No: A-041
Title: ASSE Laboratory Listing Recognition Program Procedure
Approved By: TB Revision Date: 01/04/2024

1.0 Laboratory Applications

A. Testing laboratories or agencies seeking ASSE listing shall request in writing a laboratory application form.
B. The laboratory shall submit to ASSE a copy of the Laboratory Listing Agreement, list of standards requested to be in their scopes of accreditation, resume(s) of laboratory personnel, equipment information, quality documents and manual, two laboratory evaluation report forms prepared by the laboratory, the Laboratory Capabilities List and application fee.
C. Laboratories not indicating a qualified toxicologist on staff shall be required to include toxicology compliance from agencies that have a qualified toxicologist on staff for testing to the applicable toxicology standards.
D. All new laboratory applications will be evaluated by the Technical Project Manager. The Technical Project Manager shall review the documentation for its completeness.
E. The Manager of Product Certification and Standards shall review the documentation to either approve or disapprove the laboratory as an ASSE listed testing laboratory for their scopes of accreditation to specific industry standards.
F. If approved, the laboratory applicant shall be notified by a confirmation letter and a listing certificate. If disapproved, the laboratory applicant shall be notified in writing with rationale of the disapproval.
G. Testing laboratories or agencies may not employ ASSE staff members. Previous relationships must be disclosed as a conflict of interest.

2.0 Listed Testing Laboratory Requirements

A. The laboratory applicant and/or listed testing laboratories shall adhere to the ASSE Laboratory Listing Agreement.
B. Annually, the status of the listed laboratories will be reviewed per section 4.0.
C. A copy of any ISO/IEC 17025 certificate shall be kept on file and verified annually.
D. Scope modifications or expansions shall be reviewed and approved by the Manager of Product Certification and Standards. The Manager of Product Certification and Standards will determine if the scope modification or expansion shall be granted prior to the next scheduled inspection. For example, if the laboratory already has an International Laboratory Accreditation Corporation (ILAC) signatory to ISO/IEC 17025 for the scope modification or expansion, granting approval prior to the next scheduled inspection is acceptable.

3.0 Listed Testing Laboratory Audits

A. ASSE or an ASSE-appointed representative shall conduct an initial laboratory audit. During the time of the audit, the auditor will review the laboratory's capabilities, quality control system and personnel and ensure that the laboratory meets applicable requirements of ISO/IEC 17025.

B. The laboratory shall be responsible for the audit fees.

C. The scope of the audit shall cover the ASSE and other industry standards that the lab desires to be capable of performing.

D. Laboratories shall be audited annually after the initial audit.

E. As an alternative to section 3 A-D, the laboratory may show compliance by having an audit completed by an International Laboratory Accreditation Corporation (ILAC) signatory to ISO/IEC 17025. The report shall be sent from the ILAC accreditor directly to the Product Listing Team or downloaded from the ILAC accreditor website. The scope of the laboratory accreditation must include all standards the lab desires to be capable of performing. A copy of the ISO/IEC 17025 certificate shall be kept on file and verified annually. If the certificate expires within the next 18 months, an automatic notification (4 weeks prior to the expiration) shall be set up to prompt the PLP team to; 1) ensure the laboratory has taken necessary steps to renew its certification prior to expiration or, 2) notify the Laboratory that it will be removed from the recognized laboratory list on the date of expiration.

F. After the audit, the Product Listing Team will review the selected Evaluator(s)'s evaluation of the listed testing laboratory's capabilities, quality control system, personnel and validates that the listed testing laboratory meets the applicable requirements of ISO/IEC 17065 and ISO/IEC 17025, current editions.

