



ANSI-ASQ National Accreditation Board

ISO/IEC 17025 Accreditation Requirements

Document 3

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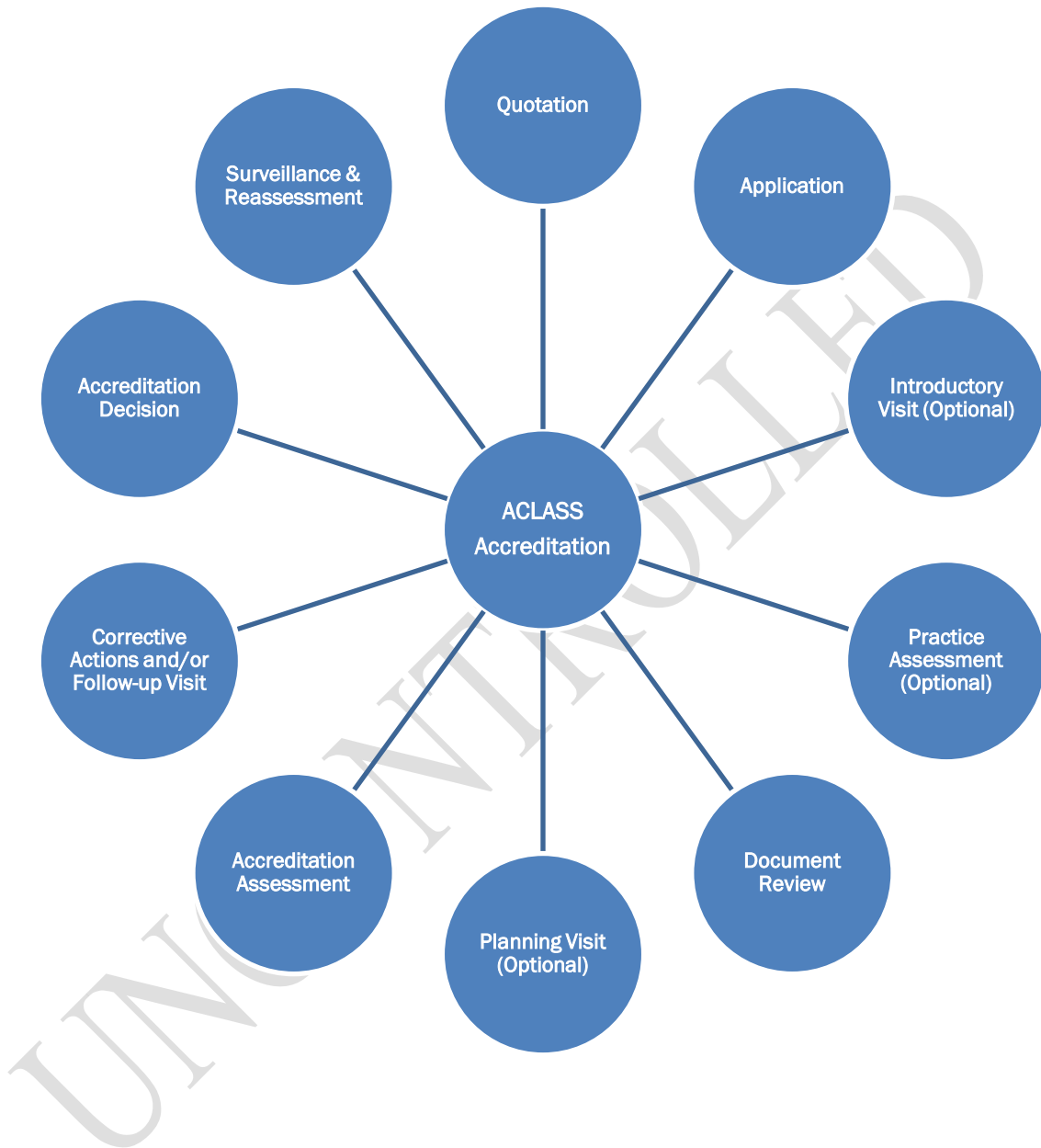
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This cycle diagram briefly shows the ACLASS accreditation process:



0.0 PURPOSE

This purpose of this document is to establish policies for and provide a general description of the ACLASS ISO/IEC 17025 accreditation process to the customer. This document is available to the general public and any interested party, and is written specifically to communicate the ACLASS ISO/IEC 17025 accreditation process to customers. This document defines all requirements for accreditation and is mandatory for all ACLASS ISO/IEC 17025 applicant 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 ACLASS fee structure is available upon request.

The term “customer” as used in this document refers to an organization seeking or holding accreditation from ACLASS.

1.0 ACCREDITATION PROCESS

1.1 Quotation and Charges

A customer can request and obtain a quotation. Any authorized ACLASS personnel can provide a quotation. 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 time spent and the number of different types of calibrations and/or tests as stated in the then current ACLASS fee schedule, which is publicly 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. 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 calibrations or tests, and number of employees. Quotations are subject to change over time.

1.1.1 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. (Significant review typically means more than five findings issued and/or one or more major non-conformance issued.) Charges are billed at a rate of \$1,100/day. 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.

1.1.2 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.

1.1.3 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 1.1.2, above.

1.1.4 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.

1.1.5 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.

1.1.6 Assessor Travel Time

AClass recognizes that traveling to customer locations requires personal time. For non-overseas travel¹, 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 domestic travel time is \$175 each way. For trips involving multiple laboratories, this amount also applies to each leg of travel between labs.

For international 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. For trips involving multiple laboratories, additional travel time may apply at the same rate. 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, *AClass Travel Cost Comparison*, shall be completed to justify the alternate mode as more cost effective for the customer. Receipts shall be submitted along with expense reports indicating travel time. Receipts shall be made available to the customer upon request.

AClass per diem for meals is \$35 per day, including travel days.

1.1.7 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.

The appeal of an invoice will follow the appeal process outlined in this document, section 8.3. If the decision is in favor of the appellant, a credit or refund will be issued, including any interest the customer may have paid.

1.2 Application

Every customer seeking accreditation must submit an application. The application form, which is typically provided with each quote, should be submitted in electronic format, when possible, and should include the following:

- locations to be covered by the accreditation

¹ Non-overseas travel includes North and South America, excluding Hawaii and Alaska.

- proposed scope of accreditation
- quality manual and associated operating procedures, however named
- uncertainty budgets, if applicable
- proficiency testing/inter-laboratory comparison activity

ACLASS accreditation activities shall be confined to the draft scope of accreditation, agreed upon during the initial accreditation assessment opening meeting.

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*. The requirements for accreditation are based on ISO/IEC 17025.

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 reasonably obtain the 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.

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.

1.3 Introductory Visit

The introductory visit is an optional service and may be completed by an ACLASS lead assessor. During this visit, ACLASS will present the accreditation process and requirements to the customer. ACLASS 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. ACLASS 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 non-conformances. This is an informal visit and there are no findings or written reports. ACLASS will provide a copy of the Confidentiality and Conflict of Interest Statement to the customer.

1.4 Practice Assessment

The Practice Assessment is another optional service offered by ACLASS. The Practice Assessment is essentially the same as an accreditation assessment, except it is “unofficial.” ACLASS 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. ACLASS will provide the customer with the assessment records.

ACLASS 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 ACLASS representative). ACLASS 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.

1.5 Document Review

ACLASS performs a document review to verify that all management system elements of the appropriate requirements are addressed, understood, and documented by the customer. This is a required step in the accreditation process.

The time allowance for review and report preparation is normally one assessor day. If the documents are difficult to follow, the customer may be asked to complete a conformity assessment program checklist with quality system references identified. ACLASS may also assign more time for the document review, if warranted.

The report shall include the relevant accreditation checklist for the respective conformity assessment program. The accreditation checklist is used to provide a paragraph-by-paragraph indication of how the customer meets the appropriate requirements. The reviewer shall include quality system references in the checklist.

The report is a summary of opportunities for improvement. Opportunities for improvement are written to document concerns and questions that may be documented as non-conformances during the initial accreditation assessment.

Ideally, the customer and lead assessor will resolve all opportunities for improvement from the document review and any additional issues from the planning visit before the

accreditation assessment. The lead assessor, in consultation with the Accreditation Manager, can decide whether to proceed if any of the issues are not resolved before the accreditation assessment.

Significant changes to the Quality Manual or Procedures may result in additional review time that will be charged to the customer.

1.6 Planning Visit

The planning visit is a very 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 formal 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 for the visit.

The following records are part of the report in EQM:

- Attendance Sheet from the opening and closing meetings
- 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, address)
- general information concerning the customer such as primary function, relationship to larger corporation, and physical location(s)

The following documents will be attached in EQM:

- draft scope of accreditation of the customer, if available
- OPIEF witnessing form, if used

The lead assessor or designee shall submit the report and all records via EQM and notify the Accreditation Manager and laboratory via email. A copy of the planning visit report

will be available to the customer and ACLASS after upload. These 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 from the planning visit before the accreditation assessment. The lead assessor, in consultation with the Accreditation Manager, can decide whether to proceed if any non-conformances are not resolved before the accreditation assessment.

1.7 Preparation for Initial Accreditation Assessment

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

- resolution 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 (See also element 4.14.1 of ISO/IEC 17025).
- a documented management review covering elements listed in the standard
- participation in at least one proficiency test or inter-laboratory comparison

1.8 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.

The accreditation assessment shall consist of:

- thorough review of the customer's compliance to the requirements of each applicable conformity assessment program
- an opening meeting with the customer's management
- daily assessor meetings and customer debriefings
- review of any open issues from the document review and planning visit, if applicable
- review of any results from proficiency testing, as applicable
- review of the laboratory's four-year plan for PT/ILC participation
- verification of recent PT/ILC participation for at least one proposed scope parameter
- review of the laboratory's four-year plan for PT/ILC participation
- verification of competence in estimating measurement uncertainty

- review of uncertainty budgets, as applicable, to ensure budgets are available and adequate for all proposed scope parameters
- witnessing of the proposed scope of accreditation to assess technical competence
- a visit to all satellite site facilities to witness calibrations/tests, as appropriate
- a visit to a customer location to witness on-site calibrations/tests, as appropriate
- a final assessment team meeting to discuss findings
- recommendation from the lead assessor in consultation with the assessment team to accredit, not to accredit, or to withhold accreditation pending non-conformance resolution
- a closing meeting

The accreditation assessment is a requirement and is the most critical step in the accreditation process. ACLASS typically notifies the customer in writing with the assessment schedule and plan 30 days before the assessment. The entire assessment team conducts the assessment. The lead assessor is responsible for the preparation of the accreditation assessment report which shall be completed and submitted to ACLASS via EQM within 5 business days after the completion of the 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 in EQM:

- Opening Meeting Check Sheet
- Attendance Sheet from the opening and closing meetings
- Confidentiality and Conflict of Interest Statement for each representative of ACLASS at the assessment
- appropriate accreditation checklist associated with each applicable conformity assessment program
- Non-Conformance Records written during the assessment
- Closing Meeting Check Sheet including a discussion of the proper use of the ACLASS symbol
- data from PT/ILC completed in the past year

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

- completed draft scope of accreditation as agreed upon by the lead assessor and the customer
- uncertainty budgets to support all scope of accreditation claims, as applicable
- completed PT/ILC Four Year Plan Form, as applicable
- the most recent version of the Quality Manual, or equivalent, if different from the original submitted
- corrective actions for any PT/ILC outliers in the past year

- appropriate OPIEF forms completed for witnessing verification

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.

ILAC-G20:2002, *Guidelines on Grading of Non-conformities*, is used as guidance for classification of non-conformances. The assessment team classifies each non-conformance as major or minor according to the following guidelines:

A Major Non-Conformance 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. The assessment team may judge numerous minor non-conformances against a single requirement to be a significant breakdown of the management system and thus a major non-conformance. Any minor non-conformance that is a repeat from the previous assessment will be considered a major non-conformance.

A Minor Non-Conformance is any other non-conformance which seems to be an isolated occurrence and is normally easily corrected and verified.

An Opportunity for Improvement is not a non-conformance or 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.

Assessors shall report a potential major non-conformance to the lead assessor immediately. The lead assessor in turn shall immediately notify the customer representative.

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

1.9 Corrective Action and Follow-up Visit

Based on the recommendation of the assessment team and results of the assessment, extensive corrective actions and/or a follow-up visit may be required. In instances where significant corrective action review is required by ACLASS, customers are billed according to our published fee schedule. Significant findings typically mean greater than five findings issued and/or major non-conformance(s) issued.

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.

1.10 Customer Internal Audit and Management Review

It is ACLASS policy that each customer must have completed an internal audit and management review covering the applicable conformity assessment program requirements prior to initial accreditation. After initial accreditation, these activities must take place at least on an annual basis each calendar year.

1.11 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.

The scope of accreditation shall be reviewed by ACLASS to ensure that it permits clear and correct identification of the best measurement capability², equipment used, methods used, and units of measurement, as necessary.

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.

1.12 Review of Accreditation Reports

This section describes the process for reviewing accreditation reports.

² This is referred to as Calibration and Measurement Capability (CMC) in calibration laboratory scopes of accreditation.

1.12.1 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 report for technical compliance to the ACLASS requirements for ISO/IEC 17025 accreditation and if warranted, ANSI/NCSL Z-540-1 and/or ANSI/NCSL Z-540.3.

ACLASS 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.

1.12.2 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.

1.12.3 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.

2.0 ACCREDITATION SCOPE, ASSESSORS, AND EXPERTS

ACLASS shall be formally recognized or shall be competent to assess the accreditation scope for each customer that applies to ACLASS for accreditation. ACLASS shall ensure that its personnel, including assessors and experts, possess the appropriate expertise. ACLASS approves every assessor and expert according to its procedures.

