.

3.3.2 If the CAR is not to be escalated, identify the modified action plan and/or due date on or by attachment to the CAR. The modified action plan will require signature concurrence by the Contract Specialist and PQ Manager. Note new due date in CAR Log. Go to Step 3.2.

3.4 When determined appropriate, the PQ Manager shall review an overdue or unsatisfactory response to a CAR with the QP Director to determine what action should be taken.

4.0 Tracking and Status Reporting

4.1 The QIM Clerk shall maintain copies of CARs and associated documentation issued and a log that indicates the following:

- CAR number
- date issued
- supplier
- response due date
- status
- CAR Originator
- date CAR closed.

4.2 The QIM Clerk shall issue monthly, the status of outstanding CARs. As a minimum, the distribution of the status report shall include the:

- Lead PQE
- PQ Manager.

REQUIRED RECORDS

The completed CARs and related correspondence created as a result of this procedure are records.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

**THIS PAGE INTENTIONALLY
LEFT BLANK**

PNL ADMINISTRATIVE PROCEDURE
9513558.2648

PROCEDURE NO.: PAP-70-1701

REVISION NO.: 4

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 10

TITLE: PAP-70-1701, RECORDS SYSTEM

PURPOSE

Provide a uniform records management system for quality assurance records. This system provides for the identification, generation, maintenance, storage, and final disposition of quality assurance records.

APPLICABILITY

PNL records management requirements are established in PNL-MA-68, Records Management and Document Control. This procedure addresses additional record requirements of NQA-1 and is applicable to PNL projects, facilities, and service groups. While the requirements for the records system explained in this procedure apply to classified records, this procedure does not include instructions for the classification or security of classified records.

Instructions for entering information, maintaining, and storing Laboratory Record Books are described in PNL-MA-68, Records Management and Document Control.

Instructions for obtaining records required to support work performed by a PNL service group or Hanford Contractor are described in PAP-70-404, Obtaining Services.

Instructions for obtaining records to support work performed by a supplier/subcontractor are described in PAP-70-401, Purchase Requisitions.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Manager (as used in this procedure, Manager is the Project Manager, Service Group Manager, Facility Manager, or Line Manager directly responsible for the documents)
- Records Custodian (Custodian)
- Records Management Representative.

DEFINITIONS

Project Deliverable - A document or item submitted to a client furnishing information or evidence applicable to the client's project or activities. If the project deliverable is the record package, the records are turned over to the client through Records Management. If the project deliverable is not the record package, the records are sent to storage through Records Management.

CONCURRENCE

PK Schuette

DATE

6/17/94

PK Schuette, Manager, Records Management and Document Control

APPROVAL AUTHORITY

JW Smith

DATE

6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

RM Dunn

DATE

6/16/94

RM Dunn

DOCUMENTATION SYSTEMS DEPARTMENT

JE McGarrah

DATE

6/20/94

JE McGarrah, Manager

PNL ADMINISTRATIVE PROCEDURE

Record Material (record) - Documented material which is originated or received by a project or activity in carrying out their objectives, that needs to be kept to provide evidence of the organization, functions, policies, decisions, procedures, operations, or other activities performed. Record material can be in any media, such as forms, reports, data, tapes, disks, or Laboratory Record Books.

Nonrecord Material - Material made or acquired and preserved solely for reference convenience, such as stocks of publications and extra copies of correspondence.

Document - Record and nonrecord material.

Records Package - A collection of completed records supporting one project, task, or activity that become quality assurance records when the project, task, or activity is completed.

Quality Assurance Records - Completed records that furnish evidence of the quality of items and/or activities affecting quality. When a project, task, deliverable, or activity is complete, the entire records package becomes a quality assurance record. Within the Standard Filing System, the file classification titled **Quality Assurance** is for filing documents that are generated due to the PNL Quality Program requirements (i.e., QA Plans, QA Audit Reports, Nonconformance Reports, Deficiency Reports). Other quality assurance records are filed according to the appropriate file classification (i.e., Administration, Personnel, Technical, etc.).

GENERAL

Service groups, such as analytical laboratories or Craft Services, generate both project-specific and nonproject-specific records. Nonproject-specific records are identified and organized in accordance with this procedure by the service group. Project-specific records requested from a service group by a project are controlled as described in the statement of work; if the statement of work does not specify records management requirements, this procedure will be the governing document.

Documents accumulated in the field and records in storage are accessible to the client for review or examination upon request.

IMPLEMENTATION

1.0 Records System Development

1.1 At the start of the project or activity, the Manager shall designate a Records Custodian (Custodian) to organize and manage documents in accordance with this procedure.

1.2 Documents shall be maintained by project, task, subtask, or activity at the discretion of the Manager. The Custodian shall follow sections 1.3 and 1.4 of this procedure for each records system developed.

1.3 Records Identification

1.3.1 The Custodian, with assistance from the Manager, shall identify potential document types and may list them on a records list. The records list is an aid for the development of the filing system and is not a required document.

1.3.2 PNL-MA-68, Exhibit 6.1, Research Project File Minimum Requirements and Sample Record Types, includes a list of types of records to be maintained for projects if they are generated.

1.3.3 When Laboratory Record Books (LRBs) are used, the Custodian shall maintain a list in the file identifying the LRB numbers, LRB Custodians, project or activity, and location of the LRBs.

1.4 Records Inventory and Disposition Schedule/File Index (RIDS)

1.4.1 The Custodian shall identify the appropriate classification from the Standard Filing System (Exhibit 3.1 in PNL-MA-68) for each document type.

1.4.2 The Custodian, with assistance from the Records Management Representative, shall identify the appropriate schedule and retention period for the records, derived from:

- National Archives and Records Administration General Records Schedules, or
- Department of Energy Records Schedules, or
- other regulatory agency schedules.

If more than one regulatory agency schedule applies to the records retention, the longest retention period that applies is used.

1.4.3 Records are classified as permanent, lifetime, or nonpermanent.

Permanent, lifetime, and nonpermanent records are considered record material and their retention periods are recorded on the RIDS.

Permanent records are records that have been determined to have historical or other value warranting permanent preservation. An example of this would be records that have exceptional value because of highly significant nature or uniqueness of the research and development involved.

Lifetime records:

- are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use
- demonstrate capability for safe operation
- are valuable in maintaining, reworking, repairing, replacing, or modifying an item
- are valuable in determining the cause of an accident or malfunction of an item
- provide required baseline data for in-service inspections.

Nonpermanent records show evidence that an activity was performed in accordance with requirements but need not be retained for the life of the item.

1.4.4 The Custodian shall list the identified document types on a Records Inventory and Disposition Schedule/File Index (RIDS) form.

- Document types for projects, tasks, and subtasks are listed on a Project RIDS form. Instructions for completing this form are contained in Exhibit 3.3 in PNL-MA-68; Exhibit 6.2 in PNL-MA-68 is an example of a completed form.
- Document types for service groups and facilities are listed on an Administrative or Office RIDS form. Instructions for completing this form are contained in Exhibit 3.3 in PNL-MA-68, Exhibit 3.4 in PNL-MA-68 is an example of a completed form.
- WordPerfect macros for the RIDS forms are available on the PNL network. Paper forms and assistance are available from the Records Management Representative.

PNL ADMINISTRATIVE PROCEDURE

1.4.5 The Custodian shall obtain the following on the RIDS form:

- Manager approval
- QP Representative (Quality Engineer) concurrence when required by the QA Plan
- Records Management Representative concurrence.

1.4.6 The Custodian, with assistance from the Records Management Representative, shall ensure that an Information Systems Inventory form (Exhibit 3.5 in PNL-MA-68) is completed for each electronic records system and submitted to Records Management along with the completed RIDS form as described in PNL-MA-68, section 3.1.3.

1.4.7 The Custodian shall distribute copies of the approved RIDS to all of the project or activity staff who are responsible for maintaining the documents identified on the RIDS.

1.4.8 The Custodian shall keep the RIDS current by:

- making changes to the RIDS as they occur (i.e., new classifications, locations, organization changes) by entering the change on the RIDS, initialing and dating the change, and sending a copy of the corrected page to the Records Management Representative
- reviewing the RIDS annually and completing a revised RIDS to include any changes made during the previous year. If no changes are needed at the time of the annual review, the Custodian shall notify the Records Management Representative in writing that there were no changes.

2.0 Generation and Maintenance of Records

2.1 The Manager shall be responsible for ensuring that records are:

- filed in cabinets or boxes when not in use to protect against damage and loss. The Manager shall ensure that the Records Management Representative is notified if records are damaged.
- maintained in accordance with the applicable RIDS
- traceable to any applicable tests, samples, etc.
- accurate and complete
- transmitted from the originator to the custodian in a timely manner.

NOTE: It is the responsibility of the Manager to determine what constitutes a "timely manner" in his/her area of responsibility.

2.2 Prior to filing records, the Custodian (or other person authorized by the Manager) shall inspect the records to verify that they are:

- signed, initialed, or otherwise authenticated and dated. Handwritten signatures are not required if the record is clearly traceable to the person or organization who created the record.
- traceable, with the project or activity identifier, task or subtask number (if applicable), and alphanumeric file classification recorded in the upper right corner of the record
- legible and reproducible. If a record is not legible and it is not possible to obtain a better copy, the record must be marked "Best Copy Available".

- corrected, if necessary, by the record originator who marks out the incorrect information with a single line, enters the correct information, and then initials and dates the correction. If the reason for the change is not obvious, then the reason must be stated.

NOTE: This requirement for corrections does not apply to markups, changes, and comments on drafts.

- 2.3 When acquiring items or services outside PNL (e.g., Hanford Contractor or offsite supplier), records requirements should be addressed. The Statement of Work, or equivalent document, should specify what records are required. The Manager shall ensure that these records are included in the appropriate files.
- 2.4 When LRBs are used, the Custodian shall obtain copies of the completed pages (including the title page and table of contents) annually or within 90 days after the project, task, or deliverable is completed, whichever is sooner. The LRB copy is then sent to the appropriate storage location (as described in section 3.0) along with the other project or activity records.

NOTE: Since LRB pages are 9 1/2 inches by 11 inches, a duplicating machine that reduces to 8 1/2 inches by 11 inches should be used.

3.0 Records Storage or Turnover to Client

1830 records are stored in the DOE Records Holding Area as described in section 3.4 unless the client has specified a requirement for tracking individual records. If so, then the 1830 records are stored in the PNWD Records Center according to instructions described in section 3.5.

Non-1830 records are stored according to instructions described in section 3.4 except the location for the records is changed to PNWD Records Center. If the client has specified a requirement for tracking individual records for non-1830 records, the instructions in section 3.5 are followed.

- 3.1 Unless otherwise specified in a QA Plan approved by the Records Management Representative, the Custodian shall transfer the records to one of the following storage areas annually or within 90 days after completion of the project, task, or deliverable, whichever is sooner. Records may be retained longer in the field if authorized in writing by the Records Management Representative with concurrence from the Quality Engineer and the records are stored in one-hour fire rated containers. The Custodian shall:

- transfer the records package to storage following instructions in section 3.4 for storage in the DOE Records Holding Area in the 712 building, or section 3.5 for storage in the PNWD Records Center
- transfer the records package to a 1-hour fire rated container for temporary storage as described in section 3.7 for up to 90 days longer than described above. The Custodian shall forward the records to the appropriate storage facility (described in sections 3.4 and 3.5) or to the client (described in section 3.8) when the authorized time for temporary storage has expired.
- turnover the records package to the client following instructions in section 3.8 if turnover to the client is required in the QA Plan.

The QA Plan should specify when records packages will be transferred to storage or turned over to the client.

- 3.2 The Custodian or Manager shall notify the Records Management Representative of any personnel or organizational changes that would affect custody or accountability of records.

PNL ADMINISTRATIVE PROCEDURE

3.3 If storage for record items other than paper is required (e.g., magnetic media, microfilm, etc.), the Custodian shall contact the Records Management Representative to arrange for special storage. When determining whether to store records on electronic media or hard copy, the following should be considered:

- floppy disks may begin to lose data after 3 1/2 years, so they should not be used to store electronic records
- tapes need to be exercised routinely
- software and hardware need to be accessible to retrieve the records.

3.4 DOE Records Holding Area (712 Building) Storage

3.4.1 To arrange for storage of 1830 records in the DOE Records Holding Area located in the 712 Building, the Custodian shall:

- request completed records from project or activity contributors
- verify that records comply with requirements in section 2.2 of this procedure
- place the records in standard-sized file boxes. Boxes are available through Central Stores. If the records package does not fill a box, the Custodian shall contact the Records Management Representative to arrange for storage.
- contact the Records Management Representative for pre-numbered labels, instructions, and blank transfer forms. A WordPerfect macro for the Records Transfer/Data Input form, including instructions for completing the form, is available on the PNL network.
- complete a Records Transfer/Data Input form as described in PNL-MA-68, Exhibit 3.8 and forward the completed transfer form to the Records Management Representative for approval
- place the original and three copies of the approved Records Transfer/Data Input form in the lowest numbered box of the group and mark an "X" under that number.

3.4.2 The Records Management Representative shall arrange for the transportation office to pick up and deliver the records to storage.

3.4.3 When the records have been received in storage, the Records Management Representative shall return the signed Records Transfer/Data Input form to the Custodian.

3.4.4 If it is necessary to add supplemental information or replace a record, the Custodian (or other person authorized by the Manager) shall contact the Records Management Representative to arrange for the addition or replacement.

3.4.5 If a record must be corrected, the Custodian (or other person authorized by the Manager) shall retrieve the box or file according to sections 3.4.6 and 3.4.7 of this procedure, ensure that the correction is made by the record originator or other authorized person, and arrange with the Records Management Representative for the box to be returned to storage.

3.4.6 To retrieve records from storage, the Custodian (or other person authorized by the Manager) shall obtain and provide the Records Management Representative with:

- written authorization signed by the Manager

- Records Requestor' name (person authorized to retrieve records)
- box number
- record title or description.

3.4.7 The Custodian (or other person authorized by the Manager) shall store the retrieved records in accordance with section 3.7.

3.5 PNWD Records Center Storage

When 1830 records are stored in the PNWD Records Center to accommodate client's requirement for tracking of individual records, dual storage requirements in section 3.6 must be followed.

3.5.1 PNWD Records Center Description

The PNWD Records Center is a totally enclosed, windowless area occupying a portion of the Battelle-owned facility identified as the Engineering Support Building (ESB). The ESB complies with the International Conference of Building Officials Uniform Building Code, in effect at the time of construction. The PNWD Records Center occupies an addition (about 2500 square feet) to the original building. The addition is enclosed on three sides by concrete block exterior walls and the shared wall with the original building is tilt-up exposed aggregate concrete. The addition is erected on a concrete foundation and floor slab. The roof structure consists of wood trusses with a plywood roof deck. The building is also equipped with a hydraulically designed, dry pipe, fire protection sprinkler system. Handheld fire protection equipment is available.

3.5.2 Security Control

- The ESB is locked at all times and access is limited to those staff who have been issued access by the Security Office. The PNWD Records Center is a controlled access area monitored by the Records Management staff.
- Only Records Management staff, QP Representatives, Auditors, Managers, and Custodians shall be allowed access to project or activity records in the PNWD Records Center. If access is required for other personnel, the Manager shall provide written authorization to the Records Management Representative.
- The Records Management Representative shall maintain a list of personnel other than the Records Management staff, QP Representatives, Auditors, Managers, and Custodians who are allowed access to records stored in the PNWD Records Center. All those entering the controlled access area, except the Records Management staff, shall be recorded on an access log maintained by the Records Management Representative.

