

A1.1 Format of the Handbook

A. Title

1. The document itself shall be titled “Standard Procedures for Aquatic Animal Health Inspections.”

B. Chapters

There shall be six chapters plus any necessary appendices.

1. Chapter 1 Introduction

This chapter will contain introductory information and explanation about this handbook.

2. Chapter 2 Sampling

This chapter will contain information about sampling animals for a health inspection.

3. Chapter 3 Bacteriology

This chapter will contain information on sampling, testing, and corroborating samples for bacterial pathogen inspection.

4. Chapter 4 Virology

This chapter will contain information on sampling, testing, and corroborating samples for viral pathogen inspection.

5. Chapter 5 Parasitology

This chapter will contain information on sampling, testing, and corroborating samples for parasitic pathogen inspection.

6. Chapter 6 Polymerase Chain Reaction

This chapter shall contain general protocols and quality assurance and quality control information for utilizing polymerase chain reaction methodologies.

7. Appendices

a. Appendix 1 The Handbook and Oversight Committee

This appendix will contain the format information for the handbook and procedural information for making changes to this handbook.

b. Appendix 2 Handbook Committee and Subcommittee Members

- i. This appendix will keep a record of those individuals serving on any committee or subcommittee, their terms of appointment, and their position on the committee.

- ii. The construction of this appendix shall be as follows:
 - 1. Each subchapter of this appendix will represent one year.
 - 2. Each committee member will be listed as a section within the subchapter of the appendix.
 - 3. Their position on the committee will then be listed as an item under their section.
 - 4. Subcommittee members will be listed as items under the committee member that chairs the subcommittee on which they serve.
 - 5. Entries will include the name, title, and affiliation of the individual.

- c. Appendix 3 Position Statements

This appendix will keep a record of all discussions by those individuals serving on any committee or subcommittee, their terms of appointment and their position on the committee. The construction of this appendix will be as follows:

 - i. Each subchapter of this appendix will represent one chapter in the handbook.
 - 1. Introduction will be Appendix 3.1.
 - 2. Sampling will be Appendix 3.2.
 - 3. Bacteriology will be Appendix 3.3.
 - 4. Virology will be Appendix 3.4.
 - 5. Parasitology will be Appendix 3.5.
 - 6. Polymerase Chain Reaction (PCR) will be Appendix 3.6.
 - 7. Appendix 1 changes will be documented in Appendix 3.7.
 - ii. Each submission will be a section within the appropriate subchapter of the appendix.
 - iii. Each position statement and the resultant changes will then be listed as items under their section.

C. Layout

The layout of the document will be as follows:

- 1. The format will be in outline form.
 - a. The alphanumeric system will be: 1.2, **A**, 1, a, i, *I*, *a*, *i*

- b. Appendices will be also be in outline format with an “A” being placed before the appendix number.
 - i. Appendix 3 of the entire document would be titled and referenced as (A3).
 - ii. Appendix 2 of chapter 3 would be titled and referenced as (3.A2).
- 2. Chapter Structure
 - a. Each chapter will have its own references.
 - b. Each chapter will have its own appendices.
 - c. Chapters 1 (Introduction), 2 (Sampling), 6 (Polymerase Chain Reaction (PCR)) and the appendices are to serve as references for the other chapters.
- 3. References to other sections within the handbook will be in the same alphanumeric form as the outline.
 - a. **Example:** Reference (1.2.C.3.a) will be found in chapter 1, subchapter 2, section C, number 3, item a.

D. Stringency

- 1. The appropriateness of methodologies shall be determined based on several factors to make these protocols realistic to accomplish.
 - a. The sensitivity of the assay.
 - b. The specificity of the assay.
 - c. The cost of the assay.
 - d. Availability of reagents.
 - e. Availability of technology.
 - f. Manpower requirements.
- 2. All methods and protocols provided in this handbook shall be referenced and scientifically defensible.
- 3. The incorporation of additional pathogens into this handbook shall be contingent on the availability of appropriate screening and COROBERATIVE tests, and because such tests are commonly required by fish health regulators.

