

**START**

0033877

43

ITAS QAMP  
Section No.: 0.0  
Date Initiated: December 20, 1984  
Revision No.: 2  
Date Revised: July 1, 1993  
Page 1 of 7

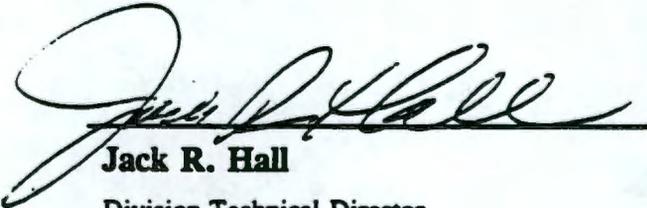
**QUALITY ASSURANCE MANAGEMENT PLAN  
INTERNATIONAL TECHNOLOGY CORPORATION**

**ANALYTICAL SERVICES DIVISION**



**Prepared by:**

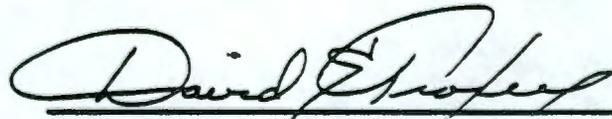
**Reviewed/Approved by:**



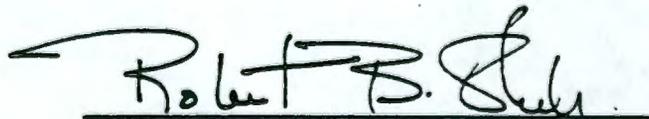


**Jack R. Hall**  
Division Technical Director  
Director, Quality Assurance/Quality Control  
IT Analytical Services

**Brad S. Figley**  
Vice President, Analytical Services  
IT Corporation



**David E. Troxell**  
Vice President, Quality and Health Services  
IT Corporation



**Controlled Copy Number:** \_\_\_\_\_

**Robert B. Sheh**  
Chief Executive Officer  
IT Corporation

**Issued to:**  
\_\_\_\_\_

9413282-0131

009377

START

ITAS QAMP  
Section No.: 0.0  
Date Initiated: December 20, 1984  
Revision No.: 2  
Date Revised: July 1, 1993  
Page 2 of 7

9413282.0132



Copyright © 1988 by IT Corporation. All rights reserved. Except as permitted under the United States Copyright Act in 1976, no part of this publication may be reproduced or distributed in any form or by any means, or stored in a database or retrieval system, without the prior written permission of IT Corporation.

INTERNATIONAL TECHNOLOGY / ANALYTICAL SERVICES

RICHLAND DIVISION

QUALITY ASSURANCE MANAGEMENT PLAN

THIS PAGE INTENTIONALLY  
LEFT BLANK

CONTROL NUMBER WHC001

CUSTODIAN Stu Higgins

DATE ISSUED 11/22/93

**THIS PAGE INTENTIONALLY  
LEFT BLANK**

0110 SYSTEM

## TABLE OF CONTENTS

	<u>Page</u>
<b>0.0 TITLE SECTION</b>	
Title Page .....	1 of 7
Copyright Statement .....	2 of 7
Table of Contents .....	3-5 of 7
List of Figures .....	6 of 7
List of Tables .....	6 of 7
List of Acronyms .....	7 of 7
<b>1.0 MANAGEMENT COMMITMENT AND ORGANIZATION</b>	
1.1 Statement of Management Position on Quality .....	1 of 5
1.2 IT Analytical Services Division Organizational Structure .....	1 of 5
1.3 Quality Organization .....	2 of 5
1.3.1 Vice President, Quality and Health Services, IT Corporation ..	2 of 5
1.3.2 Vice President, IT Analytical Services, IT Corporation .....	2 of 5
1.3.3 Division Technical Director, IT Analytical Services .....	2 of 5
1.3.4 Division Director, QA/QC, IT Analytical Services .....	3 of 5
1.3.5 Division Operations Director, IT Analytical Services .....	3 of 5
1.3.6 Laboratory or Field Analytical Services Director .....	3 of 5
1.3.7 Laboratory Staff .....	4 of 5
<b>2.0 QUALITY ASSURANCE PROGRAM DESCRIPTION</b>	
2.1 Introduction .....	1 of 7
2.2 Objectives of the Quality Assurance Program .....	2 of 7
<b>3.0 ASSOCIATE TRAINING AND QUALIFICATION</b>	
3.1 Associate Qualifications .....	1 of 2
3.2 Orientation and Training of Laboratory Staff .....	1 of 2
<del>3.2.1 Quality Assurance Orientation</del> .....	<del>2 of 2</del>
3.2.2 Quality Assurance Training .....	2 of 2



## TABLE OF CONTENTS

(continued)

	<u>Page</u>
<b>8.0 DATA COLLECTION AND PRODUCTION OPERATIONS</b> .....	1 of 2
<b>9.0 QUALITY ASSESSMENT AND RESPONSE</b>	
9.1 Nonconformance, Deficiency, and Corrective Action .....	1 of 8
9.2 Quality Assurance/Quality Control Audits .....	2 of 8
9.2.1 Performance Audits .....	3 of 8
9.2.1.1 Internal Performance Evaluation .....	3 of 8
9.2.1.2 External Performance Evaluation .....	3 of 8
9.2.2 Surveillances .....	3 of 8
9.2.3 Quality Systems Audits .....	4 of 8
9.2.4 Project Audits .....	6 of 8
9.2.5 Audit Ranking .....	6 of 8
9.2.6 Findings, Observations, Comments, and Recommendations . . .	7 of 8
9.2.7 Client Satisfaction Surveys .....	7 of 8
9.3 Quality Reports to Management .....	7 of 8
9.4 Management Review of the Quality Assurance Program .....	8 of 8

## LIST OF FIGURES

<u>NO.</u>	<u>TITLE</u>
1.2-1	Organization Chart - ITAS Division . . . . . Section 1.0, Page 5 of 5
8.0-1	Data Collection Process Flow Chart . . . . . Section 8.0, Page 2 of 2

## LIST OF TABLES

<u>NO.</u>	<u>TITLE</u>
2.1-1	ITAS Quality Assurance Management Plan Requirements Matrix . . . . . Section 2.0, Pages 4-7 of 7

9413282.0137

## LIST OF ACRONYMS

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASQC	American Society for Quality Control
ASTM	American Society for Testing and Materials
CEO	Chief Executive Officer
CHP	Chemical Hygiene Plan
CLP	Contract Laboratory Program
CRDL	Contract Required Detection Limit
CUR	Condition Upon Receipt
DQO	Data Quality Objective
EMSL-LV	Environmental Monitoring Support Laboratory-Las Vegas
FAS	Field Analytical Services
GC/MS	Gas Chromatography/Mass Spectrometry
ISO	International Organization for Standardization
ITAS	IT Analytical Services
IT	IT Corporation
JPR	Job Performance Review
LIMS	Laboratory Information Management System
MOP	Manual of Practice
NCM	Nonconformance Memo
NIOSH	National Institute for Occupational Safety and Health
OS-QAMP	Operation-Specific Quality Assurance Management Plan
PE	Performance Evaluation
QA	Quality Assurance
QAMP	Quality Assurance Management Plan
QAPjP	Quality Assurance Project Plan
QA/QC	Quality Assurance/Quality Control
QA/QCC	Quality-Assurance/Quality Control Coordinator
QC	Quality Control
SOP	Standard Operating Procedure
TQM	Total Quality Management
USEPA	United States Environmental Protection Agency

9413282.0139

9413282.0139

This page was intentionally left blank.

## **1.0 MANAGEMENT COMMITMENT AND ORGANIZATION**

### **1.1 Statement of Management Position on Quality**

IT Corporation (IT) is committed to providing quality services for environmental management; services which meet the needs of our clients, satisfy regulatory requirements, and are commensurate with the current state of the art. To satisfy our clients' quality objectives, to meet regulatory requirements, and to comply with IT corporate-wide requirements, IT Analytical Services (ITAS) Division has adopted a comprehensive Quality Assurance (QA) Program. The principles and practices of the Program apply to every associate at every level within ITAS; they are fundamental to the way we do business and to the services we provide.

This Quality Assurance Management Plan (QAMP) is an overall statement of Program policy. It provides guidance to ITAS associates in fulfilling their responsibilities, and serves as a statement to external parties of ITAS' commitment to quality.

Implementation of the QA Program is the responsibility of all ITAS associates. Management at every level has the commitment, duty and authority to lead the development and implementation of a

structured management system that provides the framework to support the QA Program. Management will assure the principles and practices of the QA Program are followed and implemented.

Quality Assurance/Quality Control Coordinators (QA/QCC) are assigned in all ITAS operations to verify that the QA Program is implemented as intended by the associates performing the work on a daily basis. Each QA/QCC has the authority and duty to stop work if and when necessary to satisfy QA Program requirements.

