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TELEDYNE ISOTOPES

QUALITY ASSURANCE MANUAL

ENVIRONMENTAL ANALYSIS DEPARTMENT

COMPLIANCE WITH 10 CFR 50, APPENDIX B

COMPLIANCE WITH REGULATORY GUIDE 4.15

IWL-0032-395

TELEDYNE ISOTOPES

50 VAN BUREN AVENUE

WESTWOOD, NEW JERSEY 07675

Note: The criteria of 10 CFR 50, Appendix B apply to all operations of the Environmental Analysis Department. Appendix I is a copy of Regulatory Guide 4.15, the NRC regulatory position for radiological monitoring programs effective February 1979. The same compliance and documentation procedures and approach included herein is followed by each service, thus this Quality Assurance Manual is used as the guide for the quality control programs for all radiological environmental analyses services.

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A record of the external distribution of this manual is available in the administrative offices of Teledyne Isotopes.

PROPRIETARY STATEMENT

The material in this Quality Assurance Manual is proprietary and is submitted to the client on a confidential basis. This manual may not be reproduced nor its contents disclosed to anyone without expressed written permission of Teledyne Isotopes.

INTRODUCTION

BASED ON CRITERIA SPECIFIED IN NRC 10 CFR 50, APPENDIX B

The purpose of this Quality Assurance Manual is to prescribe the programs approved by the management of Teledyne Isotopes for implementing the provisions of the applicable government regulations and the test specifications of the nuclear power station contractors. Among the applicable regulations are 10 CFR 50, Appendix B and Regulatory Guide 4.15. The 10 CFR 50, Appendix B establishes criteria for quality assurance programs and the controls that must be applied to the production and/or service operations, where applicable, at Teledyne Isotopes. Also included in this document is information pertaining to the managerial and administrative controls used to assure quality operations. The requirements of Regulatory Guide 4.15 are incorporated into the quality assurance program at Teledyne Isotopes. A copy of Regulatory Guide 4.15 is included herein as an Appendix.

These planned procedures and administrative controls have been approved and authorized by the management of Teledyne Isotopes and are applicable to the operations of each department producing goods or performing services for the nuclear or nuclear-related industries. In prescribing the quality assurance program, the objectives of management are to assure that the quality of the products produced or services performed equal or exceed specifications, are performed under controlled conditions to predetermined requirements, and can be verified by adequate documentation. Attainment of these objectives is basic to the success of Teledyne Isotopes in the production of quality products and the performance of quality services.

SECTION 1.0 ORGANIZATION

CRITERIA I IN NRC 10 CFR 50, APPENDIX B

1.1 Policy

The management of Teledyne Isotopes is committed to the establishment and execution of the programs prescribed in this Quality Assurance Manual. To develop, implement and update the quality assurance programs management establishes the position of Quality Assurance Manager.

1.2 Authority

Authority and organizational freedom are granted to the Quality Assurance manager to:

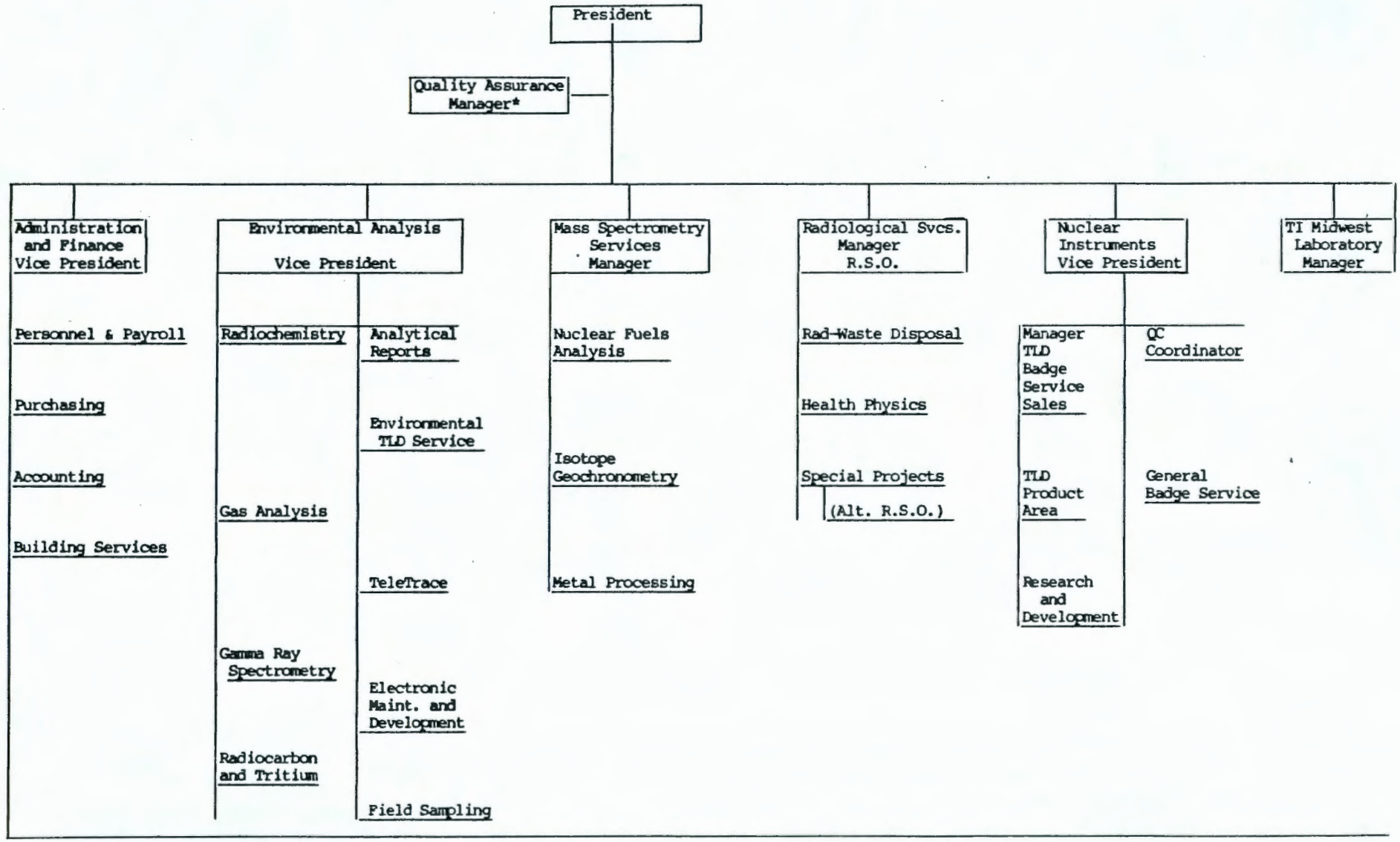
- Identify quality problems
- Initiate, recommend and provide solutions
- Verify implementation of solutions

The Quality Assurance Manager shall report directly to management at all times to provide independence from cost and schedule.

1.3 Duties

Duties of the Quality Assurance Manager shall include:

- Performing functions of attaining quality
- Performing the quality assurance functions
- Assuring that an appropriate quality assurance program is established
- Effectively executing an appropriate quality assurance program
- Verifying the quality assurance program by checking, auditing, and/or inspection
- Reviewing, issuing, and revising manuals and documents
- Assuring that sufficient controls and calibrations are executed to specify the degree of confidence of the data generated
- Assuring that all programs are documented and controlled



*Q.A. Manager reports directly to the company president.

AUTHORIZATION AND APPROVAL

The Quality Control and Assurance program defined herein has been approved by the Management of Teledyne Isotopes, and the Quality Assurance Manager has been authorized to develop and implement the procedure required to attain these goals.

- This Quality Assurance Program controls quality related operations of the Environmental Analysis Department of Teledyne Isotopes.

- Department Manager is: J. David Martin
  J. David Martin

- The Quality Assurance Manager is: Barbara I. Campbell
  Barbara I. Campbell

- Authorized by: Donald F. Schutz
  Donald F. Schutz
  President
  Teledyne Isotopes

Date: April 6, 1989

SECTION 2.0 QUALITY ASSURANCE PROGRAM

CRITERIA II IN NRC 10 CFR 50, APPENDIX B

2.1 Policy

To comply with the applicable criteria of NRC 10 CFR 50, Appendix B, and the policies of Regulatory Guide 4.15, the quality assurance program established and authorized by Teledyne Isotopes must be documented and must include written policies, procedures, and instructions for all operations affecting quality. Each department in the company producing goods or providing services to the nuclear industry must conform to the provisions of the quality assurance program described in this document. This section includes a summary of the basic principles required for implementing the quality assurance program. Also included are the areas of responsibility of managers for the ongoing operation of the program.