3.5.3 Protection of Records

- Records are protected from damage, deterioration, or loss by methods including but not limited to the following:
 - records are stored in standard records boxes with lids or in metal file cabinets
 - there are no known electromagnetic fields to damage records in the PNWD Records Center
 - room temperature is maintained by standard thermostat controls
 - the PNWD Records Center is a designated no smoking area

PNL ADMINISTRATIVE PROCEDURE

- 3.8.3 The Custodian shall contact the Records Management Representative to make arrangements for the turnover.
- 3.8.4 The Records Management Representative shall review the records and verify that they comply with section 2.2. Any deficiencies will be resolved with the Manager before the records are turned over.
- 3.8.5 The Records Management Representative shall turn over the records and request a receipt acknowledgement from the recipient. The Records Management Representative shall maintain the original receipt acknowledgement and furnish a copy to the Custodian.

4.0 Final Records Disposition

- 4.1 Within 90 days following completion of the project, task, or deliverable, or as authorized in writing by the Records Management Representative, the Custodian shall transfer the remaining records to the appropriate storage facility (described in sections 3.4 and 3.5). If the records are turned over to the client, then copies of the records are placed in storage.
- 4.2 At the end of the retention period for records in storage, the Records Management Representative shall notify the Manager or Custodian in writing that the records are eligible for destruction. The Manager shall review the records to determine if they are needed longer and if the following conditions have been met:
- deliverables required to be transferred to the client have been received
 - regulatory requirements are satisfied
 - operational status/acceptance criteria are met
 - warranty considerations are satisfied
 - client's requirements are satisfied
 - records are not required for litigation.
- 4.3 The Manager provides signed authorization to the Records Management Representative that the records may be destroyed, or justifies a longer retention period if the records are still needed.
- 4.4 The Records Management Representative, with concurrence from the Manager, shall determine the disposition of the dual storage copies after the records have been received by the client or the retention period has ended.

REQUIRED RECORDS

Records that are created as a result of this procedure are retained as records by Records Management and Document Control. The records include:

- Records Inventory and Disposition Schedule/File Index (RIDS)
- Information Systems Inventory
- Records Transfer/Data Input Form
- Records Transfer Form
- Record Correction Cover Sheet
- Receipt Acknowledgement.

Records created as a result of other procedures are identified in those procedures.

**RECORDS TRANSFER FORM
 INSTRUCTIONS**

RTF No. _____ (1)

Date Prepared _____ (2)

Project Number/QA Plan Number: _____ (3)	Task/Subtask Number: _____ (5)
Project Title: _____ (4)	
Time Period Covered by Records: _____ (6)	Project Manager: _____ (7)

The records listed below are being submitted to the PNWD Records Center for storage. These records are legible and complete in accordance with PAP-70-1701, Records System.

File Category	Document Date	Document Description	Number Pages	RECORDS CENTER USE ONLY:
(8)	(9)	(10)	(11)	(12)

Custodian Remarks: _____ (13)	Entry Date: _____
	Initials: _____
Dual Storage Required Yes [] No [] (14)	Dual Storage Location
Records Custodian _____ (15) Signature _____ Date _____	
Interim Receipt _____ (16) (Batch Only) Signature _____ Date _____	
Receipt Verified and _____ (17) Documents Filed Signature _____ Date _____ (Detailed File Log)	

RECORDS TRANSFER FORM

INSTRUCTIONS

1. **RTF No.** - Sequential number assigned by PNWD Records Center.
2. **Date Prepared** - Current date.
3. **Project Number** - Project identifier (usually finance number, may also be statement of work number or unique project number).
4. **Project Title** - Title of the project.
5. **Task/Subtask Number** - For projects maintained by task or subtask, an identifying number for the task/subtask.
6. **Time Period Covered by Records** - Inclusive dates of the records.
7. **Project Manager** - Project Manager's name.
8. **File Category** - Record file classification as identified on the RIDS.
9. **Document Date** - Date document was generated or issued.
10. **Document Description** - Unique description of each record, including document numbers.
11. **Number Pages** - Number of pages included in the record.
12. **Records Use Only** - Box number where records are stored in PNWD Records Center, date entered in PNWD Records Center computer, initials of PNWD Records Center staff, dual storage location box number. This block will be completed by PNWD Records Center staff.
13. **Custodian Remarks** - Custodian comments regarding the records, if needed.
14. **Dual Storage Required** - If dual storage is required for the records, circle yes.
15. **Records Custodian** - Custodian's signature, and date records transferred to PNWD Records Center.
16. **Interim Receipt (Batch Only)** - PNWD Records Center signature when records are received, and date received.
17. **Receipt Verified and Documents Filed** - PNWD Records Center signature when records are verified and filed, and date completed.

RECORD CORRECTION COVER SHEET - INSTRUCTIONS

 <small>PACIFIC NORTHWEST LABORATORIES</small>	RECORD CORRECTION COVER SHEET	Project/Test No. _____ (1) QA Plan No. _____ (2)
--	--------------------------------------	---

This form shall be used whenever it is necessary to correct information contained in records on file in the PNWD Records Center.

Record Title _____ (3) Record Date _____ (4)

File Class Code _____ (5) Record Location (Box No.) _____ (6)

Reason for correction _____ (7)

Authorized by _____ (8) _____

Name

Date

(9) **FOR PNWD RECORDS CENTER USE ONLY**

Corrected Record Received and Filed _____ (PNWD Records Center) _____ Date _____

Comments _____

Instructions: Attach firmly to corrected record (or corrected page) and route to PNWD Records Center with a Records Transfer Form.

RECORD CORRECTION COVER SHEET

INSTRUCTIONS

1. **Project/Task No.** - Project and task identifier (usually finance number, may also be statement of work number or unique project number).
2. **QA Plan No.** - Project or activity QA Plan number.
3. **Record Title** - Subject or title of record as identified on the Detailed File Log.
4. **Record Date** - Date record was generated or issued.
5. **File Class Code** - Record file classification used to identify the record.
6. **Record Location (Box No.)** - Box number record is stored in (from Detailed File Log).
7. **Reason for Correction** - Explanation of the correction to the record.
8. **Authorized By** - Signature of person authorized to make the correction to the record and date of signature.
9. **For PNWD Records Center Use Only** - Reference number assigned by PNWD Records Center, signature of PNWD Records Center staff correcting the record, date the record is corrected, and any comments by PNWD Records Center. This block will be completed by PNWD Records Center staff.

9513558.2655
SOFTWARE CONTROL PROCEDURE

TITLE: SCP-70-312, DETERMINATION OF SOFTWARE REQUIREMENTS

PURPOSE

Specify requirements for:

- software design, development, documentation, review, control, testing, and use
- control of data used as input to software
- transfer of software, data, and/or documentation to and from the research project.

APPLICABILITY

This procedure applies to all software, with the exception of software used as part of measuring and test equipment (M&TE) which is covered by a separate procedure, software encompassed by a technical procedure that prescribes methods for data acquisition, word processing software, and operating system software.

Details of applicability shall be determined by research project planning documents, client requirements, and intended end-use of software.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Preparer (of a Software Requirements Form)
- Process Quality (PQ) Representative
- Project Manager.

DEFINITIONS

This section contains definitions that are common to two or more software control procedures.

Acquired Software and/or Design Documentation - Software and/or design documentation obtained by procurement or transfer from outside the research project.

Application - See application run.

Application Run - Use of software to perform calculations or to manipulate data. Same as application.

Backup Copy - A copy of a data file, software, etc., on magnetic media or as a computer listing that is retained in the event that the original copy is destroyed or lost.

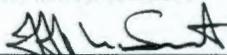
CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A


JW Smith, Director, Quality Programs

6/20/94

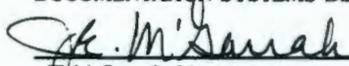
PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


JF Mucha 6/20/94


JF McGarrah, Manager 6/20/94

SOFTWARE CONTROL PROCEDURE

Benchmarking - A type of verification in which a test problem (including input and output results) is used to ensure correct model operation or to compare software.

Class Determination - Designation of software into a category. The selection of a category in turn determines other requirements.

Code - See software.

Code Custodian - A person designated to be responsible for accomplishing the actions required for configuration management; this individual is generally the main point of contact and authority for a given computer code.

Computer Model - Engineering/scientific software and data.

Configuration Management - 1. A system for orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. 2. The systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration management (taken from DOD-STD-480A).

Conversion Testing - Testing performed to ensure that calculated results obtained with software installed on a specific computer are consistent with results obtained on the computer on which the software was originally developed and tested.

Data - 1. Representation of facts/concepts in a formalized manner suitable for communication, interpretation, or processing by human or automatic means. 2. Any representation such as characters or analog quantities to which meaning is or might be reassigned. 3. Same as input data, numeric data, output data.

Database - A logically unified collection of information stored on magnetic media and maintained by a research project. Within the SCP series, a flat (sequential) file or a binary worksheet containing a collection of information in a fixed configuration is considered a database when it is used as the information base for a research project.

Database Software - Software that handles storage and retrieval of information in a database. This software is often known as a database management system (DBMS). Analytical software is regarded as database software when it is used to manage a database.

Database Steward - A person designated to be responsible for accomplishing the actions required for configuration management of a database.

Deficiency - Failure to develop, document, or implement effectively any applicable element of the QA Program or project activity established by mutual agreement with the client, or failure to follow established procedures.

Design Documentation - 1. For engineering/scientific software, documentation of software design that includes a description of mathematical models and numerical methods, and a user's manual. 2. For support software, documentation of software that includes at a minimum a user's manual.

Design Input - 1. Input to the software development process, including bases for software design, functional requirements, performance requirements, regulatory requirements, and codes and standards (taken from ASME NQA-1, Supplement 3S-1). 2. Also, termed "software requirements specifications:" functions, performances, design constraints, and attributes of software and external interfaces (taken from IEEE Std 730-1984).

Documentation - Design documentation and exhibits, memos and/or other information used to ensure traceability and reproducibility of software development, review, control, testing, and use.

Engineering/Scientific Software - Software that reads input data, computes results and provides output calculations for use in performing an analysis or making an inference. Engineering/scientific software may be transferred from

SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-312

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 10

outside PNL or outside the research project, or it may be developed at PNL. Transferred software may be used as acquired, or it may be modified at PNL. (NOTE: Does not include system maintained software or command files written to utilize such software.)

Final Internal Development Review (FIDR) - A formal review process that compares modified or developed engineering/scientific software and its documentation to its design input and design documentation requirements, evaluates the technical validity of the software, and approves software for configuration control and verification and/or validation.

Hard Copy - A computer-produced copy of information in human-readable form on paper or microfiche (as opposed to a copy on magnetic media in computer-readable form).

Incident - Any deviation from the planned or expected behavior of an activity or operation; or a course of events which has or may have a significant programmatic, safety, health, or environmental impact. Significant programmatic impacts include those associated with reliability, cost, schedule, data loss, or questions of data validity or analysis.

Independent Technical Review (ITR) - A documented critical review by qualified independent personnel to provide assurance that information is correct and satisfactory.

Internal Testing - Informal testing of software that is performed during the development process. Internal testing does not replace verification but may be used to support the verification process.

Magnetic Media - Tapes, discs, or diskettes used to record and store information in computer-readable form.

Operating System Software - A collection of software remaining permanently on a computer to provide overall coordination and control of the operation of the hardware. This collection includes compilers, link editors, and similar software.

PAP - Acronym for PNL Administrative Procedure.

Project Manager - A person designated as the manager of a research project. The term Project Manager also refers to those persons designated by the Project Manager to act on his/her behalf for specific activities.

Production Software - Software for which the detailed design can be prespecified to a level of detail acceptable for development (as opposed to research software).

Program - See software.

QP - Acronym for Quality Programs.

Research Project Planning Documents - Documents that specify agreements between PNL and a client regarding the nature of work to be performed in a research project. Examples of these documents are the Project Management Plan (PMP), the Technical Program Plan (TPP), the Quality Assurance Plan (QAP), the Statement of Work (SOW), and the Field Task Proposal/Agreement (FTP/A).

Research Software - Software for which the detailed design is being researched in the software development process, and for which comprehensive, accurate prespecification of design detail usually is not possible (as opposed to production software).

SCP - Acronym for software control procedure.

Secure Storage - Controlled access, limited to individuals that are authorized for specific purposes.

SOFTWARE CONTROL PROCEDURE

Software - A sequence of instructions suitable for processing by a computer. Same as program, code.

Software Development - The process by which new software (or a software segment) is created, including modification of the logic of existing software.

Stream of Commands - A sequence of instructions executing system maintained software that is supplied by the user for an application run.

System Maintained Software - Software that is installed and maintained at the computer system level rather than at the user level, but that is peripheral to the operation of the hardware (e.g., commercial software).

Support Software - 1. Software that may be easily and exactly verified, and that performs a simple function such as conversion of units, change in data format or plotting of data in support of engineering/scientific or system maintained software. 2. A stream of commands or sequence of streams of commands executed to utilize system maintained software, in which the system maintained software generates reportable results.

User's Manual - Documentation of software that supplies information to the user to allow preparation of input and understanding of format and/or content of output.

Validation - 1. A demonstration that a computer model (data and software) adequately describes physical reality over the range of variables of interest. 2. Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (taken from NUREG-0856).

Verification - 1. A demonstration that software correctly solves mathematical equations and performs the data processing it was designed to perform. 2. Assurance that a computer code correctly performs operations specified in a numerical model (taken from NUREG-0856).

Version - An item of software or documentation that is identifiably different from the original item.

IMPLEMENTATION

1.0 Introduction

1.1 Relationship of SCPs to NQA-1

This procedure provides the framework for compliance of the SCPs with ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities, Supplement 3S-1, Supplementary Requirements for Design Control. PNL is differentiating research software from production software, in that design input for production software is usually well defined. In the case of research software, the design process itself may be the primary objective of the research. Formal control of software need occur only after the design has been determined and the expected application has been specified. Freedom to try different algorithms and code pathways must be permitted during the formative stages of design. PNL has recognized this stage as research software design, where such freedom is permitted. This stage terminates with FIDR at which time the software and design documentation are baselined and placed under configuration management.

If the software is production software rather than research software, the SCPs have been designed as minimum requirements and provide the flexibility to require additional standards and specifications (e.g., IEEE-Std-730). In addition, the SCPs are designed to allow additions or exceptions to specific requirements either to accommodate equivalent means of maintaining traceability and reproducibility, or to tailor the stringency of requirements to the needs of a particular piece of software. NQA-1 specifies that for hardware design control, the following shall be addressed:

- *design input*
- *design process, including design analysis*
- *design verification*
- *change control*
- *interface control*
- *documentation and records.*

These SCPs are an interpretation of these hardware requirements for software.

Design input is specified in research project planning documents and on the Software Requirements Form in Sections II, IV, V, and VI of EXHIBIT 1 and Sections II through IV of EXHIBIT 2. *Design process* consists of development and internal testing of software, development of benchmark test cases, and documentation of software in accordance with design input. The design process complies with the requirements specified in research project planning documents and in the Software Requirements Form (EXHIBIT 1), and is finalized by the FIDR. The design input (requirements for the design process) receives an independent technical review (ITR). *Design analysis* is accomplished through an in-depth technical review in accordance with SCP-70-313, Final Internal Development Review of Software and Documentation. When the software and its design documentation have been approved by FIDR, configuration management of and changes to software and design documentation (including *change control*) are controlled by SCP-70-314, Software Configuration Management. The final phase before releasing software for use is *design verification*, which is accomplished by following SCP-70-315, Conversion Testing, Verification, and/or Validation of Software. Software-related aspects of *interface control* are handled by specific sections of SCPs. *Documentation* generated and required to be a record is specified in each SCP. *Records* are processed according to records control procedures.