To verify that the QA Program is successfully implemented, independent assessments are directed or conducted by the Division Director, QA/QC. In addition, the operations are subject to assessments by the Vice President, Quality and Health Services and by various regulatory authorities and other outside agencies.

### **1.2 IT Analytical Services Division Organizational Structure**

The organizational structure for the ITAS Division is displayed in Figure 1.2-1. The roles of the members of that organization are outlined in Section 1.3.

### **1.3 Quality Organization**

The achievement of the necessary quality in all activities is the responsibility of each ITAS associate led by management. Quality related responsibilities within the operational unit provide for the implementation of the QA Program and completion of Quality Control (QC) activities. The following sections describe these activities for key IT and ITAS positions. The quality related responsibilities may be reassigned by dividing the activities among different individuals or enhanced by adding activities, but they may not be eliminated.

#### **1.3.1 Vice President, Quality and Health Services, IT Corporation**

- Reports directly to the Chief Executive Officer (CEO), IT Corporation
- Approves the ITAS QAMP and the ITAS Operation-Specific QAMP
- Provides independent QA review by participating in or conducting assessments of ITAS operations
- Participates in finding solutions to quality problems not readily resolved within ITAS

#### **1.3.2 Vice President, IT Analytical Services, IT Corporation**

- Reports directly to the CEO, IT

#### **Corporation**

- Approves the ITAS QAMP, the ITAS Operation-Specific QAMP, and ITAS Manuals of Practice (MOP)
- Assumes the ultimate responsibility for the QA Program within the ITAS operations
- Assigns specific quality-related responsibilities within the operating units to the ITAS Laboratory and Field Analytical Services (FAS) Directors
- Periodically determines the effectiveness of the QA Program, recommending changes to the Division Director, QA/QC

#### **1.3.3 Division Technical Director, IT Analytical Services**

- Reports directly to the Vice President, IT Analytical Services
- Maintains current information on regulations and approved methodologies performed by ITAS laboratories
- Acts as a technical consultant, interfacing with the Division Director, QA/QC for quality related issues to assure uniform technical excellence across ITAS operations
- Provides guidance and training to all Laboratory Technical Directors
- Approves the ITAS QAMP, the ITAS Operation-Specific QAMP, and ITAS MOPs. Also reviews other quality and

technical documents produced by ITAS for accuracy, completeness, and applicability to relevant technical goals, regulations and methodologies.

- Guides implementation of the QA Program through training programs

#### **1.3.4 Division Director, Quality Assurance/Quality Control, IT Analytical Services**

- Reports directly to the Division Technical Director with a Quality Assurance "dotted line" responsibility to both the Vice President, IT Analytical Services and the Vice President, Quality and Health Services, IT Corporation
- Reviews and approves ITAS QA documents
- Approves the ITAS QAMP, the ITAS Operation-Specific QAMP, and ITAS MOPs
- Provides guidance and training to all laboratory QA/QCCs
- Oversees independent assessments (audits) of ITAS laboratories to identify areas where improvement is needed to comply with the QA Program
- Verifies completion of corrective actions required to correct nonconformances identified during assessments
- Acts as the focal point for improvements and changes to the QA Program, approves and initiates these changes

- Discusses unresolved nonconformances identified during assessments or brought to the Director's attention by the QA staff for resolution with the ITAS Operational Directors, Vice President, IT Analytical Services and/or IT Vice President, Quality and Health Services
- Suspends further processing in operational units out-of-control until the nonconformance is corrected

#### **1.3.5 Division Operations Director, IT Analytical Services**

- Reports directly to the Vice President, IT Analytical Services
- Approves the ITAS Operation-Specific QAMP
- Assumes responsibility and provides resources for implementation of the QA Program within the operational units
- Assigns specific quality-related responsibilities within the operational units to resolve problems
- Periodically determines the effectiveness of the QA program

#### **1.3.6 Laboratory or Field Analytical Services Director**

- Reports directly to the Vice President, IT Analytical Services with operational responsibility to the Division Operations Director
- Implements the QA/QC Program within the operation

9413282.0142

- Oversees QA/QC training of staff
- Approves quality related documents
- Approves the ITAS Operation-Specific QAMP
- Periodically determines the effectiveness of the QA/QC Program within the operation
- Responsible for the issuance of analysis reports for the operation
- Maintains adequate staffing as documented on organization charts
- Laboratory Document Control Coordinator
- Laboratory Data Reporting Staff

### **1.3.7 Laboratory Staff**

The quality related responsibilities for the remaining key positions, listed below are detailed in the ITAS Operation-Specific QAMP.

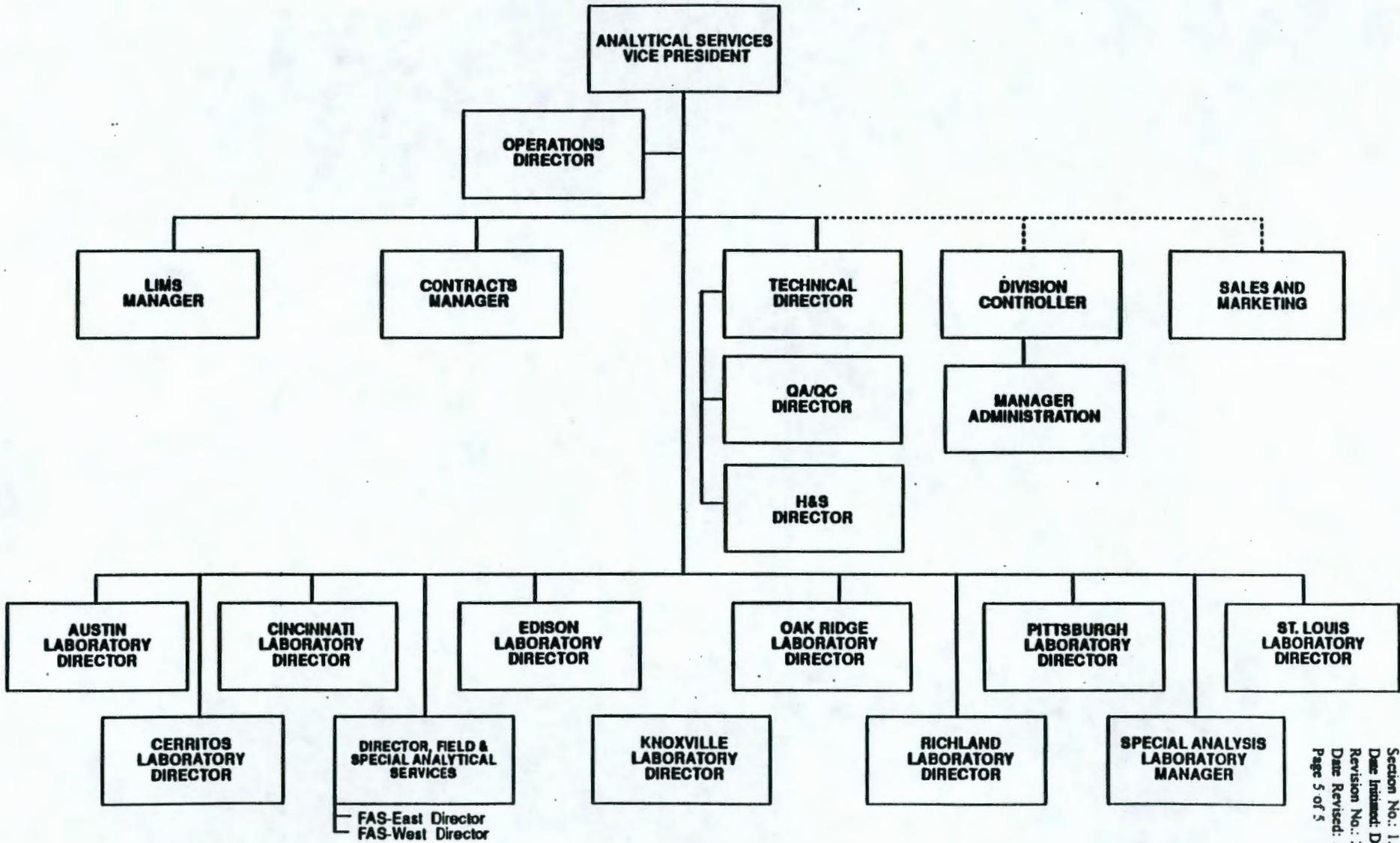
- Laboratory Systems Manager
- Laboratory Project Manager
- Laboratory Operations Manager
- Laboratory Quality Assurance/Quality Control Coordinator
- Laboratory Technical Director
- Laboratory Group/Team Leader
- Laboratory Analyst
- Laboratory Sample Custodian

9413282.0143

124 123 122 121 120 119 118 117 116 115 114 113 112 111 110 109 108 107 106 105 104 103 102 101 100 99 98 97 96 95 94 93 92 91 90 89 88 87 86 85 84 83 82 81 80 79 78 77 76 75 74 73 72 71 70 69 68 67 66 65 64 63 62 61 60 59 58 57 56 55 54 53 52 51 50 49 48 47 46 45 44 43 42 41 40 39 38 37 36 35 34 33 32 31 30 29 28 27 26 25 24 23 22 21 20 19 18 17 16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1

9413282-0144

# FIGURE 1.2-1 IT CORPORATION ANALYTICAL SERVICES DIVISION ORGANIZATIONAL CHART



9413282.0145

This page was intentionally left blank.