2.2 Implementation

To implement the provisions of the quality assurance program each department must review the criteria outlined in this document and incorporate the necessary procedures into their routine operations. Conformance must be established and demonstrated by documentation for each applicable criteria of 10 CFR 50, Appendix B and the policies of Regulatory Guide 4.15. For each department the procedures must maintain control of the following operations:

2.2.1 Organization

2.2.1.1 Show sample and data control for all service operations. For this operation describe and document the operating procedures followed by the department from the receipt of the request for service from the customer to the issuance of the final report and submission to the customer.

2.2.1.2 Show procurement and the control of components for product oriented operations. This section shall prescribe the selection and

2.2.1.2 control of components based on the design and specifications of the product and also establish control from the time of procurement through the manufacturing operations to the final testing and shipping of the product to the customer.

2.2.1.3 Show administration of the programs and include a chart showing the chain of responsibility. The qualifications and duties of personnel shall be specified. Personnel shall be trained and certification documented for the tasks performed.

2.2.2 Quality Control of Measurements and Specifications (for example, Accuracy and Precision Controls)

2.2.2.1 Show how the control of accuracy and precision of measurements is established and documented for each service oriented operation. All measurements of backgrounds, standards, blanks, spikes, and intercalibrations shall be compiled in appropriate documents to establish and verify the fundamental operating parameters of the monitoring systems used for the measurement of radioacivities or the effects thereof of samples submitted for analysis to Teledyne Isotopes. In addition, show the acceptable range of deviation or variation of all accuracy and precision measurements and specify the documents containing the compilations of these data. From a statement of the range of acceptable deviations from the mean or operating criteria, the policy of removal of systems from service and the need for corrective action shall be established and documented.

2.2.2.2 Show the control and verification of the specifications for acceptable quality for each product oriented department. Provide documentation by the use of tags, logbooks, selection procedures or other means and show the necessary operating procedures. The objectives of these quality control procedures is to improve operating efficiency and the quality of the products produced.

2.2.3 Operating Procedures and Parameters

2.2.3.1 Document the operating procedures and control parameters for each of the service departments. Distribute copies of applicable procedures to each technician performing an assigned task and keep copies in the working area. When procedures are revised, issue the new dated version and specify that the obsolete copies be destroyed or marked obsolete.

2.2.3.2 Prepare operating procedures and specifications for each of the product areas. Distribute and maintain copies of the operating manuals in the working area for the product being produced.

2.2.4 Quality Assurance Controls and Methods

2.2.4.1 Provide internal controls over general working conditions, working areas, working tools, and employees to implement the quality assurance program. Some of the required internal controls are items of company policy and are followed routinely. Document and include summaries of the existing controls.

To comply with the provisions of 10 CFR 50, Appendix B, additional internal controls are required and must be instituted and documented. Include internal controls satisfying the provisions of this quality assurance program as follows:

- Certification of laboratory personnel
- Instrument operating controls
- Reagent controls
- Component controls
- Customer program/requirement controls
- Procedures controls
- Communication controls
- Document issue and revision controls

2.2.4.2 Measures to audit and to evaluate the operations and effectiveness of the quality assurance programs are included under this category. These audits and evaluations are accomplished by periodic reviews and the use of check lists prepared by and available from the Quality Assurance Manager.

2.3 Responsibility

2.3.1 The department manager is responsible for assigning tasks for the implementation of the provisions of the procedures specified in this Quality Assurance Manual.

2.3.2 The department manager is responsible for approving all documents and programs developed to assure compliance with the provisions outlined in the Quality Assurance Manual.

2.3.3 The Quality Assurance Manager is responsible for insuring that all quality related documents are prepared in the acceptable format and are registered with the Administration Office.

2.3.4 The Quality Assurance Manager is responsible for conducting periodic audits and evaluation reviews to assure that each department subscribes to the provisions of the quality assurance program outlined in this manual.

2.3.5 The Quality Assurance Manager is responsible for evaluating the periodic review to assure and monitor the effectiveness of the quality assurance program in providing improved performance and operations.

2.3.6 The Quality Assurance Manager is responsible for summarizing the results of all audits, evaluations, and reviews submitting an Auditing Review Report to the supervisors of the laboratory. Included in this are:

- Summaries of the quality assurance observations by the Q.A. auditor
- Recommendations and/or actions required of the supervisor of the audited laboratory.

- Provisions for an action reply from the supervisor of the audited laboratory.
- Statement of the time due for the action reply.

2.3.7 The Quality Assurance Manager is responsible to oversee all external audits of Teledyne Isotopes QA program conducted by various contractors serviced. This responsibility shall include the review and final evaluation of the audit report. When required, the action response shall be the responsibility of the Quality Assurance Manager or his/her designee.

2.3.8 The laboratory manager and/or supervisor shall be responsible for the technical training of new personnel and retraining of current personnel when necessary. Personnel performing quality related activities are to be trained and qualified in the principles and techniques of the activities they perform. A technician shall be certified as soon as possible. The Quality Assurance Manager is responsible for training personnel to the importance of and the goals of the Quality Assurance program. Certification records shall be supplemented to indicate additional training and duties by the laboratory manager and/or supervisor. Proficiency of personnel shall be maintained by retraining or by periodic performance reviews. The process of certifying personnel will be in accordance with the criteria set forth in the Q.C. Internal Control (IWL-0032-365).

SECTION 3.0 DESIGN CONTROL

CRITERIA III IN NRC 10 CFR 50, APPENDIX B

No design is involved in the activities of the environmental analysis department at Teledyne Isotopes.

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SECTION 4.0 PROCUREMENT DOCUMENT CONTROL

CRITERIA IV IN NRC 10 CFR 50, APPENDIX B

4.1 Policy

To maintain quality work, each department at Teledyne Isotopes must establish and document specifications and/or the design basis for all materials and/or services procured from contractors or vendors.

4.2 Compliance

The monitoring instruments and chemical or laboratory supplies are to be purchased from selected vendors. The purchase order is based on standard specifications for grade as required for analysis. 12/89

4.3 Documentation

From the operating parameters and design requirements for each analysis, the specifications for equipment and supplies are established. These specifications are appended to the purchase requisition and/or documented on the purchase order issued by Teledyne Isotopes. Acceptance of the procured item is based solely on conformance to recognized quality, previous performance and grade as specified in purchase requisition. All procurement documents must follow the purchasing policies of Teledyne Isotopes and be controlled by the purchasing agent.

4.4 Procedures and Responsibilities

4.4.1 The laboratory managers are responsible for the establishment of suitable references and specifications and the listing thereon on all procurement documents related to items that affect quality. Items must be identified and described completely in the purchase requisition. Reagents materials, supplies and services are to be of reliable quality based on accepted practice in the industry and the experience of the laboratory manager and/or supervisor.

4.4.2 To the extent necessary, the laboratory manager must require contractors or subcontractors to provide goods and chemicals that must conform to the quality required at Teledyne Isotopes. Such goods and chemicals must conform to quality grade specifications and must show no adverse reactions when used for blanks and spiked samples.

4.4.3 It shall be the responsibility of the Quality Assurance Manager to review periodically the compliance of each department with the provisions of procurement document control.

4.5 Acceptance

4.5.1 Acceptance of purchased items shall be indicated by the signature of a qualified individual on the purchase order.

4.5.2 New equipment shall be calibrated and operated for several trial runs until results are accurate and repeatable.

4.5.3 A record of the calibration and qualifying performance checks shall be documented and stored in a manner as to be readily retrievable.

4.5.4 Repaired analytical equipment shall be accepted after a performance test shows the item to be returned to original specifications.

SECTION 5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

CRITERIA V IN NRC 10 CFR 50, APPENDIX B

5.1 Policy

All activities at Teledyne Isotopes affecting quality must be documented by instructions, procedures, and/or drawings, and each activity must be conducted in accordance with the prepared documents.

