



***ANSI-ASQ National Accreditation Board***

DoD ELAP Accreditation Requirements

Document 7

Table of Contents

**0.0 PURPOSE** .....3

**1.0 ACCREDITATION PROCESS**.....3

    1.1 Introduction .....3

    1.2 Request for Quotation and Charges .....5

    1.3 Corrective Action Review .....8

    1.4 Cancellation .....8

    1.5 Pre-Payment Requirements .....8

    1.6 Payment and Late Payments .....8

    1.7 Finance Charges .....8

    1.8 Assessor Travel Time .....9

    1.9 Appeal of Fees (Invoices) .....9

    1.10 Application .....10

    1.11 Assignment of Assessors and Experts .....11

    1.12 Schedule .....11

    1.13 Introductory Visit (Optional) .....12

    1.14 Practice Assessment (Optional) .....12

    1.15 Document Review (including Proficiency Test Sample Results) .....13

    1.16 Planning Visit (Optional) .....13

    1.17 Preparation for Initial Accreditation Assessment .....14

    1.18 Accreditation Assessment .....15

    1.19 Response by Laboratory to Non-Conformances .....17

    1.20 Corrective Action and Follow-up Visit .....18

    1.21 Accreditation Decision .....18

    1.22 Review of Accreditation Reports .....19

    1.23 Changes to Existing Scope of Accreditation .....19

**2.0 REASSESSMENT FOR CONTINUING ACCREDITATION** .....22

**3.0 SURVEILLANCE ASSESSMENTS** .....22

**4.0 CHANGE TO THE MANAGEMENT SYSTEM OR LOCATION** .....23

**5.0 DIRECTORY OF ACCREDITED LABORATORIES** .....24

**6.0 CHANGES TO THE ACCREDITATION REQUIREMENTS AND/OR ACLASS PROCEDURES** .....24

**7.0 CONFIDENTIALITY AND DISCLOSURE OF INFORMATION** .....24

**8.0 CERTIFICATE, SCOPE AND ACCREDITATION SYMBOL** .....25

    8.1 Symbol Usage on Test Reports .....25

**9.0 COMPLAINTS AND APPEALS** .....25

    9.1 Definitions .....26

    9.2 Appellant and Complainant .....26

    9.3 Appeals Procedure .....26

    9.4 Complaints Procedure .....28

**10.0 TRANSFER OF ACCREDITATION** .....29

    10.1 Transfer Minimum Requirements .....29

**Attachment 1: Scope of Accreditation Form** .....33

    Completing ACLASS Scope Listing for DoD ELAP Accreditation .....34

    Example of ACLASS DRAFT Scope .....35

**Attachment 2: Proficiency Test Results Summary, Form 35** .....36

**Attachment 3: Data Package Submission Requirements** .....38

    Data Package Contents .....39

**Attachment 4: Instructions for Completion of Method / Matrix Worksheet, Form 55** .....41

**Attachment 5: Request for Addition of New Analytical Methods** .....43

    Guidance for the Approval and Addition of New Analytical Methods .....44

**Attachment 6: Request for Addition of New Target Analytes to Existing Method Accreditations** .....45

    Guidance for the Approval and Addition of New Analytes to Methods Accredited currently Under the ACLASS DoD ELAP (Particularly arranged for analytes not available in current PT schemes) .....46

**Attachment 7: Form 53 DoD ELAP and ISO/IEC17025 Remote Surveillance Letter and Instructions** .....47

## 0.0 PURPOSE

This purpose of this document is to establish policies for and provide a general description of the ACCLASS Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP) accreditation process. This document is available to the general public and any interested party, and is written specifically to communicate the ACCLASS DoD ELAP accreditation process to customers. This document explains all requirements for accreditation and is mandatory for all ACCLASS DoD ELAP applicants and accredited customers.

ACCLASS maintains its financial stability by charging its customers fees and expenses for its services according to its approved public rates and as provided to its customers in quotation. The ACCLASS fee structure is available upon request.

The term “customer” as used in this document refers to an organization seeking or holding accreditation in the DoD ELAP program from ACCLASS.

## 1.0 ACCREDITATION PROCESS

### 1.1 Introduction

ACCLASS, one of two brands of the ANSI-ASQ National Accreditation Board, provides accreditation to ISO/IEC 17025 for testing and calibration laboratories, ISO/IEC 17020 for inspection bodies, ISO Guide 34 for reference material producers, ISO/IEC 17043 for proficiency testing providers, industry specific accreditation programs, and environmental analytical laboratories under DoD ELAP.

ACCLASS is a signatory to the [International Laboratory Accreditation Cooperation](#) (ILAC) Mutual Recognition Arrangement (MRA). Accreditation bodies around the world typically pursue ILAC recognition through one of the recognized regional cooperations of ILAC. Recognizing the value of regional information-sharing among members of the accreditation community, ACCLASS has signed the MRAs of both the [Asia-Pacific Laboratory Accreditation Cooperation](#) (APLAC) and the [Inter-American Accreditation Cooperation](#) (IAAC)

The basic steps for ACCLASS accreditation under the DoD ELAP requirements specified by the DoD Quality Systems Manual (DOD QSM), version 4.2 (or any future versions thereof) are shown in Figure 1.

Subsequent sections of this document provide more detail about the steps shown in the figure and provide examples of the documentation required to support the accreditation process.

**Figure 1**

**Basic Steps in the ACLASS DoD ELAP Accreditation Process**



## 1.2 Request for Quotation and Charges

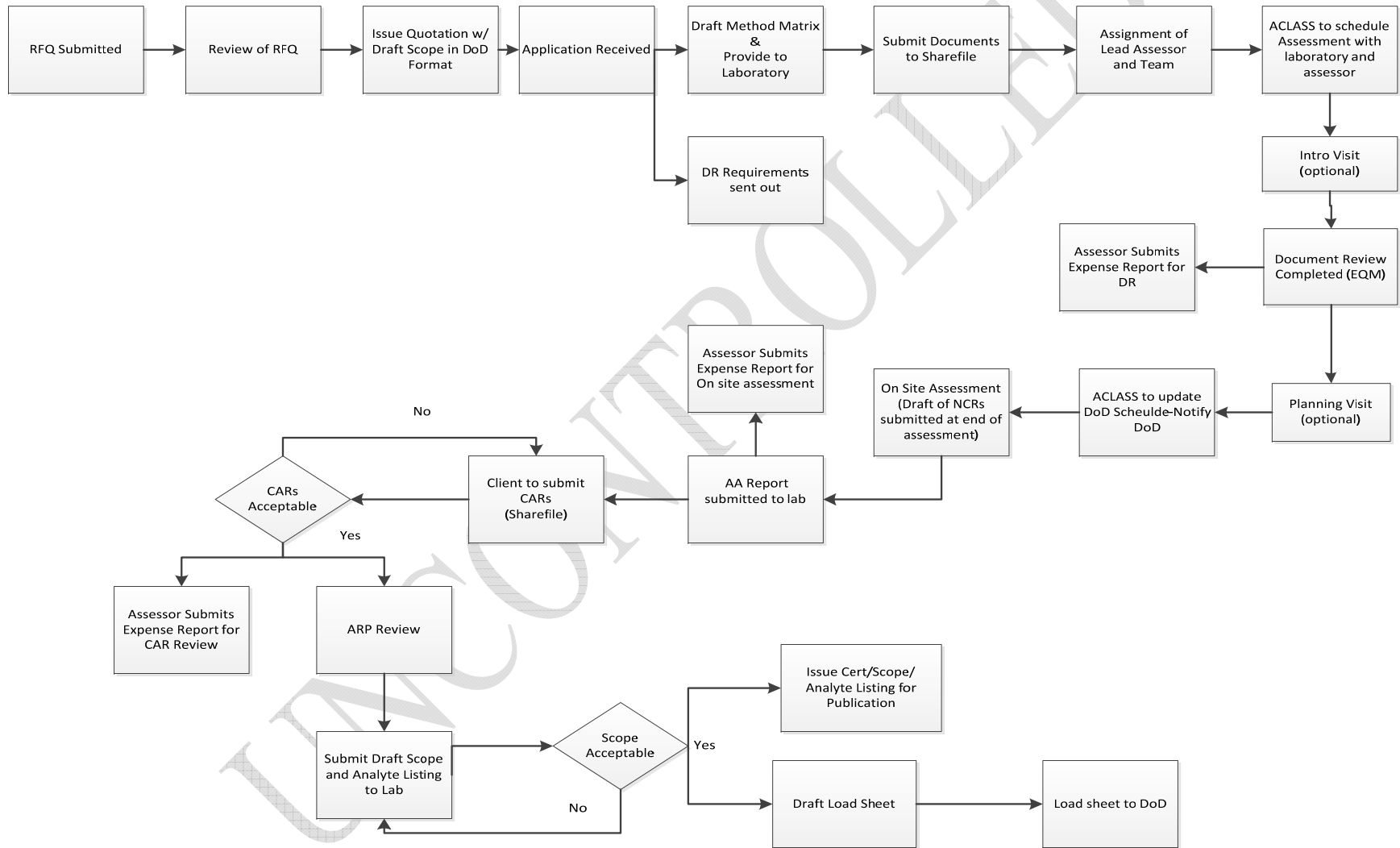
Any customer can request a quotation by going to the ACLASS web site, [www.aiclasscorp.com](http://www.aiclasscorp.com) or contacting ACLASS directly. The receipt of a request for quotation (RFQ) by ACLASS begins the process shown in Figure 2, Flowchart for the DoD ELAP Accreditation Process

Information on the number of days and rates for ACLASS services is readily available. ACLASS will charge the customer for the accreditation services on the basis of the scope of accreditation provided by the customer and the ACLASS fee schedule, which is available upon request. Based on these rates and information, ACLASS will provide a quotation with an estimate on fees for the entire accreditation process, surveillance and reassessment. Because of the importance of the laboratory's requested scope of accreditation to the development of a reliable cost estimate, ACLASS provides a standardized form for use by the laboratory as they define the scope of accreditation being requested. ACLASS takes the laboratory's request, reformats it if necessary to meet requirements of the DoD ELAP, and returns it with the quotation to the laboratory. An abbreviated example of the completed form is shown in Table 1.

