**QUALITY ASSURANCE GUIDANCE
FOR
LABORATORY ASSESSMENT PLATES
IN SUPPORT OF
EM ENVIRONMENTAL SAMPLING
AND ANALYSIS ACTIVITIES**

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MASTER

TABLE OF CONTENTS

1.0	INTRODUCTION	1
1.1	Purpose	1
1.2	Scope	2
1.3	EM Assessment Program	2
2.0	ASSESSMENT PLATES	
2.1	General Analytical Laboratory Assessment Plates	5
2.2	Radiochemical Analytical Laboratory Assessment Plates	33
2.3	Laboratory and Field Quality Assurance/Quality Control (QA/QC) Assessment Plates	64

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LABORATORY ASSESSMENT GUIDANCE

1.0 INTRODUCTION

This document is one of several guidance documents developed by the U.S. Department of Energy (DOE) Office of Environmental Restoration and Waste Management (EM). These documents support the EM Analytical Services Program (ASP) and are based on applicable regulatory requirements and DOE Orders. They address requirements in DOE Orders by providing guidance that pertains specifically to environmental restoration and waste management sampling and analysis activities.

DOE 5700.6C Quality Assurance (QA) defines policy and requirements to establish QA programs ensuring that risks and environmental impacts are minimized and that safety, reliability, and performance are maximized. This is accomplished through the application of effective management systems commensurate with the risks imposed by the facility and the project. Every organization supporting EM's environmental sampling and analysis activities must develop and document a QA program. Management of each organization is responsible for appropriate QA program implementation, assessment, and improvement. The collection of credible and cost-effective environmental data is critical to the long-term success of remedial and waste management actions performed at DOE facilities. Only well established and management supported assessment programs within each EM-support organization will enable DOE to demonstrate data quality. The purpose of this series of documents is to offer specific guidance for establishing an effective assessment program for EM's environmental sampling and analysis (ESA) activities.

Assessments are a management tool required to be implemented as part of an organization's QA program to help assure achievement of quality goals. They provide a documented means of detecting missing quality assurance requirements and potential problem areas. Assessments form one of the bases for quality improvement.

The Analytical Services Division (ASD), Office of Environmental Restoration and Waste Management (EM-263) has developed and is implementing an assessment program to evaluate EM's sampling and analysis activities to ensure that satisfactory management systems are implemented.

1.1 Purpose

The purpose of this document is to introduce assessment plates that can be used to conduct performance assessments of an organization's or project's ability to meet quality goals for analytical laboratory activities. To support this goal, the final version of this document is provided in hardcopy and available upon request from EM-263 as a series of WordPerfect 5.1 files.

1.2 Scope

These assessment plates are provided as non-prescriptive guidance to EM-support organizations that are responsible for collection of environmental data. EM-support organizations include all private sector, government-owned/contractor-operated, and government-owned/government-operated organizations collecting environmental data for EM's programs. The laboratory

assessment plates are designed to be used by the oversight organization without significant revision and to introduce a more consistent assessment program across the DOE Complex. In addition, internal and external circulation and review of the assessment plates is consistent with the recognized need for interagency harmonization.

1.3 EM Assessment Program

The collection of credible and cost-effective environmental data is critical to the long-term success of remediation and waste management programs at DOE facilities. Only with well established and supported performance evaluation and audit programs will DOE be able to demonstrate that data are of known and accountable quality. The Analytical Services Division (EM-263), in the Office of Technology Development, is responsible for assuring that all EM operations have the environmental sampling and analysis services required. The Analytical Services Division has developed and is implementing an assessment/surveillance program to evaluate field and laboratory activities, as put forward in EM's Analytical Services Program (ASP) Five Year Plan. EM-263 (in cooperation with other EM organizations) will periodically (approximately two-year intervals) conduct independent assessments of Field Office programs. An integral part of these assessments will be to validate Field Office audits of analytical laboratory support, including both contractors and sub-contractors. These technical systems audits will review the following aspects of environmental data collection:

- (1) the implementation of QA functions associated with planning, conducting, and assessing field and laboratory activities,
- (2) technical procedures to determine whether the procedures were developed and are implemented properly, and
- (3) the analytical and field data to assess quality and appropriateness of use.

2.0 ASSESSMENT PLATES

Laboratory assessments consist of an objective evaluation of all components of the analytical laboratory process to determine their proper selection and use. These assessments should include a careful evaluation of analytical laboratory quality assurance procedures and should be performed on a regularly scheduled basis during the lifetime of the EM support program.

The assessment plates are designed to be used in a modular fashion, since not every sampling or measurement activity will be used for every project or at every facility. Based on preliminary information, the assessment plates corresponding to procedures applicable to the site will become part of the assessment plan specific to the facility.

Section 2.1 provides a set of technical assessment plates for evaluating laboratory activities to be used by EM-263. Major technical areas include:

- facility organization and personnel;
- quality assurance;
- sample receipt and storage; and
- analytical processes:
 - atomic absorption and inductively coupled plasma mass spectrometry,
 - visible spectrometry,
 - automated spectrometry, and
 - gas chromatography.

Section 2.2 provides a set of assessment plates specific to radiochemical measurements. The plates address:

- facility organization and personnel;
- quality assurance;
- sample receipt and storage;
- analytical processes:
 - general instrumentation,
 - gamma-ray spectroscopy,
 - alpha-particle spectroscopy,
 - liquid scintillation spectroscopy, and
 - gross activity measurements; and
- radioactive waste management.

Because of the complex nature of EM projects at DOE sites, there will be site-specific areas of investigation not addressed in the attached assessment documentation. The assessment plan developed for a facility will include a site-specific compilation of plates to assess both routine procedures and unique site activities.

Section 2.3 provides detailed assessment plates covering quality assurance and quality control aspects of both laboratory and field assessment programs. This section is intentionally duplicated and included in both guidance documents for use in both program areas and to assure that the sampling and analysis processes are effectively linked. These assessment plates include

reviews of:

- organization,
- facilities and equipment,
- quality assurance, and
- sample management.

These specific areas of investigation have varying degrees of application in field and laboratory assessments. An effective assessment will assign most individual components to either the sampling or laboratory investigation but will include some redundancy to evaluate consistency of responses between the activity areas.

The attached assessment plates are designed to be a source document for an assessment team to highlight technical areas for investigation. Assessments are concerned with both technical procedures and the implementation of the QA program. The specific procedures for the interview process are not prescribed. Not all the questions are designed to give a "yes" or "no" response. Some of the questions are designed to reveal the possible use of methods that are inappropriate. Other questions are designed to invoke a descriptive response or a more detailed explanation. Rather than "Is it?," "How is it?" is implied. The technical experts are to be familiar with the rationale for the questions through both their prior knowledge of the subject area and their audit training. The plates are designed primarily as a guide in order to give the assessors, as technical experts, the freedom to pursue a given response in greater depth or to follow up on an unsatisfactory response. The assessors are free to approach the subject area from a viewpoint that they feel will elicit a full and satisfactory evaluation of the subject area. However, all elements contained in the assessments plates should be addressed to assure standardization, comparability, and reciprocity among EM programs. Although the assessment plates are not designed to be "checked off" question by question, they provide a useful means for documenting pertinent facts and on-the-spot comments, and constitute minimum on-site information. These recorded comments will then become part of the source materials for the reports of the assessors, which will formulate the facts noted into findings and observations.

This module is a living document, and as such, will periodically undergo modification, especially in regards to site-specific review areas. This document is designed to help establish consistent reporting and documentation of assessment findings related to the ASD's activities. Experience from the assessment activities may reveal weaknesses, or suggest improvements for a more efficient program. Recommended changes and additions, as well as general comments, should be directed to the Analytical Services Division, Office of Environmental Restoration and Waste Management.

SECTION 2.1

GENERAL ANALYTICAL LABORATORY ASSESSMENT PLATES

On-Site Audits for General Analytical Laboratories

I.	Organization and Personnel	7
II.	Quality Assurance	9
III.	Facility	12
IV.	Sample Receiving and Storage Areas	14
V.	Equipment and Reference Materials	16
VI.	Measurement Traceability and Calibration Control	18
VII.	Atomic Absorption and Inductively Coupled Plasma Mass Spectrometry	20
VIII.	Visible Spectrophotometry	25
IX.	Automated Spectrophotometry	27
X.	Gas Chromatography	30

I. Organization and Personnel

Date: _____

Lead Auditor: _____

Auditors: _____

Name of Laboratory: _____

Street Address: _____

Mailing Address: _____

Telephone: _____ FAX: _____

Parent Company: _____

Laboratory Manager

Name: _____

Title: _____

Was an interview conducted with the individual? _____

Level of education _____

Experience in field _____

Project Officer

Name: _____

Title: _____

Was an interview conducted with the individual? _____

Level of education _____

Experience in field _____

Quality Assurance Officer

Name: _____

Title: _____

Was an interview conducted with the individual? _____

Level of education _____

Experience in field _____

I. Organization and Personnel (continued)

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

QA Plans

- 1.1 Is the laboratory a permanent, temporary or mobile facility?
- 1.2 Does the facility appear to have the organizational structure necessary to perform as an analytical laboratory?
- 1.3 Do the managerial staff have the authority and resources required to discharge their duties?

Personnel

- 1.4 What protections are in place to insure that the personnel are free from any commercial, financial or other pressure which might adversely affect the merit of the work performed?
- 1.5 What measures are taken to assure confidence in the independence of judgement and integrity?
- 1.6 What is the ratio of supervisory personnel to non-supervisory personnel?

Operations Manual

- 1.7 Does the laboratory have an operations manual (however named) defining the structure, organization and responsibilities?
- 1.8 What controls are associated with the operations manual?
- 1.9 As defined in the operations manual, is the delegation of authority clear and how is delegation carried out?
- 1.10 Are there policies and procedures to ensure the protection of clients' confidential information (data) and proprietary rights?

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 2.1, 2.3

II. Quality Assurance

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

QA Plans

- 2.1 Has the laboratory established a system appropriate to the scope, type, and volume of the analytical measurements, including the instrument calibration, that are required to establish an adequate level of data quality?
- 2.2 Does the laboratory have a quality assurance officer?
 - 2.2.1 Do each of the operational units (however named) have a quality assurance officer?
 - 2.2.2 Are the duties of a quality assurance officer or some like title part of the job description for the person assigned those duties?
 - 2.2.3 Does the quality assurance officer have stop work authority and where is that documented?
- 2.3 Does the laboratory have a quality assurance plan?
- 2.4 How is the plan implemented?

QA Manual

- 2.5 Does the laboratory have a quality assurance manual?
- 2.6 Is the quality assurance manual a controlled document?
 - 2.6.1 If the quality assurance manual is not a controlled document, how does the laboratory assure that a current copy of the manual is maintained by the staff?
- 2.7 Does the laboratory have a managerial procedure for the issue, control and maintenance of the quality assurance manual and any quality assurance procedures?
- 2.8 Do laboratory personnel have ready access to the quality assurance manual?
 - 2.8.1 Do laboratory personnel have a copy of the quality assurance manual?
- 2.9 Does the quality assurance manual or laboratory manual define the laboratory's policies, objectives and commitment to good laboratory practice?

Training

2.10 Does the laboratory offer, on a continuing basis, training in the objectives of good quality assurance and the use of the manual to obtain those objectives?

2.11 How is the employee training documented?

Technical Procedures

2.12 Are the format and requirements, including review and approval, for technical procedures defined in the quality assurance plan or in procedure documents?

2.13 Do technical procedures have an adequate level of review, including an independent reviewer, health and safety, cognizant quality assurance officer and cognizant management level?

2.14 Are the technical procedures issued as controlled documents?

2.14.1 If the technical procedures are not controlled documents, what policy is in place to assure that the laboratory personnel have the most current and approved procedure available to them?

Validation

2.15 How are technical procedures validated?

2.16 Do the quality assurance procedures, at the appropriate level, assure the use of standard reference materials from the National Institute of Standards and Testing (NIST) and secondary standards from suppliers traceable to NIST?