E. Maintenance of the Handbook

1. Handbook Revision and Oversight Committee

- a. Annual review as requested by open invitation (see process below).
- b. Physical possession of the electronic editable version of the handbook in Microsoft Word 2000 format and Adobe PDF format.
 - i. This shall be held by four individuals as follows:
 1. Handbook Revision and Oversight Committee Co-chair, United States Fish and Wildlife Service Representative.
 2. Handbook Revision and Oversight Committee Co-chair, American Fisheries Society – Fish Health Section Representative.
 3. United States Fish and Wildlife Service National Fish Health Coordinator or their duly appointed representative.
 4. Chairman of the American Fisheries Society – Fish Health Section or their duly appointed representative.
- c. Maintain an appendix of position statements to keep track of discussions so as not to revisit issues that have been previously decided when no new information has come available.
 - i. Changes to the handbook shall be recorded as well, so the specifics of any given change can be examined in the future.
 - ii. Dissenting opinions shall be included in the position statements as well.

F. Distribution of the Handbook

1. New versions of the handbook shall be made available by June of each year.
2. Electronic Distribution (Non-Editable) – PDF Format
 - a. CD Rom distribution of current version.
 - b. Web site
 - i. Initial distribution.
 - ii. Yearly updates.

A1.2 Handbook Revision and Oversight Committee

A. Committee Construction

1. The handbook revision and oversight committee shall consist of eight people.
 - a. Three (3) from the U. S. Fish and Wildlife Service.
 - b. Three (3) from the American Fisheries Society – Fish Health Section.
 - c. United States Fish and Wildlife Service National Fish Health Coordinator or their duly appointed representative (Ex-Officio).
 - d. Chairman of the American Fisheries Society – Fish Health Section or their duly appointed representative (Ex-Officio).
2. The committee will be co-chaired by one individual from each organization.
3. The terms of these committee members shall be three consecutive years.
 - a. Terms shall begin two months prior to the individuals first annual meeting (July).
 - b. Terms shall conclude 10 months after the individuals third consecutive annual meeting (July).
 - c. An individual may not serve on the committee again once their three-year term has expired, unless a period of two years has elapsed.
4. Each committee member will rotate through the committee as follows.
 - a. Year one – in-coming member.
 - b. Year two – co-chair.
 - c. Year three – outgoing member.
 - d. This rotation will allow for continuity from year to year.
5. New committee members shall be invited to join the committee by the new committee co-chairs ninety (90) days prior to the annual meeting (June).

B. Committee Function

1. The Handbook Revision and Oversight Committee for each year shall hold its initial meeting in September.
2. At least 2/3 of the committee must be present to make official decisions.
3. The Handbook Revision and Oversight Committee shall address all requests for revision of the handbook.
4. The Handbook Revision and Oversight Committee shall keep the handbook current and shall update all distributables (CD-ROM, web page, and print version) at least once a year, no later than 30 days after final have been considered and adopted or declined (June).
5. The Handbook Revision and Oversight Committee shall maintain possession of the editable copies of the handbook.
6. The Handbook Revision and Oversight Committee shall oversee the distribution of the handbook.

A1.3 Process for Amending the Handbook

- A.** There may be occasions when new discoveries or editorial errors require immediate changes in the handbook. Suggestions for such changes are submitted to the co-chairs of the Revision and Oversight Committee, the President of the AFS, or the USFWS National Fish Health Coordinator. If the Committee co-chairs find that the suggestion clearly indicates that a current Handbook protocol may not produce an accurate result, the co-chairs will convene a meeting of the full committee at the soonest possible date and determine if an immediate correction is warranted. If a change is warranted, the co-chairs will coordinate the revision of the text and have it approved by the full committee. The corrected text will be provided to the USFWS; notification of the change will be included in the FHS newsletter; FHS members holding a current Blue Book subscription will be notified of the change by mail; and the changed text will be provided on the FHS web site until release of the next edition of the Blue Book. If initial review of a suggested change is not deemed urgent by the co-chairs or the Revision and Oversight Committee, it will be deferred and included in the normal revision process detailed below.
- B.** At least sixty (60) days prior to their annual meeting (July), the Revision and Oversight Committee shall, through the new committee co-chairs, send out a notice to all USFWS Fish Health Center Project leaders and shall publish a notice in the AFS-FHS newsletter with the date of the annual review of the inspection handbook. Additionally, comments and concerns should be solicited at this time for discussion at the meeting. Individuals should be encouraged to include any new information that may need to be considered when evaluating their comments and concerns.
- C.** Written requests for changes in the document or for discussion of concerns shall be submitted no later than thirty (30) days prior to the annual meeting (August) of the Revision and Oversight Committee. The requests and comments shall be submitted to the committee co-chairs who will then distribute them to the other committee members for their consideration prior to the meeting.
- D.** Committee members shall search the appendix for related issues or position statements that have addressed these concerns or similar concerns. This shall be done to aid in determining the need to address a particular query due to changes in available information.
- E.** At the annual meeting, the committee will hold discussions on each query to determine whether or not the issue merits further review.
1. If the committee calls for no further review, the committee shall write a position statement to be incorporated with the query and added to Appendix 3. Additionally, the person submitting the query shall also receive a copy of the position statement.
 2. Should the committee decide the matter warrants further discussion a subcommittee shall be formed.