This form and the instructions for its completion are found as Attachment 1. It is also available in electronic format at [www.aiclasscorp.com](http://www.aiclasscorp.com).

All quotations are subject to change after further review of the proposed scope of accreditation and/or request to extend the scope of accreditation. Quotations depend upon, but are not limited to, size of the organization, number and/or types of tests, and number of employees. Quotations are subject to change over time.

**Figure 2**  
**ACLASS DoD ELAP Accreditation Process**



**Table 1****Example of Scope of Accreditation for ACCLASS DoD ELAP**

<b>Matrix</b>	<b>Specific Test or Group of Analytes</b>	<b>Specification or Standard Method (All EPA unless specified otherwise)</b>	<b>Key Equipment or Technology Used</b>
Water	Acid digestion For metals analysis	3010A	
Solid	Acid digestion for metals analysis	3050B	
Water	Purge and trap extraction for volatiles analysis	5030B / 5030C	
Solid	Purge and trap extraction for volatiles analysis	5035 / 5035A	
Water/Solid	OP Pesticides	8141A / 8141B	GC/ECD
Water	OP Pesticides	614	GC/ECD
Water/Solid	Semi-VOA	8270C / 8270D	GC/MS
Water	Oil & Grease	SM 5520B	Gravimetry
Water	Anion analysis	300.0 / 9056 / 9056A	Ion Chromatography

### **1.3 Corrective Action Review**

Additional charges apply for review of corrective actions and/or a follow-up visit for any non-conformances. The customer will be billed if significant review of corrective actions is required by ACLASS. Any follow-up or questions directed to the lead assessor shall be responded to in a timely manner.

If a follow-up visit is required, the assessor(s) shall be reimbursed according to the normal assessor day rate and assessor travel time fees.

### **1.4 Cancellation**

Customers cancelling confirmed dates within thirty days prior to the previously confirmed date will be subject to a charge equivalent to 50% of the daily fee for each cancelled day including any costs associated with travel.

### **1.5 Pre-Payment Requirements**

All customers, during initial accreditation assessments, surveillance, and reassessments, may be required to pay an up-front deposit. The deposit is typically the equivalent of the assessor day rate for each day of their assessment at least 30 days prior to the scheduled assessment.

All remaining fees, including assessor travel related expenses, shall be invoiced upon completion of the assessment.

Failure to pay may result in the cancellation of the scheduled assessment and charges levied according to Section 1.5, above.

### **1.6 Payment and Late Payments**

Payment of all invoices is due 30 days from the date on the invoice.

ACLASS collects overdue bills by taking the following steps:

- Upon expiration of the due date, a friendly reminder is sent and finance charges apply.
- Upon 30 days after the expiration of the due date, a collection notice is sent.
- ACLASS may suspend and/or withdraw accreditation for failure to pay all fees. Suspension of accreditation typically occurs 60 days past due from initial date of invoice.
- ACLASS may seek Warrant in Debt (judgment) for past due fees.

### **1.7 Finance Charges**

Late payment results in:

- Finance charges of 2% on the outstanding amount due, backdated to the initial invoice date. The 2% finance charge will continue to accrue until the invoice is paid in full.
- Monthly finance charges of 2% on past due amounts and every 30 days thereafter.

If a customer fails to pay any charges, ACLASS may discontinue further consideration of the application for accreditation, or suspend and/or withdraw an existing accreditation. Approved certificates and scopes of accreditation shall not be issued until all invoices have been closed.

### 1.8 Assessor Travel Time

ACCLASS recognizes that traveling to customer locations requires personal time. For non-overseas travel<sup>1</sup>, it is therefore the policy of ACLASS to reimburse ACLASS assessors at a rate of **\$35.00 per hour** for travel time after the first two hours. The maximum reimbursement for non-overseas travel time is \$175 each way. For trips involving multiple labs, this maximum also applies to each leg of travel between labs.

For overseas travel, assessors are reimbursed at the rate of **\$25 per hour** for travel time including the first two hours, not to exceed \$1,100 roundtrip.

The above rates apply under the following conditions:

- When air travel is required, reimbursed travel time refers to time of actual airline departure to time of final landing only and not the time driving to and from the airports if the airport nearest the laboratory and the assessor's home is used (defined as "standard mode of transportation"). If an alternate airport is chosen, travel time for driving to and from the alternate airport may be reimbursed if the total cost with driving time is less than or equal to flying to or from the nearest airport.
- ACLASS policy is to use the standard mode of transportation unless there is documented justification to use an alternate mode. If the assessor would prefer to take an alternate mode of transportation, ACLASS Form 39, *ACCLASS Travel Cost Comparison*, shall be completed to justify the alternate mode as more cost effective for the customer. Total travel time exceeding 6 hours will require the approval of an Accreditation Manager prior to scheduling.

Receipts shall be submitted along with expense reports indicating travel time exceeded two hours. These receipts shall be made available to the customer upon request.

### 1.9 Appeal of Fees (Invoices)

A customer may appeal an invoice; however, the invoice shall be paid prior to the due date to avoid further finance charges and/or suspension as referenced above.

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<sup>1</sup> Non-overseas travel includes North and South America, excluding Hawaii and Alaska.

The appeal of an invoice will follow the appeal process outlined in this document, section 7.3. If the decision is in favor of the appellant, a credit or refund will be issued, including any interest the customer may have paid.

### 1.10 Application

Every customer seeking accreditation must submit an application. An application package with all required forms and instructions for completion is provided to the customer with the quotation. It is also available on the web at [www.aiclasscorp.com](http://www.aiclasscorp.com). The application should be submitted in electronic format to the ACLASS secure website, and must include the following:

- Completed application form (include all relevant locations to be covered by the accreditation)
- Proposed scope of accreditation and list of requested approved analytes
- Quality manual or quality assurance project plan
- Applicable quality system and technical method standard operating procedures
- Last two years assessment report(s) (e.g. NELAP, DoD, third party)
- Completed Form 34 –DoD ELAP Checklist w/ document references available for download at [www.aiclasscorp.com](http://www.aiclasscorp.com) Completed Form 35-Proficiency Testing results for at least the last three rounds ; see Attachment 2) Include a copy of the PT testing report from the PT provider.
- One complete data package for each analytical technology (e.g. GC/MS, CVAA, HPLC, etc.) covered by the proposed scope (see Attachment 3)

ACLASS accreditation activities shall be confined to the agreed upon scope of accreditation, provided with the application for accreditation. DoD ELAP accreditation is accompanied by ISO/IEC 17025 accreditation. The scope of accreditation for ISO/IEC 17025 will be identical to that of DoD ELAP unless the applicant laboratory has tests that are sought for accreditation that do not meet all the requirements of the DoD QSM but do meet those of ISO/IEC 17025. In the latter case, an additional application for ISO/IEC 17025 accreditation must be submitted to ACLASS with the additional appropriate documents.

Separate applications are required for each accreditation location. Physical locations in close proximity can be considered one location (this will be determined by ACLASS). See also *ACLASS Guidance for Classification and Assessment of Multi-Site Laboratories*.

Upon receipt of the completed application and the non-refundable application fee, ACLASS will review the application to make sure it has all the information needed, as well as to ensure ACLASS has the proper accreditation credentials and resources. ACLASS will provide accreditation services to any customer who applies if ACLASS has or can reasonable obtain proper credentials and resources. During review of the application, ACLASS will determine if additional information is required to be submitted.

After final review of the completed application form, ACLASS will acknowledge to the customer receipt of the application and ensure that all customer expectations can be met, particularly the customer's desired scheduling. The customer and ACLASS shall work in coordination with each other to determine assessment dates.

If the review reveals that ACLASS has the capability to perform the assessment, ACLASS will assign a lead assessor. The lead assessor, in coordination with ACLASS, shall verify the proposed scope of accreditation directly with the customer. Upon verification of the proposed scope of accreditation, ACLASS shall assemble a team of ACLASS assessors and/or experts, as necessary.

In addition to verifying the scope, ACLASS will create the Method/Matrix worksheet to document the assessment of important components of each sample preparation and analytical method for use during the assessment witnessing. The Method/Matrix worksheet form is returned to the laboratory for completion. It must be completed with the required information and returned to the lead assessor no later than two weeks prior to the on-site visit. An example of the Method/Matrix worksheet and instructions for completion are found in Attachment 4.

The customer will be informed of the assigned assessor(s). The customer has the right to appeal (object to) any assigned assessor(s) and/or expert(s).

ACLASS will wait for the customer's submittal of documentation if not previously supplied with the application, to begin the accreditation process. ACLASS may discuss with the customer scheduling one or more of the optional services (below) during this process.

### **1.11 Assignment of Assessors and Experts**

ACLASS is formally recognized as an accrediting body by the DoD ELAP. ACLASS shall ensure that its personnel, including assessors and experts, possess appropriate expertise to assess the various aspects of the DoD QSM, ISO/IEC 17025, and the analytical methods for which accreditation is being sought. ACLASS approves every assessor and expert according to its procedures found in ACLASS Document 2, Conformity Assessment System Policies and Procedures, which is available to customers upon request.

ACLASS assigns assessors and experts, including the lead assessor, for a customer's accreditation process upon receipt of an application. The lead assessor, supported as needed by ACLASS staff, has the responsibility to direct the customer's assessment process.

The customer is notified at least 30 days prior to an assessment, if possible, of the names of the members of the assessment team. The customer has the right and should object to any assessor who has a known conflict of interest. If a customer objects to the appointment of an assessor and/or expert, ACLASS will inquire as to the reason for such objection, review the assignment, and appoint a replacement if necessary.