Additionally, SCPs are provided to document and review application runs (SCP-70-316, Software Application Control), to transfer software or data to and from the research project (SCP-70-317, Transfer of Software, Data, and/or Documentation), and to handle database management (SCP-70-318, Control of Databases). SCP-70-318, Control of Databases, does not manage the data during its generation; ensuring quality and integrity of data during experimentation is controlled by a project-specific technical procedure. Rather, this procedure is meant to ensure the integrity of the data during its analysis and/or use in modeling.

1.2 Reporting of Preliminary Results

The process of taking software from design input to design verification may be lengthy; thus, for purposes of providing research project progress to a client, preliminary results may need to be reported.

The Project Manager shall ensure that any results reported to the client using engineering/scientific software that has not been reviewed in accordance with SCP-70-313, Final Internal Development Review of Software and Documentation, and verified in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software, are clearly marked with the following:

Results are based on the use of unverified software. No assurance is expressed or implied as to the accuracy, completeness, or usefulness of this information.

2.0 Preparation of the Software Requirements Form

- 2.1 For all software [except software used as part of measuring and test equipment (M&TE), software encompassed by a technical procedure that prescribes methods of data acquisition, word processing software, and operating system software], the Preparer of the Software Requirements Form shall designate one of the three classes of software by selection of the appropriate Software Requirements Form:

SOFTWARE CONTROL PROCEDURE

- Engineering/Scientific Software, EXHIBIT 1
- Support Software, EXHIBIT 2
- System Maintained Software, EXHIBIT 3.

Engineering/scientific or system maintained software can be used to generate reportable results. Support software must be used with engineering/scientific software, system maintained software, or another source of original data to produce reportable results.

Each application run of system maintained software used to generate reportable results requires creation and documentation of a stream of commands (e.g., command files to submit batch runs) tailored to the application. A stream of commands is written in the language of the system maintained software or in a programming language. All such streams of commands and interactions with software must be classed as support software.

- 2.2 The Project Manager shall ensure that a Software Requirements Form is completed for all research project software in the format of EXHIBIT 1, 2, or 3. Directions for completing each form are in italics on the form. The possible resulting sequences for applying the SCPs for software are indicated in the flowcharts given in EXHIBITS 1, 2, and 3. EXHIBIT 4 indicates the sequence of applying the SCPs for data used as input to software.
- 2.3 The Preparer of the Software Requirements Form (EXHIBIT 1 or 2) shall indicate the appointments for the following two positions (*these may have been identified in the Project QA Plan*):
 - code custodian in item 2
 - database steward in item 13, if appropriate.
- 2.4 The Preparer shall ensure that the appropriate impact level is noted (see PAP-70-208, Impact Levels).
- 2.5 The Preparer shall decide if any additions or exceptions to requirements (entire SCPs or parts of SCPs) are needed. If so, additions and exceptions and their explanations shall be recorded in one of the following:
 - Section VII of EXHIBIT 1, for engineering/scientific software
 - Section V of EXHIBIT 2, for support software
 - Section III of EXHIBIT 3, for system maintained software.

3.0 Approval of the Software Requirements Form

- 3.1 The Preparer shall review designation of software class, design input, design documentation requirements, testing options, and other applicable SCPs; shall ensure completeness of the Software Requirements Form (EXHIBIT 1, 2, or 3); shall indicate approval by signature and date; and shall forward the approved form to the Project Manager.
 - 3.2 The Project Manager shall determine if an ITR of the Software Requirements Form (EXHIBIT 1 or 2) is to be performed in accordance with PAP-70-604, Independent Technical Review. If not, the Project Manager shall review the Software Requirements Form (EXHIBIT 1 or 2). At a minimum, either review shall evaluate the following:
 - appropriateness of software class
 - qualifications of code custodian and database steward
 - design input
 - design documentation requirements
 - testing options
 - applicable SCPs
-

- completeness of the form.

The Project Manager shall:

- ensure that the preparer has signed and dated
- approve or ensure that a reviewer has approved
- obtain a Process Quality Department Representative concurrence of the Software Requirements Form.

3.3 The Project Manager shall provide an information copy of the reviewed Software Requirements Form to the PQ Representative.

3.4 The PQ Representative shall furnish a copy of the Software Requirements Form to the Quality Information Management (QIM) Clerk.

3.5 Upon final approval(s) of the Software Requirements Form (EXHIBIT 1, 2, or 3), the Project Manager shall ensure that a copy of the form is maintained as a research project record.

4.0 Identification of Design Input Requirements for Engineering/Scientific Software

Section 4.0 applies only if development or modification of engineering/scientific software and/or design documentation is required (see questions 11 and 12 on the Software Requirements Form, Engineering/Scientific Software, EXHIBIT 1).

4.1 The Preparer of the Software Requirements Form, Engineering/Scientific Software (EXHIBIT 1), shall reference any design input specified in the research project planning documents by indicating document name and page in question 21, Section IV of the form.

4.2 If the following design input requirements are not addressed in research project planning documents, the Preparer shall evaluate the need for their inclusion:

- bases for design (e.g., physical and chemical phenomena to be accounted for or known to be neglected; input or output formats)
- performance requirements (e.g., maximum CPU time, memory requirements)
- regulatory requirements (e.g., NUREG-0856 or other specified requirements)
- codes and standards (e.g., IEEE-Std-730).

Requirements for additional design input, including internal testing and benchmark test cases, shall be based primarily upon the intended end-use of software, its relative importance to research project results, and client requirements. Exclusions shall be documented on the Software Requirements Form (EXHIBIT 1).

4.3 If additional design input is determined to be required, the Preparer of the Software Requirements Form (EXHIBIT 1) shall attach the additional input and indicate in question 22, Section IV, that additional design input has been appended.

5.0 Identification of Design Documentation Requirements

Design documentation requirements (i.e., user's manual and mathematical models and numerical methods) shall be based primarily upon intended end-use of software, its relative importance to research project results, and client requirements.

SOFTWARE CONTROL PROCEDURE

- 5.1 The Preparer of the Software Requirements Form (EXHIBIT 1 or 2) shall determine design documentation requirements in Section V of EXHIBIT 1 or Section III of EXHIBIT 2. These sections are not applicable to acquired software requiring no development or modification, unless acquired design documentation is incomplete.
- 5.2 Design documentation for each software class shall include at a minimum the following:
- engineering/scientific software - mathematical models and numerical methods description, and user's manual. The specific items selected for inclusion are so indicated in Section V of the Software Requirements Form, Engineering/Scientific Software (EXHIBIT 1).
 - support software - user's manual. The specific items selected for inclusion are so indicated in Section III of the Software Requirements Form, Support Software (EXHIBIT 2).
 - system maintained software - available documentation for the particular software version.
- 5.3 The design documentation necessary to the FIDR (as determined by the Project Manager) and client requirements shall be completed before the FIDR. Delayed design documentation shall be specified in Section VII, Software Requirements Form, EXHIBIT 1 and shall be added by following SCP-70-314, Software Configuration Management.

6.0 SCPs Required for Engineering/Scientific Software

- 6.1 Engineering/scientific software shall be acquired in accordance with SCP-70-317, Transfer of Software, Data, and/or Documentation; or PAP-70-401, Purchase Requisitions.
- 6.2 When development or modification is required for engineering/scientific software and/or design documentation, an FIDR shall be performed in accordance with SCP-70-313, Final Internal Development Review of Software and Documentation.
- 6.3 After completion of an FIDR, or after transfer if no modification or development occurs, all engineering/scientific software shall be configuration managed in accordance with SCP-70-314, Software Configuration Management.
- 6.4 All engineering/scientific software shall be tested in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software. The tests that are performed shall, at a minimum, exercise the software options and the range of variables likely to be encountered in the application of the software. The testing shall include the following:
- all acquired engineering/scientific software shall be conversion tested
 - all engineering/scientific software shall be verified. Verification shall be independent if prescribed in research project planning documents.
 - validation of engineering/scientific software shall be performed if prescribed in research project planning documents.

Note: SCP-70-315, Conversion Testing, Verification, and/or Validation of Software, may be implemented only after placing software under configuration management.

- 6.5 Use of engineering/scientific software shall be documented in accordance with SCP-70-316, Software Application Control.

7.0 SCPs Required for Support Software

9515558.2659 SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-312

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 9 OF 10

- 7.1 Support software may be acquired in accordance with SCP-70-317, Transfer of Software, Data, and/or Documentation; or PAP-70-401, Purchase Requisitions.
- 7.2 If support software is used repeatedly or by multiple users, it shall require configuration management in accordance with SCP-70-314, Software Configuration Management.
- 7.3 If support software is acquired, it shall be conversion tested in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software. If it is developed or modified, support software shall be verified in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software.
- 7.4 Streams of commands (or sequences of streams of commands) used to execute system maintained software to generate reportable results shall be classed as support software and shall be verified in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software.
- 7.5 Use of support software shall be documented in accordance with SCP-70-316, Software Application Control, unless documented as part of an application run of engineering/scientific software.

8.0 SCPs Required for System Maintained Software

- 8.1 The Preparer of the Software Requirements Form, System Maintained Software (EXHIBIT 3), shall ensure that the name, supplier, and version of system maintained software (e.g., commercial software) are specified on the form.
- 8.2 The Preparer shall indicate the available documentation and version on the form.

9.0 SCPs Required for Data

- 9.1 As shown in EXHIBIT 4, data shall be acquired from another research project at PNL or from outside PNL in accordance with SCP-70-317, Transfer of Software, Data, and/or Documentation; PAP-70-401, Purchase Requisitions; or from open literature.
- 9.2 Data used in software development, testing or application shall be verified and configuration managed in accordance with SCP-70-318, Control of Databases; or data traceability and reproducibility shall be documented in accordance with SCP-70-316, Software Application Control.
- 9.3 The Preparer of the Software Requirements Form (EXHIBIT 1 or 2) shall indicate the name of the database steward (may have been identified in the Project QA Plan) in:
 - item 13, Section II of EXHIBIT 1, for engineering/scientific software
 - item 10, Section II of EXHIBIT 2, for support software.

10.0 Changing and Approved Software Requirements Form

After a Software Requirements Form has been approved, to make changes to the form, the Project Manager shall ensure that a revised Software Requirements Form (EXHIBIT 1, 2, or 3) is issued in accordance with this SCP and receives the same level of approval(s) as the original Software Requirements Form. A revised Software Requirements Form shall be indicated by sequentially assigning a revision number, where the initial Software Requirements Form shall be designated Revision No. 0. Revisions to Software Requirements Forms shall be maintained as research project records.

11.0 Reporting of Deficiencies

SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-312

REVISION NO.: 3

EFFECTIVE DATE: 08/31/94

PAGE 10 OF 10

If the Software Requirements Form (EXHIBIT 1, 2, or 3) is determined to be deficient after being submitted as a research project record, the Project Manager shall evaluate and document the deficiency in accordance with PAP-70-1502, Deficiency Reports.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- completed Software Requirements form - Engineering/Scientific Software
 - completed Software Requirements form - Support Software
 - completed Software Requirements form - System Maintained Software
 - revisions to any of the above
 - all support documentation for the above
 - Deficiency Reports, when generated.
-

SOFTWARE REQUIREMENTS FORM
ENGINEERING/SCIENTIFIC SOFTWARE

Revision No: _____

Impact Level I [] II []

(Answer every question or, if appropriate, specify not applicable, N/A. If not otherwise specified, proceed to the next question in sequence.)

- 1) Software Name (and version, if applicable): _____
- 2) Name of Code Custodian: _____
- 3) Project Title: _____ Project No: _____
- 4) Function of this engineering/scientific software: _____

SECTION I: Determination of Required Software Control Procedures (See p. 6 of this exhibit for a flowchart of the sequence).

- 5) Is this engineering/scientific software going to be acquired from outside PNL or from another PNL source?
 yes
 no (Mark N/A on questions 6-11. Go to question 12.)
- 6) Identify software origin and version(s): _____
- 7) Describe available software documentation and version(s): _____
- 8) Will vendor/developer support be obtained for this project?
 yes
 no (SCP-70-315 required) Mark N/A on questions 9 and 10. Go to question 11.
- 9) Describe vendor/developer support to be obtained for acquired software by checking the following items:
 Full configuration management support will be obtained including software error notification to PNL.
 Partial support will be obtained (describe). If partial support does not include error notification, testing should be performed under SCP-70-315.
- 10) Do research project planning documents or contract documents require continued software notification to PNL after end of project?
 yes Describe or reference the requirement and procedure for response.
 no
- 11) Will this engineering/scientific software and/or its design documentation be modified at PNL?
 yes Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application:

- SCP-70-317, Transfer of Software, Data and/or Documentation
(to transfer software and its documentation)
- SCP-70-313, Final Internal Development Review of Software and Documentation
- SCP-70-314, Software Configuration Management
- SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
- SCP-70-316, Software Application Control

(Indicate required SCPs in Section VI. Mark N/A on question 12. Go to question 13.)

no Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application:

- SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer software and its documentation)*
- SCP-70-314, Software Configuration Management
- SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
- SCP-70-316, Software Application Control

(Indicate required SCPs in Section VI. Mark N/A on question 12. Go to question 13.)

12) Is this engineering/scientific software and/or its design documentation going to be developed at PNL?

yes Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application:

- SCP-70-313, Final Internal Development Review of Software and Documentation
- SCP-70-314, Software Configuration Management
- SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
- SCP-70-316, Software Application Control

(Indicate required SCPs in Section VI.)

no *(You have answered "no" to questions 5 and 12. You need to reevaluate whether you have chosen the correct software class. If the class is correct, either question 5 or question 12 must be answered by "yes.")*

SECTION II: Data Associated with this Engineering/Scientific Software

13) Will data or database(s) be used to determine input for this engineering/scientific software?

yes a) Database software will be used.

Required SCP (in addition to those in Section I):

SCP-70-318, Control of Databases

(Indicate required SCP in Section VI.)

The database steward is *(may have been identified in the Project QA Plan)*: _____

b) Database software will not be used. A flat (sequential) file or binary worksheet is used to input data to software.

A database procedure is not required.

no *(Mark N/A on question 14. Go to question 17.)*

14) Will data or database(s) be acquired from outside PNL or from another PNL research project (with a different project number)?

yes Required SCP (in addition to those in Section I):

SCP-70-317, Transfer of Software, Data and/or Documentation (to transfer data and its documentation)

(Indicate required SCP in Section VI.)

no *(Mark N/A on questions 15 and 16. Go to question 17.)*

15) Identify origin of data or database(s):

16) Describe available documentation of data or database(s) including version(s):

SECTION III: Determination of Options for SCP-70-315, Conversion Testing, Verification, and/or Validation of Software

17) Is conversion testing required for this acquired engineering/scientific software? *(Applicable if engineering/scientific software is acquired from outside PNL or is being installed on a different computer or different operating system.)*

yes *(Indicate so under Section VI.)*

no

18) Is independent verification required?

yes *(Indicate so under Section VI.)*

"Independent" is defined to be verification by competent PNL individual(s) other than those from whom the work originated (they may be users, but they shall not have designed or developed the software).