ACLASS will assign all assessors and experts, including the lead assessor, for a customer's accreditation process. The lead assessor, in coordination with ACLASS, will have complete authority and responsibility for the customer's assessment process.

2.1 Notification and Objections

The customer will be notified at least 30 days prior to an assessment, if possible, of the names of the members of the assessment team. The customer may request at any time qualifications of assessment team members.

The customer has the right and should object to any assessor who has any known conflict of interest. If a customer objects to the appointment of any particular assessor and/or expert, ACLASS will inquire as to the reason for such objection.

If the customer objects to the appointment of any particular assessor and/or expert they shall, if requested:

- Submit their objection in writing to ACLASS
- Identify the particular assessor and/or expert in question
- Identify the reasons behind the objection including known conflict of interest
- Sign the letter of objection by a duly authorized representative of the organization

Upon receipt of the signed letter of objection, ACLASS shall:

- Determine whether the objection is valid
- Investigate the cause for the objection, including taking any necessary corrective and/or preventive actions
- Appoint a new assessor and/or expert
- Notify the customer in writing of the name of the new member of the assessment team, as appropriate

3.0 CERTIFICATE, SCOPE, LOGO, AND SYMBOL

ACCLASS controls the certificate, scope of accreditation, and the use of the ACLASS logo and accreditation symbol with ACLASS procedures and as provided for in each respective application for accreditation.

The customer shall ensure that the accreditation symbol is only used within the scope of accreditation. The ACLASS symbol shall 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 or calibrations shall be clearly identified on the report that is issued. The identification also shall include a footnote on the report or certificate itself which acknowledges that the report includes non-accredited work.

ACCLASS may withdraw a customer's accreditation certificate and the use of the accreditation symbol at any time for a customer's misuse of the ACLASS symbol or ILAC Mark (where applicable) or for management system failures.

3.1 ACCLASS Policy on Scopes of Accreditation for Calibration Laboratories

The scope of accreditation of an ACCLASS accredited calibration laboratory shall include the calibration and measurement capability (CMC) expressed in terms of:

- measurand or reference material;
- calibration/measurement method/procedure and/or type of instrument/material to be calibrated/measured;
- measurement range and additional parameters where applicable, e.g., frequency of applied voltage;
- uncertainty of measurement.

There shall be no ambiguity on the expression of the CMC on the scopes of accreditation and, consequently, on the smallest uncertainty of measurement that can be expected to be achieved by a laboratory during a calibration or a measurement. Particular care should be taken when the measurand covers a range of values. This is generally achieved through employing one or more of the following methods for expression of the uncertainty:

- A single value, which is valid throughout the measurement range.
- A range. In this case a calibration laboratory should have proper assumption for the interpolation to find the uncertainty at intermediate values.
- An explicit function of the measurand or a parameter.
- A matrix where the values of the uncertainty depend on the values of the measurand and additional parameters.
- A graphical form, providing there is sufficient resolution on each axis to obtain at least two significant figures for the uncertainty.

The following rules apply:

- Open intervals (e.g., " $U < x$ ") are not allowed in the specification of uncertainties.
- The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand, e.g., percent.
- A reasonable amount of contribution to uncertainty from repeatability shall be included in CMC calculation.
- In the formulation of CMC, laboratories shall include contributions to uncertainty from a "best existing device" which is available for a specific category of calibrations. NOTE: The term "best existing device" is understood as a device to be calibrated that is commercially or otherwise available for customers, even if it has a special performance (stability) or has a long history of calibration.
- Contributions due to reproducibility should be included in the CMC uncertainty calculation, when available.
- There should be no significant contribution to the CMC uncertainty component attributable to physical effects that can be ascribed to imperfections of even the best existing device under calibration or measurement.

Calibration laboratories shall demonstrate the ability to provide calibrations to customers in compliance with the above rules so that measurement uncertainties equal those covered by the CMC.

Calibration and Measurement Capabilities (CMC) must be supported by evidence of their calculations (uncertainty budgets), and represented as expanded uncertainties typically using a coverage factor of $k=2$ to approximate the 95% confidence level.

3.2 Use of ACLASS Symbol

ACLASS maintains a logo used only by ACLASS. The ACLASS symbol, which is issued by ACLASS to accredited customers to indicate their accredited status, shall be used by accredited customers only (see also ACLASS guidance document *Guidance on Use of the ACLASS Symbol and ILAC Laboratory Combined MRA Mark*).

ACLASS currently maintains separate symbols for each conformity assessment program.

A company accredited by ACLASS may use the ACLASS symbol as follows and in accordance with the application for accreditation. The application for accreditation provides explicit information concerning the use of the ACLASS symbol:

- On the Company's literature, such as: Letter Headings, Business Cards, Brochures, Advertising, and Marketing Materials.
- On the Company's website.
- May only be used within the company's scope of the accreditation. Exception: certificates and reports which contain both accredited areas/parameters and areas/parameters which are not on the customer's approved ACLASS scope of accreditation. In this case, the non-accredited tests or calibrations shall be clearly defined on the report that is issued. The identification also shall include a footnote on the report or certificate itself which acknowledges that the report includes non-accredited work.
- Any size is acceptable but all associated text shall be legible.
- The acceptable colors for the ACLASS symbol are:
 - Blue – PMS 2935 or
 - Black and white

The ACLASS symbol may not be used as follows:

- by a customer's subcontractor which is not accredited
- by applicants for accreditation
- by an accredited organization under a different name than the name in which it holds accreditation
- to indicate ACLASS approval of the results of its calibration or test

3.2.1 Symbol Usage on Calibration Labels

ACLASS allows the use of its symbol by accredited organizations on calibration labels attached to calibrated equipment. These labels should normally include:

- The name of the accredited organization

- Equipment identification
- Date of current calibration
- Cross reference to the calibration certificate issued to document the calibration.

Use of these labels on calibrated equipment is restricted to an accredited organization using methods covered by its ACLASS scope of accreditation.

3.2.2 Symbol Usage on Calibration Certificates and Test Reports

To demonstrate measurement traceability, calibration certificates shall, whenever applicable, indicate traceability to national/international standards of measurement and provide the result of the measurement and the associated uncertainty of measurement.

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

“This calibration/test is accredited under the laboratory’s ISO/IEC 17025 accreditation issued by ANSI-ASQ National Accreditation Board/ACCLASS. Refer to certificate and scope of accreditation [insert accreditation number here].”

3.3 ACLASS Symbol Enforcement

All customers that have their accreditation suspended, reduced, or withdrawn shall discontinue use of the ACLASS symbol upon written notification and in accordance with ACLASS requirements. Suspended or withdrawn customers, upon suspension or withdrawal, must remove any use of the ACLASS symbol and reference to their certificate and scope of accreditation within 30 days from notification.

All suspended and withdrawn customers will have their website reviewed for compliance of removal within the specified timeframe. If it is found that the customer is not in compliance with removal following this website review or by any other means, ACLASS shall issue a follow-up letter and reserves the right to post a notification on the ACLASS website indicating that the customer is issuing false claims of accreditation.

All active customers will have their website periodically reviewed for proper use of the ACLASS symbol.

If it is found through any means that the customer is not in compliance, ACLASS shall inform the customer of the proper use of the ACLASS symbol and provide the customer with a specified timeframe to become compliant.

ACCLASS will make every effort to enforce the proper use of the ACLASS symbol and, upon written notice to the customer, shall have the right to:

- Suspend its accreditation activities until the customer complies with its obligation

- Determine that the customer is no longer entitled to identify itself as accredited by ACLASS
- Require the customer (temporarily or permanently) to cease using in any manner the certificate and scope of accreditation (and to return such certificate and scope) and the ACLASS symbol
- Refuse to issue a certificate and scope of accreditation to the customer
- Require a corrective action
- Publish the customer's transgression
- Take other legal action

In the event ACLASS takes any of the foregoing actions, ACLASS shall not be required to reimburse any amounts to the customer.

3.4 Use of the ILAC Mark (ILAC Sub-License Agreement)

ACLASS has entered into a license agreement with the International Laboratory Accreditation Cooperation (ILAC) for the use of the ILAC Laboratory Combined MRA Mark, hereinafter referred to as "Combined MRA Mark." Upon approval, ACLASS accredited organizations are entitled to use the Combined MRA Mark together with the ACLASS symbol. When using the Combined MRA Mark, the ACLASS accreditation number shall be included with the ACLASS symbol. ACLASS accredited organizations wishing to use the Combined MRA Mark shall enter into and sign a sub license agreement.

3.4.1 Applying for Use of the Combined Mark

Accredited ACLASS customers may request to use the Combined MRA Mark by submitting a written request to ACLASS. Upon receipt of the written request, ACLASS will send the accredited organization the ILAC Laboratory Combined MRA Mark Sub License agreement, hereinafter referred to as "Sub License agreement."

The accredited organization must sign the Sub License agreement and return it to ACLASS along with an example of how the Combined MRA Mark will be used, according to the terms of the Sub License agreement and ACLASS policies and procedures.

ACLASS will then send the accredited organization written approval confirming authorization for use of the Combined MRA Mark.

3.4.2 Combined MRA Mark Guidelines

Pursuant to ACLASS policies and procedures and the terms set forth in the Sub License agreement, an ACLASS accredited organization may use the Combined MRA Mark with the ACLASS symbol on test reports, calibration certificates, pre-printed letterhead, quotations for work, advertisements, websites, and other documents in order to demonstrate accreditation by ACLASS, which is a signatory to the ILAC Arrangement.

When using the ILAC Mark, the ACLASS accreditation number (AT-XXXX, for example) must be used with the ACLASS symbol.

Accredited organizations are not permitted to use the Combined MRA Mark on business cards in order to avoid any possible confusion with the certification of persons. For more information, refer to ILAC-R7:09/2009, *Rules for the Use of the ILAC Mark*.

The Combined MRA Mark shall be used according to the example provided for within the Sub License agreement using the same proportions. As a general guideline, the ACLASS symbol should be within approximately 5% of the size of the Combined MRA Mark to ensure that the overall symmetry of the design and the relative proportions are maintained.

The Combined MRA Mark is available in a variety of formats which can be obtained from ACLASS after signing the Sub License agreement.

3.4.3 Requirements, Rights, and Duties

The Sub License agreement sets forth the extent of the license of the Combined MRA Mark.

All ACLASS accredited organizations are obliged to present its Combined MRA Mark to ACLASS for review and approval and shall not use it until receipt of written approval has been received from ACLASS.

All ACLASS accredited organizations agree to use the Combined MRA Mark in accordance with the requirements set forth in ACLASS policies and procedures and the Sub License agreement, and

- shall not use the Combined MRA Mark in any way that would harm the reputation of ILAC or ACLASS
- shall allow ACLASS to review the use of the Combined MRA Mark
- shall sign the Sub License agreement

ACCLASS may withdraw immediately the right to use the Combined MRA Mark if ACLASS determines improper use has occurred (see also Symbol Enforcement in this document). ACLASS assumes no responsibility for any consequences of withdrawal. Terms of use are conveyed in the Sub License agreement and ACLASS policies and procedures.

3.4.4 Reproduction Rules

The ILAC Mark may be used in black-and-white or color, provided the approved colors are used. Embossed, relief, or die-stamped versions are allowable. Reproduction rules also apply. All customers signing or intending to sign the Sub-License Agreement are

required to conform to ILAC-R7:09/2009. This document is available on the ACLASS website and is included in the sub-license agreement package sent to those signing the agreement.

3.5 Opinions and Interpretations

ACLASS requires that any calibration certificates or test reports from an accredited laboratory that include statements of opinions and/or interpretations include a disclaimer when referencing applications outside of the laboratory scope of accreditation. This disclaimer can be expressed in a document separate from the report or certificate itself, but it must be clearly evident and attached to the report or certificate itself, make reference to being outside of the scope of accreditation, and not sent separately. Statements of compliance to a metrological specification are not considered as opinions or interpretations. When an opinion or interpretation statement and disclaimer is noted as outside the scope of accreditation, the laboratory should be careful not to use the ACLASS symbol, ILAC Combined Mark, or other reference to the laboratory accreditation.

4.0 DIRECTORY OF ACCREDITED LABORATORIES

ACLASS will publish a listing of all the customers it accredits. This list will include the customers' scopes of accreditation and is available on the ACLASS website.

5.0 SURVEILLANCE AND REASSESSMENT

The ACLASS accreditation cycle is typically a two year reassessment timeframe. ACLASS establishes surveillance and reassessment plans based on an organization's proven stability and competence. Proven stability and competence could include current and active accreditation of a customer accredited by another ILAC MRA signatory. Basis for the decision to extend or reduce the reassessment cycle timeframe may be as a result of the consideration of compliance with an additional ISO standard, performance in PT/ILC activity, effectiveness of corrective action activity, history of assessment performance, effective internal audits and management reviews, and/or effective training of personnel.

The time and charge for this service will be detailed on the quotation presented to the customer at the beginning of the accreditation process. The time and charge for this service may vary if ACLASS determines that the customer's legal status, accreditation requirements, or scope of accreditation has changed.

ACLASS may conduct surveillance assessments on a more frequent basis or schedule an early reassessment should ACLASS determine it is warranted.

ACLASS requires its accredited customers to keep records of complaints against their calibrations or tests, or against the laboratory management system. Records shall clearly show the resolution of those complaints. Complaints, internal audits, management reviews, and PT/ILC activities are elements of the customer's laboratory management system which ACLASS will review during each surveillance and reassessment visit.

