

**SPECTRUM MANAGEMENT & SOFTWARE DEFINED RADIO**

- President of the National Association of Radio and Telecommunications Engineers (NARTE).
- Founder and chairman of the IEEE 1900 steering committee.
- Chairman ANSI C63.17, Test Methodology adopted by FCC for UPCS band, Part 15D.

**EMC AND ENVIRONMENTAL TESTING AND REGULATORY COMPLIANCE**

- Chairman ANSI C63.4-2003 revision committee, Test method adopted by the FCC for unintentional radiators.
- Improved test department efficiency by 500%, with no increase in personnel.
- Invented the EHR GTEM, patented, gained FCC approval and implemented its use.
- Member of key standards committees for EMC, RF Health, Accessibility and related areas.

**PUBLICATIONS**

Numerous professional papers and articles

(List of publications available upon request or online at [www.temconsulting.com](http://www.temconsulting.com))

**PATENTS**

Patents granted or pending

- 6,882,640: System and method for utilizing circuit switched and packet switched resources
- 6,744,750: Replicating and Recombinant Networking Systems and Methods for Wireless Networks
- 6,684,063: Integrated Hearing Aid for Telecommunications Devices
- 6,380,896: Circular polarization antenna for wireless communication system
- 6,225,917: Electromagnetic Field Probe Having a Non-Electrical Transmission Modality
- 5,754,054: Apparatus and Method for Determining the Source and Strength of EM Emissions
- 5,589,773: System and Method for Making Electromagnetic Measurements Using a Tiltable Transverse Electromagnetic Cell and a Fixed Tilt Sample Holder
- EP00805562A3: Radio-Frequency Hearing Aid Protector for Wireless Communications Products

**CURRENT EMPLOYMENT**

TEM CONSULTING, LP  
President of the General Partner

2000-Present

**EDUCATION**

BS, Physics

University of Wisconsin, Madison, WI.

*(further information and list of publications available at: [www.temconsulting.com](http://www.temconsulting.com))*



## **APLAC MUTUAL RECOGNITION ARRANGEMENT**

### **AN ARRANGEMENT TO GRANT RECOGNITION**

Having fulfilled the requirements of the APLAC Mutual Recognition Arrangement, **ACLASS, United States of America** is a signatory to the Arrangement.

APLAC MRA signatories:

- (i) use equivalent procedures under ISO/IEC 17011 in the accreditation of laboratories against ISO/IEC 17025, medical laboratories against ISO 15189 and inspection bodies against ISO/IEC 17020;
- (ii) recognise, within the scope of recognition of this MRA, the accreditation of a laboratory or inspection body by other signatories as being equivalent to an accreditation by its own organisation;
- (iii) recommend and promote the acceptance by users in their economies of endorsed test, calibration and inspection reports issued by laboratories and inspection bodies accredited by APLAC MRA signatories;
- (iv) investigate complaints initiated by a signatory resulting from test reports and calibration certificates issued by their accredited testing and calibration laboratories and/or inspection reports issued by their accredited inspection bodies; and
- (v) inform one another, as soon as possible, of any significant changes in the status and/or operational practices in their accreditation bodies.

**Accreditation Body:** Assured Calibration and Laboratory Accreditation Select Services

**Economy:** United States of America

**Scope of Recognition:** Testing/Calibration

**Date of Signing APLAC MRA:** 13 September 2006

**A J Russell**  
**APLAC Chair**

# Inter American Accreditation Cooperation



Be it known that the

## **Assured Calibration and Laboratory Accreditation Select Services (ACLASS)**

United States of America

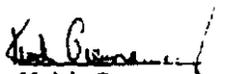
Has been accepted as a Member of the

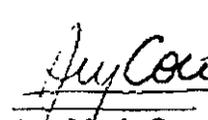
## **Inter American Accreditation Cooperation Multi-lateral Recognition Arrangement**

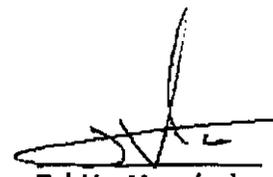
For

Accreditation Bodies of Testing and Calibration  
Laboratories

The Member on behalf of which this sheet is signed is committed to complying with the requirements and obligations of the IAAC MLA members

  
Keith Greenaway  
President/CEO

  
Ana María Coro  
IAAC Chair

  
Fabián Hernández  
IAAC MLA  
Committee Chair

Signed in Buenos Aires, Argentina, on August 11th, 2006



*ANSI-ASQ National Accreditation Board*

Conformity Assessment System  
Policies and Procedures  
Document 2

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## **0.0 PURPOSE**

The purpose of this document is to establish policies and procedures for the ACLASS conformity assessment programs to convey to personnel, assessors, and/or experts.

