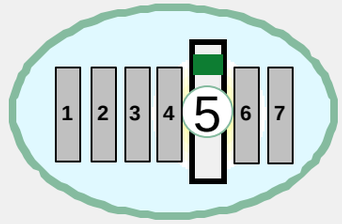
Hazardous Waste Combustion Unit Permitting Manual



COMPONENT 5

How To Conduct A Laboratory Audit

U.S. EPA Region 6 Center for Combustion Science and Engineering

Tetra Tech EM Inc.

COMPONENT FIVE

HOW TO CONDUCT A LABORATORY AUDIT

JANUARY 1998

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ATTACHMENTS

Attachment

A LABORATORY AUDIT CHECKLIST

ABBREVIATIONS AND ACRONYMS

CERI	Center for Environmental Research Information
GC/MS	Gas chromatography/mass spectrometry
ICP	Inductively coupled plasma
OSWER	Office of Solid Waste and Emergency Response
PM	Particulate matter
POHC	Principal organic hazardous constituent
QAPP	Quality assurance project plan
QA/QC	Quality assurance/quality control
RCRA	Resource Conservation and Recovery Act
SOP	Standard operating procedure
SVOC	Semivolatile organic compound
TBP	Trial burn plan
U.S. EPA	U.S. Environmental Protection Agency
VOC	Volatile organic compound
VOST	Volatile organic sampling train

BIBLIOGRAPHY

American Society for Testing and Materials (ASTM). "Annual Book of ASTM Standards." Philadelphia, Pennsylvania. Annual Series.

U.S. Environmental Protection Agency (EPA). 1988. "Resource Conservation and Recovery Act (RCRA) Laboratory Audit Procedures (RCRA Ground-Water Monitoring Systems)." Office of Solid Waste and Emergency Response (OSWER) 9950.4. RCRA Enforcement Division. Washington, D.C. September.

U.S. EPA. 1989. "Handbook: Hazardous Waste Incineration Measurement Guidance Manual." Volume III of the Hazardous Waste Incineration Guidance Series. OSWER. Washington, D.C. EPA/625/6-89/021. June.

U.S. EPA. 1990. "Handbook: Quality Assurance/Quality Control (QA/QC) Procedures for Hazardous Waste Incineration." Center for Environmental Research Information (CERI). Cincinnati, Ohio. EPA/625/6-89/023. January.

U.S. EPA. 1996. "Test Methods for Evaluating Solid Wastes: Physical/Chemical Methods. Update III (SW-846)." OSWER. Washington, D.C. December.

U.S. EPA. 1997. "Generic Quality Assurance Project Plan (QAPP)." Center for Combustion Science and Engineering, Multimedia Planning and Permitting Division, U.S. EPA Region 6. Dallas, Texas. December.

U.S. EPA. 1997. "Generic Trial Burn Plan (TBP)." Center for Combustion Science and Engineering, Multimedia Planning and Permitting Division, U.S. EPA Region 6. Dallas, Texas. December.

1.0 INTRODUCTION

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Laboratory systems must be audited to ensure that the highest quality results for both stack gases and waste feed samples are produced. Laboratory audit findings determine the degree of confidence the permit writer has in the analytical results reported by the facility. The analytical results are needed to support permit conditions and the risk assessment. Because facilities may contract more than one laboratory for analyses, it may be necessary to audit each laboratory associated with the trial burn.

The laboratory audit consists of (1) observing sample receipt, storage, preparation, and analysis, data review, and trial burn sample reporting; (2) evaluating raw data generated by the laboratory; and (3) reviewing project records. Laboratory audit activities are categorized into three groups: (1) pre-audit activities (Section 2.0), (2) audit activities (Section 3.0), and (3) post-audit activities (Section 4.0). The following sections will address each activity category, with detailed descriptions. In addition, general laboratory safety and sample or waste disposal practices should be reviewed.

Attachment A is an example of a checklist that can be used to assist in the laboratory audit. This review checklist can be used to ensure that all activities associated with a laboratory audit are completed.

Check For: Each auditor should review the following sections to ensure they are prepared for the following activities:

- ❑ Pre-audit Activities (Section 2.0)
- ❑ Conducting the Audit (Section 3.0)
- ❑ Post-Audit Activities (Section 4.0)

Example Situation: Lois and Clark of Metropolis have been selected to conduct laboratory audits in connection with the permitting process for several facilities. In the case of one facility, Clark needs to audit a laboratory for a trial burn, but he does not have the completed trial burn quality assurance project plan (QAPP).

Example Action: To complete the audit successfully, Clark needs to have copies of the trial burn QAPP, trial burn plan (TBP), and access to personnel. Clark asks that the facility provide him with copies of the trial burn QAPP and TBP, and he asks the laboratory to allow him access to laboratory personnel.

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2.0 PRE-AUDIT ACTIVITIES

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Several major steps must be accomplished to organize and conduct a laboratory audit. Each of the major steps is described in the following sections.

Check For: The following tasks should be completed by the permit writer preparing for the audit:

- ❑ Obtain basic laboratory information (see Section 2.1).
- ❑ Review facility TBP and trial burn QAPP (see Section 2.2).
- ❑ Schedule the audit with the laboratory (see Section 2.3).
- ❑ Assemble the audit team (see Section 2.4).
- ❑ Prepare a laboratory-specific audit checklist (see Section 2.5).

Example Situation: Training a new permit writer or staff member for a laboratory audit can be challenging even for staff who have chemistry training. Pre-audit activities are critical to the success of an audit. Basic laboratory information, such as which laboratories are being used for analysis, may not be clear from TBP or trial burn QAPP information, and the audit team may have to obtain this information from the testing firm or trial burn facility manager.

Example Comments: A successful audit will occur when it is organized in a thorough, step-by-step fashion similar to the guidance provided in this document. Conducting a laboratory audit without thorough planning will usually result in an incomplete audit.

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2.1 OBTAINING BASIC LABORATORY INFORMATION

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Basic laboratory information should be made available to the permit writer by the facility. Multiple laboratories may be contracted by a facility to analyze trial burn samples. It is important to obtain information from all laboratories and to understand the relationships among the facility, contractor laboratories, and subcontractor laboratories. This information is useful for verifying the accurate transfer of project-specific analysis requests and QC information from the facility to all contractors and subcontractors. Frequently, the facility contracts with an organization to prepare the TBP and trial burn QAPP, and may hire sampling and analytical contractors. It is essential to understand (1) the testing program organization, (2) the contracting responsibilities of the various parties, (3) who is responsible for communicating key information to the laboratories, and (4) who is the resource for the laboratory regarding questions about samples or analyses.

Check For: The following information should be obtained for each contracted laboratory:

- ❑ Laboratory name, address, and telephone, facsimile, and e-mail numbers (Section 2.1.1)
- ❑ Names and titles of contact personnel (Section 2.1.2)
- ❑ Relationship of laboratory to facility, sampling organization, or organization preparing the TBP and trial burn QAPP (Section 2.1.3)
- ❑ Matrices to be analyzed, methods of analysis for each, number of samples, and delivery schedule of sample to the laboratory (Section 2.1.4)

Each of the items may be summarized in tabular format, as presented in the following example situation. Each of the listed items is discussed in the following subsections.

Example Situation: In preparation for conducting a laboratory audit, Lois receives the following information from the facility.

Laboratory A has been advised by the regular contact at Facility X that it will be analyzing waste feed samples from a trial burn. The samples should arrive within the next 2 to 3 weeks, and the chain-of-custody documentation will provide all of the information that the laboratory needs for the analyses.

Name and Address	Contacts	Relationship	Matrix	Analysis	Method
Laboratory A 1111 1st Street Anywhere, USA 1-800-555-5555	Lab Director Mr. John Doe (555) 555-5551 QA Officer Ms. Jane Smith (555) 555-5552	Subcontractor to Facility X's environmental consultant	Waste feed	Viscosity BIF metals Chloride	SW-846 6010A 9250
Laboratory B 2222 1st Street Anywhere, USA 1-800-555-5555	Lab Director Mr. John Doe (555) 555-5551 QA Officer Ms. Jane Smith (555) 555-5552	Subcontractor to Facility X's environmental consultant	Stack gas	Volatiles Semivolatiles	SW-846 8260 8270
Laboratory C 3333 1st Street Anywhere, USA 1-800-555-5555	Lab Director Mr. John Doe (555) 555-5551 QA Officer Ms. Jane Smith (555) 555-5552	Subcontractor to Laboratory B	Stack gas	Dioxins and furan	SW-846 8290

Example Action: Lois determines that the amount of information provided for Laboratory A is unacceptable. Lois advises both the facility and the laboratory that Laboratory A should take no action other than logging in samples, as received, and ensuring appropriate ambient or subambient storage, until (1) the appropriate technical contact (who can respond to technical questions regarding trial burn samples) has been established, and (2) the laboratory has received a copy of the trial burn QAPP. If the laboratory cannot receive a complete copy of the trial burn QAPP, Lois requests that the facility provide tables specifying required analyses, QC measures, and control limits to the laboratory.

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2.1.1 Gathering Information Regarding Laboratory Name, Address, and Telephone Numbers

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The laboratory name, address, telephone, and facsimile numbers are basic information needed to (1) distinguish the laboratories, (2) direct correspondence, and (3) locate the laboratory for the audit. This information should be provided by the facility and located in the trial burn QAPP.

Check For:

- ❑ Whether the laboratory name is the most recent
- ❑ Whether the laboratory address is accurate so that it could be used in physically locating the facility (for example, whether the address is a post office box or a street numbers)
- ❑ Whether the telephone and facsimile numbers for the main switchboard and any key personnel contacted are correct

Example Situation: In reviewing laboratory information supplied by the facility, Clark suspects that the laboratory name and address have recently changed because it is referenced by different names in the documents reviewed. Confusion may increase if the laboratory is part of a network of laboratories.

Example Action: Clark asks that the facility clarify the basic laboratory information before he begins any other pre-audit activities.

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2.1.2 Gathering Contact Personnel Information

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The key contact for the laboratory may be any one of the following persons. It is important to obtain the name and title of the person responsible for overall project management. Accurate information can ensure that the appropriate decision-maker is notified of project requirements.

- Company president
- Laboratory director or manager
- Quality assurance (QA) officer or manager
- Project manager or scientist
- Operations manager
- Laboratory supervisor
- Client services coordinator

Check For:

- ❑ Whether the name of the key contact is accurate
- ❑ Whether the telephone and facsimile numbers obtained in the basic laboratory information can be used to reach the key contact
- ❑ Whether the key contact has appropriate authority to halt laboratory work when QC is jeopardized
- ❑ Whether the key person has appropriate authority to implement project requirements within the laboratory

Example Situation: Clark reviews the project organization in the trial burn QAPP, which identifies the QA manager as the key contact. However, Clark remembers that although laboratories often consider the QA manager to be the key contact, they may not have the authority to implement project requirements. After reviewing information from the facility further, Clark determines that the information provided is inadequate to determine the chain-of-command at the laboratory, and that he cannot proceed with the audit.

Example Action: Clark asks that the facility provide the names of key laboratory personnel and a summary of their job responsibilities so that he knows who should be contacted for the audit.

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2.1.3 Reviewing the Relationship of a Laboratory to the Facility

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Understanding the relationship of the laboratory to the facility is important because it determines how project requirements are transferred to the laboratory. Often, the laboratory is a subcontractor to an environmental firm contracted directly by the facility. If there is more than one intermediary between the facility and the laboratory, vital project-specific requirements may not be transferred effectively, which may result in poor data quality or unusable data. The project organization should be presented as shown in Section 4 of the U.S. EPA Region 6 generic trial burn QAPP, including names of specific individuals and details of all individual organizations.

Check For:

- ❑ Whether the laboratory is directly contracted by the facility
- ❑ Whether the laboratory is contracted by a facility environmental contractor
- ❑ Whether the laboratory is a subcontractor to a primary environmental contractor laboratory
- ❑ Whether the relationship is understood by the laboratory
- ❑ Whether the laboratory knows the name of the person and organization to whom it directly reports

Example Situation: If the laboratory is a subcontractor to an environmental firm contracted by the facility for the trial burn, key project-specific requirements may not be transferred effectively to the laboratory. If the TBP or trial burn QAPP have never been transferred data generated from uninformed laboratories may not meet data quality objectives established in the trial burn QAPP. For example, reporting limits required by the trial burn QAPP to meet permit requirements for metals emissions may not be achieved thereby compromising data usability.

If the analytical laboratory is working directly for the facility on similar sample matrices for a different project, ensure that trial burn analysis requirements are met. In one recent case, a laboratory was analyzing gross water content for a client; this analysis consumed the entire sample sent from the facility. While conducting an audit at this same time, Lois verified that the appropriate laboratory contact had received the facility's TBP and trial burn QAPP, which required a total waste analysis. Had the analytical laboratory proceeded in its normal fashion, without first reviewing the facility documentation, all of the waste fuel

samples would have been consumed, and water content results critical to the final data would not have been detailed enough to meet trial burn requirements.

Example Action: The auditor must understand the relationship between the laboratory and the facility and verify that trial burn QAPP and TBP requirements have been forwarded to the laboratory.

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2.1.4 Reviewing the Matrices to be Analyzed and the Analytical Methods

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Before the audit is conducted, the auditor should determine which matrices will be received by the laboratory and select the analyses. One matrix may be analyzed by different laboratories. This information may be obtained either directly from the facility or from the trial burn QAPP; guidance is provided in Appendix A of the U.S. EPA 1990 QA/QC Handbook. This information is necessary for preparing laboratory-specific audit checklists.

Check For:

- ❑ Whether Section 9.0 of the U.S. EPA Region 6 generic trial burn QAPP provides consistent information regarding matrices, analyses, methods, QC criteria, and laboratories
- ❑ Whether the laboratory knows in advance which matrices will be analyzed, the types of analysis, and the methods to be used
- ❑ Whether the laboratory has experience in analyzing the matrices indicated in the trial burn QAPP and TBP

Example Situation: In reviewing the trial burn QAPP provided by the facility for the laboratory audit, Clark discovers that the document specifies test methods that are inconsistent with the listed matrices: particulate matter (PM) analysis on waste feed samples and viscosity analysis on stack gas samples. These methods are clearly inaccurate when compared to method requirements in Chapters 5, 7, and 8 of the U.S. EPA 1990 QA/QC Handbook.

Example Action: If the laboratory has received the trial burn QAPP in advance of sample receipt, the key laboratory staff member (possibly the laboratory director or the QA manager) should review the trial burn QAPP and call the key contact at the facility (or at the contractor) and obtain the correct matrix-specific test method. If this process has not occurred prior to the audit, the auditors should call the facility key contact to confirm the correct test method (as Clark does in this case). If the laboratory has not received a copy of the updated trial burn QAPP and is relying on outdated incorrect information from chain-of-custody documentation, the laboratory may not be aware of the error.