5.2 Scope

Each instruction, procedure, and/or drawing must include:

- Detailed specifications or instructions
- Appropriate quantitative and qualitative acceptance and/or operating criteria
- Must be approved by responsible management personnel

5.3 Documentation

The Environmental Analysis Department must provide instructions and procedures for each analysis routinely performed in the laboratories. Copies of the manuals and handbooks are to be distributed to personnel performing the specified measurement. No deviations from these written instructions are permitted without written approval and documentation by the laboratory manager.

5.4 Processing

All documents which prescribe activities affecting quality must be processed in a standard manner.

5.4.1 The first page or the document control page of each document, for example, instructions, procedures, or drawings, must contain a document control form or portions thereof containing:

- An identifying code or number

- Date of issue
- Approval (signature and date) of department manager or of the designated deputy and a representative of the quality assurance department.
- Date and signature of the person who prepared the document
- When revisions are added, pages and signatures are updated in a manner similar to the format of the original issue

5.4.2 The completed document prepared according to the format prescribed in 5.4.1 is submitted to the administration office. An official Teledyne Isotopes identification number is assigned to the document and appended to the first page.

5.5 Preparation and Approval

5.5.1 The laboratory manager is responsible for initiating the preparation of instructions, procedures, and/or drawings.

5.5.2 The original copy of all instructions, procedures, and/or drawings must be approved by the laboratory manager and submitted to the Technical Vice President for approval and signature. It is then submitted to the Quality Assurance Manager for approval.

5.5.3 The Quality Assurance Manager must check the document for compliance with the preparation procedure and the assignment of the Teledyne Isotope's drawing number, procedure number, etc. The Quality Assurance Manager must sign the document after all required entries are completed.

5.5.4 If the approval of a customer is required before a procedure can be changed, the revised procedure shall be sent to the customer. If an approval is not received within 30 days, the procedure may be instituted.

5.6 Responsibility

5.6.1 The laboratory manager is responsible for initiating the

preparation of all documents. The laboratory manager is also responsible for the revisions of all documents, as experience and new information warrant.

5.6.2 The department manager is responsible for submitting the document to the administrative office for assignment of an official Teledyne Isotope's identification number at the time of issue or at the time of revision.

5.6.3 The administrative office is responsible for assigning the Teledyne Isotope identification number and recording the date, description, department, and Teledyne Isotope's identification number in a Document Control Log.

5.6.4 The administrative office is responsible for notifying the Quality Assurance Manager to check and approve the issuance of the official document after assignment of the official identification number.

SECTION 6.0 DOCUMENT CONTROL

CRITERIA VI IN NRC 10 CFR 50, APPENDIX B

6.1 Policy

Measures shall be established to control the issuance of documents such as instructions, procedures, and drawings including changes thereto which prescribe activities affecting quality.

6.2 Scope

Each document must be controlled by:

- A mechanism for the distribution and use by all personnel performing the described task
- A mechanism for updating and for distribution of revised versions
- A mechanism for internal distribution and a mechanism for external distribution

6.3 Distribution Control

6.3.1 The Quality Assurance Manager must insure that document distribution forms are prepared for each instruction, procedure, and/or drawing distributed internally and externally.

6.3.2 A Document Issue and Revision Control Form must be included on the first page or attached to the document. This form shows the issuance and revision information described in Section 5.

6.4 Documentation

Distribution of documents prescribing quality including revisions are controlled by procedures detailed in QC Internal Controls (IWL-0032-365.)

6.4.1 Internal Distribution: A document distribution form is maintained by the administrative department for all documents distributed internally at Teledyne Isotopes. All internal documents are controlled and must be destroyed or placed in storage when a revised issue is distributed.

6.4.2 External Distribution: All documents distributed externally are issued by the administrative office and are listed on a document distribution form. Most documents distributed externally are indicated as controlled in order that they may be updated when revised if required by a customer. Return of these documents to Teledyne Isotopes is not required.

6.5 Revisions

6.5.1 The laboratory manager must initiate all revisions.

6.5.2 The department manager must approve the changes and submit the revised document to the Quality Assurance Manager.

6.5.3 Step 5.4.1 must be followed for revisions and a document issue and revision form completed.

6.5.4 Revised copies of the document must be distributed and the obsolete copies destroyed or placed in storage.

6.5.5 The Quality Assurance Manager is responsible for periodically reviewing the operation status of the document control program for effectiveness.

6.5.6 Changes to documents shall be reviewed and approved by the same group that performed the original review and approval unless the applicant designates another responsible group.

6.5.7 Training in any new or revised procedure shall be supplied by management personnel as required.

SECTION 7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

CRITERIA VII IN NRC 10 CFR 50, APPENDIX B

7.1 Policy

Measures have been established by Teledyne Isotopes to assure that purchased material, equipment, and services conform to the procurement documents. It is the responsibility of the initiator of the purchase of materials, equipment, and services to evaluate and order purchased items conforming to quality standards.

7.2 Compliance

All purchased materials, equipment, or services are referenced to procurement documents and are controlled after receipt at Teledyne Isotopes.

7.3 Documentation

The Purchasing Department of Teledyne Isotopes controls the purchase of materials and equipment in accordance with procedures authorized by management of Teledyne Isotopes. A purchase requisition is prepared by the initiator and includes specifications, catalog numbers, quantity, source, approximate cost and originator.

7.4 Purchase Requisition

7.4.1 The purchase of material, equipment, and services must be initiated by preparing a Teledyne Isotopes purchase requisition obtained from the purchasing agent.

7.4.2 All entries on the purchase requisition must be completed to clearly identify the item, quantity, specification, source, approximate cost, and originator. Reagents, materials, supplies and services are to be of reliable quality based on the experience of the laboratory manager and/or supervisor and accepted practice in the industry.

7.4.3 The purchase requisition must be reviewed and approved by the department manager.

7.4.4 If the cost of the purchased item exceeds a specific limit, additional signatures of management are required.

7.4.5 The completed and approved purchase requisition is then submitted to the purchasing office for processing.

7.5 Purchase Order

Only the purchasing agent can process the purchase order prepared from the information on the purchase requisition.

7.5.1 The approved and completed purchase requisition is processed by the purchasing agent and a purchase order prepared.

7.5.2 The purchasing agent must notify the originator of any changes in the specifications, source, price, delivery, etc. of the items listed on the purchase requisition.

7.5.3 Copies of the completed purchase order are transmitted to the supplier, originator, administration and finance office, and the receiving office and are filed in the purchasing department. Note that the purchase order is subject to the terms and conditions on the face and reverse side thereof.

7.6 Changes and Modifications

7.6.1 No changes or substitutions may be made by the purchasing agent without the approval of the originator.

7.6.2 It is the responsibility of the originator of the purchase requisition to review and verify the correctness of the purchase order and to notify the purchasing agent of unacceptable conditions.

7.6.3 Any major changes or increases in cost greater than 10% will require reapproval of the purchase order.

7.7 Timely Delivery of Purchased Items

7.7.1 It is the responsibility of the purchasing agent to record the promised delivery on the purchase order.

7.7.2 It is the responsibility of the originator to notify the purchasing agent of slippage in timely delivery.

7.7.3 It is the responsibility of the purchasing agent to expedite delivery of the item and notify the originator of the new date.

7.8 Receipt of Items

7.8.1 All items shall be examined upon receipt and a copy of the purchase requisition initialed by the supervisor or a qualified designee if the item is acceptable.

7.8.2 All purchased items shall be controlled. Chemicals shall be dated or numbered in a manner to control shelf-life. They shall be discarded on the expiration date or when in the opinion of the supervisor they have degraded so that their use is inadvisable.

7.8.3 Equipment must be given an identifying name or number and be calibrated and proven to give repeatable results before being put into use.

7.9 Assessment of the Effectiveness of the Program

The Quality Assurance Manager must periodically assess the effectiveness of the program for control of purchased material, equipment, and services.

SECTION 8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, COMPONENTS

CRITERIA VIII IN NRC 10 CFR 50, APPENDIX B

8.1 Policy

All materials, parts, and components shall be identified and controlled during processing at Teledyne Isotopes.

8.2 Procedure

8.2.1 All materials, parts, and components must be assigned a discrete identification number consistent with cost effectiveness considerations.

8.2.2 Identify and control low cost and/or bulk items by the purchase order number. It will be necessary to label or tag each batch as it is received and provide a system to identify and control parts as they are removed.

