# Fish Health Laboratory Quality Assurance Program
# Basic Requirements and Application for Tier II Recognition

(After reading this document, applicants should read the accompanying guiding document for specific additional instructions on timetables and logistics related to application.)

## Introduction/overview

In recent years, the Fish Health Section of the American Fisheries Society launched an initiative relating to quality assurance for the operation, procedures and results produced from aquatic animal laboratories. The first phase of this process, titled Tier I – Prequalification has already been instituted at several laboratories throughout the U.S.

This application relates to the second level of this process entitled "Tier II – Recognition". There are several goals for this next level, including "raising the bar" even further from Tier I, verification that many of the accomplishments asserted in Tier I have been achieved, and finally, preparation for potential entry into a laboratory network or actual accreditation with an existing program. To accomplish these goals, laboratories will need to achieve an integrated quality management system (QMS).

## Application procedures

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

B. Applicants must contact Cathryn Smith (cathrynsmith@utah.gov, 435-752-1066) to receive detailed instructions for submitting application forms, supporting documents and $1,200 non-refundable application fee. Make check payable to FHS/AFS.

C. Submission date for each calendar year will be June 30.

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

## Section #1: Tier I Compliance Records

**Required material: (should be included as part of the Quality Systems Manual, see Section 3)**

*Initials*

____ a. Provide date and confirmation of Tier I Prequalification.

____ b. Provide an updated copy of your laboratory manual, including a description of any specific operational changes associated with standard procedures.

____ c. Provide two years of equipment calibration and standardization records (e.g. calibration invoices, freezer/incubator records, etc.) that have been collected since receiving Tier I approval.

____ d. Provide updated CV and qualifications of all employees.

# Tier II (Recognition) Application for Fish Health Laboratories
# American Fisheries Society/Fish Health Section

## Section #2: Laboratory Information

Facility Agency/Lab _____ Laboratory Affiliation _____

Laboratory Address _____ Laboratory Phone Number _____

City, State, Zip Code _____

Laboratory Director _____ Phone Number _____ Email _____

QA Manager _____ Phone Number _____ Email _____

Laboratory Biologists and Technicians:

_____ _____

_____ _____

_____ _____

_____ _____

**Indicate which pathogens are routinely tested for during inspections or diagnostic cases which your lab wishes to recognized for expertise:**

**Viruses**

- ☐ IHNV Infectious Hematopoietic Necrosis Virus
- ☐ IPN Infectious Pancreatic Necrosis Virus
- ☐ VHS Viral Hemorrhagic Septicemia Virus
- ☐ LMBV Largemouth Bass Virus
- ☐ CCV Channel Catfish Virus
- ☐ Other Viruses:

_____

_____

_____

**Bacteria**

- ☐ *Renibacterium salmoninarum*
- ☐ *Aeromonas salmonicida*
- ☐ *Yersinia ruckeri*
- ☐ *Flavobacterium psychrophilum*
- ☐ *Flavobacterium columnaris*
- ☐ *Aeromonas hydrophila*
- ☐ *Edwardsiella ictaluri*

Other bacteria:

_____

_____

_____

**Parasites**

- ☐ *Myxobolus cerebralis*
- ☐ *Schyzocotyle acheliognathii*
- ☐ *Ceratonova shasta*
- ☐ Other Parasites:

_____

_____

_____

## Section #3: Quality Manual

As part of an overall quality management system (QMS), the quality management system manual is an organized compilation of all the documents relating to quality assurance in the laboratory. The Quality Management System manual is the document that describes the planned and systematic activities used in the laboratory to ensure a level of quality will be achieved and maintained by the agency, lab, etc. This document should serve as the guideline for laboratory audits and for all questions related to quality management within the laboratory. The document is actually an outline of how the laboratory functions and operates. All of the work completed for the Tier 1 certification will be used in the QMS manual. The QMS manual will need a management section that most labs did not include in their Tier 1 application. There are two main sections to a quality management system: Management requirements and Technical requirements. **These requirements are listed in Appendix A.**

Specific information on creating this manual will be covered during the required QMS onsite training at Ames, IA, as mentioned later in this application.

