

an ISA organization

ASCI Chartered Testing Laboratory 2009 Approval Process

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ASCI Chartered Testing Laboratory Approval Process

Overview of ASCI Compliance Programs

The International Society of Automation (ISA) has established an Automation Standards Compliance Institute (ASCI) to develop compliance specifications for industrial automation controls (IAC) derived from internationally recognized IAC industry standards. This non-profit industry based consortium requires that specified equipment and materials (products) be tested and certified for compliance by an ASCI-recognized organization. ASCI's Chartered Testing Laboratory (ACTL) Program fulfills this responsibility by recognizing the capabilities of (mainly) private sector testing organizations to test and certify such products for manufacturers. The ACTL Program, in operation as of 2009, is an effective industry partnership between ASCI and nationally and internationally recognized testing entities. Rather than performing testing and certification itself, ASCI relies on private sector organizations, with existing private sector systems performing the work rather than maintaining ASCI facilities.

These organizations use generally accepted, consensus-based IAC product specifications derived from standards developed by governmental entities and national standards-producing organizations such as:

- _ American National Standards Institute (ANSI)
- _ International Society of Automation (ISA)
- _ International Electrotechnical Commission (IEC)
- _ Department of Homeland Security (DHS)
- _ North American Electric Reliability Corporation (NERC)
- _ American Petroleum Institute (API)
- _ Electric Power Research Institute (EPRI)
- _ American Chemistry Council (ACC)

Product Categories

ASCI requires testing for certain IAC products covered by approved compliance specifications developed in ASCI Institutes (Interest Groups). Broad categories of industrial automation control products are covered, including:

- _ Embedded Controllers
- _ Automation Control Systems
- _ Routers and Network Infrastructure Equipment
- _ Internet Protocol (IP) based hard-wired and wireless Control and Sensing devices
- _ Equipment used in Safety Instrumented Systems (SIS)

The Meaning of Product Certification

A product certified by an ASCI Chartered Testing Laboratory has met consensus-based ASCI Institute specifications for compliance. Users of that product are thereby assured that the certifying ACTL monitors the product and the process of its manufacture for compliance to the specification. The ACTL Program, in turn, assures that the organizations certifying the compliance of the products are qualified to do so.

Eligibility

To be recognized, an organization must meet ASCI's requirements. Initial recognition, valid for 5 years and for a specific scope of recognition, is granted if the application and an on-site review of the organization demonstrate the applicant is completely independent, has the capability (including equipment, personnel, and quality assurance), and meets other requirements to test and certify products for compliance based on ASCI Institute compliance specifications. An organization must have the necessary capability both as a testing laboratory and as a product certification body to receive ASCI recognition as an ACTL. In addition, for non-United States-based applications, ASCI must consider "reciprocity" of the foreign government. Once recognized, ASCI reviews each ACTL's activities to assure it continues to comply. Also, the ACTL can request an expansion of its recognition. The initial renewal of recognition is based upon a renewal application and may require an on-site review.

Program Specifications, Policies, and Procedures

Program requirements and criteria are explained in ASCI Chartered Testing Laboratory 2009 Approval Process Specification and additional ACTL Program Directives.

Program Fees

You must pay a portion of the fees at time of application. ASCI does not process and may return an application if it does not receive the applicable fees. ASCI bills you for the remainder of the application fees. Once recognized, you generally pay fees each year. The **Fees and payment schedule listed in a** table at the end of this document detail the amount that you must pay and when and where to pay the fees. For more information, you may contact ASCI at the address or phone number listed below or through the program's web page, also listed below. Fees for the ACTL Program went into effect on June 1, 2009.

Confidentiality

The name of an applicant seeking recognition remains confidential until ASCI publicly announces its preliminary finding on an application. In addition, all documents and other information in an application remain confidential to members of ASCI only.

Information

If you have questions about the ACTL Program or these guidelines, or would like to receive more information or guidance in completing an application, please call 919-990-9222

Send completed applications, amendments to applications, or other correspondence to:

Andre Ristaino Managing Director, ASCI 67 Alexander Drive Research Triangle Park, NC 27709

aristaino@isa.org

On the Web

Application and general information is available by selecting 'ACTL Programs' on the ASCI website at <u>http://www.ASCI.org</u>

Processing Steps for ASCI ACTL Applications

The specifications for the ACTL Program require that organizations applying for an initial recognition by ASCI as an ACTL, or for an expansion or a renewal of its recognition provide sufficient information and detail in its application to demonstrate that it meets the requirements and criteria for recognition, expansion, or renewal. This application guideline provides an appropriate basis for the review, determination, and evaluation of the qualifications of the organization applying for recognition under the Program. The applicant is not required, but is strongly encouraged, to submit all the information requested in the formats shown.

