

General Guidelines and Information for Tier 2 (Recognition) Application

The application for the AFS-FHS Quality Assurance Tier 2 program is scheduled to be available for inspection on the FHS website in January 2019. This program has been in development for over two years. By necessity, it is a major step upward from the Tier 1 program, is somewhat complex and will likely take a significant amount of time and effort to achieve. These guidelines are being prepared to help applicants through the process.

1. Download the application file and thoroughly review all parts of the application. Contact the committee if you have initial questions.
2. **Training**
 - a. Initiate and complete the referenced online training program with all employees of your laboratory. As noted, we urge a relaxed, meaningful pace on this training, rather than a rushed approach on the modules.
 - b. Laboratory directors and/or QA Coordinators must attend the multi-day QMS training at Ames, IA. We will share details of the next NAHLN training class when they become available.
3. Begin to compile all SOP's and upgrade/expand as needed to cover two years of all aspects of laboratory procedures, along with employee records, resumes, and other laboratory records. Assemble all documents relating to laboratory procedures and your quality management system 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**. Contact a *qualified individual* to independently determine BSL-2 certification. (See appendix B) If needed, make any necessary changes/corrections and document compliance.
5. Obtain blind bacteriology samples from one of the identified sources and have laboratory personnel perform identification and sensitivity **proficiency testing**, according to your SOP's.
6. After the completion of items 1-5, submit your completed 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 committee members and/or NAHLN representatives.
7. After successful completion of an internal audit and corrective action for any identified deficiencies, the committee will further review the application and notify the applicant of the results.