8.2.3 Items that are screened by a system of quality control and segregated into batches must be identified by the purchase order, and separated into acceptable and nonacceptable batches. Nonacceptable batches must be clearly labelled and removed from the production areas to prevent inadvertent use of incorrect or defective materials, parts, and components.

8.3 Responsibility

8.3.1 The department manager is responsible for instituting the identification program that best meets the requirements of the department for assurance of quality operations.

8.3.2 The Quality Assurance Manager is responsible for reviewing and assessing the identification program to insure compliance with the provisions of this criterion.

SECTION 9.0 CONTROL OF SPECIAL PROCESSES

CRITERIA IX IN NRC 10 CFR 50, APPENDIX B

No special processes are involved in the activities of the Environmental Analysis department at Teledyne Isotopes.

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SECTION 10.0 INSPECTION

CRITERIA X IN NRC 10 CFR 50, APPENDIX B

10.1 Policy

Routine inspection of the activities affecting quality shall be established and executed to verify conformance with documented instructions, procedures and drawings.

10.2 Implementation

10.2.1 Examination, measurements, and test controls must be performed at specific hold points to assure quality of the components to be incorporated into systems. The radiation activity results determined on the monitoring instruments are recorded on data sheets. After completion of the batch of measurements the laboratory manager or designee reviews and initials the data prior to submission to the final reporting system. The objective of this "hold point" is to inspect the results prior to input into the computerized reporting system for reasonableness and for conformity to written procedures.

By conducting these inspections, quality and cost effectiveness can be assured.

10.2.2 Indirect inspection control are achieved by process or system monitoring, methods monitoring or personnel monitoring.

10.3 Responsibility

10.3.1 The department manager shall be responsible for incorporating and documenting the inspection control points and hold points in the process.

10.3.2 The department manager shall be responsible for implementing the routine inspection program.

10.3.3 The Quality Assurance Manager shall be responsible for reviewing the inspection program and of auditing the effectiveness of the program.

SECTION 11.0 TEST CONTROL

CRITERIA XI IN NRC 10 CFR 50, APPENDIX B

11.1 Policy

Test programs are required to assure that systems and components are performing satisfactorily in service and in accordance with written test procedures which include the requirements and acceptance limits.

11.2 Implementation

11.2.1 The test procedures must include provisions for assuring that all prerequisites for a given test have been met.

11.2.2 The test procedures must assure that adequate instrumentation is available and used.

11.2.3 The test procedures must assure that the tests are performed under suitable environmental conditions.

11.2.4 Test programs such as routine measurements of backgrounds and standard samples are provided to assure satisfactory performance of monitoring instruments. From these routine measurements the precision of the measurements are established and the counter parameters are evaluated.

11.2.5 Blank and spike samples are processed on a scheduled basis. Laboratories will participate in intercomparison programs such as that conducted by the USEPA. From the results of these test controls, the accuracy of the measuring procedures are controlled.

11.2.6 Test results must be documented and evaluated to assure that requirements have been satisfied.

11.3 Responsibility

11.3.1 The department manager or deputy is responsible for implementing the provisions of the test control program.

11.3.2 The Quality Assurance Manager or deputy is responsible for reviewing the results of the test control programs.

SECTION 12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

CRITERIA XII IN NRC 10 CFR 50, APPENDIX B

12.1 Policy

Measures shall be established to assure that tools, gauges, instruments, and other testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specific periods to maintain accuracy within stated limits.

12.2 Responsibility

12.2.1 The laboratory manager or deputy is responsible for establishing the program and frequency of tests to assure compliance with the provisions of this criterion.

12.2.2 The laboratory manager is responsible for stating and documenting the accuracy limits required for acceptable operation.

12.2.3 The Quality Assurance Manager or deputy is responsible for scheduled audits to insure compliance with the stated provisions of this criteria.

12.3 Documentation

12.3.1 Calibrations of test equipment performed in the laboratories are done using absolute standards. Where applicable, certification of the accuracy of the measuring and test equipment will be provided by scheduled calibrations by the manufacturer or by an authorized servicing agency.

SECTION 13.0 HANDLING, STORAGE AND SHIPPING

CRITERIA XIII IN NRC 10 CFR 50, APPENDIX B

13.1 Policy

Measures are required to control the handling, storage, shipping, cleaning, and preservation of materials and equipment in accordance with instructions to prevent damage or deterioration. When necessary, special protective environments should be specified and provided.

13.2 Responsibility

13.2.1 It is the responsibility of each department manager or deputy to organize and document the processes for handling and storage of materials in such a manner as to prevent damage or deterioration and to permit easy identification and recovery.

13.2.2 It is the responsibility of the department manager or deputy to properly pack and complete the documents for shipment of materials as required by the shipping department. The packed materials, the shipping documents and instructions for shipment are submitted to the shipping department.

13.2.3 It is the responsibility of the shipping department to have the properly packaged and labeled material shipped as instructed by a reliable transfer agent, acceptable to the management of Teledyne Isotopes.

13.2.4 It is the responsibility of the Quality Assurance Manager or deputy to periodically assess the handling, storage, and shipping procedures to insure compliance with the objectives of quality operations.

13.3 Documentation

13.3.1 All samples shipped for analysis to the Environmental Analysis Department are received and controlled as described in Section 4 of the

Q.C. Internal Controls (IWL-0032-365). A discrete Teledyne Isotopes number is assigned to each sample and receiving documents prepared containing descriptions, analysis required, and the assigned I.D. number. Samples are stored until approved for disposal.

SECTION 14.0 INSPECTION, TEST, AND OPERATING STATUS

CRITERIA XIV IN NRC 10 CFR 50, APPENDIX B

14.1 Policy

Where applicable, indication shall be established by means of suitable documentation for inspections, test, and operating status of individual items. Indications are recorded of all inspections, tests and operating conditions of the instruments used for radiomonitoring of samples.

14.2 Responsibility

14.2.1 The laboratory manager or deputy is responsible for establishing and documenting the procedures required for maintaining control of the operating status.

14.2.2 The Quality Assurance Manager or deputy is responsible for reviewing and auditing the implementation of the program for control of the operating status.

14.3 Documentation

14.3.1 Backgrounds and standards are routinely monitored to assess optimum operation of each instrument used for radioanalysis. All results are recorded and evaluated to determine the suitability for radiocounting unknown samples. Deviations beyond predetermined limits control the removal and repair of instrument. The operating status of each instrument is documented in the laboratory notebooks described in Section 10 of the Quality Control Manual (IWL-0032-365).

SECTION 15.0 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

CRITERIA XV IN NRC 10 CFR 50, APPENDIX B

15.1 Policy

Procedures are necessary to control materials, parts, or components which do not conform to requirements. These controls shall include procedures for identifying, documenting, segregating, and disposing of nonconforming materials. The goal of this control program is to prevent inadvertent use of nonconforming items.

15.2 Responsibility

15.2.1 The department manager or deputy is responsible for documenting the procedures to identify, document, segregate, and to dispose of nonconforming materials, parts, or components.

15.2.2 The Quality Assurance Manager or deputy is responsible for periodically reviewing the effectiveness of the program for identification and disposition of nonconforming materials, parts, or components.

15.3 Documentation

15.3.1 All radiometric analysis must conform to predetermined specifications. An important requirement for environmental analysis is the limits of detections (LLD). Analyses that do not conform to this specification are controlled by adjustment of the operating parameters when possible. If conformance cannot be established, reanalysis is required. Specification of the limits of detection is included in the analytical procedure for each analysis (IWL-0032-419).

SECTION 16.0 CORRECTIVE ACTION

CRITERIA XVI IN NRC 10 CFR 50, APPENDIX B

16.1 Policy

Procedures are required to assure that conditions adverse to quality are promptly identified and corrected. Such adverse conditions are failures, malfunctions, deficiencies, deviations, defective materials, defective equipment and nonconformance. Conditions adverse to quality must be recognized, documented and corrective action taken.

16.2 Responsibility

16.2.1 The laboratory manager or deputy is responsible for recognizing and evaluating conditions adverse to quality and for implementing and documenting the corrective action taken.

16.2.2 The Quality Assurance Manager or deputy is responsible for periodic audits to assess the implementation and effectiveness of the corrective action program.