When an organization submits its application materials, ASCI staff thoroughly reviews those materials for completeness and adequacy. For applications from foreign-based organizations, ASCI must consider the "reciprocity" of the foreign government.

When the ACTL Program staff determines that the application is complete and adequate, ASCI staff perform an in-depth on-site review of the applicant's organization, programs, and facilities. If certain criteria are met, an on-site review may not be necessary.

Based upon the information obtained primarily through the on-site review, the staff prepares a report and recommendation. The report and the application provide the main basis for a preliminary finding on the application. ASCI publishes a notice of this finding on the internal ASCI SharePoint site for a 30-day comment period from ASCI members after which, ASCI must publish a final decision and response to comments on the internal ASCI SharePoint site. Publication makes the recognition official for successful applicants and officially denies the recognition for unsuccessful applicants. A formal notification from the ASCI Governing Board is sent to successful applicants. The terms of the recognition are set forth in this formal notification as well as in the final ASCI Notice. The chart below indicates the steps in this application process.



Instructions for Completing the ACTL Application

Provide information for every item contained in each part of the application, even if only to provide proper references or to note that it is not applicable. Information and documents you provide for your application must be in English unless otherwise accepted by ASCI. You may either submit hard copy of the application or complete the application electronically, using WordPerfect, Word, or other compatible word processing programs. If the application is completed electronically, insert the text of your information in the appropriate spaces following each item. Then submit a signed hard copy of the General Application Information, with the electronic file and copies of any attachments. If submitting your application in hard copy, provide your information on a separate attachment. Then, submit the application along with any hard copies of attachments. Send application and a cover letter to the address shown in the Overview section.

Contact the ACTL Program staff if you have any questions. **Note: ASCI will formally accept your application, and then schedule an on-site review, only when it has determined that the application is complete and the information provided is adequate.** At that time, ASCI may request, and you will need to provide, two more copies of the complete application.

General Application Information

Provide all information requested. Attachments should be numbered and labeled, referencing the numbering on the General Application Information sheet. The legal signatory must sign in the space provided.

Applicable Test Specification(s)

- 1. Complete one sheet for each ASCI Institute test specification for which recognition is sought. Other formats may be used if the same or equivalent information is provided. Do not submit a copy of the actual ASCI Institute test specification. If the ASCI Institute test specification is not readily available to ASCI, Program staff will ask you to provide a copy of the specification. You should apply for all test specifications for which you may qualify at the time of application.
- 2. The test specification must meet the criteria for an "appropriate test specification" in the ASCI Institute compliance test specification.
- 3. If the test specification has been issued by an organization other than ASCI, please submit documentation assuring compliance with ASCI Institute compliance test specifications.
- 4. The scope of the test specification must pertain to products covered under the ASCI ACTL Program.

Detailed Application Information/Evaluation Criteria

Provide information for every item under each of the categories. Each category represents a critical component, of the requirements for recognition that ASCI must review and evaluate.

Complete Application

In order for your application to be complete, it must include the General Application Information, Applicable Test Specifications and Detailed Application Information/Evaluation Criteria, or equivalent information, **and the following supplements**:

- 1. Organizational chart(s) (for overall organization and, if applicable, each major unit or location) that depicts owners, directors, and officers, and shows areas involved in the ACTL operations
- 2. Position descriptions/responsibilities and resumes of key personnel involved in the ACTL operations
- 3. Listing/labeling, qualification and follow-up inspection procedures; sample of agreement(s) for certification
- 4. Sample(s) of test data sheets & testing procedures, test/evaluation report procedures for ACTL operations, test and calibration equipment listing for each site
- 5. Calibration program manual (including samples of specific calibration procedures) or equivalent
- 6. Identification number or verification of registration of certification mark(s) with the US Patent and Trademark Office (USPTO), or evidence of application for registration with the USPTO
- 7. Quality manual (covering both test laboratory and certification organization operations); related detailed quality assurance procedures or appropriate samples
- 8. Detailed standard operating procedures (including work instructions) for testing and certification operations or appropriate samples
- 9. Certificate of Incorporation or proof of applicant's legal existence, pertinent by-laws or articles

Attach any other documents requested or that will assist the ASCI staff in better assessing your application. Any additional documents submitted should be for illustration or clarification, and not in lieu of the information requested. In addition, clearly label and reference each attachment to the application itself.

Expansion and renewal of recognition

After receiving its recognition, an ACTL may submit requests to expand its scope of recognition to include additional compliance test specifications or sites. Also, at the end of the initial five-year recognition period, an ACTL must request a renewal of its recognition. Please **complete and submit** the following documents to apply for an expansion or for a renewal. Send all information to the address shown in the Overview page.