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2.2 GATHERING INFORMATION FROM THE FACILITY TRIAL BURN PLAN AND QUALITY ASSURANCE PROJECT PLAN

Regulations: Not applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: A detailed discussion on reviewing the facility TBP and trial burn QAPP is presented in Components 1 and 2 of this manual. This section will discuss key items in the TBP and trial burn QAPP that the auditor needs to extract to audit the laboratory. The trial burn QAPP contains information that is most relevant to the laboratory. The information necessary for the laboratory audit is discussed in detail in subsequent sections of this component. Specific information from the trial burn QAPP should be checked against guidance documents, and used to formulate the laboratory-specific checklist. The auditor should briefly note during this activity whether all relevant sections of the U.S. EPA 1990 QA/QC Handbook are addressed in the trial burn QAPP.

Check For: The following information that must be gathered from the TBP and trial burn QAPP is discussed in the following subsections:

- ❑ Organization of personnel, responsibilities, and qualifications (see Section 2.2.1)
- ❑ QA/QC objectives (see Section 2.2.2)
- ❑ Sampling and monitoring procedures (see Section 2.2.3)
- ❑ Sample handling, traceability, and holding times (see Section 2.2.4)
- ❑ Specific calibration procedures and frequency (see Section 2.2.5)
- ❑ Analytical procedures (see Section 2.2.6)
- ❑ Specific internal QC checks (see Section 2.2.7)
- ❑ Data reduction, validation, and reporting (see Section 2.2.8)
- ❑ Assessment procedures for accuracy, precision, and completeness (see Section 2.2.9)
- ❑ Audit procedures, corrective action, and QA reporting (see Section 2.2.10)

The auditor should also check to ensure the following:

- ❑ Whether correct sampling and analytical methods are specified
- ❑ Whether any exceptions to the analytical procedures described in the methods are noted and justified

Example Situation: During a laboratory audit, Lois meets with the QA/QC manager to discuss a discrepancy between the analytical procedures normally used by the laboratory for the facility and those described in the trial burn QAPP. The trial burn QAPP provides minimal discussion of analytical procedures, simply specifying that "analytical methods are routine and do not require further discussion." However, based on prior experience with waste feed samples from the facility, the laboratory knows that waste feed samples are usually composited and homogenized prior to any analysis. Compositing and ensuring homogeneity are not routine procedures for the analytical methods. These procedures should be clearly described in the trial burn QAPP. If compositing is not completed correctly, the resulting sample will not be representative.

Example Action: Lois advises the laboratory not to prepare or analyze the samples until the discrepancy between the trial burn QAPP and prior laboratory instructions is resolved. If the trial burn QAPP is reviewed before samples are submitted to the laboratory, the auditor should point out the deficiency in the trial burn QAPP to the author so that the correct information can be added (as Lois does in this case). If the trial burn QAPP cannot be revised prior to testing, a memorandum describing the revision to the analytical method should be prepared by the facility or the contractor and supplied to the laboratory so that the laboratory is aware of the correct, modified procedures to be followed before samples prepared and analyzed.

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2.2.1 Organization of Personnel, Responsibilities, and Qualifications

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Section 4.0 of the U.S. EPA Region 6 generic trial burn QAPP presents (1) overall project management, (2) relationships of laboratories to the facility, and (3) lines of authority. Often, the project organizational chart will specify the names and responsibilities of key laboratory personnel. If this information is not provided in the trial burn QAPP (for example, when sampling and analytical contractors have not been selected at the time of trial burn QAPP approval), this information should be obtained from the key contact at the facility or the contractor who is coordinating sampling and analytical activities.

Check For :

- ❑ Relationships between laboratories and facility
- ❑ Lines of authority (which also represent lines of information transfer)
- ❑ Names and responsibilities of key laboratory personnel

Example Situation: In preparing for a laboratory audit, Clark notes that the trial burn QAPP indicates that the laboratory manager also serves as the laboratory QA officer. The trial burn QAPP also indicates that the laboratory is subcontracted by the facility's contractor environmental firm. This information enables Clark to correctly identify who is responsible for laboratory quality and how project requirements are transferred to the laboratory.

Example Comments: The auditor must be assured that the laboratory manager can be objective in implementing of the QC program. For example, the laboratory manager cannot let operating expenses influence the determination to conduct certain QC procedures.

Notes: _____

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2.2.2 Quality Assurance Objectives

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Section 5 of the U.S. EPA Region 6 generic trial burn QAPP states specific precision, accuracy, and completeness objectives for each analysis. These parameters are typically consistent with, or more stringent than, the requirements established in Section 2.1.5 and Table 2-3 of the U.S. EPA 1990 QA/QC Handbook. It is important to review the QA objectives in the approved QAPP before conducting the laboratory audit.

Check For:

- ❑ Whether the audit checklist contains project-specific trial burn QAPP criteria for accuracy and precision (this may be necessary, because project-specific criteria may be different from the criteria stated in the guidance document)

Example Situation: In reviewing the approved QAPP, Clark notes that the trial burn QAPP (see Exhibit 2.2.2-1, page 5-15) states that the accuracy criterion for the matrix spike of 1,2,3-trichlorobenzene (a principal organic hazardous constituent [POHC]) is 50 to 130 percent recovery. However, the laboratory's working QAPP states that the accuracy criterion is 40 to 160 percent recovery. The laboratory QAPP indicates a recovery range that is less stringent than stated in the laboratory's trial burn QAPP.

Example Action: Clark asks that the laboratory change the criterion to agree with the approved trial burn QAPP.

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EXHIBIT 2.2.2-1

EXAMPLE SUMMARY TABLE OF PRECISION AND ACCURACY OBJECTIVES

Parameter	Matrix	QC Procedure	Precision	Accuracy Mean Recovery %
Semivolatile POHC (1,2,3-trichloro-benzene)	Waste Feed (solid or liquid organic waste) Ash	Isotopically labeled POHC* spiked as a surrogate into every sample	<35% RSD	50 - 130% recovery
		Matrix spike with POHC; one sample per matrix	N/A	50 - 130% recovery
		1 duplicate sample analysis per matrix	<35% RSD	N/A
	Stack emissions	Isotopically labeled POHC* spiked as surrogates into each component of the SVOST	<40 RPD (<35 RSD if more than 2)	50 - 150% recovery
		Matrix spike with POHC; one sample train (each component) per trial burn	N/A	50 - 150% recovery
		1 duplicate sample analysis of all components of 1 sample train with highest POHC level	<50 RPD	N/A
Particulate	Stack emission	Balance calibration with 500 mg weight	N/A	(499.5 - 500.4) (± 0.5 mg)
Chlorine	Aqueous waste Sludge Solid wastes Organic liquid wastes Blind unknowns	Duplicate analysis for 1 run	20 20 20 20	N/A N/A N/A N/A 100 ± 10
Hydrogen Chloride	NaOH solution/water NaOH solution/water	Chloride standard in water Duplicate analysis for 1 run	N/A 30	100 ± 15 N/A

EXHIBIT 2.2.2-1 (Continued)

EXAMPLE SUMMARY TABLE OF PRECISION AND ACCURACY OBJECTIVES

Notes:

mg = Milligram
N/A = Not applicable
POHC = Principal organic hazardous constituent
RPD = Relative percent difference
RSD = Relative standard deviation
*Isotopically labeled POHC = ^{13}C-hexachlorobenzene
= $^{13}C_6$-1,2,4,5-tetrachlorobenzene

2.2.3 Sample Monitoring

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Section 6.0 of the U.S. EPA Region 6 generic trial burn QAPP is not intended to repeat the sampling details that are discussed in the TBP, but it should contain a table listing all sampling points, frequency, and total number of samples plus a field QC sample. The auditor can use information from this section to prepare the audit checklist with regard to the expected matrices, number of samples, and frequency of field QC samples (such as field blanks and field duplicates).

A field blank consists of sampling media that are shipped to the field and placed in a sampling train, but with no stack emissions pulled through the train. The field blank components are then recovered with the sampling train and returned to the laboratory for analysis. Field duplicates are duplicate samples taken at the field site: that is, duplicate stack samples taken with a dual probe and dual sampling trains, for example, or duplicate aliquots of the same waste feed sample.

It is important to determine whether the proposed laboratory is capable of analyzing all sample matrices. Some laboratories do not analyze waste samples, and others do not analyze stack gas samples.

It is important to know the number of samples per matrix that the laboratory will analyze so that the auditor can determine whether the laboratory has adequate capacity to manage sample preparation, analysis, and reporting.

Check For:

- ❑ Whether the matrix is recorded on the laboratory audit checklist so that the auditor can determine whether the laboratory can analyze the matrix
- ❑ Whether the approximate number of samples and field duplicates is recorded on the laboratory audit checklist so that the auditor can determine whether the laboratory has the capacity to analyze the number of samples expected within the holding time period

Example Situation: Two laboratories are under contract for analysis: Laboratory A is to analyze stack gas samples, and Laboratory B is to analyze waste feed samples. During the laboratory audit, Laboratory A receives a shipment of samples that contains gallon jars of a dark-colored, viscous material. The QA/QC manager realizes that Laboratory A has received the wrong samples for analysis. The gallon jars of dark-colored, viscous material are waste samples that should be analyzed by Laboratory B. He brings this error to Lois' attention.

Example Action: Lois advises the QA/QC manager that the samples should be exchanged between the two laboratories so that the analysis can be correct. If holding times have expired before the correct samples are obtained, it may be necessary to repeat testing and sampling. Lois documents the situation that has occurred.

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2.2.4 Sample Handling, Traceability, and Holding Times

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Section 7.0 of the U.S. EPA Region 6 generic trial burn QAPP should identify each sample in addition to appropriate holding times for each analysis and any required preservation techniques. All sample handling procedures for the trial burn must be described, including sample labeling, preservation, packing, shipping, laboratory, and field storage procedures. All documentation practices should be described, including field logbooks, sample analysis request forms, laboratory custody logbooks, and field chain-of-custody forms. Sample storage for archive purposes must also be presented.

Check For:

- ❑ Whether the laboratory sample storage requirements and archival requirements in the trial burn QAPP are noted in the laboratory audit checklist
- ❑ Whether a place on the audit checklist is provided to record whether actual laboratory performance on holding times and preservatives is consistent with the approved trial burn QAPP

Example Situation: In reviewing information provided by the facility for the laboratory audit, Clark notes that the trial burn QAPP states that the holding time for volatile organic compounds (VOCs) is 28 days; however, Table 3-1 of the U.S. EPA 1990 QA/QC Handbook states that the holding time is 14 days.

Example Action: During the audit, Clark brings the error to the attention of the laboratory project manager. The project manager agreed with Clark's discovery. He told Clark that the laboratory followed the 14 day holding time. Clark noted the change and requested the laboratory contact the facility before implementing any deviations to the QAPP.

Notes: _____

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2.2.5 Calibration Procedures and Frequency

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Section 8.0 of the U.S. EPA Region 6 generic trial burn QAPP presents calibration procedures and frequencies for each analysis. Because this portion of the manual deals solely with laboratory audit concerns, the auditor should be concerned about only portions of the trial burn QAPP dealing with calibration and frequency for off-site analytical methods. Calibration requirements should be presented in a concise, tabular format and should include (1) analytical method, (2) instrument, (3) frequency of initial and continuing calibrations, (4) acceptance criteria, and (5) corrective action.

Calibration requirements are found in the analytical methods, such as SW-846. Trial burn QAPP calibration requirements should be consistent with, or more stringent than, method requirements.

The laboratory audit checklist should contain calibration frequency, acceptance criteria, and corrective action. The checklist should also include an item regarding the traceability of standards to an U.S. EPA source or other certified standard reference material.

Check For:

- ❑ Whether calibration requirements in the QAPP are consistent with, or more stringent than, method requirements
- ❑ Whether the calibration requirements are included in the laboratory audit checklist
- ❑ Whether the audit checklist includes a place for the QA/QC coordinator to verify that calibration requirements have been met
- ❑ Whether the traceability of standards is included in the laboratory audit checklist
- ❑ Whether the preparation and labeling of calibration standards are included in the laboratory audit checklist
- ❑ Whether corrective actions are identified in the trial burn QAPP if calibrations fail criteria acceptance

Example Situation: In reviewing information provided by the facility for the laboratory audit, Lois notes that the trial burn QAPP states that the calibration requirement of the inductively coupled plasma (ICP) instrument for metals analysis should include at

least four concentrations of standards for each analyte and a blank; however, U.S. EPA Method 6010A states that the calibration should include three standards and a blank.

Example Action: Because trial burn QAPP requirements are more stringent than the method requirements, Lois finds the deviation to be acceptable.

Notes: _____

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2.2.6 Analytical Procedures

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Section 9.0 of the U.S. EPA Region 6 generic trial burn QAPP should not include actual procedures for all analytical tests. Rather, it should summarize methods, the quantitation limit for each analyte, and analytical method references for all analytical tests. It should also detail any modifications to the methods, as referenced. The auditor should have access to the methods to determine the applicability of the method to the sample matrix and QA objectives. A detailed description of the selection of appropriate methods is provided in Section 3.4 of the U.S. EPA 1990 QA/QC Handbook.

Check For:

- ❑ Whether the methods summary includes sample preparation and analytical methods and QC samples and criteria
- ❑ Whether the methods listed in this section are appropriate for the sample matrix, as described in the approved QAPP and method summary in the analytical reference
- ❑ Whether the method chosen is capable of achieving the required quantitation limits for the project as specified in the approved QAPP
- ❑ Whether the laboratory has demonstrated, for audit purposes, that any modifications will enhance the analysis and will meet QC criteria. The audit team should have access to documents that demonstrate test method modification is acceptable (for example, replicate analytical results using the modification method). Section 2.1.9 of the U.S. EPA 1990 QA/QC Handbook clearly indicates that an experienced chemist should make these determinations.

Example Situation: In reviewing information provided by the facility for the laboratory audit, Clark notes that the TBP states that the required reporting limit for lead in the waste feed is 5.0 micrograms per liter, and the analytical method cited in the TBP is U.S. EPA Method 6010A. Although a reporting limit of 5.0 milligrams per liter is achievable for some ICP instruments, Clark determined that the instrument presently used by the laboratory is not capable of quantifying lead at that concentration.

Example Action: Clark asked that the facility either change the cited method to one more suitable to achieving the lower reporting limit (for example, U.S. EPA Method 7421 by graphite furnace atomic absorption technique) or select another laboratory that has the required capability.

Notes: _____

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2.2.7 Internal Quality Control Checks

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Section 10.0 of the U.S. EPA Region 6 generic trial burn QAPP summarizes specific internal QC checks required for each analytical method. A QC objective should be associated with each QC check, as outlined in Section 5.0 of the U.S. EPA Region 6 generic trial burn QAPP, Section 2.2.5 of the U.S. EPA 1990 QA/QC Handbook, and the approved QAPP..

Check For:

- ❑ Whether internal QC checks are listed for each method with the acceptance criteria in the trial burn.
- ❑ Whether internal QC checks and the acceptance criteria for each analytical method are included in the laboratory audit checklist

Example Situation: In reviewing information provided by the facility for the laboratory audit, Lois notes that the matrix spike recovery for chromium by U.S. EPA Method 6010 in the trial burn QAPP is 75 to 125 percent, and the overall accuracy objective as expressed by matrix spike recovery for the project is 50 to 150 percent.

