Fish Health Laboratory Quality Assurance Program
Renewal Application for Tier 1 (Prequalification)

Application procedures

A. Tier 1 (Pre-qualification) is valid for a period of **five years**. This program was developed to improve laboratory QA procedures and to encourage programs to pursue Tier 2 status. If a laboratory does not apply for Tier 2, they can renew their Tier 1 status within the five year timeframe.

B. If a laboratory does not apply for renewal within this timeframe and their Tier 1 status has lapsed, a full application package will need to be resubmitted in accordance with Tier 1 submission guidelines.

C. Tier 1 status can be renewed by completing and submitting this application along with a $500 non-refundable application fee. If your laboratory is in compliance with these criteria, check the respective boxes, provide required materials and provide final signature from the laboratory director at the end of this application.

D. 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 application fee.

E. 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 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:

- ◯ _____
- ◯ _____
- ◯ _____

- ◯ *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: If your laboratory has been modified from the designated working areas identified in the original Tier 1 application, provide a blueprint or schematic of any modifications or updates to the laboratory facility.

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 according to established*

SOPs.

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

_____ *d. Where appropriate maintenance and temperature information is posted on its 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: Has all laboratory equipment been maintained and calibrated in accordance with the maintenance schedule identified in the original Tier 1 application? Provide updated equipment, calibration and maintenance schedule.

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

◯ Y**es** ◯ **No**

Initials

_____ *a. All reagents shall be retained with original labels from the supplier and are labeled 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**

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.*

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.)

◯ Y**es** ◯ **No**

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 in the QA/QC system.*

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

◯ **Yes** ◯ **No**

Required material: Provide training history for all employees. If you have employed any new laboratory personnel or created additional positions, provide CV or resume for any staff.

Section #4: Chain of Custody/Case Tracking

1. Are all cases/samples submitted to the laboratory and tracked according to the 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 of Sampler*
- _____ *6) Recorder Initials*
- _____ *7) Species and Age – class of fish*
- _____ *8) Condition of Samples at Receipt*

_____ *d. This Case History Record (CHR) cover sheet also contains specific numbers and tissue materials collected for the following lab assays: Bacteriology, virology, parasitology, serology, histology, molecular (PCR) 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 expert 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 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 computer records.*

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

Required material: Have all laboratory case history logs, sample tracking forms, document control records, and equipment tracking (replacement, repair, redtag, etc.) SOP's been maintained since receiving Tier 1 approval? Provide SOP and equipment tracking logs (2 year minimum).

Section #5: Standard Operating Protocols and Conduct of Tests

1. Are all laboratory procedures conducted according to standardized operating protocols (SOPs) and guidelines below?

◯ **Yes** ◯ **No**

Initials

_____ *a. Fish Health Inspection samples are assayed according to the current edition of Procedures for Aquatic Animal Health Inspections (AFS-Fish Health Section "Bluebook"), and/or other state or provincial regulations, regional fish health compact guidelines and/or international requirements (WOAH) 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: Have all laboratory SOPs been maintained within the laboratory manual since the original Tier 1 application? Provide a log of any changes to current SOPs and implementation of new procedures.

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

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

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

Required material: Have the laboratory Safety and Chemical Hygiene Plan and BSL- 2 status been maintained since the original Tier 1 application? Provide a summary of any updates or changes.

* * * * *

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