2.17 Are the batch size minimum and maximum defined at the appropriate level?

2.18 Are the quality control samples required for each batch?

2.19 List the quality control samples required for a given batch:

2.20 Are action levels, where appropriate, defined for each of the quality control measures?

2.21 Are duplicate samples and sample splits included as part of the defined quality control measures?

2.22 How are single blind quality control samples introduced in the analytical system?

2.23 Is provision made for the incorporation of double blind samples?

2.24 Who is responsible for compiling the quality control data and resolving any discrepancies that may result?

Reporting

2.25 How are the quality control data tracked?

2.26 State the frequency at which quality control reports are generated:

2.27 Are the quality control data reviewed by the appropriate level of management?

- 2.28 Are corrective actions in place and appropriate to resolve any discrepancies that may arise as a result of quality control sample exceeding an action level?
- 2.29 List the external performance evaluation and quality assurance programs in which the laboratory participates:
-
- 2.30 Are the analytical data and reports reviewed by the cognizant quality assurance officer before release?
- 2.31 Can all analytical data be traceable through the calibration standards to NIST or another national standard?

Dealing with Uncertainty

- 2.32 Do all reported analytical results have an uncertainty associated with them?
- 2.33 Were each of the sources of uncertainty evaluated or estimated?
- 2.34 Was the propagation of the uncertainty calculation reviewed by a statistician and quality assurance officer?

Auditing

- 2.35 Does the laboratory employ a local sample management system?
- 2.36 Does the quality assurance plan or procedures require internal audits, and if so, with what frequency?
- 2.37 Do the quality assurance plan or procedure documents require independent audits, assessments, surveillances, or reviews, and if so, with what frequency?
- 2.38 How are corrective actions implemented as a result of a finding or deficiency identified in an audit or assessment report?
- 2.39 Does the laboratory have a tracking system in place that would follow to closure a corrective action plan?
- 2.40 Are the corrective action plans approved and the corrective actions implemented at the appropriate level?
- 2.41 Do the quality assurance or operating procedures describe a method that will provide an adequate audit trail for the modification of analytical results or data subsequent to entry into an electronic storage device?
- 2.41.1 Is that audit trail system in place and operational?
- 2.41.2 What information does that table or field in the database contain?

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 2.5.1, 2.8.1, 2.9, 5.1, 5.2, 6.2, 6.3.4

III. Facility

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Laboratory Design

- 3.1 Does the overall design of the laboratory provide for sufficient space for the conduct of operations without adverse impact?
- 3.2 Does the overall design of the laboratory provide for the segregation of analytical operations?
- 3.3 Does the overall design of the laboratory consider the need for possible decontamination?
- 3.13 Does the design of the laboratory provide consideration for proximal locations of the analytical equipment rooms with respect to sample and standard storage rooms?
- 3.14 Does the design of the laboratory provide for the controlled storage of health and safety program records and documents external to the secondary confinement systems?

Confinement Systems

- 3.4 Do the primary confinement systems include physical and ventilation controls designed for physically isolating contaminated materials?
- 3.5 Are the integrity and performance of the primary confinement systems adequate for normal operations and for anticipated operational occurrences?
- 3.6 Is the operating pressure in the primary confinement negative with respect to the secondary confinement?
- 3.7 Will the secondary and, if in place, the tertiary confinement systems remain functional during all normal operations and anticipated off-normal occurrences?
- 3.8 Does the secondary system provide some measure of confinement against releases to the general environment during catastrophic failure of the primary confinement system?
- 3.9 Do the confinement systems in place provide the necessary protection to the workers and working environment of the laboratory?

Waste Management

- 3.10 Are the construction and finish materials such that they are readily decontaminated and minimize the amount of material that would ultimately require disposal?
 - 3.11 Does the design of the laboratory utility services provide for the collection and monitoring of all wastewater before disposal to the sanitary sewer?
 - 3.12 Does the design of the laboratory utility service provide for High Efficiency Particle Air (HEPA) filtration on the exhausts from vacuum service in controlled areas?
 - 3.15 Does the laboratory management and design provide for the generation, handling and storage of wastes generated during operations?
 - 3.16 Are the designated storage areas in compliance with RCRA and OSHA regulations for temporary and satellite accumulation areas?
 - 3.17 Cite the sources used for transportation and disposal or storage of waste that are unique to that facility or laboratory.
-

Safety and Security

- 3.18 Does the laboratory design adequately address access control and security requirements?
- 3.19 Does the design of the fire protection system provide consideration to the prevention and control of contamination and exposure during an emergency?
- 3.20 Does the design of the laboratory provide a means of controlling potentially contaminated runoffs from a fire?
- 3.21 Does the design of the laboratory provide locating analytical instrumentation in locals separate and distinct from samples and standards?
- 3.22 Are environmental conditions monitored to ensure a proper functioning of the HVAC system?

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 2.3, 3.1, 3.2

IV. Sample Receiving and Storage Areas

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

QA Plans and Records

- 4.1 Does the laboratory have a Chemical Hygiene Plan?
If so, cite controlled document reference: _____
- 4.1.1 Does the Chemical Hygiene Plan meet the requirements of OSHA?
- 4.2 Reference applicable quality assurance or technical procedures controlling operation of the sample receipt and storage area:

- 4.3 Are the procedures controlled documents?
- 4.5 Are the sample receipt and storage records maintained consistent with defined operating procedures?
- 4.6 What provision is made for supervisor oversight and procedure concurrence?

Receiving and Storage

- 4.4 Is provision made for adequate storage of the samples received?
- 4.7 Are the sample packages opened and surveyed in secondary confinement by authorized personnel?

Safety Features

- 4.8 Is a filtered hood located in the receiving area?
- 4.9 Is it of a sufficient size to receive routine samples?
- 4.10 Are the hood evaluation data posted on the hood?
- 4.10.1 Class of hood: _____
- 4.10.2 Date of evaluation: _____
- 4.10.3 Average Face Velocity: _____
- 4.10.4 Evaluated by: _____
- 4.10.5 Administrative Controls: _____
- 4.10.6 Date of next Evaluation: _____
- 4.11 Does the laboratory provide facilities for the effective control, monitoring, and recording of environmental conditions?

Sample Tracking

- 4.12 Is a log maintained on the samples received?
- 4.13 Does the laboratory have an automated sample tracking/control system?
- 4.14 Does the tracking/control system provide a means of identifying, labeling, tracking, controlling and storing samples, aliquots, digestates and extracts?

Sample Screening

- 4.15 Are the incoming samples screened by measurements of gross radioactivity levels?
- 4.16 Does the sample receipt area provide direct physical access to the necessary screening instruments?
- 4.17 Are the screening levels consistent with the Laboratory Safety Policy for identifying radioactive samples?
- 4.18 Do the administrative controls or operating procedures define actions for samples exceeding Laboratory Safety Policy limits?
- 4.19 Are the samples adequately identified as radioactive if the gross measurements exceed than administrative control limits?

Controls

- 4.20 Are controls adequate for the identification of any subsamples (aliquots) removed from samples?
- 4.21 Is the sample tracking/control system adequate for a mass/volume balance of aliquots removed for individual analyses?
- 4.22 Does the sample tracking/control system provide adequate information for the chain-of-custody requirements?

Layout of Receiving Area

- 4.23 Does the sample receiving area have direct physical access to the exterior of the building?
- 4.24 Does the sample receiving area have direct physical access to the sample storage area?
- 4.25 Is it necessary to move samples through uncontrolled areas to reach the receipt or storage areas?
- 4.26 Does the sample receiving area have sufficient space for storage of and routine access to contamination control supplies, including personal protective equipment and spill control supplies?
- 4.27 Does the sample storage area have controls and space for the separation of samples containing known high concentrations of analytes from unknown levels of the same analytes?

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 2.8.1, 3.1, 3.4, 3.5

V. Equipment and Reference Materials

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Instrument Room Layout

- 5.1 Are the instrument rooms organized in such a way as to separate standards and calibration sources from routine samples?
- 5.2 Do the instrument rooms have adequate workspace?
- 5.3 Do the rooms provide for the segregation of materials of high and low known concentrations?

Calibration

- 5.4 Are sources of distilled and/or deionized water available for the preparation of standards or calibration sources:
- 5.5 Are adequate checks performed on the purity of the reagent water used for sample dilutions and solution preparation?
- 5.6 Is all equipment that requires external calibration labeled to include calibration status?

Maintenance

- 5.7 Are the maintenance procedures of all analytical instruments documented?
- 5.8 Are amplification gain, window settings, bias supply settings, etc. documented and controlled by a technical or quality assurance procedure?
- 5.9 Are the records that log the maintenance performed on the instrumentation retained?

Analytical Balance

- 5.10 Is the analytical balance located away from sources of possible contamination or mechanical interferences?
- 5.11 Is the analytical balance located in the same room with other instruments or sample preparation materials?
- 5.12 Has the balance been calibrated within the time frame required by a quality assurance or technical procedure?
- 5.13 Is the balance calibration verified over the appropriate range using class S weights on a schedule as required by a quality assurance or technical procedure?

Technical Procedures

- 5.14 Are controlled technical procedures or methods used in preparing standards and calibration sources?
- 5.15 Are controlled technical procedures or methods used in preparing the sample fraction required for instrumental analysis?

Standards

- 5.16 Are the reagents used to prepare standards, calibration sources and samples dated upon receipt?
- 5.17 Are the reagents used to prepare standards, calibration sources and samples prepared at the frequency required by a quality assurance or technical procedure?
- 5.18 Are sample fractions, standards and calibration sources properly labeled in compliance with the laboratory requirements? The label should include at a minimum the concentration (if known), date of preparation, identity of the preparer, and date of expiration.
- 5.19 Are the primary standards traceable to the National Institute of Standards and Testing or other national standard?
- 5.20 Are receipts for standards and the certificates of standardization maintained in a manner consistent with the Laboratory Quality Assurance Plan, or a technical or quality assurance procedure?
- 5.21 Are receipt and preparation of standards and test material documented in a permanent logbook?
- 5.22 Do all standards and check sources have an expiration date?
- 5.23 Are all standards and check sources properly disposed of upon expiration?

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 2.1, 2.5, 2.9, 3.7, 4.1

VI. Measurement Traceability and Calibration Control

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

QA Plans

- 6.1 Does the laboratory have a quality assurance or technical procedure for the calibration and verification of measurement and test equipment?
- 6.1.1 Does the procedure require, so far as applicable, that the standards used in the calibration and verification of the measurement and test equipment be traceable to a national standard?
- 6.1.2 Where traceability to a national standard is not required or applicable, what procedures are in place to provide satisfactory evidence of adequate calibration and or verification?
- 6.2 Are the appropriate control charts employed to monitor instrument performance as delineated by a technical or quality assurance procedure?
- 6.3 Does the laboratory have documented instructions on the use and operation of all analytical instrumentation?
- 6.3.1 Are those instructions issued as controlled documents?
- 6.4 If operator aids are present in the instrumentation rooms, are they controlled by a procedure?
- 6.5 Does the operator understand how to make procedure and instruction change requests to controlled documents including operator aids?

Calibration Procedures

- 6.6 Cite the reference describing the procedure to be used when an instrument is no longer in calibration and must be removed from routine service:
-
- 6.7 How long are calibration records retained?
- 6.8 How are the results from a given instrument correlated to the calibration for that time frame?
- 6.9 Have the uncertainties associated with the standard reference materials used to prepare reference sources been properly evaluated and included in the propagation of error treatment when reporting analytical results?
- 6.10 Have other sources of uncertainty associated with sample preparation and standards used for instrument calibration been properly evaluated and included in the propagation of error treatment when reporting analytical results?
- 6.11 Is the software used in the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or analytical result data documented, validated and verified?
- 6.11.1 To what standard was the software documented?

- 6.12 How are changes to the software documented and the new code validated and verified?
- 6.13 Are the software documentation, validation and verification requirements delineated by a quality assurance or technical procedure?
- 6.14 Are adequate procedures used in the software and hardware to protect the security of the data, including the prevention of unauthorized access to, and especially the unauthorized modification of computer records, files or tables in the database?