## 2.0 QUALITY ASSURANCE PROGRAM DESCRIPTION

### 2.1 Introduction

IT has defined Quality as "meeting the requirements of our clients, both internal and external". To achieve Quality, a Total Quality Management (TQM) process has been established and is being implemented throughout the company. Part of this implementation is through Division QA Programs.

It is the purpose of the ITAS QA Program, as expressed in this QAMP, to provide data which are of known and acceptable quality. To achieve this, a system is described which controls:

- Preservation of samples
- Receipt and handling of samples
- Processing and analysis of samples
- Analytical equipment
- Data verification
- Data reporting
- Records management
- Management review

ITAS recognizes that all laboratory and field associates affect data quality. This QAMP has been prepared so that all IT

associates will be cognizant of the policies adopted by ITAS for the production of analytical data, and will be aware of their responsibilities. This QAMP is supplemented by an Operation-Specific QAMP which describes in greater detail the QA Program in each ITAS operating unit. Specific implementation instructions for quality practices are documented in operation-specific Standard Operating Procedures (SOPs). SOPs are further described in Section 7.1.

As cross referenced in Table 2.1-1, the ITAS QA Program meets the intent of the basic requirements of:

- Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans, OAMS-005/80, Office of Monitoring Systems and Quality Assurance, Office of Research and Development, United States Environmental Protection Agency, EPA 600/4-83-004, February 1983.
- Quality Assurance Program Requirements for Environmental Programs, American Society for Quality Control, Energy Division, Environmental Waste Management Committee, ANSI/ASQC-E4-19xx (Formerly EQA-1), July 1992.

- Quality Assurance Program Requirements for Nuclear Facilities, The American Society of Mechanical Engineers, ANSI/ASME NQA-1-1989 edition.
- Quality Assurance, Office of Nuclear Energy & Office of Environmental Safety and Health, United States Department of Energy, DOE ORDER 5700.6C, August 1991.
- Performance Criteria for Radiobioassay, ANSI N 13.30, September 1989.
- Measurement Quality Assurance for Radioassay Laboratories, ANSI N 42.2, Revised May 21, 1992, Revision 10A.
- Quality Systems-Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, ISO 9001 (ANSI/ASQC Q91-1987).

For the purposes of this QAMP, the ITAS Quality System is composed of quality assurance and quality control activities. These terms are defined and used as follows:

- Quality System - "The collective plans, activities, and events that are provided to ensure a product, process, or device will satisfy given needs." *ANSI/ASQC Standard A3*
- Quality Assurance - "All those planned or systematic actions necessary to provide confidence that a product or service will satisfy given needs." *ANSI/ASQC Standard A3*

- Quality Control - "A process which measures actual quality performance, compares with standards, and acts on the difference!" *Juran, 1974*

## 2.2 Objectives of the Quality Assurance Program

The overall objective of the QA Program for ITAS operations is to provide data of known quality that meet client requirements. In general, to accomplish this, each operating unit must:

- Maintain an effective, ongoing Quality Control (QC) Program to measure and verify laboratory performance.
- Meet data requirements for accuracy, precision, and completeness through the use of proven methodologies.
- Provide sufficient flexibility to allow controlled changes in routine methodology to meet specific data requirements.
- Monitor operational performance of the laboratory on a routine basis and provide corrective action as needed.
- Recognize and promptly correct for any factors which adversely affect quality.
- Maintain complete records from sample submittal through laboratory analysis, data verification, reporting, and sample disposal.

In order to meet these objectives, two levels of management controls are required.

9413282-0147

Controls at the organizational level include all activities that support common or standardized functions such as associate qualifications and training, document control, and material procurement. Controls at a project level consist of the project-specific QA program activities necessary to produce the desired type and quality of product.

9413282-0148

**TABLE 2.1-1  
ITAS QUALITY ASSURANCE MANAGEMENT PLAN REQUIREMENTS MATRIX**

<b>ITAS QAMP (Rev.2) &amp; OS QAMP (Rev.0)</b>	<b>ITAS QAM (REV 1)</b>	<b>ANSI/ASQC E4-19xx</b>	<b>QAMS 005/80</b>	<b>NQA-1</b>	<b>5700.6C</b>	<b>ANSI N13.30</b>	<b>ANSI/ASQC Q91-1987 (ISO-9001)</b>
<b>1 Management Commitment and Organization</b>	<b>2 Laboratory Organization</b>	<b>A1 Management Commitment and Organization</b>	<b>5.04 Project Organization and Responsibility</b>	<b>1 Organization</b>	<b>N/A</b>	<b>1.1 Introduction  1.2 Purpose 1.3 Scope</b>	<b>4.1 Management Responsibility</b>
<b>2 Quality Assurance Program Description</b>	<b>1 Introduction  3 Standard Laboratory Practice</b>	<b>A2 Quality Assurance Program Description</b>	<b>5.03 Project Description</b>	<b>2 Quality Assurance Program</b>	<b>1 Program</b>	<b>2.1 Special Word Usage  2.2 Specific Terms  5.1 Quality Assurance 5.2 Quality Control</b>	<b>4.2 Quality System</b>
<b>3 Associate Training and Qualification</b>	<b>16 Training</b>	<b>A3 Personnel Training and Qualification</b>	<b>N/A</b>	<b>2 Quality Assurance Program</b>	<b>2 Personnel Training and Qualification</b>	<b>3.2 Personnel Preparation</b>	<b>4.18 Training</b>
<b>4 Procurement of Items and Services</b>	<b>4 Material Procurement and Control</b>	<b>A5 Procurement of Items and Services</b>	<b>N/A</b>	<b>4 Procurement Document Control  7 Control of Purchased Items and Services</b>	<b>7 Procurement</b>	<b>N/A</b>	<b>4.6 Purchasing</b>

Table 2.1-1  
Page 1 of 4

ITAS QAMP  
Section No. 2.0  
Date Issued: December 20, 198  
Revision No. 2  
Date Revised: July 1, 1993  
Page 4 of 7

**TABLE 2.1-1  
ITAS QUALITY ASSURANCE MANAGEMENT PLAN REQUIREMENTS MATRIX**

<b>ITAS QAMP (Rev.2) &amp; OS QAMP (Rev.0)</b>	<b>ITAS QAM (REV 1)</b>	<b>ANSI/ASQC E4-19xx</b>	<b>QAMS 005/80</b>	<b>NQA-1</b>	<b>5700.6C</b>	<b>ANSI N13.30</b>	<b>ANSI/ASQC Q91-1987 (ISO-9001)</b>
<b>5 Document Control and Records</b>	<b>1 Introduction</b>  <b>12 Records Management</b>	<b>A6 Document Control and Records</b>	<b>5.01 Title Page</b>  <b>5.02 Table of Contents</b>	<b>6 Document Control</b>  <b>17 Quality Assurance Records</b>	<b>4 Documents and Records</b>	<b>3.6 Direct Bioassay-Record Retention</b>  <b>4.5 Indirect Bioassay-Record Retention</b>	<b>4.5 Document Control</b>  <b>4.16 Quality Records</b>
<b>6 Use of Computer Hardware and Software</b>	<b>10 Data Verification</b>	<b>A7 Use of Computer Hardware and Software</b>	<b>N/A</b>	<b>3 Design Control</b>  <b>11 Test Control</b>	<b>N/A</b>	<b>N/A</b>	<b>ISO 9000-3</b>
<b>7 Work Processes and Operations</b>	<b>9 Analytical Procedures</b>  <b>14 QA/QC Audits</b>	<b>A8 Work Processes and Operations</b>  <b>B1 Planning and Scoping</b>  <b>B2 Design of Data Collection Operations</b>	<b>N/A</b>	<b>1 Organization</b>  <b>5 Instructions, Procedures, and Drawings</b>  <b>10 Inspection</b>  <b>14 Inspection, Test and Operating Status</b>	<b>5 Work Processes</b>  <b>6 Design</b>  <b>8 Inspection and Acceptance Testing</b>	<b>3.1 Facility Criteria</b>	<b>4.9 Process Control</b>

Table 2.1-1  
Page 2 of 4

ITAS QAMP  
Section No. 2.0  
Date Issued: December 20, 1984  
Revision No. 2  
Date Revised: July 1, 1993  
Page 5 of 7