### **1.12 Schedule**

After the lead assessor has been assigned, ACLASS works in concert with the customer and the lead assessor to establish the schedule for all accreditation activities. Most schedules revolve around the date of the on-site assessment. The ACLASS team normally uses a 30-day (approximately) lead time to arrange travel at favorable early booking rates and to conduct the necessary off-site document review. The final assessment report based on the on-site evaluation of laboratory operations is normally issued in less than 10 business days after the on-site visit concludes. In general, the accreditation certificate is issued within 10 days of the successful

completion of any required corrective actions, the accreditation decision has been made and all invoices have been paid.

ACCLASS responds affirmatively to customer requests for an accelerated schedule based on:

- Extent and complexity of the scope of the assessment
- Availability of assessor resources
- Travel considerations

### **1.13 Introductory Visit (Optional)**

A customer may arrange for an introductory visit to acquaint the staff and management with the basic outline and approach used by ACCLASS to accredit the laboratory. This visit is an optional service and may be completed by an ACCLASS lead assessor. During this visit, ACCLASS will present the accreditation process and requirements to the customer. ACCLASS will review with the customer the proposed scope of accreditation to which the customer is seeking accreditation and may answer any specific questions regarding the process and requirements of DoD ELAP and ISO/IEC17025. They interact with staff about the witnessing and interview process used by the assessment team to evaluate critical factors influencing the outcome of the assessment, including but not limited to:

- Laboratory quality system, including controlled documents and records
- Implementation of standard operating procedures by staff
- Staff education, experience, training
- Facilities and equipment

ACCLASS is not permitted to give any advice nor consult in any manner although the assigned assessor(s) may, during the introductory visit, tour the facility and point out any obvious findings. . This is an informal visit and there are no observations, potential findings, or written reports. ACCLASS will provide a copy of the confidentiality and conflict of interest statement to the customer.

### **1.14 Practice Assessment (Optional)**

The Practice Assessment is another optional service offered by ACCLASS. The Practice Assessment is essentially the same as an accreditation assessment, except it is “unofficial.” ACCLASS will conduct the assessment in the same manner as an actual accreditation assessment and will document compliance and non-conformances on the same forms as in an actual assessment. ACCLASS will provide the customer with the assessment records.

ACCLASS will only maintain records for traceability to ensure and demonstrate impartiality of the customer's accreditation process (i.e., a Confidentiality and Conflict of Interest Statement from each ACCLASS representative). ACCLASS limits itself to two practice assessments per customer. The practice assessment has no influence on the actual accreditation assessment.

Assessor(s) assigned to perform the practice assessment normally will not perform the accreditation assessment.

### **1.15 Document Review (including Proficiency Test Sample Results)**

The ACLASS assessment team conducts an off-site review of the quality system (QS) documents, completed checklists (with quality system references identified), PT results, and data packages as soon as practical after the schedule has been agreed upon. The lead assessor will provide the customer with a document review summary report where ACLASS believes items failing to conform to the DoD QSM standard are identified. The report is a summary of findings and opportunities for improvement. Findings are deficiencies which would result in a non-conformance during assessment. Opportunities for improvement are written to document concerns and questions that may become non-conformances later in the accreditation process. This report is usually submitted no more than 30 days and no less than 10 days prior to the on-site assessment. This schedule can be altered based on the customers' needs.

ACCLASS uses the document review process to gauge the level of preparedness of the laboratory to undergo assessment and succeed in their quest for DoD ELAP and ISO/IEC17025 accreditation.

The DoD ELAP has stringent requirements for laboratory performance on Proficiency Test (PT) sample results, based on traditional NELAP practices. ACLASS examines PT performance history during the document review phase of the assessment. In cases where the laboratory performance does not meet the DoD QSM requirements, the non-conforming results, by analytical method and target analyte, are listed in the document review summary report.

In cases where the document review reveals significant weakness in the laboratory's quality system's documents, the lead assessor contacts the laboratory and discusses the preliminary findings from the document review. The lead assessor will encourage the use of a planning visit to prepare the laboratory for a full assessment if, in their opinion, it will allow the laboratory to revise the QS documents and reduce the number of findings related to basic QS issues during the full assessment.

The assigned reviewer shall complete the report on ACLASS' secure website for access by the customer and ACLASS. The report becomes part of the customer's record. Significant changes to the Quality Manual and Procedures, however named, may result in additional review time that will be charged to the customer.

### **1.16 Planning Visit (Optional)**

The planning visit is an important step in the accreditation process, but is not a requirement for accreditation. The time allowance for the visit and report preparation is normally one to two assessor days. Assigned assessors are encouraged to contact the customer before completing an agenda to discuss customer needs and expectations. The purpose and content of the planning visit may be to:

- Present ACLASS and its accreditation process to the customer
- Resolve any questions concerning the scope of accreditation and analyte listing
- Review findings from the document review and identify any additional issues
- Verify and briefly review any other relevant documentation
- perform sample assessment questioning to identify any gross non-conformances
- Plan for the accreditation assessment.

Generally, the planning visit is used to judge if the customer is ready for the accreditation assessment. ACLASS normally notifies the customer in writing at least 30 days before the planning visit with a schedule and then conducts the visit and prepares the report. The Accreditation Manager may provide guidance to the lead assessor as requested and as needed. The following records are part of the report generated:

- Attendance sheet from the opening presentation
- Confidentiality and conflict of interest statements as needed
- The planning visit report
- A copy of the accreditation checklist if used
- The status of all issues from the Document Review and this visit
- The general features of the customer (corporate entity name and address)
- General information concerning the customer such as primary function, relationship to larger corporations and physical locations

The following documents will be attached on the ACLASS secure website:

- The draft scope of accreditation and analyte listing
- Method/matrix form, if used

The lead assessor or designee shall submit the report and all records via ACLASS' secure website. A copy of the planning visit report will be available to the customer and ACLASS after upload. The records from this visit become part of the customer's records maintained by ACLASS. The customer should be asked to complete an assessment survey for feedback to ACLASS.

Ideally the customer and lead assessor will resolve all non-conformances from the document review and any additional issues for the planning visit before the accreditation assessment. The lead assessor, in consultation with the Accreditation Manager, can decide whether to process if any non- conformances are not resolved before the accreditation assessment.

### **1.17 Preparation for Initial Accreditation Assessment**

All customers, prior to initial accreditation assessment, must have completed at a minimum:

- Review and resolution, if possible, of issues identified from the document review (and planning visit if applicable)

- an internal audit covering all elements of the standard. This must also include witnessing a sampling of the proposed accredited tests or calibrations by the laboratory
- a documented management review covering elements listed in the standard
- Submittal of draft Scope of accreditation and analyte listing
- PT Summary (Form 35) with the last 18 months results

### **1.18 Accreditation Assessment**

The purpose of the accreditation assessment is to sample the customer's quality and technical management system and determine through the use of interviews, reviewing procedures, data, and records whether the customer's system is effectively implemented and meets applicable requirements. The assessment team uses the accreditation assessment to judge if the customer is ready to be accredited. A team of assessors assigned by ACLASS performs an in-depth and objective accreditation assessment. This team normally consists of two persons for a full service environmental laboratory. Smaller facilities or those with a limited scope of services (e.g. air analysis) may be assigned to one assessor to save travel-related expenses. External experts may be part of an assessment team.

The accreditation assessment shall consist of:

- a thorough review of the customer's compliance to the requirements of the DoD QSM and ISO/IEC 17025
- an opening meeting with the customer's management
- daily assessor meetings and customer debriefings
- a review of any open issues from the document review and planning visit, if applicable
- a review of any results from proficiency testing (ACLASS Form 35)
- a review of any estimations of measurement uncertainty, which includes review of uncertainty budgets, as applicable
- witnessing of the proposed scope of accreditation
- a final assessment team meeting to discuss findings
- a recommendation from the lead assessor in consultation with the assessment team to accredit, not to accredit, or hold accreditation pending non-conformance resolution
- a closing meeting

The accreditation assessment is a requirement and is the critical step in the accreditation process. ACLASS typically notifies the customer in writing with the assessment schedule and plan 30 days before the accreditation assessment. The entire assessment team conducts the accreditation assessment. The lead assessor is responsible for the preparation of the accreditation assessment report which shall be completed and submitted to ACLASS via its secure website within 10 business days after the completion of the accreditation assessment.

The quotation is used as a guide to determine estimated assessment days. Upon further review of the draft scope of accreditation, assessment days may be adjusted as necessary to complete the assessment. The lead assessor shall confer with ACLASS prior to or during the assessment for approval of any adjustments, as needed.

The accreditation assessment comprises the following steps and actions within the secure website:

- opening meeting check sheet
- attendance sheet from the opening and closing meetings
- confidentiality and conflict of interest statement for each representative of ACCLASS at the assessment
- assessment checklist
- non-conformance records written during the assessment
- closing meeting check sheet including a discussion of the proper use of the ACCLASS symbol

In addition, the following documents will be attached, as applicable:

- completed draft scope of accreditation and analyte listing as agreed upon by ACCLASS and the customer
- uncertainty budgets to support scope of accreditation claims, as applicable
- data from PT/ILC completed in the past 18 months (PT Summary- ACCLASS Form 35)
- completed PT/ILC Four Year Plan Form, as applicable
- corrective actions for any PT/ILC outliers in the past year, if applicable
- the most recent version of the Quality Manual, or equivalent, if different from the original submitted
- appropriate Method/Matrix (OPIEF) forms completed for witnessing verification (ACCLASS Form 55)

Please note that the Method/Matrix Table (ACCLASS Form 55) and PT sample results (ACCLASS Form 35) are important records of laboratory performance and assessment oversight. They must be completed with care by the laboratory prior to the assessment and verified by the assessment team. Taken together with the final assessment report and the DoD QSM checklist (ACCLASS Form 34), they constitute the principal documentation of laboratory scope of services and assessment inspection and witnessing.

