Fish Health Laboratory Quality Assurance Program
Basic Requirements and Application for Tier 1 (Prequalification)

Introduction/overview

The purpose of the Quality Assurance/Quality Control Program (QA/QC) is to ensure the quality, reproducibility and accuracy of the information and results generated within a fish health laboratory. Inspection and diagnostic protocols provided in updated versions of *Suggested Procedures for the Detection and Identification of Certain Finfish and Shellfish Pathogens* (https://units.fisheries.org/fhs/fish-health-section-blue-book-2020/) AFS Fish Health Section Blue Book provide excellent standards by which the laboratory can abide when conducting laboratory assays. Following a carefully written protocol, however, does not in itself assure a quality product. In order for a laboratory to assure quality services it must first establish a quality assurance program by which every aspect of laboratory management and structure are implemented. This document is designed for adaptation at small laboratories as well as large establishments and will serve to begin addressing many of the critical elements provided in the International Organization for Standardization (ISO) and International Electrochemical Commission (IEC) International Standards 17025, as well as those standards published by the World Organization for Animal Health (WOAH), founded as the Office International de Epizooties (OIE).

To implement this process a three tier system has been developed (Tier 1 Prequalification, Tier 2 Recognition, Tier 3 Accreditation). Tier 1 is the prequalification step which includes identification of key personnel and their qualifications, required laboratory facilities, standard operating procedures and laboratory safety. The objective of Tier 1 is to demonstrate that a particular laboratory has established a quality system and is suitable to move on to Tier 2. Specific guidelines to assist in meeting Tier 1 requirements can be found in the AFS Fish Health Section Blue Book, Chapter 3 (*Model Quality Assurance/Quality Control Program for Fish Health Laboratories)*. If the Tier 1 designation expires then the laboratory will need to re-apply for the prequalification status before moving on to Tier 2.

Application procedures

A. Thoroughly review each category throughout the application. If your laboratory is in compliance with the 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 $500 non-refundable application fee.

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

D. Application will be reviewed by the committee and approved/denied within 60 calendar days following submission.

E. The Prequalification designation associated with Tier 1 is valid for a period of **five years** during which time the laboratory is qualified to apply for Tier 2 status.

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

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 #2: Laboratory Facilities

1. Does your laboratory facility meet the following criteria?

◯ **Yes** ◯ **No**

Initials

_____ *a. Laboratories should designate separate areas for administrative activities, fish handling and laboratory testing.*

_____ *b. Each laboratory room has adequate space and safe environmental conditions to perform assigned tasks.*

_____ *c. All laboratory space is adequate to maintain equipment, supplies, samples and chemicals without danger of cross contamination.*

Required material: Provide a blueprint or schematic of laboratory facilities.

2. Do all laboratory equipment and supplies used in your laboratory meet the following requirements?

◯ **Yes** ◯ **No**

Initials

_____ *a. All equipment and instruments in use are calibrated and maintained on a routine basis.*

_____ *b. Equipment used for generating measurements are calibrated and/or standardized according to recommendations provided in Appendix A (also referenced in Section II, Appendix E within the Blue Book) or according to individual laboratory operations manual.*

_____ *c. Calibration and maintenance records are kept for each instrument.*

_____ *d. Where appropriate, maintenance and temperature information is posted on equipment (hoods, balances, refrigerator/freezers, incubators).*

_____ *e. Defective or suspect equipment is taken out of service until repaired, tested and recalibrated.*

_____ *f. Operation manuals are available for each piece of laboratory equipment.*

Required material: Provide equipment, calibration and maintenance SOP's along with maintenance schedule.

3. Are reagents maintained under proper storage conditions, labeled and handled appropriately by all laboratory staff according to the following guidelines?

◯ **Yes** ◯ **No**

Initials

_____ *a. All reagents shall be retained with original labels from the supplier and are identified by name, date of receipt, chemical abstracts number (CAS) or code number, lot number, expiration and will include National Fire Protection Association (NFPA), Globally Harmonized System of Classification and Labeling of Chemicals (GHS) or other label which identifies hazards, safe use and storage requirements.*

_____ *b. Mixing substances - When test, control or reference substances are mixed, the date of preparation, initials of the preparer and the exact contents of the mixture shall be labeled on each storage and working container.*

Section #3: Personnel

1. Have you identified a Fish Health Laboratory (FHL) Director who has met the following qualifications?

◯ **Yes** ◯ **No**

Note: The FHL Director shall have overall responsibility for the technical integrity of the tests as well as for interpreting, analyzing, documenting and reporting results. The Director will ensure that:

Initials

____ *a. Employees clearly understand the functions which they are to perform and are properly trained to perform their duties and that training is documented;*

____ *b. Any deviations from this QA/QC Program or unforeseen circumstances that may impact the integrity of the tests are corrected and documented and;*

____ *c. All test data are accurately and precisely recorded and reported.*

Required material: Specifically identify the FHL Director and attach a CV or resume which includes qualifications, skills, experience and certifications.

2. Have you identified a Quality Assurance Coordinator who has met the following qualifications? (Note: Depending on laboratory personnel, the Director and Coordinator may function in the same position.)

◯ **Yes** ◯ **No**

Note: The FHL shall have a Quality Assurance Coordinator whose responsibilities include the following:

Initials

____ *a. Implementing and monitoring the QA/QC Program.*

____ *b. Implementing all necessary quality controls to ensure the accuracy and precision of reported data.*

____ *c. Monitoring laboratory practices to verify continuing compliance with policies and procedures.*

____ *d. Evaluating instrument calibration and maintenance records.*

____ *e. Ensuring the validation of new technical procedures.*

____ *f. Investigating technical problems, proposing remedial and corrective actions and verifying their implementation.*

____ *g. Providing recommendations for training to improve the competence of laboratory staff.*

____ *h. Proposing corrections and improvements to the QA/QC system.*

Required material: Specifically identify the Quality Assurance Coordinator and attach a CV or resume which includes qualifications, skills, experience and certifications.