4.0 Laboratory renewal

A. At the beginning of each year, the status of the listed laboratory files will be reviewed by the Product Listing Team. This review includes:

1. For laboratories which are accredited (by an ILAC-MRA signatory Accreditation Body) for the scope for which ASSE has recognized, verification of continued accreditation, to the current edition ISO 17025,
    a. If the Laboratory's certificate of accreditation is to expire within the next 18 months, ensure the laboratory has taken necessary steps to renew its certification prior to expiration by:
        i. Including a statement in the renew invoice letter, "Our records indicate that your accreditation to ISO 17025 is due to expire in the next 18 months. Please advise of the status of you accreditation and any scheduled accreditation assessments to maintain that accreditation."
        ii. Notify the Laboratory that it will be removed from the listed laboratory list on the date of expiration.
        iii. Set an electronic task reminder (i.e. outlook task) to prompt the PLP team to check on the status 4 weeks prior the expiration date.
        iv. If the laboratory's accreditation to ISO 17025 lapses, a full laboratory audit to ISO 17025 will be required prior to accepting any test date from that laboratory. Until such time the laboratory is suspended.

2. Verify the laboratory has successfully completed an ASSE Laboratory audit, except as provided in section 3.0 E, in the past 12 months.
3. Review any outstanding findings/non-conformances.
4. Review any actions required of the laboratory for the adoption of a new revision for the standards within the laboratory's ASSE scope.
5. Generate renewal invoice letter, document *RIL- renewal invoice letter (template)*. Include in this report any outstanding items identified above.
6. The Renewal invoice letter shall accompany the invoice for the ASSE Listed Laboratory renewal.

B. Upon receipt of payment, a renewal certificate will be sent to the listed testing laboratory which includes an addendum showing the scope of testing for which the ASSE certificate is valid.
C. The PLT shall identify which standards within each laboratory's scope are to be included in the next annual Laboratory standards.
D. The PLT shall provide the auditors with the list of standards to be included in the audit.

5.0 Testing and Reporting

A. For obtaining product listings through ASSE, testing shall be performed by an ASSE recognized testing laboratory or a laboratory that is accredited by an ILAC signatory with the applicable standard in its accredited scope that has been approved by the Executive Director.
B. The listed testing laboratory shall complete the ASSE laboratory report for testing to ASSE International standards for those applicants seeking ASSE product(s) listing. Passing laboratory reports in the laboratory's format shall be submitted for all other standards and transfer applications included in ASSE's certification scope.
C. All laboratory reports and Factory Audit Inspection Test Report forms completed by an independent listed testing laboratory shall be signed.
D. All laboratory reports and Factory Audit Inspection Test Report forms completed by a manufacturer's in-house listed testing laboratory shall include a signature of an authorized representative of the company supervising the evaluation.
E. Original, or scanned, digital copies of the laboratory report shall be submitted to the Product Listing Team as required in Section 3.1.A.1 of A-001 *ASSE Certification Scheme Procedures*.

6.0 Laboratory Performance

A. Should the Evaluator(s), Product Listing Team, or a Seal Control Board member notice a significant technical error on a laboratory report, a warning letter regarding the error will be sent to the listed testing laboratory.

B. If a second error is found in another report, a second warning letter shall be sent to the listed testing laboratory.

C. Should a third error be found, the Manager of Product Certification and Standards with reasoning from the Product Listing Team shall remove the laboratory as an ASSE listed testing laboratory.

The listed testing laboratory shall be removed as an ASSE recognized testing laboratory, letter of notification will be sent to the laboratory. A notice shall be posted in the ASSE e*Newsletter* and on the ASSE website. All listees will receive a notification of the current list of listed laboratories.

7.0 Re-listing Procedures for Removed Laboratories

A. A laboratory shall wait six months from the date of notification of removal before filing a new application to become re-listed as an ASSE listed testing laboratory.

B. The laboratory shall be responsible for a new application fee, a re-inspection fee, and all expenses for performing the audit.

C. In addition to following Section 1.0, the laboratory shall provide evidence of corrective action and/or preventative action which was implemented in order to address the issues which led to the removal of their listing.

D. After approval by the Product Listing team, the laboratory will be notified of the status of their application.

E. Should a significant technical error occur within one year, the laboratory will be removed as an ASSE listed laboratory.

F. Should a laboratory request to be removed as an ASSE listed testing laboratory, the lab shall be removed as an ASSE listed laboratory.