16.2.3 The Quality Assurance Manager or deputy is responsible for resolving and reporting to management any extreme condition adverse to quality.

16.3 Documentation

16.3.1 Included in the background and standards log books are measures to verify correct operation of the monitoring instruments. Deviations beyond the operating range require reporting immediately to the laboratory manager and the taking of corrective action to resolve the conditions adverse to quality. See Section IV, Q.C. Internal Controls (IWL-0032-365) for documents required for corrective action.

SECTION 17.0 QUALITY ASSURANCE RECORDS

CRITERIA XVII IN NRC 10 CFR 50, APPENDIX B

17.1 Policy

Sufficient records are to be maintained to furnish evidence of activities affecting quality. These records include the following:

- Operating logs and the results of reviews
- Inspections and tests
- Monitoring of work performance
- Audits and evaluations

The records also shall include closely related data such as qualifications of personnel, procedures, equipment, and other internal controls affecting quality. All records shall identify the originator and/or inspector and the date of generation and/or inspection.

Consistent with regulatory requirements, the record retention requirements are to be established governing record retention, duration, location, and assigned responsibility.

17.2 Responsibility

17.2.1 The department manager or deputy is responsible for compliance with the provisions of the quality assurance records criteria.

17.2.2 The laboratory manager or deputy is responsible for the implementation, maintenance and operation of the quality assurance records system.

17.2.3 The Quality Assurance Manager or deputy is responsible for periodically reviewing the quality assurance records for compliance and adequacy.

17.2.4 The Quality Assurance Manager or deputy is responsible for

evaluating the quality assurance program and issuing a summary report.

17.3 Documentation

17.3.1 The control procedures outlined in the Environmental Analysis Quality Control Manual (IWL-0032-361) specify the operational quality assurance records that are generated. In addition the quality assurance procedures in the Q.C. Internal Controls (IWL-0032-365, Sec. IV) specify internal controls and records such as the certifying of personnel, evaluation and audits, etc., that are generated and filed by the laboratory performing the analysis. Sufficient records are maintained to assure traceability of all measurements affecting quality for each sample analyzed.

SECTION 18.0 AUDITS

CRITERIA XVIII IN NRC 10 CFR 50, APPENDIX B

18.1 Policy

Planned and periodic audits will be carried out to verify compliance with all aspects of the quality assurance program.

18.2 Objective

The objective of auditing is to assess the effectiveness of the quality assurance program and determine the need for actions to improve quality operations.

18.3 Procedure

18.3.1 Audits will be performed in accordance with written procedures or check list by the Quality Assurance Manager.

18.3.2 Audit results are documented and reviewed by the Quality Assurance Manager or deputy.

18.2.3 Follow-up action, including reaudits of deficient areas, or the issuance of citations shall be taken where indicated.

18.4 Documentation

18.4.1 The audits by the Quality Assurance Manager are every 12 months and not to exceed 13 months. Copies of the Audit Evaluation Check List (IWL-25), and the Compliance Check List (IWL-24) are filed in the office of the Quality Assurance Manager.

In addition an Auditing Review Report (IWL-26R) is submitted to the supervisor of the audited laboratory indicating the auditors observations and recommendations. An action reply is required by the supervisor to document compliance with the auditors recommendations. The time for completion of the action reply is specified on the Auditing Review Report.

APPENDIX I

QUALITY ASSURANCE MANUAL (IWL-0032-395)

ENVIRONMENTAL RADIATION MONITORING SERVICE

ENVIRONMENTAL ANALYSIS DEPARTMENT

APPENDIX I

COMPLIANCE WITH REGULATORY GUIDE 4.15

EFFECTIVE OCTOBER 15, 1980

QUALITY ASSURANCE

RADIOLOGICAL ENVIRONMENTAL MONITORING PROGRAM

The quality assurance program prescribed for the Radiological Environmental Monitoring Program conducted by Teledyne Isotopes was originally outlined in manual IWL-0032-395 in November 1976. This program was developed from the criteria specified in 10 CFR 50, Appendix B.

Regulatory Guide 4.15, Revision 1 and issued in (February 1979) presents the NRC regulatory position on quality assurance for radiological monitoring programs (NORMAL OPERATIONS)-effluent streams and the environment. This regulatory guide is also developed from sections of 10 CFR including 10 CFR 50, Appendix B. Most of the criteria listed in IWL-0032-395 already addresses the elements cited in Regulatory Guide 4.15.

To conform to the latest regulatory position of the NRC, the elements of Reg. Guide 4.15 (included herein as Appendix I) must be followed in the same manner as the criteria specified in IWL-0032-395.

Specified in Section 2.0 of this manual and in Regulatory Guide 4.15 under C-2 is the requirement for training and certifying of personnel performing quality related activities. The quality assurance manager is responsible for the program of indoctrination of personnel on:

- the nature and goals of the quality assurance program
- the principle and techniques of the activities performed
- the proficiency of personnel performing quality related functions

This program is maintained by providing and reviewing with supervisors the quality assurance publications issued by the NRC and by periodic performance reviews.

U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
February 1979

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 4.15

QUALITY ASSURANCE FOR RADIOLOGICAL MONITORING PROGRAMS (NORMAL OPERATIONS) — EFFLUENT STREAMS AND THE ENVIRONMENT

A. INTRODUCTION

This guide describes a method acceptable to the NRC staff for designing a program to assure the quality of the results of measurements of radioactive materials in the effluents and the environment outside of nuclear facilities during normal operations.

The NRC regulations that require the control of releases of radioactive materials from nuclear facilities, that require the measurements of radioactive materials in the effluents and environment outside of these facilities, that require quality assurance programs and establish quality assurance requirements for certain facilities, or that authorize license conditions not otherwise authorized in the regulations are as follows:

Section 20.106, "Radioactivity in Effluents to Unrestricted Areas," of 10 CFR Part 20, "Standards for Protection Against Radiation," provides that a licensee shall not release to an unrestricted area radioactive materials in concentrations that exceed limits specified in 10 CFR Part 20 or as otherwise authorized in a license issued by the Commission. Section 20.201, "Surveys," of 10 CFR Part 20 further requires that a licensee conduct surveys, including measurements of levels of radiation or concentrations of radioactive materials, as necessary to demonstrate compliance with the regulations in 10 CFR Part 20.

Paragraph (c) of Section 20.1, "Purpose," of 10 CFR Part 20 states that every reasonable effort should be made by NRC licensees to maintain radiation exposure, and releases of radioactive materials in effluents to unrestricted areas, as far below the limits specified in Part 20 as is reasonably achievable, taking into account the state of technology and the economics of improvements in relation to public health and safety and to the utilization of atomic energy in the public interest.

Section 30.34, "Terms and Conditions of Licenses," of 10 CFR Part 30, "Rules of General Applicability to Licensing of Byproduct Material," provides that the Commission may incorporate in any byproduct material license such terms and conditions as it deems appropriate or necessary in order to protect health.

Section 40.41, "Terms and Conditions of Licenses," of 10 CFR Part 40, "Licensing of Source Material," provides that the Commission may incorporate in any source material license such terms and conditions as it deems appropriate or necessary to protect health.

Section 50.50, "Issuance of Licenses and Construction Permits," of 10 CFR Part 50, "Licensing of Production and Utilization Facilities," provides that each operating license for a nuclear power plant issued by the Nuclear Regulatory Commission will contain such conditions and limitations as the Commission deems appropriate and necessary.

Section 70.32, "Conditions of Licenses," of 10 CFR Part 70, "Special Nuclear Material," provides that the Commission may incorporate such terms and conditions as it deems appropriate or necessary to protect health.

Section IV.B of Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low As Is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents," to 10 CFR Part 50, "Licensing of Production and Utilization Facilities," requires that licensees establish an ap-

*Lines indicate substantive changes from previous issue.

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. This guide was revised as a result of substantive comments received from the public and additional staff review.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

The guides are issued in the following ten broad divisions:

1. Power Reactors
2. Research and Test Reactors
3. Fuels and Materials Facilities
4. Environmental and Siting
5. Materials and Plant Protection
6. Products
7. Transportation
8. Occupational Health
9. Antitrust and Financial Review
10. General

Requests for single copies of issued guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Technical Information and Document Control.

propriate surveillance and monitoring program to provide data on quantities of radioactive material released in liquid and gaseous effluents and to provide data on measurable levels of radiation and radioactive materials in the environment. Section III.B of Appendix I to 10 CFR Part 50 provides certain effluent and environmental monitoring requirements with respect to radioactive iodine if estimates of exposure are made on the basis of existing conditions and if potential changes in land and water usage and food pathways could result in exposures in excess of the guidelines of Appendix I to 10 CFR Part 50.

