Fish Health Laboratory Quality Assurance Program
Basic Requirements and Application for Tier 2 (Recognition)

(Applicants should review this application and accompanying guiding document for submission instructions)

Introduction/overview

In recent years, the Fish Health Section (FHS) of the American Fisheries Society (AFS) launched an initiative relating to quality assurance (QA) for the operation, procedures and results produced from aquatic animal laboratories. The first phase of this process, titled "Tier 1 – Prequalification" has already been instituted in aquatic animal health laboratories throughout the U.S.

This application relates to the second level of the FHS QA program, which is titled "Tier 2 – Recognition". There are several goals for this program, which include "raising the bar" even further from Tier 1 requirements by verifying accomplishments asserted during the Prequalification process have been maintained, developing a quality management system (QMS) manual, competency testing of laboratory employees and internal audit/GAP analysis for Tier 2 laboratories.

Application procedures

A. Thoroughly review each category in the application. If your laboratory is in compliance with this criteria, check the respective boxes and initial subcategories.

B. Applicants can contact the QA/QC committee at afsfhsqaqc@gmail.com to receive detailed instructions for submitting application forms and supporting documents. The FHS treasurer can be contacted at afsfhs00@gmail.com to receive detailed instructions for submitting the $1,200 non-refundable application fee.

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

D. Applications will be reviewed and approved or denied within 6 months of completing and submitting all required materials.

E. The Recognition status associated with successful completion of Tier 2 is valid for a period of **five years**. If the Tier 2 designation expires then the laboratory will need to re-apply or move toward acquiring Tier 3 (Accreditation) status.

Section #1: Tier 1 Compliance Records

Required material: Provide a summary of the following compliance records.

Initials

_____ a. Date of Tier 1 approval.
_____ b. Revision logs for SOP's and/or any specific operational changes.
_____ c. Updated CV and qualifications of all laboratory personnel.

Section #2: General Laboratory Information

Facility	Agency Affiliation
Mailing Address	Phone Number
City, State, Zip Code	

Laboratory Director	Phone Number	Email
QA Director	Phone Number	Email

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:

- ◯ _____
- ◯ _____
- ◯ _____

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

Others:

- ◯ _____
- ◯ _____
- ◯ _____

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

Others:

- ◯ _____
- ◯ _____
- ◯ _____

Section #3: QMS Training

Specific QMS training requirements for AFS-FHS 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).
iii. Applicants can contact the QA Chair and/or Executive Secretary to discuss other training options. 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://cvent.me/EgBK38). The committee **highly recommends** the QA manager oversee this process to ensure training is done in a meaningful fashion over an adequate and reasonable period of time.

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. The laboratory will maintain personnel training records (two year minimum) for laboratory competency that will be available for review during the Internal Audit/Gap Analysis.

Section #4: QMS 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 audits and for all questions related to quality management within the program. There are two main sections to the QMS manual that include: Management requirements and Technical requirements, which are outlined in **Appendix A** and will be reviewed in detail during QMS training identified in Section #3 of this application. Much of this initial work was completed during the Tier 1 process, but will need to be organized along with a management section into the final QMS document.

Required material:

Initials

_____ a. Provide a copy of the laboratory QMS manual.

Section #5: Biosafety Level 2 Compliance

The original Tier 1 application required laboratories to assert they meet all the requirements for Biosafety Level 2 (BSL-2) capabilities. Tier 2 applicants must include acknowledgment from an outside reviewer that minimum BSL-2 requirements are being achieved according to standards and the general checklist provided in **Appendix B**. External reviewers may include a USDA/APHIS Veterinary Medical Officer, State or university safety officer or other qualified individuals (with committee pre-approval).

Required Material:

Initials

_____ a. Submit a copy of the completed BSL-2 checklist (**Appendix B**).

_____ b. Submit a record of all correspondence with the external BSL-2 reviewer, including a summary of any deficiencies and corrective actions.

Section #6: Competency Assessment

Competency assessments are used to confirm that personnel are adequately performing their laboratory duties. The common goal of this process includes a formal evaluation of an employee's capabilities in relation to position responsibilities to 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. 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 an annual schedule to evaluate and document competency of all laboratory personnel.

i. The competency testing schedule and description of procedures for each section must be developed as working SOPs and incorporated into the QMS manual. An example of competency testing may include blind testing of reference samples using presumptive and confirmatory methods to accurately identify bacterial, viral or parasitic pathogens.

ii. The applicant should provide references to the specific sections in their QMS manual on how competency assessments are scheduled, used and monitored to demonstrate that laboratory employees are competent to perform laboratory assays. Standard operating procedures will also be referenced by the applicant on how specific competency assessments are carried out in each discipline/program in the laboratory.

iii. Competency test results will be reviewed at the time of the initial audit/GAP analysis described in Section #7 below. At least one annual competency assessment for each employee should be complete and a summary of findings provided during internal audit. Results will remain confidential between the testing laboratory, the auditors and the QA Committee.

Required material:

Initials

_____ a. Specific guidelines for competency testing must be identified in the QMS manual and operational SOPs, which must be provided to the QA/QC Committee for review.

_____ b. Provide a copy of the competency testing schedule based on the established QMS employee training requirements (See **Appendix C** for scheduling example).

Section #7: 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 internal audits in their QMS manual. These procedures are monitored to ensure the validity of test results and calibration of testing equipment.

i. The lab-defined audits will typically be conducted onsite by the Lab Director and Quality Assurance Manager, but the initial audit required for the Tier 2 application will be coached and directed by NAHLN personnel and/or QA Committee members.
ii. A vertical audit approach will be used to select a particular test where all inputs, operations and activities associated with that test are examined. This may include safety procedures, sample tracking, completing and storing testing records, and/or examination of individual testing SOPs. The process will include selecting random cases that the applicants are expected to produce a two year history of all records for review. A checklist is available in **Appendix D** to assist with audit preparation.
iii. The laboratory will retain equipment maintenance and calibration records identified during the Tier 1 process and have them available during the internal audit/Gap Analysis.

Required material:

Initials

_____ a. Schedule a time and date with the QA committee chair (Wade Cavender, 435-720-2784) to conduct the audit/GAP analysis. Participating QA committee members may have limited availability, so the number of audits/year is limited and would be ideally scheduled within a six month window of submitting the Tier 2 application.

_____ b. Following audit/GAP analysis, each program QA Manager must provide an audit report and a summary of any corrective actions identified during the process

_____ c. (*Committee use only) – Application and documentation of completed audit received.*

* * * * *

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 _____