## **1.0 PERSONNEL AND ASSESSORS**

All assessors and experts shall meet the requirements of the ACLASS procedure for Personnel and Assessors Criteria and Training, Section 24. Assessors are responsible for maintaining their credentials and having the latest copies of the various standards and ACLASS documents. The latest revisions of this and all relevant ACLASS documents associated with each conformity assessment program are available on the ACLASS website and/or ACLASS Headquarters.

At least one assessor conducting the assessment shall have recognized expertise<sup>1</sup> in the function of the customer being assessed. Each assessor shall sign a Confidentiality and Conflict of Interest Statement for each customer for whom he or she performs an assessment, review, or conducts a visit.

The Senior Accreditation Manager(s)<sup>2</sup> and/or the Program Managers appoint all members of the assessment team. The lead assessor assigned to a customer seeking accreditation has full authority and responsibility for that customer's accreditation process, unless specifically defined otherwise in this document.

No assessor shall provide any direct advice (i.e., consulting) to a customer. No assessor shall advise a customer as to how to document and set-up its management system.

ACLASS and the lead assessor shall be sensitive to the customer's scheduling needs.

### **1.1 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.<sup>3</sup> 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, the Senior Accreditation Manager(s) and/or the Program Manager(s) 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:

- Submit their objection in writing to the Program Manager
- Identify the particular assessor(s) and/or expert(s) in question
- Identify the reason(s) behind the objection including known conflict of interest
- Sign the letter of objection by a duly authorized representative of the organization

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<sup>1</sup> e.g., calibration(s), test(s), inspection(s), RMP(s), PT providers or any other area as necessary

<sup>2</sup> ACLASS maintains Senior Accreditation Manager(s) and Program Manager(s)

<sup>3</sup> The customer may request at any time qualifications of assessment team members.

Upon receipt of the signed letter of objection, the Senior Accreditation Manager(s) and/or the Program Manager(s) 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(s) and/or expert(s)
- Notify the customer in writing of the names of the new member(s) of the assessment team, as appropriate.

## **2.0 REQUIREMENTS**

ISO 19011 is used as guidance for the ACLASS assessment process. The assessment, if conducted according to this document, will meet ISO 19011. Checklists, forms and procedures provided to perform assessment activities are for guidance. They provide the method for the assessment team to document how a customer is meeting the requirements.

The policies and procedures for the ACLASS conformity assessment programs are documented for the customer in Document 3 (for ISO/IEC 17025), Document 4 (for Reference Material Producers (using ISO Guide 34), Document 5 (for ISO/IEC 17020), and Document 6 (for PT providers using ISO Guide 43 and ILAC G13, soon to be replaced with ISO/IEC 17043). The policies written in each above mentioned document shall apply to all applicant and accredited customers.

The Senior Accreditation Manager(s) and/or the Vice President have the authority and responsibility for the official ACLASS interpretation of the standard(s) and ACLASS policies.

The ACLASS web site will contain all the current versions of documents, forms and templates.

## **3.0 QUOTATION AND OTHER INFORMATION**

A customer can request and obtain a quotation. Any authorized ACLASS personnel can provide a quotation. Quotes are made on the ACLASS Quotation Sheet. Quotes are according to ACLASS published rates. Quotations depend upon, but are not limited to, size of the organization, number of employees, and scope of accreditation.

ACLASS' conformity assessment programs provide a general description of each ACLASS accreditation system and are available to the public.

There may be additional charges for review of corrective action(s) and/or a follow-up visit for any non-conformance. The customer will be billed if significant review of corrective actions is required by ACLASS. Any follow-up and/or questions directed towards the lead assessor shall be responded to in a timely manner. Assessor domestic travel time is billed at

the rate of \$35/hour up to a maximum of \$350 roundtrip. International assessor travel time is billed on a case-by-case basis.

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

Customers canceling 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 canceled date.

All customers, including initial accreditation assessments and surveillance and reassessments, may be required to pay a deposit as defined by ACLASS. 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 as mentioned above up to and including suspension of accreditation.

#### **4.0 APPLICATION**

Every customer seeking accreditation from ACLASS must submit an application using the appropriate application form for each respective conformity assessment program. The accreditation process begins when ACLASS receives the completed application form and fee.

The Program Managers and/or ACLASS staff checks the application form to make sure it's complete and accurate. The applications are also reviewed to ensure that ACLASS has or can obtain the proper expertise to conduct the accreditation. Then, the Program Manager(s) and/or ACLASS staff sign off on the application and appoints the lead assessor and any additional team members, as necessary.

The draft scope of accreditation to be included in the application should be completed, as best as possible to ensure the customer's operations are adequately conveyed to ACLASS.