General Design Criterion 60, "Control of releases of radioactive materials to the environment," of Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 requires that nuclear power plant designs provide means to control suitably the release of radioactive materials in gaseous and liquid effluents. General Design Criterion 64, "Monitoring radioactivity releases," of Appendix A to 10 CFR Part 50 requires that nuclear power plant designs provide means for monitoring effluent discharge paths and the plant environs for radioactivity that may be released from normal operations, including anticipated operational occurrences, and from postulated accidents.

General Design Criterion 1, "Quality standards and records," of Appendix A to 10 CFR Part 50 requires that a quality assurance program be established for those structures, systems, and components of a nuclear power plant that are important to safety in order to provide adequate assurance that they will satisfactorily perform their safety functions.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes quality assurance requirements for the design, construction, and operation of those structures, systems, and components of these facilities that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

The need of quality assurance is implicit in all requirements for effluent and environmental monitoring, and this need has been widely recognized. Regulatory Guide 1.21, "Measuring, Evaluating, and Reporting Radioactivity in Solid Wastes and Releases of Radioactive Materials in Liquid and Gaseous Effluents from Light-Water-Cooled Nuclear Power Plants;" Regulatory Guide 4.1, "Programs for Monitoring Radioactivity in the Environs of Nuclear Power Plants;" Regulatory Guide 4.8, "Environmental Technical Specifications for Nuclear Power Plants;" and Regulatory Guide 4.14, "Measuring, Evaluating, and Reporting Radioactivity in Releases of Radioactive Material in Liquid and Airborne Effluents From Uranium Mills," all give some guidance on means for assuring the quality of the measurements of radioactive materials in effluents and the environment outside of nuclear facilities. More complete and extensive guidance on this subject is provided in this document for nuclear power reactor facilities and for other facilities for which radiological monitoring is required by the NRC. This guidance does not identify separately the activities that are within the scope of Appendix B to 10 CFR Part 50. However, this guidance is intended to be consistent with the requirements of Appendixes A and B to 10 CFR Part 50 in that quality assurance requirements should be consistent with the importance of the activity. For the monitoring of production and utilization facilities that is within the scope of Appendix B to 10 CFR Part 50, other regulatory guides that provide guidance on meeting the quality assurance requirements of Appendix B to 10 CFR Part 50 should also be consulted.

B. DISCUSSION[1]

As used in the context of this guide, quality assurance comprises all those planned and systematic actions that are necessary to provide adequate confidence in the results of a monitoring program, and quality control comprises those quality assurance actions that provide a means to control and measure the characteristics of measurement equipment and processes to established requirements; therefore, quality assurance includes quality control.

To assure that radiological monitoring measurements are reasonably valid, organizations performing these measurements have found it necessary to establish quality assurance programs. These programs are needed for the following reasons: (1) to identify deficiencies in the sampling and measurement processes to those responsible for these operations so that corrective action can be taken, and (2) to obtain some measure of confidence in the results of the monitoring programs in order to assure the regulatory agencies and the public that the results are valid.

Existing published guidance on specific quality assurance actions that are applicable to radiological monitoring is limited and, in general, is restricted to quality control practices for radioanalytical laboratories (Refs. 1-5). However, quality assurance should be applied to all steps of the monitoring process, which may include sampling, shipment of samples, receipt of samples in the laboratory, preparation of samples, measurement of radioactivity, data reduction, date evaluation, and reporting of the monitoring results.

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[1]Definitions of special terms used in this guide are given in the glossary on page 4.15-10.

The scope of this guide is limited to the elements of a quality assurance program, which is a planned, systematic, and documented program that includes quality control. Guidance on principles and good practice in the monitoring process itself and guidance on activities that can affect the quality of the monitoring results (e.g., design of facilities and equipment) are outside the scope of this guide. However, some references are provided to documents that do provide some guidance in these areas. The citation of these references does not constitute an endorsement of all of the guidance in these documents by the NRC staff. Rather, these references are provided as sources of information to aid the licensee and the licensee's contractors in developing and maintaining a monitoring program.

Every organization actually performing effluent and environmental monitoring, whether an NRC licensee or the licensee's contractor, should include the quality assurance program elements presented in this guide.

C. REGULATORY POSITION

The quality assurance program of each organization performing effluent or environmental monitoring of nuclear facilities for normal operations should be documented by written policies and procedures and records. These documents should include the elements given in this section.

In addition to its own program, a licensee should require any contractor or subcontractor performing monitoring activities for the licensee to provide a quality assurance program and to routinely provide program data summaries (sufficiently detailed to permit ongoing quality assurance program evaluation by the licensee) consistent with the provisions of this guide, as follows:

1. Organizational Structure and Responsibilities of Managerial and Operational Personnel

The structure of the organization as it relates to the management and operation of the monitoring program(s), including quality assurance policy and functions, should be presented. The authorities, duties, and responsibilities of the positions within this organization down to the first-line supervisory level should be described. This should include responsibilities for review and approval of written procedures and for the preparation, review, and evaluation of monitoring data and reports.

Persons and organizations performing quality assurance functions should have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

2. Specification of Qualifications of Personnel

The qualifications of individuals performing radiological monitoring to carry out their assigned functions should be specified and documented (e.g., as in a job description).

An indoctrination and orientation program, appropriate to the size and complexity of the organization and to the activities performed, should provide that (a) personnel performing quality-related activities are trained and qualified in the principles and techniques of the activities performed, (b) personnel are made aware of the nature and goals of the quality assurance program, and (c) proficiency of personnel who perform activities affecting quality is maintained by retraining, reexamining, and recertifying or by periodic performance reviews, as appropriate.

3. Operating Procedures and Instructions

Written procedures should be prepared, reviewed, and approved for activities involved in carrying out the monitoring program, including sample collection; packaging, shipment, and receipt of samples for offsite analysis; preparation and analysis of samples; maintenance, storage, and use of radioactivity reference standards; calibration and checks of radiation and radioactivity measurement systems; and reduction, evaluation, and reporting of data. Individuals who review and approve these procedures should be knowledgeable in the subjects of the procedures.

Guidance on principles and good practice in many of these activities is presented in NRC regulatory guides (Refs. 6-9) and other publications (Refs. 2-5, 10-35). In addition to these publications, Scientific Committee 18A of the NCRP has prepared NCRP Report 58, "A Handbook of Radioactivity Measurements Procedures," (Ref. 36) that is a revision of NCRP Report 28, NBS Handbook 80, "A Manual of Radioactivity Procedures."

4. Records

The records necessary to document the activities performed in the monitoring program should be specified in the quality assurance program.

One key aspect of quality control is maintaining the ability to track and control a sample in its progress through the sequence of monitoring processes. Records to accomplish this should cover the following processes: field and inplant collection of samples for subsequent analysis, including sample description; sample receipt and laboratory identification coding; sample preparation and radiochemical processing (e.g., laboratory notebooks); radioactivity measurements of samples, instrument backgrounds, and analytical blanks; and data reduction and verification.

Quality control records for laboratory counting systems should include the results of measurements of radioactive check sources, calibration sources, backgrounds, and blanks.

Records relating to overall laboratory performance should include the results of analysis of quality control samples such as analytical blanks, duplicates, interlaboratory cross-check samples and other quality control analyses; use of standards (radioactivity) to prepare working standards; preparation and standardization of carrier solutions; and calibration of analytical balances.

Additional records that are needed should include the calibration of inline radiation detection equipment, air samplers, and thermoluminescence dosimetry systems; verification and documentation of computer programs; qualifications of personnel; and results of audits.

The minimum period of retention of the records should be specified. For nuclear power plants, requirements for record retention are given in the plant technical specifications. In general, for other types of facilities, only the final results of the monitoring programs need be retained for the life of the facility.