The internal audit program shall be performed at least once each calendar year (effective January 1, 2012) and address all elements of the management system including witnessing of a sampling of accredited testing or calibration activities (see also element 4.14.1 of ISO/IEC 17025). Use of the ACLASS symbol and ILAC Mark (if applicable) should also be reviewed.

Management reviews shall be performed at least once each calendar year (effective January 1, 2012) and cover all elements required by the applicable standard.

Internal audits and management reviews for laboratories maintaining satellite sites or performing on-site calibrations/tests shall include these activities.

ACLASS intends for the surveillance and reassessment to be a value added service (see also *ACLASS Guidance on Surveillance and Reassessments*). Additionally and with customer concurrence, ACLASS assessors may point out and/or record continuous improvement opportunities. At no time shall an assessor make recommendations or give advice on how to address these opportunities. The customer's choice of action or non-action with regard to these opportunities shall have no bearing on continuing accreditation.

If the results of the surveillance and reassessment yield excessive non-conformances or if major modifications occur, ACLASS may require a follow-up visit, surveillance assessment, or early reassessment and may charge the customer for additional assessment time. ACLASS will charge any additional fees for corrective action review and/or follow-up visits at ACLASS' current rates.

Any resulting non-conformance from a reassessment or surveillance visit shall be responded to by the customer in EQM within 30 days for review by the lead assessor or designee. 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-conformances or for non-response to findings in the allotted time. ACLASS may suspend and/or withdraw accreditation if one or more major non-conformances are discovered during a surveillance or reassessment visit in accordance with this document. In particular, if any major non-conformance causes ACLASS to have any material doubt about the performance of a calibration or 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 provide a surveillance and reassessment report to the customer following each visit via EQM.

6.0 PROFICIENCY TESTING / INTER-LABORATORY COMPARISONS

Customers are required to participate in proficiency testing or other inter-laboratory comparisons except where this is not reasonable or not possible. The customer shall select and judge with ACLASS concurrence that the organization conducting the proficiency testing or inter-laboratory comparison is competent in accordance with ISO/IEC 17043, *Conformity assessment - General requirements for proficiency testing*.

6.1 PT/ILC Requirements

The purpose of this section is to establish the requirements for participation in proficiency testing or inter-laboratory comparison programs for all laboratories accredited by ACLASS. ACLASS requires that any laboratory applying for accreditation must show evidence of participation in relevant proficiency testing, if available. For further guidance, see also *ACLASS Guidance on Proficiency Testing/Inter-Laboratory Comparisons* available on the ACLASS website.

6.2 Definitions and Introduction

Inter-laboratory Comparisons (ILC): The organization, performance, and evaluation of calibration or test results for the same or similar item by two or more laboratories in accordance with predetermined conditions

Inter-laboratory comparisons are accomplished for several reasons or purposes. Some uses are:

- Determination of a laboratory's performance in the conduct of specific tests or calibrations
- Monitoring of an accredited laboratory's ongoing performance by the laboratory's accreditation body
- Identification of possible problems in test or calibration laboratories and the initiation of any required remedial actions that may be related to such issues as individual staff performance or calibration of standards
- Providing confidence in a laboratory's measurements to its customers
- Determination of a method's performance characteristics, effectiveness, or comparability of a new method with established methods

Proficiency Testing (PT): The evaluation of calibration or test results against pre-established criteria by means of inter-laboratory comparisons

A laboratory's participation in proficiency testing enables the laboratory to assess and demonstrate the reliability of the resultant measurement data by comparison with results from other participating laboratories. Ideally, in PT programs, laboratories are given in their reports independent feedback on potential biases in their measurement systems.

Proficiency testing is most often used to assess a laboratory's capability to perform competent tests or measurements. The data resulting from a proficiency test may be used by the accreditation body, a laboratory customer, or the laboratory itself, and thus can supplement the laboratory's internal quality program. Customers of calibration or testing laboratories desire confidence that the services they are receiving are reliable and accurate.

Major Discipline: Defined as Calibration and Testing

Major Sub-Discipline: Parameters falling within the two major disciplines of Calibration and Testing. Some examples of Calibration major sub-areas include: dimensional, electromagnetic dc/low frequency, mechanical, and thermodynamic. Some examples of Testing major sub-areas include: environmental-soil, environmental-air, chemical-organic (or inorganic), etc. See also ILAC-P9, *ILAC Policy for Participation in Proficiency Testing Activities* available at www.ilac.org.

6.3 Accreditation Requirements

ACLASS requires that any laboratory applying for accreditation must show evidence of successful participation in relevant proficiency testing (if available) prior to initial accreditation. Effective January 1, 2012, satellite sites are subject to the same requirement. ACLASS customers shall submit the results of proficiency testing to ACLASS during assessments, via email, or at any time via EQM, when available. Assessors shall also ask for an ACLASS form 15, *PT/ILC Four Year Plan form*, completed with a four-year plan for participation, at each assessment. This includes the laboratory's plan to ensure coverage of the scope of accreditation over a four year period (including satellite sites).

If proficiency testing is not available for a particular measurement discipline or parameter through existing proficiency testing programs, internal performance-based data demonstrating laboratory competence and measurement performance in comparison with another laboratory entity can be substituted for achieving and/or maintaining accreditation. In instances where accreditation is granted because of a lack of availability of reasonable artifacts, ACLASS will ensure that normal PT/ILCs take place in the future when artifacts become available.

Participation in at least one PT/ILC is to be completed prior to the granting of initial accreditation or prior to adding a satellite site to the scope of accreditation (effective January 1, 2012). Results shall be reported to ACLASS within six months of initial accreditation.

Each accredited laboratory and satellite site will be expected to participate in a minimum of one proficiency test/inter-laboratory comparison for each major sub-area of major disciplines of the scope of accreditation at least every four years. Should any significant

change to a laboratory's staff occur after initial accreditation, ACLASS may elect to shorten the required interval.

For all laboratories and satellite sites (effective January 1, 2012), the minimum participation required is once a year (defined as a calendar year). Of course, laboratories are highly encouraged to participate more frequently, as individual circumstances may dictate.

For additional guidance, refer to *ACCLASS Guidance on Proficiency Testing/Inter-Laboratory Comparisons*.

For calibration laboratories, the ACLASS evaluation of a laboratory's results of proficiency testing will usually be based upon the following equation:

$$E_n = \frac{(Lab - Ref)}{\sqrt{(U_{95}Lab)^2 + (U_{95}Ref)^2}}$$

where *Lab* and *Ref* are the laboratory and reference measurement values for the measurement in question and $U_{95}Lab$ and $U_{95}Ref$ represent the expanded uncertainties expressed at the 95% confidence level for the laboratory and reference laboratory, respectively. E_n values greater than 1 or less than -1 (or a z-score greater than 3) are considered unsatisfactory in that they indicate either an uncertainty issue or a laboratory's measurement result deviates significantly from the reference measurement result.

Should the above equation not be applicable to the measurement in question for whatever reason (e.g. a testing laboratory), the proficiency testing provider's interpretation/calculations may be used, in addition to other applicable calculations of performance found in ISO/IEC 17043.

A laboratory that receives unsatisfactory results during a proficiency test is required to promptly provide to ACLASS evidence of action taken to correct the problem. Should a thorough investigation fail to identify a cause for the unsatisfactory result, or if a follow-up test results in another outlier, the laboratory is required to provide ACLASS all details of their investigation for further review and determination of the subsequent course of action to be taken, which may include suspension, reduction in scope of accreditation, or withdrawal of accreditation.

6.4 Selection of Proficiency Testing Schemes/Programs

Laboratories accredited by ACLASS are highly encouraged to select proficiency testing providers that can demonstrate their programs are accredited and comply with the requirements of ISO/IEC 17043. Where appropriate accredited proficiency testing providers are not available, laboratories should use programs that operate in accordance with ISO/IEC 17043. ACLASS also reserves the right to require mandatory participation

of any laboratory it accredits to take part in any future proficiency program that may be mandated or administered by APLAC, ILAC, or IAAC.

ISO/IEC 17043 provides guidance to accreditation bodies for selection and use of proficiency testing schemes. Any laboratory that is unable to locate a suitable proficiency provider or requires assistance in the selection thereof, should contact ACLASS for assistance.

6.4.1 Internal or Non-Commercial PT/ILC Programs

Laboratories that organize their own inter-laboratory comparisons or PTs (whether internal or external to their organization) must provide ACLASS with the reason for not using a commercial PT provider and must submit a plan to ACLASS using ACLASS form 40. This plan must be approved by the ACLASS Accreditation Manager prior to beginning the test. The plan must be documented and include the following:

- Designated coordinator with name and contact information
- The objective, nature, and purpose of the plan
- A procedure for selection of PT/ILC participants or criteria to be met before participation is allowed
- Anticipated number of participants
- A description of the manner in which PT items are to be obtained, processed, checked, and distributed, which takes account in its design of the major sources of analytical errors involved in the area of PT offered
- Designation of the reference laboratory
- A description of the information which is to be supplied to participants (pre-notification) and the time schedule for the various phases of the plan
- Information on methods or procedures which participants may need to use to perform the tests or measurements (commonly their routine procedures)
- The basis of performance evaluation techniques, where appropriate
- A description of the extent to which test results, and the conclusions that will be based on the outcome of the plan, are to be made
- The origin and traceability of any reference values
- The traceability of the key reference standards of each participant lab, as warranted
- (For calibration laboratories) the plan to include CMC and MU for each participant in the reports
- Additional details as warranted, such as assuring artifact stability

The PT reports which result from the related PT programs will need the following:

- Name and contact details of the provider
- Date of participation and date of report
- Number of pages and clear identification of the end of the report
- Report number and clear identification of the plan

- Clear description of the PT items used
- Laboratory participation codes and test results
- Statistical data and summary, including assigned values and range of acceptable results
- Procedures used to establish any assigned value or reference values
- Details of traceability and uncertainty, as warranted, of the reference value(s)
- Assigned value and summary statistics for test methods used by each participant
- Comments on participants' performance by the technical advisors, as warranted
- Procedures used to statistically analyze the data

Multi-site organizations (see Section 15 of this document) may perform internal PTs using a designated site as the reference laboratory. These sites are also required to submit a plan to ACLASS for approval according to the above requirements.

ACCLASS Accreditation Managers are responsible for review and approval of the submitted internal PT plan. The laboratory will be notified of approval or disapproval and approved plans will be attached in EQM for assessment verification.

7.0 TRACEABILITY AND MEASUREMENT UNCERTAINTY

The purpose of this section is to establish guidance on traceability and measurement uncertainty requirements for all laboratories accredited by ACLASS. Customers are required to demonstrate traceability and measurement uncertainty.

7.1 Definitions

Traceability: Property of a measurement result whereby the result can be related to a stated reference through a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty. (VIM 2.41 2007)

Measurand: The quantity intended to be measured. (VIM 2.3)

Uncertainty of Measurement (also referred to as Measurement Uncertainty or MU): Parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. (VIM 2.27)

Calibration and Measurement Capability (CMC) (calibration laboratories only): The smallest uncertainty of measurement a laboratory can achieve within its scope of accreditation, when performing more or less routine calibrations of nearly ideal measuring instruments under nearly ideal conditions.

7.2 Traceability

The term “traceability” means a process whereby the indication of a measuring instrument (or a material measure) can be compared with a national standard for the measurand in question in one or more stages.

Traceability is characterized by a number of essential elements:

- There must be an unbroken chain of comparisons going back to a standard acceptable to the parties, usually a national or international standard and ending with laboratory working reference standards used in a metrology laboratory.
- Measurement uncertainty for each step in the traceability chain must be calculated according to defined methods and must be stated so that an overall uncertainty for the whole chain may be calculated.
- Each step in the chain must be performed according to documented and generally acknowledged procedures. The results must be equally documented (calibration certificate or test report).
- Laboratories performing one or more steps in the chain must supply evidence for their technical competence. Accreditation by an ILAC signatory accreditation body is considered evidence of technical competence within the scope of accreditation.
- Appropriate standards must be primary standards (national, international, or intrinsic) for the realization of the SI units.
- Calibrations must be repeated at appropriate intervals. The length of these intervals depends on a number of variables (uncertainty required, frequency of use, type of use, stability of equipment, etc.).

7.3 Calibration Certificates/Test Reports

To demonstrate measurement traceability, calibration certificates shall indicate traceability to national/international standards of measurement and provide the result of the measurement and the associated uncertainty of measurement, as applicable.

Certificates and reports will contain a statement of traceability. The traceability statement shall affirm the calibration was performed using standards traceable to an appropriate national, international, intrinsic, or mutual consent standard. Calibration certificates which refer only to a NIST report of test numbers as evidence of traceability are not considered sufficient demonstration of measurement traceability. NIST reports of test numbers do not in and of themselves provide a statement of uncertainty associated with the farthest link in the chain from NIST (the last facility providing the measurement value).

Calibration certificates/test reports shall be accompanied by a recognized accreditation body symbol, or otherwise make reference to accredited status, to be considered satisfactory for traceability purposes. Recognized bodies include bodies recognized by ILAC, APLAC, and IAAC. Additionally, recognized bodies are those accredited by ACLASS. See also *AClass Guidance on Traceability*.

7.4 Measurement Uncertainty

Measurement uncertainty, and the calculation thereof, is one of a number of essential elements contributing to the concept of traceability.

The measurement uncertainty for each step in the traceability chain must be calculated according to defined methods and must be stated so that an overall uncertainty for the whole chain may be calculated.