Example Action: Because the method criteria are more stringent than the overall project objective, Lois finds the method criteria to be acceptable.

Notes: _____

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2.2.8 Data Reduction, Data Validation, and Data Reporting

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: For each analytical method, a brief description of the following items are included in Section 11.0 of the U.S. EPA Region 6 generic trial burn QAPP:

- Data reduction scheme for nonroutine methods
- Listing of all final experimental data to be reported in the trial burn report
- Listing of all QC data to be reported in the trial burn report

This information is important to the laboratory auditor, because it will determine the level of reporting that is required of the laboratory. Internal QC results must be evaluated with regard to overall QC objectives for the project (usually referred to as validation). The data should be validated by a qualified environmental chemist.

Check For:

- ❑ Whether the laboratory employs the data reduction scheme for nonroutine methods discussed in the approved QAPP
- ❑ Whether the laboratory lists experimental data in the trial burn report according to the approved QAPP
- ❑ Whether the laboratory plans to list all QC data in the trial burn report according to the approved QAPP
- ❑ Whether the laboratory lists target analytes with reporting limits and correct units for reporting in the trial burn report
- ❑ Whether the laboratory indicates the specific use of blank data

Example Situation: In reviewing information provided by the facility for the laboratory audit, Clark notes that the trial burn QAPP states that blank sample results will be used to correct concentration values for associated sample results. Section 2.1.11 of the U.S. EPA 1990 QA/QC Handbook states that correction of stack gas sample results for blank analysis is not recommended.

Example Action: Clark asks that the facility clarify this issue before samples are collected and analyzed and that the facility notify the laboratory reporting staff of the change.

Notes: _____

2.2.9 Assessment Procedures for Accuracy and Precision

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Accuracy and precision are the assessment criteria used in determining whether data quality meets project objectives (see Section 13 of the U.S. EPA Region 6 generic trial burn QAPP). Accuracy and precision are derived from equations listed in Section 2.1.13 of the U.S. EPA 1990 QA/QC Handbook.

Check For:

- ❑ Whether the laboratory is using the correct equations for accuracy and precision, as listed in the approved QAPP
- ❑ Whether the laboratory correctly identifies each variable in the equations, as listed in the approved QAPP
- ❑ Whether the laboratory is using acceptance criteria as identified in the approved QAPP

Example Section: In reviewing information provided by the facility for the laboratory audit, Lois notes that the laboratory states that the equation for accuracy is as follows:

Percent Recovery = 100 (found)/(amount found + amount spiked)

Example Action: The correct definition of percent recovery, as defined by Section 2.1.13 of the U.S. EPA 1990 QA/QC Handbook, is as follows:

Percent Recovery = 100 (found - native amount)/(amount spiked)

Lois asks that the laboratory correct the equation before samples are collected and analyzed, and that the facility notify the laboratory staff of the change.

Notes: _____

2.2.10 Audit Procedures, Corrective Action, and QA Reporting

Regulations: No regulations are applicable to this section of the manual.

Guidance: U.S. EPA. 1990. "Handbook: QA/QC Procedures for Hazardous Waste Incineration." CERI. Cincinnati, Ohio. U.S. EPA/625/6-89/023. January. Sections 2.1.14, 3.4, and 3.5.

Explanation: Section 14 of the U.S. EPA Region 6 generic trial burn QAPP should specify the requirements of internal audits (performed by the facility or contractors) and external audits (conducted by federal or state environmental agencies or agency contractors). Audits may include the following:

- Systems audit of field and laboratory operations
- Instrument calibration check samples
- Blind spikes (amount known only to auditing agency) of blank semivolatile organic sampling trains with POHC and surrogate POHC
- Submittal of blind calibration check standards for each instrument
- Submittal of blind spikes of the POHC waste feed
- Submittal of U.S. EPA or National Institute for Standards and Testing reference samples for target analytes
- Audits of field records, analytical data, and other project records
- Overall data quality assessment, based on reported QC data

Check For:

- ❑ Whether the laboratory's records indicate that laboratory systems audits have been performed
- ❑ Whether the laboratory audit was conducted by personnel independent from the trial burn team (see Section 2.1.4 of this component for more information regarding selection of the laboratory audit team).
- ❑ Whether the laboratory audit will be conducted while samples from the trial burn are being prepared and analyzed

Example Situation: In reviewing correspondence provided by the facility for the laboratory audit, Clark notes that the trial burn field task leader will conduct the laboratory audit. Section 3.4 of the approved trial burn QAPP states that the laboratory audit will be performed by personnel who are independent from the trial burn team.

Example Action: Clark asks that the facility revise their correspondence to require a person, independent of the project, conduct the audit before samples are analyzed.

Notes: _____

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2.3 SCHEDULING THE AUDIT

Regulations: No regulations are applicable to this section of the manual.

Guidance: U.S. EPA. 1990. "Handbook: QA/QC Procedures for Hazardous Waste Incineration." CERI. Cincinnati, Ohio. U.S. EPA/625/6-89/023. January. Section 3.4.

Explanation: The trial burn audit should be scheduled with each laboratory as soon as the field team has determined the expected sample arrival date at the laboratory. The audit should be performed after the laboratory has received the first samples and begun preparation and analysis. The best time for the audit is when a few samples have been prepared and are being analyzed. This approach allows the auditor to (1) verify the accuracy of tracking documentation, and (2) review current procedures for preparation and analysis before it is too late to correct problems without compromising the project.

Check For:

- ❑ Check frequently with the trial burn project manager regarding the field sampling events
- ❑ Allow at least 2 to 10 days between sampling commencement and the laboratory audit so that samples will be in the laboratory system. If more than 10 days have lapsed from the last sampling date and the laboratory audit, samples will probably have been prepared and in the analytical or reporting stage.
- ❑ Plan to be at the laboratory for 1 full working day, if more than one test method is being used. If the laboratory is analyzing stack gases, waste feed, and ash for both organic and inorganic analyses, increase the plan to 1½ working days. Remember that the complexity and initial findings of the audit may cause the audit to extend for more than 1½ days.
- ❑ Whether all key personnel identified in Section 2.1 of the U.S. EPA 1990 QA/QC Handbook will be available during the tentative audit schedule

Example Situation: When scheduling the laboratory audit, Clark discovers that on the day chosen for the laboratory audit, the laboratory's designated project manager for the trial burn is away for meetings. The tentative scheduled day is only the fourth day after the beginning of sampling.

Example Action: Because it is early in the laboratory process, Clark chooses another day when key personnel are available.

Notes: _____

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2.4 ASSEMBLING THE AUDIT TEAM

Regulations: No regulations are applicable to this section of the manual.

Guidance: U.S. EPA. 1990. "Handbook: QA/QC Procedures for Hazardous Waste Incineration." CERI. Cincinnati, Ohio. U.S. EPA/625/6-89/023. January. Section 3.5.2.

Explanation: The composition of the audit team is very important to the success of the audit effort. A complete team should consist of at least two individuals who are independent of the trial burn team. The audit can be conducted with only one auditor; however, two auditors reduces the possibility of errors or misunderstandings.

At least one of the team members should be an analytical chemist (preferably with direct experience in an environmental laboratory). A nonchemist may be capable of conducting a laboratory systems audit, but the chances of missing subtle, important issues is greater. The team may consist of two chemists with different backgrounds (for example, one organic and one inorganic). Both members should be thoroughly familiar with the project-specific approved QAPP.

Check For:

- ❑ Whether the auditors are independent of the trial burn team
- ❑ Whether at least one of the auditors is an analytical chemist (preferably with direct experience in an environmental laboratory)
- ❑ Whether both auditors have a thorough understanding of the trial burn QAPP

Example Situation: Lois, one of the auditors on the team, is an analytical chemist specializing in instrumental techniques; Clark, the other auditor, specializes in sampling techniques and field sample recovery. Lois finds a problem with the matrix spike being added to a metals analysis scheme after the sample is digested. Clark discovers that volatile organic compounds (VOC) are being scheduled for the same sample as semivolatile organic compounds (SVOC) and the volatiles aliquot is being taken after the semivolatiles aliquot.

Example Action: The expertise of both auditors was needed in this case. Lois recommends that the laboratory conform to the specified metals preparation procedures in the method. Clark recommends that volatile samples be taken first, before the headspace of the waste feed sample has been violated.

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2.5 PREPARING A LABORATORY-SPECIFIC CHECKLIST

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Printed checklists can be used to ensure that all systems have been fully inspected and that all issues have been adequately addressed. Checklists can be tailored to individual trial burn analytical methods and should include sections for each of the items in the "Check For" list that follows. Appendix A, Part Two of the U.S. EPA 1988 RCRA Laboratory Audit Procedures provides an example of a typical laboratory audit checklist. The guidance was designed for the auditing of groundwater monitoring programs; however, the same information is applicable to the trial burn laboratory audit. The example was used to prepare the checklist used by U.S. EPA contractors and is included as Attachment A. The general checklist described here is adequate for use in performing a laboratory audit.

If more detail is required in the general checklist (for example, the auditors are not chemists), additional checklists may be produced for each individual preparation and analysis method that the laboratory uses during the trial burn. Information that must be included in individual method checklists is listed in Item 2 of the "Check For" list that follows, and is also included in each method of the analytical reference (such as U.S. EPA 1996 SW-846).

Check For:

- ❑ Whether the checklist contains a general laboratory practices section, including the following items:
  - ❑ Laboratory address and contacts
  - ❑ QA manual review
  - ❑ Personnel
  - ❑ Laboratory equipment and supplies
  - ❑ Receipt and storage samples
  - ❑ Data handling and reporting
- ❑ Whether each individual analytical method section includes the following topics and whether modifications to methods are being used:
  - ❑ Method number and reference
  - ❑ Sample tracking documentation
  - ❑ Apparatus and materials
  - ❑ Reagents and standards
  - ❑ Procedures (for preparation and cleanup methods, list the steps for performing the procedure; for analysis, include instrument setup and calibration and procedures for analyzing samples)

- ❑ QC requirements (list required QC with acceptance criteria and corrective action requirements)

- ❑ Whether the person is preparing individual method checklists is a chemist with experience in an environmental laboratory

- ❑ If the requirements of the trial burn QAPP and the referenced analytical method differ, whether the approved trial burn QAPP requirements are used

Example Situation: Attachment A includes examples of general and individual method checklists. In creating the laboratory audit checklists, Lois plans to include specific information regarding chromium analysis in waste feed, conducted by Method 6010 and refers to U.S. EPA 1996 Test Methods for Evaluating Solid Wastes: Laboratory Manual, Physical/Chemical Methods (SW-846) Method 6010. Each section of Method 6010 describes the requirements and will contain the information listed in Item 2 of the "Check For" list.

Example Comments: Lois and Clark must decide whether the laboratory checklist should contain detailed method-specific sections based on past experience with the laboratory, past audit records of the laboratory, and their familiarity with the methods being reviewed.

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3.0 CONDUCTING THE AUDIT

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The following sections describe each of the on-site audit activities on the basis of information in guidance documents and actual experience of environmental QA chemists.

Check For: While conducting laboratory audits, auditors should conduct the following tasks:

- ❑ Pre-audit briefing (Section 3.1)
- ❑ Laboratory facility walkthrough (Section 3.2)
- ❑ Checklist completion (Section 3.3)
- ❑ Post-audit debriefing (Section 3.4)

The auditors should also conduct the following activities:

- ❑ Whether the laboratory audit date has been confirmed with the laboratory
- ❑ Whether applicable laboratory checklists are available for the auditors
- ❑ Whether key laboratory personnel will be available on the day of the audit
- ❑ Whether the auditors have verified that samples from the trial burn have been received by the laboratory and are being prepared and analyzed

Example Situation: In preparing for the laboratory audit, Clark—a nonchemist—completes the review checklist to ensure that he is ready to begin the on-site audit.

Example Action: Clark notes that he has collected information regarding each of the preceding topics. With his partner Lois—an experienced environmental QA chemist with first-hand laboratory audit experience—and this manual for information, Clark makes final preparations to travel to the first laboratory.

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3.1 CONDUCTING THE PRE-AUDIT BRIEFING

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Upon arrival at the laboratory, the audit team should conduct the pre-audit laboratory briefing to:

- Introduce key laboratory personnel to the audit team
- State the purpose of the audit
- Describe the scope of the audit
- Answer questions or address issues that laboratory personnel have already encountered or expect to encounter during sample analysis

The following subsections describe each of the pre-audit laboratory briefing activities.

Check For:

- ❑ Whether key laboratory personnel are present for the briefing (Section 3.1.1)
- ❑ Whether the auditors know the purpose and scope of the audit (Sections 3.1.2 and 3.1.3)
- ❑ Whether the auditors are ready to present trial burn QAPP changes, if any, to the laboratory (Section 3.1.4)
- ❑ Whether any unusual circumstances are expected surrounding the sample analysis (Section 3.1.4)

Example Situation: Upon arrival at the laboratory, the manager immediately escorts Lois and Clark to the sample receiving area for the laboratory walkthrough.

Example Action: Lois and Clark should provide the laboratory key person with an audit agenda as soon as they arrive; that way, the key person will know that the pre-audit briefing is conducted prior to the laboratory walkthrough. Because the pre-audit laboratory briefing is very important, Lois and Clark should insist that a conference room be secured for the briefing.

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3.1.1 Introducing Key Personnel

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The first purpose of the briefing is to introduce the audit team to all key laboratory personnel. If possible, all key laboratory personnel, identified in the general laboratory information (see Section 2.2.1 of this Component), should attend the briefing. Each person should indicate name, title, and overall responsibilities with regard to trial burn samples.

Laboratory division managers (inorganic and organic) are often unavailable during the briefing because of their operational duties. In such cases, another laboratory manager present at the briefing should be delegated the responsibility for disseminating information to other laboratory managers. Auditors do not intend to inhibit the normal working activity of the laboratory, and they should try to accommodate, within reason, the busy schedules of laboratory management.

Check For:

- ❑ Whether all key laboratory personnel are available
- ❑ Whether all key laboratory personnel clearly understand the nature of trial burn samples and their analysis
- ❑ Whether all key laboratory personnel clearly understand their individual responsibilities with regard to these trial burn analyses

Example Situation: During the introduction of personnel and responsibilities, Lois notes that the person primarily responsible for implementing QC efforts is not present at the briefing.

Example Action: Identify the personnel responsible for implementing the QC program and request their presence at the briefing. If the person is not immediately available, schedule a time during the audit to meet with the person (as Lois does in this case).

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3.1.2 Stating the Purpose of the Audit

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Section 3.1 of this manual lists audit purposes, which should be stated in the pre-audit briefing.