5. Quality Control in Sampling (Including Packaging, Shipping, and Storage of Samples)

Continuous sampling of liquids and gases involves the measurement of sample flow rates and/or sample volumes. The accuracy of the devices used for this purpose should be determined on a regularly scheduled basis, and adjustments should be made as needed to bring the performance of the devices within specified limits. The results of these calibrations should be recorded. The frequency of these calibrations should be specified and should be based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. Procedures for continuous sampling should use methods that are designed to ensure that the sample is representative of the material volumes sampled. The collection efficiencies of the samplers used should be documented; usually such documentation is available from manufacturers of the sampling equipment.

Procedures for grab samples should include steps designed to ensure that the sample is representative of the material sampled. Replicate grab samples should be taken periodically to determine the reproducibility of sampling.

Procedures for sampling, packaging, shipping, and storage of samples should be designed to maintain the integrity of the sample from time of collection to time of analysis. Aqueous samples may present a particular problem in this regard, and one of the most severe problems has been encountered with aqueous samples of radioactive wastes from operating nuclear reactors (Ref. 23).

Guidance on the principles and practice of sampling in environmental monitoring is provided in several publications (Refs. 2, 4, 5, 21, 23-31, 33, 35, 37). In addition, workers at the National Bureau of Standards (NBS) have published the results of a survey of information on sampling, sample handling, and long-term storage for environmental materials (Ref. 15). Some guidance on the principles and practice of air sampling is provided in References 17, 19, 24, 28-31, 33. Guidance on the principles and practice of water sampling is provided in numerous publications (Refs. 13, 14, 25-27, 35, 37).

6. Quality Control in the Radioanalytical Laboratory

6.1 Radionuclide Reference Standards—Use for Calibration of Radiation Measurements Systems

Reference standards are used to determine counting efficiencies for specific radionuclides or, in the case of gamma-ray-spectrometry systems, to determine counting efficiency as a function of gamma-ray energy. A counting efficiency value is used to convert a sample counting rate to the decay rate of a radionuclide or to a radionuclide concentration. Guidance on the calibration and usage of germanium detectors for measurement of gamma-ray emission rates of radionuclides has been prepared as an ANSI standard (Ref. 38). For converting gamma-ray emission rates to nuclear decay rates, two reports from the Oak Ridge National Laboratory (Refs. 39 and 40) provide useful compilations of gamma-ray intensities and other nuclear decay data for radionuclides in routine releases from nuclear fuel cycle facilities. The data from Reference 40 are included in NCRP Report 58 (Ref. 36).

Radionuclide standards that have been certified by NBS or standards that have been obtained from suppliers who participate in measurement assurance activities with NBS[2]

[2]Satisfactory measurement assurance interactions between source suppliers and NBS involve two basic mechanisms: (1) The supplier submits a calibrated radioactivity source (preferably selected from a batch or prepared series of sources) to NBS for confirmation that the supplier's calibration value agrees with NBS results within certain specified limits or (2) NBS provides calibrated radioactivity sources of undisclosed activity (test samples) to a supplier who is able to make activity or emission-rate measurements on the source that agree within certain specified limits with the measurements of NBS. For the routine production of commercial radioactivity standards, the first mechanism is preferable to the second but is not always feasible. These two mechanisms are used both in Measurements Assurance Programs (MAPs) with key laboratories and in other measurement assurance activities.

Two key laboratory source suppliers participate in MAPs with NBS and use both of the two basic mechanisms: (1) The NRC reference laboratory for the Confirmatory Measurements Program (for effluent monitoring) of the NRC Office of Inspection and Enforcement and (2) The EPA Environmental Monitoring and Support Laboratory in Las Vegas, which prepares and

should be used when such standards are available. In these measurement assurance activities, the supplier's calibration value should agree with the NBS value within the overall uncertainty stated by the supplier in its certification of the same batch of sources (when these are sampled for measurement by NBS) or in its certification of similar sources.

An "International Directory of Certified Radioactive Materials" has been published by the International Atomic Energy Agency (Ref. 41).

Acceptable standards for certain natural radionuclides may be prepared from commercially available high-purity chemicals. For example, potassium-40 standards for gross beta-particle measurements or gamma-ray spectrometry may be prepared gravimetrically from dried reagent-grade potassium chloride.

The details of the preparation of working standards from certified standard solutions should be recorded. The working standard should be prepared in the same form as the unknown samples, or close approximation thereto.

Efficiency calibrations should be checked periodically (typically monthly to yearly) with standard sources. In addition, these checks should be made whenever the need is indicated, such as when a significant change in the measurement system is detected by routine measurements with a check source.

6.2 Performance Checks of Radiation Measurement Systems

Determination of the background counting rate and the response of each radiation detection system to appropriate check sources should be performed on a scheduled basis for systems in routine use. The results of these measurements should be recorded in a log and plotted on a control chart. Appropriate investigative and corrective action should be taken when the measurement value falls outside the predetermined control value.

A check source for determining changes in counting rate or counting efficiency should be of sufficient radiochemical purity to allow correction for decay but need not have an accurately known disintegration rate, i.e., need not be a standard source.

For systems in which samples are changed manually, check sources are usually measured daily. For systems with automatic sample changers, it may be more convenient to include the check source within each batch of samples and thus obtain a measurement of this source within each counting cycle. For proportional counter systems, the plateau(s) or response(s) to the check source(s) should be checked after each gas change. Background measurements should be made frequently, usually daily or before each use, to ensure that levels are within the expected range. For systems with automatic sample changers, background measurements should be included within each measurement cycle.

For alpha- and gamma-ray-spectrometry systems, energy-calibration sources (i.e., a source containing a radionuclide, or mixture of radionuclides, emitting two or more alpha or gamma rays of known energies) are counted to determine the relationship between channel number and alpha- or gamma-ray energy. The frequency of these energy calibration checks depends on the stability of the system but usually is in the range of daily to weekly. The results of these measurements should be recorded and compared to predetermined limits in order to determine whether or not system gain and zero level need adjustment. Adjustments should be made as necessary.

Additional checks needed for spectrometry systems are the energy resolution of the system and the count rate (or counting efficiency) of a check source. These should be determined periodically (usually weekly to monthly for energy resolution and daily to weekly for count rate) and after system changes, such as power failures or repairs, to determine if there has been any significant change in the system. The results of these measurements should be recorded.

6.3 Analysis of Quality Control Samples

The analysis of quality control samples provides a means to determine the precision and accuracy of the monitoring processes and includes both intralaboratory and interlaboratory measurements.

The analysis of replicate samples (containing significant detectable activity) provides a means to determine precision; the analysis of

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distributes calibrated radioactivity standards primarily to laboratories involved in radiological environmental monitoring. Additionally, seven major radiopharmaceutical manufacturers (some of which supply radioactivity standards commercially) participate in a MAP organized by the Atomic Industrial Forum and NBS. In this MAP, NBS distributes standards as test samples to the manufacturer (second mechanism) and receives certified samples from the manufacturer for verification by NBS (first mechanism).

Measurement assurance interactions that use the first mechanism are available via special NBS calibration services. NBS will, on request and for a fee, perform calibrations of representative samples of standards provided by the supplier for NBS confirmation of the supplier's reported values. Calibration services are available for a large variety of radionuclides provided certain requirements (as to sample stability and suitable activity range) are met. Measurement assurance interactions that use the second mechanism are available via the issuance of test standards by NBS. For a nominal charge (beyond the price of the standard), NBS radioactivity Standard Reference Materials (SRMs) can be purchased as test sources of undisclosed activity that can be used to demonstrate agreement, within certain specified limits, between the source supplier's measurements and those of NBS. A Report of Test (for the first mechanism) or a Report of Measurement (second mechanism), containing both the source supplier's and NBS values, is issued by NBS to document the source supplier's participation in the measurement assurance activity.

samples containing known concentrations of radionuclides provides a means to determine accuracy. The analysis of laboratory blanks provides a means to detect and measure radioactive contamination of analytical samples, a common source of error in radiochemical analysis of low-level samples. The analysis of analytical blanks also provides information on the adequacy of background subtraction, particularly for environmental samples.

The fraction of the analytical effort needed for the analysis of quality control samples depends to a large extent on (1) the mixture of sample types in a particular laboratory in a particular time period and (2) the history of performance of that laboratory in the analysis of quality control samples. However, for environmental laboratories, it is found that at least 5%, and typically 10%, of the analytical load should consist of quality control samples.