"Independent" is defined to be verification by competent individual(s) outside PNL.

"Independent" is defined to be verification by:

no

19) Is validation required?

yes *(Indicate so under Section VI.)*

no

N/A 20) Left intentionally blank.

SECTION IV: Design Input *(applicable if answer to question 11 or 12 is "yes")*

21) List research project planning documents (title and page numbers) containing design input (see Section 4.1):

22) Is additional design input attached (see Section 4.2)?

yes

no

Explain any exclusions of items in section 4.2:

SECTION V: Design Documentation (*applicable if answer to question 11 or 12 is "yes". Mark all items to be included.*)

23) Mathematical models and numerical methods descriptions shall include:

- Design input (i.e., documentation of items 21 and 22)
- Statement and description of the problem
- Applicable assumptions and limitations (e.g., appropriateness of algorithms)
- Numerical techniques/methods
- Relevant discretized (or otherwise transformed numerical solution) equations and derivations
- Numerical stability and accuracy of methods
- Notation for variables and equations
- Important computational characteristics
- References and sources
- Other: _____

24) User's manual shall include:

- Hardware requirements including computer type and operating system
- Software listing (handwritten, computer generated or on microfiche)
- Testing documentation relevant to Final Internal Development Review
- Structure and organization of the software by flowchart, software design language, or other appropriate means
- Data input and output information
- Model and system interfaces
- Coding standards
- Sample and/or test problems
- Input/output requirements (e.g., libraries and compilers)
- Other: _____

25) Do research project planning documents or other contractual documents require compliance to a specific standard?

yes Identify the standard:

no

SECTION VI: Summary of Required SCPs

- SCP-70-312, Determination of Software Requirements
- SCP-70-313, Final Internal Development Review of Software and Documentation
- SCP-70-314, Software Configuration Management
- SCP-70-315, Conversion Testing, Verification, and/or Validation of Software
 - conversion testing
 - verification (independent? yes no)
 - validation
- SCP-70-316, Software Application Control
- SCP-70-317, Transfer of Software, Data and/or Documentation
 - software
 - document of software
 - data
 - documentation of data
- SCP-70-318, Control of Databases

SECTION VII: Additions or Exceptions to 1-25 (*attach additional pages if necessary*)

- 26) Describe any additions or exceptions to the above:
- 27) Provide explanations for additions or exceptions:

SECTION VIII: Approvals of Answers to Questions 1-27

- 28) Prepared by:

Signature Date

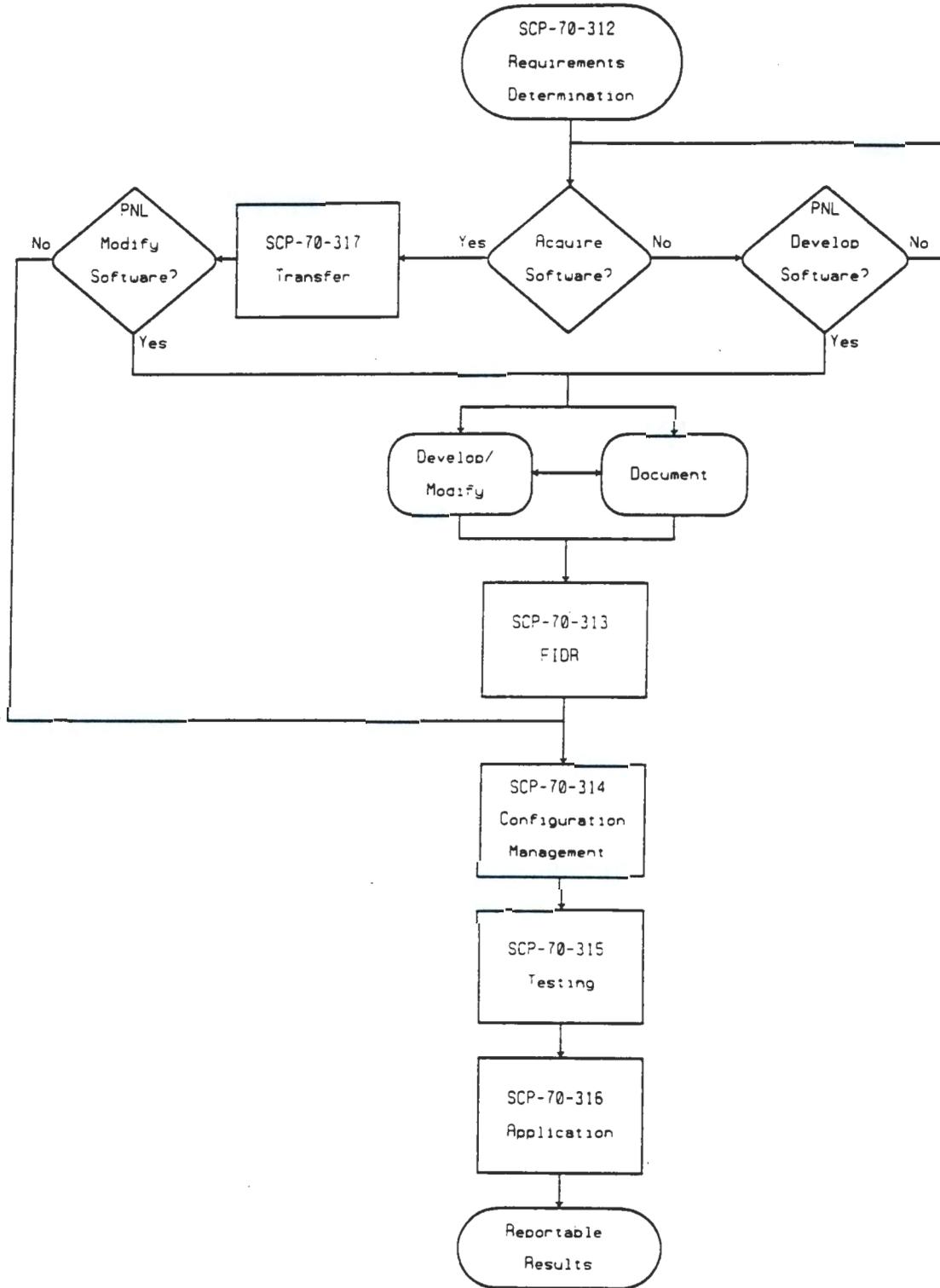
- 29) Approved by:

Project Manager, or Independent Technical Reviewer Date
(if required)

- 30) Concurred by:

Process Quality Representative Date

ENGINEERING/SCIENTIFIC SOFTWARE



SOFTWARE REQUIREMENTS FORM
SUPPORT SOFTWARE

Revision No:

Impact Level I [] II []

(Answer every question, or if appropriate for a question with a line in front of the question number, specify not applicable, N/A. If not otherwise specified, proceed to the next question in sequence.)

1) Software Name (and version, if applicable):

2) Name of Code Custodian:

3) Project Title:

Project No.:

4) Function of this support software:

5) Is this support software a stream of commands used to execute system maintained software?

 yes Identify name and version of system maintained software: no**SECTION I:** Determination of Required Software Control Procedure.

6) Will this support software receive repeated use or be used by multiple users?

 yes Required SCP (in addition to SCP-70-312, Determination of Software Requirements): SCP-70-314, Software Configuration Management*(Indicate required SCP in Section IV.)* no

7) Is this support software going to be acquired from outside PNL or from another PNL research project (with a different project number)?

 yes Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application *(apply SCP-70-314 before SCP-70-315, if SCP-70-314 is required from question 6):* SCP-70-317, Transfer of Software, Data and/or Documentation *(to transfer software and its documentation)* SCP-70-315, Conversion Testing, Verification, and/or Validation of Software SCP-70-316, Software Application Control*(Indicate required SCPs in Section IV.)* no Required SCPs (in addition to SCP-70-312, Determination of Software Requirements) in order of application *(apply SCP-70-314 first, if SCP-70-314 is required from question 6):* SCP-70-315, Conversion Testing, Verification, and/or Validation of Software SCP-70-316, Software Application Control*(Indicate required SCPs in Section IV. Mark N/A on questions 8 and 9. Go to question 10.)*

8) Identify software origin and version(s):

9) Describe available software documentation and version(s):

SECTION II: Data Associated with this Support Software

10) Will data or database(s) be used to determine input for this support software?

yes The database steward is ~~(may have been identified in the Project QA Plan)~~: _____

yes No database steward is required because database software will not be used. A flat (sequential) file or binary worksheet is used to input data to software.

no *(Mark N/A on question 11. Go to question 14.)*

11) Will data or database(s) be acquired from outside PNL or from another PNL research project (with a different project number)?

yes Required SCPs (in addition to those in Section I) in order of application:

SCP-70-317, Transfer of Software, Data and/or Documentation (to transfer data and its documentation)

SCP-70-318, Control of Databases

(Indicate required SCPs in Section IV.)

no Required SCP (in addition to those in Section I):

SCP-70-318, Control of Databases

(Indicate the required SCP in Section IV. Mark N/A on questions 12 and 13. Go to question 14.)

12) Identify origin of data or database(s):

13) Describe available documentation of data or database and version(s):

SECTION III: Design Documentation *(Mark all items to be included.)*

14) User's manual shall include:

Hardware requirements including computer type and operating system

Software listing (handwritten, computer generated or on microfiche)

Testing documentation

Structure and organization of the software by flowchart, software design language, or other appropriate means

Data input and/or output information

Model and system interfaces

Coding standards

Sample and/or test problems

Input/output requirements (e.g., libraries and compilers)

Other:

SECTION IV: Summary of required SCPs

SCP-70-312, Determination of Software Requirements

SCP-70-314, Software Configuration Management

SCP-70-315, Conversion Testing, Verification, and/or Validation of Software

- conversion testing
- verification
- validation
- SCP-70-316, Software Application Control
- SCP-70-317, Transfer of Software, Data and/or Documentation software
 - software
 - documentation of software
 - data
 - documentation of data
- SCP-70-318, Control of Databases

SECTION V: Additions or Exceptions to Questions 1-14.

15) Describe any additions or exceptions to the above:

16) Provide explanations for additions or exceptions:

17) For the following ITRs, can independent be defined to be a review by technically competent PNL individual(s) other than the principal author of the work? [NOTE: Independent is otherwise defined to be a review by competent PNL individual(s) other than those from whom the work originated (they may be users, but they shall not have designed or developed the software).]

SCP-70-314: A review of a new version of software and/or design documentation?

- yes
- no

SCP-70-315: A review of testing and its documentation?

- yes
- no

SCP-70-316: A review of an application package before reporting results to a client?

- yes
- no

SCP-70-318: A review of database design, if such is required by the project manager?

- yes
- no

SECTION VI: Approvals of Answers to Questions 1-17

18) Prepared by:

Signature Date

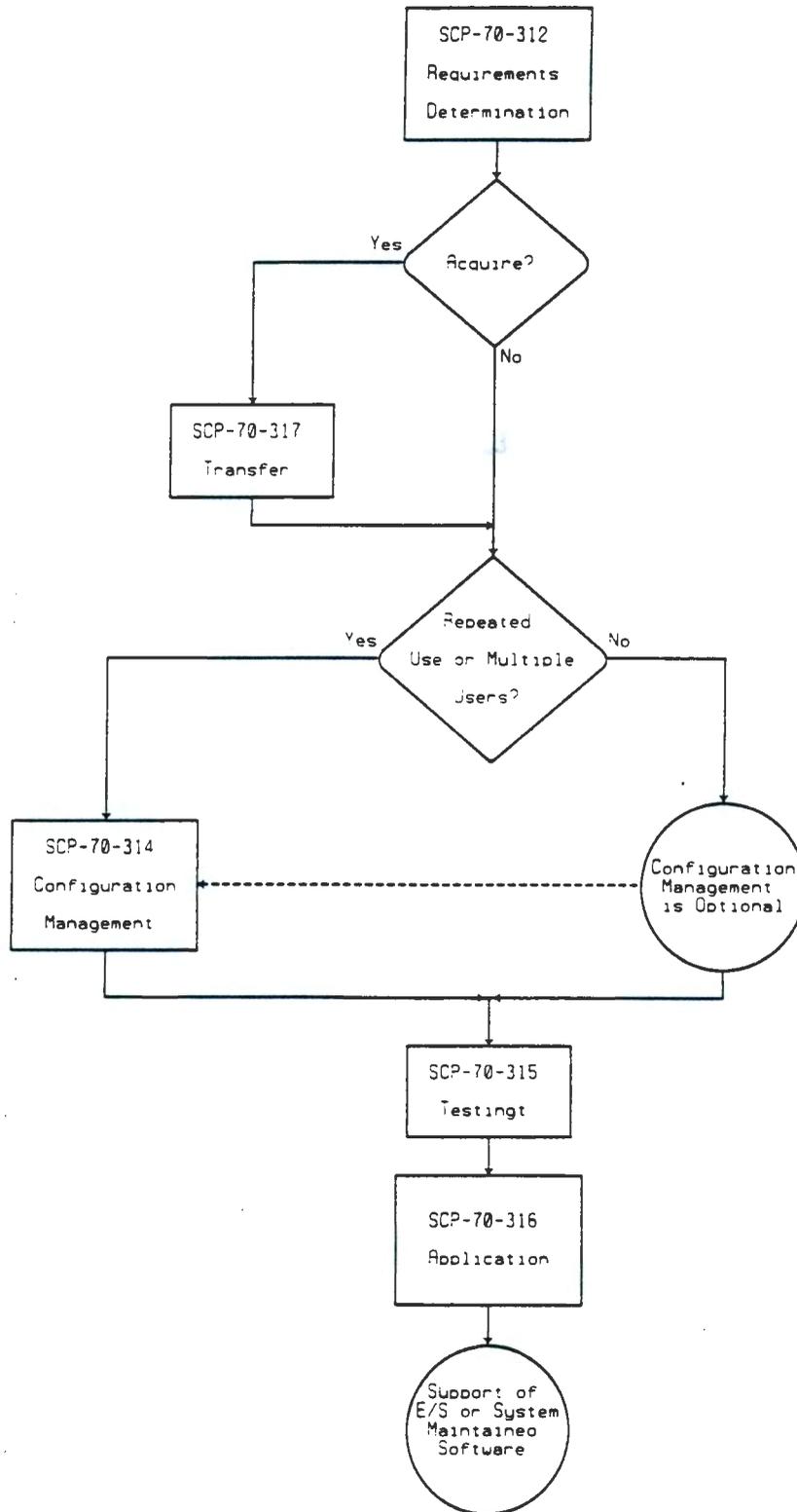
19) Approved by:

Project Manager, or Independent Technical Reviewer
(if required) Date

20) Concurred by:

Process Quality Representative Date

SUPPORT SOFTWARE



**THIS PAGE INTENTIONALLY
LEFT BLANK**

SOFTWARE REQUIREMENTS FORM
SYSTEM MAINTAINED SOFTWARE

Revision No: _____

(Answer every question or, if appropriate for a question with a line in front of the question number, specify not applicable, N/A. If not otherwise specified, proceed to the next question in sequence.)

- 1) Software Name (and version, if applicable): _____
- 2) Project Title: _____ Project No.: _____
- 3) Function of this system maintained software: _____
- 4) Does this system maintained software require a stream of commands to execute various options?
- ___ yes (Class each stream of commands as support software in accordance with Section 7.4.)
- ___ no Explain: _____

SECTION I: Determination of Required Software Control Procedures.