Check For:

- ❑ Whether key laboratory personnel clearly understand the purpose of the audit after the auditors have explained it to them

Example Situation: Laboratories are constantly audited by personnel from regulatory agencies and local clients and each audit has a different purpose. Regulatory agencies often audit for compliance with regulations and require a stringent review of systems and documentation. Client audits are often less rigorous and may require only a laboratory tour. Lois and Clark arrive at the laboratory and conduct a pre-audit briefing. If the purpose is not stated, the laboratory does not know how to respond to questions or how much documentation to have available for review.

Example Action: In the pre-audit briefing, Lois and Clark state that the audit is in support of U.S. EPA's trial burn oversight. To demonstrate compliance with applicable regulations and method procedures, the laboratory should be prepared to provide the full extent of documentation of sample receipt, preparation, analysis, and reporting.

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3.1.3 Describing the Scope of the Audit

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: It is important to describe the scope of the audits by specifying the areas of the laboratory facility that will be audited. The audit should be tailored to review only areas that will directly participate in the receipt, storage, preparation, and analysis of trial burn samples. In addition, areas of data reporting and sample disposal should be reviewed. The relationship of the laboratory to the trial burn facility should be discussed. The order in which areas of the laboratory will be reviewed should be discussed. If the laboratory is small (less than 20 personnel), the areas listed in Section 3.2 of this component, rather than being separate locations in the laboratory, may overlap. Typically, the audit starts at the point at which samples are received by the laboratory and follows through each area of processing, ending with the data reporting section.

Check For:

- ❑ Whether key laboratory personnel are aware of laboratory areas that will be handling trial burn samples
- ❑ Whether each area reviewed has an analyst or supervisor present to discuss the particular area
- ❑ Whether key laboratory personnel understand their relationship with the facility with regard to information transfer
- ❑ Whether auditors and laboratory personnel have selected a route to follow to cover all required areas

Example Situation: During the laboratory walkthrough, Lois and Clark discover that the audited laboratory has two senior staff members (a general manager and an operations manager) and five analysts that are located in a small section (three large rooms, plus offices) of a larger facility building. Samples are received directly into the sample preparation area (which includes inorganic and organic preparations), because it is located at the back entrance. One of the laboratory analysts is the acting sample custodian. The facility clearly has neither (1) separate, partitioned rooms for the areas listed in Section 3.2 of this component, or (2) dedicated staff members for each of the job descriptions listed in Section 2.1.1.2. of this component. The laboratory arrangement is not critical unless the actual area in which samples are received contains (1) solvent fumes (detectable by smell), (2) opened containers of waste samples (samples that are potentially contaminated heavily with organics and metals), or (3) rusty hoods that may contribute to metals contamination when new samples are opened; Lois and Clark do not observe any of these items.

Example Action: A laboratory analyst may act as the sample custodian if the responsibilities of each role are fully understood. In a small laboratory (staff of 15 to 20), it is not at all unusual for personnel to serve multiple functions. If multiple functions are served, it is essential that the audit team verify that:

- Laboratory staff have received adequate training for multiple functions
- Laboratory training records completely document staff training and are up-to-date and comprehensive
- The laboratory QA officer is, and remains, organizationally independent of analysis and data generation or (if the QA officer serves as a backup analyst in one or more areas) that an alternative QA review is obtained by another senior staff organizationally independent of the analysis area

Lois and Clark verify that the laboratory analyst has also received sample custodian training.

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3.1.4 Answering Questions and Addressing Issues From Laboratory Personnel

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: To ensure a complete understanding of the project scope, it is important to allow laboratory personnel to ask questions about the trial burn. Questions may concern a variety of subjects including (1) field sampling schedules, (2) changes in the number of samples taken, (3) sample condition upon receipt, and (4) discrepancies in sample receipt documentation. During the briefing, actions items—and the responsible personnel—should be identified.

Check For:

- ❑ Whether key laboratory personnel understand their roles in the trial burn
- ❑ Whether action items—and the responsible personnel—are identified
- ❑ Whether any action items require immediate attention that may compromise data

Example Situation: During a laboratory audit, Clark discovers that the number of samples received significantly exceeds the initial estimate in the trial burn QAPP. Clark is concerned that the increased sample load may overload the laboratory system, thereby causing the holding time to be exceeded and ultimately compromising data quality.

Example Action: Such issues are major and should be addressed immediately. Clark arranges a conference call with the facility trial burn manager and the laboratory QA manager to resolve the issue.

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3.2 CONDUCTING THE WALKTHROUGH

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: As discussed in Section 3.1.3, of this component, a walkthrough route should be selected during the briefing.

Check For:

- ❑ Whether the walkthrough route was determined during the briefing
- ❑ Whether the checklist covers all areas reviewed during the audit
- ❑ Whether the laboratory offers safety protection for areas requiring eye protection
- ❑ Whether safety concerns are addressed: (1) gas cylinders are restrained, (2) adequate hoods are available and are being used appropriately to transfer solvents, prepare aliquots of samples, or perform sample digests, (3) analysts are using safety glasses or other eye protection, and
  (4) appropriately labeled containers for waste disposal are available in the lab
- ❑ Whether laboratory housekeeping issues are addressed: (1) work areas are neat and uncluttered, (2) instruments are being operated under appropriate temperature control conditions, (3) laboratory functions are appropriately isolated, and (4) walkways are free of obstructions and clutter

The most logical route through the laboratory is as follows:

- ❑ Sample receiving, storage, and custody area (Section 3.2.1)
- ❑ Organic sample preparation laboratory (Section 3.2.2)
- ❑ Organic analytical laboratory (Section 3.2.3)
- ❑ Inorganic sample preparation laboratory (Section 3.2.4)
- ❑ Inorganic analytical laboratory (Section 3.2.5)
- ❑ Physical chemistry laboratory (Section 3.2.6)
- ❑ Data reduction and reporting area (Section 3.2.7)

- ❑ Sample archival and disposal point (Section 3.2.8)

Example Situation: From past audit experience, Lois has learned that unless the facility is contained in multiple buildings, the laboratory should accommodate the route described in "Explanation." Laboratories sometimes are scattered in different buildings, and the logistics of moving from one area to another in the prescribed order is difficult.

Example Comments: Lois has also learned that the order of the laboratory walkthrough may be influenced by the times at which key personnel can be available to discuss laboratory operations and work flow. The order may be changed, provided that all pertinent areas are covered.

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3.2.1 Sample Receiving, Storage, and Custody Area

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Section V of the example checklist provided in Attachment A of this component covers the requirements for trial burn sample receipt, storage, and custody. The checklist provides detailed questions that must be answered during the review of this area of the laboratory. The sample receiving area and refrigeration systems should be neat and orderly. There should be no broken or leaking sample containers exposed or solvent containers opened. The area should have ventilation hoods for opening sample shipping containers.

Check For:

- ❑ Whether the sample entry point of the laboratory is secure (for example, whether the exterior door has controlled access)
- ❑ Whether the sample custodian is present and able to answer the questions on the checklist
- ❑ Whether samples are entered into the laboratory master log immediately upon receipt. If the laboratory master log is a manual system, good practices for laboratory notebooks are followed in making the sample entries: (1) entries are made legibly, in black ink; (2) entries are signed or initialed and dated; (3) entry errors are corrected properly -- single line strike-through that does not obscure original data entry, with signature, date, and explanation for the correction
- ❑ Whether trial burn samples have been entered into the laboratory system and the documentation has been reviewed
- ❑ How the laboratory work request is generated (for example, how do analysts find out that samples have been received and that specific analyses must be performed). If the sample custodian is responsible for generation of the work request documentation for each laboratory, the sample custodian knows which analyses are to be performed. When laboratory work requests have been generated, they are reviewed to ensure that correct analyses have been requested.
- ❑ Whether the sample custodian can direct the auditor to the sample based on the sample receipt and storage documentation generated by the laboratory. The laboratory tracks the sample movement through the laboratory (for example, when an analyst takes a sample out of storage to remove an aliquot, this information is recorded).

- ❑ Whether the sample receiving area is neat and apparently contaminant-free
- ❑ Whether samples are labeled adequately for identification: (1) labels are clear and unambiguous and (2) each sample is assigned a unique laboratory identifier that is associated with that sample throughout the laboratory
- ❑ Whether storage refrigerators are operating within required temperature limits and documented daily
- ❑ Whether volatile organic sampling train samples are stored in a refrigerator separate from solvents, standards, or reagents

Sample storage refrigerators with identification numbers and temperature records

Example Situation: Each laboratory has a unique tracking and documentation system. During an audit, the sample custodian instructs Clark about internal laboratory documentation. One of Clark's checklist items asks whether volatile samples are stored separately from nonvolatile or semivolatile samples. Using chain-of-custody records and documentation prepared by the laboratory, Clark locates an individual sample container to determine whether it is a volatile sample and whether it is stored in a refrigerated area with only volatile samples. Clark discovers that volatile samples are stored in the same refrigerator as nonvolatile samples.

Example Actions: Clark completes the checklist by placing an "X" in the "NO" column and enters his observation in the "Comment" column. Clark discusses the noncompliance with the sample custodian and the QC manager.

Notes: _____

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3.2.2 Organic Sample Preparation Laboratory

Regulations: No regulations are applicable to this section of the Manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Organic sample preparation methods are found in SW-846 Volume 1B (3000 series methods for organic analytes), Section 4.2 (Sample Preparation Methods). Sample preparation and sample cleanup methods are separate (in most cases) from the analytical methods. However, sample preparation methods (and cleanup methods, if applicable) are a part of the complete analytical method for a particular analyte. Individual checklists prepared for each preparation method will describe the requirements to be reviewed.

The following activities are performed by the organic sample preparation laboratory, and each should be accompanied by completed documentation (see "Check For" section).

- Receiving the sample from the laboratory sample custodian or from sample storage
- Weighing or measuring aliquots of the sample matrix for preparation
- Preparing reagents, surrogate compounds, and standards
- Adding required spiking compounds or surrogate compounds as required by the method
- Performing required extractions/concentrations on sample matrices
- Placing the extract in the correct container with proper identification
- Secondary review of documentation by a supervisor or peer

Check For:

- ❑ Whether the laboratory documents sample transfer from storage to the appropriate person for preparation
- ❑ Whether the laboratory has standard operating procedures (SOP) that correspond to the analytical methods being audited. Whether the SOPs are available in the laboratory and are in use for trial burn samples

- ❑ Whether the laboratory has logbooks or datasheets to document the weighing or measuring of the sample matrix
- ❑ Whether the sample preparation logbook or data sheet indicates that the correct amount of sample was measured according to the preparation method
- ❑ Whether the laboratory has a reagent or standard preparation logbook that documents reagent and standard sources, solution preparation, preparation date, expiration date, and preparer's initials
- ❑ Whether the laboratory maintains maintenance and calibration logbooks for instruments
- ❑ Whether the laboratory logbook or datasheet indicates to which samples spiking compounds or surrogate compounds have been added, the concentration, and stock solution reference for traceability
- ❑ Whether the laboratory logbook or datasheet indicates which and in what quantity reagents are added to each sample
- ❑ Whether the laboratory uses clearly labeled containers to hold the extracts and concentrates
- ❑ Whether the laboratory logbook or datasheet indicates secondary review of the work

Example Situation: The trial burn QAPP requires that U.S. EPA Method 3542 be used for preparation of samples generated by U.S. EPA Method 0010; this method requires separate extraction of each of the sampling train components and concentration of each extract to a final volume of 5 milliliter (mL). The audited laboratory, however, usually combines all three of the fractions and concentrates the extract to a final volume of 1 mL to enhance method detection limits. Lois determines that the combination of the extracts represents a deviation from the accepted method.

Example Action: Because this method deviates from the one specified in the trial burn QAPP, Lois discusses the potential impact of the modification with laboratory personnel. This procedure should be thoroughly described in the approved trial burn QAPP if the laboratory is expected to follow the modified method. If the modification results in a negative effect (for example, the detection limits become higher than the required limits), then the modification should be immediately stopped. If the modification results in a positive effect (for example, the detection limits become lower than the required limits), then the effect should be noted in the comment section of the checklist and audit report.

Notes: _____

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3.2.3 Organic Analytical Laboratory

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Organic analytical methods are found in U. S. EPA 1996 SW-846 Volume 1B (8000 series methods for organic analytes). Organic analytical methods are separate (in most cases) from preparation methods. However, the organic analytical methods are a part of the whole method for the particular analyte or set of analytes. Individual checklists are available for each analytical method that describe the requirements to be reviewed.

Organic analytes may be volatile (boiling point $\leq 100^{\circ}C$), and the analytical methodology for the two classes of organic analytes is different. For volatile organic analytes, the analytical methodology applied will be either purge and trap (for example, U.S. EPA Method 8260) or thermal desorption from a sorbent (for example, the VOST coupled with either gas chromatography or gas chromatography/mass spectrometry (GC/MS). Analytical instrumentation for performing VOC analysis is usually isolated from the organic preparation laboratory and other instrumentation for performing SVOC analysis to avoid contamination by organic solvents that are in common use in these areas. For SVOC analytes, the analytical methodology applied will involve injection of a liquid solution (typically an extract of water, wastewater, sludge, or sorbent or a dilution of a waste feed sample) into a gas chromatograph or a GC/MS.

Although each of the individual organic analytical methods has separate requirements, the following routine activities are performed by the organic analytical laboratory for most methods, and each should be accompanied by completed documentation (see "Check For" section).

- Receiving the sample, extract, or concentrate from the organic preparation laboratory, the sample custodian, or sample storage, as appropriate for the individual sample
- Preparing reagents and standards
- Setting up and calibrating instrumentation
- Determining method detection limits for each analyte
- Analyzing multipoint calibration samples, calibration check samples, and blanks

- Analyzing other QC check samples required by the analytical method
- Reducing bench-level data
- Evaluating bench-level data
- Performing a secondary review of documentation by a supervisor or peer

Check For:

- ❑ Whether the laboratory documents sample transfer from the preparation laboratory or from sample custody to the appropriate analyst
- ❑ Whether the laboratory has appropriate storage for standards (for example, standards are stored separately from samples and volatile standards are stored separately from samples and from semivolatile standards or samples)
- ❑ Whether the laboratory has a reagent or standard preparation logbook or datasheet that documents the preparation methodology for reagents and standards, the preparation date, the expiration date, preparer's signature or initials, and the source of the material for traceability. The preparation of reagents and standards may be included in the preparation laboratory logbooks or datasheets.
- ❑ Whether (1) the laboratory has SOPs for the methods being audited, (2) the SOPs are available in the laboratory, and (3) the SOPs are in use for the methods being audited
- ❑ Whether instruments are set up and calibrated correctly for the methods being audited. Calibration data receive both primary and secondary review before a calibration curve is used.
- ❑ Whether the laboratory has instrument maintenance logs to document any maintenance activities for analytical instrumentation and whether these logs are accurate, up-to-date, and signed
- ❑ Whether the laboratory has method detection limits for each analyte that is less than or equal to reporting requirements in the trial burn QAPP for each matrix analyzed
- ❑ Whether the laboratory analyzes QC samples required by the method at the proper frequency, and whether analytical results meet method acceptance criteria

- ❑ Whether the laboratory has internal QC acceptance criteria by which to evaluate QC sample results (for example, control charts are accurate and current)

- ❑ Whether the laboratory QC acceptance criteria for each QC sample type is consistent with, or more stringent than, project trial burn QAPP requirements

- ❑ Whether the laboratory analyst reduces the data at the bench to the final reporting units. If not, who is responsible for generating the final reporting units for each measurement?