6.3.1 Intralaboratory Analyses

Replicate samples, usually duplicates, should be analyzed routinely. These replicates should be prepared from samples that are as homogeneous as possible, such as well-stirred or mixed liquids (water or milk) and solids (dried, ground, or screened soil, sediment, or vegetation; or the ash of these materials). These samples may be replicates of monitoring program samples, replicates of reference test materials, or both. The size and other physical and chemical characteristics of the replicate samples should be similar to those of single samples analyzed routinely.

The analysis of the replicate samples as blind replicates is desirable but is not practicable for all laboratories or for all types of samples. For example, in small laboratories it may not be practicable to prevent the analysts from being aware that particular samples are replicates of one another.

Obtaining true replicates of all types of samples also is not practicable. For example, obtaining replicate samples of airborne materials usually is not practicable on a routine basis because it requires either a separate sampling system or splitting a single sample (e.g., cutting a filter in half). Use of replicate samplers usually is not economically feasible and splitting of samples results in replicates that do not represent the usual sample size or measurement configuration (counting geometry) for direct measurement. However, simulated samples of airborne materials may be prepared in replicate and submitted for analysis as unknowns.

Analysis of intralaboratory blank and spiked samples is an important part of each environmental laboratory's quality control program. To check for contamination from reagents and other sources, known analytical blank samples should be included frequently in groups of unknown environmental samples that are analyzed radiochemically. Spiked and blank samples should be submitted for analysis as unknowns to provide an intralaboratory basis for estimating the accuracy of the analytical results. These blanks and spikes may include blind replicates.

6.3.2 Interlaboratory Analyses

Analysis of effluent and environmental samples split with one or more independent laboratories is an important part of the quality assurance program because it provides a means to detect errors that might not be detected by intralaboratory measurements alone. When possible, these independent laboratories should be those whose measurements are traceable to NBS.[3]

Analysis of split field samples, such as samples of milk, water, soil or sediment, and vegetation, is particularly important in environmental monitoring programs to provide an independent test of the ability to measure radionuclides at the very low concentrations present in most environmental samples.

The NRC Office of Inspection and Enforcement conducts a Confirmatory Measurements Program for laboratories of licensees that measure nuclear reactor effluents. The analyses of liquid waste holdup tank samples, gas samples, charcoal cartridges, and stack particulate filters are included in this program. The results of the licensee's measurements of samples split with the NRC are compared to those of an NRC reference laboratory whose measurements are traceable to the National Bureau of Standards. Thus the results of this comparison provide to the NRC an objective measure of the accuracy of the licensee's analyses.

Laboratories of licensees or their contractors that perform environmental measurements should participate in the EPA's Environmental Radioactivity Laboratory Intercomparison Studies (Cross-check) Program, or an equivalent program. This participation should include all of the determinations (sample medium/radionuclide combinations) that are both offered by EPA and included in the licensee's environmental monitoring program. Participation in the EPA program provides an objective measure of the accuracy of the analyses because the EPA measurements are traceable to the National Bureau of Standards. If the mean result of a cross-check analysis exceeds the control limit as defined by EPA (Ref. 42), an investigation should be made to determine the reason for this deviation and corrective action should be taken

[3] NBS and NRC staffs recognize the need for a clearer definition of the term "traceability" as it applies to radiation and radioactivity measurements. These staffs are working together to develop such a statement, which will be published separately.

as necessary. Similarly, an investigation and any necessary corrective action should take place if the "normalized range," as calculated by EPA, exceeds the control limit, as defined by EPA. A series of results that is within the control limits but that exhibits a trend toward these limits may indicate a need for an investigation to determine the reason for the trend.

6.4 Computational Checks

Procedures for the computation of the concentration of radioactive materials should include the independent verification of a substantial fraction of the results of the computation by a person other than the one performing the original computation. For computer calculations, the input data should be verified by a knowledgeable individual. All computer programs should be documented and verified before initial routine use and after each modification of the program. The verification process should include verification, by a knowledgeable individual, of the algorithm used and test runs in which the output of the computer computation for given input can be compared to "true" values that are known or determined independently of the computer calculation. Documentation of the program should include a description of the algorithm and, if possible, a current listing of the program. Guidelines for the documentation of digital computer programs are given in ANSI N413-1974 (Ref. 43).

7. Quality Control for Continuous Effluent Monitoring Systems

Guidance on specification and performance of onsite instrumentation for continuously monitoring radioactivity in effluents is given in ANSI N13.10-1974 (Ref. 18).

The specified frequency of calibration for a particular system should be based on considerations of the nature and stability of that system. For nuclear power plants, specific requirements for calibrations and checks of particular effluent monitoring systems usually are included in the technical specifications for the plant.

Initial calibration of each measuring system should be performed using one or more of the reference standards that are certified by the National Bureau of Standards or standards that have been obtained from suppliers that participate in measurement assurance activities with NBS (see footnote 2). These radionuclide standards should permit calibrating the system over its intended range of energy and rate capabilities. For nuclear power plants, sources that have been related to this initial calibration should be used to check this initial calibration at least once per 18 months (normally during refueling outages).

Periodic correlations should be made during operation to relate monitor readings to the concentrations and/or release rates of radioactive material in the monitored release path. These correlations should be based on the results of analyses for specific radionuclides in grab samples from the release path.

Any flow-rate measuring devices associated with the system should be calibrated to determine actual flow rates at the conditions of temperature and pressure under which the system will be operated. These flow rate devices should be recalibrated periodically.

Whenever practicable, a check source that is actuated remotely should be installed for integrity checks of the detector and the associated electrical system.

8. Review and Analysis of Data

Procedures for review and analysis of data should be developed. These procedures should cover examination of data from actual samples and from quality-control activities for reasonableness and consistency. These reviews should be performed on a timely basis. General criteria for recognizing deficiencies in data should be established.

Provisions should be made for investigation and correction of recognized deficiencies and for documentation of these actions.

9. Audits

Planned and periodic audits should be made to verify implementation of the quality assurance program. The audits should be performed by individuals qualified in radiochemistry and monitoring techniques who do not have direct responsibilities in the areas being audited.

Audit results should be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, should be taken where indicated.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which the applicant or licensee proposes an acceptable alternative method, the staff will use the methods described herein in evaluating an applicant's or licensee's capability for and performance in complying with specified portions of the Commission's regulations after March 30, 1979.

If an applicant or licensee wishes to use the method described in this regulatory guide on or before March 30, 1979, the pertinent portions of the application or the licensee's performance will be evaluated on the basis of this guide.

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GLOSSARY

Accuracy–a qualitative concept in the statistical treatment of measurement data used to describe the agreement between the central tendency of a set of numbers and their correct value (or the accepted reference value). It is also used to describe the agreement between an individual value and the correct value (or the accepted reference value).

Analytical Blank (Sample)–ideally, a sample having all of the constituents of the unknown sample except those to be determined. In radioanalytical practice, the term often refers to the radiochemical processing of carrier(s) or tracers without the sample matrix material.

"Blind" Replicate (Sample)–replicate samples that are not identified as replicates to the persons performing the analysis.

Calibration–the process of determining the numerical relationship between the observed output of a measurement system and the value, based on reference standards, of the characteristics being measured.

Calibration Source–any radioactive source that is used for calibration of a measurement system.

Check Source (or instrument check source or performance check source)–a radioactive source used to determine if the detector and all electronic components of the system are operating correctly.

Instrument Background–the response of the instrument in the absence of a radioactive sample or other radioactive source.

Precision–a qualitative concept in the statistical treatment of measurement data used to describe the dispersion of a set of numbers with respect to its central tendency.

Quality Assurance (QA)–the planned and systematic actions that are necessary to provide adequate confidence in the results of a monitoring program.

Quality Control (QC)–those quality assurance actions that provide a means to control and measure the characteristics of measurement equipment and processes to established requirements. Thus, quality assurance includes quality control.

Reference Test Material–a large batch of homogeneous material from which aliquots may be taken for interlaboratory comparisons or for internal use by the laboratory. The material must be uniform but need not be standardized.

Spiked Sample–a sample to which a known amount of radioactive material has been added. Generally, spiked samples are submitted as unknowns to the analysts.

Split Sample–a homogeneous sample that is divided into parts, each of which is analyzed independently by separate laboratory organizations.

Standard (radioactive) Source–a radioactive source having an accurately known radionuclide content and radioactive decay rate or rate of particle or photon emission.