Requesting an expansion of recognition

- 1. Complete any of the sections 1 through 10 of the General Application Information, if not previously submitted or to reflect major changes since the date of the most recent Application and sign section 12. Also, complete any applicable sections of the Detailed Application information/Evaluation Criteria specifically requested below. Include a cover letter, or only submit a letter to apply if these instructions require no other information.
- 2. For additional test specifications, complete an Applicable Test Specification sheet for each test specification unless the necessary information has been previously submitted.
- 3. For an additional site(s), complete the Basic Information portion of the Detailed Application Information/Evaluation Criteria to provide the necessary information or to identify information previously submitted that will apply. Do not address the "Independence" section of the Detailed Application Information/Evaluation Criteria unless information was not previously submitted or previously submitted information has changed. Also, submit an Applicable Test Specification sheet for each specification to be used for the site(s), and submit any applicable supplements listed in the "Complete Application" section above.
- 4. For a "supplemental" program(s), complete the applicable Optional Information of the Detailed Application Information/Evaluation Criteria to provide the necessary information.

Requesting a renewal of recognition

Submit a letter requesting the renewal of recognition. Complete any of the sections 1 through 10 of the General Application Information, if not previously submitted or to reflect major changes since the date of the most recent application and sign section 12. Also, complete any applicable portions of the Detailed Application Information/Evaluation Criteria to reflect major changes since the date of the most recent application.

Amendments

You may amend the application any time prior to publication of the preliminary notice. Submit an original version and 2 copies of amendments unless it is just a letter.

SUPPLEMENTAL INFORMATION:

Program Specifications, Policies, and Procedures

The application shall be prepared in compliance with all applicable requirements in the Program Specifications, Policies, and Procedures. The Program specifications are contained in this document, which specifies the requirements an ACTL must meet to be recognized, and specifies the general requirements and process that ASCI will use to evaluate and recognize an ACTL. The Program policies and procedures are also contained in this document, which further details how ASCI will evaluate and recognize an ACTL, monitor the ACTL's recognition, and administer aspects of the Program. Additional Criteria describes the "programs," whereby the ACTL may qualify other organizations to partially test and/or certify products and to provide support services.

Legal Signatory

The legal signatory signs the application and any amendments. The legal signatory(s) of the applicant is recognized by ASCI as the individual responsible for submitting the application, and who can legally bind the applicant to the conditions and requirements for recognition. The legal signatory is the applicant's official contact for ASCI. To change the legal signatory, the current legal signatory (or an individual that can legally bind the organization) sends a letter to ASCI regarding the change.

General Application Information

Please provide the following information about the applicant's organization.

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2. Street address

Mailing address (if different)

Telephone and fax numbers

E-mail address and website address, if available.

3. List of owners (with beneficial interests >2%) and percentage of ownership.

4. Name and affiliation of Directors

5. Explanation of complete independence (See policy on Independence in Appendix A)

6. Name and title of Officers and key staff (and affiliations, if significant)

7. All organizational components, including locations and functions, noting individual sites for which accreditation is sought

8. Primary field of testing

9. Summary of Proposed Scope of Recognition (sites, specifications, & programs)

10. Legal Signatory and alternate contact person(s) (include phone and fax numbers, and email address if different from item #2 above)

11. Brief history of company and principal line(s) of business

12. Statement on Terms of Recognition

As legal signatory for, the applicant, I attest that all statements and information contained in our application are correct to the best of my knowledge and are made in good faith. We agree to comply with all the policies, conditions, and requirements for recognition that ASCI imposes through its specifications, policies, guidelines and, notices of recognition.

We also agree to operate as an ACTL only within our approved scope of recognition (applicable test specifications, sites, & programs), following the policies, procedures, structures, and practices described in our original or amended application accepted by ASCI, or in appropriate revisions we make after recognition. We further agree to promptly submit details to ASCI of any major changes in those operations.

Legal signatory (Type or print Name, then sign and date within the space provided)

Applicable Test Specification

Complete one for each specification for which recognition is requested. Note: this is a sample format. Other formats may be used if the same or equivalent information is submitted.

Specification Designation (e.g., ISASecure Core,), and Title

Year of Issue or Revision and Approved by ASCI.

Laboratory Site(s) and Address(s) where specification will be used

1. Test Equipment

Specification Section *	Test or Measurement	Test Equipment Needed	Equipment In Place

* Section number of test specification.

2. Test Procedures

Specification Section *	Laboratory Test Procedures **	Procedures in Place?

* Section number of test specification

** Name/Number of in-house test procedure to satisfy specification section number.

3. Special Apparatus or Facilities

Specification Section *	Description of apparatus or Facilities	Apparatus in Place?