The lead assessor and/or the Program Manager(s) shall verify the scope directly with the customer. Upon verification of the scope, the Program Manager(s) and/or the lead assessor shall assemble a team of ACLASS assessors and/or experts, as necessary.

The Senior Accreditation Manager(s) and/or the Vice President or their designees have the authority and responsibility to select and assign all assessors and/or experts, in accordance with this document Section 24.

## **5.0 INTRODUCTORY VISIT**

The introductory visit is an optional service and may be completed by an ACLASS lead assessor. ACLASS schedules the visit to the customer to review and answer any questions regarding the requirements of accreditation and the ACLASS accreditation process. As appropriate and as time permits ACLASS may perform a walk through review of the facility.

This is an informal visit and there are no findings or written reports. ACLASS will sign and provide a copy of the Confidentiality and Conflict of Interest Statement to the customer. The original becomes part of the customer's record maintained by ACLASS.

## **6.0 PRACTICE ASSESSMENT**

Practice assessments are an optional service and can take up to the same number of assessor days as the accreditation assessment. Up to two (2) practice assessments may be conducted for each accreditation customer. ACLASS schedules and notifies the customer in writing with assessment schedule approximately 30 days before the assessment. The assessment team then visits the customer. The assessment team conducts the practice assessment just as an accreditation assessment would be conducted, except that it is informal.

This is an informal visit and the assessment records and written report are brief. All findings are left with the customer. ACLASS only maintains minimum records of a practice assessment to guarantee impartiality and to preserve traceability as indicated in the next paragraph. Practice assessments have no influence on the accreditation assessment.

The lead assessor shall provide the customer signed copies of the Confidentiality and Conflict of Interest Statement to the customer for each representative of ACLASS. The originals with a short report prepared by the lead assessor become part of the customer's records maintained by ACLASS. Also, the lead assessor shall ask the customer to complete and return to ACLASS an Assessment Activity Survey. Each assessor should complete the Assessor Assessment Record and should supply a copy to ACLASS to help them maintain their credentials. It is, however, the responsibility of the assessors and/or experts to maintain this file for their credentials.

The Program Manager(s) may provide guidance to the lead assessor as requested and needed.

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

## **7.0 DOCUMENT REVIEW**

The program manager, lead assessor and/or designee perform a document review to verify that all management system elements of the appropriate requirements are addressed, understood and documented by the customer. ACLASS requires the customer to have a

documented management system. The customer's documentation normally starts with a document known as the Quality Manual.

This is a required step in the accreditation process. After verification of the application, and assignment of the lead assessor by the Program Manager(s) and/or the Senior Accreditation Manager, ACLASS contacts the customer to request that the customer submit its management system documentation, if not previously received with the application, for review. Until this step is complete, no further steps in the accreditation process can begin. The program manager, lead assessor and/or a member of the accreditation assessment team, as assigned by the lead assessor performs this review and report preparation. The report shall include the use of the relevant accreditation checklist for the respective conformity assessment program with the document review column completed as well as the document review report to be sent to the customer. The time allowance for review and report preparation is normally one assessor day.

The report is a summary of information, issues and comments. The accreditation checklist is used to provide a paragraph-by-paragraph indication of how the customer meets the appropriate requirements. The reviewer shall include objective evidence (i.e., quality system references) in the document review column, as appropriate. Issues are definite violations or missing elements of the requirements. The assessor shall use comments to document concerns and questions that may become issues later in the accreditation process.

The lead assessor (or designee) shall submit the report including the checklist to the Program Manager(s) (or their designee) and/or the Senior Accreditation Manager for review and distribution to the customer and the ACLASS files. This report becomes part of the customer's records maintained by ACLASS.

The Program Manager(s) may provide guidance to the lead assessor as requested and needed. Also, the Program Manager(s) may provide a copy of an example report to the reviewer.

## **8.0 PLANNING VISIT**

The purpose and content of the planning visit are to:

- present ACLASS and its accreditation process to the customer
- resolve any questions concerning the scope of accreditation and formal listing
- review all issues and comments 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 to judge if the customer is ready for its assessment.

The planning visit is a very important step in the accreditation process, but is not a requirement for accreditation. ACLASS normally notifies the customer in writing at least 30

days before the planning visit with a schedule, and then conducts the visit and prepares the report. The time allowance for the visit and report preparation is normally one to two assessor days. This visit may be waived by request of the lead assessor to the Senior Accreditation Manager(s) and/or the Program Managers. Additionally, the planning visit may be waived at the request of the customer, as determined by ACLASS.

The following records result from this visit:

- Attendance Sheet from the opening presentation
- Confidentiality and Conflict of Interest Statements as needed
- the Planning Visit Report
- A copy of the accreditation checklist, when completed.