- ❑ Whether the laboratory analyst, QA officer, or supervisor reviews all QC data and determines data acceptability relative to the method and/or trial burn QAPP acceptance criteria. Which procedure does the laboratory follow for QC data that fails to meet acceptance criteria?

- ❑ Whether data are reviewed by a peer or supervisor or QA officer before submission to the data reporting section of the laboratory

- ❑ At what stage of the analysis/reporting process is the data set reviewed for completeness?

- ❑ Whether sample holding times are tracked in the laboratory to ensure that all samples are prepared/analyzed within holding times

- ❑ Whether a logbook for sample analysis is maintained daily and signed by the analyst

GC/MS for Volatile Organic Analysis with Purge and Trap Apparatus

Example Situation: One requirement for VOC analysis by GC/MS is the daily analysis of a calibration check sample that must meet method acceptance criteria before sample analysis is performed. Acceptance criteria for calibration check samples are available in the U.S. EPA 1996 SW-846 method, the laboratory SOP, the trial burn QAPP, and the method-specific laboratory checklist. The correct calibration procedure must be immediately implemented. During the audit, Clark verifies that calibration check samples are taken and analyzed daily in method accordance criteria.

GC/MS for Semivolatile Organic Analysis with Autosampler

Example Action: If the laboratory fails to perform the required calibration check or if the calibration check fails to meet acceptance criteria but samples are analyzed, these items should be noted in the laboratory checklist.

Notes: _____

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3.2.4 Inorganic Sample Preparation Laboratory

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Inorganic sample preparation methods are in U.S. EPA 1996 SW-846 Volumes 1A (3000 series methods for metals) and 1C (9000 series methods for nonmetals) (U.S. EPA 1994). Most of the metals preparation methods are separate from analytical methods; however, nonmetals preparation methods are included in the overall analytical method for the particular analyte. Individual checklists prepared for each preparation method will describe the requirements to be reviewed.

The inorganic preparation laboratory performs the following activities, each of which should be completely documented (see "Check For" section).

- Receiving the sample from the laboratory sample custodian
- Receiving the laboratory work request
- Weighing aliquots of the sample matrix for preparation
- Preparing reagents and standards
- Adding required spiking compounds, when required by the method
- Performing acid digestions or distillations on sample matrices
- Containerizing the digest or distillate with proper identification
- Performing a secondary review of documentation by supervisor or peer

Check For:

- ❑ Whether the laboratory documents sample transfer from storage to the appropriate person for preparation
- ❑ Whether the laboratory has SOPs that correspond to the analytical methods being audited
- ❑ Whether the laboratory has logbooks to document the weighing of the sample matrix

- ❑ Whether the preparation logbook indicates that the correct amount of sample was measured, in accordance with the preparation method
- ❑ Whether the laboratory has a reagent or standard preparation logbook that documents reagents and standards recipes, last preparation date, and preparer's initials
- ❑ Whether the laboratory logbook indicates the samples to which spiking compounds have been added and the concentration
- ❑ Whether the laboratory logbook indicates the reagents that are added to each sample and the amount
- ❑ Whether the laboratory uses clearly labeled containers to hold digests and distillates
- ❑ Whether the laboratory logbook reflects a secondary review of the work
- ❑ Whether instrument calibration logbooks are maintained

Example Situation: One requirement for the digestion of samples for metals analysis is the addition of nitric acid to the sample. This information is available in both U.S. EPA 1996 SW-846 and the laboratory checklist. During an audit, Lois discovers that the laboratory uses sulfuric acid instead of nitric acid for this procedure, which is a deviation from the method.

Example Action: If the auditor is not experienced enough to determine the acceptability of this modification, an experienced inorganic chemist should be consulted immediately. The chemist should determine that the use of sulfuric acid may produce an unacceptable result, because sulfate compounds of many metals are less soluble than their nitrate form. Lois advises the laboratory QC manager that the procedure should be immediately corrected; she also notes the problem on the checklist and in the audit report.

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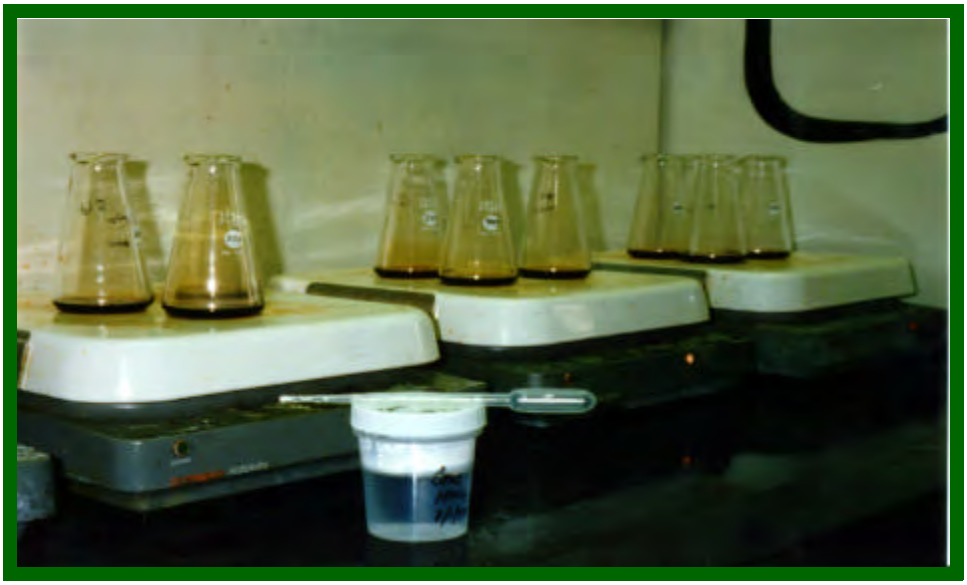

Acid digestion hood associated with inorganic sample preparation

3.2.5 Inorganic Analytical Laboratory

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Inorganic analytical methods are in U.S. EPA 1996 SW-846, Volumes 1A (Method 6010A and 7000 series methods for metals) and 1C (9000 series methods for nonmetals). Most of the metals analytical methods are separate from preparation methods; however, nonmetals analytical methods are included in the overall method for the particular analyte. Individual checklists are available for each analytical method that will describe the requirements to be reviewed.

Although each of the individual analytical methods has separate requirements, the inorganic analytical laboratory performs the following routine activities for most methods. Each activity should be completely documented (see "Check For" section).

- Receiving the sample digest or distillate from the inorganic preparation laboratory
- Receiving a laboratory work request from the sample custodian or other source
- Preparing reagents and standards
- Setting up and calibrating instrumentation
- Obtaining method detection limits for each analyte
- Analyzing calibration checks and blanks
- Analyzing other method-required QC samples
- Reducing bench-level data
- Evaluating bench-level data
- Performing a secondary review of documentation by a supervisor or peer

Check For:

- ❑ Whether the laboratory documents the sample digest or distillate transfer from the preparation laboratory to the appropriate person for analysis
- ❑ Whether the laboratory receives a work request prior to sample receipt
- ❑ Whether the laboratory has a reagent or standard preparation logbook that documents reagents and standards recipes, last preparation date, and the preparer's initials (may be incorporated into preparation laboratory logbooks)
- ❑ Whether working standards can be traced to certified stock standards
- ❑ Whether sample analysis logbooks are maintained and signed by analysts
- ❑ Whether the laboratory has SOPs for the analytical methods being audited
- ❑ Whether these SOPs are accessible and are being used in the laboratory
- ❑ Whether the instrumentation is set up and calibrated in accordance with the methods being audited
- ❑ Whether the laboratory has method detection limits for each analyte that are less than, or equal to, the reporting requirements established in the trial burn QAPP for each matrix for which analysis is conducted
- ❑ Whether the laboratory analyzes the method-required QC samples at the proper frequency
- ❑ Whether the laboratory has QC acceptance criteria to use in evaluating QC sample results
- ❑ Whether laboratory QC acceptance criteria for each QC sample type are consistent with, or more stringent than, trial burn QAPP requirements
- ❑ Whether the laboratory analyst reduces data at the bench to the units and reporting limits described in Attachment A (if not, find out who is responsible for this task)
- ❑ Whether the laboratory analyst, QC officer, or supervisor reviews all QC data and determines its acceptability on the basis of acceptance criteria
- ❑ Whether data are reviewed by a peer or supervisor before submittal to the data reporting section of the laboratory

Example Situation: One requirement for the analysis of metals by ICP in accordance with Method 6010A is that an initial calibration verification sample be analyzed following calibration, and that a calibration verification sample be analyzed for 1 of every 10 samples. This information is available in U.S. EPA 1996 SW-846 and the laboratory checklist. During the audit, Clark discovers that the laboratory analyzes calibration verification samples for 1 of every 20 samples.

Example Action: Clark advises the laboratory QC manager that the procedure should be immediately corrected; he also notes the deviation on the checklist and in the audit report.

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Mercury analysis

Inductively coupled argon plasma emission spectrometer

Atomic absorption spectrometer

3.2.6 Physical Parameter Laboratory

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Methods for the determination of physical parameters (for example, British thermal unit [Btu], chloride content, oil and grease content, ignitability, sulfur content, density, ash, and moisture content) are found in SW-846 for some of the parameters and in the ASTM series of methods. The methods as written incorporate both sample handling and analysis. Individual checklists are available for each analytical method that describe the requirements to be reviewed.

Each of the individual analytical methods has separate requirements and, in the typical laboratory that performs the determination of waste fuel physical parameters, physical parameter determination is usually performed in a laboratory area removed from the location of inorganic and organic analytical instrumentation.

The following routine activities are conducted by the physical parameter determination laboratory for most of the methods used, and each should be accompanied by completed documentation (see "Check For" section).

- Receiving the sample from the laboratory sample custodian or from sample storage
- Receiving a work request in the laboratory to ensure that the staff understands which analysis should be performed
- Weighing and measuring aliquots of the sample matrix for preparation; preparing composites of waste fuel matrices sampled throughout the duration of a sampling run; homogenizing waste fuel samples prior to removing an aliquot for analysis, and diluting the waste fuel matrix for organic analysis
- Preparing the reagents, surrogate compounds, and standards
- Adding the required spiking compounds or surrogate compounds, as required by the method
- Performing required dilutions on homogenized waste fuel matrix
- Placing the sample in the correct container with proper identification

- Performing a secondary review of documentation by a supervisor or peer

Check For:

- ❑ Whether the laboratory documents sample transfer from storage to the appropriate person for preparation and analysis and whether extremely viscous waste fuels are stored appropriately under ambient conditions with restricted access
- ❑ Whether (1) the laboratory has SOPs that correspond to the analytical methods being audited; (2) the SOPs are available in the laboratory, and (3) the SOPs are in use for trial burn samples
- ❑ Whether the laboratory has logbooks or datasheets to document the sample matrix compositing, aliquoting, weighing, or measuring
- ❑ Whether the laboratory has appropriate facilities for safe handling of large quantities of waste fuel. If heating of extremely viscous waste fuel samples is required before a composite can be prepared, the matrices are heated safely in a hood
- ❑ Whether the sample preparation logbook or datasheet indicates that the correct sample amount was measured according to the preparation method
- ❑ Whether (1) the laboratory has instrument run logs and instrument maintenance and calibration logs for each of the analytical instruments in use; (2) these logs are maintained according to good laboratory practice for maintaining a notebook; and (3) the logs are current
- ❑ Whether the laboratory has a reagent or standard preparation logbook that documents reagents and standards sources, solution preparation, preparation date, expiration date, and the preparer's initials
- ❑ Whether the laboratory logbook or datasheet indicates to which samples spiking compounds or surrogate compounds have been added and the concentration
- ❑ Whether the laboratory logbook or datasheet indicates which and in what quantity reagents are added to each sample
- ❑ Whether the laboratory uses clearly labeled containers to hold samples
- ❑ Whether the laboratory logbook or datasheet indicates secondary review of the work

Example Situation: Waste fuel samples must be diluted, often by a factor of 1,000 or more, to perform a qualitative VOC analysis without saturating analytical instrumentation and to bring the analytes that are present into an appropriate range for the calibration curve. While performing an audit, Lois notes that a 1,000-fold dilution of a composited waste fuel yields a chromatographic peak for benzene that is still saturated.

Example Action: No meaningful analytical results can be reported on the basis of saturated chromatographic peaks. To obtain meaningful analytical results for the waste fuel composite, solvent blanks must be analyzed on the analytical instrument until the absence of benzene carryover is demonstrated. Lois discusses this issue with the laboratory QC manager and advises that the laboratory personnel dilute a composited waste fuel sample to an appropriate level (for example, 10,000-fold) and analyze it to obtain quantitative values for benzene.

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BTU calorimeter

BTU Parr bombs

3.2.7 Data Reduction and Reporting Procedures

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Data reduction and reporting procedures are in U.S. EPA 1996 SW-846, Chapter One, Section 4.4.6 (Data Handling). The section of the laboratory responsible for gathering all analytical, sampling, and QC data should report the limits specified in the trial burn QAPP; and assemble the data package deliverable.

Supporting documentation should include, at a minimum, the following items:

- Laboratory name and address
- Sample information (including unique sample identification, sample collection date and time, sample receipt date, and sample preparation and analysis dates)
- Complete field and laboratory chain-of-custody records
- Analytical results reported with an appropriate number of significant figures
- Detection limits that reflect dilutions, interferences, or correction for equivalent dry weight
- Method reference
- Appropriate QC results for each batch of samples included in the report
- Data qualifiers with appropriate references
- Written narrative about the quality of the results

Check For:

- ❑ Whether the laboratory report contains the preceding information
- ❑ Whether the laboratory uses computer-aided reporting
- ❑ Whether computer software programs for data reduction are periodically verified with hand-calculated results
- ❑ Whether a manager or other senior laboratory staff member writes the case narrative

- ❑ Whether the case narrative provides information regarding any QC check that does not meet acceptance criteria established in the trial burn QAPP

- ❑ Whether the entire data package is reviewed by a manager or other senior laboratory staff member before submittal to the client.

Example Situation: During an audit, Lois discovers that all chloride results are hand-entered into the laboratory information management system by a nontechnical clerk and that following entry, the data are reported without a secondary review by a technical staff member.

Example Action: Lois notes in the checklist and the audit report that data are reported without a secondary technical review; she also advises the laboratory QC manager that this practice should be immediately addressed.

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3.2.8 Archival and Disposal of Samples

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Sample archival is important in the event that the facility, based on initial reported results, needs follow-up or different analyses. Because every laboratory has its own SOPs for archival and sample disposal, the requirements for each laboratory being audited should be noted. Some laboratories require that the unused sample be shipped back to the sampling source.

