

## General Guidelines and Information for Tier 2 (Recognition) Application

1. The AFS-FHS Tier 2 program is a major step upward from the Tier 1 requirements and will likely take a significant amount of time and effort to achieve. This document is being provided to guide applicants through the process. Download the application file and thoroughly review along with this guiding document to address all program requirements. Contact the QA Committee Chair if you have questions.
2. **Training**
  - a. Initiate and complete the referenced online training program for all employees within your laboratory. We urge a thorough, meaningful pace for completing these training modules, rather than a rushed approach to finish quickly.
  - b. The Laboratory Director and/or QA Manager must attend a multi-day interactive training that addresses QMS fundamentals, auditing and corrective action procedures. Applicants can contact the QA Chair and/or Executive Secretary for available training options. For example, the National Animal Health Laboratory Network (NAHLN) offers free in-person fundamental QMS training in Ames, Iowa. This training is preferred, but is only offered every other year (2024, 2026, etc.) and open seats may be limited. The NAHLN program also offers advanced QMS training for laboratory personnel interested in acquiring additional experience. Alternatively, the A2LA program (<https://www.a2lawpt.org/>) offers fee based in-person and virtual QMS training options. Minimum requirements for this training includes: 1) Quality Fundamentals, 2) Understanding ISO 17025 for testing and calibration labs and 3) Auditing Your Laboratory to ISO/IEC 17025:2017.
  - c. Laboratories may substitute a comparable QMS course, with prior QA/QC Committee approval. Alternate courses must include a minimum of 25 hours of training that covers QMS requirements, corrective action, non-conformities and auditing.
3. Organize SOP's that cover all aspects of laboratory procedures, along with employee records, resumes and other laboratory records (2 year minimum history). Assemble all documents relating to laboratory procedures and your quality management system (QMS) into a **Quality Manual**, which will be submitted later with your application.
4. Complete any changes to laboratory infrastructure, equipment and procedures necessary to comply with **BSL-2 standards**. If needed, make any necessary changes/corrections, document compliance and include a summary of these changes along with the BSL-2 checklist under Section #4 of the application.
5. Establish a schedule and method to document competency of all laboratory personnel. Based on the established QMS competency assessment plan, provide one cycle of

competency results (See Appendix C for scheduling example), according to established laboratory SOP's.

6. After completing items 1-5 above, submit your finished application along with supporting documents and appropriate fees to the committee. Once a successful preliminary examination of the application has been performed, you will be contacted to schedule an **internal audit**, which will be overseen and supported by QA committee members and/or NAHLN representatives.
7. Following successfully completing the internal audit and any corrective actions associated with identified deficiencies, the committee will provide final review of the application and notify the applicant of the results.