The planning visit report in addition to the above records shall include:

- the draft scope of accreditation of the customer, if available
- the status of all issues from the Document Review and this visit
- the general features of the customer (corporate entity name, address, legal status, human and technical resources)
- general information concerning the customer, such as primary function, relationship to larger corporation, and physical location(s)
- reference to the quality manual and revision, as well as scope and revision

The lead assessor (or designee) shall submit the report and all records except the survey to the Program Manager(s) (or their designee) and/or the Senior Accreditation Manager for review and distribution. A copy of the Planning Visit Report is typically left with the customer at the end of the visit, and a blank copy of the Assessment Activity Survey is given to the customer who should be asked to complete it and return it to ACLASS Headquarters. The records and report from this visit become part of the customer's records maintained by ACLASS.

Ideally, the customer and lead assessor will resolve all issues and comments from the document review, and any additional issues from the planning visit before the accreditation assessment. The lead assessor with the Program Manager(s) and/or the Senior Accreditation Manager can decide whether to proceed if all issues and comments are not resolved before the accreditation assessment.

The Program Manager(s) may provide guidance to the lead assessor as requested and as needed. Also, the Program Manager(s) may provide a copy of an example schedule and planning visit report to the lead assessor.

## **9.0 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 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.

The accreditation assessment shall consist of:

- thorough review of 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
- a review of any open issues from the document review and planning visit, if applicable
- a review of any results from proficiency testing, as applicable<sup>4</sup>
- a review of any estimations of measurement uncertainty, which includes review of uncertainty budgets, as applicable<sup>5</sup>
- witness scope of accreditation
- a final assessment team meeting to discuss findings
- a recommendation from the lead assessor in consultation with the assessment team to accredit, not to accredit, or hold accreditation pending non-conformance resolution
- a closing meeting

The accreditation assessment is a requirement, and is the critical step in the accreditation process. ACLASS typically notifies the customer in writing with assessment schedule and plan 30 days before the accreditation assessment. Then, the entire assessment team conducts the accreditation assessment. The lead assessor is responsible for the preparation of the accreditation assessment report. The accreditation assessment report shall be completed and submitted to the Program Manager(s) (or their designee) and/or the Senior Accreditation Manager within 5 business days after the completion of the accreditation assessment.

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

The accreditation assessment comprises the following steps and actions as indicated by these records that shall result from the accreditation assessment:

- Opening Meeting Check Sheet
- Attendance Sheets from the opening and closing meetings
- Confidentiality and Conflict of Interest Statement for each representative of ACLASS at assessment
- Appropriate accreditation checklist associated with each applicable conformity assessment program
- Non-conformance Records written during the assessment,

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<sup>4</sup> See also Section 11, Proficiency Testing / Inter-Laboratory Comparisons, within this document

<sup>5</sup> See also Section 12, Traceability and Measurement Uncertainty, within this document

- Accreditation Recommendation Record
- Closing Meeting Check Sheet including a review of the use of the ACLASS symbol
- Completed draft scope of accreditation as agreed upon by ACLASS and the customer
- BMC budgets to support scope of accreditation claims, as applicable
- PT/ILC Summary Report Form, as applicable
- Accreditation Assessment Report

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.

Assessors shall record each non-conformance on a Non-conformance Record. Response to any non-conformance is due within thirty days unless otherwise agreed upon between the customer and ACLASS. Responses shall be sent to ACLASS for distribution to the lead assessor. The assessment team classifies each non-conformance as major or minor.

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-conformities 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 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 operations.<sup>6</sup>

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

The lead assessor shall submit the accreditation assessment report and all records (except the Assessment Evaluation Survey) to ACLASS for review and distribution. The lead assessor will typically leave a copy of the entire report with the customer.<sup>7</sup> The records and report from this visit become part of the customer's records maintained by ACLASS.

The accreditation assessment final report in addition to the records indicated above shall consider and include:

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<sup>6</sup> ILAC-G20:2002 Guidelines on Grading of Non-conformities is used as guidance for classification of non-conformances

<sup>7</sup> At a minimum, non-conformance records and a copy of the checklist should be left with the customer

- dates(s) of assessment
- name(s) of assessment team
- names and location of customer
- reference to scope of accreditation which is an attachment
- the assessment team's evaluation as to the customer's compliance to the requirements
- the technical qualification, experience and authority of the customer's staff
- the names of the customer's staff responsible for the certificates and reports
- the adequacy of the internal organization and procedures
- physical facility and resources, including maintenance and volume, size, and staffing
- the results and the use of the results of proficiency and other inter-laboratory comparisons, when used and as applicable
- action to correct previous non-conformances

The Program Manager(s) may provide guidance to the lead assessor as requested and as needed. The Program Manager(s) may also provide a sample accreditation assessment report to the lead assessor.