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 1.4, 2.5.2, 2.8, 4.1, 6.1

VII. Atomic Absorption and Inductively Coupled Plasma Mass Spectrometry

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Equipment Identification

7.1 Equipment:

Type	Make	Model	ID #	Installation Date

7.2 Are the operating manuals readily available to the operator?

- 7.2.1 Are the operating manuals the original manuals supplied by the manufacturer?
- 7.2.2 Do the manuals reflect the current operating procedures for the equipment?
- 7.2.3 Are the manuals issued as controlled documents?

Calibration

7.3 Is there a controlled copy of the technical procedure describing the calibration protocol readily available to the operators?

7.4 Are the results of the calibration recorded and maintained, and if so, for how long?

Maintenance

7.5 Are the service and maintenance records retained as permanent files?

7.6 Have any modifications been made to the instruments?

- 7.6.1 If so, how have these modifications been documented?
- 7.6.2 What forms of verification and validation have been implemented to assure that the integrity and quality of the instrumentation have been retained?

- 7.6.3 Did any of the modifications invalidate the service or warranty contracts of the instrumentation?
- 7.7 Is the instrument properly vented?
 - 7.7.1 What visual method is used to ensure the vent is working properly before using the instrumentation?

Atomic Absorption

- 7.8 Does the laboratory employ atomic absorption (AA) spectroscopy as part of their analytical capability?
 - 7.8.1 Is the atomic absorption (AA) spectrophotometer a single or dual channel instrument?
 - 7.8.3 Does the AA have background correcting, and if so, list the lamps or sources used?
 - 7.8.4 Give the focal length of the grating: _____
 - 7.8.5 Does the AA have a photomultiplier detector?
 - 7.8.6 Does the AA have adjustable slits?
 - 7.8.7 Give the wavelength range of the AA _____
 - 7.8.8 Does the system have a response time capable of measuring the generated signal?
 - 7.8.9 Has the instrument detection limit for each analyte been evaluated, verified, and documented?

Furnace Analysis

- 7.9 Does the laboratory employ a furnace analysis (FA) as part of their analytical capability instrumentation?
 - 7.9.1 Does the FA use a mechanical strip chart or automated data processing software/hardware to record the data?
 - 7.9.2 If a mechanical strip chart is used, give the width of the chart?
 - 7.9.3 List the full scale response time: _____
 - 7.9.4 List the input in mV: _____
 - 7.9.5 If a mechanical strip chart is used, give the speeds or the range associated with a variable speed chart drive: _____
 - 7.9.6 Has the instrument detection limit been evaluated, verified, and documented for each analyte?

Equipment Checks

- 7.10 Are the fuels used for the above instrumentation of a commercial, technical or reagent grade?
 - 7.10.1 What methods are in place to assure the quality of the fuels? _____

 - 7.10.2 What is the tank pressure for the acetylene? _____
 - 7.10.3 What is the source for the ambient air? _____
 - 7.10.4 Does the system include a moisture trap between the air source and the spectrophotometer?
 - 7.10.5 Are the fuel tank pressures greater than the instrument operating pressures?

- 7.10.6 Are the gauges and couplings correctly mated?
- 7.11 Are the burner heads associated with the above instrumentation appropriate for the analysis?
- 7.11.1 Is the burner head ventilation adequate and proper?
- 7.11.2 Are the drains equipped with explosion traps?
- 7.11.3 Do the drains empty directly into the sanitary sewage?
- 7.12 List and describe (single or multi element, or electrodeless discharge) any lamps used with the above equipment:
-
- 7.12.1 Are the lamps dated or a record maintained stating when the lamps first went into service?
- 7.12.2 Are lamps available for use corresponding to all elements that are claimed for analytical capability?
- 7.13 Have the proper corrections for background been applied for each of the above pieces of instrumentation?

Mercury Cold Vapor Analyzer

- 7.14 Does the laboratory employ a Mercury cold vapor analyzer as part of its analytical capability instrumentation?
- 7.14.1 If not, does the laboratory have a Mercury cold vapor attachment?
- 7.14.2 Is the laboratory required to perform Mercury vapor analyses?
- 7.14.3 Has the instrument detection limit been evaluated, verified, and documented?

Graphite Furnace

- 7.15 Does the laboratory employ a graphite furnace as part of their analytical capability instrumentation?
- 7.15.1 Has the instrument detection limit for each analyte been evaluated, verified, and documented?
- 7.16 Does the laboratory employ the use of standard addition?

ICP-MS

- 7.17 Does the laboratory employ the use of an Inductively Coupled Plasma - Atomic Emission Spectrometry (ICP-AES) / - Mass Spectrometry (ICP-MS) as part of their analytical capability instrumentation?
- 7.17.1 How is the background correction applied and is it correct for the analyte list?
-
-
-
- 7.17.2 Is the background correction documented according to the sample matrix?
- 7.17.3 Has the instrument detection limit for each analyte been evaluated, verified, and documented?
- 7.17.4 Has the absence of spectral interference for analytes of interest been verified and documented?

- 7.17.5 How has salt build-up on the nebulizer tip been controlled? _____
- 7.17.6 Explain the procedure (serial dilution, spike addition, etc.) used to eliminate potential interference when a new matrix is encountered:

- 7.17.7 Describe the use and frequency of a calibration blank:

- 7.17.8 Describe the use and frequency of a reagent blank:

- 7.17.9 Describe the procedure used to clean the glassware:

- 7.17.10 Is (are) the method(s) used for sample preparation and preservation available to the analyst?
- 7.17.11 What method(s) are used to assure system decontamination between sample or calibration runs?

- 7.17.12 If a method other than the standard addition technique is used, explain the procedure and reason of choice:

- 7.17.13 List the internal performance evaluation samples used to evaluate the system and describe whether the values are known or unknown to the analyst:

- 7.17.14 List the external performance evaluation samples (programs) used to evaluate the system and how the results of these programs are incorporated in the quality assurance of the system:

- 7.17.15 Describe how the standard reagent curve is prepared:

7.17.16 When routine analyses are performed, how is the standard curve verified?

7.17.17 How do the verification checks compare with the original curve?

7.17.18 For ICP-AES, describe how the instrument drift control is determined:

7.17.19 For ICP-AES, describe how the background correction factors are applied:

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 2.5.1, 2.8.1, 2.9, 3.7, 4.1, 6.1

VIII. Visible Spectrophotometry

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Equipment Identification

8.1 Equipment:

Type	Make	Model	ID #	Installation Date

8.2 Are the operating manuals readily available to the operator?

- 8.2.1 Are operating manuals the original manuals supplied by the manufacturer?
- 8.2.2 Do the manuals reflect the current operating procedure for the equipment?
- 8.2.3 Are the manuals issued as controlled documents?

Calibration

- 8.3 Is a controlled copy of the technical procedure which describes the calibration protocol readily available to the operators?
- 8.4 Are the results of the calibration recorded and maintained, and if so, for how long?

Maintenance

- 8.5 Are the service and maintenance records retained as permanent files?
- 8.6 Have the instruments undergone modifications?
 - 8.6.1 If so, how have the modifications been documented?
 - 8.6.2 What forms of verification and validation have been employed to assure that the integrity and quality of the instrumentation have been retained?

- 8.6.3 Did any of the modifications invalidate the service or warranty contracts of the instrumentation?
- 8.7 To what cell size is the compartment adaptable?
- 8.8 Describe the procedure used to assess the wavelength and repeatability of the instrument:
-
-
- 8.9 Are the results of the verification procedures documented?
- 8.10 Describe the procedure used to assess the photometric accuracy and repeatability checks:
-
-
- 8.11 Are the cells clean, free of scratches, finger prints and evaporated film residues?
- 8.12 Describe and document the procedure used to clean the cells:
-
-
- 8.13 Are matched cells examined for equivalency and are the results documented?

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 2.5.1, 2.8.1, 2.9, 3.7, 4.1, 6.1

IX. Automated Spectrophotometry

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Equipment Identification

9.1 Equipment:

Type	Make	Model	ID #	Installation Date
------	------	-------	------	-------------------

9.2 Are the operating manuals readily available to the operator?

9.2.1 Are the operating manuals the original manuals by the manufacturer?

9.2.2 Do the manuals reflect the current operating procedure for the equipment?

9.2.3 Are the manuals issued as controlled documents?

Calibration

9.3 Is there a controlled copy of the technical procedure describing the calibration protocol readily available to the operators?

9.4 Are the results of the calibration record and maintained, and if so, for how long?

Maintenance

- 9.5 Are the service and maintenance records retained as permanent files?
- 9.6 Have any modifications been made to the instruments?
- 9.6.1 If so, how have these modifications been documented?
-
- 9.6.2 What forms of verification and validation have been implemented to assure that the integrity and quality of the instrumentation have been retained?
-
- 9.6.3 Did any of the modifications invalidate the service or warranty contracts of the machine?

Operation

- 9.7 Describe and reference the procedure for the cleaning of glassware used in the determination of phosphoric acid:
-
- 9.8 Describe and reference the procedure used in the preparation of standards and samples for nitrogen analysis:
-
- 9.8.1 Does the procedure require the use of ammonia free water?
- 9.9 Describe the substitute used in the analysis of saline solutions:
-
- 9.10 Describe and reference the technical procedure employed for instrument warm up:
-
- 9.11 Is an adequate chemical drain used?
- 9.12 Describe the approach used to obtain a stable base line:
-
- 9.13 Is the tubing diameter and composition appropriate for the analysis?
- 9.14 How are the standards employed in the analysis of phosphorus arranged in the sampler?
- 9.15 How are the TKN standards arranged in the sampler?

9.16 Reference the procedure defining the additional standards/samples that will be included in the sampler load for a phosphorus analysis:

9.16.1 What percent of each sample load are sample duplicates or spiked samples?

9.17 Reference and describe the procedure employed in the calibration of non-linear chemistries:

9.18 What are the minimum samples in a run?

9.19 Describe and reference the procedure for TKN analyses defining the rerunning of samples with computed concentrations of less than ten percent of the immediate prior sample:

9.20 Describe and reference the procedure for phosphorus analyses defining the rerunning of samples with computed concentrations of less than five percent of the immediate prior sample:

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 2.5.1, 2.8.1, 2.9, 3.7, 4.1, 6.1

X. Gas Chromatography

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Equipment Identification

10.1 Equipment:

Type	Make	Model	ID #	Installation Date

10.2 Are the operating manuals readily available to the operator?

- 10.2.1 Are the operating manuals the original manuals supplied by the manufacturer?
- 10.2.2 Do the manuals reflect the current operating procedure of the equipment?
- 10.2.3 Are the manuals issued as controlled documents?

Calibration

- 10.3 Is there a controlled copy of the technical procedure describing the calibration protocol readily available to the operators?
- 10.4 Are the results of the calibration record and maintained, and if so, for how long?
- 10.5 Are the service and maintenance records retained as permanent files?
- 10.6 Have any modifications been made to the instruments?
- 10.6.1 If so, how are the modifications documented?
-
- 10.6.2 What forms of verification and validation have been implemented to assure that the integrity and quality of the machine have been retained?
- 10.6.3 Did any of the modifications invalidate the service or warranty contracts of the machine?

Operation

- 10.7 Is the column oven capable of controlling the isothermal temperature to $\pm 0.2^{\circ}\text{C}$ up to 220°C ?
- 10.8 Is the injector port glass lined?
- 10.9 Describe the detector used in the analysis of chlorinated hydrocarbons and chlorphenoxys:
-
-
- 10.10 Describe and justify choice of the detector used in the analysis of TTHM:
-
-
- 10.11 How wide is the chart width on the recorders?
- 10.12 What is the full scale response time?
- 10.13 Is the instrument matched to the input signal?
- 10.14 State the range of the variable chart speed:
-
- 10.15 State the detection limit for each of the THM's when analyzed by the purge and trap method:
-
- 10.15.1 How is this documented?
-
- 10.16 State the reproducibility (in terms of some percent standard deviation at a given concentration) with which the system will measure each THM using purge and trap methods:
-
- 10.16.1 How is this documented?
-
- 10.17 Does the purge inlet-gas dispenser provide the proper dimension and division of gas bubbles through the sample?