It is important and required that each assessor during the assessment document how each requirement is met while in the area being assessed. This shall be accomplished using the appropriate accreditation assessment checklist for each applicable conformity assessment program. Assessor notes become part of the accreditation records and are to be kept on the assessment checklist and supplemental note form.

The assessment team classifies each non-conformance as a finding or opportunity for improvement according to the following guidelines:

A Finding is the absence of or the failure to implement and maintain one or more of the accreditation checklist requirements or a situation which would, on the basis of available objective evidence, raise significant doubt as to operations or appropriateness of the results reported by the accreditation customer.

An Opportunity for Improvement is not a finding. It is used to document items that may help a customer improve their operations. The laboratory does not have to respond to Opportunities for Improvement.

Response to any non-conformance is due within thirty days unless otherwise agreed upon between the customer and ACLASS. Responses shall be entered into ACLASS' secure website for review by the lead assessor or designee.

The customer will also receive a detailed accreditation assessment report. This report contains information about the customer, details about the accreditation and scope, identification and information about the assessors, a summary of the assessment results, and copies of each finding. The report will also include copies of the assessors' accreditation checklist and any notes.

ACCLASS will post the assessment report on its secure website accessible only to each respective customer and ACLASS. The customer will have secure access to these reports through a username and password. This is necessary to assure, where relevant, the confidentiality of documents and assessment records. DoD ELAP program requirements require release of assessment reports and nonconformance reports to DoD ELAP as part of the program criteria.

As part of the assessment report, the assessment team makes a recommendation to ACLASS about extending accreditation to the laboratory pending the resolution of any findings. The recommendation may include a follow-up visit, or not to accredit the customer. The recommendation must be supported with documentation.

ACCLASS intends that this reporting and recordkeeping methods will enhance the consistency of the assessment, reassessment and surveillance process. That is, the documentation report should be useful to both ACLASS and the customer in answering issues addressed during the accreditation assessment which may again arise during surveillance and reassessments.

*Special Note:* DoD has placed a requirement upon the accrediting bodies supporting their program to report, immediately and directly to the DoD ELAP Manager, any findings, supported by objective evidence, related to lack of data integrity and/or unethical behavior. These issues are clearly described in DoD QSM, version 4.2, section 5.2.7 and associated Grey Box 18. The ACLASS lead assessor records and reports these issues to management immediately. The ACLASS DoD ELAP representative notifies the DoD through their ELAP representative within five days upon the completion of the assessment. The assessor follows the instructions from DoD/ACCLASS with regard to including these findings in the accreditation report issued to the laboratory.

### **1.19 Response by Laboratory to Non-Conformances**

DoD ELAP program requirements specify all non-conformances be resolved prior to accreditation or continuing accreditation. This includes but is not limited to:

- a corrective action plan,
- objective evidence of successful implementation of the plan, and

- review and approval by ACLASS.

Any resulting non-conformance from accreditation assessments shall be responded to by the customer within 30 days of receipt of the assessment report. Responses shall be sent to ACLASS for distribution to the lead assessor and assessment team for review. The lead assessor notifies the laboratory within 10 days of submission of the corrective actions and supporting evidence of approval of the action or disapproval of the action with a clear explanation of the reason(s) the corrective action was insufficient. The customer must re-submit an additional corrective action response within 10 days for ACLASS approval. Should the second submission be deemed insufficient, the lead assessor turns over the completed record to the ACLASS Director of Accreditation or their designee who contacts the laboratory to construct a satisfactory solution to the un-resolved finding(s). Customers are invoiced for corrective action review based on the time needed to conduct adequate review of corrective action responses.

### **1.20 Corrective Action and Follow-up Visit**

Based on results of the assessment, recommendation of the assessment team, and extent of corrective actions, a possible follow-up visit to the laboratory may be required. If a follow-up visit is required, the amount of time to perform this service will depend on the severity of the situation. The charge for a follow-up visit will be at ACLASS' current rate, including assessor expenses.

The timing for this part of the assessment process will be coordinated between ACLASS and the customer.

A follow-up visit report will be issued to the laboratory, covering any unresolved findings. The expected response time for findings is described in section 1.18

### **1.21 Accreditation Decision**

The content and format of the assessment report will be in accordance with ACLASS procedures. There will be a one-time charge for the processing of the accreditation decision and assessment report.

ACCLASS requires the assessment and accreditation decision to be separate. Members of the assessment team will not take part in the review process.

ACCLASS will review the recommendation of the assessment team and before acting on a recommendation to grant accreditation to a customer, ensure that all accreditation requirements have been met and are properly documented in accordance with ACLASS procedures. ACLASS will notify the customer of the accreditation decision.

The date upon which the accreditation decision was made shall be the valid date of accreditation for each customer. The accreditation decision date shall determine the surveillance and reassessment cycle.

If an accreditation decision is unfavorable or if a customer has withdrawn its application, ACLASS will consider any new application only after the customer has demonstrated that adequate corrective actions have been taken as necessary, or that the reasons for the withdrawal no longer apply.

If the accreditation decision is favorable and all payments have been received, ACLASS will grant accreditation and will issue a certificate and scope of accreditation.

## **1.22 Review of Accreditation Reports**

This section describes the process for reviewing accreditation reports.

### **1.22.1 Accreditation Assessment Report Review**

Upon receipt of the accreditation reports, ACLASS shall establish the Accreditation Review Panel. The purpose of the panel is to review the customer's accreditation reports for technical compliance to the ACLASS requirements for ISO/IEC 17025 and DOD ELAP accreditation.

ACCLASS shall distribute the accreditation report to the Accreditation Review Panel. Members of the Accreditation Review Panel shall review customer accreditation reports submitted by the lead assessor and provide concurrence or non-concurrence with the accreditation recommendation to ACLASS. ACLASS then reviews the final recommendations to ensure the appropriate ACLASS processes were followed. A signed certificate and scope of accreditation is then issued upon a favorable decision on accreditation.

### **1.22.2 Surveillance Assessment Report Review**

Upon receipt of the surveillance assessment report, ACLASS shall review the report and determine whether to continue accreditation.

In instances when surveillance assessments are conducted and the customer requires a modification in its scope of accreditation and/or technical capabilities, the Accreditation Review Panel may be convened at the discretion of ACLASS.

### **1.22.3 Reassessment Report Review**

Upon receipt of the reassessment report, ACLASS shall review each reassessment report and determine whether to continue accreditation.

In instances when reassessments are conducted and the customer requires a modification in its scope of accreditation and/or technical capabilities, the Accreditation Review Panel may be convened at the discretion of ACLASS.

## **1.23 Changes to Existing Scope of Accreditation**

The DoD ELAP accreditation process supports laboratories whose scope of services must be expanded on short notice to accommodate changing client requests for analytical services.

ACLASS accepts requests from laboratories seeking to expand their scope of accredited methods or approved target analytes at any time. The laboratory must submit their request in writing to ACLASS, along with a draft scope, completed according to the directions provided with the template (see Attachment 1) and supporting documentation as outlined below. ACLASS will respond with an estimated cost based on the information contained in the application. Costs reflect the estimated level of effort to review documentation supporting the application and the on-site visit if one is required.

### **1.23.1 Additional Analytical Method(s)**

In cases where the laboratory seeks to add a new method dependent on an analytical technology currently used in an accredited method (e.g. GC, GC/MS, ICP-MS), ACLASS will propose a desk audit based on the following submittals:

- Copies of applicable SOPs
- Analyst training records
- Detection limit, limit of detection, and limit of quantitation data for each matrix requested in the added scope
- Updated PT Tracking Sheet (Form 35) showing successful PT results (two passing out of the last three) for which PT samples are commercially available for each matrix
- Complete data package for review covering all new analyses

ACLASS will deliver an appraisal of the application material by providing any findings in the same format as the on-site laboratory assessment report. The laboratory must submit a corrective action plan for each finding; these are evaluated against applicable standards. If approved, ACLASS will notify the laboratory of expansion of the scope and provide an updated certificate of accreditation. The ACLASS web site will be updated at the next scheduled update. ACLASS will provide DoD ELAP with notification of the expanded scope and other information as requested by the DoD ELAP.

If the corrective actions are not approved, ACLASS will furnish reasons and allow the laboratory to continue the corrective action process. The laboratory must follow the same timeline presented in Section 1.19.

Where the laboratory is seeking to expand their scope with analytical methods using technologies they are not currently accredited for (e.g. adding a radiochemical technique when no radiochemical methods are on the exiting scope), ACLASS will conduct an on-site evaluation at the laboratory facility. Prior to the on-site, the laboratory must submit the materials listed above. Following the on-site assessment, an assessment report will be issued and any non-conformances will be addressed using standard ACLASS procedures. The laboratory must submit a corrective action plan for each finding; these will be evaluated against applicable standards. If approved, ACLASS will notify the laboratory of expansion of the scope and provide an updated certificate of accreditation. The ACLASS web site will be updated at the next scheduled update. ACLASS will provide DoD ELAP with notification of the expanded scope and other information as requested by the DoD ELAP. This process is also outlined in Attachment 5 of this document.