- a. Number of products evaluated under this specification at this site:
- b. Number of products currently listed under this specification:

Approved By (Signature, Title, and Date)

(Use additional sheets when submitting in hard copy, if necessary)

Detailed Application Information / Evaluation Criteria

Outlined below are the evaluation categories pertaining to each of the four recognition requirements in ASCI ACTL 2009 Approval Process Specification. Under each category are detailed criteria that ASCI will use in evaluating whether the applicant meets or an ACTL continues to meet the recognition requirements. **Provide the necessary detailed information for each applicable category to explain how the criteria will be met. Include the policies, procedures, methods, personnel, or practices that are pertinent to meeting the criteria.**

If not applicable or information is not available, please so state. If the criteria for one or more categories are applicable but not fully met, submit sufficient information and detail to clearly demonstrate how you meet the corresponding requirement(s). The information you provide should be adequate and primarily related to your planned (if not yet recognized) or actual (if recognized) operations as an ACTL. General references and cross referencing may be used, where appropriate.

If using a word processing program, insert the text of your information following each criterion or the list of evaluation criteria for the category. Do not use the space provided for our auditor's review and findings. If submitting your application in hard copy, provide your information on a separate attachment. Provide the OPTIONAL INFORMATION if relevant to the application.

Outline level examples:

I. Capability (recognition requirement)

A. Testing Facilities (evaluation category)

3. Adequate measures are taken to ensure good housekeeping. (evaluation criteria)

I. Capability

A. Testing Facilities

- 1. Accommodations, calibration and test areas required by the test specifications are available and adequate for tests.
- 2. Access to, and control of, areas with incompatible activities are defined and controlled.
- 3. Adequate measures are taken to ensure good housekeeping.
- 4. Energy sources, lighting, heating and ventilation required by the test specifications are available for calibrations and tests.

- 5. Facilities required by the test specifications are available to monitor, control and record environmental conditions during tests.
- 6. Laboratory procedures for handling of test samples address control and monitoring of environmental conditions, protection from adverse conditions, item inventory, secure storage, and proper tagging or marking.
- 7. Laboratory measures and procedures related to security include provisions for: controlling access, off hours security, and fire protection for the facility; protection of proprietary rights and confidential information of its clients; informing all personnel of confidentiality and security policies; limiting distribution of confidential information; limiting access to and safe storage of records (including certificates and reports); back-up or off-site storage; and designate personnel responsible for monitoring security.

B. Testing equipment

- 1. Testing equipment is available in the lab to perform tests required by the specifications to be used for the ACTL Program.
- 2. Records maintained for each item of equipment and all reference materials contain the following, at a minimum: name of the item, manufacturer's name, type and serial number, date received/placed into service, current location, condition when received, manufacturers' instructions, dates and results of calibration and dates of next calibration, details of maintenance carried out and planned, and history of damage, malfunction, modification and repair.
- 3. Equipment that has been subjected to overloading or mishandling, or which gives suspect results, is taken out of service and not used until it has been repaired and calibrated.
- 4. Written procedures are available for the laboratory to examine effects of defective equipment on calibrations and tests, and take appropriate action.
- 5. Equipment is properly maintained.

ASCI auditor's review & findings:

C. Testing, Evaluation, and Processing Procedures

- 1. Each test method or procedure has sufficient detail instructions that assure reasonable repeatability of tests and include or address the: title, effective date, specific test equipment to use, minimum accuracy requirements, warnings/caution statements to alert the operators of potential hazards, normal and any unusual ambient conditions (including tolerances) for tests, test data to be obtained and recorded, the minimum resolution of measurements, objective acceptance criteria for results, testing techniques (unless obvious), and test operator instructions on equipment operation and on handling and preparation of test samples (if applicable, including multiple sample marking).
- 2. Test data sheets or similar documents include the test procedure and specification used, product or component tested, test equipment used in the test, date of the test, test report number, signature of the personnel performing the test, the ambient test conditions, and test results.

- 3. Procedures for developing and maintaining test methods and procedures identify the personnel responsible for developing, reviewing and maintaining the procedures, specify frequency of review by management, ensure consistency with recognized specifications, ensure that deviations still assure the product conforms with the specification, and ensure modifications are reviewed by personnel who are familiar with the specification.
- 4. Procedures for evaluating test data require the investigator to: verify and use the latest specification edition, provide written justification of how a product complies with each section of the specification (including a reference to a test procedure for sections that require tests be conducted), and address components that are not listed, have a non-standard design, or are tested by a foreign test laboratory.
- 5. Policies on evaluation of test data identify personnel responsible for technical decisions on the specification, how to decide which applicable section of a specification applies, how to handle newly developed technologies when the specification does not apply; require that interpretations of the specifications are documented and made readily available for the appropriate investigators; and require the resolution of product discrepancies without the lab engaging in the redesign of the product, except to explain the failures in regard to the product testing specification.
- **6.** Standard operating procedures, related to product testing, evaluation, certification and other processes, are or will be used in operating as an ACTL.
- 7. Procedures for processing a certification application identify the steps for the application, administrative/technical processing of the investigation in chronological order, personnel responsible for each stage of the process, and records maintained at various steps of the process.
- 8. Procedures for processing require the ACTL to select a product specification for certification, and identify the steps and criteria for selection, personnel responsible for decision (who are experienced in the product area), manner of resolving disagreements concerning the applicability of a specification, and manner of handling products covered by two or more specifications.
- 9. Procedures for developing and maintaining processing procedures identify personnel responsible for developing, reviewing and maintaining the procedures, the frequency for review, and personnel responsible for verifying that the procedures are being followed.