**TABLE 2.1-1  
ITAS QUALITY ASSURANCE MANAGEMENT PLAN REQUIREMENTS MATRIX**

ITAS QAMP (Rev.2) & OS QAMP (Rev.0)	ITAS QAM (REV 1)	ANSI/ASQC E4-19xx	QAMS 005/80	NQA-1	5700.6C	ANSI N13.30	ANSI/ASQC Q91-1987 (ISO-9001)
8 Data Collection and Production Operations	5 Sample Receipt and Initiation of Testing	B1 Planning and Scoping	5.05 QA Objectives for Measurement Data	2 Quality Assurance Program	1 Program	3.1 Facility Criteria	4.8 Product Identification and Traceability
	6 Calibration Practices	B2 Design of Data Collection Operations	5.06 Sampling Procedures	3 Design Control	6 Design	3.4 Direct Bioassay-Performance Criteria for Service Laboratories	4.11 Inspection, Measuring, and Test Equipment
	7 Preventive Maintenance	B3 Implementation of Planned Operations	5.07 Sample Custody	5 Instructions, Procedures, and Drawings	8 Inspection and Acceptance Testing	3.5 Direct Bioassay-Reporting Results	
	8 Analysis of Quality Control Samples		5.08 Calibration Procedures and Frequency	8 Identification and Control of Items		4.1 Indirect Bioassay-Responsibilities of the Service Laboratory Customer	
	9 Analytical Procedures		5.09 Analytical Procedures	9 Control of Processes		4.2 Indirect Bioassay-Analytical Methodology	
10 Data Verification		5.11 Internal Quality Control Checks	11 Test Control		4.3 Indirect Bioassay-Performance Criteria for Service Laboratories		
			5.13 Preventive Maintenance	12 Control of Measuring and Test Equipment		5.2 Quality Control	
				13 Handling, Storage, and Shipping			

Table 2.1-1  
Page 3 of 4

9443282.0152

**TABLE 2.1-1  
ITAS QUALITY ASSURANCE MANAGEMENT PLAN REQUIREMENTS MATRIX**

ITAS QAMP (Rev.2) & OS QAMP (Rev.0)	ITAS QAM (REV 1)	ANSI/ASQC E4-19xx	QAMS 005/80	NQA-1	5700.6C	ANSI N13.30	ANSI/ASQC Q91-1987 (ISO-9001)
9 Quality Assessment and Response	13 Nonconformance and Corrective Action	A4 Management Assessment	5.10 Data Reduction, Validation, and Reporting	2 Quality Assurance Program	3 Quality Improvement	3.3 Direct Bioassay- Interpretation of Measurements	4.10 Inspection and Testing
	14 Quality Assurance/Quality Control Audits	A9 Quality Improvement	5.12 Performance and System Audits	13 Handling, Storage, and Shipping	9 Management Assessment	3.5 Direct Bioassay- Reporting Results	4.13 Control of Nonconforming Products
	15 Quality Reports to Management	B4 Assessment of Data Usability	5.14 Specific Routine Procedures Used to Assess Data Precision, Accuracy, and Completeness	15 Control of Nonconforming Items	10 Independent Assessment	4.4 Indirect Bioassay- Reporting Results	4.14 Corrective Action
		B5 Quality Assessment and Response	5.15 Corrective Action	16 Corrective Action		6.1 Direct Bioassay Measurements	4.17 Internal Quality Audits
			5.16 Quality Assurance Reports to Management	18 Audits		6.2 Indirect Bioassay Measurements	4.20 Statistical Techniques

\*Quality Management and Quality Assurance Standards, ISO 9000, Part 3, "Guidelines for the application of ISO 9001 to the development, supply and maintenance of software".

9413282.0153

This page was intentionally left blank.

### 3.0 ASSOCIATE TRAINING AND QUALIFICATION

All quality related activities performed by ITAS shall be accomplished by associates qualified on the basis of education, experience, and training. The following definitions are relevant to the discussion of training in this section:

- Training - In-depth instruction to develop proficiency in the application of requirements, methods, and procedures. Such instruction may be internal or external classroom sessions, courses, or on-the-job assignments.
- Indoctrination - To instruct in fundamentals so as to provide understanding of principles involved.
- Qualification (Personnel) - The characteristics or abilities gained through training or experience or both, that enable an individual to perform a required function.
- Certification - The action of determining, verifying, and attesting, in writing, to the qualifications of personnel (associates) or material.
- Orientation - The act or process of acquainting individuals with the existing situation, environment, or condition.

#### 3.1 Associate Qualifications

Each laboratory shall have job descriptions for all positions. These job descriptions must specify the minimum qualifications in

terms of education and experience, knowledge, and skills necessary for an associate to carry out work. The operational supervisors shall compare each associate's performance with the qualifications established in his/her job description at least annually. This should be done in conjunction with the associate's Job Performance Review (JPR).

ITAS normally expects necessary knowledge and fundamental chemical laboratory skills to have been demonstrated by formal academic training to include course work in general chemistry, qualitative analysis, quantitative analysis, and instrumental analysis. Qualifications of all professional associates shall be documented by resumes which include academic credentials, employment history, experience, and professional registrations.

#### 3.2 Orientation and Training of Laboratory Staff

Training is performed to maintain proficiency and promote improvement. It should stimulate professional development. ITAS operational staffs include professional associates who are scientists. Such associates shall be assigned duties within the capabilities of their education and

9413282.0154

experience by the appropriate supervisor and shall be qualified to perform and train others on specified procedures based on this experience.

ITAS associates are qualified through indoctrination and experience which will be documented in their resumes and training files. Each new associate shall be supervised in their activities by experienced associates until, in the opinion of the supervisor, they are capable of independently performing their duties. This authorization to perform independently shall be documented in the training files. In addition, training for management associates shall include: professional, managerial, communication, and interpersonal skills. On-going or periodic assessments will be performed to determine training needs and effectiveness of instruction.

### **3.2.1 Quality Assurance Orientation**

Each newly hired ITAS associate is required to go through QA orientation. The QA/QCC shall conduct this orientation in accordance with SOPs within two weeks of the associate's report-to-work date. The QA/QCC shall review the following topics (at a minimum) with the new associate:

- ITAS Philosophy on data integrity and meeting Client requirements

- ITAS QA documents
- Pertinent regulatory QA requirements
- Data recording practices
- Nonconformance and Corrective Action

### **3.2.2 Quality Assurance Training**

Training in the nature and goals of the QA Program shall be provided at least once a year to all laboratory associates. Formal training sessions will be conducted and documented by the QA/QCC. The training program shall address regulatory requirements as appropriate, basic quality control practices, responsibilities of the technical staff, responsibilities of the QA/QCC, the reporting of nonconformances, and the performance of audits. In addition, each ITAS associate shall become familiar with the operating unit QA Program by reading QC procedures and pertinent sections of the ITAS QAMP and the Operation-Specific QAMP appropriate to his/her position.

## 4.0 PROCUREMENT OF ITEMS AND SERVICES

This chapter defines the ITAS requirements for the procurement of items and services.

This program will provide for:

- Assurance that purchased items and services meet established requirements and perform as expected
- Evaluation and selection of vendors
- Inclusion of applicable technical and administrative requirements in procurement documents

### 4.1 Selection of Vendors

Prospective vendors will be evaluated and selected based on the following criteria as appropriate:

- Evaluation of the vendor's history of providing an identical or similar product which performs satisfactorily in actual use
- Objective evaluation of the vendor's current quality records supported by documentation
- Direct audit of the vendor's technical and quality capability

The QA/QCC shall determine the needed level of qualification based on the importance of the item or service being purchased. Vendors which provide test and measuring equipment, standards, quality related service contracts, or subcontracted

laboratory services (quality related items) shall be subject to the more rigorous controls below.

For the procurement of test and measuring equipment, it is recognized that the environment in which the measurement system is placed may have a bearing on its performance. Therefore the QA/QCC may substitute an acceptance testing plan to assure that the measurement system is able to meet specifications in the laboratory environment, in lieu of other supplier qualification activities.

### 4.2 Procurement of Quality Related Items

The quality of instruments, equipment, standards, reagents, solvents, other chemicals, gases, water, and laboratory containers used in analyses must be known so that their effect upon analytical results can be defined. Items purchased by an ITAS operating unit shall meet the requirements and specifications of client contracts or analytical methods as detailed in SOPs.

Quality specifications shall be included or referenced in the purchasing documents for the procurement of applicable items. The

QA/QCC shall approve vendors or items purchased. This approval will be maintained by Purchasing as a "QA Approved" list of vendors and items. If items which may affect laboratory quality are requested from non-preapproved vendors, QA approval must be obtained prior to placing the order.

