

Disposal of Test, Substances

Chapter 7: TEST, REFERENCE, AND CONTROL SUBSTANCES
AHETF-7.C.O.

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1.0 PURPOSE AND SCOPE

- 1.1 This Standard Operating Procedure (SOP) describes how test substances are to be disposed of by the Agricultural Handlers Exposure Task Force (AHETF) or contract facilities, the documentation required at the completion of an AHETF study, and the AHETF policy on container retention.

2.0 PROCEDURE

- 2.1 A reserve sample from each batch of test substance will be retained from each study more than four weeks in duration [EPA GLPs §160.105 (d)]. Storage time is only to be as long as the sample affords evaluation. Samples may only be discarded with written permission from the Study Director.
- 2.2 Samples of test substances that have been archived may be discarded after acceptance of the final report by the AHETF or returned to the AHETF Study Director. Written authorization must be obtained from the AHETF Study Director or designate prior to disposal of any of the test, control, or reference substances.
- 2.3 Disposition of all substances must be recorded on an appropriate inventory log.
- 2.4 If the AHETF study was conducted using a registered or experimental material from an outside source or AHETF company member, the Study Director is responsible for assuring that the remaining test,

reference, and control substances are returned to the supplier or manufacturer, if requested, or disposed of. Written authorization must be maintained in the AHETF study file upon the return or disposal of the test, control, or reference substances. Refer to SOP AHETF-7.A. for shipping guidelines or follow the appropriate contract facility SOP(s).

- 2.5 Once sponsor approval has been obtained, all materials will be properly disposed of by the AHETF or contract laboratories/test sites per federal, state and local regulations.

3.0 CONTAINER RETENTION

- 3.1 Label requirements for container handling and disposal after use (e.g., triple rinsing before disposal, or special conditions for disposal) will be considered part of the handling exposure period for each AHETF study. Containers will only be retained by the AHETF or designated facilities after handling activities have been completed.
- 3.2 All original test substance containers used in each AHETF study **will be retained** in compliance with the GLPs, unless an exemption is granted by the EPA. The location of the containers will be documented in the appropriate study file.
- 3.2 If a waiver for container retention is granted, then empty containers will not be retained; however, the following documentation must be maintained in the study data files:
- (a) Information of shipments pertaining to each container leaving the storage site (e.g., shipping requests, bills of lading, carrier bills, monthly inventories, etc.)
 - (b) Test substance receipt records at each testing facility or field site.
 - (c) Complete usage logs of material taken from each container.
 - (d) A record of the final destination of the container(s), including the place and date of disposal or reclaiming, and any appropriate receipts.

- 3.3 In addition, the AHETF will be responsible for the following documentation:
- a. A statement will be included in the final report indicating the compliance or noncompliance required by 40 CFR 160.12 describing that this exception to Good Laboratory Practices is in accordance with the conditions provided under the exemption.
 - b. An inventory of empty containers before disposal, including sufficient information to uniquely identify containers will be prepared and maintained; the inventory will be periodically updated to indicate the arrival and disposal of empty containers. NOTE: this inventory is considered raw data.
 - c. The identity of the locations of each facility where: test substances are stored; empty containers are stored prior to disposal; records of use, shipment, and disposal of containers are maintained; and the test substances were used in each study.
- 3.4 Individual study protocols will provide information regarding any GLP exemptions. Exemptions may be granted, based upon the design of the proposed studies, the length of time per study, and amount of material to be used.
- 3.5 Should the EPA request an inspection of the AHETF studies, the EPA will be notified - within two (2) weeks of the inspection - of the locations described in 3.3 c. This information will be sent to:

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