10.18 Is the trapping device used in the purge and trap analysis capable of retaining THM's at room temperature?

10.19 Describe the control limits associated with heating the desorber:

10.20 Reference the type of glassware use:

10.21 State the reference defining the grade of acetone to be used in the final cleaning rinse of the glassware:

10.22 Are the fuels used for the above instrumentation of a commercial, technical or reagent grade?

10.22.1 What methods are in place to assure the quality of the fuels?

10.22.2 What is tank pressure for the acetylene? _____

10.22.3 What is the source for the ambient air? _____

10.22.4 Does the system include a moisture trap between the air source and the spectrophotometer?

10.22.5 Are the fuel tank pressures greater than the instrument operating pressures?

10.22.6 Are the gauges and couplings correctly mated?

Comments:

Attach sheets for each device in use

See Laboratory Quality Assurance Guidance Document, Sections 2.5.1, 2.8.1, 2.9, 3.7, 4.1, 6.1

SECTION 2.2

RADIOCHEMICAL ANALYTICAL LABORATORY ASSESSMENT PLATES

On-Site Audits for Radiochemical Analytical Laboratories

I.	Organization and Personnel	35
II.	Quality Assurance	41
III.	Facility	45
IV.	Sample Receiving and Storage Areas	47
V.	Sample Analysis Instrumentation	50
A.	General Instrumentation	50
B.	Gamma-Ray Spectroscopy	53
C.	Alpha-Particle Spectroscopy	56
D.	Liquid Scintillation Spectroscopy	58
E.	Gross Activity Measurements	60
VI.	Radioactive Waste Management	62

I. Organization and Personnel

Date: _____

Lead Auditor: _____

Auditors: _____

Name of Laboratory: _____

Street Address: _____

Mailing Address: _____

Telephone: _____ FAX: _____

NRC License Number: _____

Date of issue: _____

Parent Company: _____

Laboratory Supervisor

Name: _____

Title: _____

Was an interview conducted with the individual? _____

Level of education _____

Experience in field _____

Project Officer

Name: _____

Title: _____

Was an interview conducted with the individual? _____

Level of education _____

Experience in field _____

Quality Assurance Officer

Name: _____

Title: _____

Was an interview conducted with the individual? _____

Level of education: _____

Experience in field: _____

Radiation Control Officer

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Gamma-Ray Spectroscopy

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Alpha-Particle Spectroscopy

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Beta-Particle Spectroscopy

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Gross Measurements

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Fluorometer/Spectrophotometer

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Mass Spectroscopy

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Health Physicist

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Data Validation/Statistician

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Electronic Support

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

Officer used for external analytical services contracts

Name: _____
Title: _____
Was an interview conducted with the individual? _____
Level of education: _____
Experience in field: _____

I. Organization and Personnel (continued)

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Key Personnel

- 1.1 Discuss the method(s) employed to demonstrate competency in the each of the above-named areas of expertise. State whether certification is required by a regulatory agency, and if so, the requirements.

- 1.2 List the documentation describing the qualifications, experience and training of the above-named personnel.

Additional Comments:

Safety

- 1.3 Cite the laboratory Radiation Safety Policy.

1.4 How is the Radiation Safety Policy implemented?

1.5 Does the organizational structure provide radiological safety operations independent of routine production operations?

1.6 Name the individual responsible for development and implementation of the Radiation Safety Program.

1.7 Does this individual have sufficient authority to suspend, limit, or otherwise control laboratory operations in the event that a radiation safety problem is identified or suspected?

Responsibilities

1.8 Indicate the individuals or positions responsible for the following functions. Also cite the reference that identifies responsible parties and delegates authority.

1.8.1 Preparation, review and approval of radiation safety procedures.

Name or Position: _____
Reference: _____

1.8.2 Development and administration of dosimetry and bioassay programs.

Name or Position: _____
Reference: _____

1.8.3 Administration of the Radioactive Material Handling License.

Name or Position: _____
Reference: _____

1.8.4 Development and administration of the radiation and contamination monitoring program.

Name or Position: _____
Reference: _____

1.8.5 Adherence to radiation safety policies.

Name or Position: _____
Reference: _____

1.8.6 Development and management of a radioactive waste management program.

Name or Position: _____
Reference: _____

Policy on Dose Levels

- 1.9 Cite the reference implementing a policy for maintaining radiation exposures As Low As Reasonably Achievable (ALARA).

- 1.10 What dose levels does the Radiation Safety Policy use to define radiation areas?

- 1.11 Does the Radiation Safety Policy address the requirements for a dosimetry program?

- 1.12 Does the Radiation Safety Policy require accreditation (DOELAP) of their dosimetry program?

- 1.13 Do the records of occupational radiation exposures, and the program to assess those exposures meet the requirements of ANSI N13.6?

Monitoring

- 1.14 Do the occupational radiation workers receive routine internal contamination monitoring (whole body counts)?

- 1.15 Are the results of the dosimetry and internal contamination monitoring programs made available to the occupational radiation workers in a timely fashion?

- 1.16 Does the Radiation Safety Policy establish an adequate bioassay program for the occupational radiation workers?

- 1.17 Does the Radiation Safety Policy document include requirements for contamination surveys, including their scope, frequency, procedures, responsibilities, and documentation?

Emergency Response

- 1.18 Does the Radiation Safety Policy of the laboratory provide for formal communication with the responsible fire control authorities of the information necessary to support effective emergency response?

Chain of Custody

- 1.19 Does the laboratory provide a chain-of-custody for radioactive samples and other accountable material?

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 2.1, 2.1.1, 2.2, 2.3, 3.3

II. Quality Assurance

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

QA Plans

- 2.1 Has the laboratory established a system appropriate to the scope, type, and volume of the analytical measurements, including the instrument calibration, that are required to establish an adequate level of data quality?
- 2.2 Does the laboratory have a quality assurance officer?
- 2.2.1 Do each of the operational units (however named) have a quality assurance officer?
- 2.2.2 Are the duties of a quality assurance officer or some like title part of the job description for the person assigned those duties?
- 2.2.3 Does the quality assurance officer have stop-work authority and where is that documented?
- 2.3 Does the laboratory have a quality assurance plan?
- 2.4 How is the plan implemented?

QA Manual

- 2.5 Does the laboratory have a quality assurance manual?
- 2.6 Is the quality assurance manual a controlled document?
- 2.6.1 If the quality assurance manual is not a controlled document, how does the laboratory assure that a current copy of the manual is maintained by the staff?
- 2.7 Does the laboratory have a managerial procedure for the issue, control and maintenance of the quality assurance manual and any quality assurance procedures?
- 2.8 Do laboratory personnel have ready access to the quality assurance manual?
- 2.8.1 Do laboratory personnel have a copy of the quality assurance manual?

- 2.9 Does the quality assurance manual or laboratory manual define the laboratory's policies, objectives and commitment to good laboratory practice?

Training

- 2.10 Does the laboratory offer, on a continuing basis, training in the objectives of good quality assurance and the use of the manual to obtain those objectives?

2.10.1 How is the employee training documented?

Technical Procedures

- 2.11 Are the format and requirements, including review and approval, for technical procedures defined in the quality assurance plan or procedures?

- 2.12 Do the technical procedures undergo adequate review by an independent reviewer, health and safety reviewers, the cognizant quality assurance officer and the cognizant management level?

- 2.13 Are the technical procedures issued as controlled documents?

2.13.1 If the technical procedures are not controlled documents, what policy is in place to assure that the laboratory personnel have the most current and approved procedure available to them?

Validation

- 2.14 How are the technical procedures validated?
-
-
-

- 2.15 Do the quality assurance procedures, at the appropriate level, assure the use of standard reference materials from the National Institute of Standards and Materials (NIST) and secondary standards from suppliers traceable to NIST?

- 2.16 Are the batch size minimum and maximum defined at the appropriate level?

- 2.17 Are quality control samples required for each batch?

- 2.18 List the quality control samples required for a given batch:
-
-
-

- 2.19 Are action levels, where appropriate, defined for each of the quality control measures?

- 2.20 Are duplicate samples and sample splits included as part of the defined quality control measures?

2.21 How are single blind quality control samples introduced in the analytical system?

2.22 Is provision made for the incorporation of double blind samples?

2.23 Who is responsible for compiling the quality control data and resolving discrepancies?

Reporting

2.24 How are the quality control data tracked?

2.25 State the frequency at which quality control reports are generated.

2.26 Are the quality control data reviewed by the appropriate level of management?

2.27 Are corrective actions in place and appropriate to resolve any discrepancies that may arise as a result of quality control sample exceeding an action level?

2.28 List the external performance evaluation and quality assurance programs in which the laboratory participates.

2.29 Are the analytical data and reports reviewed by the cognizant quality assurance officer before release?

2.30 Can all analytical data be traced through the calibration standards to NIST?

Dealing with Uncertainty

2.31 Do all reported analytical results have an uncertainty associated with them?

2.32 Were each of the sources of uncertainty evaluated or estimated?

2.33 Was the propagation of the uncertainty calculation reviewed by a statistician and quality assurance officer?

Auditing

- 2.34 Does the laboratory employ a local sample management system?
- 2.35 Does the quality assurance plan or procedures require internal audits, and if so, with what frequency? _____
- 2.36 Does the quality assurance plan or procedures require external audits, assessments, surveillances, or reviews, and if so, with what frequency?
- _____
- 2.37 How are corrective actions implemented as a result of a finding or deficiency identified in an audit or assessment report?
- _____
- _____
- _____
- 2.38 Does the laboratory have in place a tracking system that would follow to closure a corrective action plan?
- 2.39 Are the corrective action plans approved and the corrective action implemented at the appropriate level?
- 2.40 Do the quality assurance or operating procedures describe a method that will provide an adequate audit trail for the modification of analytical results or data subsequent to entry into an electronic storage device?
- 2.40.1 Is that audit trail system in place and operational?
- 2.40.2 What information does that table or field in the database contain?

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 2.5.2, 2.6, 5.1, 5.2, 6.1, 6.2, 6.3

III. Facility

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Laboratory Design

- 3.1 Does the overall design of the laboratory provide for sufficient space for the conduct of operations without adverse impact?
- 3.2 Does the overall design of the laboratory provide for the segregation of radiation from non-radiation operations?
- 3.3 Does the overall design of the laboratory allow for possible decontamination?
- 3.4 Does the design of the laboratory provide consideration for proximal locations of the analytical equipment rooms with respect to sample and standard storage rooms and associated radiation fields?
- 3.5 Does the design of the laboratory provide for the controlled storage of radiation safety program documents external to the secondary confinement systems?

Confinement Systems

- 3.6 Do the primary confinement systems include physical and ventilation controls designed for physically isolating contaminated materials?
- 3.7 Are the integrity and performance of the primary confinement systems adequate for normal operations and for anticipated operational occurrences?
- 3.8 Are the primary confinement systems, including ventilation and off-gases systems shielded, as appropriate, to maintain occupational exposures to a minimum (ALARA)?
- 3.9 Is the operating pressure in the primary confinement negative with respect to the secondary confinement?
- 3.10 Are the off-gas systems in the primary confinement required to be filtered through HEPA filters?
- 3.11 Will the secondary and, if in place, the tertiary confinement systems remain functional during all normal operations and anticipated off-normal occurrences?
- 3.12 Does the secondary system provide some measure of confinement against releases to the general environment during catastrophic failure of the primary confinement system?
- 3.13 Do the confinement systems in place provide the necessary protection to the workers and working environment of the laboratory?

Waste Management

- 3.14 Are the construction and finish materials readily decontaminated and such that they minimize the amount of radioactive material that would ultimately require disposal?