### **9.1 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.

## **10.0 ISSUANCE OF ACCREDITATION**

The Vice President or his designees have the authority and responsibility to determine if a customer is to receive and continue accreditation from ACLASS (see also this document section 10.1 below). Based on the review of the accreditation assessment records and the recommendation of the assessment team, the Program Manager(s) (or their designee) issue a final recommendation to the Senior Accreditation Manager and/or the Vice President for the decision to issue or not to issue accreditation (see also section 10.1). ACLASS notifies the customer.

The accreditation certificate shall include:

- the signature of an officer of ACLASS
- identity and logo of ACLASS
- reference to the standard(s) used for the assessment
- the name and address of the customer
- reference to the scope of accreditation
- description of the scope
- the terms for the accreditation
- a unique serial number

The scope of accreditation shall include:

- the signature of an officer of ACLASS
- the name and address of the customer
- clear identification of the type, methods, areas of accreditation, or other relevant information
- effective date and term of accreditation
- certificate number to which scope applies
- names of person(s) recognized as responsible for the scope of accreditation

The Program Manager(s) and/or the Senior Accreditation Manager shall not make the accreditation recommendation, review reports nor sign the accreditation decision for a customer if the Program Manager(s) and/or the Senior Accreditation Manager have participated in the assessment. The Senior Accreditation Manager(s) may appoint another qualified individual to make the accreditation decision according to this document Section 24, Personnel and Assessor Criteria and Training (see also section 10.1). The appointed employee in this case shall not have participated in the assessment.

No certificate shall be issued with a recognition mark or indication which is not supported by a recognized scope.

The date upon when the accreditation decision was made shall be the valid date of accreditation for each customer. The accreditation decision date shall determine the annual surveillance and reassessment cycle. Evidence of the accreditation decision date shall be documented on the ACLASS management information system database.

## **10.1 Review of Accreditation Reports**

This section describes the process for reviewing customers' accreditation reports.

### **10.1.1 Accreditation Assessment Report Review**

Upon receipt of the accreditation reports and satisfactory resolution of all non-conformances from that report, the Program Manager(s) shall establish the Accreditation Review Panel (see also 10.2). The purpose of the panel is to review the customer's accreditation reports for technical compliance to the ACLASS requirements for applicable conformity assessment program for which the customer has applied.

The Program Manager(s) shall distribute the customers' accreditation reports 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 objective evidence to the Program Manager(s). The Program Manager(s) shall review the panel's results and submit their final recommendation to the Senior Accreditation Manager or Vice President.

The Senior Accreditation Manager and/or Vice President shall review the reports and the final recommendation to ensure the appropriate ACLASS processes were followed. The

Senior Accreditation Manager and/or Vice President shall then sign the certificate and scope of accreditation upon a favorable decision on accreditation.

Approval is indicated on each customer's assessment record maintained on ACLASS' management information system database.

#### **10.1.2 Surveillance Assessment Report Review**

Upon receipt of the surveillance assessment reports, the Program Manager(s) shall review each surveillance report and recommend whether to continue accreditation (see also section 10.1.1). Approval is indicated on each customer's assessment record maintained on ACLASS' management information system database.

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 the Program Manager(s) (see also section 10.1.1).

#### **10.1.3 Reassessment Report Review**

Upon receipt of the reassessment reports, the Program Manager(s) shall review each reassessment report and recommend whether to continue accreditation (see also section 10.1.1).

In instances when reassessments are conducted and the customer requires a modification in its scope of accreditation and/or technical capabilities or there are numerous non-conformances, the Accreditation Review Panel may be convened at the discretion of the Program Manager(s) (see also section 10.1.1).

Approval is indicated on each customer's assessment record maintained on ACLASS' management information system database.

### **10.2 Accreditation Review Panel**

The purpose of the Accreditation Review Panel (ARP) is to review the customer's accreditation reports for technical compliance to the ACLASS requirements for each applicable conformity assessment program. Members of the Accreditation Review Panel shall review customer accreditation reports submitted by the lead assessor and provide concurrence or non-concurrence with objective evidence to the Program Manager(s).

The Accreditation Review Panel receives its authority from the Accreditation Council.

The Accreditation Review Panel shall maintain impartiality and objectivity and has the freedom to make its own recommendation independent of any commercial interest and/or pressure.

The Accreditation Review Panel\* shall comprise individuals that represent all areas of a customer's scope of accreditation. The Program Manager(s) and/or Senior Accreditation Manager shall serve and are permanent members of the panel provided that the Program Manager(s) and/or the Senior Accreditation Manager shall not make the accreditation recommendation, review reports nor sign the accreditation decision for a customer if the Program Manager(s) and/or the Senior Accreditation Manager have participated in the assessment.

