

U.S. Fish and Wildlife Service
Marquette Biological Station
3090 Wright Street
Marquette, Michigan 49855
U.S.A.

and

U.S. Fish and Wildlife Service
Ludington Biological Station
5050 Commerce Drive
Ludington, Michigan 49431
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and

Fisheries and Oceans Canada
Sea Lamprey Control Centre
1219 Queen Street East
Sault Ste. Marie, Ontario P6A 2E5
Canada

ADMINISTRATIVE OPERATING PROCEDURE

PROCEDURE TITLE:

Management of Data and Records from Quality Assurance Measures for Lampricide Standards and Vendor Products

APPLICABILITY:

Applies to all raw data and reports generated in the quality assurance program for lampricides.

PURPOSE:

To securely maintain all raw data, supporting documentation, and ancillary information generated in quality assurance procedures pertaining to vendor batches of lampricides and lampricide standards.

PROCEDURE:

Quality Assurance (QA) procedures are in place for ensuring that lampricide vendor production batches are of specified quality and lampricide field standards of indicated concentration. Measures taken to ensure quality are outlined in AOP:001.x, TOP:019.x, and TOP:027.x.

- I. Lampricide vendor production batches
 - A. Tests are conducted at the Upper Midwest Environmental Sciences Center (UMESC) and the Hammond Bay Biological Station (HBBS).

- B. Batches of lampricides are analyzed to assure purity, quality, efficacy, and percent active ingredient. The results of several types of tests are documented before shipments of lampricides are accepted. The data and subsequent reports based on these data are maintained as follows:
1. Vendor purity analysis – All batches of lampricides are analyzed to ensure that they contain the stated purity and concentration of active ingredient (AOP:001.x, TOP:027.x).
 - a. Analyses conducted at UMESC and HBBS
 - b. Report provided to Great Lakes Fishery Commission (GLFC) Secretariat
 2. Toxicity tests – Static toxicity tests are conducted on batches of TFM to assure that toxicity to lampreys and rainbow trout is consistent with expected values.
 - a. Tests completed at HBBS
 - b. Report provided to GLFC Secretariat
 3. Confirmation of contracted quality parameters – Batches of lampricides are analyzed to ensure that physical and chemical properties are consistent with values stipulated in the purchase contract.
 - a. Analyses are provided by HBBS
 - b. Report provided to GLFC Secretariat

II. Lampricide field standards

- A. Lampricide field standards are analyzed throughout preparation and use to assure proper content of active ingredient.
1. Lampricide field standards are prepared at HBBS. Formulation of these standards and a check for concentration of active ingredient are documented through a **Certificate of formulation** (AOP:001.x).
 2. The concentrations of lampricide active ingredient in field standards is independently confirmed prior to distribution (TOP:019.x). This confirmation is documented in a **Statement of confirmation**.
 3. The concentrations of lampricide active ingredient in field standards are again confirmed after distribution (TOP:019.x). Randomly-selected unopened standards are returned to HBBS for analysis. Results of these analyses are documented in a **Statement of standard verification**.
- B. Chain of Custody – Possession of field standards is documented throughout formulation and use. All standards receive a unique identifying number when formulated (TOP:019.x), and are tracked through use or disposal.
1. The standards are transferred, after formulation and confirmation of concentration, from HBBS to the agents (TOP:019.x). Transfer and receipt of the standards is documented in a **Statement of transfer**.
 2. **Field standard use log** – The Marquette, Ludington, and Sault Ste. Marie stations each maintain log books for documenting the possession and use of TFM and niclosamide field standards.

III. Location

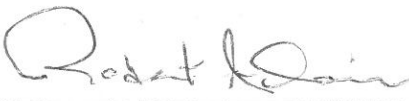
A. Documentation of quality assurance measures applied to lampricide stocks and lampricide field standards is produced at several locations. Records and data are maintained at:

1. GLFC Secretariat, Ann Arbor, Michigan
2. UMESC, LaCrosse, Wisconsin
3. HBBS, Millersburg, Michigan
4. Marquette Biological Station (MBS), Marquette, Michigan
5. Ludington Biological Station (LBS), Ludington, Michigan
6. Sea Lamprey Control Centre (SLCC), Sault Ste. Marie, Ontario

B. Records are stored in file cabinets specified by facility archivist. All records are kept for a minimum of five years. Only the responsible person or their designee may access the files. Locations at which quality assurance data and records are stored are:

1. **Statement of transfer:** On file at HBBS, MBS, LBS, and SLCC
2. **Field standard use log:** Active copies at MBS, LBS, SLCC; archived copies at MBS; responsible person is Chemist
3. **Certificate of formulation:** On file at HBBS
4. **Statement of confirmation:** On file at UMESC and HBBS
5. **Statement of standard verification:** On file at HBBS and MBS
6. Records pertaining to and resulting from vendor purity analysis, toxicity tests, and work conducted for confirmation of contract parameters: On file at GLFC Secretariat, HBBS, and UMESC.

This procedure has been reviewed and approved by the undersigned representatives of the U.S. Fish and Wildlife Service and Fisheries and Oceans Canada.

REVIEWED/APPROVED  DATE 2-12-14
Field Supervisor (U.S.)

REVIEWED/APPROVED  DATE 2-12-14
Division Manager (Canada)

Program Manager (Canada)