Defined methods for calculation of measurement uncertainties may be found in the following publications:

- ISO Guide 98-3:2008, *Guide to the Expression of Uncertainty in Measurement*
- NIST TN 1297:1994, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*
- ANSI/NCSL Z540-2-1997, *Guide to Expression of Uncertainty Expression of Uncertainty in Measurement*
- EA-4/02, *Expression of the Uncertainty of Measurement in Calibration*

7.4.1 Uncertainties on Calibration Certificates

Effective January 1, 2012, all accredited calibration certificates issued by ACLASS accredited calibration laboratories shall include measurement uncertainties as required by ILAC P14, *ILAC Policy for Uncertainty in Calibration*.

The following rules apply:

- The measurement result shall normally include the measured quantity value y and the associated expanded uncertainty U . In calibration certificates the measurement result should be reported as $y \pm U$ associated with the units of y and U .
- Tabular presentation of the measurement result may be used, and the relative expanded uncertainty $U / |y|$ may also be provided if appropriate.
- The coverage factor and the coverage probability shall be stated on the calibration certificate. To this an explanatory note shall be added, which may have the following content: *“The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %.”* Uncertainty statements not specifying (as a minimum) the coverage factor/confidence level will be considered incomplete and inadequate for purposes of demonstrating measurement traceability.

- The numerical value of the expanded uncertainty shall be given to, at most, two significant figures.
- The numerical value of the measurement result shall in the final statement be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result.
- For the process of rounding, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided in Section 7 of the GUM. NOTE: For further details on rounding, see ISO 80000-1:2009 [7].
- Contributions to the uncertainty stated on the calibration certificate shall include relevant short-term contributions during calibration and contributions that can reasonably be attributed to the customer's device. Where applicable, the uncertainty shall cover the same contributions to uncertainty that were included in evaluation of the CMC uncertainty component, except that uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device.
- Random contributions that cannot be known by the laboratory, such as transport uncertainties, should normally be excluded in the uncertainty statement. If, however, a laboratory anticipates that such contributions will have significant impact on the uncertainties attributed by the laboratory, the customer should be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.

As the definition of CMC implies, ACLASS accredited calibration laboratories shall not report a smaller uncertainty of measurement than the uncertainty of the CMC for which the laboratory is accredited.

Calibration laboratories are required to report Measurement Uncertainty (MU) for all test points on all accredited calibration certificates unless issuing only a statement of compliance to a specification. Statements of compliance on calibration certificates (and test reports) are understood to include any check box or other designation that a measured value or property meets manufacturer's specification or other defined specification. Uncertainty consideration may often impact accept or reject criteria for a measurement when this is reported. Since uncertainty of measurement must be considered in this determination in accordance with ISO/IEC 17025, an accredited laboratory must clearly indicate on these certificates or reports if uncertainties were not considered so the customer will know to do that calculation. In these cases, MU shall be included on the calibration certificate.

When issuing a statement of compliance without MU, laboratories are reminded that ISO/IEC 17025 still requires that the MU be calculated and maintained for possible future needs. Documentation of a customer request for a statement of compliance without MU shall be available in contract review records.

When statements of compliance are made on calibration certificates or test reports, the uncertainty of the measurements must be taken into consideration or the laboratory must clearly identify on the certificate or report that it was not considered. In these cases, measurement uncertainty shall be included in the certificate.

In some instances, a calibration certificate will contain the statement "in tolerance," along with a statement that the measurement uncertainty does not exceed a certain fraction of

the tolerance. These fractions are often called “test accuracy ratios (TARs)” or “test uncertainty ratios (TURs).” Uncertainty statements phrased in terms of TARs or TURs are not acceptable for demonstrating measurement traceability or for measurement uncertainty replacements.

For calibration laboratories that use calibration procedures accessed through the Government-Industry Data Exchange Program (GIDEP), the laboratory shall either (1) incorporate the procedure used into its Document Control system, assigning its own number, or (2) reference the GIDEP procedure number with revision date on the certificate.

7.5 Scopes of Accreditation

A laboratory’s scope of accreditation is a document specifically stating the disciplines or parameters that have been verified by ACLASS. The scope defines the type and ranges of the accredited measurand, key equipment, methods, and reference standards used and, for calibration scopes, the CMC expressed as an uncertainty for each measurand and range.

ACLASS requires scopes of accreditation to meet NIST SP 811, *Guide for the Use of the International System of Units (SI)*, where available. This guide has been prepared to assist those who may have need of such assistance in the use of the SI in their work, including the reporting of results of measurements. NIST SP 811 can be accessed on the ACLASS website at www.aiclasscorp.com.

7.5.1 Change or Expansion of Scope of Accreditation

Accredited customers at times may request changes to or expansion of their scope of accreditation at or between their normal assessment schedules. In these situations, customers are required to use ACLASS form 28, *Scope Expansion Form*, (available on the ACLASS website) to request this service. A scope expansion typically warrants a visit to the customer to verify procedures, competence, and standards. The vast majority of the time, this occurs in concert with a surveillance or reassessment visit. Under certain circumstances, with very minor scope changes, this visit may be preempted by satisfactory documentation and discussions with customer representatives.

When an abbreviated scope expansion visit takes place, this will not replace any assessment visit normally scheduled for any accredited customer. A customer may request an earlier planned assessment, which may include additional assessment days to address a scope expansion.

At any time, an accredited customer has the option of expanding their scope of accreditation, as long as certain requirements are met. These include:

- adequate advance notification and submittal of the appropriate form to ACLASS concerning the intention and the specific line items to be added to a scope of accreditation
- arrangements with ACLASS to have a qualified ACLASS assessor perform the witnessing, either during a scheduled assessment visit or any separate visit. The length of the visit is dependent on the depth and breadth of the scope expansion
- satisfactory provision of related documents and records, including methods, uncertainties as needed, and any related corrective actions as a result of the witnessing
- satisfactory payment of all associated costs to ACLASS for such services
- satisfactory review and approval by ACLASS according to the ACLASS decision process

Normally, scopes of accreditation may be regularly updated with newer uncertainties or slight adjustments in range that are not subject to this “expansion” category. Any change, however, that is due to a new method, reference standard, or technology may be witnessed per ACLASS procedures.

7.6 Use of OEMs for Traceability

It is recognized that laboratories receive calibration certificates from OEMs of common tools and there is no other source or economical means to have a tool calibrated except by the OEM. In some instances, however, the OEM is not accredited to ISO/IEC 17025.

In the case of a non-accredited OEM, the customer and any other interested party should encourage the OEM to achieve accreditation to ISO/IEC 17025. The OEM may be considered acceptable for traceability if the customer receives information, as best as possible, and submits such information to ACLASS for review.

The OEM must meet a number of essential elements for traceability. As a minimum, the following must be provided to ACLASS by the laboratory seeking support from OEMs for consideration:

- an unbroken chain of comparisons going back to standards acceptable to the parties, usually a national or international standard
- proof that measurement uncertainty in the traceability chain has been calculated according to accepted methods (i.e. GUM) and stated so that an overall uncertainty for the whole chain may be calculated
- proof that each step in the chain has been performed according to documented and generally acknowledged procedures, including documenting results (before and after data)
- evidence of technical competence
- proof that appropriate standards are primary standards for the realization of the SI units
- evidence that calibrations have been repeated at appropriate intervals

For additional guidance refer to *ACLASS Guidance on Traceability* and ILAC P10:2002, *ILAC Policy on Traceability of Measurement Results*.

7.6.1 Issuance of a Non-Conformance for Traceability

A non-conformance shall be issued against section 5.6 of the standard if evidence exists that instruments have been calibrated using an OEM not compliant with ILAC P10. A non-conformance shall also be issued against the same element if evidence exists that instruments have been calibrated using a laboratory accredited by an Accreditation Body that is not a signatory to the above-mentioned co-operations or even a subcontracted laboratory from a signatory AB that has not provided an accredited certificate of calibration or is not accredited specifically for the parameter calibrated. The severity of the non-conformance is dependent upon the effect on the resultant calibrations done with that device and other considerations.

7.7 Reference Materials and Reference Cultures

Chemical, microbial, and other reference materials represent a completely different arena within traceability. Chemicals and strains of microorganisms require assurance of both purity and identity. Primary sources of these chemicals include NIST and US Pharmacopeia. Microbes should normally be obtained from the American Type Culture Collection (ATCC) or other internationally recognized source. Traceability of reference materials can often be achieved through the sources mentioned here and, in general, organizations accredited to ISO Guide 34:2009. Unfortunately, the vast majority of reference materials are still not available as Certified Reference Materials.

8.0 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.

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.

8.1 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.

8.2 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.

8.3 Appeals Procedure

The ACLASS appeals 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.

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

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 appeals panel.

An appeal shall be lodged in writing no later than 30 days after notification to the customer of the decision or action, or whenever the appropriate appeals 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 Chair. For level 1, the panel members are appointed by the ACLASS Vice President and/or Director of Accreditation. 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 timeframe for communicating the documented final decision (normally not to exceed two weeks)
 - Inform all parties that the appeal may be escalated to the next level of appeal within 30 days of receipt of the panel decision
 - 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 appeals 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 appeals 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.

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

8.4 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.

ACLASS requires the complainant, alleging non-conformance of an accredited customer with the accreditation requirements, 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
- Take any steps necessary to ensure that if the complaint affects an ACLASS customer it is addressed first by the customer
- Take any necessary actions and assess their effectiveness
- Record the complaint
- Respond in a timely manner to complaint

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. 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.

ACLASS may require the customer to undergo an on-site visit, in which case ACLASS shall outline the expectations to the customer prior to the visit. If the customer does not meet those expectations, ACLASS 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.

9.0 ACCREDITATION SCOPE, ASSESSORS, AND EXPERTS

ACCLASS shall be formally recognized or shall be competent to assess the accreditation scope for each customer that applies to ACLASS for accreditation. ACLASS shall ensure that its personnel, including assessors and experts, possess the appropriate expertise. ACLASS approves every assessor and expert according to its procedures.

ACCLASS will assign all assessors and experts, including the lead assessor, for a customer's accreditation process. The lead assessor, in coordination with ACLASS, will have complete authority and responsibility for the customer's assessment process.

9.1 Notification and Objections

The customer will be notified at least 30 days prior to an assessment, if possible, of the names of the members of the assessment team. The customer has a right at any time to request the qualifications of an assigned assessor. The customer has the right and should object to any assessor who has any known conflict of interest. If a customer objects to the appointment of any particular assessor and/or expert, ACLASS will inquire as to the reason for such objection.

If the customer objects to the appointment of any particular assessor and/or expert they shall, if requested:

- Submit their objection in writing to ACLASS
- Identify the particular assessor or expert in question
- Identify the reason behind the objection including known conflict of interests
- Sign the letter of objection by a duly authorized representative of the organization

Upon receipt of the signed letter of objection, ACLASS shall:

- Determine whether the objection is valid
- Investigate the cause for the objection, including taking any necessary corrective and/or preventive actions
- Appoint new assessor or expert
- Notify the customer in writing of the names of the new member of the assessment team, as appropriate

10.0 MODIFICATION OR TERMINATION OF THE ACCREDITATION, SCOPE OR CHANGE TO THE LABORATORY MANAGEMENT SYSTEM

If the customer wishes to modify, terminate, or change the scope of its accreditation or laboratory 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.

ACCLASS 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 and Combined MRA Mark, if applicable.

If the scope of accreditation is changed, ACLASS may issue a new certificate reflecting the change of scope after properly verifying and assessing that all accreditation requirements are met. An additional visit may be needed at customer expense.

10.1 Laboratory Relocation (Move Policy)

If a customer 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, the customer shall 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, the customer shall submit the required information on the appropriate form within 3 weeks 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.
- The visit, if needed, will be completed within 30 days as best as possible. Special or extenuating circumstances which affect this timeframe will be considered.
- Non-conformances may be issued as a result of the visit. If non-conformances are issued, 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.

11.0 PUBLICATIONS, PUBLIC NOTICE, AND INFORMATION

ACLASS maintains a current listing of its accredited customers and their scopes of accreditation. This information is publicly available and may be published or submitted to parties who maintain and publish lists of accredited organizations. ACLASS may make public announcements of the application for, granting of, and renewal or withdrawal of accreditation unless the customer expressly prohibits disclosure pursuant to Section 12.0 below.

The ACLASS website will contain the current version of this document.

12.0 CHANGES TO ISO/IEC 17025 ACCREDITATION REQUIREMENTS 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. ACLASS will give each customer a reasonable amount of time to document and implement the change.

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

13.0 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 ACLASS with, in writing, permission to release such information.

All reports and information which ACLASS acquires during the ACLASS accreditation process will be treated as confidential by all ACLASS employees, assessors, experts, and associates. Assessment team members are required to maintain confidentiality regarding information obtained about the customer and its operations. Each ACLASS assessor and expert will indicate in the assessment report the responsibility to conform to this confidentiality policy for each customer for whom accreditation services are provided.

14.0 CONFLICT OF INTEREST

The ACLASS ISO/IEC 17025 assessment team members will have no current, previous, or future consulting ties with the customer being assessed. No ACLASS assessor shall have provided any laboratory system consulting service to a customer that assessor is appointed to assess for 24 months before the date of the assessment activity.

Additionally, no ACLASS assessor shall provide any accreditation service other than from ACLASS or any consulting to an ACLASS customer for 12 months after the date of the last appointed accreditation service.

15.0 CUSTOMERS WITH MULTIPLE LOCATIONS

ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*, is used by ACLASS for all of its calibration and testing laboratory accreditations. Although ISO/IEC 17025 applies to laboratories which perform tests or calibrations in the main laboratory and at other locations, additional clarification is necessary. For the purposes of this document, the term “on-site” refers to tests or calibrations performed at the customer or a third party location.

15.1 Definitions

Multi-Site Laboratory: Laboratory whose activities are carried out at more than one location. These organizations may have satellite sites under the oversight of the main laboratory, may conduct on-site calibrations or tests, or may have more than one address for the main laboratory. A Multi-Site Laboratory is presumed to maintain a single accreditation that covers the main laboratory and all satellite and on-site operations.