When ordering such items, a system shall be put in place in each laboratory to assure the quality of the item received. Each laboratory shall assign individuals responsible for purchasing materials and controlling them in the laboratory. This person can be the QA/QCC or other as assigned by the responsible manager. Responsibility for this work shall be defined in the Operation-Specific QAMP. Duties include:

- Specifying in purchase orders or requisitions, suitable grades of materials (grade shall be defined by the QA/QCC or responsible manager)
- Verifying upon receipt that materials meet requirements and that, as applicable, material certificates are provided and maintained in the laboratory Quality/Operations records system
- Identifying and storing materials
- Verifying that material storage is properly maintained, and removing materials from use when shelf life has expired

#### **4.2.1 Role of IT Purchasing**

IT Purchasing supports the laboratory by:

- Maintaining contractual requirements of materials contracts
- Negotiating new contracts
- Identifying potential vendors and subcontractors
- Identifying vendors for unique or scarce materials

In order to enhance standardization of the product within the laboratory network, IT Purchasing shall pursue National Contracts for:

- Laboratory supplies of known quality and proven reliability
- Instrumentation
- Standards from traceable, certified sources

#### **4.2.2 Procurement Procedures**

The specifications for standards, chemical reagents, solvents, gases, water, and other items specified in approved analytical methods shall be met by the laboratory and written in method SOPs. In addition, each laboratory must have SOPs that cover:

- Checking the purity of standards, reagents, water, solvents, and other chemicals versus intended use

9413282-0157

- Storage and expiration of standards, reagents, solvents and other chemicals
- Requirements for laboratory containers (e.g. volumetric glassware, sample containers)
- Cleaning of glassware prior to use

Corrective action for failure of an item to meet required specifications are:

- Review current supplies and eliminate from use
- Return to vendor
- Evaluate a new lot or alternate supplier

The Division Technical Director or the Division Director, QA/QC shall be notified immediately of any quality problems with national vendors.

#### **4.3 Procuring Services**

**Subcontract Laboratory Services** - A subcontract laboratory is defined, for the purposes of this QAMP, as a laboratory external to the ITAS laboratory network. A subcontract laboratory will be used only in the event that (a) ITAS laboratories do not have the capability or capacity to perform the requested testing, or (b) the customer so directs (in which case the customer then assumes responsibility for subcontractor performance). A subcontract laboratory will be used only after approval is obtained

from the client and the quality of the laboratory is determined to be acceptable by ITAS QA/QC staff.

Once it is determined that a subcontract laboratory is required and approval is obtained from the client to use a laboratory external to the ITAS network, the QA/QCC must perform a quality systems audit of the selected subcontract laboratory. This audit must be approved by the Division Director, QA/QC and documented in the Quality/Operations records at the laboratory and in Division subcontract laboratory files. The procedure for the approval to use a subcontract laboratory is detailed in ITAS Division SOP No. IT-QC-0002.

9413282-0158

This page was intentionally left blank.

## 5.0 DOCUMENT CONTROL AND RECORDS

ITAS has designed and implemented a system to control, distribute, and revise documents affecting quality. These documents are approved by the appropriate positions as described in the Operation-Specific QAMP. Controlled documents are required to be reviewed and revised if necessary on a scheduled basis. The frequency of this review is dependent on regulations and client requirements, but should occur at least annually. Controlled documents include but are not limited to this QAMP, the Operation-Specific QAMP, Quality Assurance Project Plans (QAPjPs), and SOPs.

### 5.1. ITAS QAMP

The QAMP provides ITAS QA policy. It is applicable to and provides direction for all ITAS operations. The QAMP discusses all aspects of QA and QC, both administrative and technical. It is not however, intended that the Plan provide in-depth technical discussion. The Operation-Specific QAMP and SOPs supplement the QAMP to provide the details of implementation. The QAMP has precedence in policy matters over all other ITAS quality-related documents.

### 5.2 Operation-Specific QAMP

The Operation-Specific QAMP is designed

to supplement the ITAS QAMP and provide additional information both common and specific to each ITAS operating unit. The Operation-Specific QAMP along with SOPs describe the implementation of the QAMP within the laboratory. This document enhances and provides further detail to the QA/QC policies laid out in the ITAS QAMP. The Operation-Specific QAMP provides specific QC criteria for ITAS standard procedures and may detail contract specific QC criteria for long term, ongoing projects (e.g. those that last a minimum of 1 year).

### 5.3 Manuals of Practice (MOP)

Manuals of Practice are developed to provide in-depth technical discussions of specific topics. For example, a MOP for the field collection, preservation, and shipment of samples to ITAS laboratories provides specific uniform direction to IT associates. The ITAS Chemical Hygiene Plan (CHP) and Safety Manual are also considered MOPs. MOPs are usable across ITAS operations.

### 5.4 Standard Operating Procedures (SOP)

SOPs are the backbone of the documented QA Program within ITAS. There are two

65107022116

9443282.0160

levels of SOPs, Division and Operation-Specific. Division SOPs specify methods that are common to all operations and are standard across the network. Operation-specific SOPs detail procedures that pertain to that operation only. All SOPs are written, detailed instructions describing specific laboratory operations and performance of routine laboratory tasks. They specify what is done, whose responsibility it is to perform tasks and whose responsibility it is to verify their correctness. They are sufficiently detailed to provide data of acceptable quality and integrity with a minimum loss of data due to out-of-control situations. They also provide for documentation to record the performance of all tasks and their results, and demonstrate the verification of the data each time the data are recorded, calculated, or transcribed. SOPs are written to address the major elements upon which analytical quality depends. ITAS has adopted a standard SOP format for use within the Division.

### **5.5 Quality Assurance Project Plans (QAPJP)**

Frequently, contractual and regulatory demands, or uniqueness of a project's scope of work, require the preparation and implementation of a project-specific QAPJP. If a specific project requires a unique QA Program, that program with full

documentation must be provided to the ITAS operation for implementation. The requirements of the project will take precedence over conventional ITAS QA practices for that work. The requirements of the project may not be less stringent than minimum ITAS QA/QC requirements unless requested by the client in writing or approved by the Division Director, QA/QC. Typical project requirements are as follows:

- The development and/or use of new or modified testing methods
- Special requirements for equipment calibration and maintenance
- Specific contract required detection limits (CRDLs)
- Defined data quality objectives (DQOs) such as accuracy and precision limits or the statistical treatment of data
- Additional or unique documentation or records management requirements.

### **5.6 Records Management**

The ITAS QA Program has been developed to provide analytical results of known quality that meet client requirements. To demonstrate that quality has been achieved, each ITAS laboratory maintains a records management system that includes documents which demonstrate the analytical performance of the laboratory.

Laboratory records are maintained in two broad categories:

- **Project Records:** Documents which are specific to a project or a group of samples within an ongoing project, such as chain-of-custody and raw analytical data.
- **Quality/Operations Records:** Documents which demonstrate overall laboratory operation, such as instrument log books, calibration data, and control charts. These records will directly affect the data for a specific project, but in general their applicability is not limited to one project.

All operating unit records, from time of sample receipt through reporting and disposal, shall be available and stored in a manner that safeguards their integrity from tampering or physical damage and loss. For ITAS, this will be separate files in a file cabinet in a 24-hour per day secure area at a minimum. Any documentation that bears on the reported results must be available if requested by the client or if production is compelled by an authorized regulatory agency or court of law. This includes operational and project-specific data. Data may be stored in "real-time" as it is produced, or filed in a manner to allow prompt retrieval and assembly into a complete project file. Operation-specific SOPs shall describe how the complete set of documentation is compiled, including the

flow of data forms, locations, responsibilities, and checks on the records management system implemented.

9413282-0161

This page was intentionally left blank.

## 6.0 USE OF COMPUTER HARDWARE AND SOFTWARE

The purpose of defining controls for computer hardware and software is to protect the integrity of computer-resident data in the laboratory. SOPs shall be put in place in each location so that computer resident data are accurate and defensible. The following references shall be used as guidance for implementation of this system of controls:

- Good Automated Laboratory Practices, US Environmental Protection Agency, (draft), December 28, 1990
- Quality Management and Quality Assurance Standards ISO 9000, Part 3: "Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software"
- ASTM Method E3140-1 (draft) "New Standard Guide for Laboratory Information Management Systems (LIMS)"
- ANSI N413 "Guidelines for the Documentation of Digital Computer Programs"

### 6.1 Use of Hardware

Computer equipment used in the generation, measurement, or assessment of client data shall be of appropriate design and of adequate capacity to function according to specifications. It shall be suitably located for operation, inspection, cleaning and maintenance. There shall be a written

description of the computer system(s) hardware. The computer shall be installed in accordance with manufacturer's recommendations and undergo validation which demonstrates that the computer equipment correctly performs its stated capabilities and functions. Changes to computer hardware shall be made only after review and approval of the Laboratory Information Management System (LIMS) Manager and Laboratory Director.