- 3.15 Does the design of the laboratory utility services provide for the collection and monitoring of all waste water disposed of the sanitary sewer?
- 3.16 Does the design of the laboratory utility service provide for HEPA filtration on the exhausts from vacuum service in controlled areas?
- 3.17 Does the design of the laboratory utility service provide reserve tanks for the decay of radon daughters in compressed air and distilled or deionized water supplies?
- 3.18 Does the laboratory management and design provide for the generation, handling and storage of radioactive and mixed wastes generated during operations?
- 3.18.1 Does the design include designated locations for the accumulation and storage of radioactive solid wastes, including the necessary monitoring?
- 3.18.2 Does the design include designated locations for the accumulation and storage of radioactive liquid wastes, including the required mixed wastes?
- 3.18.3 Are these designated locations in compliance with OSHA regulations for temporary and satellite accumulation areas?
- 3.18.4 Cite the sources used for transportation and disposal or storage of radioactive and/or mixed waste.
- _____
- _____
- _____

Safety and Security

- 3.19 Does the laboratory design adequately anticipate reducing radioactive exposure in conjunction with maintenance operations?
- 3.20 Does the laboratory design adequately address access control and security requirements?
- 3.21 Does the design of the fire protection system provide consideration to the prevention and control of contamination and exposure during an emergency?
- 3.22 Does the design of the laboratory provide a means of controlling potentially contaminated runoffs from a fire?
- 3.23 Does the design of the laboratory provide locating analytical instrumentation in locals separate and distinct from samples and standards?
- 3.24 Are environmental conditions monitored to ensure a proper functioning of the HVAC system?

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 2.3, 3.1, 3.2

IV. Sample Receiving and Storage Areas

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

QA Plans and Records

- 4.1 Cite applicable technical or standard operating procedures controlling operation of the sample receipt and storage area.

- 4.2 Are the procedures controlled documents?

- 4.3 Does the design of the area provide for adequate storage of the samples received?

- 4.4 Are the sample receipt and storage records maintained consistent with defined operating procedures?

- 4.5 What provision is made for supervisor oversight and procedure concurrence?

- 4.6 Are the controls adequate/followed for the surveillance of a package containing a radioactive sample?

Personal Survey

- 4.7 Is personal survey instrumentation available to the personnel?

- 4.8 Are personal surveys required by the Radiation Safety Policy?

- 4.9 Is there a technical procedure or method defining the constituents and methods of a personal survey?

- 4.10 Cite the reference describing the calibration of personal survey equipment.

- 4.11 Cite the reference describing the operations checks that must be performed and the frequency with which they should be completed.

- 4.12 Does the personal survey instrumentation have a documented program of maintenance?
- 4.13 Do the personal survey instruments have identification stating the calibration date, the next calibration due date, and the initials of the person performing the calibration?
- 4.14 Are the sources used to calibrate the survey instruments traceable the National Institute of Technology and Standards?
- 4.15 Have the operators of the survey equipment received the proper training in the use of said equipment?
- 4.16 Where is that training documented? _____
- 4.17 Are the results of radiation surveys documented?
- 4.18 How long are the results retained? _____

Safety Features

- 4.19 Are the sample packages opened and surveyed in secondary confinement by authorized personnel?
- 4.20 Is a filtered hood located in the receiving area?
- 4.21 If a filtered hood is located in the receiving area, is it of a sufficient size to receive routine samples?
- 4.22 Is the hood evaluation data posted on the hood?
 - 4.22.1 Class of hood: _____
 - 4.22.2 Date of evaluation: _____
 - 4.22.3 Average Face Velocity: _____
 - 4.22.4 Evaluated by: _____
 - 4.22.5 Administrative Controls: _____
 - 4.22.6 Date of next Evaluation: _____
- 4.23 Is a health physicist or trained radiation worker required to survey the incoming sample packages?

Sample Tracking

- 4.24 Is a log maintained on the results of sample package surveys?
- 4.25 Does the laboratory have an automated sample tracking/control system?
- 4.26 Does the tracking/control system provide a means of identifying, labeling, tracking, controlling and storing samples, aliquots, digestates and extractants containing radioactivity?

Sample Screening

- 4.27 Are the incoming samples screened by measurements of gross activity levels?
- 4.28 Does the sample receipt area have direct physical access to the necessary screening instruments?
- 4.29 Are the screening levels consistent with the Radiation Safety Policy for identifying radioactive samples?
- 4.30 Are the samples adequately identified as containing radioactivity if the gross measurements exceed the administrative control limits?

Controls

- 4.31 Are controls adequate for the identification of any sub-samples removed for samples designated as radioactive?
- 4.32 Is the sample tracking/control system adequate for a mass balance of aliquots removed for individual analyses?

- 4.33 Does the sample tracking/control system provide adequate information for the chain-of-custody requirements?
- 4.34 Do the administrative controls or operating procedures define actions for samples exceeding Radiation Safety Policy limits?
- 4.35 Does the sample storage area have controls for the separation of samples containing radioactivity from samples defined as non-radioactive?
- 4.36 Are samples declared to be radioactive placed in secondary confinement in the storage area?

Layout of Receiving Area

- 4.37 Is it necessary to move samples through uncontrolled areas to reach the receipt or storage areas?
- 4.38 Does the sample receiving area have sufficient space for storage of and routine access to contamination control supplies, including personal protective equipment and spill control supplies?
- 4.39 Does the sample receipt area have direct physical access to the exterior of the building?
- 4.40 Does the sample receipt area have direct physical access to the sample storage area?

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 2.8.1, 3.1, 3.4, 3.5

V. Sample Analysis Instrumentation

A. General Instrumentation

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Instrument Room Layout

- 5.1.1 Are the instrument rooms organized in such a way as to separate standards and calibration sources from routine samples?
- 5.1.2 Do the instrument rooms have adequate work space?
- 5.1.3 Do the rooms provide for the segregation of high and low activity levels?

Analytical Balance

- 5.1.4 Is the analytical balance located away from possible sources of radioactive contamination?
- 5.1.5 Is the analytical balance located in the same room with any of the counting instrumentation or sample preparation?
- 5.1.6 Has the balance been certified for use in radiation fields of the type that may be present?
- 5.1.7 Has the balance been calibrated within the constrained time frame as required by a technical or quality control procedure?
- 5.1.8 Is calibration of the balance verified over the appropriate range using class S weights on a schedule as required by a technical or quality control procedures?

Technical Procedures

- 5.1.9 Are controlled technical procedures or methods used in preparing standards and calibration sources?
- 5.1.10 Are controlled technical procedures or methods used in preparing the sample fraction required for instrumental analysis?

Standards

- 5.1.11 Are the reagents used to prepare standards, calibration sources and samples dated upon receipt?
- 5.1.12 Are the reagents used to prepare standards, calibration sources and samples prepared at the frequency required by a technical or quality assurance procedure?
- 5.1.13 Are sample fraction, standards and calibration sources properly labeled with concentrations, date of preparation, and the identity of the preparer?

- 5.1.14 Are the standards, calibrations sources and if required the prepared sample fraction labeled according to the Radiation Safety Policy requirements?
- 5.1.15 Are the primary standards traceable to the National Institute of Technology and Standards?
- 5.1.16 Are the receipt of the standards and certificates of standardization maintained in a manner consistent with Radiation Safety Policy, or a technical or quality assurance procedure?
- 5.1.17 Have the uncertainties associated with the standard reference materials used to prepare counting efficiency sources been properly evaluated and included in the propagation of error treatment when reporting analytical results?
- 5.1.18 Have other sources of uncertainty associated with sample preparation, standards used for counting efficiency determination or calibration been properly evaluated and included in the propagation of error treatment when reporting analytical results?

QA Plans

- 5.1.19 Are efficiency, resolution and background control charts employed to monitor instrument performance as delineated by a technical or quality assurance procedure?
- 5.1.20 Are amplification gain, window settings, bias supply settings, etc., documented and controlled by a technical or quality assurance procedure?
- 5.1.21 If operator aids are present in the instrumentation rooms, are they controlled by a procedure?
- 5.1.22 Does the operator understand how to make procedure and instruction change requests for controlled documents to include operator aids?

Calibration

- 5.1.23 Are the sources of distilled and/or deionized water available for the preparation of standards or calibration sources?
- 5.1.24 Is the conductivity and gross radioactivity of the distilled and/or deionized water routinely check and recorded?
- 5.1.25 Cite the reference describing the procedure to be used when an instrument is no longer in calibration and must be removed from routine service.

- 5.1.26 How long are calibration records retained? _____
- 5.1.27 How are the results from a given instrument correlated to the calibration for that time frame?

- 5.1.28 Cite the reference for the technical procedure used for instrument counting efficiency calibration.

- 5.1.29 Cite the reference for the technical procedure describing the energy calibration and energy calibration checks.

- 5.1.30 Cite the reference for the technical procedure describing the energy resolution and energy resolution checks.

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 2.3, 2.5.2, 2.8.3, 3.7, 4.1

B. Gamma-Ray Spectroscopy

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Standard Operating Procedures

- 5.2.1 Are the technical procedures describing the operation of the gamma-ray spectroscopy instrument available to the user?

Safe Storage

- 5.2.2 Is there an enclosed, labeled and secure area for the safe storage of radioactive standards?
- 5.2.3 Is there an enclosed, labeled and secure area for the safe storage of radioactive samples?
- 5.2.4 Is adequate precaution taken to assure that the standards do not contaminate the samples?
- 5.2.5 Are the vaults constructed of a material that will sufficiently shield the sample from outside radiation during the count?
- 5.2.6 Do the vaults contain fluorescent lights?
- 5.2.7 Are the Dewars supported by scales or foam pads? _____

Records

- 5.2.8 Is there a log containing the dates when the detectors were filled with liquid nitrogen?
- 5.2.9 Cite the reference for the procedure describing the filling of the detectors with liquid nitrogen.
- _____
- 5.2.10 Is the correct personal safety equipment available for use when filling the detector with liquid nitrogen?
- 5.2.11 Are the detector specifications as listed by the manufacture documented and retained?
- 5.2.12 Cite the reference for the technical procedure describing the retention of the system parameters for a given time frame.

Data Verification

- 5.2.13 Is the software used for data reduction validated and verified?
- 5.2.14 How was the data reduction software validated and verified?
-
-
-
- 5.2.15 Are the software programs documented as defined in a nationally accepted standard such as ANSI N4.13?
- 5.2.16 Is provision made for reducing the gamma-ray spectra when the computer is off-line?
- 5.2.17 Are corrections for vault backgrounds made?
- 5.2.18 How are the vault backgrounds correlated to the samples analyzed during the applicable time frame?
- 5.2.19 Give the algorithm used when correcting for an interfering peak in the main photopeak region.
-
-
- 5.2.20 How many interfering peaks will the software successfully resolve?
- 5.2.21 How does the software resolve the presence of U-235 when analyzing for Ra-226?
- 5.2.22 Give the relative efficiency for any one of the HPGe detectors?
- 5.2.23 Give the absolute efficiency of the 661 keV line for the same detector?
- 5.2.24 How does the system detect and resolve resolution changes during the sample count?
- 5.2.25 Have sample holders been made to minimize random placement on the detector?

Dealing with Uncertainty

- 5.2.26 Have the placement errors and their propagation been evaluated in the uncertainty calculations associated with the measurement?
- 5.2.27 Have the random errors of volumetric delivery to a counting geometry and their propagation been evaluated in the uncertainty calculations associated with the measurement?
- 5.2.28 List the other sources of systematic uncertainty evaluated in the propagation of error treatment.
-
-

5.2.29 Give the algorithm used to determine the detection limit for Co-60 in a liquid sample for a common counting geometry.

5.2.30 List the elements used in the algorithm to determine if an identified peak is correctly associated with an isotope.

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 2.5.1, 2.8, 3.1.4, 3.7, 6.1, 6.2

C. Alpha-Particle Spectroscopy

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Standard Operating Procedures

- 5.3.1 Are the technical procedures describing the operation of the instrumentation available to the user?

Safe Storage

- 5.3.2 Is there an enclosed, labeled and secure area for the safe storage of radioactive standards?
- 5.3.3 Is there an enclosed, labeled and secure area for the safe storage of radioactive samples?
- 5.3.4 Are adequate precautions taken to assure that the standards do not contaminate the samples?