D. Calibration Program

- 1. Persons responsible for the calibration program and authorized to perform each type of calibration are identified.
- 2. Calibration intervals are established for each type or item of equipment, and policies and procedures are in place for extending the calibration of an instrument.
- 3. Records for each calibration contain sufficient information to permit their repetition.
- 4. Each item of equipment, including reference materials, is labeled, marked or otherwise identified to indicate its calibration status.
- 5. Written procedures are available that address calibrations and reference standards or materials, and that ensure their traceability to the appropriate standards maintained by the U.S. National Institute of Standards and Technology (NIST), or if in a foreign country, to equivalent standards or materials maintained by a nationally or internationally recognized body.
- 6. Primary standards are appropriately identified and maintained.
- 7. New, leased, rented, and repaired equipment are calibrated prior to use.
- 8. Procedures are in place to check calibration and to re-evaluate test results if the calibration interval is exceeded during tests.

E. Quality Assurance (QA)

- 1. Quality Manual and quality procedures or documents
 - Are readily available to the personnel
 - Contain a corporate quality policy statement, and provisions for ensuring quality policy are understood, implemented and maintained
 - Cover the entire "quality loop" from application for services to final testing or listing of products including follow-up services
 - Address how to identify and remedy potential or actual quality problems
 - Identify how to supplement or revise the Quality Manual
 - Identify the relationship of quality manuals, laboratory procedures, and other relevant documents.
 - Identify the personnel responsible for quality, other general and the specific responsibilities for quality, and the authority delegated to each activity
 - Specify the coordination necessary between different activities
 - Identify the control over activities that affect quality

2. Internal quality audit policies and procedures specify

- a. The frequency of routine audits, the qualifications and independence of the audit personnel, and the bases for conducting audits
- b. The reporting and management review of audit findings, reasons for deficiencies, conclusions, recommendations on corrective actions, and the effectiveness of corrective actions
- c. How permanent changes resulting from corrective actions are recorded in standard operating procedures, instructions, manuals and specifications
- 3. Audit reports include the name(s) of the auditor(s), the areas audited, the dates of the audit and the signature of the auditor(s), the discrepancies encountered, corrective action plan (including time for completion and evidence of implementation), and review by upper management.
- 4. QA oversight of company owned satellite facilities include routine and documented internal audits of satellite facility personnel, regular headquarter's review and audit of the quality assurance program and audits conducted by satellite personnel, and consistency of technical records and interpretations among all facilities

F. Records (including Specifications Library)

- 1. Policies and procedures for test specifications distribution & control identify the: personnel responsible for maintaining and distributing revised specifications, methods to control the distribution of specifications, method to notify all relevant locations, including clients and agents, about modifications or amendments, and effective date that laboratory clients must comply with the requirements of a modified specification.
- 2. Current issues of the appropriate specifications are available at all relevant locations and superseded specifications are removed from use throughout the organization, and archived.
- 3. Records maintained for testing and certification identify the personnel responsible for maintaining records; specify a retention period for each record, persons authorized to access records, and how to correct or modify information on a record; and contain information showing the way each certification procedure was applied, including test/inspection reports.

G. Personnel

- 1. Sufficient personnel are available with the education, training, technical knowledge and experience for their assigned functions.
- 2. Each position description is maintained up-to-date, and specifies the responsibility and limitations, education, experience, technical knowledge and training needed for the position.
- 3. Records are maintained on the relevant qualifications, training, skills, and experience of the technical personnel.
- 4. Staff are qualified or trained to carry out specific tests, evaluations or calibrations.
- 5. Staff training is kept up-to-date and staff keep up-to-date of current test specification issues (includes participation in technical groups or committees).
- 6. The employee safety program identifies, evaluates, and prevents or controls laboratory hazards.

II. Control Programs

A. Listing and Labeling

- 1. The certification mark used for the ACTL Program is registered with the U.S. Patent and Trademark Office, or an application for registration has been submitted to the USPTO.
- 2. The mark is applied to each unit of the product certified, or, if not feasible, to the smallest package, and test specification(s) to which the unit is certified is shown in the marking.
- 3. Procedures and resources are in place to properly control the certification mark, to monitor advertisements, catalogues and brochures for incorrect references or misleading use of its certification, and to take appropriate corrective actions.
- 4. Proper controls are in place to assure accuracy of information in the listing book.