Computer hardware shall be inspected, cleaned, and maintained on a regular basis at a minimum of annually. Each laboratory shall:

- Have SOPs for validation, maintenance, and security of hardware
- Designate an associate (usually the LIMS Manager) to be responsible for system performance
- Maintain written records of all hardware validations
- Maintain written records of all maintenance

### 6.2 Security

Each operating unit shall have procedures in place which secure computer hardware and software systems if that system:

- Contains confidential information that requires protection from unauthorized disclosure
- Contains data in which the integrity must be protected against unintentional error or intentional fraud
- Is used to acquire, process, or report data

When the computer system(s) contain data that must be secured, each laboratory shall ensure the system is physically secured, physical and functional access to the system is limited to authorized associates, and introduction of unauthorized external programs or software is prohibited.

### 6.3 Use of Software

If computer software is used to acquire, process, or report client data, it is necessary to demonstrate the software correctly performs its intended function. The following definitions are important to the this discussion:

- Validation - establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. This process demonstrates that the mathematical or statistical model embodied in the computer program is an acceptable representation of the process or system for which it is intended and meets all specified requirements.

- Verification - the process of checking the accuracy of manually or automatically (electronically) entered information.

In general, software is verified by comparing its performance against known results. Verification may be done in several ways (see Sections 6.3.1 and 6.3.2). Each laboratory shall have a software SOP(s) describing the following:

- Software verification
- Data entry and verification
- Changing data
- Data analysis, processing, storage and retrieval
- Backup and recovery of data and software
- Electronic reporting of data
- Definition and storage times for data and software

#### 6.3.1 Industry Standard Software

Industry standard programs are defined as those which are widely used throughout the profession, brought into ITAS, and used without modification. If the program has been prepared external to IT, independent validation is not required. However, the program should be verified prior to use on an ITAS system. To verify the software, example problems should be processed to

demonstrate that the program is fully operational. Example problems must fully test the utilized capabilities of the software.

### **6.3.2 ITAS Developed Software**

For programs developed within ITAS, and externally prepared programs which are modified by ITAS, complete validation and verification must be performed. Validation must be performed in accordance with an approved reference (Section 6.0) and IT Standard Quality Practice, ITC0010 "Software Development and Usage". The verification process is dependent upon the function of the software as follows:

- For software which only performs numerical manipulation, sample sets of numbers for which results are known should be processed and compared. In this case, known results are usually generated by performing hand calculations using the same equations and procedures as the software. Verification of the software must test the software production of the intended results. Problems must test both the theory, or basis for computation, and the ability of the software to store and manage data.
- Software which performs as part of instrument operation should be verified by processing reference materials through the instrument system. Processed instrument response should be compared against the standards used. Verification shall be performed annually, at a minimum.

### **6.3.3 Control of Software Changes**

Changes to software shall be controlled. Detailed software control procedures must be available in each ITAS laboratory. Standard forms are used to document and track changes. An ITAS associate in each laboratory must be assigned to maintain software control, usually the LIMS Manager or programmer. Whenever a program is changed, reverification is necessary. If the software has had features added, previous test problems should be rerun to demonstrate their function has not been affected. New test problems should be processed as discussed above to verify added performance. If software revision changes the basic operation of the program, complete reverification of the program is required. All changes must be completely documented.

### **6.3.4 Software Review and Reverification**

Spreadsheets and unprotected software shall be reverified on an annual basis at a minimum. The test problems used to provide initial verification shall be reprocessed and the results compared to demonstrate that performance of the software is unchanged. If software performance has changed, the effect of the change upon intended function and usage since last verification shall be assessed.

"Effect" must be determined on a case-by-case basis for the scope and impact of incorrectly reported results. If necessary, the data shall be reprocessed and recipients of affected data reports notified. All other software programs must be validated upon creation or change and verified annually.

### **6.3.5 Software Verification Documentation**

Software verification shall be documented by the associate performing the work, by signing and dating in ink the computer output, and supporting calculations. If test problems are used, the input shall be marked to indicate correct usage and the output checked to indicate acceptable comparison. If reference materials are used as the basis for verifying instrument software, the "true" values or certificates for the materials shall be included with the output to demonstrate performance. The verification documentation must be reviewed and approved by the associate's immediate supervisor, the LIMS Manager or computer programmer, and QA/QCC.

All software verifications, whether for initial or subsequent reverification, shall be maintained in the Quality/Operations records management system. A historical file shall be maintained for each program. The file shall include the basis for the

verification, such as the test problems or hand calculations, results of the software performance, the results of subsequent reverifications, applicable program code, user manuals, technical documentation, and a copy of the program.

9413282.0165

## 7.0 WORK PROCESSES AND OPERATIONS

Much of the environmental project activity is planned and designed external to the laboratory or field operation and presented in the form of a contract, work plan, or QAPjP. Laboratory and field activities are in turn planned, implemented, and assessed to meet client requirements according to approved procedures and methodologies. Many QA systems have been put in place to document the implementation of planned activities. The planning and design of operational systems to accomplish documented implementation are detailed in operation-specific SOPs. The entire process is assessed on a regular basis for conformance to prescribed requirements.

### 7.1 Standard Operating Procedures

SOPs are required to be written in all ITAS operating units for all analytical and administrative procedures from the receipt of samples in the laboratory through analysis, reporting, and subsequent sample disposal. This includes auxiliary functions as well, such as training, QA/QC and health and safety procedures. Standard ITAS SOP formats are discussed in the Operation-Specific QAMP.

ITAS operations shall prepare and maintain, in addition to the Operation-Specific

QAMP, a Standard Operating Procedure Manual. The requirements of this QAMP for activities such as calibration, field procedures, material procurement and control, preventive maintenance, training, and QC sample analysis shall be incorporated into the SOPs as appropriate.

### 7.2 Analytical Methods

Whenever possible, ITAS operations utilize industry and regulatory agency recognized analytical methods from source documents published by agencies such as the U.S. Environmental Protection Agency (USEPA), American Society for Testing and Materials (ASTM), and the National Institute for Occupational Safety and Health (NIOSH).

### 7.3 Detection Limits

All analytical methodologies have an associated detection limit below which an analyte present in the sample cannot be accurately determined. The detection limit is the quantity of analyte measured within a stated confidence level above the background. A detection limit value may be reported in one of three ways:

- as a less than (<) value
- as not detected (ND)
- as an undetected (U) value

In all cases, the detection limit will also be reported for reference. For USEPA Contract Laboratory Program (CLP) methods, values that are below the contract required detection limit (CRDL), but can still be quantified, are reported using data qualifiers specified in the protocol.

Detection limits indicated in methods are highly matrix dependent and are provided for guidance. Depending upon the exact sample composition, stated detection limits may not always be achievable.

For radiochemistry, whether the net result is negative, zero, or positive, the actual calculated result is reported with its associated propagated uncertainty. The detection limit is affected by many factors, such as the length of count, chemical yield, half-life, background of the instrument, counting efficiency, and the matrix interference. The minimum detection limit for radiochemical analyses is defined as the smallest concentration of material that yields a net count above background with a 95% probability (a true signal is reported 95% of the time) and no greater than a 5% probability of calling a blank a true signal. Detection limit calculations, the frequency for performing detection limit studies, and procedures for specific analytical methods shall be documented in operation-specific

SOPs.

#### **7.4 Variance from Stated Analytical Methods**

Work processes will be performed in accordance with SOPs derived from the methods referenced unless specific project requirements or needs dictate adoption of an alternate method or modification of the cited methods. For example, GC/MS procedures may be "CLP-modified", as specified by the USEPA's CLP.

ITAS has developed in-house SOPs for some matrices and analytes that are based on regulatory methods but which may include modifications to improve reproducibility and/or accuracy. If an operation is performed in an alternate manner, the method shall be documented in the project records.

#### **7.5 Assessment of Work Processes**

All work processes or operations are subject to assessment as described in Section 9.2.

9413282.0167

## 8.0 DATA COLLECTION AND PRODUCTION OPERATIONS

Laboratory analyses are designed to produce data representative of conditions when the sample was obtained. The data collection design includes field sampling events, sample handling and custody, analytical operations, data verification, techniques to assess limitations on data use, and data reporting requirements.

To provide representative samples for analysis, both field and laboratory personnel must satisfactorily perform their activities. Although at times the sampling may be performed by non-ITAS associates, the importance of sampling and transportation is understood and must be considered in data validation. Figure 8.0-1 shows the sample collection, transportation, and holding process used by ITAS. The steps presented are described in detail in the Operation-Specific QAMP and SOPs.