The Program Manager(s) shall ensure and select appropriate individuals for inclusion on the Accreditation Review Panel that comprise all areas of each customer's scope of accreditation being reviewed.

The Accreditation Review Panel shall submit the results of their review to the Program Manager(s). The results of the review shall include a recommendation to: accredit; hold accreditation pending further review; or not to accredit.

Members of the Accreditation Review Panel may be removed with cause.

#### **10.2.1 Request for Additional Information**

The ARP panel may request additional information before issuing their recommendation to the Program Manager(s). This request will go through the Program Manager(s) for dissemination to the appropriate individual(s) and/or organizations(s).

In instances where the ARP panel disagrees with the assessment team's recommendation, this will be documented. The Program Manager(s) will discuss the disagreement with the panel through any available means (i.e. email, teleconference, video conference, etc.), including but not limited to, review of additional information requested by the panel. The result (i.e. notes) from the discussion and review will be documented, with the Program Manager(s) final recommendation.

#### **10.2.2 ARP Assessor Feedback**

Accreditation Review Panel experts may provide feedback to ACLASS on assessor expertise as a result of their accreditation report review. Feedback may be documented, through email correspondence, letters, telephone or any other possible medium.

If any negative feedback is received regarding assessor(s) and/or expert(s), ACLASS shall take any necessary corrective action according to this document section 23. ACLASS may take the necessary corrective action to include but not limited to:

- Maintaining of notes for follow-up training
- Request for additional competency information
- Changes in approval areas

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\* Members of the Accreditation Review Panel are considered experts and shall meet the requirements of this document section 24.6

Feedback from the Accreditation Review Panel may include, but is not limited to:

- Highlight of deficiencies in reports
- Comments on assessor(s) and/or expert(s)
- General comments on the overall assessment

## **11.0 PROFICIENCY TESTING / INTER-LABORATORY COMPARISONS**

The requirements for proficiency testing/inter-laboratory comparisons are found in each respective ACLASS document for each conformity assessment program, as required.

Where proficiency testing or inter-laboratory comparisons are required, it should be conducted in accordance with ISO/IEC Guide 43-1, Proficiency Testing by Inter-laboratory Comparisons - Part 1: Development and Operation of Proficiency Testing Schemes (or any future versions thereof).<sup>9</sup> For further guidance, see also ACLASS Guidance on Proficiency Testing/Inter-laboratory Comparisons available at [www.aiclasscorp.com](http://www.aiclasscorp.com).

## **12.0 TRACEABILITY AND MEASUREMENT UNCERTAINTY**

The requirements for traceability and measurement uncertainty are found in each respective ACLASS document for each conformity assessment program, as required.

### **12.1 Multi-Lateral Recognition Arrangements**

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, inspection bodies, reference material producers, PT providers, or any others as relevant.
- The recognition of a laboratory, inspection body, reference material producer, PT provider or any others as relevant, as equivalent to an ACLASS accredited customer
- Accept endorsed calibration/test/inspection reports of MRA/MLA signatories
- Promote the acceptance of international MRA/MLA
- Investigate complaints
- Contribute to the appropriate MRA/MLA Councils
- Provide other available resources as determined by ACLASS

### **12.2 Scopes of Accreditation**

A customer's scope of accreditation is a document specifically stating the capabilities for which accreditation is granted. Details of specific scopes of accreditation can be found in each respective ACLASS document for each respective conformity assessment program.

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<sup>9</sup> It is expected that ISO/IEC 17043 will be published and will replace ISO Guide 43

### **12.3 Change or Expansion of Scope of Accreditation**

Accredited customers at times may request of ACLASS changes to or expansions of their scope of accreditation at or between their normal assessment schedules. In these situations customers are required to obtain the appropriate form (available at [www.aiclasscorp.com](http://www.aiclasscorp.com)), complete and submit it to ACLASS to request this service. A scope expansion typically warrants an on-site visit to the customer to verify the practices, competence and records. The vast majority of time, this occurs in concert with a surveillance or reassessment visit. Under defined circumstances, with very minor scope changes, this visit may be pre-empted by satisfactory documentation and discussions with customer representatives.

When an abbreviated scope expansion visit takes place, this will not replace any assessment visits normally scheduled for any accredited customer.<sup>10</sup>

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
- Scheduling 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 (BMCs) 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 BMCs or slight adjustments in range that are not subject to this "expansion" category. If there is any change however that is due to a new method, any new reference standard or technology or apparatus, it may be witnessed per ACLASS procedures.

### **12.4 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. Traceability for chemical reference materials is adequately covered in Appendix A of ISO Guide 34:2000 (E). This covers gases and gas mixtures, metal alloys, pure compounds, trace elements, organics, molecular biologics, and others. ACLASS subscribes to the descriptions in this appendix. Primary sources of these chemicals include NIST and

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<sup>10</sup> A customer may request an earlier planned assessment, which may include additional assessment days to address a scope expansion

US Pharmacopeia. Microbes should normally be obtained from the American Type Culture Collection (ATCC) or other internationally recognized source.