### 1.23.2 Additional Target Analytes

In cases where the laboratory seeks to add additional analytes, the laboratories must meet the requirements of DOD QSM section 5.9.1 and Grey Box 43 and successfully participate at least twice a year in available PT programs, whenever possible. The Laboratory must submit this request in writing with the updated PT Tracking sheet (Form 34). The laboratory must pass at least 2 out of 3 of the most recent analyte acceptances for each analyte to be approved. In addition to successful PT participation, a full data package documenting the satisfactory performance in the following must be submitted before new analytes will be added to the laboratory list of approved analytes:

- Initial Instrument Calibration Records -Section 5.5.2.2.1.a.- h. inclusive and QSM Grey Boxes 32, 33, & 34
- Demonstration of Capability- Appendix C, section C.1.a. - f., inclusive.
- Limits of Detection - Appendix C, section C.3.1.a.- c., inclusive and QSM Grey Box D-13
- Limits of Quantitation - Appendix C, section 3.2.a - c., inclusive and QSM Grey Box D-14
- Evaluation of Selectivity - Appendix C, section 4. Note: The use of a single analyte QC sample to demonstrate capability, precision, and bias as allowed in the previous sections of the QSM cited above is not sufficient to demonstrate selectivity for multi-analyte methods. Selectivity can be demonstrated by the use of a multi-analyte QC sample for all above demonstrations or by spiking the new candidate analyte into a multi-analyte QC sample at an appropriate concentration. If the candidate analyte is contained within PT samples previously analyzed by the laboratory, and the laboratory reprocesses the original PT data and can demonstrate achievement of a satisfactory score as shown on the PT provider's summary report from the past study, selectivity will be satisfactorily demonstrated.

ACCLASS reserves the right to conduct a site visit to witness the laboratory conformance with the reference method and DoD QSM. This process is also outlined in Attachment 6 of this document.

### 1.23.3 Elimination of Methods/Analytes

Upon written request or notification from the laboratory, ACCLASS will reduce the coverage of the scope of accreditation. For any methods which might have been previously verified, approved and accredited in the program, if key personnel or equipment or business decisions make any technology or testing no longer verifiable, the scope of accreditation and the associated analyte approvals will be amended to reflect these changes.

## **2.0 REASSESSMENT FOR CONTINUING ACCREDITATION**

ACLASS will conduct a formal document review and full on-site reassessment of accredited customers once every two years for verification of continued compliance with the ACLASS DoD ELAP and -ISO/IEC17025 accreditation requirements. The reassessment process employs the same sequence of steps described in previous sections and illustrated in Figure 2. The application process is simplified because the laboratory has an existing accredited scope and continuous PT performance record.

ACLASS will provide a reassessment report to the customer as described above (Section 1.17). The report will include, but not be limited to, details of those areas assessed and any non-conformances.

Any non-conformance resulting from a reassessment shall be responded to by the customer within 30 days. Responses shall be sent to ACLASS for distribution to the lead assessor and assessment team for review. In addition ACLASS may withdraw or suspend the customer's accreditation in accordance with ACLASS procedures and the application for accreditation depending upon the nature and severity of the non-conformities.

In instances when reassessments are conducted and the customer requires a modification in its scope of accreditation and/or technical capabilities, the Accreditation Review Panel may be convened at the discretion of ACLASS.

If the results of the reassessment yield excessive non-conformities or if major modifications occur, ACLASS may require a follow-up visit and/or surveillance assessment. Applicable charges will apply.

## **3.0 SURVEILLANCE ASSESSMENTS**

While the accreditation cycle is typically a two year reassessment cycle, ACLASS establishes surveillance and reassessment plans based on an organizations proven stability and competence. ACLASS may conduct surveillance assessments on a more frequent interval should ACLASS and/or DoD ELAP determine surveillance is warranted. Surveillance assessments may be scheduled or unscheduled at the discretion of ACLASS.

At the discretion of ACLASS, a remote surveillance assessment (RSA) may be conducted in lieu of an on-site assessment. If ACLASS opts to perform a remote surveillance the laboratory must submit the appropriate documents as outlined in Attachment 7.

ACLASS will provide a surveillance report to the customer after the completion of each visit or remote surveillance. The report will include, but not be limited to, details of those areas assessed, and any non-conformance.

Any non-conformance resulting from a surveillance visit shall be responded to by the customer within 30 days. Responses shall be sent to ACLASS for distribution to the lead assessor and assessment team for review. The timeline for non-conformance submittal and review is outlined in section 1.19. In addition ACLASS may withdraw or suspend the customer's accreditation in accordance with ACLASS procedures and the application for accreditation depending upon the nature and severity of the non-conformities. In particular, if any major non-conformity causes ACLASS to have any material doubt about the performance of a test by the customer, ACLASS upon the recommendation of the lead assessor may suspend the customer's accreditation immediately until final determination is made by ACLASS. ACLASS will charge any additional fees for corrective action review and/or follow-up visits at ACLASS' current rates.

#### **4.0 CHANGE TO THE MANAGEMENT SYSTEM OR LOCATION**

If the laboratory wishes to modify, terminate or change its management system (i.e., legal, commercial or organizational status; key management; quality manual and documentation; premises; significant personnel, equipment, facilities, working environment, other resources; authorized signatories; or other criteria of competence), it must notify ACLASS. Any changes, as described above, must be submitted in writing to ACLASS.

ACLASS will make the appropriate decision as to the actions to take in accordance with its procedures. ACLASS may require the customer to forthwith return the certificate and scope of accreditation and cease using the ACLASS symbol.

If a laboratory relocates or is in the process of relocating to a facility that is different from the location that was part of the most recent assessment, the following shall apply:

- At least 30 days prior to the move, inform ACLASS in writing of the relocation and the date of the move. ACLASS in response will forward to the organization the relocation form which will include required verification information to be submitted to ACLASS for review
- Once the move has physically occurred, submit the required information on the appropriate form within 10 business days of the move. Once the above information has been received, the customer's accreditation is reviewed to verify satisfactory transition has been made. Upon satisfactory review, a new certificate and scope of accreditation will be issued reflecting the customer's new location
- Should concerns remain after this review, the organization may be suspended until these concerns are resolved. A verification visit or unscheduled surveillance assessment may be required for resolution of the concerns.
  - Should a visit be necessary, the customer will be notified and a date for the assessment will be agreed upon. Where possible the follow-up visit will take place within 30 days of notification. Special or extenuating circumstances which affect this time frame will be considered.
  - If non-conformances are issued as result of the visit, suspension will be continued until all issues are resolved. Once issues are resolved, the new certificate and scope of accreditation will be issued reflecting the customer's new location.

## **5.0 DIRECTORY OF ACCREDITED LABORATORIES**

ACCLASS publishes a listing of all the laboratories it accredits. This list includes the scopes of accreditation and is available on the ACCLASS website. The listing is also provided to DoD ELAP for publication.

## **6.0 CHANGES TO THE ACCREDITATION REQUIREMENTS AND/OR ACLASS PROCEDURES**

Changes made to the requirements and procedures for accreditation shall be communicated to the customer. This communication will include the date on which the changes are to go into effect and become mandatory to all customers. ACCLASS will give each customer a reasonable amount of time to document and implement the change.

ACCLASS will present changes of the accreditation requirements to all customers in a timely manner via the quarterly newsletter, ACCLASS web site, and/or additional written communication through mail, email, facsimile, or other means, as necessary to ensure each ACCLASS customer has a reasonable amount of time to document and implement any necessary change. The customers' response to these changes will normally be reviewed at their next surveillance, unless the changes to the accreditation requirements warrant earlier verification, as determined by ACCLASS.

## **7.0 CONFIDENTIALITY AND DISCLOSURE OF INFORMATION**

The information included in the application for accreditation, an assessment or other information associated with a customer's assessment process is considered confidential. Such information shall not be released unless the customer provides, in writing, to ACCLASS permission to release such information.

All reports and information which ACCLASS acquires during the ACCLASS accreditation process will be treated as confidential by all ACCLASS employees, assessors, experts and associates. ACCLASS assessment team members are required to maintain confidentiality regarding information obtained about the customer and its operations. Each ACCLASS assessor and expert will sign a confidentiality statement for each customer for whom accreditation services are provided by the ACCLASS assessor and expert.

All information gathered for the DoD ELAP is open for review by personnel identified by the DoD ELAP. The outcome of the accreditation, assessment report, non conformances and laboratory corrective action are submitted to the DoD ELAP as required by the program criteria.

DoD ELAP requires the retention of all accreditation documentation to be maintained for a minimum of five (5) years.

## **8.0 CERTIFICATE, SCOPE AND ACCREDITATION SYMBOL**

ACLASS controls the certificate, scope of accreditation and the use of the ACLASS accreditation symbol with ACLASS procedures and as provided for in the application for accreditation. The customer may use the ACLASS accreditation symbol on letterhead, websites, marketing documentation, test reports, test certificates, etc. At no time or in any way may the customer use the symbol to indicate ACLASS approval of the results of its test(s).

The customer shall ensure that the accreditation symbol is only used within the scope of the accreditation. The ACLASS symbol may not be used on certificates and reports which contain areas/parameters which are not on the customer's approved ACLASS scope of accreditation, except in the case of a certificate or report which contains both accredited and non-accredited areas/parameters. In this case, the non-accredited tests shall be clearly identified on the report that is issued. The identification should also include a footnote on the report or certificate itself which acknowledges that the report includes non-accredited work.

ACLASS may withdraw a customer's accreditation certificate and the use of the accreditation symbol at any time for a customer's misuse of the symbol, or laboratory management system failures.

### **8.1 Symbol Usage on Test Reports**

All ACLASS customers are required to either use the ACLASS symbol on all accredited test reports or include the following statement (edited as appropriate) on accredited tests reports:

“This test is accredited under the laboratory's DoD ELAP accreditation issued by the ANSI-ASQ National Accreditation Board/ACLASS. Refer to certificate and scope of accreditation [insert accreditation number here].”

ACLASS Document 3 provides a complete description of the proper use of the ACLASS Certificate, Scope of Accreditation, and the ACLASS symbol. Prohibited uses are also explained.

## **9.0 COMPLAINTS AND APPEALS**

The purpose of this section is to provide for the fair and equitable handling of external complaints and appeals from any interested party (appellant/complainant). Complaints and appeals brought before ACLASS by customers or other external parties shall be subject to this ACLASS procedure. Complaints and Appeals related to DoD laboratories may require review and input from the DoD ELAP in order to ensure consistency of the program.