8.0 Complaints Regarding ASSE Listed Testing Laboratories

A. All complaints about an ASSE listed testing laboratory shall be submitted in writing to the Product Listing Team with supporting evidence for the complaint.

B. The complaint shall be processed in accordance with Complaints Procedure R-017.

C. Should ASSE receive or issue a written complaint regarding performance of a listed testing laboratory, the listed testing laboratory will be notified in writing that a complaint has been received regarding the listed testing laboratory's performance and the nature of the complaint.

D. The letter should request the listed testing laboratory to provide evidence of internal audits, management reviews and evidence of how the requirements of ISO/IEC 17025 and the ASSE Seal Control Procedures are being implemented.

E. The listed testing laboratory will be requested to provide evidence of conformance to their Quality Control Manual and evidence of corrective and/or preventative action(s) performed to address the complaint.

F. The listed testing laboratory will have 60 days from the date of notification to submit the required information. If the requested information is not submitted within the 60 days, the listed testing laboratory shall be removed as an ASSE listed testing laboratory.

G. The complainant's information shall be kept confidential.

9.0 Corrective Action for Listed Testing Laboratories

A. If a non-conformity is found during an inspection of a listed testing laboratory or of the listed testing laboratory's system, the listed testing laboratory will be notified in writing by the Product Listing Team. Corrective actions shall be documented in accordance with R-037 *Corrective and Preventative Actions Procedure*.

B. The listed testing laboratory shall be responsible for submitting corrective action.

C. All corrective actions shall be submitted within 60 days from notification.

D. All corrective actions shall be evaluated by the Product Listing Team.

E. The Product Listing Team shall determine if the corrective action satisfies the non-conformity.

F. If the Product Listing Team determines that the corrective action is satisfactory, the listed testing laboratory shall be notified that the corrective action has been accepted and the non-conformity has been closed out.

G. If the Product Listing Team determines further information is needed, the listed testing laboratory shall be notified.

H. If the necessary corrective action is not submitted by the deadline, the listed testing laboratory shall be notified that the necessary corrective action was not submitted by the required due date and that the listed testing laboratory has 10 additional business days to submit the corrective action or arrange a timeline as agreed on to submit the corrective action.

I. If the listed testing laboratory has not responded within the 10 business days or by the timeline agreed upon, the laboratory will be removed as an ASSE listed testing laboratory. For re-instatement as an ASSE listed testing laboratory, the procedures in Section 7.0 A-D shall be followed.

10.0 Testing Subcontracted Out by the ASSE Listed Testing Laboratory

A. At times, an ASSE listed testing laboratory may need to subcontract out certain portions of the applicable testing to another laboratory.

B. When conducting testing for ASSE, prior to subcontracting to another laboratory, the ASSE listed testing laboratory shall ensure that the subcontracted laboratory meets the requirements of ISO/IEC 17025.

1. If the subcontracted laboratory is ISO/IEC 17025 accredited by a recognized signatory of the International Laboratory Accreditation Cooperation (ILAC), the ASSE listed testing laboratory shall provide the current accreditation certificate to ASSE.
2. If the subcontracted laboratory does not have nationally recognized accreditation to ISO/IEC 17025, ASSE shall audit the subcontracted laboratory to confirm compliance

to the applicable requirements of ISO/IEC 17025. All costs involved for this audit will be billed to the ASSE listed testing laboratory.

C. All evaluation or testing subcontracted by the laboratory shall be supervised by an official of the laboratory overseeing the evaluation and testing of the applicable product.

D. When testing is subcontracted, the ASSE listed testing laboratory shall include, along with the Laboratory Evaluation Report or Factory Audit Inspection Test Report, a separate document that includes the following information:

1. Name of subcontracted laboratory;
2. Name of ASSE listed laboratory responsible party supervising the testing;
3. Explanation of why the testing was subcontracted;
4. List of tests performed;
5. List of equipment used for testing at the subcontracted laboratory;
6. Evidence that the ASSE listed testing laboratory verified subcontracted laboratory acceptance with ASSE.