Multi-Laboratory Corporation: Organization with more than one main laboratory whose corporate site may conduct some key activities (see definition below). Key activities are also carried out at each main laboratory. The corporate site may provide guidance and oversight or maintain quality documents but the individual laboratories operate on a day-to-day basis as autonomous organizations. Each laboratory applies for accreditation separately and is assessed and accredited as a separate entity, including a separate scope of accreditation for each laboratory. The individual laboratories may themselves be multi-site laboratories as defined above.

Main Laboratory: An organization which performs key activities including calibrations or tests and which operates on a day-to-day basis as an autonomous organization. The main laboratory may administer operations that include one or more satellite locations or on-site calibrations or tests.

Laboratory with Satellite Sites: An organization that is comprised of a main site and satellite site(s) that perform calibrations or tests at a remote permanent or semi-permanent location. The main site provides oversight of the satellite site activities.

Satellite Site: Permanent or semi-permanent remote site which operates as a subsidiary to the main laboratory. Calibrations or tests (and possibly other key activities) are conducted at the satellite site. Customers' equipment or test samples are usually received at the satellite site and are not normally processed through the main laboratory. All test reports and calibration certificates issued by such a site must be issued from the main laboratory, but the location of the actual test or calibration must also be identified on the report or certificate. The main laboratory provides oversight of all satellite site key activities.

Multi-Location Main Laboratory: An organization with more than one address. Calibrations or tests done at each address are distinct and one address must be designated as the main laboratory address for identification on the ACLASS certificate and scope of accreditation. The alternate address is considered another room of and is assessed as part of the main laboratory. All test reports and calibration certificates issued by such a laboratory must be issued from the main laboratory, but the location of the actual test or calibration must also be identified on the report or certificate.

On-Site Calibration or Testing: Calibrations or tests completed by the staff of the main or satellite laboratory at a customer or customer-designated location on a temporary basis.

Multi-Site Assessment: An assessment conducted for multi-site organizations

Key Activities: Key activities include calibration or testing activities, test report or calibration certificate generation, policy formulation, process or procedure development, and, as appropriate, contract review, planning conformity assessments (internal audits), reviews, approvals, and decisions on the results of conformity assessments.

15.2 Multi-site Laboratory Accreditation Procedure

15.2.1 Application

Upon submittal of the application packet for accreditation, the customer must identify the addresses of the laboratory and any satellite sites where accredited tests or calibrations will be performed. On-site capability must also be identified. If the laboratory is part of a multi-laboratory corporation as defined above, the corporate site must apply for accreditation at the same time or must already be accredited by ACLASS.

ISO/IEC 17011, section 7.5.7, states that in addition to visiting the main site or head office during initial assessment, visits shall be made to all other premises of the laboratory from which one or more key activities are performed and which are covered by the scope of accreditation.

15.2.2 Multi-Laboratory Corporations

These laboratories will be assessed and accredited individually, including a separate scope of accreditation for each laboratory. If the quality management system is written and maintained by the corporate site, assessors will emphasize the laboratory's compliance to the corporate quality system. Deficiencies in the corporate quality system may also be identified during the assessment. Responses to all findings must be received within 30 days of the closing meeting where they are presented to the laboratory.

Individual laboratories may also be multi-site laboratories as defined in this document (i.e., have satellite sites, on-site capabilities, and/or multiple addresses).

15.2.3 Multi-Site Laboratories

15.2.3.1 Laboratories with Satellite Sites

Laboratory sites will be considered satellite sites if they meet the following requirements:

- The main laboratory provides oversight of all satellite site key activities.
- The laboratory and the site(s) form one legal entity.
- The accreditation is for the entire organization. Only one certificate and scope of accreditation will be issued with the corporate organization's address.
- One management system exists covering the entire organization.
- Adequate procedures exist to protect the integrity of the reference standards and equipment used for each calibration or test.
- All calibration certificates or test reports are issued from the main laboratory.

All satellite sites will be visited during initial accreditation assessment (or before being added to an existing scope of accreditation) and at least every four years thereafter during reassessment. As a minimum during initial assessments and all reassessments, ACLASS assessors shall witness at least 33 % of the technicians from each satellite site either at the satellite site or at the main laboratory. Records of all technicians from the corporate and satellite sites shall be made available. Additional technicians may be witnessed at surveillance visits.

During each assessment, ACLASS assessors shall ensure that the following have been addressed by the main laboratory (or corporate site, if applicable) for each satellite site:

- internal audit
- management review
- adherence to the ACLASS additional requirements for satellite sites in the ISO/IEC checklist (form 1) available on the ACLASS website
- PT/ILC requirements for each site. Effective January 1, 2012, satellite site PT/ILC requirements are the same as those for the main laboratory, i.e. annual

participation and coverage of all major sub-areas from the scope that apply to the satellite site over a four year period.

15.2.3.2 Multi-Location Main Laboratories

If a main laboratory operates out of more than one location, it may be classified as a multi-location main laboratory instead of being considered a main laboratory with satellite sites. If the customer equipment is processed through the main laboratory and the calibration or testing capabilities at the main laboratory and the other site are distinct, the site may be considered as part of (another room of) the main laboratory. In this case, the laboratory will be assessed as one entity and should be considered as such during the laboratory's internal audits, management reviews, and PT/ILC activities.

15.2.3.3 On-Site Calibrations and Tests

On-site activities introduce critical variables to the operational environment. This includes factors outlined in ISO/IEC 17025 such as environmental effects on tests or calibrations, site security, and transportation issues.

ACLASS assessors shall witness calibration or testing on-site during the accreditation assessment and at least every four years thereafter during reassessment. Extra costs may be incurred if the location of on-site calibration or testing adds additional time to the assessment. Simulation of these tests or calibrations shall be minimized. On-site witnessing is required only for laboratories that perform accredited tests or calibrations on-site.

Additional requirements for on-site calibration or tests are spelled out in the ISO/IEC 17025 checklist (ACLASS form 1) available on the ACLASS website.

15.2.4 Scope of Accreditation for Multi-Site Calibrations and Tests

The scope of accreditation shall indicate which parameters are available at satellite sites and on-site, if less than the full scope of accreditation. Locations of satellite sites or additional addresses (in the case of multi-location laboratories) will be identified in footnotes.

Applicant and accredited customers shall, when indicating on-site uncertainties on certificates, state:

“Since on-site conditions are typically more variable than those in the laboratory, larger measurement uncertainties are expected in the field than what is reported on the accredited scope.”

15.2.5 Use of Personnel for Multi-Laboratory Corporations

Multi-laboratory corporations frequently exchange personnel for technical activities. Accredited laboratories need to assure that all technical personnel, including those assigned temporarily from another site of the corporation, are appropriately trained and approved for their accredited work. Evidence of this training and approval is required in the laboratory where the work is taking place.

16.0 WITHDRAW, WITHHOLD, SUSPEND, REDUCE ACCREDITATION

An organization may be suspended as a result of a relocation of their laboratory, personnel changes, ownership changes, etc., that may cause the organization to not meet the ACLASS requirements for accreditation.

Upon the recommendation of the lead assessor and agreement of ACLASS, ACLASS may withdraw, withhold, and/or suspend a certificate and scope of accreditation if one or more major non-conformances are discovered during any assessment activity. In particular, if any major non-conformance causes ACLASS to have any material doubt about the performance of a calibration and/or test by the customer, ACLASS upon the recommendation of the lead assessor may withdraw, withhold, or suspend the customer's accreditation and certificate until final determination is made by ACLASS.

If the ACLASS symbol is misused in any manner, ACLASS may withdraw, withhold, or suspend the customer's accreditation in accordance with this document and the application for accreditation. This also includes improper use of the Combined MRA Mark, pursuant to the Sub License agreement, where applicable.

ACLASS may withdraw, withhold, or suspend the customer's accreditation if payment has not been made for services ACLASS has performed in accordance with the application for accreditation.

ACLASS may withdraw, withhold, or suspend the customer's accreditation if an accredited customer persistently fails to meet ACLASS requirements.

An ACLASS accredited customer may ask for a suspension or withdrawal of their accreditation in accordance with ACLASS requirements.

ACLASS may reduce a customer's scope of accreditation for those parts of the scope of accreditation where the customer regularly fails to meet ACLASS requirements for accreditation, including competence in accordance with the application for accreditation.

An ACLASS accredited customer may ask for a reduction in their scope of accreditation at any time in accordance ACLASS requirements.

All customers that have their accreditation suspended, reduced, or withdrawn shall discontinue use of the ACLASS symbol upon written notification and in accordance with ACLASS requirements. Upon suspension or withdrawal, customers must remove any

use of the ACLASS symbol and reference to their certificate and scope of accreditation within 30 days from notification. A customer whose scope of accreditation has been reduced must immediately cease the use of the ACLASS symbol for the affected capabilities. This also includes the use of the Combined MRA Mark, pursuant to the Sub License agreement, where applicable.

17.0 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 ACLASS 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 ACLASS 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 Accreditate a Conformity Assessment Body (CAB) Within Another Economy Where There is an APLAC MRA Signatory* (or future versions thereof). ACLASS reserves the right to modify or change these minimum requirements from time to time.

17.1 Transfer Minimum Requirements

Accreditation: Only organizations whose accreditations meet the ACLASS Transfer Minimum Requirements are eligible for transfer. Organizations holding accreditations that do not meet the ACLASS 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 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 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 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

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.

18.0 SUBCONTRACTING ASSESSMENT

ACLASS does not subcontract the assessment process. Subcontracting the assessment may occur if ACLASS does not have all of the resources to meet the needs of the customer and it is determined that subcontracting the assessment is the best available option. If ACLASS were to subcontract the assessment, ACLASS would use an MRA signatory to the ILAC, APLAC, and/or IAAC MRA/MLA arrangements, whenever possible, and would follow the procedures outlined in this section.

ACLASS has expended significant effort and cost in preparing to perform ISO/IEC 17025 accreditation activities, including training, introductory visits, practice assessments, document reviews, planning visits, accreditation assessments, corrective action reviews, and annual scope maintenance. The conditions for subcontracting typically would occur when a customer's scope of accreditation falls outside of ACLASS' capabilities. In these cases, ACLASS may either subcontract the assessment as mentioned in this section or refer the customer to another MRA/MLA accreditation body with expertise in the scope of accreditation.

ACLASS may appoint a subcontractor to conduct accreditation activities on behalf of ACLASS. The subcontractor will possess the credentials and experience to perform accreditation activities on behalf of ACLASS.

ACLASS shall obtain written consent from the customer if a subcontractor has been appointed.

ACLASS shall review and approve the qualifications of the subcontractor in order to determine technical competency. ACLASS shall then assign the appropriate assessment team.

A legal binding agreement shall be drafted and signed by top management, including confidentiality and conflict of interest between ACLASS and the subcontractor.

The subcontractor shall submit to ACLASS the following in order for ACLASS to track responsibly the accreditation process and to make the final accreditation decision:

- copies of documentation during each stage of the accreditation process

- the document review report as soon as possible, once completed by the subcontractor, and prior to the accreditation assessment
- all supporting technical materials, including a final report, along with any additional objective evidence obtained while performing accreditation activities for ACLASS, as needed.

The accreditation decision, including granting, maintaining, extending, reducing, suspending, or withdrawing accreditation shall be made exclusively by ACLASS.

19.0 ACLASS MRA/MLA OBLIGATIONS

AClass will honor and enforce the requirements of each respective MRA and/or MLA for which ACLASS is a signatory, including but not limited to:

- The use of equivalent procedures in the accreditation of laboratories
- The recognition of a laboratory as equivalent to an ACLASS laboratory
- Accepting endorsed calibration/test/inspection reports of MRA/MLA signatories
- Promoting the acceptance of international MRA/MLA
- Investigating complaints
- Contributing to the appropriate MRA/MLA Councils
- Providing other available resources as determined by ACLASS

20.0 USE OF ACLASS DOCUMENTS AND GUIDANCE DOCUMENTS

AClass encourages customers to use guidance documents that are publicly available and/or published by ACLASS. Many organizations, including ACLASS, publish guidance documents covering specific technical areas of calibration and testing. Other guidance documents exist to help in calculating measurement uncertainties or help in determining the proper expression of SI units.

AClass has made several guidance documents available on its website for use by any interested party and encourages all customers to review any relevant guidance documents. Because of space limitations on the ACLASS website, the guidance documents available on the website do not represent all guidance documents available by ACLASS, rather only a sample.

AClass maintains a database of public guidance documents that are available to any interested party upon request.

21.0 DELAYS WITH ASSESSMENTS

During the course of most ACLASS assessment visits, there are findings (i.e. non-conformances) written. These highlight either minor or major deficiencies found in the

system being assessed. At the closing meeting of each visit, these findings are reviewed, and the anticipated timeframe of closure of the findings is also reviewed.

Whenever findings are written related to an assessment visit, the affected organization is notified of the expectation for them to reply to ACLASS within 30 days of the closing meeting specifically to each finding. At a minimum, this response should outline the steps to be taken to close out the finding. If possible, the response may also include sufficient evidence of corrective actions and documents or records that will allow this closure. If the objective evidence submitted is not enough for closure, it should at least outline the plan and timeframe for closure.

There are times, however, when organizations are delayed in their corrective action responses. Such delays could have a negative effect on the relevant organization's accreditation process.

If an applicant customer, during initial accreditation, fails to respond to all non-conformances in writing within six months after the date of the closing meeting (i.e. last day of the initial accreditation assessment), ACLASS may require the customer to submit a new application, subject to new fees, and undergo a full reassessment.