Technical Procedures

- 5.3.5 Are the samples electrodeposited or counted as a precipitate?
- 5.3.6 How are the electrodeposited sources disposed of?
- _____
- _____
- 5.3.7 Is a substrate used to keep the precipitate "on top of" the filter paper?
- 5.3.8 Are internal tracers used to determine chemical yield and counting efficiency?
- 5.3.8.1 If not, how are counting efficiencies determined?
- _____
- _____
- 5.3.9 Are the chambers operated at a reduced atmospheric pressure?
- 5.3.9.1 If so, is the mercury contained in secondary confinement?
- 5.3.9.2 At what pressure do the chambers operate?
- 5.3.9.3 Is a vacuum reading log book used?

Records

- 5.3.10 Are the detector specifications as listed by the manufacture documented and retained?
- 5.3.11 How is backscatter controlled?
- _____
- 5.3.12 Cite the reference for the technical procedure describing the retention of the system parameters for a given time frame.
- _____
- _____

Data Verification

- 5.3.13 Is the software used for data reduction validated and verified?
- 5.3.14 How was the data reduction software validated and verified?
- _____
- 5.3.15 Are the software programs documented as defined in a nationally accepted standard such as ANSI N4.13?
- 5.3.16 Is provision made for reducing the alpha-particle spectra when the computer is off-line?
- 5.3.17 Explain how the algorithm resolves tailing into a lower energy peak.
- _____

Dealing with Uncertainty

- 5.3.18 How are the uncertainties associated with the tailing discussed above propagated in the reported results?
- _____
- _____
- 5.3.19 Are the reagent, vault and detector backgrounds evaluated in the result calculations?
- 5.3.20 Are reagent blanks included with each set of routine samples?
- 5.3.21 How large can a sample set be? _____
- 5.3.22 Is a matrix blank included with a sample set?
- 5.3.23 Is a spike included with each sample set?
- 5.3.23.1 If so, give the level of the spike. _____

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 2.5.1, 2.8, 3.1.4, 3.7, 6.1, 6.2

D. Liquid Scintillation Spectroscopy

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Standard Operating Procedures

- 5.4.1 Are the technical procedures describing the operation of the instrumentation available to the user?

Safe Storage

- 5.4.2 Is there an enclosed, labeled and secure area for the safe storage of radioactive standards?
- 5.4.3 Is there an enclosed, labeled and secure area for the safe storage of radioactive samples?
- 5.4.4 Are adequate precautions taken to assure that the standards do not contaminate the samples?

Technical Procedures

- 5.4.5 Are organic (toluene) -based scintillators used?
- 5.4.6 How is disposal of the produced mixed wastes accomplished?
- _____
- _____
- 5.4.7 Cite the reference describing the storage of mixed waste in a satellite accumulation area.
- _____
- 5.4.8 Is the satellite accumulation area in the counting room with the liquid scintillation equipment or in the laboratory where the samples are prepared?
- 5.4.9 Are multiple discriminator channels available?
- 5.4.10 Are the liquid scintillation units refrigerated?
- 5.4.11 Are external or internal standard used?

Dealing with Uncertainty

- 5.4.12 What sources of uncertainty and error propagation have been evaluated?

- 5.4.13 How are the uncertainties and error propagation treated in the result calculation?

- 5.4.14 Cite the technical procedure describing the determination of the counting efficiency for tritium.

- 5.4.15 How are quench corrections made and how is the uncertainty of this correction included in the propagation of error treatment?
- 5.4.16 Are reagent blanks included with each set of routine samples?
- 5.4.17 How large can a sample set be? _____
- 5.4.18 Is a matrix blank included with a sample set?
- 5.4.19 Is a spike included with each sample set?
- 5.4.19.1 If so, give the level of the spike. _____

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 2.5.1, 2.8, 3.1.4, 3.7, 6.1, 6.2

E. Gross Activity Measurements

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Standard Operating Procedures

- 5.5.1 Are the technical procedures describing the operation of the instrumentation available to the user?

Safe Storage

- 5.5.2 Is there an enclosed, labeled and secure area for the safe storage of radioactive standards?
- 5.5.3 Is there an enclosed, labeled and secure area for the safe storage of radioactive samples?
- 5.5.4 Are adequate precautions taken to assure that the standards do not contaminate the samples?

Technical Procedure

- 5.5.5 Are efficiency, resolution and background control charts used to monitor individual performance?
- 5.5.6 Cite the technical or quality assurance procedure detailing the frequency with which backgrounds will be taken for the gross gamma counters.
-
- 5.5.7 Are the calibration and window settings documented, showing proper conditions for routine counting conditions?
- 5.5.8 How is the self absorption coefficient determined for gross alpha measurements?
-
- 5.5.9 Is there a reference for this determination?

Dealing with Uncertainty

- 5.5.10 Have the uncertainties for the absorption coefficient and the propagation of error been evaluated?
- 5.5.11 How many points were used to determine the self-absorption curve? _____
- 5.5.12 Are the operating (voltage) plateaus and crosstalk between alpha and beta channels evaluated on a periodic or required frequency?
- 5.5.13 What nuclide was used for the gross alpha calibration?
- 5.5.14 What nuclide was used for the gross beta calibration?
- 5.5.15 What nuclide was used for the gross gamma calibration?
- 5.5.16 Is there a procedure describing the action required when the background for the gross alpha instrumentation exceeds the defined limits?

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 2.5.1, 2.8, 3.1.4, 3.7, 6.1, 6.2

VI. Radioactive Waste Management

NAME OF FACILITY:	
SITE ID:	
DATE OF AUDIT:	
AUDITOR(S):	
KEY PERSONNEL CONTACTED:	
NAME/TITLE	

Standard Operating Procedure

6.1 Does the laboratory have in place a program ensuring that radioactive low-level waste shall be managed on a systematic basis using the most appropriate combinations of waste generation reduction, segregation, treatment and disposal practices?

6.2 How does the laboratory implement that program?

RCRA Compliance

6.3 Does the laboratory have in place a program to ensure compliance with the regulations of the responsible regulatory authorities under the Resource Conservation and Recovery Act for the management of low-level radioactive waste containing non-radioactive hazardous waste components (mixed waste)?

6.4 How does the laboratory implement that program?

Waste Minimization

- 6.5 Does the laboratory's radioactive waste management program address the needs of:
- 6.5.1 reducing the gross volume of waste generated and/or the amount of radioactivity requiring disposal?
 - 6.5.2 separation of uncontaminated waste from low-level waste to facilitate cost effective treatment and disposal?
 - 6.5.3 initiating measures to minimize the generation of low-level wastes?
 - 6.5.4 characterizing low-level waste with sufficient accuracy to permit proper segregation, treatment, storage and disposal?
 - 6.5.5 maintaining records of the characterization as required?

Comments:

See Laboratory Quality Assurance Guidance Document, Sections 1.4, 2.5.2, 2.8.3, 3.2

SECTION 2.3

**LABORATORY AND FIELD
QA/QC ASSESSMENT PLATES**

OUTLINE
LABORATORY AND FIELD QA/QC ASSESSMENT PLATES

I. Organization Evaluations	67
A. Personnel	68
B. Training	68
C. Personnel Safety	68
II. Quality Assurance	69
A. Quality Assurance Program	69
B. Maintenance Procedure	70
1. Instrument Maintenance	70
2. Calibration Procedures	70
3. Service Contracts	70
C. QC Materials and Methods	70
D. Standards	71
E. Water	71
F. Performance Evaluation Samples	72
G. Internal Assessment And Corrective Action	72
H. Decontamination Procedures	72
I. Data Documentation	72
III. Facilities and Equipment	73
A. General	73
B. Hoods	74
C. Safety Equipment	74
D. Balances	75
E. Ovens / Drying Areas	76
F. Cold Storage	77
G. Reagents/Chemicals Storage and Disposal	78

IV. Sample Management	79
A. Sampling Site Safety	79
B. Sample Tracking	79
1. Chain of Custody	79
2. Sample Receipt	79
3. Sample Variance	79
C. Sample Documentation	80
1. Sample Logbooks	80
2. Holding Times	80
D. Storage and Disposal	81
1. Sample Storage	81
2. Sample Disposal	81
E. Contractor Laboratory	81
F. Sample Archiving	81
1. Sample Labeling	81
2. Archiving Procedure	81
G. Data Documentation	82
1. Analyst Logbooks	82
2. Data Quality Checks	82
H. Data Management Validation Procedure	82
I. Computer Systems	82
1. Data Input	82
2. Data Output	83
3. Backup System	83
4. Performance Documents	83
5. Nonconformance Documents	83
J. Records Management	84
1. Procedures	84
2. Records Area	84

I. ORGANIZATION EVALUATIONS

NAME OF FACILITY: _____

SITE ID: _____

DATE OF ASSESSMENT: _____

ASSESSOR(S): _____

CONTACTS: (NAME/TITLE)

Sampling Technician

SOP IDENTIFICATION:

Project Manager/Title: _____

QA Officer: _____

Data Management: _____

Assessment Team Leaders: (Listed below)

Sampling: _____

Sampling: _____

Sampling: _____

Laboratory: _____

Laboratory: _____

Laboratory: _____
(P=Produce, F=Fish, M=Milk, G=Grass)

Sample Control Officer: _____

Health & Safety Officer: _____

PERSONNEL

- 1.1 Has a laboratory manager been identified?
- 1.2 Has the QA officer been identified?
- 1.3 To whom does the QAO report go? _____
- 1.4 Has a RSO been identified?
- 1.5 Has a sample custodian been identified?
- 1.6 Have all analysts been identified?

- 2.1 Was the Project Director _____ and/or Manager _____ available during the evaluation?
- 2.2 Are resumes available for all laboratory personnel?
- 2.3 Are the same personnel described in the Sampling and/or QA plan performing on-site sampling procedures?

- 3.1 Is there adequate supervision of the technical staff?

TRAINING

- 1.1 Is a written training plan available?
- 1.2 Does the written training plan outline the training frequency and re-training procedures?
- 1.3 Does the written training plan outline the required performance criteria needed to be accomplished before training is considered complete?

- 2.1 Are there established written procedures for training staff to perform analytical methods?
- 2.2 Have all laboratory and sampling personnel been trained according to site requirements?
- 2.3 Are appropriate individuals performing the training?
- 2.4 Is the training documented?
- 2.5 Do these procedures contain specific precision and accuracy levels to be achieved by the analysts before they can begin working on actual samples?

- 3.1 Do interview and inspection of records indicate that personnel are trained to meet laboratory objectives?
- 3.2 Are the assigned laboratory personnel qualified to perform the work assigned to them in accordance with laboratory QA/QC manual requirements?

PERSONNEL SAFETY

- 1.1 Is a Safety Officer designated?
- 1.2 Are personnel involved in safety program identified?
- 1.3 Are backup personnel designated?

- 2.1 Do laboratory personnel observe safety regulations?
- 2.2 Are the laboratory personnel wearing the following, where required?
 - a) Safety glasses/goggles
 - b) Gloves
 - c) Lab coats/apron
 - d) Safety shoes
 - e) Respirators

- 3.1 Is a Health and Safety Coordinator (HSC) on site?
- 3.2 Is the HSC a professional Industrial hygienist?
- 3.3 Has a Safety Plan been approved?
- 3.4 Is the Safety Plan in place?