Check For:

- ❑ Whether the laboratory has a standard procedure for archival and disposal of samples (note the requirement for each laboratory.)
- ❑ Whether the laboratory requires that the sample be sent back to the source
- ❑ Whether the laboratory has a contractor available to dispose of unused samples in accordance with applicable state and federal regulations
- ❑ Whether the laboratory keeps records of sample disposal
- ❑ Whether the laboratory retains samples for a specified period of time under appropriate storage conditions (for example, refrigerated or ambient)
- ❑ Whether the laboratory will make special provisions if the facility wants the samples archived (1) longer than the standard time, or (2) under nonstandard conditions

Example Situation: During an audit, Clark notes that the reported result for chlorine in the waste feed is 10 times greater than the results expected on the basis of prior analyses, and he questions the current laboratory findings. Clark discusses the possibility of reanalysis with the laboratory QC manager.

Example Action: If the sample matrix (waste feed) is still available for analysis in the laboratory, the facility may request a reanalysis. Most laboratories do not keep field samples for more than 30 days after the report is submitted, and the sample is not always kept in cold storage. Sample availability and condition, upon request for reanalysis, may determine whether reanalysis is feasible. Clark locates the sample in question in archival, reviews its storage condition, evaluates the holding time that has elapsed, and determines that reanalysis is feasible and will produce valid results. He indicates to both the facility trial burn manager and the laboratory QC manager that sample reanalysis is advisable.

Notes:

3.3 COMPLETING THE AUDIT CHECKLIST

Regulations: No regulations are applicable to this section of the manual

Guidance: No specific references are applicable to this section of the manual.

Explanation: As stated in Section 2.5 of this component, the use of printed checklists ensures that all systems are fully inspected and that all issues have been adequately addressed. It is important that the audit team complete the checklist by hand before leaving the laboratory. This practice ensures that, if the auditors have omitted any items, the laboratory can respond before the auditors leave. Completing the checklist also enables the auditors to discuss deficiencies or discrepancies noted before leaving the laboratory.

Check For:

- ❑ Whether the auditors have completed all checklist sections (Section 3.3.1)
- ❑ Whether the auditors failed to see any part of the laboratory system that affects project sample analysis (Section 3.3.2)
- ❑ Whether the auditors failed to obtain any information from the laboratory concerning any issue (Section 3.3.2)
- ❑ Whether the auditors noted any deficiencies or discrepancies that require resolution (Sections 3.3.3 and 3.3.4)

Example Situation: When the audit team begins to prepare the audit report, they discover that they did not record on the checklist the name or telephone number of the laboratory QC officer. Lois and Clark need clarification on a particular issue that requires contact with the laboratory QC officer.

Example Action: Lois calls the laboratory to identify the QC officer and to obtain his/her telephone number before the report is complete. Because they failed to obtain the telephone number earlier, an additional step to the auditing process must be added.

Notes: _____

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3.3.1 Answering the Checklist Questions

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The auditor may also include additional comments regarding positive aspect of the laboratory audit, describing procedures that the laboratory performs exceptionally well.

Upon return to the office, auditors should review all checklists that were completed during the course of the audit. If the audit was performed by a team of two individuals, each auditor will have a completed checklist. Although a preliminary review of the checklists was performed before leaving the laboratory, it is still possible that some area was overlooked. A final review of the checklists, together with the U.S. EPA Region 6 generic trial burn QAPP, should be performed to ensure that all checklist questions are answered, all negative responses have explanatory comments, and all other questions have been answered, and any discrepancies between areas audited and the U.S. EPA Region 6 generic trial burn QAPP have been resolved.

Check For:

- ❑ Whether comments require clarification or amplification after some time has elapsed after the audit

Example Situation: While completing an audit checklist, Clark indicates a negative response to the checklist question (below) and cross-references the comment with a number. The numbering system he uses includes the section number followed by a numerical sequence beginning with one.

SECTION IV GENERAL LABORATORY SUPPLIES AND EQUIPMENT

Requirement	Yes	No	NA	Comments (Explain all negative responses)
Are all reagents and solutions labeled to indicate identity, concentration, storage requirements, preparer's name, preparation date, and expiration date?		IV-1		IV-1 Reagents and solutions were clearly labeled; however, the expiration date was not included.

Example Action: Clark completes the checklist as the audit is conducted so that all findings are recorded. The checklist should be completed as indicated above. For responses that do not require a comment, the auditor may use an "X" or a check mark.

Notes: _____

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3.3.2 Noting Omissions

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Before the auditors conduct the debriefing (see Section 3.4 of this component), they should note and review any omissions. The appropriate laboratory section should be re-reviewed to include the omission. The omission may be covered by a question to the laboratory QC officer or supervisor.

Check For:

- ❑ Whether the auditors noted any areas of the laboratory system that were missed during the walkthrough
- ❑ Whether the omission can be resolved by asking a question or whether the audit team must return to the laboratory area for the review
- ❑ Whether the auditor completed the question on the checklist after the re-review

Example Situation: In preparation for the audit debriefing, Lois and Clark discover that they did not see the calibration record for the mercury autoanalyzer.

Example Action: Lois and Clark request that the laboratory supervisor bring the record to them, and alternatively, auditors may ask to return to the inorganic analytical laboratory to see the record. After reviewing the record, Lois completes the question on the checklist.

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3.3.3 Noting Deficiencies

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Before the auditors conduct the debriefing (see Section 3.4 of this component), they should note and prepare to discuss any deficiencies. Deficiencies are areas that do not meet either method-specific or trial burn QAPP requirements. These issues should be brought to the attention of the key personnel present for the debriefing.

When audit checklists have been completed and reviewed, areas may exist in which checklist questions were answered in the negative and are accompanied by comments on the checklist. There may be other observations of deficiencies from the laboratory walk-through that do not correspond directly with a specific area of the checklist. Each auditor should compile a list of deficiencies, and assess whether they have or do not have an impact on the quality of the data. Evaluating whether a deficiency impacts the data quality may require reviewing the observation against the approved QAPP, as well as the methods and procedures being used.

Deficiencies that have an impact on the quality of the data encompass the following concerns:

- Inconsistency with requirements of the U.S. EPA Region 6 generic trial burn QAPP
- Insufficient QC, based on U.S. EPA 1990 QA/QC Handbook
- Major unauthorized modifications of analytical methods cited in the U.S. EPA Region 6 generic trial burn QAPP

Check For:

- ❑ Whether areas of deficiencies were noted and, if so, the impact on data quality
- ❑ Whether auditors have proof of deficiencies
- ❑ Whether all negative responses on the checklist have a comment explaining the response
- ❑ Whether any other laboratory deficiencies noted in the laboratory walk-through are thoroughly documented

Example Situation: During the audit, Lois and Clark discover that the laboratory calibrates the mercury analyzer with two calibration standards and a blank. U.S. EPA Method 7471A, Section 7.3, states that four standards and a blank must be used for initial

calibration of the mercury analyzer. Section 8.0 of the U.S. EPA Region 6 generic trial burn QAPP, states that instruments will be calibrated in accordance with U.S. EPA 1996 SW-846 methods.

Example Action: Lois and Clark note this deficiency and are prepared to cite the references in SW-846 and the trial burn QAPP to key laboratory personnel in the debriefing. As documentation of the deficiency, Clark makes a copy of the instrument run log signed by the analyst and showing the sequence of analyses.

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3.3.4 Noting Additional Questions

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: During the audit, the audit team may remember other questions regarding sample analysis that do not directly affect this project. These questions may concern other services that the laboratory provides that may be of use on future projects or on future work for this project. The questions may also concern the theory of specific techniques or new developments in techniques that add to the auditors' understanding.

Check For:

- ❑ Whether auditors noted any other areas requiring clarification that are not critical to the project

Example Situation: During the audit, Lois and Clark discuss the relevance of using mass spectrometry with ICP to enhance the analysis of trace metals. The technique is not directly relevant to the project, because it is not referenced in the trial burn QAPP; however, it is important to continually investigate new techniques or ideas to further the personal education of the team.

The audit team may have read publications that deal with high pH digestion (alkaline digestion) used for hexavalent chromium analysis. The laboratory may be able to provide first-hand information concerning practical uses of this technique for future work on this project.

Example Actions: No action is required; however, the information obtained can be used to enhance future projects.

Notes: _____

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3.4 CONDUCTING THE AUDIT DEBRIEFING

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: After checklist completion, the audit debriefing should be conducted and should include the following items:

- Key laboratory personnel meet with the audit team (same personnel as in the briefing, see Section 3.1)
- State whether the purpose of the audit was met (see Section 3.1.2)
- Describe positive and negative initial findings (see Section 3.3.2)
- Discuss the required follow-up by the laboratory (see Sections 3.3.3 and 3.3.4)

Because all of these items, except the last one, are discussed in other sections, no further detailed discussion is necessary. It is important to discuss the required follow-up by the laboratory. Deficiencies should be categorized by priority: (1) major concerns which compromise data quality, or (2) minor concerns which deviate from prescribed methods but do not compromise data quality. The laboratory should address concerns in writing, providing documented proof of the corrective action taken. Auditors should explain to the laboratory what will be expected regarding follow-up on all issues.

Check For:

- ❑ Whether key laboratory personnel are present for the debriefing
- ❑ Whether the audit satisfied the purpose and scope
- ❑ Whether the auditor presents deficiencies to laboratory personnel
- ❑ Whether the auditor has references to support the deficiencies
- ❑ Whether the audit team has a plan for laboratory follow-up
- ❑ Whether auditors or laboratory personnel have other questions

Example Situation: During an audit, Lois and Clark realize that the laboratory failed to analyze a matrix spike with a batch of waste feed samples. Without matrix spike data, the data reviewer cannot judge the potential effect of matrix interference. Especially in an organic matrix, the potential for matrix interference is high; without spike evaluation, the interface effect cannot be determined.

During an audit, Lois and Clark note that laboratory results for impinger solutions are in milligrams per liter (mg/L) instead of nanograms per liter, as required by the trial burn QAPP. The results are correctly calculated to mg/L, so Lois and Clark are not overly concerned. Laboratories are often able to program the laboratory information system to report in different units, and the laboratory should verify that the change is implemented correctly.

Example Action: In the first example, Lois and Clark consider this deficiency to impact data quality and require follow-up by the laboratory. The laboratory may offer data from another batch of samples from the same project or another project with a similar matrix.

In the second example, Lois and Clark request that the laboratory follow up by correcting the error and documenting the corrective action taken.

The issues presented above should be thoroughly discussed with the key personnel present at the debriefing. If the issue is relevant to a particular area of the laboratory, the supervisor of that group may be asked to attend the debriefing. Most issues will already have been addressed at the point of discovery. Key issues should be brought up again, along with the most efficient solution to the problem.

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4.0 POST AUDIT ACTIVITIES

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The following sections describe each of the post audit activities based on (1) information in guidance documents listed above, and (2) actual experience of environmental QA chemists.

Check for:

- ❑ After the audit debriefing with laboratory staff, is the audit team taking adequate notes and descriptive material from the laboratory to prepare a detailed audit report?

The following tasks should be completed away from the laboratory site by auditors:

- ❑ Review checklists prepared after the laboratory walk-through and compile a list of deficiencies (Section 4.1)
- ❑ Define concerns that have been uncovered during the audit (Section 4.2)
- ❑ Prepare the audit report (Section 4.3)

Example Situation: The auditors agree that the laboratory can carry out the minimum requirements of the project, but were distracted by the untidiness and overall disorganization of the facility.

Example Action: Assimilating objective information is the key to a successful audit. The auditors must decide if the observations were merely housekeeping issues, health and safety issues, or if the observations are indicative of underlying problems that may affect the overall validity of the analytical data.

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4.1 REVIEWING AUDIT INFORMATION

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The printed checklists in Attachment A are in a question format. Each auditor will answer each question with one of three responses: Yes, No, or Not Applicable. In addition, in the checklist column for comments, each auditor will provide a comment to identify or clarify the problem for each negative response. The auditor may also include additional comments regarding positive aspects of the laboratory audit, describing procedures that the laboratory performs exceptionally well.

On returning to the office, auditors should review all checklists that were completed during the course of the audit. If the audit was performed by a team of two individuals, each auditor will have a completed checklist. Although a preliminary review of checklists was performed prior to leaving the laboratory, it is still possible that some area was overlooked. A final review of checklists, together with the trial burn QAPP, should be performed to ensure that all checklist questions are answered, all negative responses have explanatory comments, all other questions have been answered, and any discrepancies between audited areas and the trial burn QAPP have been resolved.

When audit checklists have been completed and reviewed, areas may exist in which checklist questions were answered in the negative and are accompanied by comments. Other observations of deficiencies from the laboratory walk through may not correspond directly with a specific area of the checklist. Each auditor should compile a list of deficiencies, ranking the deficiencies either as major (having an impact on data quality) or minor (not having an impact on data quality). Deciding whether a deficiency represents a major or a minor concern may require reviewing the observation against the trial burn QAPP, as well as methods and procedures being used.

The following deficiencies, if present as applied to the activity, procedure, method, or documentation being reviewed, would be considered major:

- Inconsistency with requirements of the risk burn plan for the facility
- Inadequate QC, based the U.S. EPA 1990 QA/QC Handbook
- Major modifications of analytical methods cited in the trial burn plan

Check for:

- ❑ Do all checklist questions have a response?
- ❑ Do all negative responses have a comment explaining the response?
- ❑ Are the comments correctly cross-referenced to the response?
- ❑ After some time has elapsed after the audit, do the comments require clarification or amplification?
- ❑ Do all negative responses on the checklist have a comment explaining the response?
- ❑ Are any other laboratory deficiencies noted in the laboratory walk through thoroughly documented?
- ❑ Are all deficiencies compiled into a list?
- ❑ Are deficiencies considered to be major or minor based on the trial burn QAPP and actual methods?

Example Situation: Upon review of the audit checklist on the day after returning to his office, Clark auditor realizes that a cryptic comment, "Problems with calibration," does not provide sufficient detail to show exactly what the problem was and how laboratory practices for calibration failed to satisfy trial burn QAPP requirements.

Example Action: The auditor may recall sufficient information to provide an detailed explanation of the nature of the problem (as Clark does in this case), or a call to the laboratory contact person or one of the key personnel may be required to provide sufficient clarification so that the auditor can clarify or amplify his comment.

Notes: _____

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4.2 ANALYSIS OF DEFICIENCIES

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: In the preparation of the final audit report, the audit team must summarize checklist comments and categorize deficiencies as major or minor.

The following deficiencies, if present as applied to the activity, procedure, method, or documentation being reviewed, would be considered major:

- Inconsistency with requirements of the risk burn plan for the facility
- Inadequate quality control, based on the U.S. EPA 1990 QA/QC Handbook
- Major modifications of analytical methods cited in the trial burn plan

The laboratory must respond and address major concerns raised by the audit team.

Minor concerns are laboratory deficiencies that do not have an impact on data quality. The laboratory may respond but is not required to do so.