If an applicant customer responds formally to the non-conformances within 6 months, but fails to have all relevant non-conformances closed by ACLASS as a result of reasonable and appropriate corrective actions within one year, they may be required to undergo a full reassessment. ACLASS reserves the right to require a reassessment of an organization before an initial accreditation decision is made based on timeliness of corrective actions, the seriousness of the non-conformances written, and appropriateness of the corrective actions.

Organizations undergoing surveillance or reassessment are required to respond to all non-conformances in writing within 30 days after the date of the closing meeting. Failure to resolve all non-conformances within 60 days (unless another timeframe has been agreed to by ACLASS) from the date of the closing meeting may result in the suspension or withdrawal of accreditation for that organization.

Organizations which have submitted an application for accreditation to ACLASS but no activity has occurred for a period of one year may be required to submit a new application and subject to a new application fee.

22.0 RESPONSIBILITIES AND OBLIGATIONS OF THE CUSTOMER

By signing the application for accreditation, the customer requests ACLASS to perform ISO/IEC 17025 accreditation activities pursuant to the application submitted to ACLASS by the customer. ACLASS shall perform the accreditation activities in accordance with the ACLASS then current accreditation system. ACLASS shall make available to the

customer, at the customer's request, the documents comprising the ACLASS ISO/IEC 17025 accreditation system.

ACCLASS shall determine in its sole discretion whether the customer meets ACLASS requirements for accreditation to the applicable requirements (accreditation criteria) as set forth in the ACLASS ISO/IEC 17025 accreditation system. In the event ACLASS determines that the customer meets the accreditation criteria, ACLASS shall deliver to the customer the ACLASS certificate and scope of accreditation which shall include a copy of the ACLASS symbol. The certificate and scope of accreditation shall be deemed to be evidence of the customer's accredited status pursuant to the ACLASS accreditation criteria.

ACCLASS shall have the right to carry out surveillance and reassessment pursuant to the ACLASS ISO/IEC 17025 accreditation system to verify the customer's continuous compliance to the accreditation criteria.

The customer shall conform to the following:

- Maintain impartiality and integrity for all services provided under their scope of accreditation
- Commit to meet the requirements of the ACLASS accreditation criteria including adapting to changes in the requirements for accreditation
- Take such actions as necessary to allow ACLASS to perform the accreditation activities. These include providing for the examination of documentation and the assessment of all areas, records, and personnel for the purposes of assessment, surveillance, reassessment, resolution of complaints, and access to relevant documents that provide insight into the level of independence and impartiality from any related body
- Record and address complaints, report complaints to ACLASS, and otherwise continuously comply with all relevant provisions of the accreditation criteria and claim accreditation only in respect to the requirements and scope for which the customer has been granted accreditation. The ACLASS certificate and scope of accreditation does not extend to subcontracted calibrations.
- Notify ACLASS within 30 days of changes to the customer's laboratory management system or changes significantly affecting the customer. These may include, for example, change of ownership, location, key personnel, main policies, resources, or equipment or if analysis of a complaint or other information indicates that the customer no longer complies with the accreditation criteria.
- Allow ACLASS to conduct surveillance and reassessment of the customer in the event of a change as identified above
- Not expose assessors or others representing ACLASS to unsafe working conditions or environments and to provide all assessors and others appropriate protective equipment
- Arrange witnessing of services performed at the request of ACLASS including allowing third parties selected by ACLASS to witness ACLASS assessments
- Not use its accreditation in a manner that may bring ACLASS into disrepute

- Pay ACLASS for accreditation activities as set out in ACLASS procedures

The ACLASS logo is a registered trademark solely owned by ACLASS. So long as the customer maintains its status as being accredited by ACLASS pursuant to the ACLASS accreditation criteria, the customer shall have the non-exclusive and non-transferable right to use the certificate and scope of accreditation and the ACLASS symbol (except as provided for directly in the paragraph below) in the customer's advertising, marketing materials and campaigns, and certificates and reports.

In no event shall the customer use the certificate and scope of accreditation and the ACLASS symbol (or a confusingly similar certificate and scope of accreditation or symbol) in a misleading or unauthorized manner. This includes, but is not limited to, representing that the certificate and scope of accreditation and the ACLASS symbol exemplify a product, service, or performance conformity certification; using the certificate and scope of accreditation or the ACLASS symbol in connection with requirements or activities not approved by ACLASS; or otherwise acting to bring ACLASS or the ACLASS symbol in disrepute.

If ACLASS expresses any concern with respect to the use of the certificate and scope of accreditation or the ACLASS symbol as being inconsistent with or impermissible under the ACLASS ISO/IEC 17025 accreditation system, (improper use), ACLASS may request the customer to cease and desist the improper use, and it shall be deemed to be a condition to the customer's continued accreditation that such improper use is immediately discontinued.

In addition, in the event of such improper use or in the event ACLASS determines that the customer is not complying with any obligation of the customer, ACLASS shall have the right upon written notice to the customer to (a) suspend its Accreditation Activities until the customer complies with its obligation, (b) determine that the customer is no longer entitled to identify itself as accredited by ACLASS and to require customer (temporarily or permanently) to cease using in any manner the certificate and scope of accreditation (and to return such certificate and scope of accreditation), the ACLASS symbol and/or ILAC MRA Mark, (c) refuse to issue a certificate and scope of accreditation to the customer, (d) require a corrective action, (e) publish the customer's transgression or (f) take other legal action.

In the event ACLASS takes any of the foregoing actions, ACLASS shall not be required to reimburse any amounts to the customer.

ACLASS and its assessor shall perform accreditation activities in a workmanlike manner consistent with the ACLASS then current accreditation system. The warranty set forth in this section is the sole and exclusive warranty of ACLASS under this application and the services contemplated to be provided herein and no other express or implied warranties exist, including but not limited to any warranty of merchantability and any warranty of fitness for a particular purpose. The customer acknowledges that ACLASS does not warrant and has no liability or responsibility for (and such liability and responsibility

belongs solely to the customer) the customer and safety of any product or service produced, manufactured, delivered, sold, or otherwise distributed by the customer.

ACCLASS and the customer are independent parties and nothing set forth in the ACCLASS application creates a joint venture, partnership, or other concerted activity.

If, in ACCLASS' sole discretion, an assignment and/or activity by the customer effects a change to the customer's management system or if changes are made by ACCLASS to the accreditation criteria, the customer shall cooperate and take the actions necessary to allow the assignment to occur based on a reassessment or surveillance visit or such other activity as ACCLASS reasonably deems necessary.

The responsibilities and obligations of the customer shall be governed by, and construed and enforced in accordance with, the laws of the State of Wisconsin. Any dispute under the ACCLASS application shall be resolved pursuant to the appeals procedure adopted by ACCLASS from time to time. In the event the customer makes any claim that a dispute is not subject to the appeals process or has not been adjudicated pursuant to the rules provided therein, the customer shall not have the right to bring any action with respect thereto before a court of law or equity, but shall only have the right to seek a determination from one arbitrator pursuant to the rules of the American Arbitration Association as to whether such dispute was subject to the appeals process or was adjudicated pursuant to the rules provided therein. Such arbitration shall be conducted in the State of Wisconsin, and each party shall bear its own expense for such arbitration.

23.0 SUPPLEMENTAL REQUIREMENTS FOR EMC TESTING & CAB DESIGNATION UNDER THE APEC TEL MRA

In addition to the above requirements the following shall apply. The purpose of this section is to establish additional policies for and provide a supplement to the ACCLASS ISO/IEC 17025 accreditation program for conformity assessment bodies as testing laboratories under electromagnetic compatibility testing (EMC) in order to meet FCC regulations and/or the foreign EMC/telecom technical requirements for conformity assessment body (CAB) designation under the APEC Tel MRA.

ACCLASS is committed to superior accreditation services including those for conformity assessment bodies of telecommunications equipment following the FCC Accredited Test Laboratory Technical Assessment Evaluation Checklist (or future versions thereof) in combination with ISO/IEC 17025 and/or those seeking accreditation to the foreign technical requirements under applicable government to government MRAs such as Phase I of the APEC Tel MRA. In addition to using the ACCLASS ISO/IEC 17025 checklist, assessments also involve the use of the FCC Accredited Test Laboratory Technical Assessment Evaluation Checklist as found at www.fcc.gov/oet/ea/mra and ACCLASS Form 31.

Our processes for such accreditation offer applicant bodies the opportunity to assure their customers of their compliance with international standards, compliance of equipment subject to the FCC EMC Regulations contained in 47 CFR Parts 2, 15, and 18, requirements for EMC and telecom products under specific APEC Tel Phase I economies, and international recognition of good practices. Requirements for APEC Tel Phase I economies can be found at http://ts.nist.gov/Standards/Conformity/mra/how_to_apply.cfm

23.1 Conformity Assessment of Telecommunication Equipment

The following is an excerpt from the Federal Communications Commission at www.fcc.gov/oet/ea/mra:

The purpose of an MRA for Conformity Assessment of Telecommunications Equipment is to facilitate trade by allowing Conformity Assessment Bodies (CABs) in one country to test and/or certify products to the technical standards of another country. For APEC and CITELE countries participation is voluntary; however, if a country agrees to participate, certain rights and obligations apply. Once an MRA for Conformity Assessment of Telecommunications Equipment is in place the United States implements the MRA by exchanging letters with the participating country, which identify the responsible parties and their obligations. The exchange letters also identify the scope (acceptance of test reports and/or equipment approval) of the MRA.

Mutual Recognition Agreements (or arrangements) (MRAs) are government-to-government trade facilitating measures aimed at a global approach to conformity assessment [these agreements should not be confused with the Mutual Recognition Arrangements between accrediting organizations]. The government-to-government agreements can be multi-sector, as in the U.S.-EU MRA, covering more than one group of products. The agreements can also be multi-lateral, as in the APEC MRA, providing a guideline for all member economies (countries) to follow. In each of the agreements, participating countries agree to accept the test results and/or product approvals performed by the Conformity Assessment Bodies (CABs) of the other country based on the use of a set of internationally accepted procedures. The present MRAs only address the issue of harmonizing conformity assessment procedures and do not attempt to harmonize regulatory standards or technical standards. These agreements were initiated and supported by the U.S. industry to allow for the acceptance of each other's conformity assessment procedures. An objective in implementing MRAs is to ease the burden on manufacturers and reduce their costs and time to market for products by implementing transparent conformity assessment processes that are similar within multiple countries while ensuring that products that reach the market are compliant.

23.2 Conformity Assessment Body

Within the text of the Mutual Recognition Agreements (MRAs) the term Conformity Assessment Body (CAB) was developed to identify the organizations performing conformity assessment. A Conformity Assessment Body is a body which may include a

third party or a supplier's testing laboratory, or a certification body, that is designated to perform conformity assessment to an importing Party's Technical Regulations under this Arrangement.

Under the FCC's Equipment Authorization Program there are two types of Conformity Assessment Bodies:

- Accredited testing laboratories are used to perform testing of equipment subject to requirements that permit the use of a Declaration of Conformity to demonstrate compliance.).
- Telecommunication Certification Body (TCB) is used to perform third-party certification of equipment subject to the FCC requirements that require the product to be certified.

23.3 CAB Designation under the APEC Tel MRA

Our program includes the appropriate EMC/telecom testing requirements, which may also include product safety testing standards of foreign regulatory authorities covered under the government-to-government MRAs. An example of these types of requirements for EMC and telecom products can be found under the specific APEC Tel Phase I economies at the following link:

http://ts.nist.gov/Standards/Conformity/mra/how_to_apply.cfm

23.3.1 How to Apply for NIST CAB Designation

The National Institute of Standards and Technology (NIST) is the Designating Authority for CAB designations in the United States.

In order to apply for Phase-I CAB designation, please follow the steps noted at this website: http://ts.nist.gov/Standards/Conformity/mra/how_to_apply.cfm. In case an organization is seeking CAB designations at multiple locations, apply for each location separately. Before applying, have your laboratory accredited by an accreditation body that is acceptable to NIST for standards/test methods of APEC economy of interest. Once NIST has reviewed the application and confirmed its completeness, NIST will forward a designation request to the economies in question. Under the terms of the MRA, economies have up to 60 days to respond to NIST. There are currently no NIST fees associated with designation requests and recognition.

23.4 FCC Participation in MRAs

The Federal Communications Commission (FCC) participates in several MRAs. Access to these MRAs can be found by visiting the following website:

<http://www.fcc.gov/oet/ea/mra/>.

23.4.1 FCC Implementation of MRAs

The Federal Communications Commission implements the MRA in accordance with policies found by visiting <http://www.fcc.gov/oet/ea/mra/>.

23.4.2 Scope and Measurement Techniques

The scope includes all equipment subject to telecommunication regulations, including wire-line and wireless equipment. For such equipment, the MRA covers electromagnetic compatibility (EMC) and telecommunications aspects of the conformity.

The FCC maintains a series of documents that are a non-exclusive list of measurement techniques that may be used when testing equipment to determine its compliance with FCC rules. This list can be accessed by visiting the following link: <http://www.fcc.gov/oet/ea/eameasurements.html>. This list is provided as a reference tool to aid interested parties in locating measurement techniques. Any party making measurements to show compliance with the FCC rules should select the appropriate measurement methods as required and specified in the particular part of the FCC rules. (For example, for Part 15 devices see §§15.31, 15.32, 15.33, and 15.35 of title 47 of the Code of Federal Regulations (C.F.R.)). The FCC Knowledge Database found at <https://fjallfoss.fcc.gov/oetcf/kdb/index.cfm> provides additional guidance on testing devices subject to the FCC's rules.