### **13.0 CUSTOMERS WITH MULTIPLE LOCATIONS**

Each location where calibration(s), test(s), inspection(s), and/or RMP occur will normally be treated as a separate accreditation.<sup>11</sup> This would not include a location with different buildings in close proximity.

### **14.0 SURVEILLANCE AND REASSESSMENT**

The purpose of the surveillance is to ensure that the customer's organizational management system is maintained and remains effective. It is important that surveillance provide a value added function to the customer. Assessors may recognize improvement opportunities and communicate these to the customer.

Each surveillance and reassessment visit shall consist of:

- brief opening meeting
- verification that the ACLASS accreditation symbol is being used properly<sup>12</sup>
- review of any changes to the customer's operational system
- review of any changes to the accreditation scope
- verification of correction of non-conformances from the previous visit
- assessment of management reviews
- assessment of internal audit system and its effectiveness
- assessment of the complaints and corrective action system
- witness scope of accreditation
- review of any results, schedule and status from proficiency testing, as applicable
- assessments of other sections from relevant standards or assessment checklists that have not been assessed in the previous two years or the requirement clauses that have not been assessed for the longest time
- recommendation and subsequent determination concerning continuing accreditation
- closing meeting

Surveillances are important in that they not only determine if the customer continues to meet the requirements, but they allow the opportunity for the assessor to provide additional value to the customer. If the customer is in concurrence, the assessor may identify continuous improvement opportunities during surveillances by using the opportunity category on the non-conformance record. The assessor may not advise or suggest how the customer may

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<sup>11</sup> Customers with multi-sites, where the customer's satellite site(s) do not conduct key activities may meet the ACLASS Multi-Site Policy. The guidance and requirements for the ACLASS Multi-Site Policy are available within the ACLASS Guidance Document area on our web site and ACLASS Document 3, 4 and 5, as appropriate. The purpose of this multi-site policy is to develop a method to evaluate those corporate sites with satellite sites that do not conduct key activities.

<sup>12</sup> Customers having signed the ILAC sub-license agreement shall have its use verified

make improvements. The customer's action or inaction about any identified opportunity shall not affect their accreditation status.

Surveillances are conducted at least yearly after the date of initial accreditation. ACLASS typically notifies the customer in writing with schedule at least 30 days before the surveillance. The amount of time to conduct this assessment shall be according to the quotation, unless otherwise determined by ACLASS. The lead assessor or team with the Program Manager(s) and/or the Senior Accreditation Manager shall increase the time if needed due to changes in personnel, changes in equipment, any change in scope, receiving complaints, or other reasons.

The following records shall result from surveillance visits:

- an Attendance Sheet from the closing meeting
- Confidentiality and Conflict of Interest Statements for each ACLASS representative
- Appropriate accreditation checklist used during this visit
- any Non-conformance Action Records written during this visit,
- a Surveillance Report

During each visit each assessor shall document how the customer meets each requirement for each section of the checklist being assessed. This shall be accomplished using the appropriate section of the checklist. Assessor notes become part of the surveillance records and are to be kept on the appropriate checklist and supplemental note form.

A single assessor or assessment team may conduct surveillance visits. The assessor is assigned by the Program Manager(s) and/or the Senior Accreditation Manager, and is responsible for the preparation of the surveillance visit report and providing a copy to the customer. The assessor shall sign the surveillance report. The customer receives a copy of the report at the conclusion of the visit. The assessor sends the report to ACLASS for processing.

Any resulting non-conformances shall be responded to by the customer within 30 days. Responses shall be sent to ACLASS for distribution to the lead assessor. The Program Manager(s) and/or Assessment Coordinator shall monitor this time limit, and take any appropriate action. Such appropriate action may include suspension or withdrawal of accreditation.

The review of surveillance reports and decision to continue accreditation is according to this document section 10.1.

Additional surveillance visits and/or time may be required if significant non-conformances result from the surveillance and/or reassessment visit. Also, additional surveillance visits and/or time may occur to verify changes in and/or additions to the customer's management system.

The Program Manager(s) may provide guidance to the lead assessor as requested and as needed. The Program Manager(s) may also provide a sample and outline for a surveillance report to the assessor and/or assessment team.

As part of each surveillance visit the assigned assessor performs a “continual reassessment” site visit. That is, each and every surveillance visit includes reviewing changes to the management system and manual; scope of accreditation and the management system documentation for the elements assessed. During the reassessment cycle, management system documentation shall be continually assessed during assessment visits. Evidence of review is according to this document section 10.1.