**Required material:**

*Initials*

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

## Section #4: Biosafety Level 2 Verification

Tier I required laboratories to assert that they met all the requirements for Biosafety Level 2 (BSL-2). The Tier II application is requiring laboratories to be BSL-2 certified. Applicants should include a letter of approval or a letter detailing corrective actions and evidence for compliance from qualified individuals which could consist of a USDA/APHIS Veterinary Medical Officer, a State or university safety officer or other qualified individuals (with committee pre-approval). All correspondence should be included in the QMS manual. **More information regarding BSL-2 is included in Appendix B + C.**

**Required Material:**

*Initials*

____ a. Provide a BSL-2 compliance letter from a qualified inspector associated with entities such as USDA/APHIS, Veterinary Medical Officer, state or university safety officer or other qualified individuals that have been pre-approved by the QA/QC Committee.

## Section #5: Training

Laboratory management must ensure the competence of all personnel performing the 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. Training must be documented. Provide two years of the most recent training records for all laboratory personnel.

Specific training requirements on quality management systems for personnel in AFS-FHS Tier-II Laboratories includes the following:

i. The Laboratory Director and/or QA Manager must attend National Animal Health Laboratory Network's (NAHLN) multi-day onsite training on quality management systems at Ames, IA. Laboratories outside the U.S. may substitute a comparable course, with prior Committee approval.

ii. All other laboratory personnel must complete the self-directed online training course on laboratory quality management (https://apps.aoi.wsu.edu/qms/).

(1) Submit training records, which include a self-test for each module.

(2) 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.

iii. Certificates of training will be examined by the committee and/or an internal auditor.

**Required material:**

*Initials*

_____ a. Provide confirmation (certificate of completion) that the Lab Director or QA Manager has attended the NAHLN QMS training in Ames, IA.

_____ b. Provide all employee certificates associated with completion of the online QA training course.

_____ c. Provide all personnel training records for laboratory competency for the past two years.

## Section #6: Proficiency Testing (PT)

Tier II laboratories are expected to conduct and maintain proficiency testing. **Additional information and references for proficiency testing can be found in Appendix D.** Results of testing will be analyzed during the initial internal audit/GAP analysis. The following proficiency testing will be required:

i) The lab-defined audits will be conducted onsite by the Lab Director and Quality Assurance Manager, but the initial audit will also be coached and directed by NAHLN personnel and/or a QA Committee member.

ii) A record of schedule, details and results will be maintained in the QMS manual.

iii) Proficiency testing will begin with bacterial fish pathogens and include identification and sensitivity testing.

iv) The laboratory Director or QA Manager will provide lab personnel with blind samples for identification (should be one of the designated bacterial pathogens of laboratory's asserted expertise).

v) The Veterinary Laboratory Association (http://www.vetlabassoc.com/quality-assurance-program/) offers a comprehensive proficiency program for aquatic bacterial pathogens and histopathology. The QA Committee can assist if needed to help provide other sources of samples (USFWS, ATTC, other labs, etc.).

vi) Results of testing, at present, will remain confidential between the testing laboratory, the auditors and the QA Committee.

**Note:** The nature and scope of proficiency testing required in subsequent years will likely change as reagents, testing methods and professional services become available.

**Required material:**

*Initials*

____ a. Provide completed proficiency test results to Committee once the internal audit has been scheduled.

## Section #7: Internal Audit/Gap Analysis

Specific quality control requirements for AFS-FHS Tier II Laboratories include an internal audit/GAP analysis. AFS-FHS Tier II Laboratories are expected to have lab-defined quality control procedures embedded as internal audits into their quality management system. These procedures are monitored to ensure the validity of test results and calibration of testing equipment.

i. The lab-defined audits will be conducted onsite by the Lab Director and Quality Assurance Manager, but the initial audit will also be coached and directed by NAHLN personnel and/or QA Committee member.

   (1) Committee will arrange a date with NAHLN personnel.

   (2) NAHLN personnel have limited time, so the number of audits/year is limited and would be ideally scheduled within a six month window of submitting the Tier II application.

   (3) The committee will fund travel expenses for auditors.

   (4) A vertical approach to gap analysis will be used. In a vertical approach gap analysis randomly selected cases are audited from when the samples arrive at the laboratory through reporting of the testing results. All documentation on each case will be reviewed. This may include safety procedures, paperwork or electronic records on accessioning, chain of custody on samples, testing records, review process of testing prior to reporting and reporting of test results, as well as all other Tier I requirements. Applicants are expected to produce a two year history of all records for review.

**ii. A sample list is available at Appendix E to help prepare for the audit.**

iii. Committee will review the report of Auditor/QA Manager and any GAP analysis recommendations and corrective action requirements before Tier II applications are approved.

**Required material:**

*Initials*

____ a. Schedule a time and date with the QA committee chairperson (Chris Wilson, 435-757-7493) to schedule and conduct an audit.

____ b. *(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 | |