The ACLASS DoD ELAP representative will notify the DoD within 5 days of receipt of any complaint or appeal related to a DoD accreditation. The DoD laboratory may assign a person to participate in the review of the appeal or complaint process.

If an accreditation customer seeking or maintaining accreditation has received an unfavorable report, action or decision, the customer may appeal the report, action or decision in accordance with this ACLASS procedure. Complaints may be initiated from other than accreditation customers.

## 9.1 Definitions

*Appeals:* Appeals are normally actions taken by accredited laboratories or applicant laboratories to ACLASS and its requirements for accreditation objecting to any adverse decision taken in any step of the process from application for accreditation to the final decision on accreditation.

*Complaints:* Complaints are an expression of dissatisfaction with any aspect of ACLASS and its operations lodged by anyone in writing or otherwise.

## 9.2 Appellant and Complainant

A party who has an interest in an action, decision, or report is the appellant/complainant. This may include an appeal coming from the customer about the handling of accreditation matters, a complaint from the users of the services provided by the customer, or a complaint from any other external party regarding any other matter. Any negative feedback provided by the customer from the customer survey will be handled according to this document.

The accreditation customer is informed of this procedure upon receipt of the quotation and is briefed about this process during the closing meeting in accordance with this document.

## 9.3 Appeals Procedure

The ACLASS appeal process has two levels: Level 1 appeals are heard by a panel of ACLASS staff and/or assessors; level 2 by a panel of the Accreditation Council. If unsettled, an appeal also has the 3<sup>rd</sup> stage possibility of resolution with the ANSI Appeals Board.

Level 1 appeals are heard by a panel of three consisting of staff and/or accreditation assessors not involved in the assessment and a DoD representative. This is normally the level applied to any appeal of an assessment nonconformance.

Level 2 appeals are made to the Accreditation Council and heard by a panel of three members of the Council. This is the first level for any appeal of an accreditation decision or any other decision of the Accreditation Council. It is also the second level of appeal if either party (the appellant or ACLASS) is not satisfied with the decision made by the level 1 appeal panel. In addition to the panel of Accreditation Council members, at least one member of the level 2 appeals panel will be a DoD representative. This person may be different than the person participating as a member of a Level 1 appeal. This is left to the discretion of the DoD.

A level 2 appeal shall be lodged in writing no later than 30 days after notification to the customer of the decision or action from the level 1 appeal, or whenever the appropriate appeal panel may reasonably assume the decision or measure in question to be known to the appellant.

Appeals shall be lodged using the appeals form and will include appropriate substantiation for the appellant's position.

A panel of three members is appointed, with one of the three members appointed as chair. For level 1, the panel members are appointed by the ACLASS Vice President and/or Senior Accreditation Manager. For level 2, the panel members are appointed by the chair of the Accreditation Council. The appellant and ACLASS shall be informed of the members of the panel and have an opportunity to object to the selection(s).

Appeals are not legal proceedings. Therefore, ACLASS shall be notified at least 10 days in advance if an appellant intends to have legal counsel present to ensure ACLASS has sufficient advance notice so that it can also have legal counsel present.

The appeal shall be heard within 60 days unless otherwise agreed by all parties.

Unless otherwise agreed in advance, the level 2 appeals hearing shall be conducted as follows:

- Introductions.
- Presentation by the appellant, limited to 30 minutes.
- Presentation by ACLASS, limited to 30 minutes.
- Rebuttals, limited to 10 minutes for each party.
- Questions by the panel.
- Closing of the hearing. The chair shall:
  - Make a formal projection regarding the expected time frame for communicating the documented final decision (normally not to exceed two weeks).
  - Alert all parties of the possibility of 3<sup>rd</sup> level resolution at the ANSI appeals board level if required.
  - Dismiss the parties.

Following the hearing, the panel members will deliberate without any involvement by the appellant or ACLASS.

The chair shall document the panel's decision and send it concurrently to the designated representatives of the appellant and ACLASS.

The appeal panel's decision will be documented. However, any notes made by panel members in preparing for the appeal, during the hearing, or during the subsequent deliberations will not be maintained.

If a level 2 decision by an appeal panel of the Council is unfavorable to the appellant, the appellant may lodge a final appeal in writing to ACLASS. ACLASS shall immediately transmit this letter to the designated responsible ANSI staff for timely consideration and action by the

ANSI Appeals Board. The process is described in the ANSI Appeals Board Operating Procedures and can be accessed by visiting [www.ansi.org](http://www.ansi.org).

ANSI shall communicate the decision of the ANSI Appeals Board to the appellant and ACLASS.

#### **9.4 Complaints Procedure**

Users of the services provided by the ACLASS customer, or any other external party regarding any other matter may file a complaint using the complaint form. Any complaint shall be directed to the Vice President.

ACCLASS requires the complainant, alleging non-conformance of an accredited customer with the accreditation requirements and scope, to first file a complaint directly with the customer in question and allow for the customer's complaint process to be initiated and completed. If the complainant finds the results of the customer's investigation unacceptable, the complainant may submit the appropriate form to ACLASS and ACLASS shall subsequently carry out an additional investigation.

If a well-reasoned complaint is submitted to ACLASS in writing, the ACLASS Vice President will investigate. ACLASS shall inform the complainant and customer of the results of the investigation.

If the complaint is valid, any cost of the investigation may be charged to the offending customer. If the complaint is determined to be unfounded, the customer shall not be charged for any cost of the investigation.

If the complaint is from a competitor of an ACLASS customer, to prevent the competitor from initiating a complaint inappropriately, ACLASS may require the complainant to agree to pay for the ACLASS investigation in the event that the allegation cannot be substantiated.

Upon submission of a complaint, ACLASS shall:

- Decide on the validity of the complaint(s)
- Take any steps necessary to ensure that if the complaint(s) affects an ACLASS customer it is addressed first by the customer
- Take any necessary actions and assess their effectiveness
- Record the complaint(s)
- Respond in a timely manner to complaint(s)

The Vice President shall establish a plan of action upon receipt of a valid complaint. This plan of action could include the establishment of a committee, delegation, or any other action deemed necessary to address the complaint. The plan of action will be documented. The action plan will include the notification and determination of the involvement of one or more members of the FSMO. If action is necessary to address the complaint, the action and decision will also be documented. The Vice President will inform the complainant and customer in writing (i.e. email, facsimile, or letter) of the action(s) taken and the decision.

ACCLASS may require the customer to undergo an on-site visit, in which case ACCLASS shall outline the expectations to the customer prior to the visit, which will be the focus of the on-site visit. If the customer does not meet those expectations, ACCLASS shall intervene and facilitate the direction of the visit and the assessor(s) may pursue assessment trails of the organization's system. All costs associated with this visit, including review of reports is the responsibility of the customer.

If such a visit is required, the visit will not count as the annual surveillance and/or reassessment visit. The outcome of the visit will be made known to both the complainant and the customer.

## 10.0 TRANSFER OF ACCREDITATION

Any laboratory requesting to transfer accreditation bodies (still in good standing) is required to meet the minimum requirements defined below under Section 16.1. The transfer of accreditation may occur when legal status changes in accordance with this document, the application for accreditation, and ACCLASS Document 2.

The term "in good standing" is defined as an organization that transfers with an active status (i.e. not suspended or under threat of suspension) during the middle of their then current accreditation cycle from their then current Accreditation Body. If the organization transfers at the end of their then current accreditation cycle, a full assessment shall be conducted against all elements of the standard.

The ACCLASS minimum requirements are referenced from IAF-GD6-2003, *IAF Guidance on the Application of ISO/IEC Guide 66* (or future versions thereof) and APLAC MR 010, *Guidelines for an APLAC MRA Signatory When Requested to Accredite a Conformity Assessment Body (CAB) Within Another Economy Where There is an APLAC MRA Signatory* (or future versions thereof). ACCLASS reserves the right to modify or change these minimum requirements from time to time.

### 10.1 Transfer Minimum Requirements

**Accreditation:** Only organizations whose accreditations meet the ACCLASS Transfer Minimum Requirements are eligible for transfer. Organizations holding accreditations that do not meet the ACCLASS Transfer Minimum Requirements shall be treated as new customers.

Transfer Review (as defined below) will normally occur from an organization that is still in good standing with their then current Accreditation Body. If the transfer organization meets the minimum requirements as defined under Transfer Review, accreditation shall be granted for one year with a full reassessment occurring at the end of one year.

If the organization is seeking a transfer of accreditation and their accreditation has been suspended or withdrawn or is known to have been suspended or withdrawn, transfer will not be accepted. In such instance, the organization shall be treated as a new customer.

The granting of accreditation to an organization that seeks to transfer their accreditation to ACLASS and meets the minimum requirements as defined under Transfer Review shall be granted accreditation according to the current ACLASS decision process.

**Transfer Review:** ACLASS shall carry out a review of the organization applying for transfer of accreditation, still in good standing, to ensure that all elements of the DoD QSM and ISO/IEC 17025 standard and the full scope of accreditation have been assessed. Transfer Review shall be conducted against all elements of the standard and the full scope of accreditation by reviewing the reports of the organization's previous Accreditation Body and a site visit to the organization.

Transfer Review will also only occur if the organization is transferring in good standing from an ILAC MRA signatory.