To provide services in conformance with client requirements, ITAS employs a multi-level review of all work. This review consists of:

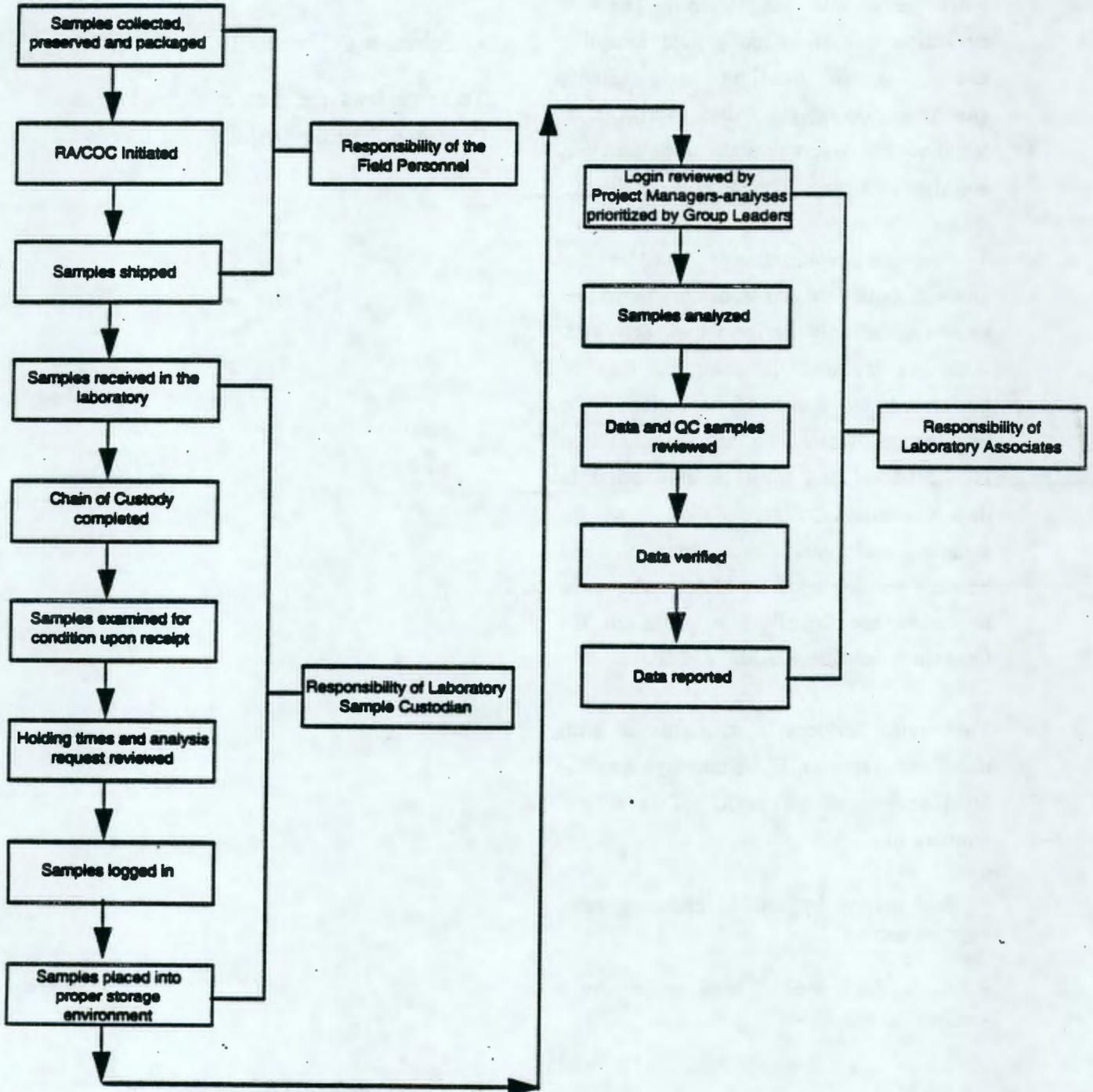
- Self review by double checking ones own work
- A thorough second level review by a peer or supervisor

- A systematic review by a project manager to verify compliance to the client's needs
- Selective QC review by the QA/QCC

These reviews are further defined in the Operation-Specific QAMP.

9413282-0168

FIGURE 8.0-1  
DATA COLLECTION PROCESS FLOW CHART



## 9.0 QUALITY ASSESSMENT AND RESPONSE

Each ITAS operating unit shall establish, implement, and document procedures to detect, prevent, and correct quality problems and to ensure quality improvement. Items and processes that do not meet established requirements must be investigated to determine their cause. Improvements must be implemented in the operations which will prevent a recurrence of these quality problems and provide overall quality performance. All phases of laboratory work should be designed with the objective of preventing problems and improving quality on a continuous basis.

### 9.1 Nonconformance, Deficiency, and Corrective Action

A nonconformance is a deviation or event beyond the limits and criteria established for standard operations which may lead to a degradation of quality to an unacceptable or indeterminate level. Nonconformances over which the operating unit has control must have the root cause determined such that the possibility of the nonconformance recurring is minimized or eliminated.

Nonconformances may include (but are not limited to) the following:

- Sample holding time exceeded

- Incorrect sample collection, preparation or analysis techniques used
- Calibration criteria not met
- QC sample data (blank, spike, duplicate, surrogates, LCS, etc.) are outside acceptance criteria
- Data recording errors, transcription errors, calculation errors
- Data verification errors
- Any situation that might adversely affect the final data quality

A deficiency is a deviation from documented procedures, practices, standards, or a defect in an item that is determined *not* to render the quality of an item or service unacceptable or indeterminate. The QA/QCC shall determine whether the deviation is a nonconformance or a deficiency.

As soon as deviation from accepted laboratory practice is discovered, it is required to be documented. There are two types of documentation within the ITAS system for nonconformances and deficiencies; the Nonconformance Memo (NCM) and the Condition Upon Receipt Variance Report (CUR). These forms are shown in the Operation-Specific QAMP.

9443282-0170

All nonconformances shall have a **corrective action**. The process by which corrective action is performed requires a determination of root cause, immediate action, and actions taken to prevent recurrence. The latter two may be the same action. Corrective actions may include (but are not limited to) the following:

- Recalibration of instruments, using freshly prepared calibration standards
- Reanalysis of samples
- Replacement of solvent lots or other reagents that yield unacceptable blank values
- Additional training of laboratory associates in correct implementation of sample preparation and analytical techniques
- Reassignment of associates
- Communication with the client to determine appropriate action (e.g. resampling, processing the sample "as is", terminating analysis, etc.)

**Responsibilities** - All ITAS associates are responsible for identifying and reporting any deviation from accepted laboratory practice that might affect the quality of the data. Once a possible nonconformance is identified, a NCM or a CUR is generated and routed to that person's supervisor for further review and documentation.

QA/QC personnel are responsible for verifying corrective actions and for tracking NCMs until closure.

## **9.2 Quality Assurance/Quality Control Audits**

Analytical laboratories are subject to numerous assessments in the form of audits, both internal (self assessment) and external (independent assessment). Laboratory audits within ITAS can be broken down into four major categories:

- Performance Audits
- Surveillances
- Systems Audits
- Project Audits

Audits of laboratories are performed to determine the degree of adherence to policies, procedures, and standards which include:

- IT and ITAS QA policy
- IT and ITAS procedures
- Contractual requirements
- Regulatory obligations

Correctly performed, audits serve as a useful management tool to evaluate the appropriateness of QA policies. They identify areas for improvement with regard

9413282.0171

to compliance with policies, procedures, and standards. They also provide a means for correction prior to system failure requiring shut down. In addition, they serve to strengthen the documentation trail assuring known data quality.

### **9.2.1 Performance Audits**

Performance audits are conducted on an ongoing basis within the laboratory by the QA/QCC. These audits are reported to the Laboratory Director and the Division Director, QA/QC. Performance audits vary with the needs of the laboratory and are described in greater detail in the Operation-Specific QAMP. Performance audits include internal and external performance evaluation (PE) samples. These are discussed in the following sections.

#### **9.2.1.1 Internal Performance Evaluation**

The QA/QCC has the responsibility of monitoring the performance of the laboratory by inserting blind QC samples into the sample stream quarterly and analyzing the results. These samples demonstrate data quality through statistical analysis. The results of these samples may also be used to document the training level of the analyst(s) performing the work. These results are linked to the analyst(s) in the associate training files.

In addition, ITAS employs a "double blind" PE sample program involving semiannual studies. This program applies to all ITAS laboratories. The results of the study are reported to the Vice President, IT Analytical Services, the Division Technical Director, and the Division Director, QA/QC. Recommendations for quality improvement are submitted to the Laboratory Directors, and corrective actions are implemented as necessary.

#### **9.2.1.2 External Performance Evaluation**

Each laboratory participates in a variety of external performance evaluation programs as described in the Operation-Specific QAMP.

### **9.2.2 Surveillances**

Each month (unless a systems audit or follow-up audit is performed) it is the responsibility of the QA/QCC in each laboratory to perform a surveillance. The scope of the surveillance is determined by the QA/QCC. This allows concentrated focus on areas of the laboratory that may be suspect or require additional monitoring to verify compliance with policies, procedures, and standards. The QA/QCC may use the nonconformance/corrective action system to determine trends in a laboratory area that required further investigation. The purpose

of a surveillance is to find and correct problems before they become out-of-control situations.