3. Have you identified other technical staff members that will participate in developing and implementing the QA/QC program?

◯ **Yes** ◯ **No**

Required material: Specifically identify other technical staff members and responsibilities. Attach a CV or resume which includes qualifications, skills, experience, certifications and any additional good laboratory practice (GLP) training received.

Section #4: Chain of Custody/Case Tracking

1. Are all cases/samples submitted to the laboratory and tracked according to the following protocols described below?

◯ **Yes** ◯ **No**

Initials

_____ *a. All samples are given a case history number as they are received at the laboratory.*

_____ *b. The case history number uniquely identifies the test samples on receipt and tracks the case throughout the laboratory. Upon receipt, the case number is assigned and labeled on all sample containers.*

_____ *c. The case history number, along with information pertaining to the specifics of the samples received, is recorded on either a Case History Record (CHR) cover sheet and/or in a Case Report book. The following information is to be included.*

_____ *1) Case History Number*
_____ *2) Date of Receipt*
_____ *3) Date Sample Taken*
_____ *4) Sample Site (including, where possible, GIS information)*
_____ *5) Name Collector of Samples*
_____ *6) Recorder Initials*
_____ *7) Species and Age – class of fish*
_____ *8) Condition of Samples at Receipt*

_____ *d. This CHR cover sheet also contains specific numbers and tissue materials collected for the following lab assays: Bacteriology, virology, parasitology, serology, histology, molecular and "other". In addition, any descriptive information received with the samples is attached to the CHR.*

_____ *e. All sample material is assigned a number which corresponds directly with the description recorded in the CHR.*

_____ *f. All CHR's are transcribed in ink.*

2. Sample tracking in individual labs

Initials

_____ *a. If sample items are sent to an outside laboratory for analysis, the transfer of that item is properly entered on the CHR. Results from the outside laboratory are obtained in writing and attached to the CHR.*

_____ *b. Within each laboratory area (bacteriology, virology, etc.), a separate record system is maintained to record samples received into the area, assays requested and performed and results obtained. At completion of all assays, the results are recorded onto the original CHR and any supporting paperwork is attached.*

_____ *c. When all assays are completed and results are obtained, the CHR with all necessary attachments is provided to the designated staff member for a case report write-up. All reports refer to the appropriate CHR number and copies are maintained in laboratory files.*

3. Record Retention

Initials

_____ *a. Hard copies of records are retained in office files for at least seven years. This record*

retention standard also applies to archived computer records.

_____ b. *Equipment logs are maintained for a minimum of two years.*

Required material: Provide example of laboratory case history log, sample tracking forms, document control records, and equipment replacement/repair/redtag SOP's within the laboratory manual.

Section #5: Standard Operating Protocols and Conduct of Tests

1. Are all laboratory procedures conducted in accordance with standard operating protocols according to the following guidelines?

◯ **Yes** ◯ **No**

Note: Each fish health laboratory shall adhere in strict accordance with the specific protocols depending upon the type of case being conducted.

Initials

_____ a. *Fish Health Inspection samples are assayed according to the current edition of Procedures for Aquatic Animal Health Inspections (AFS-Fish Health Section "Blue Book"), and/or other state or provincial regulations, regional fish health compact guidelines and/or international requirements that may apply.*

_____ b. *Directors are responsible for approving other protocols prior to their use. Critical protocol deviations must be documented on the CHR with a description of the procedures used and/or citation from the literature.*

_____ c. *Data generated during all tests shall be documented, in ink and attached to the CHR. Result summaries are entered directly onto the CHR cover sheet.*

_____ d. *Pertinent entries are dated and initialed by the employee performing the work.*

_____ e. *Any changes to the original entry should not obscure the original entry and the reason for the change should be indicated, dated and initialed by the employee performing the change.*

Required material: Copies of all SOP's and a Table of Contents must be submitted with your application. A recommended format for all laboratory SOP's can be found in Appendix B.

2. Is your laboratory in compliance with the laboratory safety procedures outlined below?

◯ **Yes** ◯ **No**

Initials

_____ a. *Fish Health Laboratories working with infectious agents that pose moderate hazards to personnel and the environment must comply with national and local standards of health and safety at or equivalent to BioSafety Level 2 (BSL-2) containment. Laboratory personnel need not confine established cultures with low aerosol potential to an approved safety cabinet. Laboratory biosafety level 2 criteria are outlined in Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Public Health Services, Center for Disease Control* (https://www.cdc.gov/labs/BMBL.html)*, and National Institutes of Health, U.S. Government Printing Office, Washington D.C.*

_____ b. *Copies of Material Safety Data Sheets (MSDS) for all chemicals and reagents in the laboratory are kept on file (hardcopy, digital or web-based) within easy access and viewing for all personnel. All personnel are to follow safety precautions published within MSDS's*

for each chemical or reagent used at the laboratory.

____ c. *Necessary personal protective equipment and training in equipment use and safety is provided for all laboratory personnel.*

____ d. *Fish Health Labs should have a "Safety and Chemical Hygiene Plan"* (*see Appendix C*). *All laboratory personnel are to utilize equipment and reagents in compliance with this plan.*

Required material: Attach a copy of your Safety and Chemical Hygiene Plan and a summary of BSL-2 requirements as described within CDC hyperlink above (see section within this link containing Laboratory Biosafety Level Criteria).

* * * * *

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 _____