

## Fish Health Laboratory Quality Assurance Program Renewal Application for Tier 2 (Recognition)

### Application procedures:

- A. Tier 2 (Recognition) is valid for a period of **five years**. The Tier 2 program was developed as a step process to ensure laboratories maintain original Tier 1 requirements, develop and follow a laboratory QMS manual, and to encourage laboratories to pursue final Tier 3 status (Accreditation) according to ISO17025 standards. The QA/QC committee understands the requirement for final laboratory accreditation will take time and significant commitment to achieve. If final accreditation is not achieved within this period, laboratories can also renew their Tier 2 status by following guidelines provided throughout this document.
- B. If a laboratory does not apply for renewal within this timeframe and their Tier 2 status has expired, a full application package will need to be resubmitted in accordance with annual Tier 2 guidelines.
- C. Thoroughly review each category throughout this application. If your laboratory is in compliance with these criteria, provide the required materials and provide a final signature from the laboratory director at the end of this application.
- D. Applicants can contact the QA/QC committee at [afsfsqaqc@gmail.com](mailto:afsfsqaqc@gmail.com) to receive detailed instructions for submitting application forms and supporting documents. The FHS treasurer can be contacted at [afsfs00@gmail.com](mailto:afsfs00@gmail.com) to receive detailed instructions for submitting the \$1,200 non-refundable application fee.

Submission date for each calendar year is **September 1**.

### Section #1: General Laboratory Information

Facility	Agency Affiliation	
Mailing Address	Phone Number	
City, State, Zip Code		
Laboratory Director	Phone Number	Email
QA Director	Phone Number	Email
Date of Original Tier Approval		

**Indicate which pathogens are routinely tested for during inspections or diagnostic cases:**

IHNV - Infectious Hematopoietic Necrosis Virus  
IPNV - Infectious Pancreatic Necrosis Virus  
VHSV -Viral Hemorrhagic Septicemia Virus  
LMBV - Largemouth Bass Virus  
CCV - Channel Catfish Virus

Others:

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*Renibacterium salmoninarum*  
*Aeromonas salmonicida*  
Other *Aeromonas* spp.  
*Yersinia ruckeri*  
*Flavobacterium psychrophilum*  
*Flavobacterium columnare*  
*Edwardsiella ictaluri*

Others:

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*Myxobolus cerebralis*  
*Schyzocotyle acheilognathi*  
(formerly *Bothriocephalus acheilognathi*)  
*Ceratonova Shasta*

Others:

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**Section #2: Quality Management System Manual**

The QMS manual is an organized compilation of all documents relating to quality assurance in the laboratory. The QMS manual is the document that describes the planned and systematic activities that are used to ensure quality standards will be achieved and maintained by the agency, laboratory, and/or testing facility. This document is an outline of how the laboratory operates and should serve as the guideline for laboratory audits and for all questions related to quality management within the program. The initial Tier 2 application required laboratories to develop a QMS manual and implement practices identified under the Management and Technical section of this document along with maintaining general SOP requirements.

**Required material:**

*Initials*

- \_\_\_\_\_ a. Provide a copy of the laboratory QMS manual revision log.
- \_\_\_\_\_ b. Provide a copy of the laboratory SOP revision log.
- \_\_\_\_\_ c. Provide a copy of the annual equipment maintenance log prior to applying for Tier 2 renewal (2-year minimum).

**Section #3: QMS Training Records**

The initial Tier 2 application required laboratories to assert that all employees meet Quality Management System (QMS) training requirements. Laboratory management must ensure QA training for all current

and new personnel has been completed. Specific QMS training requirements for personnel working in Tier 2 laboratories include the following:

- i. The Laboratory Director and/or QA Manager must attend a multi-day interactive training that addresses QMS fundamentals, auditing and corrective action procedures.
- ii. For example, the National Animal Health Laboratory Network (NAHLN) offers free in-person QMS training in Ames, Iowa. The NAHLN fundamental QMS 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 (<https://www.a2lawpt.org/>) and ANAB programs (<https://anab.ansi.org/training/>) offer fee based in-person and virtual QMS training options. Minimum requirements for this training would include: 1) Understanding the Requirements and Concepts of ISO/IEC 17025, 2) Auditing to ISO/IEC 17025 Standards and 3) The Corrective Action Process.
- iii. Applicants can contact the QA Chair and/or Executive Secretary to discuss these and other training options. Alternate courses must include a minimum of 25 hours of training that covers QMS concepts for ISO 17025, auditing and corrective action.

**Required material:**

*Initials*

- \_\_\_\_\_ a. *Provide confirmation (certificate of completion) that the Lab Director and/or QA Manager have attended the multi-day training that addresses QMS fundamentals, auditing and corrective action procedures.*

**Note: Although not a direct requirement for Tier 2 Recognition, the QA/QC committee recommends a minimum of one facility representative acquire and retain an Aquatic Animal Health Inspector and/or Fish Pathologist certification.**

**Section #4: Biosafety Level 2 Compliance**

The initial Tier 2 application required laboratories to assert that they meet all the requirements for Biosafety Level 2 (BSL-2) capabilities.

**Required Material:**

*Initials*

- \_\_\_\_\_ a. *Provide a summary of any changes to the BSL-2 since the last Tier 2 approval.*

**Section #5: Competency Assessment**

Laboratory management must ensure the competence of all personnel performing testing outlined in approved and current written protocols. Personnel shall be qualified to perform an assay on the basis of education, experience and/or skills demonstrated. Competency assessments are used to confirm that laboratory personnel are adequately performing their duties. The common goal of competency testing is a formal evaluation of an employee's capabilities in relation to position responsibilities. The QA Committee recognizes that it is not possible to have a single approach for every testing need (bacteriology, parasitology, and virology) and that competency assessment needs may vary according to an individual laboratory's testing scope and different testing methods. However, AFS-FHS Tier 2 laboratories must establish a schedule and method to evaluate and document the competency of all laboratory personnel.

**Required material:**

*Initials*

- \_\_\_\_\_ a. *Provide annual competency testing log and annual testing schedule for all laboratory employees since original Tier 2 approval.*

**Section #6: Internal Audit/Gap Analysis**

Specific quality control requirements for AFS-FHS Tier 2 laboratories include an internal audit/GAP analysis. AFS-FHS Tier 2 laboratories are expected to have lab-defined quality control procedures embedded as annually scheduled internal audits within their quality management system.

**Required material:**

*Initials*

- \_\_\_\_\_ a. *Provide internal audit/GAP analysis logs and related corrective actions since the last Tier 2 approval.*

***PLEASE SIGN AND DATE PRIOR TO SUBMISSION***

**I do hereby attest that I have reviewed all the information and responses contained within this application, and that they are accurate to the best of my knowledge.**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Title