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- a. Subcommittees shall be formed with regard to the chapter under review (i.e. Bacteriology, Virology, and Parasitology), this will ensure consistency within any chapter. Subcommittees formed to deal with issues within Chapter 1, Chapter 2, Chapter 6, or Appendix 1 should focus on how changes will affect all sections of the handbook as these relate to all the other chapters.
 - b. A member of the Revision and Oversight Committee shall chair each subcommittee.
 - c. Each subcommittee will address all the queries regarding their chapter moved forward by the Revision and Oversight Committee.
 - d. The subcommittees shall be composed of 6 to 12 members.
 - i. Members are drawn from both the USFWS and the AFS-FHS.
 - ii. Equal representation is not required on subcommittees; however, there must be at least two representatives of each organization on each subcommittee.
 - iii. The subcommittee chair will invite individuals to participate on the subcommittee.
 - iv. The invitees shall be experts or have extensive experience in the discipline being discussed.
 - v. The invitees shall represent a diverse area of the country and have a broad species interest, to ensure equal consideration of all potential culture situations.
- F.** The subcommittee chair shall assemble the subcommittee, provide them with the queries to be addressed and any other material needed and schedule a meeting within 30 days of the annual meeting (October).
1. At least 2/3 of the subcommittee must be present to make official decisions.
 2. The subcommittees shall determine again if the query needs to be addressed.
 - a. If it is determined by the subcommittee that the issue does not warrant action:
 - i. The subcommittee shall write a position statement explaining why this decision was made and it will be submitted to the Revision and Oversight Committee for inclusion in Appendix 3.
 - ii. The submitter of the query will also be provided a copy of the position from the subcommittee.
 - b. If the subcommittee finds the query needs to be addressed they shall:
 - i. Determine the most appropriate changes to be made to the document.

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- ii. Submit line-by-line recommendations in a position statement, which is delivered to the Revision and Oversight Committee within ninety (90) days of the subcommittee's first meeting (January).
- G.** At this time, the Revision and Oversight Committee shall have thirty (30) days (February) to review these changes and determine if they fit with the other parts of the handbook and are in-line with the purpose and intent of the handbook.
3. If the committee accepts them:
 - e. The Revision and Oversight Committee co-chairs make the changes to the handbook.
 - f. The changes as well as the subcommittee position statement are added to Appendix 3.
 - g. The individual submitting the query shall receive a copy of the position statement and notice of the subsequent changes to the handbook.
 2. If the Revision and Oversight Committee rejects the suggested changes, they shall supply a written position statement for these actions to the subcommittee chair, who in turn shall provide it to the subcommittee members.
- H.** The subcommittee shall have an additional sixty (60) days (April) to:
1. Resubmit their changes by submitting a new position statement to the Revision and Oversight Committee through the subcommittee chair.
 2. Drop the changes and issue a new position statement for inclusion in Appendix 3.
- I.** The revision and oversight committee shall have thirty (30) days (May) to re-review these changes.
1. If the new submittal is accepted by the Revision and Oversight Committee, they shall:
 - h. Write a position statement.
 - i. Make the changes to the handbook.
 - j. Add the changes well as all position statements to Appendix 3.
 - k. Supply the query submitter a copy of both the position statement and the subsequent changes to the handbook.
 2. If the submission is once again rejected, the Revision and Oversight Committee shall:
 - a. Provide a position statement, which shall be included in Appendix 3 and a copy provided to the individual that made the request.

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- b. The request will then be considered closed and will only be reconsidered if re-submitted in the future.

- J.** Position statements may be written by any member of the subcommittee or Revision and Oversight Committee and signed off on by all committee members before being added to Appendix 3. It is essential that all opinions, including those dissenting from the decision, be included in the position statement.

- K.** The Revision and Oversight Committee shall have thirty (30) days (June) to incorporate all accepted changes, add appropriate information to Appendix 2, add the position statements to Appendix 3, and release the new version of the document.

Figure 1. Flow chart of procedures to handle requests to change the handbook.

