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Upper Midwest Environmental Sciences Center
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GENERAL OPERATING PROCEDURE

PROCEDURE TITLE: Procedures for Labeling Chemicals and Specimens

APPLICABILITY: All personnel in the Branch of Aquatic Ecosystem Health at the Upper Midwest Environmental Sciences Center (UMESC), La Crosse, Wisconsin.

PURPOSE: To provide minimum acceptable labeling practices for chemicals and test specimens to meet requirements of Good Laboratory Practice (GLP) regulations.

DEFINITIONS: Based on GLP regulations.

A. ***Reagent***: Every chemical used in direct support of laboratory studies that is not a test chemical, control chemical, reference standard, or a test specimen.

B. ***Test Chemical***: Any chemical or mixture that is being evaluated and administered to a test system.

C. ***Control Chemical***: Any chemical or mixture, or any other material other than a test chemical, feed, or water that is administered to the test system for the purpose of establishing a basis for comparison with the test chemical for known chemical or biological measurements.

D. ***Reference Standard***: Any chemical, mixture, analytical standard, or material other than a test chemical, feed, and water that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test chemical for known chemical or biological measurements.

E. ***Test Specimen***: Any material derived from a test system for examination or analysis.

PROCEDURE: GLP requirements are italicized and enclosed in quotation marks and example labels follow each category. **Note**: For Occupational Safety and Health Administration and the National Fire Protection Association labeling requirements, see the UMESC Chemical Hygiene Plan.

A. Labeling Reagents

1. **Reagent original container** (Example: 4-L bottle of Sigma HPLC-grade methanol): "*All reagents and solutions in the laboratory areas shall be labeled to indicate identity* (name and lot number), *titer or concentration, storage requirements, and expiration date.*" **Note:** If these requirements are not already on the product's label, they need to be added. Document the date received, date opened, expiration date[1] (month/year), and the initials of the person making each of those entries (preprinted labels are available and recommended).

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[1]Manufacturer's expiration date if printed on the chemical bottle, or record 5 years from the date of receipt or some other date prearranged with the Chemical Hygiene Officer.

Date Received/Initials_____
Date Opened/Initials_____
Expiration Date/Initials_____

2. **Reagent non-original container**: (Example: 250-mL beaker of methanol used over a period of a day for an extraction). *"All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date."* The signature or initials of the person transferring the reagent and the date of the transfer must also be included.

Methanol, 100% Expires: 09Jun13 Store at room temperature 06Aug12 TMS

3. **Reagent—solution purchased from a manufacturer** (Example: Fisher pH 7 Buffer): This would be labeled the same as a reagent in the original container (see A.1.)

4. **Reagents—solution prepared by UMESC personnel** (Example: Solution used to make extraction buffer): *"All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date."* The signature or initials of the person preparing the solution and the date of preparation must also be included. **Note:** The expiration date for a solution must be based on established stability information.

0.1M citric acid monohydrate solution in water Store at room temperature Expires: 19Aug14 08Feb13 MAT

Reagents—immediate use: Exemptions for labeling requirements will be made for chemical transfers from a labeled container into a container that is intended only for the immediate use of the employee who performs the transfer. The transfer device is also exempt from the labeling requirements. (Example 1: 25 mL of a MeOH is transferred from the original, labeled container graduated cylinder. The graduated cylinder is then immediately emptied into a labeled sample container for an extraction procedure. The graduated cylinder does not have to be labeled. Example 2: A syringe is used to spike control tissue with test chemical. The syringe does not have to be labeled.). **Note:** Unlabeled labware must be discarded or removed for cleaning immediately after use.

B. Labeling Test Chemicals, Control Chemicals, and Reference Standards

1. **Test chemical, control chemical, or reference standard—original container**: *"Each storage container for a test, control or reference substance shall be labeled by* ***name, chemical abstracts service number (CAS), or code number***[2]*, batch* (lot) *number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity and composition of the test, control, or reference substance."* **Note:** If these requirements are not already on the product's label, they need to be added.

   In addition to label requirements, document the date received, date opened, expiration date, and the initials of the person making each of those entries. For additional information and requirements for test chemicals, see SOP Nos. GEN 011 and 012. See A.1 for expiration date information.