ASCI auditor's review & findings:

B. Follow-up and field inspections

- 1. Procedures and resources are in place to survey the manufacturer's products, process and quality management system, and these procedures identify the frequency of inspections, and the process involved.
- 2. Initial assessment of the manufacturing facility checks for controls on the production, on conformance with specifications, to uniquely identify batches or runs of product, to isolate products in case of nonconformance, to notify the laboratory if changes in the product, process or quality management system may affect the product.
- 3. Initial assessment of the manufacturer's quality control system checks for the separation of the head of quality assurance from production, quality audit checks, use of appropriate QC sampling procedures, independent tests on products using the relevant specifications, and inspections and tests conducted by personnel independent from production.
- 4. Initial assessment of the manufacturer's records and documents system checks for periodic updating of master specifications, production records maintained for an appropriate period of time, control of specification modifications, and tracking and documentation of product defects, claims and complaints.
- 5. Initial and follow-up assessment of the manufacturer's evaluations and tests, required by a test specification, checks for consistency of procedures with the standard, test equipment properly maintained and routinely checked by qualified personnel.
- 6. The initial assessment of the manufacturer is conducted by qualified personnel.
- 7. Follow-up inspections procedures identify who conducts the periodic follow-up inspections and the reports and records that must be generated and retained
- 8. Agents that are used for follow-up inspections have the facilities and qualified staff for adequate surveillance and routinely report the results of the manufacturer's surveillance.

- 9. Appropriate contracts, covenants, or agreements are used in providing testing and certification services to clients and include:
 - a. Provision(s) for submitting products for inspection and testing
 - b. Provision(s) for permitting periodic inspections by the applicant
 - c. Provision(s) for permitting samples of product to be selected from production for independent testing
 - d. Covenants from the client to observe and comply with the applicable specifications
 - e. Controls to prevent the client from releasing the products resulting from changes (in the product, process or quality management system) until the laboratory has notified the client
 - f. Provision(s) for unobstructed access to the manufacturing premises without prior notification
 - g. Provision that the product will be produced to the same specifications as the sample submitted for initial testing
 - h. Controls to ensure that all quality management system and production records will be open and readily available for inspection by the laboratory.
- 10. Procedures or agreements are in place to address each of the following situations: instituting a recall, removing the mark of conformity from products, rebuilding a product so it will comply with the specification, scrapping or replacing a return part if it is not practical to remove the mark or rebuild the product.

III. Independence

- A. There are no organizational affiliations with a supplier or major user of products that an ACTL must certify, and such products are not supplied (i.e., manufactured or distributed) or used substantially.
- B. Significant financing is not provided to a supplier or major user of products that an ACTL must certify; no significant product design, similar services or products are sold to such a supplier or major user; and there are no significant investments in either.
- C. No supplier or major user of products that an ACTL must certify owns more than two percent (2%) of the ACTL, and no owner is also a major owner of such a supplier or major user.
- D. Significant financing is not received from a supplier or major user of products that an ACTL must certify, or their major owners.
- E. No person holding a substantial position with the ACTL has a significant financial interest in a supplier or major user of products that an ACTL must certify, or is a director or key personnel of either.
- F. Conflict of interests policies are in place and are followed and conflict of interest's statements are signed by all personnel.

IV. Report and Complaint Procedures (see also follow-up programs section)

A. Reports

- 1. Test reports include
 - a. Name and address of laboratory, and location where the test was carried out if different
 - b. Unique identification (serial number), page numbers and total number of pages
 - c. Name and address of client
 - d. Description and unambiguous identification of the item tested (complete component list, supplier, manufacturer, model number, etc.)
 - e. Characterization and condition of the calibration or test item
 - f. Date of receipt of calibration or test item and date(s)of performance of calibration or test
 - g. Calibration or test method, or an unambiguous description of any nonstandard method used
 - h. Statement of the estimated uncertainty of the test results, where relevant
 - i. Signature and title (or equivalent) of the person responsible for the content of the report and the date of issue
 - j. Statement that the certificate or report shall not be reproduced without prior written consent of the laboratory
- 2. Procedures for preparing technical reports are written and
 - a. Identify personnel responsible for preparation, review of technical content, and initial or revision approval
 - b. Have a clear and organized report format and allow data to be extracted easily
 - c. Ensure reports contain sufficient information to permit their repetition
 - d. Require the appropriate test and evaluation procedures
 - e. Ensure that technical corrections involve qualified personnel
- 3. Procedures for report distribution limit copies of the test report only to those who needs the information.