Check for:

- ❑ Are all laboratory deficiencies compiled into a list by each auditor?
- ❑ Are the deficiencies considered to be major or minor based on the trial burn QAPP and actual methods?

The following subsections describe these subjects in more detail:

- ❑ Comparing findings between audit team members (Section 4.2.1)
- ❑ Identifying major concerns (Section 4.2.2)
- ❑ Identifying minor concerns (Section 4.2.3)
- ❑ Preparing preliminary comments (Section 4.2.4)

Example Situation: In reviewing the laboratory's SOPs and in discussing with laboratory key personnel the laboratory's practices and procedures for staff training, Lois and Clark discover that the laboratory training practice is as follows: (1) an analyst is

taught a given procedure by an experienced senior analyst, (2) the analyst performs the procedure under the supervision of the senior analyst for a specified period of time, and (3) when the senior analyst is satisfied with his performance, the trainee may perform the procedure unsupervised. However, no central file exists in the laboratory that contains written documentation that Analyst A has received training in Procedure X and has completed this training satisfactorily.

Example Action: If Analyst A has completed this process to his trainer's satisfaction, he is performing the procedure correctly and consistently with the laboratory's SOPs. The laboratory should have an up-to-date, central file that provides documentation to certify which analyst has been trained in which procedures, but Lois and Clark conclude that the lack of a central file does not have an adverse effect on analytical data. Lois and Clark advise the laboratory manager that it would be highly beneficial for the laboratory to create and maintain a central training file.

Notes: _____

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4.2.1 Comparing Findings Between Audit Team Members

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The product of the laboratory audit is one checklist that represents a composite of audit team findings. Auditors are responsible for providing an assessment of laboratory procedures and their effect on data quality. Assessment of data quality is straightforward if agreement exists between auditors on QA objectives, QA/QC procedures, and acceptance criteria for these parameters, all of which should be clearly identified in the trial burn QAPP. Auditors must discuss and compare their findings and reach a consensus on positive and negative observations for the checklists and on concerns. Reference to the trial burn QAPP, methods, or SOPs may be necessary to resolve differences.

The following questions must be answered:

- Has each measurement of precision and accuracy and each instrument calibration that does not meet criteria established in the method or the trial burn QAPP been discussed in terms of its effect on sample results?
- Do both auditor checklists agree that an answer is "YES?" If so, no further discussion of the specific point is required.
- Do both auditor checklists agree that an answer is "NO?" If so, auditors must resolve whether the issue constitutes a major or a minor concern.
- Do auditor checklists disagree? If so, each auditor must defend his reasoning, and consensus must be reached.

Check for:

- ❑ Have data quality objectives for the trial burn been met?
- ❑ Are auditors in agreement on issues?

Example Situation: Lois notes that, for a given method, laboratory control spikes were not prepared and analyzed at the frequency specified by the trial burn QAPP. The trial burn QAPP specifies that three laboratory control samples should be analyzed, one for each day of analysis. However, the laboratory performed all of the sample analyses first, then analyzed three laboratory control samples sequentially on the day following field sample analysis. Lois identifies this analytical sequence as a major concern, because the protocol specified in the trial burn QAPP was not followed. Clark identifies the same sequence of events, acknowledges that trial burn QAPP protocol was not followed, but considers the effect on data quality to be minor.

Example Action: Lois and Clark discuss their points of view and consider additional data, such as recovery of surrogate compounds in samples and recovery of analytes in laboratory control samples. All surrogate and analyte compound recoveries are acceptable, and Lois and Clark agree that the effect of altering the sequence of analyses from trial burn QAPP protocol has had a minimal effect on data quality and therefore is considered to be a minor concern.

Notes: _____

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4.2.2 Identifying Major Concerns

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Data quality assessment for a trial burn is straightforward if QA objectives, QA/QC procedures, and acceptance criteria for these parameters are clearly identified in the trial burn QAPP. A major concern is any observation applied to the activity, procedure, method, or documentation being audited that compromises data quality.

The following deficiencies, if present as applied to the activity, procedure, method, or documentation being reviewed, would be considered major:

- Inconsistency with requirements of the risk burn plan for the facility
- Inadequate QC, based on the U.S. EPA 1990 QA/QC Handbook
- Major modifications of analytical methods cited in the risk burn plan

The following questions must be answered and should have been answered in the course of the laboratory audit:

- Has the laboratory followed methods specified in the trial burn QAPP?
- Has the laboratory performed at least the number and type of QC analyses specified in the trial burn QAPP?
- Has each measurement of precision and accuracy and each instrument calibration that does not meet criteria established in the method or the trial burn QAPP been discussed in terms of its effect on sample results?
- Has every QC sample been evaluated to ensure that acceptance criteria presented in the trial burn QAPP have been met?
- Have any issues of data completeness been resolved?
- Do auditors agree on observations of areas of major concern?

Check for:

- ❑ Have data quality objectives for the trial burn been met ?

- ❑ Are auditors in agreement on issues?

Example Situation: While conducting a laboratory audit, Clark discovers that in the course of logging waste feed samples into the laboratory for a series of analyses, a box of samples was dropped, and all of the bottles containing waste fuel were broken. The trial burn QAPP specifies that, for waste feed analyses, the laboratory shall make a composite of a specified number of waste feed samples corresponding to a given sampling run. The laboratory used the remaining bottles of waste fuel to make the composite and performed the requested analyses using 5 samples rather than 10 to make the composite before analysis.

Example Action: The laboratory failed to follow the procedure specified in the trial burn QAPP. Clark considers this failure to be a major concern, because the representativeness of the composite waste feed sample was compromised, significantly affecting data quality.

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4.2.3 Identifying Minor Concerns

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Minor concerns are deficiencies as applied to the activity, procedure, method, or documentation being reviewed, that do not have a significant effect on the quality of analytical data. Auditors must agree that a specified deficiency does not compromise the quality of analytical data for the deficiency to be identified as a minor concern.

Some areas of minor concern that might be identified in the laboratory audit are:

- The laboratory has a logbook for preparation of standards that specifies the chemical source, the standard preparation date, and a standard expiration date and identifies the preparer of the standard. However, the label on the standard bottle identifies only the preparer and the date of preparation.
- The laboratory has a comprehensive and thorough program for training analysts but does not have a central training file.
- The laboratory has SOPs for all methods presently in use in the laboratory. However, these SOPs are kept only in the laboratories where they are in use. There is no central file.
- QC samples are checked against trial burn QAPP acceptance criteria by the analyst and the QA officer. However, the laboratory does not maintain control charts to monitor QC sample results over time.
- Analysts in the laboratory all have notebooks, keep them current, record results, and show all calculations. The notebooks are frequently checked by the analyst's peer or supervisor, but this secondary review is not documented on the page of the notebook being checked.

Areas of minor concern in the laboratory usually arise where laboratory practices are adequate to meet trial burn QAPP requirements and, if a question arises, supporting data are available to answer the question. However, there is some area of deficiency in the completeness of the documentation.

Check for:

- ❑ Does the observed deficiency have a significant effect on the quality of analytical data?

- ❑ Are auditors in agreement on issues?

Example Situation: While conducting a laboratory audit, Lois is informed that in the course of sample extraction for U.S. EPA Method 0010 train components, a Soxhlet extractor has gone dry, and the sample cannot be recovered.

Example Action: In this case, the sampling contractor has performed an extra sampling run to provide a backup sample to be archived, although not required. Because the sample loss occurred within holding times specified for sample extraction, Lois determines that substitution of the backup sample for the original sample will have no significant effect on the quality of the analytical data. Lois considers the lapse in accepted procedures in the laboratory to be a minor concern.

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4.2.4 Preparing Preliminary Comments

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: Comments to be included in the final audit report generally characterize laboratory operations, are not considered to be major or minor concerns, and do not require any response on the part of the audited laboratory. Comments by the auditor can be used to describe unusual situations that occurred in the course of the laboratory's analytical activities to support the trial burn and how the laboratory dealt with the unusual situation. Audit report comments can also be used to acknowledge outstanding performance by the laboratory in some specific area or to offer suggestions to the laboratory for areas of improvement. The auditor may also wish to comment on some aspect of the laboratory facility or on specific analytical procedures or instrumentation.

Material sources to provide comments for the final audit report are the general and method-specific laboratory checklists, where the auditor may have made comments in the course of the laboratory walk through. Auditor notes, independent of checklists, may also provide observations on which auditors wish to expand in the final audit report.

Each auditor should collect these comments from checklists and audit notes and combine them into a preliminary compilation. This preliminary compilation can then be reviewed by another auditor to ensure that both auditors agree on their observations and wish to comment on the specific area.

Check for:

- ❑ Have relevant notes and observations been made by auditors to provide raw material for formulating comments?
- ❑ Are auditors in agreement on issues?

Example Situation: In the course of the laboratory audit for the Company XYZ trial burn, Lois and Clark note that manufacturers' requirements for acceptable operating conditions for the analytical instrumentation have been met. However, they also note that while acceptable QC practices are in place, the combination of laboratory housekeeping practices and crowded facilities results in limited workspace for analysts and an extremely cluttered laboratory environment.

Example Action: Because the general crowded conditions and poor housekeeping practices at the laboratory could, at some future time, negatively impact health and safety or data quality, Lois and Clark encourage the laboratory to improve in these areas or expand the laboratory into additional space, if available.

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4.3 PREPARING THE AUDIT REPORT

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: An audit report is prepared as a result of a laboratory audit. The audit report represents a consensus of the auditing team and includes a textual audit report and a composite for each of the checklists prepared by individual auditors.

Check for: The textual audit report incorporates the following sections:

- ❑ Overview of the trial burn test (Section 4.3.1)
- ❑ Overview of the laboratory (Section 4.3.2)
- ❑ Summary of auditor concerns (Section 4.3.3)
- ❑ Summary of comments (Section 4.3.4)
- ❑ Recommendations (Section 4.3.5)
- ❑ Conclusions (Section 4.3.6)

The following sections describe each part of the audit report.

Example Situation: Lois and Clark prepare the report and use discussions of complex analytical mechanisms; however, the ultimate reader and user of the report is a nonchemist. The reader is confused and frustrated by the report.

Example Action: While the findings of the audit may deal with complex chemistries, the reader simply needs to know if the findings reflect a potential for invalid data. The auditor should consider the reader's background and ultimate purpose of the report before beginning to write. Lois and Clark revise the report to explain their findings in a clearer, less technical manner.

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4.3.1 Overview of the Trial Burn Test

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The section of the audit report discussing the TBP overview should include the following information:

- Brief summary of the unit being tested, the trial burn test design, the sampling and analytical methods being used, and the goal of the test. Adequate information to provide the level of detail desired for this section will be available in the facility TBP and trial burn QAPP
- Description of why the laboratory audits are being conducted
- Description of the laboratory or laboratories being audited, including laboratory name and address, key contacts, analyses, and matrices analyzed
- Summary of audit activities at each audited laboratory

Check for:

- ❑ Has complete information regarding laboratory location, key contacts, matrices analyzed, and analyses performed been obtained for each laboratory?
- ❑ Is sufficient information available in the trial burn QAPP to provide a description of the facility where the trial burn is occurring?
- ❑ Have auditors been careful to verify the correct spelling of names, accuracy of addresses, and other information that will be used in the audit report?
- ❑ Have auditors been careful to verify that the laboratory name is complete and correct?

Example Situation: The sign on the outside of the laboratory building when Lois and Clark arrive says “Smith.” Upon exchange of business cards, auditors find that the company is named “Smith Laboratories.” On the corporate brochure, the organization is described as “Smith Environmental Laboratories, Inc.”

Example Action: During the audit, Lois asks the company president to verify the correct name of his company for the audit report.

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4.3.2 Overview of the Laboratory

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The section of the audit report discussing the laboratory overview should include the following information:

- Brief discussion of the analyses the laboratory is conducting for this trial burn
- Description of laboratory functions (which analyses does the laboratory perform, not limited to analyses specifically for the trial burn). Company brochures, which can be requested by the auditors either prior to the laboratory audit or at the time of the audit, are usually very useful for providing information about laboratory capabilities.
- Brief description of physical facilities of the laboratory. Company brochures, which can be requested by the auditors either prior to the laboratory audit or at the time of the audit, are usually very useful for providing information about laboratory facilities.
- Brief discussion of the laboratory organization, including key personnel and their responsibilities. Auditors should acknowledge specifically the laboratory staff member with overall responsibility for guiding the laboratory walkthrough and locating requested information.

Check for:

- ❑ Has complete information regarding laboratory location, key contacts, matrices analyzed, and analyses performed been obtained for each laboratory?
- ❑ Have auditors collected information to be able to provide a short description of laboratory physical facilities?
- ❑ Have auditors been careful to verify the correct spelling of names and accuracy of addresses and other information that will be used in the audit report?

- ❑ Have auditors been careful to verify the names of key personnel and their functions in the laboratory?

Example Situation: Lois and Clark disagree as to the level of detail to include in the laboratory overview with regard to the actual square footage of the radiochemistry laboratory; however, no radiochemistry analyses were required for the project.

Example Action: The information included should have relevance to the performance of analytical services for the project. The square footage of a laboratory is valuable information, especially when the facility is very small, because the potential for bumping into equipment and dropping samples and extracts is high. However, if the particular laboratory area is not being utilized for the project, the concern becomes negligible and should not be included in the report. After further discussion, Lois and Clark decide not to include the square footage of that portion of the laboratory in the laboratory overview.

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4.3.3 Summarizing Concerns

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The section of the audit report discussing concerns should be divided into major and minor concerns. The following deficiencies, if present as applied to the activity, procedure, method, or documentation being reviewed, would be considered major:

- Inconsistency with requirements of the project-specific approved QAPP
- Insufficient QC, based on U.S. EPA's "Handbook: QA/QC Procedures for Hazardous Waste Incineration" (U.S. EPA 1990)
- Major unauthorized modifications of analytical methods cited in the project-specific approved QAPP

Major concerns have a significant impact on the quality of the data being generated. Minor concerns are deficiencies that apply to the activity, procedure, method or documentation being reviewed that do not have a significant impact on the quality of the data being generated.

For example, items such as laboratory substitution of an alternative analytical method for the analytical method specified in the trial burn QAPP or failure to analyze samples within hold times specified by the method would be major concerns. Items such as a lack of documentation of laboratory training records or calculating analytical results in the wrong units would be minor concerns.

The audit report should address:

- ❑ Definition of what constitutes a major concern
- ❑ Listing of any major concerns as determined by auditor consensus
- ❑ Explanation and discussion of each major concern, including the auditor's observation and any discussion with laboratory staff involving the major concern
- ❑ Definition of what constitutes a minor concern
- ❑ Listing of any minor concerns as determined by auditor consensus

- ❑ Explanation and discussion of each minor concern, including the auditor's observation and any discussion with laboratory staff involving the major concern

Example Situation: Not applicable to this section of the manual.

Example Action: Not applicable to this section of the manual.