- 5) Is this system maintained software to be purchased or transferred?
- ___ Purchased. (See PAP-70-401, Purchase Requisitions.)
- ___ Transferred. Required SCP (in addition to SCP-70-312, Determination of Software Requirements):
- SCP-70-317, Transfer of Software, Data and/or Documentation (to transfer software and its documentation)
- (Indicate required SCP in Section III.)
- ___ Neither. (Software is already installed from previous purchase or transfer.)
- 6) Identify origin (vendor) of software and version(s):
- 7) Describe available software documentation and version(s):

SECTION II: Summary of Required SCPs.

- SCP-70-312, Determination of Software Requirements
- ___ SCP-70-317, Transfer of Software, Data and/or Documentation
- ___ software
- ___ documentation of software

SECTION III: Additions and Exceptions to Questions 1-7 (attach additional pages if necessary).

- 8) Describe any additions or exceptions to the above:
- 9) Provide explanations for additions or exceptions:

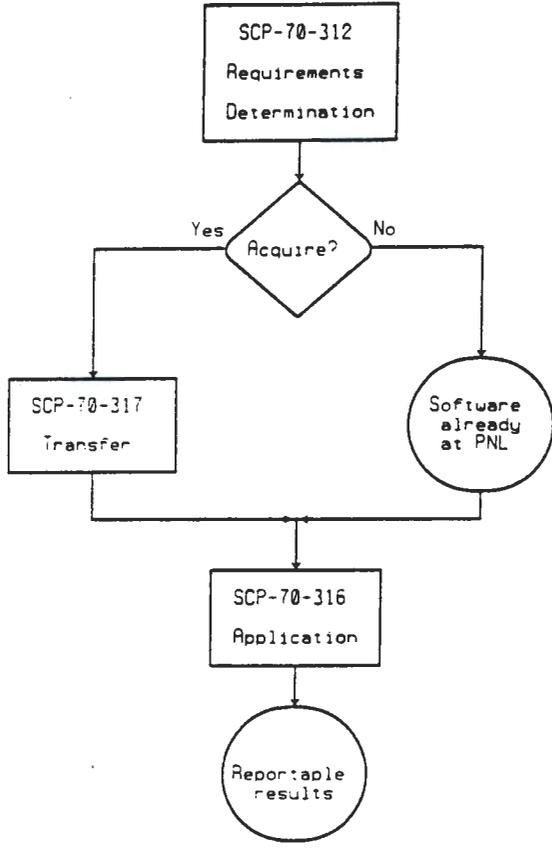
SECTION IV: Approvals of Answers to Questions 1-9.

- 10) Prepared By: _____

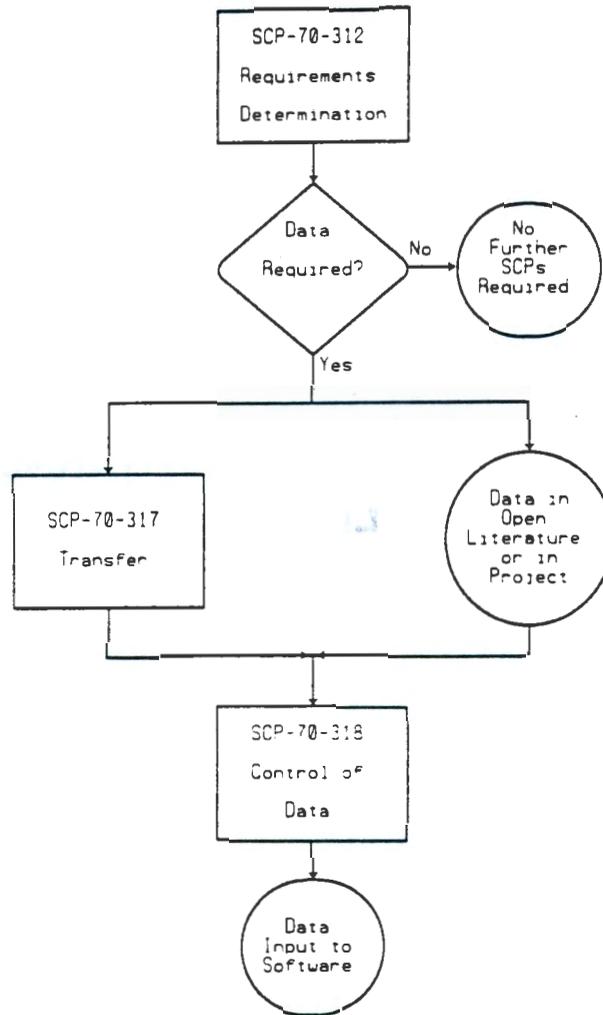
Signature

Date

SYSTEM MAINTAINED SOFTWARE



INPUT DATA TO SOFTWARE
(To development, Testing or application)



**THIS PAGE INTENTIONALLY
LEFT BLANK**

SOFTWARE CONTROL PROCEDURE

9513558.2668

PROCEDURE NO.: SCP-70-313

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: SCP-70-313, FINAL INTERNAL DEVELOPMENT REVIEW OF SOFTWARE AND DOCUMENTATION

PURPOSE

Describe the Final Internal Development Review process that approves the software and design documentation for readiness for verification and/or validation in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software. The process also provides a base version of software and design documentation and benchmark test cases for configuration management in accordance with SCP-70-314, Software Configuration Management.

APPLICABILITY

When selected on the Software Requirements Form in accordance with SCP-70-312, Determination of Software Requirements, this procedure applies to the review of engineering/scientific software and design documentation developed or modified at PNL, and other documentation of the software design process. The review shall be performed in accordance with PAP-70-604, Independent Technical Review.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Project Manager
- Reviewer.

DEFINITIONS

Terms used in this procedure are defined in SCP-70-312, Determination of Software Requirements.

IMPLEMENTATION

1.0 Performance of FIDR

- 1.1 The Project Manager shall ensure that the Final Internal Development Review (FIDR) is performed as an independent technical review (ITR) in accordance with PAP-70-604, Independent Technical Review.
- 1.2 The Project Manager shall specify review items for each reviewer on that reviewer's copy of the Document Review Record (DRR). (These items shall also be listed in the FIDR Summary, EXHIBIT 1. See Section 2.1.) At a minimum, each of the following shall be assessed by at least one Reviewer:
 - design input and design documentation specified in the Software Requirements Form

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

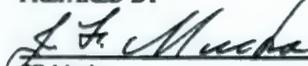
DATE


JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE


JF Mucha 6/20/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


JE McGarragh, Manager 6/20/94

SOFTWARE CONTROL PROCEDURE

- one or more benchmark test cases that demonstrate correct model operation and provide for future comparison of software versions
- other documents or software items, as appropriate.

1.3 Approval of the items in Section 1.2 shall be based on one or more of the following criteria, as appropriate:

- adequacy of documentation of design input
- conformance of software design to design input specified on the Software Requirements Form
- conformance of design documentation to documentation requirements specified on the Software Requirements Form
- adherence of software items and documentation to references and/or sources of specifications
- adequacy of benchmark test cases
- correctness of mathematical derivations
- adherence of procedures/methods and assumptions to accepted practices in the applicable field
- evidence of use of good engineering or scientific judgment.

2.0 Transmittal of FIDR Results

2.1 The Project Manager shall prepare a document in the format of EXHIBIT 1, FIDR Summary. The summary shall reference items generated by the FIDR and shall list the names of reviewers and the items they reviewed.

2.2 The Project Manager shall ensure the preparation and approval of the FIDR package, consisting of the following:

- appropriate Software Requirements Form
- ITR Report (The ITR Report contains the closed-out DRRs and other documentation submitted for and generated by the ITR.)
- FIDR Summary, EXHIBIT 1.

2.3 The Project Manager shall maintain a copy of the FIDR package as a research project record and transmit a copy to the designated code custodian.

3.0 Reporting of Deficiencies

If the performance of the FIDR is found to be deficient after the FIDR package is submitted as a research project record, the Project Manager shall evaluate and document the deficiency in accordance with PAP-70-1502, Deficiency Reports.

SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-313

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

REQUIRED RECORDS

The FIDR (2.3) package created as a result of this procedure is a record and consists of the following:

- appropriate Software Requirements Form
 - ITR Report
 - FIDR Summary
 - Deficiency Reports, when generated.
-

**THIS PAGE INTENTIONALLY
LEFT BLANK**

FINAL INTERNAL DEVELOPMENT REVIEW SUMMARY

Software Name and Version:

Design Documentation Name and Version:

Project Title and Number:

Impact Level: [] I, [] II, [] III

Reviewer

Review Items (see Section 1.2)

Items Generated By FIDR: (see Section 2.1)

FIDR Package Reviewed By:

Project Manager

Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

SOFTWARE CONTROL PROCEDURE

9513558-2671

PROCEDURE NO.: SCP-70-314

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 8

TITLE: SCP-70-314, SOFTWARE CONFIGURATION MANAGEMENT

PURPOSE

Describe a system for the orderly control of the configuration of software.

APPLICABILITY

When selected on the Software Requirements Form in accordance with SCP-70-312, Determination of Software Requirements, this procedure applies to engineering/scientific software and designated support software.

For engineering/scientific software being developed or modified at PNL, this procedure shall apply after the base version of the software is established by the FIDR in accordance with SCP-70-313, Final Internal Development Review of Software and Documentation. Configuration management during development is optional but is highly recommended on large projects, especially those with several developers.

For acquired engineering/scientific software that needs no development or modification, this procedure shall apply after the class of the software has been determined or after the software has been transferred in accordance with SCP-70-317, Transfer of Software, Data, and/or Documentation, if applicable.

For support software, this procedure shall apply if designated on the Software Requirements Form (see EXHIBIT 2 of SCP-70-312, Determination of Software Requirements). If support is going to be used repeatedly or by multiple users, configuration management is recommended.

This procedure does not apply to system maintained software. However, a stream of commands used to execute system maintained software and classed as support software shall adhere to the configuration management requirements of that class.

Configuration management of data base software that is not classed as system maintained software is covered by this procedure.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Code Custodian
- Project Manager
- User.

DEFINITIONS

Terms used in this procedure are defined in SCP-70-312, Determination of Software Requirements.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A


JW Smith, Director, Quality Programs

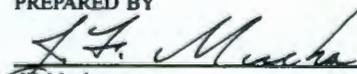
6/20/94

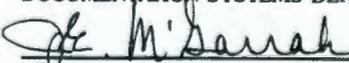
PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE


JF Mucha 6/20/94


JE McGarrah, Manager 6/20/94

SOFTWARE CONTROL PROCEDURE

IMPLEMENTATION

1.0 Transfer of Software Items for Configuration Management

The Project Manager shall ensure that the software (in machine-readable form) and documentation described below are transmitted to the code custodian to be configuration managed. The Project Manager shall ensure that software and documentation are maintained as research project records.

1.1 Software documentation consists of the following:

- for developed or modified engineering/scientific software that has been approved by an FIDR, documentation shall include the FIDR package
- (Impact Level I only) for developed or modified support software, the documentation shall include the Software Requirements Form for Support Software and the user's manual
- for acquired engineering/scientific and/or support software documentation shall include the Software Requirements Form and all documentation transferred with the software
- after initiation of configuration management, additional documentation shall include software testing documentation in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software.

1.2 If not included as part of the software documentation, the Project Manager shall ensure that one or more benchmark test cases are developed to demonstrate correct model operation and provide for future comparison of software versions. Benchmark test cases are optional for support software.

2.0 Initiation of Configuration Management

2.1 On receipt of software and documentation described in Section 1.0, the Code Custodian shall assign a unique version number to software and design documentation, and shall identify the software version and the associated document version on a Software Version Log in the format of EXHIBIT 1.

(Impact Level I only) On completion of each page of the Software Version Log, EXHIBIT 1, the Project Manager shall ensure that a copy is maintained as a research project record.

2.2 The Code Custodian shall ensure that the unique software version number is identified in the software listing and is printed in the engineering/scientific software output.

2.3 If the engineering/scientific software has not received a Final Internal Development Review and/or been verified, the Code Custodian shall ensure that the software listing and software output include the following.

Results are based on the use of unverified software. No assurance is expressed or implied as to the accuracy, completeness or usefulness of this information.

3.0 Maintenance of Software Items

3.1 The Code Custodian shall create on magnetic media a backup of the master copy of the latest version of software, data files required to run the software, and other software records normally resident on the computer. For support software (e.g., streams of commands), hardcopy backup may be sufficient if manual reentry into the computer will produce a reliable copy.

SOFTWARE CONTROL PROCEDURE

- 3.2 The Code Custodian shall control access to the master copy and backup copy in machine-readable form (except backup hard copies as noted in Section 3.1).
- 3.3 The Code Custodian shall establish and maintain a Magnetic Media Log in the format of EXHIBIT 2 to identify and record the location of magnetic media items received or created by the code custodian for the purposes of configuration management, as follows:
- magnetic media items maintained onsite under physical control of the code custodian shall be logged with a unique log number and externally labeled with software name, version, creation date, and log number
 - magnetic media items not under physical control of the code custodian (e.g., in an offsite library) shall be logged with the identifiers by which they may be accessed in the host computer system
 - a list of contents (e.g., file directory) of each magnetic media item identified in the log shall be filed with the log until the item is erased or released
 - when a magnetic media item is moved, released or erased, the action shall be recorded on the next numbered column under location/disposition and date.
- 3.4 (Impact Level I only) On completion of each page of the Magnetic Media Log, EXHIBIT 2, the Project Manager shall ensure that a copy is maintained as a research project record.
- 3.5 The Code Custodian may release backup copies of magnetic media for reuse when they become obsolete (i.e., when a new master version and its backup are created).
- 3.6 The Code Custodian shall maintain a backup copy of all associated design documentation. The Code Custodian shall maintain a working index of the design documentation, completed forms, logs, etc., and their location.

4.0 User Access Control

- 4.1 The Project Manager may authorize the code custodian to grant onsite user access to configuration-managed software items.
- 4.2 The Project Manager shall document authorization of offsite user access in a letter to those users, with copies to the code custodian and to research project records
- 4.3 The Code Custodian shall complete the Software User List (EXHIBIT 3) in the following manner:
- initial access to a software version shall be indicated in column 1 under software version/date of release
 - as a user receives a new software version, the version identifier shall be noted on the next numbered column under software version/date of release
 - when user access is terminated, the date of termination shall be noted under the appropriate column of software version/date of release.
- 4.4 (Impact Level I only) On completion of each page of the Software User List, the Project Manager shall ensure that a copy of the list is maintained as a research project record.

5.0 Problem Reporting and Change Requests

SOFTWARE CONTROL PROCEDURE

Users may request changes to software and/or design documentation to correct errors, to add new features and models, or to modify existing features. The change request may be in the form of a letter, memo, telefax, telephone call, etc., or in the format of a Change Request Form, EXHIBIT 4, Part 1.

This section prescribes procedures for reporting and processing requests for software and design documentation changes. Note that procedures to create new versions of software are prescribed in Section 6.0. New versions of the design documentation are provided for in Section 7.0.