- 4.1 Is staff trained in safety procedures/policies?
- 4.2 Is training documented? _____ At what interval is training? _____

Comments:

See Analytical Laboratory Quality Assurance Guidance Document, Sections 2.1, 2.2
See Sampling Quality Assurance Guidance Document, Sections 2.1, 2.2

II. QUALITY ASSURANCE

NAME OF FACILITY:	
SITE ID:	
DATE OF ASSESSMENT:	
ASSESSOR(S):	
CONTACTS: (NAME/TITLE)	
Sampling Technician	
SOP IDENTIFICATION:	

QUALITY ASSURANCE PROGRAM

- 1.1 Has a QA Plan been implemented?
- 1.2 Are QA responsibilities clearly defined?
- 1.3 Are QA reporting relationships clearly defined?
- 1.4 Does the overall quality assurance program ensure the accomplishment of the laboratory objectives?
- 1.5 Are all procedures and protocols for implementing the QA program approved by the QA officer and senior laboratory management prior to use?
- 1.6 Are all the QA procedures and revisions documented in written form and assigned a unique identification code including date of implementation?
- 1.7 Is the QA/QC plan available to lab personnel?
- 1.8 Are personnel aware of their QA responsibilities?

- 2.1 Does the laboratory maintain a manual specific to all the analyses performed in the laboratory?
- 2.2 Is the laboratory procedures manual available to laboratory personnel? controlled copies?
- 2.3 Is the manual reviewed/updated regularly?
- 2.4 Are the following elements adequately covered, maintained and implemented:
 - a.) Personnel
 - b.) Organization chart
 - c.) QA/QC responsibilities
 - d.) QA/QC reporting relationships
 - e.) Facilities and equipment
 - f.) Analytical instrument operations
 - g.) Procurement and inventory practice
 - h.) Documentation of procedures
 - i.) Preventive maintenance
 - j.) Reliability of data
 - k.) Proficiency/reference material used
 - l.) Data review and validation
 - m.) Feedback and Corrective Action
 - n.) Technical complaint handling procedure
 - o.) Instrumentation calibration
 - p.) Recordkeeping and data storage
 - q.) Security

- 3.1 Are the QA/QC procedures specified in the manual followed as required?
- 3.2 Are written protocols provided for modifying existing methods?
- 3.3 Are written protocols provided for approving new methods?
- 3.4 Is there a plan for the management to review analytical data records?
- 3.5 Is there a plan for the management to review sampling and screening records?

- 4.1 Do responses indicate that project and supervisory personnel place positive emphasis on QA/QC?
- 4.2 Have the responses of personnel with respect to QA/QC been open and direct?
- 4.3 Do the responses indicate that the project and supervisory personnel are aware of the application of QA to the project?
- 4.4 Was the QA Officer available during the evaluation?
- 5.1 Have any QA deficiencies been discussed during the evaluation/preassessment?
- 5.2 What procedures are followed when QA/QC deficiencies are identified?

MAINTENANCE PROCEDURES

Instrument Maintenance

- 1.1 Are schedules for instrument maintenance established?
- 1.2 Are the schedules followed?
- 1.3 Have maintenance procedures been written for each device used for lab analysis, field screening, and field sampling?
- 1.4 Is a manufacture's manual available to support these written procedures?
- 1.5 Are dedicated instrument operation logs maintained for each analytical instrument?
- 1.6 Are records maintained in a logbook of all instrument maintenance?
- 1.7 Have the instruments been maintained in accordance with the applicable QA/QC manual and instrument operation manual?
- 1.8 Are all instrument modifications documented in a permanent record?

Calibration Procedures

- 2.1 Have calibration procedures been prepared for each instrument used for sample analysis?
- 2.2 Is the calibration verified by reference material or independent standards?
- 2.3 What was the date of the last calibration for the instrument: _____
- 2.4 What was the maximum time between calibrations for this instrument: _____

Service Contracts

- 3.1 Are there service contracts on any (or all) major analytical instruments?
- 3.2 Is information on the service contracts for the instruments available?

QC MATERIALS AND METHODS

- 1.1 Are the following materials and methods used:
 - a.) Reference materials
 - b.) Surrogates
 - c.) Blanks
 - d.) Duplicate samples
 - e.) Spiked samples
 - f.) Quality control charts with defined limits
- 1.2 Are corrective actions steps defined and followed for out-of-control conditions?
- 1.3 Are QC summaries prepared regularly and properly recorded?
- 1.4 Are analysts responsible for data entry on QC charts?
- 1.5 Are QC charts reviewed?
- 1.6 If yes to 1.5, who reviews the charts? _____
- 1.7 If yes to 1.5, how often? _____
- 1.8 If yes to 1.6, is this an appropriate individual?
- 2.1 Have written analytical procedures for instrument standardization been provided for all analyses for each instrument used for sample analysis?
- 2.2 Are the analytical procedures used for instrument standardization the same procedures used for actual sample analysis?

STANDARDS

- 1.1 Are laboratory analytical standards traceable to recognized standard reference materials such as NIST, or, are they certified by the supplier?
- 2.1 Is a standards preparations and tracking logbook maintained?
- 3.1 Are prepared standards labeled with:
 - a) Identification
 - b) Concentrations
 - c) Date of preparation
 - d) Date of expiration
 - e) Initials of the person who prepared the standard
 - f) Lot or batch number
 - g) Solvent
- 4.1 Are standards properly prepared and stored?
- 4.2 Are standards stored within the shelf life?
- 5.1 Are reagent grade or higher purity chemicals used to prepare standards?
- 6.1 Is the following information available for reference materials and standards:
 - a) Chemical grade or purity
 - b) Manufacturer
 - c) Date of expiration
 - d) Identification and lot or batch number
 - e) Container opening record
 - f) Shelf-life
 - g) Receipt date
 - h) Date of preparation
 - i) Procedures used for preparation

WATER

- 1.1 Does the laboratory have a source of deionized/demineralized water?
- 1.2 Is ASTM Type II water (or equivalent) produced by distillation or deionization so that the conductivity is less than 1 mho/cm?
- 1.3 Is this water used for:
 - Standards
 - Blanks
 - Analysis
- 2.1 Is the lab water checked daily for conductivity and properly recorded?
- 2.2 Does the purity of the water meet the established requirements?
- 2.3 Is the result recorded in a logbook and initialed?
- 2.4 If yes to 2.3, at what frequency?
- 2.5 Is the lab water source properly maintained?
- 2.6 Is 2.5, documented?
- 3.1 Can the laboratory document that analyte water is available for preparation of standards and blanks?
- 3.2 Is the lab water documented to be free of all the analytes being tested for?
- 3.3 If yes to 3.2, what is the frequency of this testing?
- 3.4 If yes for 3.3, this testing documented?

PERFORMANCE EVALUATION SAMPLES

- 1.1 Are performance evaluation samples routinely analyzed?
EPA: _____
DOE: _____
Others: _____
- 1.2 Is this documented?
- 1.3 Are all results within applicable QC limits?
- 1.4 Are there procedures for "out-of control" situations?
- 1.5 Have corrective actions plans resulting from performance evaluations samples been implemented?

INTERNAL ASSESSMENT AND CORRECTIVE ACTION

- 1.1 Who is responsible for receiving assessment samples?
- 1.2 Who is responsible for splitting, preparation and duplicate samples?
- 1.3 Are assessment samples submitted double blind?
- 2.1 How often are internal assessments done? _____
- 2.2 Is the internal assessment program effective?
- 3.1 Has a formal corrective action program been implemented?
- 3.2 Have corrective action recommendations during previous evaluation been implemented?
- 3.3 Have corrective actions been documented?
- 3.4 Is there a technical complaint handling procedure?

DECONTAMINATION PROCEDURES

- 1.1 Do lab personnel conform with the appropriate decontamination procedures?

DATA DOCUMENTATION

- 1.1 Have standard curves and quality control limits been adequately documented?
- 1.2 Are the limits of detection determined and reported for each analyte or parameter?
- 1.3 Are quality control charts maintained for each routine analysis?
- 1.4 Does the analytical and QC data meet the QC criteria as specified in the applicable QAP, QAPJP, SAP, DQO, QA/QC manual etc.?
- 1.5 When data is out of control, do the records indicate some statement on the usefulness of the data?
- 1.6 Do QC records show corrective action when analytical results fail to meet QC criteria?
- 1.7 Do records indicate corrective action that has been taken on rejected (unreportable) data?
- 1.8 Are QC data accessible for all analytical results?
- 2.1 Are all data and records retained under security for the time period required by the applicable QA project plan and applicable sampling and analysis plan?
- 2.2 Are data calculations documented?
- 2.3 Are data calculations checked by a second person?
- 2.4 Do supervisory personnel routinely review the data and QC results?
- 2.5 Are in-house QA evaluations conducted at least annually?

Comments:

See Analytical Laboratory Quality Assurance Guidance Document, Sections 2.6, 2.9, 4.1, 4.3, 5.1
See Sampling Quality Assurance Guidance Document, Sections 2.3, 2.5.1, 2.6, 2.9

III. FACILITIES AND EQUIPMENT

NAME OF FACILITY:	
SITE ID:	
DATE OF ASSESSMENT:	
ASSESSOR(S):	
CONTACTS: (NAME/TITLE)	
<u>Sampling Technician</u>	
SOP IDENTIFICATION:	

GENERAL (FACILITIES)

- 1.1 Does the laboratory have adequate workspace?
- 1.2 Is the laboratory maintained in a clean and organized manner?
- 1.3 Are adequate facilities provided for separate storage of supplies, samples, extracts and standards, including cold storage?
- 1.4 Does the laboratory have adequate workspace for sample preparation?
- 1.5 Is the general housekeeping of sampling and/or sample preparation facilities maintained?
- 1.6 Are laboratory areas provided for trace level analytical work appropriately designed to prevent cross contamination?
- 1.7 Are the wet chemical analyses performed away from the instrument room(s)?
- 1.8 Are the samples and standards prepared for analysis in different locations?
- 1.9 Are contamination free work areas provided?
- 2.1 Are voltage control devices used on major instrumentation?
- 3.1 Are all the instruments properly vented?
- 3.2 Is laboratory airflow, temperature, and circulation adequate?
- 4.1 Is the laboratory secure?
- 4.2 Is the distribution of keys limited?
- 4.3 Is access to controlled areas enforced?

HOODS

- 1.1 Are exhaust hoods provided that allow adequate workspace within?
- 1.2 Do the exhaust hoods have adequate airflow?
- 1.3 Is the airflow checked regularly?
- 1.4 Is the exhaust hood area used as a storage device?

- 2.1 Do the exhaust hoods have a face velocity of 80-100 ft./min.?
- 2.2 Are there any records to document 2.1?
- 2.3 Are the hoods supplied with at least 70% outside air?
- 2.4 Are there any records to document 2.3?

- 3.1 Are hoods provided for work with the following?
 - a) Perchloric Acid
 - b) Corrosive materials
 - c) Dusty materials
 - c) Volatile materials
 - d) Radioactive material

- 3.2 Are operations that should be performed in a hood actually performed in a hood?

SAFETY EQUIPMENT

- 1.1 Are safety showers installed?
- 1.2 Are safety showers checked at required intervals?

- 2.1 Are eye wash stations available?
- 2.2 Are eye wash stations operable?
- 2.3 Are eye wash stations checked at required intervals?

- 3.1 Are fire extinguishers available?
- 3.2 If yes to 3.1, are regular maintenance schedules followed?
- 3.3 Is a fire blanket available?

BALANCES

	Quantity	Model/Manufacturer	Condition
Analytical:			
Top Loaders:			
Class S Weights:			
Balance Table:			

- 1.1 Are analytical balances located away from drafts?
- 1.2 Are analytical balances located away from areas subject to rapid temperature changes?
- 1.3 Have the balances been calibrated within the last year by a certified technician?
- 1.4 Is 1.3 documented?
- 1.5 Are the balances checked with Class S standard weights on a routine basis and properly recorded in a log book?_____ At what frequency?_____
- 1.6 Are calibrated check weights used prior to sampling?_____ At what frequency?_____
- 1.7 Is this documented?

OVENS/Drying Areas

	QUANTITY	MODEL	CONDITION
Drying Ovens:			
Air Drying Surfaces:			
Muffle Furnaces:			

- 1.1 Is the temperature of the unit recorded in logbooks? ____ At what frequency?
- 1.2 Do the records indicate satisfactory operation of the units?
- 1.3 Does the laboratory have adequate workspace for adequate drying?
- 1.4 Is cross contamination between samples in drying areas prevented?
- 1.5 Are the ovens in use designed with proper air flow to prevent cross contamination?