Surveillances are detailed inspections of specific areas of a laboratory and its QA program. Surveillances do not require the extensive planning and preparation required of audits and are conducted on a more informal basis. The QA/QCC shall observe the activity of interest while it is in process and/or review objective evidence. A checklist for the applicable documents and criteria may be used for this review.

Once the surveillance is complete, the QA/QCC will issue a report to the responsible manager and the Laboratory Director. The report will detail the results of the surveillance and request a corrective action plan complete with target dates and associate assignments. The QA/QCC must work with the surveyed group to recommend corrective action and must then follow-up after the proposed target date to verify that corrective action was indeed performed. The QA/QCC shall document by memorandum that corrective action was taken.

### **9.2.3 Quality Systems Audits**

Four times per year, each laboratory undergoes an internal audit to identify the

level of compliance with established, documented quality assurance systems. Two of these audits are conducted by the QA/QCC. The remaining two are conducted by the Division Director, QA/QC or designee. The audits usually consist of a 2-4 day comprehensive review of all quality systems in the laboratory. Six months later, a second (follow-up) audit is conducted to assess compliance with the corrective action plan established by the audited laboratory after completion of the first audit. The follow-up audit can be performed in 1-2 days. The Lead Auditor reserves the right to lengthen the audit or require a complete re-audit in 3 to 6 months depending upon the extent of the problems discovered. Findings which have not been satisfactorily resolved between the two audits, shall be specifically reported to the Division Operations Director and Vice President, IT Analytical Services for resolution.

Systems audits not conducted by the QA/QCC are lead by an ITAS certified Lead Auditor (see System Procedure 8907-QAC-04, "Standard Operating Procedure for Auditors Certification at ITAS Laboratories") under the direction of the Division Director, QA/QC. The Division Director, QA/QC will prepare a schedule of audits to be conducted during the fiscal year and will select appropriate audit teams

9413282-0173

depending upon the nature and depth of the audit. The source documents for systems audits are the ITAS QAMP, the ITAS Operation-Specific QAMP and SOPs. The scope of the audit takes into account the expectations of external auditors, contracts and regulatory requirements. A quality systems audit checklist is prepared for the fiscal year and is used in all locations audited in order to provide for consistency and objectivity to the audit.

At the beginning of the audit, the audit team will meet with the Laboratory Director and the QA/QCC to discuss the goals of the audit. The QA/QCC should be available to assist the audit team throughout the audit.

At the close of the audit, the audit team will debrief the Laboratory Director, QA/QCC, Division Technical Director, Project Managers, and Group Leaders and will present the audit findings and observations. Additional laboratory staff may be invited to the debriefing as deemed necessary by the Lead Auditor. The Lead Auditor can close audit findings and observations during the debriefing if the laboratory staff can satisfactorily demonstrate that the finding/observation is inappropriate or has been corrected prior to the debriefing. Also during this meeting, recommendations for corrective actions will

be discussed. If corrective action is requested to be taken immediately after audit closure, the action must be taken.

An audit report will be prepared by the Lead Auditor and will include the following:

- Cover memo summarizing the audit process, any findings and announcing the preliminary audit ranking
- Finding Report(s)
- Observation Report
- Corrective Action Plan (to be completed by the laboratory)

The audit report shall be completed as soon as possible after completion of the audit, but shall take no longer than 45 days. The audit report will be addressed to the Laboratory Director, who is responsible for responding within the designated time frames established by the Lead Auditor. A complete copy of the systems audit report will be sent to the laboratory QA/QCC and the Division Director, QA/QC.

Upon receipt of the audit response, the Lead Auditor or the Division Director, QA/QC will evaluate the proposed corrective action plan and reply stating acceptance or rejection of the plan or its elements. Approximately six months later,

9413282.0174

the Lead Auditor or designee will return to the audited laboratory to verify completion of the corrective action plan. The Lead Auditor will then issue a final audit report detailing the results of implementation and will assign a final audit ranking for the year. A positive change in ranking is indicative of improvement in implementation of the QA program.

#### **9.2.4 Project Audits**

Project or data quality audits are designed to address the DQOs (precision, accuracy, representativeness, and completeness) of all data associated with a particular project. These audits also review a project for compliance with contractual requirements set forth in a QAPjP or formal contract. Project audits may be conducted by IT, ITAS or Project QA staff. A project-specific checklist is prepared using the QAPjP and/or contract as the source document(s). The audit report is addressed to the Laboratory Director who is required to respond within the designated time frame stipulated by the Lead Auditor. As with all other audits, a follow-up audit for verification of compliance with the corrective action plan may be performed.

#### **9.2.5 Audit Ranking**

Internal ITAS QA Systems audits require a preliminary and final rank in order to be

assessed. Operations are ranked as excellent, acceptable, marginal, or unacceptable. These ranks are described as follows:

- Excellent - Meets or exceeds established requirements for all areas audited.
- Acceptable - Audited work meets all requirements of the ITAS QA Program with only a few minor deviations from established requirements.
- Marginal - Audited work represents a basic QC practice with actions required by the laboratory to improve operations immediately.
- Unacceptable - Audited work indicates that quality practice is not implemented on a regular basis and one or more areas will be shut down for correction.

The Division Director, QA/QC will issue a memorandum to all QA/QCCs and Laboratory Directors annually describing the process of determining the audit rank.

While audit ranking allows for comparison of laboratories across the network, caution is advised in using the ranking alone without a detailed review of the situations or conditions observed that caused the Lead Auditor to arrive at that rank.

**9.2.6 Findings, Observations,  
Comments, and  
Recommendations**

Findings represent areas in which the operating unit or section of the operating unit as a system is not in compliance with the requirements of the ITAS QA Program. Findings are situations that could directly affect the quality of resulting work. Findings require that a corrective action plan be developed by the Laboratory Director, identifying the root cause of the deficiency and scheduling action(s) to prevent recurrence.

Observations represent isolated instances of noncompliance or questionable practice. They present situations that could become findings if left unresolved. As with findings, a corrective action plan is required.

Comments or recommendations may be written by the Lead Auditor in an attempt to share information and provide constructive criticism in order to improve performance or documentation in an area. Comments might also indicate areas that are on the verge of being noncompliant. If attention is not paid to the comment, it is likely to become an observation. Comments and recommendations do not require a formal response by the audited

organization, but it is strongly recommended that they be reviewed for appropriate action. Included in the comments and observations are those which describe exemplary practices. Audit reports should not focus only on negative aspects of the program and should include observations of exemplary practice.

**9.2.7 Client Satisfaction Surveys**

Each ITAS operating unit has the responsibility to understand client needs and whether ITAS services are meeting those needs and expectations. At least three client satisfaction surveys should be performed monthly within each laboratory to randomly selected clients by the QA/QCC or designee. The IT Corporation Client Satisfaction Survey form, Revision 0, April 1992 should be utilized with distribution to the ITAS Project Manager, Laboratory Director, Division Operations Director, Vice President, IT Analytical Services, Vice President, Quality and Health Services, and the Division Director, QA/QC. Any corrective or follow-up action must be documented on the form and implemented by the Project Manager or Operating Unit Director.

**9.3 Quality Reports to  
Management**

The QA/QCC and the Division Director,

QA/QC shall prepare reports to management on a monthly basis indicating the effectiveness of the QA Program.

#### **9.4 Management Review of the Quality Assurance Program**

Management at all levels shall assess the QA Program and its performance. Management assessment shall identify barriers that hinder the organization from achieving its objectives in accordance with quality, safety, and environmental requirements. Results of management assessments shall be documented and acted upon. The effectiveness of the implementation of corrective actions shall be included in the next management assessment.

An example of the management assessment approach is to conduct double blind studies on the appropriate laboratories. In such studies, a client contacts the laboratory and submits a sample of known parameters and values for analysis that is totally blind to the laboratory management and the analysts. These studies allow assessment of the total process from initial client contact through final reporting.

Review of the appropriateness of the adequacy of the ITAS QA Program is ongoing. At any time, the Division Operations Director, a Laboratory or FAS

Director, or the Division Technical Director may present, in writing, recommended changes to the Division Director, QA/QC. During the QA systems audits, the QA Program is discussed with the management of the facility audited. This feedback is valuable and necessary to the progress of the QA Program to meet the constantly changing needs of the environmental industry.

In addition to these ongoing reviews, the Vice President, IT Analytical Services shall conduct an annual review of the QA Program considering:

- Results of the QA systems audits. Are undesirable trends occurring?
- Status of QA Documents. Are the current documents adequate? Are new documents needed?
- Is the auditing program fulfilling its purpose?

The Vice President, IT Analytical Services will consult with the Division Operations Director, Laboratory Directors and the Vice President, Quality and Health Services as deemed necessary during the review. To document the review, the Vice President, IT Analytical Services will issue a memo to the Division Director, QA/QC stating the extent of the review and will present recommendations.

9413282.0177