

## 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 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 lapsed, 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 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 [afsfhsqaqc@gmail.com](mailto:afsfhsqaqc@gmail.com) to receive detailed instructions for submitting application forms and supporting documents. The FHS treasurer can be contacted at [afsfhs00@gmail.com](mailto:afsfhs00@gmail.com) to receive detailed instructions for submitting the \$1,200 non-refundable application fee.
  
- E. Submission date for each calendar year is **September 1**.

### Section #1: General Laboratory Information

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Facility

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Agency Affiliation

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Mailing Address

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Phone Number

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City, State, Zip Code

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Laboratory Director

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Phone Number

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Email

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QA Director

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Phone Number

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Email

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Date of Original Tier Approval

**Indicate which pathogens are routinely tested for during inspection 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.

**Required material: Provide a copy of the laboratory QMS manual revision log, management review meeting minutes/notes, SOP revision logs and complete equipment maintenance schedule since last Tier 2 submission.**

**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 training is preferred, but may be limited due to annual scheduling and travel restrictions. Alternatively, the A2LA program (<https://www.a2lawpt.org/>) offers fee based in-person and virtual QMS training options. Minimum requirements for this training would include: 1) Quality Fundamentals (MS 050), 2) Auditing Your Laboratory to ISO/IEC 17025 (AUD 102) and Improving the Corrective Action Process (AUD 103). Applicants can contact the QA Chair and/or Executive Secretary to discuss other training options.
- iii. 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.
- iv. All other laboratory personnel must complete the self-directed online training course on laboratory quality management (<https://event.me/EgBK38>).

**Required material:**

*Initials*

- \_\_\_\_\_ a. Provide confirmation (certificate of completion) that the Lab Director and/or QA Manager has attended the multi-day training that addresses QMS fundamentals, auditing and corrective action procedures.
- \_\_\_\_\_ b. Provide confirmation (certificates of completion) that all employees completed the on-line QA training course.
- \_\_\_\_\_ c. Provide a 5 year history of training records for all laboratory personnel and CVs for new employees.

**Note: Although not a direct requirement for Tier 2 Recognition, the QA/QC committee recommends a minimum of one facility representative acquiring and retaining 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 an update for the laboratories Biosafety Level 2 status and any changes that may have been implemented to this program since the last Tier 2 submission.

**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 demonstrated skills. 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 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 submission.*

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***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