B. Complaints

- 1. A record is maintained of all complaints, appeals, and disputes received from clients, product users, or other parties.
- 2. Complaints, appeals, and disputes are resolved following documented policies and procedures that require documenting findings, remedial action, and effectiveness of solutions; and that provide complainants with a fair and reasonable opportunity for input.
- 3. Appropriate action is taken to correct root causes of situations leading to the complaints.

OPTIONAL INFORMATION

Provide information for the following two sections only if applicable to the application. Note: roman numerals I and II of the following outline do not represent recognition requirements.

I. Supplemental Programs

For this section, address the criteria shown under "Use of Supplemental Programs" or under each program, explaining how each criteria will be met. (Note: Program 1 is the basic program under which all product testing and evaluation is performed **in-house** by the ACTL that will certify the product. The evaluation to grant this program is encompassed in the overall evaluation for the initial recognition of an ACTL).

A. Use of Supplemental Programs

To use a supplemental program, the applicant or ACTL

- 1. Is recognized to perform the ASCI tests and evaluations before it can accept such services from other organizations, except for unique or special testing needs.
- 2. Uses assessors having qualifications consistent with the competence requirements of the ASCI Auditors or appropriate national standards and international guides to qualify organizations on ASCI's behalf.
- 3. Ensures that all aspects of certification work performed by others on their behalf-including participants, locations of testing, witnessing, and evaluations--are identified in the ACTL and client records and report in compliance with ASCI ACTL recordkeeping requirements.

ASCI auditor's review & findings:

B. Programs 2 and 3 Evaluations Using Independent Organizations

- 1. ASCI can authorize the Applicant ACTL to use the services of independent test organizations to generate test data on their behalf. For acceptance of test data (Program 2) where the Applicant ACTL is using the services of another testing lab the ACTL must:
 - a. Ensure that the independent lab is capable of doing the tests and that its relationship with the lab will not compromise the ACTL's independence
 - b. Retain control and responsibility for all aspects of the product certification scheme

- c. Review each test package and completes the product evaluation for the test specification
- d. Ensure that all test data originates with the test lab
- e. Assess the test lab using a written qualification program, which includes assuring the lab is accredited to ISO Guide 25 or its equivalent
- f. Has qualification procedures for evaluating the organization's independence, facilities, utilities, environmental controls, personnel, testing and calibration equipment, written testing procedures, calibration procedures, quality assurance program, and other elements as outlined in ISO Guide 25 or its equivalent
- g. Use a surveillance program, meeting the appropriate national standards and international guides, to ensure continued qualification of organization.

2. For acceptance of product evaluations (Program 3), the applicant or ACTL:

- a. Meets the criteria for Program 2
- b. Reviews each evaluation package and completes the required product evaluations before the product certification is issued
- c. Ensures that the evaluations are from an outside organization which it has qualified
- d. Ensures that all data have been developed under the program established by the ACTL
- e. Requires the organization to maintain documentation of technical correspondence and test interpretations
- f. Requires the organization to follow the written procedures established by the ACTL, in preparing the evaluation package
- g. Ensures that independence is maintained
- h. Uses the ACTL's qualification program to qualify the organization relative to each product type it may be asked to evaluate, and to assure the relationship between the ACTL and the organization does not compromise the ACTL's independence
- i. Has a minimum period of 12 months and level of mutual effort for confidence-building as part of its qualification program.

C. Program 4 Witnessed Testing

For acceptance of witness testing (Program 4), the applicant or ACTL

- 1. Retains control and responsibility for all aspects of the product certification plan
- 2. Trains its staff to participate in the various phases of testing, including specific testing procedures for appropriate product types they may witness
- 3. Ensures that the organization is capable of conducting the tests
- 4. Ensures that the relationship between the ACTL and the organization does not compromise the ACTL's independence
- 5. Assesses the organization using a written qualification program, which includes assuring the lab is accredited to appropriate section of ISO Guide 25 or its equivalent
- 6. Has qualification procedures for evaluating the organization's facilities, utilities, environmental controls, personnel, testing and calibration equipment, written testing procedures, calibration procedures, quality assurance program, and other elements as outlined in ISO Guide 25 or its equivalent
- 7. Uses only its personnel to qualify organizations and for witness testing.

ASCI auditor's review & findings:

D. Programs 5 & 6 Evaluations from Non-Independent Organizations

1. In certain instances, the ACTL will find it necessary to use testing and resulting data compiled by a non-independent organization (for example a supplier's internal test labs). **For acceptance of test data** (Program 5), the applicant or ACTL

- a. Meets the criteria for Program 2, except for the need to document the labs independence
- b. Establishes procedures and maintains records which will demonstrate that test data are unbiased
- c. Ensures that the organization providing the data is capable of conducting the tests
- d. Ensures that the relationship between the ACTL and the organization does not compromise the ACTL's independence
- e. Establishes in its qualification procedures a minimum 12 period for building confidence in the organization

- f. Verify testing capability through witnessing tests at the organization and by replicating tests at the ACTL's facility during the confidence-building period
- g. Performs as part of its surveillance program annual site evaluations, review of test packages, and random sampling and retests.
- 2. For acceptance of evaluation data (Program 6), the applicant or ACTL
 - a. Meets the criteria for Programs 2, 3, and 5, excluding the need for independence
 - b. Ensures that no product is released to the market until the ACTL has verified the organization's testing data and concurred with the evaluation
 - c. Maintains records of any procedural or product deficiencies identified and the corresponding corrective actions
 - d. Maintains records that demonstrate that the organization continues to be proficient in testing and evaluation
 - e. Ensures that the relationship between the ACTL and the organization does not compromise the ACTL's independence.