The Transfer Review shall cover the following:


- Confirmation that the customer's accredited activities fall within the activities of ACLASS
- Verification that a valid (ILAC MRA signatory) accredited certificate and scope of accreditation, in terms of authenticity, duration, and scope of activities covered by the organization's scope of accreditation, is held with respect to the site or sites wishing to transfer accreditation.
- The state in the current accreditation cycle. (If transfer occurs at the end of their current accreditation cycle, then a full assessment shall occur, i.e., treated as a new customer).
- Review of the last assessment/reassessment reports, subsequent surveillance reports, and any outstanding non-conformances arising from the reports. A review to ensure the entire scope of accreditation, as well as all elements of the DoD QSM and ISO/IEC 17025 was assessed by the previous Accreditation Body.
- ACLASS surveillance visit to the site or sites according to the ACLASS surveillance policy.
- The Transfer Review process will not begin until all previous reports of the organization's previous Accreditation Body have been reviewed and evidence suggests the organization previously has met the requirements for DoD QSM and ISO/IEC 17025 accreditation by their then current Accreditation Body.
- A potential customer shall make its request for transfer by submitting to ACLASS an ISO/IEC 17025 Application together with the application fee then charged by ACLASS and the necessary information required as mentioned under Transfer Review.
- If for any reason the customer is unable to provide evidence that their management system was previously assessed against all the requirements of DoD QSM ISO/IEC

17025 and are currently in good standing with their then current Accreditation Body, the customer shall be treated as a new customer.

- Any organization (still in good standing) requesting an extension of scope, during this Transfer Review, to an already approved scope of accreditation by their previous Accreditation Body shall be subject to on-site verification. Additional assessment days may be necessary.

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Approval:

  
\_\_\_\_\_  
/s/  
Vice President

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**Attachment 1: Scope of Accreditation Form**

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## Completing ACLASS Scope Listing for DoD ELAP Accreditation

1. Use only the ACLASS matrix identification terms as shown in the table below. It is acceptable to list multiple matrices as a single line item as long as the group of target analytes and specification or standard method applies to all matrices. See items #8 in the example scope provided.

ACLASS Matrix Identifier Term	Description
Drinking Water	
Water	All forms of water other than drinking water
Solid	Any solid, including soils, sediments, sludges, solid waste, oils
Air	Air or vapor phase

2. Use any generally accepted descriptors for the Specific Test or Group of Analytes.
3. EPA method numbers can be used without the “EPA” lead term but other methods should use the generally accepted term for the source, e.g. SM for Standard Methods, ASTM for ASTM, etc.
4. Multiple versions of the same method, e.g. 8270C and 8270D should be listed as a single line item with the appropriate ACLASS matrix term. See items #3, 4, 5, and 9 in the example scope provided. The listing of different methods as a single line item is acceptable as shown in item #11 in the example as long as the matrix identifiers and target analytes remain the same for all methods. Do Not list methods which apply only to aqueous or solid matrices on the same line e.g. 7470 and 7471B even if the target analytes are the same.
5. All sample preparation and cleanup methods should be listed as single line items with the appropriate ACLASS matrix term and specific test or group of analytes using the conventions described in #4, above. Do Not associate preparation methods/cleanup methods with specific determinative methods e.g. 8270C / 5030B / 5035 on the scope.

Special Note: The fact that a laboratory may develop a standard operating procedure to cover a combination of closely related methods e.g. EPA 624 and 8260B, does not mean that the methods should be listed as a single line item in the draft scope. In the example given here, EPA method 624 is restricted to aqueous samples by its scope (Item #7) and it would be inappropriate to list it as the analytical method used to analyze soil samples; EPA method 8260B would be listed as the analytical method for waters and/or soils (Item#8). For DoD ELAP work, the laboratory preparation method for the soil or other solid matrix destined for volatile analysis by 8260B must also be reported and must be on the laboratory’s scope of accreditation as discussed in item #5, above.

### Example of ACLASS DRAFT Scope

MATRIX		SPECIFIC TEST or GROUP of ANALYTES	SPECIFICATION OR STANDARD METHOD (all EPA unless specified otherwise)	KEY EQUIPMENT OR TECHNOLOGY USED
1	Water	Acid digestion for metals analysis	3010A	
2	Solid	Acid digestion for metals analysis	3050B	
3	Water	Purge and trap extraction for volatiles analysis	5030B / 5030C	
4	Solid	Purge and trap extraction for volatiles analysis	5035 / 5035A	
5	Water/Solid	OP Pesticides	8141A / 8141B	GC/ECD
6	Water	OP Pesticides	614	GC/ECD
7	Water	VOAs	624	GC/MS
8	Water/Solid	VOAs	8260B	GC/MS
9	Water/Solid	Semi-VOA	8270C / 8270D	GC/MS
10	Water	Oil & Grease	SM 5520B	Gravimetry
11	Water	Anion analysis	300.0 / 9056 / 9056A	Ion Chromatography

**Attachment 2: Proficiency Test Results Summary, Form 35**

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**Attachment 3: Data Package Submission Requirements**

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## Data Package Contents

For each method listed in the proposed scope of accreditation, data packages must be generated. These data packages should normally include a copy of the records/data stated below. Some of the records/data stated below may not be applicable to the analytical technique/method. All records and data must be clearly labeled and provide a traceable link to the method. **Any items below not found in the laboratory-assembled data packages will warrant assessors, when on-site, to check their presence in the system and write findings, as appropriate, for their absence from the packages prepared.**

1. Correspondence between the client and laboratory regarding sample collection and sample containers. If laboratory personnel did not collect the sample, a copy of the laboratory's sample acceptance policy that was sent to client.
2. Example(s) of Sample Labeling (Field and Laboratory Labels)
3. Analytical Final Report Issue to Client including any re-issuance of the report
4. Case Narrative with explanation of qualified data, as applicable
5. Completed Chain of Chain Form(s) (include all types of COC forms, internal tracking forms and evidentiary COC form, if applicable)
6. Daily Instrument Run Log
7. Associated Instrument Performance Check(s) / Performance Summary w/ record determining acceptance, For example:
  - a) GC/MS: Tune
  - b) ICP: Spectral interference check
  - c) GFAA: Stability Check
8. Method Blank(s)
  - a) Instrument Printout(s) including instrument response and concentration w/ record determining acceptance.
9. Associated Initial Calibration
  - a) Instrument Printout(s) including instrument response and concentration w/ record determining linearity acceptance. Include equation for the curve, as applicable.
  - b) Copy of applicable page(s) of Standard Receipt/Preparation Log(s)
10. Associated Initial Calibration Verification Check
  - a) Instrument Printout(s) including instrument response and concentration w/ record determining acceptance.
  - b) Copy of applicable page(s) of Standard Preparation Log(s)
11. All Continuing Calibration Checks (CCVs)
  - a) Instrument Printout(s) including instrument response w/ record determining of acceptance.
  - b) Copy of applicable page(s) of Standard Preparation Log(s)

12. All Continuing Calibration Blanks (CCBs)
  - a) Instrument Printout(s) including instrument response and concentration w/ record determining acceptance.
13. Surrogate Performance Summary w/ record determining acceptance, as applicable.
  - a) Quality Control Charts, as applicable
14. Internal Standard Performance Summary w/ record determining acceptance, as applicable
15. Matrix Spike
  - a) Instrument Printout(s) including instrument response and concentration w/ record determining acceptance.
  - b) Copy of applicable page(s) of Standard Preparation Log(s)
  - c) Quality Control Charts, as applicable
16. Matrix Spike Duplicate or Sample Duplicate (MSD)
  - a) Instrument Printout(s) including instrument response and concentration w/ record determining acceptance.
  - b) Quality Control Charts, as applicable
17. Laboratory Control Sample (LCS)
  - a) Instrument Printout(s) including instrument response and concentration w/ record determining acceptance.
  - b) Copy of applicable page(s) of Standard Preparation Log(s)
  - c) Quality Control Charts, as applicable
18. Analytical Sample Results (including any confirmatory and/or re-analyses)
  - a) Instrument Printout(s) including instrument response and concentration w/qualifiers, as applicable.
19. Copy of applicable page(s) of Preparation / Extraction Log(s)
20. Copy of applicable page(s) documenting chemical preservation, turbidity checks, % solids determination, weights etc.. This documented information may have been provided in one of the previous documents.
21. Copy of documentation verifying the completion of data review / cross checks.
22. Record of Sample Disposal
23. Copies of any corrective action reports issued during the associated analyses w/investigation and corrective action.
24. Associated worksheets or other documents where manual calculations have been performed on the data.
25. Information on reporting limits and the laboratory's reasoning for setting limits or reference to where this is documented.
26. LOD and LOQ determinations for each method.

**Attachment 4: Instructions for Completion of Method / Matrix Worksheet,  
Form 55**

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### ACLASS Method/Matrix Worksheet for DoD ELAP

DoD ELAP-ISO/IEC 17025 ASSESSOR REPORT METHOD REVIEW MATRIX			LAB NAME:			ASSESSMENT DATE(S):			Page ___ of ___		
Parameter/ Test Name or Technology	Method(s) (From Scope)	Depth of Assessment *see codes	Name(s) of Trained Personnel (interviewed by assessment team**)	Accom & Environment Equipment & Ref. Mat'ls.	Procedure/ Operating Instructions [filename]	Measurement Uncertainty Verification	Traceability; Verification/ Calibration	Sampling; Handling/ Prep.	Quality Checks	Records	Report/ Certificate
Analysis of Volatile Compounds by GC/MS	8260B	To be completed by assessment team after the on- site	Staff names to be provided by laboratory  John Doe Carol Expert Kermit Frog**	List major equipment in each test e.g.  GC #1 – HP 5800 GC#2 – Varian 1250	List applicable SOPs -- to be cited by laboratory staff e.g. SOP#77 – VOA SOP#17 - VOA	RSD of LCS  Uncertainty reported as range of values at 95% confidence limit	As per the method SOP and reference method	As per the method SOP and reference method	ICal.; ICV; MB, MS/MSD; LCS.; CCV; Dup; Surr; IS; RT; per method, as appropriate; PT samples	Log books, Instrument e- records, Instrument printouts, Spreadsheets, as appropriate	Data Package identifier provided by laboratory
Analysis of Explosives by HPLC	8330/ 8330B					RSD of LCS  Uncertainty reported as range of values at 95% confidence limit	As per the method SOP and reference method	As per the method SOP and reference method	ICal.; ICV; MB, MS/MSD; LCS.;; CCV; Dup; Surr; IS; RT; per method, as appropriate; PT samples	Log books, Instrument e- records, Instrument printouts, Spreadsheets, as appropriate	
Automated Soxhlet Extraction	3541					NA	NA	As per the method SOP and reference method	NA	Log books	NA
Solid Phase Extraction	3535/3535A					NA	NA	As per the method SOP and reference method	NA	Log books	NA

#### Instructions for completion of the Method/Matrix Worksheet

- 1) The first two columns are completed by the ACLASS lead assessor or designee and forwarded to the laboratory.
- 2) The columns highlighted in green are completed by the lab and the worksheet is returned to ACLASS no less than 2 weeks prior to the on-site assessment.
- 3) The remaining columns will be completed by the assessor(s) at the time of the on-site assessment.