23.5 Accreditation Process

23.5.1 Quotation and Charges

See this document Section 1.0

23.5.2 Application

An application form is provided with each quotation. Every customer seeking accreditation must submit an application packet. This packet should be submitted in electronic format, when possible, and must include the following: See also this document section 1.0.

- A completed application form (include all relevant locations to be covered by the accreditation)
- Quality Manual
- Standard operating procedures and work instructions
- Completed draft scope of accreditation to include the following:
 - Identify the type/class of testing
 - Identify the specific tests or properties measured
 - Identify the specifications, standard method or techniques used
 - Where appropriate, identify the detection limit, range, or equipment used

ACCLASS accreditation activities shall be confined to the attached scope provided with the application.

23.5.2 Notification and Objections

See this document Section 9.1

23.5.3 Introductory Visits/Practice Assessments

See this document Section 1.3 and 1.4.

23.5.4 Document Review

Upon receipt of the application packet containing the required documentation under Section 3.2 above, ACLASS will conduct a document review. ACLASS will perform an evaluation to begin the determination of conformance of the customer's ISO/IEC 17025 management system to the requirements. The customer must have a documented ISO/IEC 17025 management system which conforms to the requirements. ACLASS may ask the customer for additional documentation and information during the document review process.

ACCLASS will deliver to the customer a document review report indicating which requirements are adequately addressed and a summary of any issues. If significant issues arise from the document review, ACLASS may recommend to the customer the option of a planning visit to ensure readiness for the accreditation assessment.

For all reassessments, a formal document review shall also be conducted and documented.

23.5.5 Planning Visit

See this document Section 1.6

23.5.6 Assessment Preparation

Before all assessments, the assessor shall review all appropriate management system documentation to determine compliance with ACLASS requirements, including the requirements of the FCC Accredited Test Laboratory Technical Assessment Evaluation Checklist, requirements for EMC and telecom products under the specific APEC Tel Phase 1 economies, and/or other requirements that have been or may have been added to this program.

During this review, the assessor and/or assessment team may request additional documentation from the laboratory. This includes but is not limited to, relevant test method(s), standard operating procedures (i.e. test procedures). If requested, the laboratory shall provide the requested information.

The advance planning for all assessments shall consist of:

- Thorough documentation review

- Review of the scope of accreditation
- Selection of critical tests that must be witnessed at the upcoming visit
- Advance communication with the laboratory to help plan the assessment schedule
- Finalizing the schedule / agenda for the assessment visit

23.5.7 Accreditation Assessment

The purpose of the accreditation assessment is to sample the customer's quality and technical management system in the area(s) of electromagnetic compatibility testing and determine through the use of interviews, reviewing procedures, data, and records, plus witnessing selected procedures or technical methods that the customer's system is effectively implemented and meets the applicable requirement(s) (some economies include product safety testing standards). The assessment team uses the accreditation assessment to judge if the customer is ready to be accredited.

The accreditation assessment shall consist of:

- thorough review of customer's compliance to the requirements for accreditation including use of the FCC Accredited Test Laboratory Technical Assessment Evaluation Checklist
- an opening meeting with the customer's management
- staff interviews to ensure proper training and technical competence
- daily assessor meetings and customer debriefings
- a review of any open issues from the document review and planning visit, if applicable
- on-site assessment to determine compliance and to evaluate expertise in the area(s) applied for

Assessors will sample and witness a sufficient number of test methods across technologies within the scope of accreditation. They shall ensure enough notice is provided to the laboratory in order for the laboratory to schedule the variety of tests with an artifact or sample under test, whenever possible. Such tests may include normalized site attenuation, product safety tests, MIL-STD-462, antenna pattern tests, C63-17 among others.

- 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 customer will 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 notes.

AClass may provide guidance to the lead assessor as requested and as needed.

23.5.8 Witnessing Scope of Accreditation

As a result of the large number of test methods and applicable standards within the EMC/telecom/electrical community, the assessor and/or assessment team utilizes the “scope/method assessment review” sheets in conjunction with the applicable checklists to review the laboratory’s conformance with test methods. This review consists of recording the extent to which the test was assessed by observing the test, interviewing personnel, reviewing procedures, reviewing and inspecting equipment, and assessing on-site tests. At a minimum, the assessor and/or assessment team must ensure the laboratory has equipment, method, and trained personnel to perform each test on the proposed scope of accreditation.

AClass assessors verify the competency of laboratories to conduct various types and/or groups of test on the scope of accreditation by using a variety of sampling methods including but not limited to, sampling across technologies, sampling high risk methods, sampling those tests done more frequently and those done rarely.

Demonstrations of specific test procedures will include at a minimum discussions with personnel conducting the tests, preparation of the test item, test conditions, and use of major equipment. The “scope/method assessment review” sheet is used to document this examination.

All equipment necessary to conduct testing related to the scope of accreditation shall be available during each assessment. The assessor and/or assessment team shall examine the equipment, accommodation and environmental conditions.

23.5.9 Non-Conformances

The assessment team shall record findings on AClass' Non-Conformance Record traceable to the AClass ISO/IEC 17025 Accreditation Checklist and the FCC Accredited Test Laboratory Technical Assessment Evaluation Checklist. Team members will classify each finding as a major non-conformance or a minor non-conformance and note each one on the respective location in the checklist. ILAC-G20:2002, *Guidelines on Grading of Non-conformities*, is used as guidance for classification of non-conformances:

A Major Non-conformance 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 the activities conducted by the accreditation customer. The assessment team may judge numerous minor non-conformities against a single requirement to be a significant breakdown of the management system and thus a major non-conformance.

A Minor Non-conformance is any other non-conformance which is an isolated occurrence and is normally easily corrected and verified.

An Opportunity is neither a major nor minor non-conformance. It is used to document items that may help a customer improve their quality or technical systems.

If during the initial accreditation assessment a significant number of non-conformances are identified and these non-conformances affect considerably the completion of the assessment, the lead assessor may, in coordination with ACLASS, recommend to the customer that the initial accreditation assessment be considered a practice assessment. If such a case, the initial accreditation assessment will then be re-scheduled.

23.5.10 Customer Corrective Actions

During the accreditation process, surveillance and reassessment, ACLASS assessors will identify issues and non-conformities. The customer and ACLASS will agree upon the deadline (normally 30 days) for corrective actions. ACLASS reserves the right to verify whether the customer has taken and effectively implemented adequate corrective action. Responses shall be sent to ACLASS for distribution to the lead assessor.

ACLASS requires the customer to take prompt actions on any issues or problems identified by the customer during internal audits or reviews as well as to ACLASS assessments.

Based on the recommendation of the assessment team, results of the assessment and extensive corrective actions a possible follow-up visit may be required. The amount of time to perform this service will depend on the severity of the situation. The charge for this service will be at ACLASS' current rate. The timing for this part of the assessment process will be coordinated between ACLASS, the lead assessor and with the customer.

23.5.11 Decision on Accreditation

See this document Section 1.10.

23.5.12 Surveillance Assessment

ACLASS accreditation is for two years. After the initial year of accreditation, each customer shall undergo, at a minimum, a one-day surveillance assessment. The purpose of the surveillance is to ensure that the customer's organizational management system is maintained and remains effective.

At a minimum, complaints, internal audits, management reviews and any changes to key personnel or facilities are elements of the customer's management system which ACLASS will review during each surveillance visit.

ACLASS may conduct surveillance assessments on a more frequent occurrence should ACLASS determine surveillance is warranted.

Any resulting non-conformance 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. ACLASS shall monitor this time limit, and take any appropriate action. Such appropriate action may include suspension or withdrawal of accreditation in accordance with ACLASS procedures and the application for accreditation.

If the results of the surveillance visit yield excessive non-conformities or if major modifications occur, ACLASS may require a follow-up visit and/or additional assessment time.

23.5.13 Reassessment

ACLASS will conduct a formal document review and full on-site reassessment of accredited customers at least once every two years for verification of continued compliance with ACLASS' accreditation requirements. The reassessment process is similar to the accreditation assessment (see also section 4.6).

Any resulting non-conformance from a reassessment visit shall be responded to by the customer within 30 days. Responses shall be sent to ACLASS for distribution to the lead assessor. ACLASS shall monitor this time limit, and take any appropriate action. Such appropriate action may include suspension or withdrawal of accreditation in accordance with ACLASS procedures and the application for accreditation.

If the results of the reassessment visit yield excessive non-conformities or if major modifications occur, ACLASS may require a follow-up visit and/or additional assessment time.

23.5.14 Complaints and Appeals

See this document Section 8.0.

23.5.15 Withdrawal, Withholding, Reducing, Suspending Accreditation

See this document Section 16.0.

23.6 Measurement Uncertainty and Traceability

Customers are required to demonstrate traceability and measurement uncertainty, where appropriate. In such instances, ACLASS' policy on traceability shall apply; see this document section 6.0. See also, ACLASS Guidance on Traceability on the ACLASS website.

Measurement uncertainty shall be estimated for all test methods within the laboratory's scope of accreditation, as applicable.

23.7 Proficiency Testing

Customers are required to participate in proficiency testing or other inter-laboratory comparisons. The customer shall select and judge with ACLASS concurrence that the organization conducting the proficiency testing or inter-laboratory comparison is competent in accordance with ISO/IEC 17043. See also PT/ILC Requirements in this document section 6.0. For further guidance, see also ACLASS Guidance on Proficiency Testing/Inter-Laboratory Comparisons available at www.aiclasscorp.com.

23.8 Technical Experts for Programs

A technical expert that will evaluate the technical competence of a prospective conformity assessment body shall have extensive knowledge and experience in the EMC/Telecom/Electrical arena, FCC rules and telecommunication equipment, and/or requirements for EMC and Telecom products under the specific APEC Tel Phase I economies. A technical expert shall meet the requirements found in ACLASS Document 2 and will be accompanied by an experienced ACLASS lead assessor.

24.0 SUPPLEMENTAL REQUIREMENTS EPA NATIONAL LEAD LABORATORY ACCREDITATION PROGRAM (NLLAP)

The EPA National Lead Laboratory Accreditation Program (NLLAP) was established by the EPA Office of Pollution Prevention and Toxics (OPPT) under the legislative directive of Title X, the Lead-Based Paint Hazard Reduction Act of 1992 Sections 405 (a) and (b) requiring EPA to set minimum standards for laboratory analysis of lead in paint films, soil and dust.

24.1 Introduction and Purpose

In addition to the above applicable requirements within this document, the following shall apply. The purpose of this section and the following sections is to convey the requirements for use by ACLASS when accrediting laboratories performing environmental testing activities under NLLAP. NLLAP is based on the requirements of ISO/IEC 17025. ISO/IEC 17025 will be used as the base requirements with the additional requirements found in the most current version of the Laboratory Quality System Requirements (LQSR).

The requirements of LQSR apply to all lead testing laboratories participating in the EPA's NLLAP. In addition to meeting ISO/IEC 17025 and LQSR, lead testing laboratories must also successfully participate in the Environmental Lead Proficiency Analytical Testing Program (ELPAT).

NLLAP is for laboratories that perform quantitative and/or qualitative analytical testing of paint chip (film), dust, and/or soil samples for lead analysis. NLLAP and ACCLASS requires accredited laboratories to employ quality assurance/quality control systems that meet the requirements described the LQSR and ISO/IEC 17025, to monitor for potential sample matrix and environmental interferences as well as laboratory operational deficiencies.

ACCLASS will only accredit laboratories under NLLAP which practice the sub-contracting of routine samples analyses to another NLLAP recognized laboratories for the same analyses.

24.2 Laboratory Types

For the purposes of NLLAP, a laboratory is defined as an operation that performs sampling and/or quantitative analytical testing of paint chip (film), dust, and/or soil samples for lead analysis regardless of the number of personnel or the extent of the scope of testing activities.

NLLAP recognizes three types of laboratory operations:

Fixed Site: An operation that performs analytical lead testing at a permanent location under controlled environmental conditions

Mobile Facility: A transportable, self contained operation that can perform analytical lead testing under controlled environmental conditions

Field Sampling and Measurement Organization (FSMO): An operation that performs on-site sampling and lead testing using portable testing technologies

A laboratory may include one, two or all three of these types of operations. In cases where a laboratory does not perform one or more of the operations addressed above, the requirements relating to those activities do not apply.

24.3 Accreditation Process

24.3.1 Quotation and Charges

See this document section 1.0

24.3.2 Application

An application form is provided with each quotation. Every customer seeking accreditation must submit an application packet. This packet should be submitted in electronic format. See also this document section 1.0.

ACCLASS accreditation activities shall be confined to the attached scope provided with the application.

24.3.3 Notification and Objections

See this document Section 9.1

24.3.4 Introductory Visits/Practice Assessments

See this document Section 1.3 and 1.4.

24.3.5 Document Review

Upon receipt of the application packet containing the required documentation under section 3.2 above, ACLASS will conduct a document review. ACLASS will perform an evaluation to begin the determination of conformance of the customer's laboratory management system to the requirements of ISO/IEC 17025 and LQSR. The customer must have a documented ISO/IEC 17025 and LQSR management system which conforms to the requirements. ACLASS may ask the customer for additional documentation and information during the document review process.

ACLASS will deliver to the customer a document review report indicating which requirements are adequately addressed and a summary of any issues. If significant issues arise from the document review, ACLASS may recommend to the customer the option of a planning visit to ensure readiness for the accreditation assessment.

24.3.6 Planning Visit

See this document Section 1.6

24.3.7 Assessment Preparation

Before all assessments, the assessor shall review all appropriate laboratory management system documentation to determine compliance with ACLASS requirements, including the requirements of the LQSR.