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4.3.4 Summarizing Comments

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The section of the audit report discussing comments should include the following information:

- Definition of a comment, pointing out that comments are not considered to be major or minor concerns and do not require any response on the part of the laboratory
- Concise discussion of each comment on which the auditing team agrees
- Concise discussion of laboratory procedures

Check for:

❑ Auditors must reach consensus on comments. No comment should be included in the audit report unless auditors agree on its relevance.

Example Situation: Lois and Clark are very impressed with the personalities, generosity, hospitality, and visual aesthetics of the laboratory personnel and facility. It is common to want to include positive comments regarding these items in the report; however, often such comments are published in sales brochures and other propaganda that the laboratory produces for marketing purposes.

Example Action: Lois and Clark refrain from making complimentary remarks about the laboratory in the audit report, because comments of this nature do not directly affect the integrity of sample data.

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4.3.5 Preparing Recommendations

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: This section of the audit report can include other observations that would improve data from the audited laboratory. Recommendations require no action and do not affect the results of a particular audit. However, recommendations could include the following information:

- Suggestions by auditors for improvements in laboratory operations
- Suggestions by auditors for improvements in laboratory documentation
- Suggestions by auditors for improvements in laboratory communication
- Suggestions that auditors feel will improve the quality of the laboratory's analytical data

Check for:

- ❑ Auditors must reach consensus on recommendations. No recommendation should be included in the audit report unless auditors agree on its relevance.

Example Situation: Lois and Clark observe that the laboratory's reporting section does not have sufficient space to archive all data in an accessible way and are inclined to provide detailed solutions to the data archival problem.

Example Action: Auditors should refrain from providing or requiring a specific solution to problems. In this report, Lois and Clark suggest that the archival problem of insufficient space be solved, because data archival is important to the project being reviewed. The laboratory should be allowed to explore possibilities and report a solution by a given date.

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4.3.6 Preparing the Conclusions

Regulations: No regulations are applicable to this section of the manual.

Guidance: No specific references are applicable to this section of the manual.

Explanation: The section of the audit report discussing conclusions should include the following information:

- Conclusions by auditors that data quality objectives for the trial burn have or have not been met because of laboratory operations
- Assessment of whether any of the laboratory operations have an adverse effect on data quality
- General conclusions regarding laboratory competence and staff

Check for:

- ❑ Auditors must reach consensus on conclusions. No conclusion should be included in the audit report unless auditors agree on its relevance.

Example Situation: Lois and Clark find that the ICP's precision is not as good as its potential and that detection limits are unusually high for several metals. Lois and Clark want to include the issue in the major comment section and conclude that the instrument is incapable of operating to its potential. However, in reviewing the trial burn QAPP, they note that the high detection limits are sufficient to meet the sensitivity objective of the trial burn.

Example Action: Lois and Clark decide to place the comment about the ICP's detection limits in the comment section only and not present it as a major or minor concern, because the overall trial burn objectives have been met.

Notes: _____

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ATTACHMENT A

LABORATORY AUDIT CHECKLIST

(14 Sheets)

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

SECTION I GENERAL INFORMATION

Reviewers: _____
Date Completed: _____

Facility Representative: _____

Facility Name: _____
Address of Facility: _____
_____

Telephone No.: _____

Evaluation Firm: _____
_____
_____
_____

Names of inspectors: _____ Date(s) of inspection: _____
_____
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SECTION II QUALITY ASSURANCE MANUAL

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Determine if the laboratory's quality assurance manual includes the following:				
Names an individual as the laboratory quality assurance manager and specifies job requirements for the position?				
Includes a current summary of training, experience, and job description required for each member of the laboratory staff?				
Describes quality control paperwork flow and identifies those who are authorized to approve data and results?				
Identifies personnel responsible for corrective action procedures?				
Describes the laboratory's system for developing or revising technical procedures and identifies those who have authorization to do so?				
Requires dating chemicals upon receipt and using them on a first-in, first-out basis?				
Specifies use of reagent-grade or high-purity chemicals to prepare standards?				
Requires testing of chemicals used in analyses to ensure they contain no contaminants that may interfere with analyses?				
Requires labeling of all reagents and solutions to indicate identity, concentration, storage requirements, preparer's name, preparation date, and expiration date?				
Requires routine checking and recording of the conductivity of distilled and demineralized water?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Specifies use of reagent-grade water, as required by the specific method?				
Specifies use of distilled water, as required by the specific method?				
Requires discontinuing the use of any reagents or solutions labeled with expiration dates that have passed?				
Requires storage of samples and standards containing analytes of interest in areas other than those where trace analysis is performed?				
Requires storage of standards separately from sample extracts?				
Specifies the use of analysis request sheets or work orders?				
Includes and requires the use of written calibration procedures, analytical procedures, computational procedures, quality control procedures, and operating procedures?				
Specifies the use of standard curves and check samples for calibration purposes?				
Specifies the use of logs to record all instrument and equipment checks?				
Describes when an analytical system is "out of control" through internal quality control samples?				
Requires corrective procedures when an analytical system is "out of control"?				
Specifies the use of Class A glassware?				
Names a sample custodian in the laboratory?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Describes storage requirements for incoming samples?				
Specifies the assignment of unique laboratory numbers to all incoming samples?				
Requires maintenance of proper temperatures for incoming samples?				
Describes chain-of-custody procedures that the laboratory will use?				
Specifies the use of a master schedule sheet or logbook of all samples being analyzed, indexed by laboratory numbers, client, date of arrival, and analysis to be performed?				
Specifies maximum holding times for samples?				
Requires the daily temperature recordings in cold storage areas? Specifies the use of matrix spikes (one per analytical batch per matrix, or one per every 20 samples, whichever is more frequent)?				
Requires the use of laboratory duplicates (one per analytical batch per matrix, or one per every 20 samples, whichever is more frequent)?				
Requires the use of blanks (one per analytical batch per matrix, or one per every 20 samples, whichever is more frequent)?				
Requires the use of field duplicates (one per analytical batch, or one per every 20 samples, whichever is more frequent)?				
Requires the use of check samples (one per analytical batch, or one per every 20 samples, whichever is more frequent)?				
Requires the use of surrogates for volatile and semivolatile organics and pesticides (added to every blank, standard, sample, and quality control sample)?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Requires gas chromatograph/mass spectrometer (GC/MS) instrument performance check (in which the initial five-point calibration is verified with a single-point calibration once every 12 hours of instrument operation and, if the sensitivity and linearity criteria are not met, a new five-point initial calibration must be generated)?				
Requires a system that independently examines and validates raw data from the laboratory?				
Requires owner/operator to have a system that examines and validates raw data when a subcontractor laboratory is used?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

SECTION III PERSONNEL

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Review the laboratory's personnel qualifications and organizational structure.				
Has the laboratory appointed a quality assurance manager who routinely performs the following actions:				
- Ensures adherence to quality assurance requirements for sampling?				
- Ensures that all test and measuring equipment are properly calibrated?				
- Monitors logging in of samples?				
- Approves project plans, specific analyses, and final reports?				
- Maintains a copy of the master schedule sheet?				
- Maintains separate copies of all methods performed by the laboratory?				
- Maintains written and signed records of periodic inspections?				
- Maintains all quality assurance records in one location?				
Are qualified individuals used to perform the required analyses?				
Does the laboratory have a documented program of personnel training?				
Does the laboratory routinely verify proficiency of personnel in the various methods?				
Are qualified individuals authorized to approve data and results?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

SECTION IV GENERAL LABORATORY SUPPLIES AND EQUIPMENT

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Review the procedures for maintaining the laboratory's supplies and equipment.				
Are adequate laboratory facilities and instruments available to perform the required analyses?				
Is the solvent storage area properly vented and appropriate for the prevention of possible laboratory contamination?				
Are analytical and sample storage areas isolated from all atmospheric sources of solvent?				
Are chemicals dated upon receipt and used on a first-in, first-out basis?				
Are reagent-grade or high-purity chemicals used to prepare standards?				
Are chemicals used in analyses tested to ensure that they contain no contaminants that may interfere with the analyses?				
Are all reagents and solutions labeled to indicate identity, concentration, storage requirements, preparer's name, preparation date, and expiration date?				
Is a source of distilled or demineralized water available?				
Is the conductivity of distilled or demineralized water routinely checked and recorded?				
Is reagent-grade water used for organic methods?				
Is distilled water used for inorganic methods?				
Are any of the reagents or solutions being used labeled with an expiration date that has passed?				
To avoid contamination, are samples and standards containing the analytes of interest stored or used in areas other than those where trace analysis is performed?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)

IV - 1

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Are standards stored separately from sample extracts?				
Do chemical handling areas consist of either a stainless-steel bench or an impervious material covered with absorbent materials?				
Are contamination-free areas provided for trace level or organic analytical work?				
Are exhaust hoods provided to allow contamination-free work with volatile materials (that is, venting for preparation, extraction, and analysis)?				
Is an adequate supply of routinely needed in-house replacement parts available to ensure that analytical equipment is not inoperable during a critical period?				
Is a service record logbook maintained for each analytical instrument?				
Are instruments properly vented and appropriate traps in place, as required?				
Are chemical waste disposal policies and procedures well-defined and followed by the laboratory?				
Is Class A glassware used or is it calibrated to ensure that the amount marked on the glassware coincides with the amount delivered?				
Is the glassware cleaned correctly after each use to ensure that there will be no contamination with the next use?				
Is the analytical balance located away from drafty areas and areas subject to rapid temperature changes?				
Has a certified technician calibrated and checked the balance within 1 year?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

SECTION V SAMPLE RECEIPT AND STORAGE

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Review sample handling procedures at the laboratory.				
Is a sample custodian appointed to log incoming samples?				
Is a written SOP available that describes sampling requirements (such as, type of sampling container, preservation technique, and storage container) for each analysis?				
If no custodian is appointed, are the individuals logging in samples aware of the sampling requirements for each analysis?				
Does the custodian know the process for storing incoming samples?				
Is a sample label affixed to each container?				
Do sample labels contain information sufficient to identify the sample and ensure that it is has been sampled in the correct manner (including facility name, station number, date sampled, time sampled, type of analysis requested, preservation used, and signature of sampler)?				
Are samples collected in the type of container specified for each analysis?				
Are samples preserved as required and cooled to 4°C?				
Do samples shipped to the laboratory arrive at the correct temperature to ensure that the sample has remained in a preserved state?				
Are water samples for volatile analyses checked for air bubbles?				
Are trip blanks, field blanks, and field duplicates used as required?				
If so, are they identified as such?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)
If used, are spiked samples identified?				
Is a chain-of-custody form filled out and kept on file?				
Is the information on the sample tag and chain-of-custody form verified and matched?				
Are unique laboratory numbers assigned to all incoming samples (including quality control samples)?				
Does the laboratory maintain a master schedule sheet or logbook of all samples being analyzed, indexed by laboratory number, client, date of arrival, and analysis to be performed?				
Is the laboratory number written on the sample label, the master schedule sheet, and any documents related to that sample?				
Are completed sample analysis work orders available for each sample?				
Does each sample have a separate work order for each analysis or group of analyses (that is, organic and inorganic) to be performed (to ensure that each analyst who must perform an analysis on that sample will have a work order)?				
After all analyses have been completed, are all work orders attached to all appropriate summary sheets for each analysis?				
Are all samples analyzed within required holding times?				
Are samples maintained at the correct temperature until the time of analysis?				
Are adequate facilities provided for storage of incoming samples, including cold storage?				
Are volatile samples stored separately from nonvolatile or semivolatile samples?				
Is the temperature of the cold storage recorded daily in a logbook?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Are temperatures outside of control limits noted, and are appropriate actions taken when required?				
If reused, are sample containers cleaned properly?				
Are the possession and handling of samples traceable from the time and date of collection to the time and date of analysis and reporting?				
Demonstrate by tracing at least one sample in the laboratory. Summarize by completing Form V-1.				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

FIGURE V-1
Sample Tracing Form

Use this form to demonstrate the traceability of samples from collection to reporting.

Trace at least one sample from the trial burn facility through the laboratory systems.

Sample ID Information	Sample A	Sample B	Sample C	Comments (Explain all negative responses)
Field Sample Number				
Laboratory Name				
Laboratory Address				
Sample Collection Location				
Sampler Name or Initials				
Date Sampled				
Time Sampled				
Date Received at Laboratory				
Laboratory Sample Number				
Analyses Requested				
Storage Procedures				
Date of Sample Preparation				
Date of Sample Analysis				
Analysts' Initials				
Methods Used				
Date Results Reported				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

SECTION VI QUALITY CONTROL PROGRAM

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Does the laboratory appear to have sufficient capacity to prepare and analyze all samples within holding times?				
Is one matrix spike used for every analytical batch or every 20 samples, whichever is most frequent?				
Are matrix spike accuracies analyzed to establish that the analytical measurement system is functioning properly with the desired sensitivity?				
Are precision results of sample replicates measured for each method to indicate reproducibility among individual measurements of the same property under similar conditions?				
Are the precision and accuracy results used to determine the control limits for all operating parameters?				
Are these precision and accuracy results organized in the form of quality control charts?				
Are quality control charts or tabulation of mean and standard deviation (or the equivalent) used to document the validity of data on an as-run basis?				
Are matrix spike results compared to control charts on an as-run basis to determine whether the analysis is "in control"?				
Is one check sample used per analytical batch or every 20 samples, whichever is more frequent?				
Is one laboratory method blank used per analytical batch or every 20 samples, whichever is more frequent, to ensure that there are no contaminants that may interfere with the analysis?				
Is one field duplicate used per analytical batch or every 20 samples, whichever is more frequent?				
Are laboratory duplicates prepared and analyzed per analytical batch or every 20 samples, whichever is more frequent (not including reinjection or reanalysis of same set of standards or samples)?				

Laboratory Name: _____
Reviewers: _____
Date Completed: _____

Requirements	Yes	No	NA	Comments (Explain all negative responses)

SECTION VII DATA HANDLING AND REPORTING

Requirements	Yes	No	NA	Comments (Explain all negative responses)
Review procedures for data handling, reporting, and recordkeeping.				
Are computerized and manual checks applied at various appropriate levels of the measurement process to ensure data validation?				
Are the data validation criteria documented (including limits on operational parameters, calibration data, special checks, statistical tests, and manual checks)?				
Does the laboratory have procedures for data handling and reporting, including the recording of data on standard forms and in laboratory notebooks?				
If so, is this reporting format described with example forms provided?				
Are sample calculations available for inspection?				
Are bound notebooks used for all laboratory activities?				
Do notebooks, logbooks, and run logs have the following pertinent data: - Title - describing the activity being recorded - Instrumentation - type and ID number (for example GC #3) - Date of preparation or analysis - Initials of preparer or analyst - For preparation notebooks or logbooks - details of activity, such as sample measurements, reagents and quantities, and procedure times, if applicable - For instruments runlogs - run sequences, identity of each sample and analyte - Units of measurements - Calculations, if applicable - Peer or supervisory review signature and date				
Are notebooks reviewed by a peer or supervisor (as indicated by a signature and date)?				
Are raw data archived and documented properly?				
Are records readily available for review?				

Are records maintained for at least 3 years?				