ASCI auditor's review & findings:

E. Program 7 Acceptance of Continued Certification

In the normal course of business, manufacturer's products may change and improve over time. In instances where a manufacturer has made minor modifications to products that do not disqualify continued certification of the product, the following conditions apply.

For acceptance of continued certification (Program 7), the applicant or ACTL

- 1. Meets the criteria for Programs 2, 3, 5 and 6
- 2. Defines what specifically is meant by minor modifications
- 3. Reviews each test and evaluation report for each product modification
- 4. Ensures that each manufacturer providing test data and evaluation is capable of conducting the tests and evaluations
- 5. Ensures that the relationship between the ACTL and the manufacturer does not compromise the ACTL's independence
- 6. Maintains records that demonstrate that the organization continues to be proficient in testing and evaluation.

F. Program 8 Acceptance of IEC-CB Product Evaluations

This program addresses requirements for program participants who function as part of the International Electrotechnical Commission Certification Body (IEC-CB) Scheme.

For acceptance of product evaluations under the IEC-CB Scheme (Program 8), the applicant or ACTL

- 1. Retains control and responsibility for the product certification scheme
- 2. Physically evaluates each product
- 3. Reviews each test and evaluation report and certificate to determine that the correct nationally recognized specifications have been used and that any U.S. deviations have been applied
- 4. Uses written procedures for evaluation and interpretation of results
- 5. Establishes records that demonstrate the organizations' continued competence and understanding of the U.S. deviations and their applications
- 6. Determines that components used are tested to a specification comparable to the appropriate nationally recognized specification
- 7. Determines that components used have been certified by an appropriate regulatory authority, including routine evaluation of the manufacturer's process.

ASCI auditor's review & findings:

G. Program 9 Contract Services (Other Than Testing or Evaluation)

For acceptance of contract services (Program 9), the applicant or ACTL

- 1. Retains control and responsibility for all aspects of the product certification scheme
- 2. Ensures that those performing such services have been assessed and qualified by the ACTL
- 3. Ensures that subcontractors or agents use the ACTL's follow-up procedures
- 4. Maintains records of the results of the follow-up visits
- 5. Ensures that subcontractors or agents are capable of performing the service and that the ACTL's relationship with the subcontractor or agent does not compromise the ACTL's independence
- 6. Demonstrates that subcontractors or agents are capable of providing services equivalent to those provided by the ACTL

- 7. Has written procedures to qualify subcontractors or agents, to monitor their performance, to obtain proper reports and documentation of their activities, and to maintain manufacturers' confidentiality
- 8. Assures subcontractors or agents maintain quality assurance or self-auditing programs and appropriate documentation of these activities
- 9. Uses its staff to train subcontractor or agent staff
- 10. Ensures that only qualified follow-up inspectors conduct inspections
- 11. Provides a surveillance program for routine audits of facilities, staff and procedures
- 12. Ensures that follow-up in foreign countries is as stringent as that required in the U.S.
- 13. Ensures that the follow-up program includes assessment of manufacturer procedures, quality control system, maintenance procedures, record keeping and other elements from appropriate national specifications and international guides
- 14. Ensures that the follow-up program has the capability to identify variations in the manufacturer's ability to control quality of production
- 15. Inspects samples of products for compliance

ASCI auditor's review & findings:

II. ANSI, A2LA, and NVLAP or other third party assessment data

The applicant or ACTL may submit assessment reports or data from third party auditors such as ANSI, A2LA, or NVLAP. If any such reports are submitted, they must include documentation showing the tracking and completion of corrective actions. In addition, to be accepted by ASCI:

- A. The on-site review or data must be dated within two years of the date of the filing of the application for ACTL recognition, and must be updated if there have been any significant changes in procedures, key personnel, facilities or programs, since the date of the data or the report.
- B. The entire report or data is submitted to ASCI with a signed letter that releases the report for use by ASCI, and identifies any sections of the report that are not to be used.
- **C.** The report is signed, dated, identifies the personnel that performed the review, and the dates of the review.

Fee Schedule

Contact ASCI Managing Director at 919-990-9222.