Review of reassessments and all the periodic reassessment site visits is according to this document section 10.1. This review shall ensure that the following was accomplished:

- verify the overall continuing effectiveness of the customer’s operational system in its entirety
- ensure the effective inter-action between all the elements of the system
- ensure the overall effectiveness of the system in its entirety in the light of changes in operation
- review of any results, schedule and status from proficiency testing, as applicable
- ensure the organization’s demonstrated commitment to maintain the effectiveness of the system
- ensure the technical competency of the organization
- witness scope of accreditation

For reassessment and surveillance visits, the assessment team will include in their report the recommendation for continued accreditation or suspension of accreditation pending corrective actions.<sup>13</sup> In instances where a recommendation is made for suspension pending corrective actions, the customer has 30 days to respond with acceptable corrective actions or immediate suspension may occur. ACLASS will make decisions to suspend and/or withdraw accreditation, including immediate suspension and/or withdrawal, when an accredited organization has persistently failed to meet requirements of accreditation or failed to abide by the ACLASS rules for accreditation.<sup>14</sup>

Our accreditation cycle is typically a two year reassessment timeframe. ACLASS establishes surveillance and reassessment plans based on an organization’s proven stability and competence.<sup>15</sup>

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<sup>13</sup> In instances when customers receive a recommendation for “suspension of accreditation pending corrective actions,” customers will have 30 days to submit corrective action plans. Upon submission of corrective actions, ACLASS will review the plans according to our normal procedure and the customer may remain in good standing.

<sup>14</sup> Recommendation for suspension of accreditation pending corrective action occurs when one or more major non-conformities are issued and/or the assessment team has significant doubts about the competence of the organization.

<sup>15</sup> Proven stability and competence could include current and active accreditation of a customer accredited by an 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(s); performance in PT/ILC activity;

## **15.0 ACCREDITATION RECORDS**

The Senior Accreditation Manager, Program Manager(s) and/or ACLASS Headquarters are responsible for the review/content, distribution, and retention/maintenance of all accreditation records. Accreditation records consist of (but are not limited to) application forms, assessment reports, correction action files, and reports relating to granting, maintaining, extending, suspending or withdrawing accreditation. ACLASS shall make available to its customers all the reports and forms required by this procedure through a secure portal of the ACLASS website. ACLASS and the customer have sole and only access.

The initial customer accreditation record/package maintained by ACLASS will consist of the following accreditation documents (as a minimum):

- application
- document review report
- planning visit report (if applicable)
- accreditation report
- proficiency testing summary report, as applicable
- copy of certificate and scope of accreditation

After each subsequent surveillance or reassessment, the decision to determine whether continued (extending) accreditation is merited and approved is according to this document section 10.1. Subsequent surveillance or reassessment reports will become a permanent part of the customer accreditation record, as will any subsequent changes to the customer scope of accreditation.

ACLASS shall maintain all accreditation records in its offices and in electronic format, when available, under the supervision of the Vice President. Accreditation records will be accessible only to the ACLASS management, staff, or other personnel designated by the Senior Accreditation Manager(s) and/or the Vice President who needs access in the performance of their duties. This restricted access is to ensure the confidentiality of any information obtained relating to applications, assessment and accreditation of ACLASS customers. ACLASS will not release confidential information about a customer to any other entity without either customer consent or legal mandate.

## **16.0 WITHDRAW, WITHHOLD, SUSPEND, OR REDUCE ACCREDITATION**

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

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effectiveness of corrective action activity; effective internal audits and management reviews; effective training of personnel.

Upon the recommendation of the assessor and agreement of the Program Manager(s), and/or Senior Accreditation Manager(s), ACLASS may withdraw, withhold and/or suspend a certificate if one or more major non-conformances are discovered during a surveillance and/or reassessment visit in accordance with this document and each respective ACLASS document for each applicable conformity assessment program. In particular, if any major non-conformance causes the assessor to have any material doubt about the performance of the operations of the customer, ACLASS upon the recommendation of the assessor may withdraw, withhold, and/or suspend the customer's accreditation until final determination is made by the Program Manager(s) and/or the Senior Accreditation Manager(s).

If the ACLASS symbol is misused in any manner, ACLASS may withdraw, withhold, and/or suspend the customer's accreditation in accordance with the ACLASS requirements including the responsibilities and obligations of the customer found in each respective application for accreditation.<sup>16</sup>

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

ACLASS may withdraw, withhold, and/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 and/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 ACLASS requirements.

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

All customers that have their accreditation suspended, reduced, and/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.<sup>17</sup>

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<sup>16</sup> This also includes improper use of the ILAC mark, according the sublicense agreement

<sup>17</sup> This also includes the use of the ILAC mark, pursuant to the sublicense agreement