- 5.1 Upon receipt, the Code Custodian shall document the request on the Change Request Form, EXHIBIT 4, Part 1, if not already in that format, and proceed as follows:
 - if a software problem is being reported, EXHIBIT 4, Part 1 shall include a description of the problem and a listing of input for a test case that demonstrates the error (or sufficient information to allow a test case to be developed)
 - if the information submitted is incomplete (e.g., lacks test case input) or illegible, the Code Custodian shall request clarification or reject the change request and return the Change Request Form, EXHIBIT 4, to the originator without action.
- 5.2 When the change request is accepted for action, the Code Custodian shall assign it a change request number and shall enter the number on the Change Request Form, EXHIBIT 4, and on the Software Change Request Log in the format of EXHIBIT 5. On completion of each page of the Software Change Request Log, EXHIBIT 5, the Project Manager shall ensure that a copy is maintained as a research project record.
- 5.3 If a software problem is being reported, the Code Custodian shall ensure that software is run using input supplied with or described in Part 1 of the Change Request Form, EXHIBIT 4, and that the appropriate action below is accomplished:
 - if the error cannot be duplicated with the input provided or if it is found that the supplied input is in error, the Code Custodian shall note this information on Part 2 of the Change Request Form, EXHIBIT 4, and under "Disposition" on the Software Change Request Log, EXHIBIT 5; and shall send a copy of the Change Request Form, EXHIBIT 4, to the user identified in Part 1 of the form and to research project records. No further action shall be required for the change request.
 - if the error occurs as described in Part 1 of the Change Request Form, EXHIBIT 4, or if any other errors occur in the run, the Code Custodian shall complete Part 2, sign and date the form, and forward the form and input and output to the project manager.
- 5.4 The Project Manager shall review the Change Request Form, EXHIBIT 4, to assess the impact of the software problem, to determine disposition of the request, and to determine if users shall be notified. The Project Manager shall indicate the disposition of the request on Part 3, sign and date the form, and return the completed form to the Code Custodian.
- 5.5 The Code Custodian shall enter the appropriate information from Part 3 of the Change Request Form, EXHIBIT 4, on the Software Change Request Log, EXHIBIT 5, and shall take the following actions as appropriate on the disposition as specified by the Project Manager:
 - if the change request is approved, the Code Custodian shall ensure changes to the software and design documentation are developed in accordance with Sections 6.0 and 7.0, respectively
 - if the requested change is disapproved, the Code Custodian shall send a copy of the complete Change Request Form, EXHIBIT 4, to the originator. The Project Manager shall ensure that a copy is maintained as a research project record

SOFTWARE CONTROL PROCEDURE

9513558.2675

PROCEDURE NO.: SCP-70-314

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 5 OF 8

- if users are to be notified of an error, the Code Custodian shall ensure that a copy of the Change Request Form, EXHIBIT 4, is sent to each person on the Software User List, EXHIBIT 3.

5.6 The Code Custodian may notify users of and provide user access to interim corrections for software errors that have been processed in accordance with Sections 5.1 through 5.5 before formal release of a new version of the software. The Code Custodian shall include a transmittal letter or memo stating that Users assume all risks and responsibilities for use of software containing such interim corrections and that Users shall modify the version identifier prescribed in Section 2.2 to reflect the changes installed and shall include the verification disclaimer specified in Section 2.3.

6.0 Creation of New Versions of Software

New versions of software are created to install one or a set of software error corrections or other changes that have been reported in Section 5.0. Section 7.0 describes the procedures for making corresponding revisions to the software design documentation.

6.1 To initiate creation of a new software version, the Project Manager shall complete Part 1 of the New Version Report in the format of EXHIBIT 6 to identify the base version of the software to be revised, specify changes to be installed in the designated version, and select test cases to be used. In addition,

- only those changes reported and logged in accordance with Section 5.0 may be selected
- at a minimum, the test cases shall be comprised of the benchmark test cases (see Section 1.2) and input provided with the selected Change Request Forms, EXHIBIT 4
- additional test cases may be developed, as appropriate.

The Project Manager shall transmit the New Version Report, EXHIBIT 6, with Part 1 completed to the code custodian.

6.2 On receipt of the New Version Report, EXHIBIT 6, the Code Custodian shall ensure that the following tasks are performed:

- assign a unique version identifier to the new version of software and enter it on the New Version Report, EXHIBIT 6
- provide access to the version of the software to be revised for the person(s) who will create the new version
- develop a revised version of the software that includes the selected changes and obtain a listing thereof
- obtain a computer-generated listing of software modifications that compares the revised version with the designated base version
- perform application runs to test the revised version of the software on the designated computer system using the specified test cases
- develop revisions to design documentation as required by the selected change requests in accordance with Section 7.0.

6.3 The Code Custodian shall ensure that all additional software and design documentation errors discovered during software revision or testing are handled as new change requests in accordance with Section 5.0, and that revisions to correct them are included in the revised software and design documentation.

SOFTWARE CONTROL PROCEDURE

6.4 When the actions in Sections 6.2 and 6.3 are accomplished, the Code Custodian shall complete Part 2 of the New Version Report, EXHIBIT 6, and shall deliver the listing of the revised version of software, listing of modifications, testing documentation, and design documentation revisions to the Project Manager for review in accordance with Section 8.0.

7.0 Creation of New Versions of Design Documentation

New versions of the design documentation corresponding to new versions of the software are created if the change requests selected in Part 1 of the New Version Report, EXHIBIT 6 (see Section 6.1), require documentation changes. In this case, the actions in Sections 7.1 through 7.4 are performed concurrently with those in Sections 6.1 through 6.4. Design documentation may also be revised independently of software if significant changes are requested in Section 5.0.

7.1 To initiate creation of a new version of design documentation, the Project Manager shall complete Part 1 of the New Version Report in the format of EXHIBIT 6 to identify the base versions of design documentation, and the revision to be implemented. Only those changes reported and logged in Section 5.0, and typographical and minor editorial changes that clarify but do not change the meaning of the text, may be implemented and reviewed in accordance with Section 8.0.

The Project Manager shall transmit the New Version Report with Part 1 completed to the Code Custodian.

7.2 On receipt of the New Version Report, EXHIBIT 6, the Code Custodian shall ensure that the following tasks are performed:

- a unique version identifier is assigned to the new design documentation and entered on the New Version Report, EXHIBIT 6
- a copy is obtained of the designated base version of design documentation to be revised
- a revised version of the design documentation is developed that includes the selected changes. The revised version may be in the form of a new document or a set of replacement pages, with replacement instructions for the designated base version.
- each page in the new design documentation or each replacement page is marked with the new version identifier to differentiate it from the designated base version.

7.3 The Code Custodian shall ensure that all additional errors (except typographical and minor editorial changes) in the design documentation discovered during the revision process are handled as new change requests in accordance with Section 5.0, and that these errors are corrected in the revised design documentation.

7.4 When the actions in Sections 7.2 and 7.3 are completed, the Code Custodian shall complete Part 2 of the New Version Report, EXHIBIT 6, and shall deliver the draft revised design documentation or draft replacement pages and instructions to the project manager for review in accordance with Section 8.0.

8.0 Independent Technical Review of New Versions of Software and/or Design Documentation

8.1 The Project Manager shall ensure that an ITR of the new version of software and/or design documentation is conducted in accordance with PAP-70-604, Independent Technical Review.

8.2 The Project Manager shall designate items for review and include at minimum the following:

- New Version Report, EXHIBITS with Parts 1 and 2 completed
-

SOFTWARE CONTROL PROCEDURE

9515558.2674

PROCEDURE NO.: SCP-70-314

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 7 OF 8

- copies of all Change Request Forms, EXHIBIT 4, for changes included in the new version
- documents developed in Section 6.2, including listings of revised software, listings of software modifications, testing documentation, and results of application runs used for testing
- revised design documentation or replacement pages and instructions developed in Section 7.2.

8.3 The criteria for approval of the ITR items designated in Section 8.2 shall be the following, at a minimum:

- satisfactory implementation of the designated requested changes
- conformance of revised software to design input specified on the Software Requirements Form, SCP-70-312, Determination of Software Requirements.
- conformance of revised design documentation to the requirements specified on the Software Requirements Form, SCP-70-312, Determination of Software Requirements.
- adequacy and correctness of testing of the revised software version, including input, input assumptions and results
- adherence of the software to the requirements for version identification in Section 2.2 and for the disclaimer statement in Section 2.3.

8.4 When the new version is approved for release by the ITR, the Project Manager shall ensure that Part 3 of the New Version Report, EXHIBIT 6, is completed and that copies of the New Version Report, the ITR Report, the new version of software and the new version of design documentation are transmitted to the code custodian and are also maintained as research project records.

9.0 Release of New Versions of Software and/or Design Documentation

9.1 On receipt of the new version of software and/or design documentation from the Project Manager, the Code Custodian shall:

- indicate completion of each installed software change in the Software Change Request Log, EXHIBIT 5
- (Impact Level I only) identify the new version of software and/or design documentation and incorporated changes (by change request log numbers) in the Software Version Log, EXHIBIT 1.
- create backup copies and identify new magnetic media items in the Magnetic Media Log, EXHIBIT 2, in accordance with Section 3.0.
- notify users identified on the Software User List, EXHIBIT 3, of the availability of the new version of the software and/or design documentation.

9.2 If the user requests the new version of software and/or design documentation, the Code Custodian shall update the next numbered column under software version/date of release in the Software User List, EXHIBIT 3.

10.0 Termination of Configuration Management

Upon completion of the project supporting configuration management, the Code Custodian shall notify all persons listed on the Software User List (EXHIBIT 3, Section 4.3) of the termination of configuration management support. Other PNL projects may assume the configuration management function in accordance in

SOFTWARE CONTROL PROCEDURE

with Section 1.0, and applicable sections of SCP-70-312, Determination of Software Requirements and SCP-70-317, Transfer of Software Data and/or Documentation.

11.0 Reporting of Deficiencies

If the documents produced by this procedure are found deficient, the Project Manager shall evaluate and document the deficiencies with Deficiency Reports in accordance with PAP-70-1502, Deficiency Reports.

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- Software Version Log
- Magnetic Media Log
- Software User List)
- Processed Change Request Form
- Software Change Request Log
- New Version Report
- one or more benchmark test cases
- Deficiency Reports, when generated.

Documentation generated by other software control procedures that constitute part of the configuration management document package includes, but are not limited to:

- the Final Internal Development Review (FIDR) package for developed or modified software (SCP-70-313)
- completed Software Requirements Form - Engineering/Scientific and/or Support Software, including related documentation (SCP-70-312).
- completed Software Testing Plan (SCP-70-315).

SOFTWARE VERSION LOG

Software Name: _____
Design Documentation Title: _____
Project Title and Number: _____

SOFTWARE VERSION	DESIGN DOCUMENTATION VERSION(S)	CREATION DATE	DESCRIPTION (e.g., Change requests incorporated)

Page Completion Certified By:

Code Custodian

Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

MAGNETIC MEDIA LOG

Software Name: _____
Project Title and Number: _____

MEDIA TYPE AND LOG NO.	DESCRIPTION (e.g., Software Version Number)	LOCATION/DISPOSITION AND DATE			
		1	2	3	4

Page completion Certified By:

Code Custodian _____ Date _____

**THIS PAGE INTENTIONALLY
LEFT BLANK**

SOFTWARE USER LIST

Software Name: _____
Project Title and Number: _____

NAME AND ADDRESS OF USER	SOFTWARE VERSION/DATE OF RELEASE				
	1	2	3	4	5

Page completion Certified By:

Code Custodian _____ Date _____

**THIS PAGE INTENTIONALLY
LEFT BLANK**

CHANGE REQUEST FORM

Change Request Number _____
(To be entered by code custodian)

Software Name and Version: _____
Computer Type and Operating System: _____
Document Title and Version: _____

PART 1 Person requesting code or document change or reporting problem:

Submitted by Name: _____ Date Submitted: _____

Address: _____ Telephone: _____

Change(s) and/or problem(s) reported (if a software problem is being reported, include a description of input data that can be used to duplicate the error):

PART 2 To be completed by the code custodian.

_____ Probable software error. _____ Probable documentation error. _____ No errors found.

Description/Recommendation:

Request Evaluated By:

Code Custodian Date

PART 3 To be completed by the project manager.

1) Does this change affect previously reported information? _____ Yes _____ No

2) Should users (as identified on Software User List, EXHIBIT 3) be notified?

_____ Yes _____ No, for the following reason(s):

3) Disposition of change request.

_____ Approved _____ Disapproved

Comments/Instructions:

Reviewed and Approved By:

Project Manager Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

SOFTWARE CHANGE REQUEST LOG

Software Name: _____
Project Title and Number: _____

CHANGE REQUEST NO. (FROM EXHIBIT 4)	DATE RECEIVED	REQUIRES DOCUMENTATION REVISION? (Y/N)	DISPOSITION			REVISED SOFTWARE/DESIGN DOCUMENTATION VERSION IDENTIFIER
			ACCEPT	REJECT	DATE USERS NOTIFIED	

Page Completion Certified By:

Code Custodian

Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

NEW VERSION REPORT

NEW SOFTWARE VERSION _____
NEW DOCUMENT VERSION _____
(To be entered by Code Custodian)

PART 1 To be completed by the Project Manager.

Base Software Name and Version: _____
Computer Type and Operating System: _____
Base Design Documentation Title and Version: _____
Project Title and Number: _____

List change request numbers to be installed:

List the test case(s) to be used:

Reviewed and Approved By:

Project Manager

Date

PART 2 To be completed by the Code Custodian.

Are additional software and/or design documentation changes required? If so, complete Part 1 of the Change Request Form, EXHIBIT 4, and note associated change request number(s) below.

Identify items submitted for ITR:

Reviewed and Approved By:

Code Custodian

Date

PART 3 To be completed by the Project Manager.

The revised version of the software is approved for use.

Release Date: _____

Reviewed and Approved By:

Project Manager

Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

SOFTWARE CONTROL PROCEDURE

9513358.2681

PROCEDURE NO.: SCP-70-315

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: SCP-70-315, CONVERSION TESTING, VERIFICATION, AND/OR VALIDATION OF SOFTWARE

PURPOSE

Describe the methods including conversion testing, verification, and validation used to verify the design of software.

APPLICABILITY

When selected on the Software Requirements Form in accordance with SCP-70-312, Determination of Software Requirements, this procedure applies to both engineering/scientific software that has been configuration managed in accordance with SCP-70-314, Software Configuration Management, and support software.

Application runs to test software shall be performed and documented in accordance with SCP-70-316, Software Application Control, if specified on the Software Requirements Form. Hand calculations (if applicable) shall be performed in accordance with PAP-70-301, Hand Calculations, General.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Code Custodian
- Project Manager
- Testing Personnel.

DEFINITIONS

Only the definition unique to this procedure is included here. Other terms are defined in SCP-70-312, Determination of Software Requirements.

Testing - A general term for the purpose of this SCP, referring to conversion testing, verification, validation, or any combination thereof.

IMPLEMENTATION

1.0 Requirements for Conversion Testing, Verification, and/or Validation

- 1.1 The **Project Manager** shall ensure that conversion testing, verification (including benchmarking), and/or validation required for engineering/scientific software and support software as indicated on the Software Requirements Form is performed.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

J.F. Mucha
J.F. Mucha

6/20/94

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

J.E. McGarrah
J.E. McGarrah, Manager

6/20/94

SOFTWARE CONTROL PROCEDURE

- 1.2 The Project Manager shall ensure that testing personnel are qualified to test the software for the uses being evaluated.
- 1.3 The Code Custodian shall ensure that testing personnel obtain the current version of software, design documentation, and documentation of any previous testing.

2.0 Preparation of the Software Testing Plan

- 2.1 Testing Personnel shall prepare a Software Testing Plan in the format of EXHIBIT 1. The Software Testing Plan, EXHIBIT 1, shall specify the testing documentation required, and the evaluation methods and acceptance criteria for review of testing. The tests that are performed shall, at a minimum, exercise the software options and the range of variables likely to be encountered in the application of the software.
- 2.2 The Project Manager shall review the Software Testing Plan, EXHIBIT 1, for completeness and correctness, and shall indicate approval by signature and date.