Date Received/Initials_____
Date Opened/Initials_____
Expiration Date/Initials_____

2. **Test chemical, control chemical, and reference standard—non-original container** (Example: 1 L of hydrogen peroxide is removed from the original container to conduct a field treatment): *"Proper identification is maintained throughout the distribution process." "Each storage container for a test, control, or reference substance shall be labeled by* ***name, chemical abstracts services number (CAS), or code number***[2] *batch* (lot) *number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity and composition of the test, control, or reference substance."* The signature or initials of the person making the transfer, and the date of the transfer must also be included. **Note**: The Environmental Protection Agency and Food and Drug Administration (FDA) believe transferring test article out of the original container into a non-original container encourages contamination, mixups, and lack of accountability. Whenever possible, do not remove test chemical into non-original containers for storage (FDA 1987; Preamble #38).

Oxytetracycline hydrochloride Lot #: 033H0667 Expires: 23Aug13 Store at room temperature 08Jun12 MGD

[2]All three are not required. List the chemical name (if possible), otherwise list the CAS or code number.

3. **Test chemical, control chemical, and reference standard—solutions** (Example: Florfenicol brought to solution in water to be used as a standard for an HPLC calibration curve and as a test chemical solution to spike plasma samples): *"Proper identification is maintained throughout the distribution process. All solutions in the laboratory areas shall be labeled to indicate identity, study number, titer or concentration, storage requirements, and expiration date."* The signature or initials of the person preparing the solution and the date of preparation must also be included. **Note:** Expiration dates for test chemical/control chemical and reference standard solutions must be based on known stability data.

AEH-11-FFC-01 1 g florfenicol (Lot #5084) in 20 mL water Store at room temperature Expires 06Mar12 06Feb12 JRM

4. **Test chemical, control chemical, and reference standard—immediate use:** No label is needed. See item A.5.

C. Labeling Test Specimens

1. **Test Specimen** (Example 1: Fillets collected from rainbow trout. Example 2: Oxytetracycline extracted from a top-coated Silvercup feed sample for HPLC analysis): *"Specimens shall be identified by test system, study, nature, and date of collection. This information shall be on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data."* Study number, unique identity, nature (type of sample such as fillet tissue, fillet homogenate, feed extract, plasma, etc.), date of handling, and identity of person processing the specimen (signature or initials) must be included. **Whenever possible, label the specimen container directly.** At times, however, the size or condition of the sample prevents this. In those cases, a simple letter, number, or brief code may be used, but a "decoding" sheet must accompany or be easily accessible showing the full label associated with the letter, number, or code.

AEH-11-EUGNL-01 0-hour, RBT T2 Skin-on fillets 08Apr12 TMJ

AEH-09-PTSA-04 24-hour, RBT T4 Skin-on R. fillet 08Dec09 LIW

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2. **Specimen Disposal** (Example 1: Residual carcass of lake trout in a study that only collected the fillet tissue from the test animals. Example 2: The disposal of mortalities from an acclimation tank of channel catfish): Animal samples will be labeled with the number of animals, species, study number (if applicable), and date of disposal and the initials of the employee responsible for preparing the specimen for disposal (see SOP Nos. GEN 132 and 138).

AEH-11-EUGNL-01 Fish 1-20, residual carcass (RBT) 08Jan13 TGM	AEH-12-H2O2-4 5 CCF 22Oct12 HNJ

D. Labeling Radioactive Materials

1. Radioactive materials must include the isotope and yellow-magenta radioactivity tape in addition to other labeling requirements stated in this SOP and SOP No. GEN 104.

E. Labeling Organic Solvent Waste

1. Each work area will have two types of organic solvent waste containers: halogenated and non-halogenated. All waste containers will be properly identified by affixing hazardous waste labels with the chemical accumulation start date. They will be labeled "halogenated solvent waste" and "non-halogenated solvent waste" (see APP No. 063).

REFERENCES

A. Food and Drug Administration, September 4, 1987, Good Laboratory Practice for Nonclinical Laboratory Studies, 21 CFR 58.

B. Environmental Protection Agency, August 17, 1989, FIFRA, Good Laboratory Practice Standards, 40 CFR 160.

C. Environmental Protection Agency, August 17, 1989, TSCA, Good Laboratory Practice Standards, Final Rule, 40 CFR 792.

REVIEWED BY: Jose E. Rivera — Quality Assurance Officer **DATE:** 1/26/2013

APPROVED BY: _____ — Branch Chief, Aquatic Ecosystem Health **DATE:** 01 Mar 2013