During this review, the assessor and/or assessment team may request additional documentation from the laboratory. This includes but is not limited to, relevant test method(s), standard operating procedures (i.e. test procedures). If requested, the laboratory shall provide the requested information.

The advance planning for all assessments shall consist of:

- Thorough documentation review
- Review of the scope of accreditation
- Selection of critical tests that must be witnessed at the upcoming visit
- Advance communication with the laboratory to help plan the assessment schedule
- Finalizing the schedule / agenda for the assessment visit

24.3.8 Accreditation Assessment

The purpose of the accreditation assessment is to sample the customer's quality and technical management system in the area(s) of paint chip (film), dust, and/or soil samples for lead analysis (as applicable) and determine through the use of interviews, reviewing procedures, data, and records, plus witnessing selected procedures or technical methods that the customer's system is effectively implemented and meets the applicable requirement(s). The assessment team uses the accreditation assessment to judge if the customer is ready to be accredited.

ACCLASS will perform a complete systems assessment on applicant laboratories inclusive of an on-site assessment which will include ISO/IEC 17025 and the minimum requirements stated in the most recent revision of the NLLAP Laboratory Quality System Requirements (LQSR).

The accreditation assessment shall consist of:

- thorough review of customer's compliance to the requirements for accreditation including use of the LQSR Checklist
- an opening meeting with the customer's management
- staff interviews to ensure proper training and technical competence
- daily assessor meetings and customer debriefings
- review of any open issues from the document review and planning visit, if applicable
- on-site assessment to determine compliance and to evaluate expertise in the area(s) applied for
- sampling and witnessing a sufficient number of test methods across technologies within the scope of accreditation. Assessors shall ensure enough notice is provided to the laboratory in order for the laboratory to schedule the variety of tests with an artifact or sample under test, whenever possible.
- final assessment team meeting to discuss findings
- 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 customer will 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 notes.

ACCLASS may provide guidance to the lead assessor as requested and as needed.

24.3.9 Non-Conformances

The assessment team shall record findings on ACLASS' Non-Conformance Record traceable to the ACLASS ISO/IEC 17025 Accreditation Checklist and the LQSR Checklist. Team members will classify each finding as a major non-conformance or a minor non-conformance and note each one on the respective location in the checklist. ILAC-G20:2002 Guidelines on Grading of Non-conformities is used as guidance for classification of non-conformances.

A Major Non-conformance 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 the activities conducted by the accreditation customer. The assessment team may judge numerous minor non-conformities against a single requirement to be a significant breakdown of the management system and thus a major non-conformance.

A Minor Non-conformance is any other non-conformance which is an isolated occurrence and is normally easily corrected and verified.

An Opportunity is neither a major nor minor non-conformance. It is used to document items that may help a customer improve their quality or technical systems.

If during the initial accreditation assessment a significant number of non-conformances are identified and these non-conformances affect considerably the completion of the assessment, the lead assessor may, in coordination with ACLASS, recommend to the customer that the initial accreditation assessment be considered a practice assessment. If such a case, the initial accreditation assessment will then be re-scheduled.

24.3.10 Customer Corrective Actions

During the accreditation process, surveillance and reassessment, ACLASS assessors will identify issues and non-conformities. The customer and ACLASS will agree upon the deadline (normally 30 days) for corrective actions. ACLASS reserves the right to verify whether the customer has taken and effectively implemented adequate corrective action. Responses shall be sent to ACLASS for distribution to the lead assessor.

ACLASS requires the customer to take prompt actions on any issues or problems identified by the customer during internal audits or reviews as well as to ACLASS assessments.

Based on the recommendation of the assessment team, results of the assessment and extensive corrective actions a possible follow-up visit may be required. The amount of time to perform this service will depend on the severity of the situation. The charge for this service will be at ACLASS' current rate. The timing for this part of the assessment process will be coordinated between ACLASS, the lead assessor and with the customer.

24.3.11 Decision on Accreditation

See this document Section 1.10.

24.3.12 Surveillance Assessment

ACCLASS accreditation is for two years. After the initial year of accreditation, each customer shall undergo, at a minimum, a one-day surveillance assessment. The purpose of the surveillance is to ensure that the customer's organizational management system is maintained and remains effective.

At a minimum, complaints, internal audits, management reviews and any changes to key personnel or facilities are elements of the customer's management system which ACLASS will review during each surveillance visit.

ACCLASS may conduct surveillance assessments on a more frequent occurrence should ACLASS determine surveillance is warranted. Laboratories which have been cited as having performed inadequately based on customer complaints or poor performance in the NLLAP program will be subject to more frequent re-evaluations.

Any resulting non-conformance 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. ACLASS shall monitor this time limit, and take any appropriate action. Such appropriate action may include suspension or withdrawal of accreditation in accordance with ACLASS procedures and the application for accreditation. A fee may be charged for review of corrective actions.

If the results of the surveillance visit yield excessive non-conformities or if major modifications occur, ACLASS may require a follow-up visit and/or additional assessment time.

24.3.13 Reassessment

ACCLASS will conduct a full on-site reassessment of accredited customers at least once every two years for verification of continued compliance with ACLASS' accreditation requirements. The reassessment process is similar to the accreditation assessment (see also section 4.6 and 24.3.8).

Any resulting non-conformance from a reassessment visit shall be responded to by the customer within 30 days. Responses shall be sent to ACLASS for distribution to the lead assessor. ACLASS shall monitor this time limit, and take any appropriate action. Such appropriate action may include suspension or withdrawal of accreditation in accordance with ACLASS procedures and the application for accreditation.

If the results of the reassessment visit yield excessive non-conformities or if major modifications occur, ACLASS may require a follow-up visit and/or additional assessment time.

24.3.14 Complaints and Appeals

See this document Section 8.0.

24.3.15 Withdrawal, Withholding, Reducing, Suspending Accreditation

See this document Section 16.0.

24.4 Measurement Uncertainty and Traceability

Customers are required to demonstrate traceability and measurement uncertainty, where appropriate. In such instances, ACLASS' policy on traceability shall apply; see this document Section 6.0. See also *ACLASS Guidance on Traceability* on the ACLASS website.

Measurement uncertainty shall be estimated for all test methods within the laboratory's scope of accreditation, as applicable.

24.5 Proficiency Testing

Customers are required to participate in proficiency testing or other inter-laboratory comparisons. Specifically, all NLLAP customers must have successfully performed in an Environmental Lead Proficiency Analytical Testing Program (ELPAT) as administered by American Industrial Hygiene Association, LLC (AIHA, LLC) or other NLLAP recognized lead laboratory accreditation organizations.

Laboratories must participate in the ELPAT program on a quarterly bases as new rounds of proficiency testing samples are made available. ACLASS will manage and process the data of participating laboratories.

24.6 Complaints Received from Customers of the Accredited Laboratory

ACLASS requires its accredited customers to keep records of complaints against its laboratory management system. Records shall clearly show the resolution of those complaints. Complaints, internal audits, management reviews and PT/ILC activity are elements of the customer's laboratory management system which ACLASS will review during its assessment visits records of complaints received from customers of the accredited laboratory will be maintained by ACLASS.

25.0 SUPPLEMENTAL REQUIREMENTS FOR ENERGY STAR LABORATORY RECOGNITION

The U.S. Environmental Protection Agency (EPA) has established Conditions and Criteria for Recognition of Accreditation Bodies for ENERGY STAR Laboratory Recognition and Conditions and Criteria for Recognition of Laboratories for the ENERGY STAR Program.

25.1 Introduction and Purpose

The purpose of this section and the following sections is to convey the requirements for use by ACLASS when accrediting laboratories performing testing activities under the ENERGY STAR Laboratory Recognition Requirements.

ACCLASS will assess laboratory operations to ISO/IEC 17025 and for compliance with ENERGY STAR Laboratory Recognition Requirements. Assessors will be provided with the energy star product requirements. Upon a satisfactory outcome, ACLASS will attest, by granting accreditation and issuing a certificate and scope of accreditation, to the technical competence of laboratories to perform tests required for ENERGY STAR qualification as outlined in the ENERGY STAR Laboratory Recognition Requirements.

In addition to the above applicable ISO/IEC 17025 requirements within this document, the following shall apply.

25.2 General Requirements

In order to serve as an EPA-recognized accredited laboratory for the ENERGY STAR program, a laboratory shall meet the following requirements:

1. Maintain accreditation to ISO/IEC 17025
2. Develop and maintain separate laboratory test procedures for each accredited ENERGY STAR test method that detail how testing will be conducted utilizing the laboratory's test facilities, fixtures, equipment and personnel.
3. Notify EPA/DOE and ACLASS immediately of any attempt to hide or exert undue influence over test results.
4. Have recorded in its scope of accreditation its specific competence to carry out the test methods as outlined in the ENERGY STAR program for which the laboratory intends to test products. The relevant test procedures are included in the product testing section of each ENERGY STAR specification.

http://www.energystar.gov/index.cfm?c=product_specs.pt_product_specs#hea

5. At a minimum the title of the relevant ENERGY STAR product category will be included on the scope of accreditation. If the laboratory is unable to perform the required test procedures for every product subtype within the program requirements, it should also list specific subtypes covered within those requirements.
 - a. Note: To decrease the burden to laboratories and ACLASS, EPA will not require laboratories to update their scopes of accreditation when an ENERGY STAR specification is revised. However, EPA will require that the laboratory ensures its methods remain consistent with the test methods described in the program requirements of the currently effective version of the specification. Further, major changes in test method, for example, when a specification revision calls for a different test method altogether from the preceding specification version, will necessitate a scope of accreditation update to reflect the newly required test method. In such cases, the ACLASS policy on scope expansions shall apply.
6. Allow EPA or an EPA-appointed representative, at its discretion, to witness any testing performed for qualification or verification of qualification to the requirements of the ENERGY STAR program. EPA and ACLASS will jointly determine when such witnessing will occur. ACLASS will appropriately notify the laboratory. EPA or its appointed representative agrees to operate solely as an observer and not participate in any way with the testing activities of the laboratory.

25.3 Inter-laboratory Comparison Testing / Proficiency Testing

In addition to the regular proficiency testing requirements to achieve and maintain ISO/IEC 17025 accreditation, EPA recognized laboratories for the ENERGY STAR program shall:

1. Agree to participate in relevant and available inter-laboratory comparison testing (ILC) when EPA/DOE deems it necessary.
2. Carry out ILC in accordance with normal testing/calibration and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider. ACLASS requires, at minimum, annual submittal of ILC/Proficiency test activity, including any corrective actions taken.
3. Submit to EPA/DOE upon request:
 - a. The results of the ILC
 - b. The analysis of those results; and,
 - c. Detailed corrective action responses for any outlying or unacceptable results.

25.4 Impartiality

ISO/IEC 17025 section 4.1.5 b) requires laboratories to “have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.” The EPA expects ACLASS to systematically monitor and assess the impartiality of laboratories on an ongoing basis. Document and on-site review, consistent with the requirements of ISO/IEC 17025, shall include but may not be limited to the following:

1. Organization chart showing that the responsibilities, authorities, and inter-relationships of all personnel who manage, perform or verify laboratory results are free from influence that may adversely affect the quality of their work
2. Dates of internal audits, audit findings, and any corrective actions taken
3. Any customer complaints and corrective action taken
4. Original testing records containing sufficient information for repeatability, including the names of staff who participated
5. Evidence that laboratory employees participate in an regularly pass ethics and compliance audits
6. Evidence that mechanisms for reporting and responding to attempts to exert undue influence on test results are in place

25.5 Reporting

EPA recognized laboratories for the ENERGY STAR program are required to:


1. Submit to the EPA a digital copy of the ACLASS accreditation certificate and scope of accreditation. The ACLASS scope and certificate of accreditation will contain at a minimum:
 - a. Accreditation effective date;
 - b. Accreditation expiration date; and,
 - c. ENERGY STAR-relevant accredited test methods
2. Authorize ACLASS to share with EPA copies of assessment documentation related to ENERGY STAR testing, including corrective action plans and deficiency resolutions. Submittal of an application for accreditation to ACLASS expressly provides authorization to ACLASS. Additionally, a laboratory’s consent is a condition of their recognition by EPA.

3. Report to both EPA and ACLASS within 30 days of any major changes that affect the laboratory's:
 - a. Legal, commercial, organization, or ownership status;
 - b. Organization and management, e.g., key managerial staff;
 - c. Policies or procedures, where appropriate;
 - d. Location;
 - e. Personnel, facilities, working environment or other resources, where significant; and,
 - f. Other such matters that may affect the laboratory's capability, scope of recognized activities, or compliance with the ENERGY STAR requirements and relevant technical documents.
4. Forward any questions related to ENERGY STAR test methods to EPA for resolution, and abide by the decisions of EPA relative to the resolution of those questions.

25.6 Questions Related to Test Procedures

Should questions arise related to ENERGY STAR test procedures, ACLASS shall forward such questions to the EPA for resolution and abide by the decisions of the EPA relative to the resolution of those questions. ACLASS will also notify EPA of any observed test method interpretations that require clarification.

Approvals:



ks/
Vice President

UNCONTROLLED

REVISION HISTORY

<u>Date</u>	<u>Description/Author</u>
March 21, 2000	Draft. C. Shillito
March 31, 2000	C. Miller review. C. Shillito
March 31, 2000	Initial release. C. Shillito
August 1, 2000	Review/correction. C. Shillito
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February 12, 2003	Revised to distinguish from new HACCP system. B. Hirt
February 20, 2003	Review/Corrections – K. Greenaway
June 11, 2003	Updated document in response to NACLA input from NACLA Accreditation Body Recognition Procedure Requirements – K. Greenaway
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July 8, 2004	Final Review – K. Greenaway
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