**Attachment 5: Request for Addition of New Analytical Methods**

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## Guidance for the Approval and Addition of New Analytical Methods

In cases where the laboratory seeks to add a new method dependent on an analytical technology currently used in an accredited method, e.g. GC, GC/MS, ICP-MS, ACLASS will propose a desk audit based on the following submittals:

- Copies of applicable SOPs
- Analyst training records
- Detection limit, limit of detection, and limit of quantitation data for each matrix requested in the added scope
- Successful PT results [two passing out of the last three] for which PT samples are commercially available for each matrix
- Complete data package for review covering all new analyses

ACLASS will deliver an appraisal of the application material by providing any findings in the same format as the on-site laboratory assessment report. The laboratory must submit a corrective action plan for each finding; these are evaluated against applicable standards. If approved, ACLASS will notify the laboratory of the expansion of the scope and provide an updated certificate of accreditation. The ACLASS web site will be updated at the next schedule update. ACLASS will provide DoD ELAP with notification of the expanded scope and other information requested by the ELAP.

If the corrective actions are not approved, ACLASS will furnish reasons and allow the laboratory to continue the corrective action process.

Where the laboratory is seeking to expand their scope with analytical methods using technologies they are not currently accredited for, e.g. adding a radiochemical technique when no radiochemical methods are on the exiting scope, ACLASS will conduct an on-site evaluation at the laboratory facility. Prior to the on-site, the laboratory must submit the materials listed above. An assessment report will be issued and any non-conformances will be addressed using standard ACLASS procedures. The laboratory must submit a corrective action plan for each finding; these will be evaluated against applicable standards. If approved, ACLASS will notify the laboratory of the expansion of the scope and provide an updated certificate of accreditation. The ACLASS web site will be updated at the next schedule update. ACLASS will provide DoD with notification of the expanded scope and other information requested by the ELAP.

Questions about specific laboratory plans may be submitted to [gbowman@anab-aclass.org](mailto:gbowman@anab-aclass.org) or [lpeytonj@comcast.net](mailto:lpeytonj@comcast.net).

**Attachment 6: Request for Addition of New Target Analytes to Existing Method Accreditations**

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## **Guidance for the Approval and Addition of New Analytes to Methods Accredited currently Under the ACCLASS DoD ELAP (Particularly arranged for analytes not available in current PT schemes)**

Additional target analytes may be added to a laboratory's list of approved / accredited analytes at any time based the fulfillment of certain requirements. This guidance is offered to assist laboratories in these efforts but does not replace the laboratory's responsibility in exercising professional judgment in the interpretation of the most recent version of the Department of Defense Quality Systems Manual [DoD QSM].

Each application for the addition of new analytes to a method currently accredited under the ACCLASS program will be evaluated based on its technical merits and the submission of data demonstrating experimental confirmation that the laboratory meets the performance standards contained in the method and the requirements of the DoD QSM.

The following guidance applies to both standard analytes, i.e. those listed within the scope of the published method, and non-standard analytes not currently listed in the published method. Each element of the guidance is referenced to the applicable sections of the DoD QSM, version 4.1 as shown below:

- I. Section 5.5.2.2.1.a.- h. inclusive and QSM Grey Boxes 32, 33, & 34 (related to Initial Instrument Calibration)
- II. Appendix C, section C.1.a. - f., inclusive. (related to Demonstration of Capability)
- III. Appendix C, section C.3.1.a.- c., inclusive and QSM Grey Box D-13 (related to LOD)
- IV. Appendix C, section 3.2.a - c., inclusive and QSM Grey Box D-14 (related to LOQ)
- V. Appendix C, section 4. (related to Selectivity) Note: The use of a single analyte QC sample to demonstrate capability, precision, and bias as allowed in the previous sections of the QSM cited above is not sufficient to demonstrate selectivity for multi-analyte methods. Selectivity can be demonstrated by the use of a multi-analyte QC sample for all above demonstrations or by spiking the new candidate analyte into a multi-analyte QC sample at an appropriate concentration. If the candidate analyte is contained within PT samples previously analyzed by the laboratory, and the laboratory reprocesses the original PT data and can demonstrate achievement of a satisfactory score as shown on the PT provider's summary report from the past study, selectivity will be satisfactorily demonstrated.

A full data package documenting achievement of satisfactory performance in I to V above must be submitted before new analytes will be added to the laboratory's list of approved analytes. On rare occasion, ACCLASS may conduct a site visit to witness the laboratory conformance with the reference method and DoD QSM.

Questions about specific laboratory plans may be submitted to [gbowman@anab-aclass.org](mailto:gbowman@anab-aclass.org) with a copy to [lpeytonj@comcast.net](mailto:lpeytonj@comcast.net).

**Attachment 7: Form 53 DoD ELAP and ISO/IEC17025 Remote Surveillance  
Letter and Instructions**

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**DATE****CONTACT  
COMPANY  
STREET  
CITY, STATE ZIP****RE: Remote Surveillance – DoD ELAP / ISO 17025**Dear **CONTACT**:

ACCLASS establishes surveillance and reassessment plans based on an organization's proven stability and competence. For each reassessment we require the review of certain elements of the standard and maintain records of this review. Please submit the information requested in the following list.

- Provide a copy of the quality manual/QAPP if there has been any change since the last visit (if not already sent to ACLASS) as well as applicable quality system and technical method standard operating procedures.
- If there are any desired changes to the accreditation scope(s), please revise the attached MS Word copy of your scope(s) from ACLASS and make changes to them. Include the changed file with your submission. **Scope(s) attached.**
- As part of your previous assessment, you were required to submit successful corrective actions to all findings. Provide evidence of your recent review of the corrective actions and attestation that all corrective actions are still in place and continue to be effective. A copy of the corrective actions accepted by ACLASS from your last assessment is included.
- Present representative samples of your use of the ACLASS symbol, if appropriate.
- Describe any changes to the management & organization (4.1) structure.
- Submit a current organization chart.
- Provide evidence of any complaints (4.8) and their resolution.
- Provide a copy of your most recent internal audit (4.14)
- Provide a copy of your most recent management review (4.15)
- Provide copies of proficiency testing results beyond those studies listed here from our ACLASS records with the updated PT Tracking Sheet (Form #34): **List attached.**
- Provide a list of all current DoD ELAP-related DLs, LODs, LOQs, and precision and bias estimates for all LOQs.
- Provide a copy of recent data packages for each matrix type and analytical method identified on the attached list. A copy of the data package requirements is also provided.

A reminder checklist has been provided on the next page. Please complete it within 30 days of receipt and return this entire form with attachments to your assigned Sharefile folder (<https://aclass.sharefile.com>).

If you have any questions please do not hesitate to contact the ACLASS DoD ELAP Program Manager, [lpeytonj@comcast.net](mailto:lpeytonj@comcast.net), with a copy to the ACLASS Accreditation Manager for Testing Laboratories [gbowman@anab-aclass.org](mailto:gbowman@anab-aclass.org).

Sincerely,

Accreditation Manager, Testing  
ANSI-ASQ National Accreditation Board/ACCLASS

Requirement		Comments
Has the Quality Manual / QAPP been revised?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Has a copy of the most recent revision been sent to ACLASS?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	
Do you have interest in any changes to the scope of accreditation for ISO 17025 or for DoD ELAP ? If yes, submit MS Word versions of the change.	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Has your point of contact changed as listed on the scopes of accreditation? Indicate new contact in Comments box.	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Has evidence for full implementation of your corrective actions to previous ACLASS report findings been provided?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	
Have examples of ACLASS symbol usage been supplied?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Has the management structure changed?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Has a description of the changes been provided?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	
Has evidence of ISO 17025 or DoD ELAP complaint resolution been provided?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Has evidence of internal audit been supplied?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
Has evidence of management review been supplied? If done at the corporate level in multi-site organizations, include the lab's input into management review.	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Have any additional PT studies been completed beyond those listed in the letter above (that are relevant for ISO 17025 or DoD accreditations)?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Have all current DoD ELAP-related DLs, LODs, LOQs , and precision and bias estimates for all LOQs been attached?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Are the requested recent data packages for each matrix type and analytical category attached for review?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Have you attached any corrective actions related to PT study responses?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Contact name		
Contact title		
Contact email		
Telephone number		
Fax number		
Number of sites		
Number of technical staff members		
Number of non-technical staff members		

**REVISION HISTORY**

<b><u>Date</u></b>	<b><u>Description/Author</u></b>
May 28, 2009	Document initiated for the DoD ELAP requirements.
June 4, 2009	Review and edits – K. Greenaway
June 12, 2009	Review and edits – Hirt, Greenaway
June 28, 2009	Review and edits – Hirt, Moore
June 29, 2009	Review and edits – K. Greenaway
July 11, 2009	Review and edits – B. Hirt, M. Moore
July 13, 2009	Review and edits – K. Greenaway, R. Muse
July 15, 2009	Approval – K. Greenaway
May 2010 – April 1 2011	Complete re-write of document – G. Bowman, L. Jackson, B. Hirt
April 5, 2011	Final review and approval – K. Greenaway

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