COLD STORAGE (refrigerators and freezers)

	Quantity	Model	Condition
Freezers:			
Refrigerators:			

- 1.1 Is the temperature of the cold storage units recorded in logbooks? ____ At what frequency?
- 1.2 Is the temperature of the cold storage units verified by an independent temperature recording device?
- 1.3 Is there a temperature gauge on the outside of each cold storage unit that measures the temperature of the unit?
- 1.4 Is the location of the temperature gauge (on the outside of the unit) such that it represents the temperature throughout the unit?

- 2.1 Is a NIST certified thermometer available?
- 2.2 Are the thermometers calibrated against this certified thermometer on an annual basis?
- 2.3 Is 2.2 documented?

- 3.1 Are adequate cold storage facilities provided for sample storage?
- 3.2 Are contingency plans available if the cold storage units malfunction?
- 4.1 Are all stored samples tightly closed?
- 4.2 Are any open samples stored in cold storage units?
- 4.3 Are the cold storage units labeled "FOR LAB USE ONLY, NO FOOD OR DRINK"?
- 4.4 Are any food or drinks stored in the sample storage cold units?
- 4.4 Are there any biological samples stored in the units?
- 4.5 Are there any reagents stored in the units?
- 4.6 If chemicals are stored in refrigerator, is the storage proper (do the chemicals require it be explosion proof)?
- 4.7 Are precautions taken to minimize cross contamination of chemicals or samples by chemical vapors?

REAGENTS/CHEMICALS STORAGE and DISPOSAL

- 1.1 Are reagent preparations properly labelled?
- 1.2 Are reagents properly stored and dated upon receipt and when first opened?
- 1.3 Are sample bottles, preservatives, and other supplies quality assured?
- 1.4 Are all chemicals dated upon receipt and discarded when the shelf life expires?
- 2.1 Are reagents and chemicals of adequate grade for the intended use?
- 2.2 Is certification of material composition provided when required?
- 3.1 Are materials adequately stored to prevent degradation?
- 3.2 Are proper storage facilities available for chemicals?
- 3.3 Are storeroom personnel trained in:
 - a) Proper handling?
 - b) Storage of chemicals?
 - c) Is this documented?
- 4.1 Are chemical waste disposal procedures/policies adequate?
- 4.2 Are chemical waste disposal procedures/policies known and followed?

Comments:

See Analytical Laboratory Quality Assurance Guidance Document, Sections 2.3, 3.1, 3.1.4, 3.1.5
 See Sampling Quality Assurance Guidance Document, Sections 2.3, 3.2.3

IV. SAMPLE MANAGEMENT

NAME OF FACILITY:	
SITE ID:	
DATE OF ASSESSMENT:	
ASSESSOR(S):	
CONTACTS: (NAME/TITLE)	
Sampling Technician	
SOP IDENTIFICATION:	

SAMPLING SITE SAFETY

- 1.1 For sampling sites where routine operations do not occur and there is no established protocol, are the principal hazards and the protective measures taken determined by document review by the team leader and the contractor H&S representative?
- 2.1 Are acid/base spill kits and eye wash kits available in each sampling vehicle?
- 3.1 Are normal on-site field sampling activities conducted in at least Level-D-protection? (Coveralls, steel toed boots, latex surgical gloves, safety glasses and hard hats where required).
- 4.1 Are any food, drink, tobacco or lotions being used during sampling activities?
- 5.1 Are sampling personnel fit-tested and trained in the use of respirator protection?
- 5.2 Are any members of the sampling team trained in First Aid/CPR?
- 6.1 Have all sampling personnel undergone medical examination as required by protocol?
- 6.2 Do all sampling personnel have their radiation exposure histories completed prior to beginning sampling? (where applicable)
- 7.1 Are Material Safety Data Sheets available at all times for inspection by the field sampling team?
- 8.1 Are sample locations surveyed for radiation and vapor hazards using portable instruments? (where applicable)

SAMPLE TRACKING

Chain Of Custody

- 1.1 Is a sample custodian designated?
- 1.2 Are sample custodian procedures and responsibilities documented?
- 1.3 Are chain of custody procedures documented? _____ Effective? _____
- 1.4 Is there evidence that one individual has been assigned the responsibility to ensure that the chain of custody procedures have been met?

Who: _____

- 1.5 Does the implementation of chain of custody procedures require that only authorized personnel collect, transfer, store, analyze, and dispose of or destroy samples?
- 1.6 Are the following items included on the chain of custody:
- a) Sampling time and location?
 - b) Sample identification?
 - c) Client identification?
 - d) Contract/Project code?
 - e) Field sample identification code?
 - f) Laboratory identification code?
 - g) Analysis requested?
 - h) Documentation of sample preservation?
 - i) Sample analysis dates?
 - j) Sample reporting dates?
 - k) Time of Receipt?
 - l) Date of Receipt?
 - m) Shipping record?
 - n) Sample ID for sample splits sent off-site?
 - o) Documentation of sample disposal?
 - p) Sample extracts and digestates?
- 1.7 Is all sample data traceable to all points from sample receipt to sample analysis reports?

Sample Receipt

- 1.1 Is the custody traceable after receipt by the laboratory?
- 1.2 Is the sample receipt documented? and include the following:
- a) Sample ID
 - b) Identity of the receiver
 - c) Date and time of receipt
- 1.3 Is a unique sample ID code assigned to each sample?
- 1.4 Is the condition of the sample upon receipt routinely documented?
- 1.5 Are pH and temperature checked to verify acceptable preservation?
- 1.6 Are procedures established if preservation is unacceptable?

Variance

- 1.1 Are procedures available for overload situations?
- 1.2 Are procedures available for mishandling?
- 1.3 Are corrective action reports associated with variances and nonconformance with sample documentation available?

SAMPLE DOCUMENTATION

Sample Logbooks

- 1.1 Are detailed sample logbooks routinely maintained and documented?
- 2.1 Are samples logged in promptly?

Holding Times

- 1.1 Are samples prepared, digested, extracted and analyzed within recommended holding times?

STORAGE AND DISPOSAL

Sample Storage

- 1.1 Is the storage facility for samples and sample extracts adequate?
- 1.2 Is sample storage secure and documented?
- 1.3 As appropriate, are samples stored in the dark and/or at 4°C to maintain appropriate preservation?
- 1.4 Is sample removal from storage routinely documented in terms of the following?
 - a) Date and time of removal
 - b) Responsible person
 - c) Date and time of return
 - d) Volume of sample removed

Sample Disposal

- 1.1 Are sample extracts and digestates stored under appropriate custody and security and other conditions necessary to maintain sample integrity?
- 1.2 Is date and time of sample disposal (including all extracts and digestates) routinely recorded, along with identity of disposer, in a logbook or by another procedure?

CONTRACTOR LABORATORY

- 1.1 Are contractor laboratories used?
- 1.2 If yes to 1.1, is the contract laboratory QA/QC program equivalent to guidelines of the facility administering the contract?

SAMPLE ARCHIVING

Labeling

- 1.1 Are archived samples labelled?
- 1.2 Is sample identification permanent and legible?

Procedure

- 1.1 Is there a sample storage procedure?
- 1.2 If yes to 2.1, explain: _____

- 1.3 Is a map or key showing the location of the archived samples readily available?
- 1.4 Are archived samples easily retrieved?
- 1.5 Are sample numbers cross referenced with field data and documented?
- 2.1 Are the procedures and responsibilities of the sample custodian documented?

DATA DOCUMENTATION

Analyst Notebooks

- 1.1 Are written procedures documented for preparation of analysts notebooks?
- 1.2 Are the analyst laboratory notebooks routinely completed for all analysis?
- 1.3 Are the analysts records permanently bound with preprinted consecutively numbered pages?
- 1.4 Do analysts logbooks routinely contain the applicable information, which should include the following?
 - a. Identification of analysts?
 - b. Signature of analyst on each page of logbook?
 - c. Analysis type (analyte and parameter)?
 - d. Sample prep used?
 - e. Analytical method used?
 - f. Samples analyzed?
 - g. Date and time of each analysis?
 - h. Date and time of sample preparation?
 - i. Volume of sample used and dilution factors?
 - j. Analytical results?
 - k. Analytical problems encountered and corrective actions taken?
 - l. All factors affecting reported results (including QC limits exceeded)?
 - m. All raw and reduced data (including e.g. chromatograms)?
- 1.5 Has the analyst avoided obliterating entries to logbooks and other data and instrumentation?
- 1.6 Are the logbooks maintained in a legible manner?
- 1.7 Are all corrections to the data initialled and dated?
- 1.8 Is "white-out" used?
- 1.9 Is pencil used for entering data?
- 1.10 Are inserts (e.g. chromatograms, instrument printouts) permanently affixed in the logbook and signed across the insert edge and page?
- 1.11 Where applicable, is the analyst referencing reports or memoranda pertinent to the contents of the entry?
- 1.12 Has the supervisor of the analyst maintaining the laboratory records examined the records periodically and certified with date, signature, and appropriate comments whether the records are being maintained in the required manner?

Data Quality Checks

- 1.1 Is there an established procedure for re-analysis of samples?
- 1.2 Is data approved, verified and does it receive final QC checks before release?

DATA MANAGEMENT VALIDATION PROCEDURE

- 1.1 Are there written procedures and protocols for data handling, storage and processing?
- 1.2 Are there established procedures for determining the degree of data completeness and adequacy?

COMPUTER SYSTEMS

Data Input

- 1.1 Does the data system include a user log which prevents undetected or unreported access to the system?
- 1.2 Are there established procedures to verify the correctness of the data entry?
- 1.3 Are the procedures outlined in 2.2 routinely implemented?

Data Output

- 1.1 Are there established procedures for verifying the correctness and consistency of data output in relation to entered raw data?
- 1.2 Are the procedures outlined in 1.1 routinely implemented?
- 2.1 Are the data reasonably accessible to authorized users?
- 2.2 Are data reduction and manipulation techniques acceptable and well documented?
- 2.3 Has a suitable format for reporting data been established?

Backup System

- 1.1 Are backup records of the data management system files routinely prepared and filed?

Performance Documents

- 1.1 Does the analytical report contain the following:
 - a. Name and address of the laboratory?
 - b. Unique identification (including pages)?
 - c. Test item identification and description?
 - d. Date of receipt of test item?
 - e. Date of analysis?
 - f. Analysis results?
 - g. Chain of custody forms?
 - h. Identity of analytical method, with any additions and modifications?
 - i. Description of sampling procedure?
 - j. Identification of any non-standard methods used?
 - k. Measurement uncertainty?
 - l. Signature and date?
 - m. Statement regarding reproduction of the report?

Nonconformance Documents

- 1.1 What type of flagging system is used for nonconformance data?
- 1.2 Does SOP say that nonconformance data to be indicated in the report?
- 1.3 Is 1.2 implemented?
- 1.4 What does sample manager do if data is not in compliance with contract and/or QC requirements?

RECORDS MANAGEMENT

Procedures

- 1.1 Are document custody procedures written and accessible to all appropriate individuals?
- 1.2 Are written document preparation and custody procedures available to all appropriate personnel?
- 1.3 Does the laboratory maintain project files which include all sample and laboratory custody and analysis data, documents and records?
- 1.4 Are all documents in a project file uniquely and sequentially numbered?
- 1.5 Are all records maintained permanently?

Records Area

- 1.1 Does the facility have a secure designated area where all laboratory and sampling records are stored?
- 1.2 Is access to this area restricted to authorized personnel?
- 1.3 Are records kept in fire-proof file cabinet?

- 2.1 Is a master inventory list maintained?
- 2.2 Are all records present as represented by the inventory?
- 2.3 Are records regularly reviewed and approved?

- 3.1 Are records adequate to permit repeat of test/analysis?

Comments:

See Analytical Laboratory Quality Assurance Guidance Document, Sections 3.0, 5.1, 6.2, 6.3
See Sampling Quality Assurance Guidance Document, Sections 3.2, 3.3, 3.4, 5.1