3.0 Performance and Documentation of Testing

- 3.1 The Testing Personnel shall perform and document testing in accordance with the approved Software Testing Plan, EXHIBIT 1.
- 3.2 Testing Personnel shall complete and document application runs for testing in accordance with SCP-70-316, Software Application Control. Hand calculations in support of testing shall be documented in accordance with PAP-70-301, Hand Calculations, General, if required by the applicable QA plan.
- 3.3 If a software error is discovered during testing, the Testing Personnel shall report the error to the code custodian in accordance with SCP-70-314, Software Configuration Management, and to the project manager who shall determine whether testing shall continue. If the error is so severe as to require a new software version, the testing shall not continue. In this case, the Project Manager shall document that the Software Testing Plan is no longer applicable.
- 3.4 If testing shall not continue, Testing Personnel shall prepare a new testing plan in accordance with Section 2.0 for use with a corrected version of the software.
- 3.5 When testing is completed, Testing Personnel shall provide the project manager with testing documentation required by the Software Testing Plan, EXHIBIT 1.

4.0 Independent Technical Review of Testing

- 4.1 The Project Manager shall assure that an ITR of the testing method and testing documentation required by the Software Testing Plan, EXHIBIT 1, is conducted in accordance with PAP-70-604, Independent Technical Review.
 - 4.2 Evaluation methods and acceptance criteria for the review shall comply with the Software Testing Plan, EXHIBIT 1.
 - 4.3 If applicable, the Project Manager shall write a memo to the Code Custodian and users stating that the software is verified and the disclaimer notification shall be removed from subsequent output and listings. The Project Manager shall ensure that the memo is maintained as a research project record.
 - 4.4 The Project Manager shall ensure that an approved testing results package consisting of the following is prepared:
 - Software Testing Plan, EXHIBIT 1
-

SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-315

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

- ITR Report.

The Project Manager shall ensure that a copy is maintained as a research project record, with a copy sent to the code custodian.

5.0. Reporting of Deficiencies

If the Software Testing Plan (EXHIBIT 1), testing results, or documentation of testing are found to be deficient, the Project Manager shall evaluate and document the deficiency in accordance with PAP-70-1502, Deficiency Reports.

REQUIRED RECORDS

The Software Testing Package ~~created as a result of this procedure is a record.~~ Typically the Software Testing Package consists of:

- testing results package
- hand calculations generated in support of testing activities
- Application Package
- Deficiency Reports, when generated.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

SOFTWARE TESTING PLAN

Impact Level I II

- 1) Project title and number:
- 2) Software name and version:
- 3) Computer type and operating system:
- 4) Purpose and scope of testing:

- Testing of New Version Conversion Testing E/S Software Validation
- E/S Software Verification Software Verification

- 5) Tests to be run:
- 6) Evaluation methods:
- 7) Acceptance criteria:
- 8) Testing documentation required:
- 9) Sponsor and/or additional requirements:

Reviewed and approved by:

10) _____
 Preparer Date

11) _____
 Project Manager Date

INSTRUCTIONS FOR COMPLETING SOFTWARE TESTING PLAN

- 1-2) Enter the project title and number and the software name and version on this page and any attached pages.
- 3) Enter the computer type and operating system on which the testing is to be performed (e.g., DEC VAX 11/780 with VMS; or CDC 7600 with LTSS).
- 4) Check the appropriate space and describe the purpose and scope of testing. NOTE: Software verification can encompass both conversion testing and verification.
- 5) Describe the test runs to be made in enough detail so that an equally competent person can reproduce them. Attach additional pages, if required. This description could consist of references to previous test documents, drawings, experimental test descriptions, run matrices, and other similar items. Input listings shall be attached, if necessary. The tests that are performed shall, at a minimum, exercise the software options and the range of variables likely to be encountered in the application of the software.
- 6-7) Describe the evaluation methods and acceptance criteria to be used by the independent technical reviewers. Attach additional pages, if required. Evaluation methods can include comparison of specific results with experimental data or hand calculations, with previous standard test case results, or with other software. Since acceptance criteria are the basis for reviewers to approve the testing results, they shall be quantified.
- 8) Describe testing documentation required (e.g., computer output).
- 9) Include specific sponsor requirements or other additional requirements for testing, evaluation or documentation. The Software Requirements Form or research project planning documents may be referenced here as appropriate.
- 10) The preparer shall sign this space and enter the date the Software Testing Plan, EXHIBIT 1, was prepared.
- 11) The project manager shall indicate approval of the Software Testing Plan, EXHIBIT 1, by signature and date.

SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-316

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: SCP-70-316, SOFTWARE APPLICATION CONTROL

PURPOSE

Describe the method for the preparation and review of the documentation package required when software is used to perform calculations or to manipulate data.

APPLICABILITY

When selected on the Software Requirements Form in accordance with SCP-70-312, Determination of Software Requirements, this procedure applies to the use of software to generate or process data to develop conclusions that are to be reported to the client; to document testing done in accordance with SCP-70-315, Conversion Testing, Verification, and/or Validation of Software; and/or to document new-version testing performed in accordance with SCP-70-314, Software Configuration Management.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Project Manager
- User.

DEFINITIONS

Only the definition unique to this procedure is included here. Other terms are defined in SCP-70-312, Determination of Software Requirements.

Application Package - A package consisting of the Application Report (EXHIBIT 2) as a cover page, an Application Record Log (ARL, EXHIBIT 1), and an orderly series of application runs, including the associated pre- and post-processor codes.

IMPLEMENTATION

1.0 Minor Changes to Software

This section is not applicable to application runs performed for the purpose of testing new versions of software. However, for other application runs, minor software changes that do not affect software logic (e.g., changes in array dimensions or input/output format) shall be allowed, provided that the User provides documented assurance that the changes do not introduce errors in application run results. The changes are only for use with a specific application run and shall not be accessed by other users.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

J.F. Mucha
JF Mucha 6/20/94

JE McGarrah
JE McGarrah, Manager 6/20/94

SOFTWARE CONTROL PROCEDURE

1.1 The User shall document minor changes and include the following:

- assurance that the changes do not introduce errors in the application run results. Acceptable assurance shall be provided by performing, as an example, an application run with the modified version, with results comparable to an application run with the base version.
- computer-generated listing to indicate differences between the configuration-managed version of the software and a version of the software with changes installed.

1.2 The User shall reference minor changes in the "software name and version" section of the ARL in the format of EXHIBIT 1, and in item 4 of the Application Report in the format of EXHIBIT 2, when an application run is made using the software with minor changes.

2.0 Preparation of an Application Package

The output of all or a logical subset of a series of computer runs along with supporting data and documentation shall make up an application package. Though an application package may occasionally include only a single computer run, the more usual case comprises an orderly series of many runs including application runs of pre- and post-processor codes, i.e., support software. Only application runs developing information to be reported to the client or submitted as a testing record shall be included in an application package.

2.1 The User shall prepare an application package. This package shall include:

- ARL (EXHIBIT 1)
- Application Report (EXHIBIT 2)
- input data or review documentation referenced in item 3 or item 4 of the Application Report (EXHIBIT 2)
- hand calculations (in accordance with PAP-70-301, Hand Calculations, General).

2.2 The User shall prepare an ARL using the format of EXHIBIT 1. The user reference application runs to be reported to the client by a unique ARL number recorded on the ARL, EXHIBIT 1.

2.3 The User shall mark record copies of the input, output, and data bases (if any) of each application run with the ARL number and date of run. If record copies of input, output and/or data bases are on magnetic media, the user shall attach documentation to the ARL as necessary to make each file on the magnetic media traceable to the ARL. The magnetic media shall be externally labeled to make it traceable to the ARL. (NOTE: Temporary or intermediate data files created by one run and used as input to another need not be saved as long as the data file is reproducible with the information provided.)

2.4 The User shall prepare a signed and dated Application Report in the format of EXHIBIT 2 (as a cover page to the application package).

2.5 The User shall submit an application package to the project manager for review in accordance with Section 3.0.

3.0 Independent Technical Review of the Application Package

This section is not applicable to application runs performed for the purposes of testing new versions of software or for verification or validation.

3.1 The Project Manager shall ensure that an Independent Technical Review (ITR) of the application package (see Section 2.1) is performed in accordance with PAP-70-604, Independent Technical Reviews.

SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-316

REVISION NO.: 2

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

3.2 The criteria for approval of the reviewed items shall be one or more of the following, as appropriate:

- appropriateness and correctness of input and input assumptions, if not previously reviewed
- correctness of application runs after minor changes have been made (see Section 1.1)
- adequacy and correctness of documentation
- adequacy and correctness of results.

3.3 On completion of ITR, the Project Manager shall sign and date the Application Report, EXHIBIT 2, to indicate that the application package is approved by ITR for reporting to the client or for use as evidence of adequate testing.

3.4 The Project Manager shall ensure that a copy of the application package is maintained as a research project record.

4.0 Reporting of Software Errors

While performing software application runs, if the user discovers an error in software or design documentation, the User shall report this error to the Project Manager and Code Custodian in accordance with SCP-70-314, Software Configuration Management. If the Project Manager determines that the error adversely affects results, provisions for rerunning the application run with a corrected version shall be made, if appropriate.

5.0 Reporting of Deficiencies

In an application run is found to be deficient after being reported to the client, the Project Manager shall evaluate and document the effect of the deficiency in accordance with PAP-70-1502, Deficiency Reports.

REQUIRED RECORDS

Documents in the application package ~~created as a result of this procedure are records~~. Typically the application package consists of:

- Application Record Log
- Application Report
- Independent Technical Review Report(s) (3.4 and PAP-70-604, Independent Technical Review)
- input data/review documentation referenced in item 3 or 4 of the Application Report
- hand calculations generated in support of application activities
- Deficiency Reports, when generated.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

APPLICATION RECORD LOG

1) Project Title and Number:

2) Application Record Log Number	3) Date and Time of Run	4) Software Name (Title), Version, and Operating System	5) Computer Type/Operating System/ Compilers/Libraries	6) Comments	7) Date Input/ Identifier

8) Prepared By:

Signature

Date

9513358.2686

INSTRUCTIONS FOR COMPLETING THE APPLICATION RECORD LOG

- 1) Enter the project title and number.
- 2) Assign a unique number to each application run in the package.
- 3) Indicate the date and time the application run was generated.
- 4) Indicate the correct name and version of the software used to generate the application run.
- 5) Enter the computer type and operating system used in the application package. Include specific system library(ies) and compiler(s) if unique to the application run.
- 6) Indicate in this column, as needed, a more detailed description of the application run, any errors discovered in the application run, and other relevant information to aid in traceability or reproducibility of the application run. Note here if software has not received an FIDR per SCP-70-313, Final Internal Development Review of Software and Documentation, or it has not been verified per SCP-70-315, Conversion Testing, Verification, and/or Validation of Software.
- 7) Identify the input file(s) and database identifiers used in the application run.
- 8) The preparer shall sign and date upon completion.

APPLICATION REPORT

- 1) Project Title and Number:
- 2) Purpose of application package and relationship to other work:
- 3) List original sources of input data, assumptions, and derivations used to obtain it, and justification for its use, as appropriate. (If input information has been previously reviewed, reference the documentation of this review.)
- 4) Minor changes made in the software that produced the application run (see Section 1.0).
- 5) Describe interrelationships and dependencies of each application run in the application package:
- 6) Summarize the overall output of the application package in relation to the purpose stated in item 2 above (including tables and graphs, as appropriate):
- 7) Submitted for ITR by:

Preparer

Date

- 8) Approved for reporting results to sponsor by:

Preparer

Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

9515558.2688
SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-317

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 3

TITLE: SCP-70-317, TRANSFER OF SOFTWARE, DATA, AND/OR DOCUMENTATION

PURPOSE

Describe the methods for the transfer of software, data, and related documentation between organizations to ensure that the required information is sent and received.

APPLICABILITY

When selected on the Software Requirements Form in accordance with SCP-70-312, Determination of Software Requirements, this procedure applies to all software, data, and/or documentation that is transferred between PNL and clients or external contractors, and between research projects at PNL.

This procedure does not apply to transfer of software items obtained by purchase requisition under PAP-70-401, Purchase Requisitions.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Custodian
- Project Manager
- Receiver of Request for Transfer
- Requestor.

DEFINITIONS

Only definitions unique to this procedure are included here. Other terms are defined in SCP-70-312, Determination of Software Requirements.

Custodian - A generic term for the purposes of this procedure that refers to either the code custodian or the database steward, as applicable.

Receiver - An individual to whom software, data, and/or documentation are transferred.

Request for Transfer (RFT) - A request for software, data, and/or documentation in the form of a letter, memo, telefax, etc.

Requestor - An individual who submits a request for transfer of software, data, and/or documentation.

CONCURRENCE

DATE

N/A

APPROVAL AUTHORITY

DATE

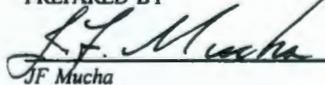


6/20/94

JW Smith, Director, Quality Programs

PREPARED BY

DATE

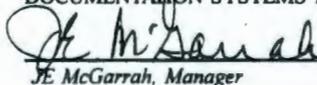


6/20/94

JF Mucha

DOCUMENTATION SYSTEMS DEPARTMENT

DATE



6/20/94

JE McGarran, Manager

SOFTWARE CONTROL PROCEDURE

IMPLEMENTATION

1.0 Transfer to Outside Contractors, Clients, or to Another Research Project at PNL

- 1.1 A transfer is initiated when a Requestor submits a request for software, data, and/or documentation to a PNL organization. A request may be in the form of a letter, memo, telefax, telephone call, etc., or may be in the format of a Request for Transfer form (RFT, EXHIBIT 1). If the request is not in the format of EXHIBIT 1, the Receiver shall record the request on an RFT, and forward it to the Custodian.
- 1.2 On receipt of the RFT, the Custodian shall ensure that the following activities are performed:
 - A sequential control number is assigned to the RFT
 - Part II of the RFT is completed by specifying items to be included in the transfer package. When approved, the transfer package shall consist of the RFT, and items listed in Part II.
 - The RFT is sent to the Project Manager for approval.
- 1.3 If the RFT was not originated by the client of the research project, the Project Manager shall contact the client (via letter or phone) to request approval for transfer. This contact shall be documented on the RFT. (NOTE: This approval is required even if another branch or office of the sponsoring organization requests software, data, and/or documentation.)
- 1.4 The Project Manager shall review the RFT and indicate approval or disapproval by signature and date on Part III of the RFT.
- 1.5 On receipt of Project Manager's approval of the RFT, the Custodian shall ensure that the following activities occur:
 - The transfer package as specified in Part II of the approved RFT is prepared.
 - The approved RFT and those items of the transfer package not transferred electronically are sent to the requestor.
 - Those items of the transfer package specified on the RFT are transmitted by electronic means.
 - The requestor of the transfer package is added to the Software User List in SCP-70-314, Software Configuration Management.
- 1.6 If the RFT is disapproved by either the Project Manager or the client, the Custodian shall ensure that a letter is sent to the requestor explaining the disapproval. A copy of the letter shall be attached and maintained as a research project record.
- 1.7 If there are problems with the transfer (e.g., incomplete package, damage enroute, etc.) as indicated by the requestor by telephone, letter, telefax, or on the Acknowledgement of Receipt, Part IV of the RFT, the Custodian shall:
 - document the steps taken to complete the transfer and final resolution on Part V of the RFT
 - ensure that additional transfers (if any) of the originally approved package are accomplished in accordance with Section 1.5
 - ensure that any other items requested are approved by submitting additional RFTs in accordance with Section 1.3.

SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-317

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 3

1.8 Upon successful completion of transfer, the Custodian shall maintain the RFT as a research project record.

2.0 Transfer from Outside PNL or from Another Research Project at PNL

2.1 The Custodian shall initiate a request for transfer of software, data, and/or documentation from another research project in PNL or from a source outside PNL by completing Part I of the RFT and submitting it to the Project Manager for approval.

2.2 The Project Manager shall review and approve the RFT by signature and date on Item 10 and return the RFT to the Custodian. Item 11 does not require client approval and should be marked N/A.

2.3 The Custodian shall assure that the approved RFT is sent to the potential supplier of the software, data, and/or documentation.

2.4 On receipt of the requested items, the Custodian shall ensure that the contents coincide with the requirements specified on the RFT. If the items are not correct or are incomplete, the Custodian shall ensure that a notice of contingency is sent to the supplier requesting the corrected items.

2.5 When transfer is complete (i.e., the items are correct, complete, and accepted), the Custodian shall ensure that the following occur:

- Completion of successful transfer is documented on Part VI of the RFT.
- The sender is notified of receipt of the transferred items, and a copy of the RFT is maintained as a research project record.

3.0 Reporting of Deficiencies

If data, software, and/or documentation are found to be deficient after being sent to a requestor or received from another PNL research project, the Project Manager shall evaluate and document the deficiencies in accordance with PAP-70-1502, Deficiency Reports.

REQUIRED RECORDS

Requests for Transfer (RFT) created as a result of this procedure are records.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

Control No.:

REQUEST FOR TRANSFER
(See Instructions)

PART Ia: Please transfer the following described software, data and/or documentation to:

- 1) Name:
- 2) Address:
- 3) Phone Number:

PART Ib, REQUESTED

PART II, TRANSFER PACKAGE

4) Items Requested (include version number where appropriate):	Electronic Transfer	7) Items Transferred:	Electronic Transfer
5) Magnetic media type and format:		8) Magnetic media type and format:	
6) Reason for request:		9) Explanation of differences:	

PART III, APPROVAL OF TRANSFER

Reviewed:

- 10) _____
Project Manager APPROVED/DISAPPROVED (circle one) Date
- 11) _____
Client Contact APPROVED/DISAPPROVED (circle one) Date
(For transfers from the research project.)

REQUEST FOR TRANSFER INSTRUCTIONS

- PARTS Ia and Ib -** The Requester shall provide the following information to the custodian:
- 1) The identity of the individual requesting the software, data and/or documentation.
 - 2) The company and address of the individual.
 - 3) The requester's phone number.
 - 4) Software or data items requested: indicate electronic transfer, if applicable.
 - 5) Type and format of magnetic media requested.
 - 6) The reason for the request of the information.
- PART II -** The supplier or Custodian preparing the transfer shall assign the corresponding control number and provide the following information:
- 7) Software or data items available to be supplied: indicate if electronic transfer is requested and possible.
 - 8) The type and format of magnetic media to be supplied.
 - 9) If software items or magnetic media type and format to be supplied differ from those requested, an explanation (included or attached). If there are none, indicate N/A.
- PART III -** The following are the required approvals for transfer:
- 10) The Project Manager indicates approval or disapproval of the RFT, EXHIBIT 1, by signature, date, and circling of either approved or disapproved.
 - 11) The client indicates approval or disapproval of the RFT, EXHIBIT 1, by signature, date, and circling of approved or disapproved. If client approval is verbal or by letter, the project manager shall note such in Item 11. The client approval is required for transfers to other PNL research projects, to outside contractors, or to the client, if the person or organization requesting the transfer is not the client technical contact.
- PART IV -** The Requester of the software, data and/or documentation shall provide the following:
- 12) Address for return of acknowledgment of receipt.
 - 13) Status of acceptance of transferred software, data and/or documentation.
 - 14) Explanatory comments regarding the transfer package, as necessary.
 - 15) Signature of requester and date of signature.
- PART V -** Resolution of problems.
- 16) The Custodian shall document actions taken to resolve any problem described in Item 14 above. If none, so state.
- PART VI -** Completion of transfer.
- 17) When the transfer is complete and/or all actions have been completed, the Custodian and Project Manager shall indicate completion by signature and date.

**THIS PAGE INTENTIONALLY
LEFT BLANK**

9513358.2692
SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-318

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 1 OF 5

TITLE: SCP-70-70-318, CONTROL OF DATABASES

PURPOSE

Describe the methods used for database management to ensure the integrity of the data during its analysis and/or use in modeling.

APPLICABILITY

When selected on the Software Requirements Form in accordance with SCP-70-312, Determination of Software Requirements, this procedure applies to the design, implementation, maintenance, and control of a computerized database and/or database documentation for a specific research project. It does not apply to the control of quality and integrity of data during its generation from experiments or survey, or to the update of a dynamic database, which shall be covered by a project-specific technical procedure.

Use of data from a database in application runs is covered in SCP-70-316, Software Application Control, and management of database software is covered in SCP-70-314, Software Configuration Management. Data transfer is covered in SCP-70-317, Transfer of Software, Data, and/or Documentation.

RESPONSIBILITIES

Staff with responsibilities for implementing this procedure are:

- Database Steward
- Database User
- Project Manager.

DEFINITIONS

Only definitions unique to this procedure are included here. Other terms are defined in SCP-70-312, Determination of Software Requirements.

Database Design - A structure designed and implemented to allow efficient storage and retrieval of data using database software.

Database Documentation - Documentation of a database including, but not limited to, written descriptions of database structure, units of measurement, missing value codes, instructions for use of database software, interfaces with other software, and criteria for checking database software functions.

Data Listing - A computer-produced copy of data in human-readable form.

Data Set - A set of data that is entered into database software.

CONCURRENCE

DATE

APPROVAL AUTHORITY

DATE

N/A

JW Smith
JW Smith, Director, Quality Programs

6/20/94

PREPARED BY

DATE

DOCUMENTATION SYSTEMS DEPARTMENT

DATE

JF Mucha
JF Mucha 6/20/94

SE McGarr
SE McGarr, Manager 6/20/94

SOFTWARE CONTROL PROCEDURE

Data Set Identifier - Identification of a file or data set that indicates the unique name or number of the file or data set on the computer.

Data Sheets - Documented hard copy of data (as opposed to data on magnetic media).

IMPLEMENTATION

1.0 Access to Data

- 1.1 The Project Manager shall assign personnel (Database Users) with authority to access data in a database. The assignment shall be documented in a memorandum to the assigned staff and to the Database Steward, and shall be maintained as a research project record. Included in the assignment shall be type of access of each user (e.g., read only, read-write, etc.).
- 1.2 The Database Steward shall ensure that database access by each user is limited to the type designated.
- 1.3 The Database Steward shall maintain a list of authorized Database Users and the type of access of each user.

2.0 Definition and Documentation of Database Design (Database Documentation)

- 2.1 The Database Steward shall ensure that the database design is documented and submitted to the Project Manager for evaluation (see Section 2.2). The database documentation shall reference or include, but shall not be limited to, the following:
 - database software to be used (all database software shall be classed in accordance with SCP-70-312, Determination of Software Requirements)
 - structure of the database, including unique keys for retrieval and/or sorting of information
 - units of measurement and missing value codes (e.g., explanation of what names or symbols are used)
 - instructions for use of database software, including methods to input, retrieve, or modify data
 - criteria for checking database software functions (e.g., available test cases).
- 2.2 The Project Manager shall determine if an ITR in accordance with PAP-70-604, Independent Technical Review, of database design and database documentation is necessary. If so, the Project Manager shall ensure that the review is performed and documented.
- 2.3 The Project Manager shall return the database documentation to the Database Steward for maintenance as a research project record. The copies shall be submitted following an ITR, if one has been required in Section 2.2.

3.0 Input of Data to Database Software

- 3.1 The Database Steward shall ensure that acquired data and/or documentation are transferred to the research project in accordance with SCP-70-317, Transfer of Software, Data, and/or Documentation.
- 3.2 (Impact Level I only) The Database Steward shall log acquired data and/or documentation on the Data Management Log (DML) in the format of EXHIBIT 1. The data and/or documentation shall be identified by a unique identifier. When each page of the DML, EXHIBIT 1, is completed, the Database Steward shall sign and date the form, and ensure that it is maintained as a research project record.

SOFTWARE CONTROL PROCEDURE

PROCEDURE NO.: SCP-70-318

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 3 OF 5

3.3 The Database Steward shall maintain a copy of acquired data and/or documentation as a research project record.

4.0 Verification of Data Input: Data Received as Hard Copy (Data Sheets)

4.1 If data are received on data sheets, the Database User (see Section 1.1) shall enter data into the database software. The user entering the data shall generate a listing of data entered that includes data set identifiers and date of entry.

4.2 The Database User entering data shall ensure correct entry into the database software by comparing received data sheets with the data listing. If errors are discovered, the errors shall be corrected and a new data listing generated. When data are correctly entered, the Database User entering the data shall sign and date the correct data listing and submit it to the Database Steward.

4.3 The Database Steward shall ensure that a copy of the verification of correct input or transfer of data to the database is maintained as a research project record.

5.0 Verification of Data Input: Data Received on Magnetic Media

5.1 If data are received on magnetic media, the Database User shall enter data from magnetic media into the database software using a computer system supported option that verifies correct transfer. Upon completion of correct transfer, Database Users shall generate a hard copy including as a minimum the following:

- data set identifiers
- date of entry
- method used to verify transfer.

The Database User entering the data shall sign and date the hard copy and submit it to the Database Steward.

5.2 The Database Steward shall ensure that a copy of the verification of correct input or transfer of data to the database is maintained as a research project record.

6.0 Modification of Data, Database Design, and/or Database Documentation

6.1 If the data, database design, and/or database documentation must be modified, Database Users (see Section 1.1) shall document proposed modifications using a Modification Request in the format of EXHIBIT 2 and submit it to the Project Manager.

6.2 The Project Manager shall review the proposed modifications described on the Modification Request, EXHIBIT 2, and shall either indicate approval by signature and date, or reject the modification request and document the reason in a signed and dated memo to the Database Steward and to research project records. If approved, the Project Manager shall forward the Modification Request, EXHIBIT 2, to the Database Steward.

6.3 The Database Steward shall return rejected modifications to the requester with the Project Manager's reason for rejection.

6.4 The Database Steward shall assign the approved Modification Request a sequential number.

6.5 The Database Steward shall implement approved modifications, shall verify correct implementation, and shall indicate such by signature and date on the Modification Request, EXHIBIT 2.

SOFTWARE CONTROL PROCEDURE

- 6.6 The Database Steward shall notify users after completion (see Section 1.3) by sending each a copy of the approved Modification Request, EXHIBIT 2.
- 6.7 The Database Steward shall ensure that a copy of the completed Modification Request, EXHIBIT 2, is maintained as a research project record.

7.0 Backup of Database and Database Documentation

- 7.1 The Project Manager shall document the method and frequency of backup of the database and other associated computer files on magnetic media in a memo to the database steward. This backup may be accomplished using a computer system supported option that verifies correct transfer (e.g., the VAX BACKUP/VERIFY option). The Project Manager shall ensure that the documentation of the frequency and method of backup and documentation of backup verification are maintained as a research project record.
- 7.2 The Database Steward shall ensure that databases are backed up and hard copy directory listings of all files backed up are generated. The Database Steward shall provide secure storage and control access to all copies.
- 7.3 The Database Steward shall ensure that secure storage is provided for two copies of database documentation and other related documents.
- 7.4 The Database Steward shall maintain a DML, EXHIBIT 1, to identify and record the location of magnetic media items created for the purposes of backup, as follows:
 - Magnetic media items maintained onsite under physical control of the database steward shall be logged with a unique data set identifier and externally labeled with database identifier/name and creation date.
 - Magnetic media items not under physical control of the database steward (e.g., in an offsite library) shall be logged with the identifiers by which they may be accessed in the host computer system.
 - A list of contents (e.g., file directory) of each magnetic media item identified in the log shall be filed with the log until the item is erased or released.
 - When a magnetic media item is moved, released or erased, the action shall be recorded on the next numbered column under location/disposition and date.

(Impact Level I only) On completion of each page of the DML, EXHIBIT 1, the Database Steward shall ensure that a copy is submitted as a research project record.

- 7.5 The Database Steward may release backup copies of magnetic media when they become obsolete (i.e., when a new master version and its backup copy are created).

8.0 Transfer of Data and/or Database Documentation

Transfer of data and/or database documentation from the research project shall be accomplished in accordance with SCP-70-317, Transfer of Software, Data, and/or Documentation, when specified on the Software Requirements Form.

9.0 Reporting of Deficiencies

If data, database design, and/or database documentation are discovered to be deficient, the Project Manager shall evaluate and document the deficiency in accordance with PAP-70-1502, Deficiency Reports.

SOFTWARE CONTROL PROCEDURE

9513358.2694

PROCEDURE NO.: SCP-70-318

REVISION NO.: 1

EFFECTIVE DATE: 08/31/94

PAGE 5 OF 5

REQUIRED RECORDS

Records that are created as a result of this procedure include:

- list of authorized database users including type of access
 - database documentation
 - documented review of data and/or documentation
 - copy of acquired data and/or documentation
 - documented verification of correct data input or transfer activities to the database
 - completed Modification Requests
 - documentation of frequency and method of backup, and verification of backup
 - completed Data Management Log, DML,
 - Deficiency Reports, when generated.
-

**THIS PAGE INTENTIONALLY
LEFT BLANK**

DATA MANAGEMENT LOG

Project Title and Number:

Database Title:

DATA SET IDENTIFIER	MEDIA TYPE	DESCRIPTION OF CONTENTS	LOCATION/DISPOSITION & DATE			
			1	2	3	4

Completion certified by:

Database Steward

Date

**THIS PAGE INTENTIONALLY
LEFT BLANK**

MODIFICATION REQUEST

Request No.:

Project Title and Number:

Database Title:

Requester:

Identification of data, data base design and/or data base documentation to be modified:

Specific modifications (e.g., old value and new value, or new data added):

Reason for modifications:

Reviewed and Approved By:

Project Manager

Date

Implemented By:

Database Steward

Date

Distribution

**No. of
Copies**

**No. of
Copies**

Offsite

- 2 DOE/Office of Scientific and
Technical Information

Greg Coomes
Washington State Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600

Gonzaga University
Foley Library Center
502 Boone Avenue
Spokane, WA 99258

Portland State University
Branford Price Miller Library
Science and Engineering Floor
P.O. Box 1151
Portland, OR 97207

Doug Shurwood
U.S. Environmental Protection Agency
712 Swift Blvd., Suite 5
Richland, WA 99352

Tri-Cities Washington State University
Public Reading Room
100 Sprout Road
Richland, WA 99352

University of Washington
Suzzallo Library
Government Publications Room
Box 352900
Seattle, WA 98195-2900

Connie Wilson
Environmental Data Management Center
2440 Stevens Center Place, H6-08
Richland, WA 99352

Onsite

DOE Richland Operations Office

- 3 **Pacific Northwest Laboratory**

Manuals Administration (1)
Technical Report Files (2)