

Raw Data Handling
Chapter 9: DOCUMENTATION
AHETF-9.G.O.

Effective Date : February 1, 2003

APPROVAL <u><i>Daniel Johnson</i></u>	DATE <u>01-22-03</u>
APPROVAL <u><i>William D. L. L.</i></u>	DATE <u>1-28-03</u>
Last Revision Date: N/A	Previous Version Number: N/A

1.0 PURPOSE AND SCOPE

- 1.1 This Standard Operating Procedure (SOP) describes the methods to follow when contract facilities forward raw data to the Agricultural Handlers Exposure Task Force (AHETF).

2.0 PROCEDURE FOR THE SHIPPING OF RAW DATA

- 2.1 The contract facility will assemble all original data plus a detailed itemized list of all data/material being sent, and prepare it for shipping via acceptable carrier (e.g., one providing tracking accountability such as Federal Express). An appropriate Chain of Custody Form will accompany the data. (Refer to the attached example).
- 2.2 The facility will produce true copies of the original data, which will be subject to QA review (if necessary).
- 2.3 The true copies will be shipped to the AHETF QAU, Study Director or other designee for report preparation and review. Originals will be shipped directly to the AHETF archives. Copies and originals may not be shipped together or at the same time (i.e., one complete set must be secured by the contractor or AHETF while the other is in transit).
- 2.4 Data should be sent via overnight carrier, or transferred to the Study Director, committee member, or designated personnel for hand delivery.

- 2.5 Upon receipt of the shipment, the data package will be inspected. The condition of the data package will be noted and acknowledgment of receipt will be noted on the Chain of Custody form.
- 2.6 The AHETF Task Force Manager, Study Monitor, or designate will review the copies and the report for scientific accuracy and regulatory compliance. The copies will be maintained as long as the data are required for report preparation or review. Upon completion of the final report, but prior to finalization (Study Director signature), all original raw data will be placed in the AHETF designated archives.

3.0 RETURN POLICY

- 3.1 All original data and contractor report(s) should be sent directly to the designated archives. The contract test facility will be responsible for the condition of the data until it has been received by the AHETF archives.
- 3.2 True copies of the raw data will be maintained by the Study Director or AHETF Quality Assurance Unit (QAU). All original raw data will be maintained in the AHETF archives after study completion. The AHETF will authorize all transfers and distributions of AHETF study data.
- 3.3 No contract laboratory may retain copies of AHETF study data unless authorized in writing by the AHETF. Raw data packages will consist of original AHETF data, and true copies of lab/facility specific data (*i.e.*, temperature records, SOPs, personnel records, maintenance logs, *etc.*).

Attachment

Chain of Custody Form

(example)

Agricultural Handlers Exposure Task Force

Data Chain of Custody

AHETF Study No. AHE99	Data Type: Analytical raw data	Priority: Overnight	Page: 1 of 1
Ship To: AHETF Archives Archivist Address City, State Zip Code		Ship From: Study Director Facility/Company Address City, State Zip Code	
Shipper/Carrier: FedEx	Airbill No. 123-456-7A	Date Shipped/Initials: 10/16/02 mm	
Comments: 3 boxes packed with raw data			
Shipped:	Description of Materials Sent:	Received:	
✓	Box 1: Field notebook	✓	
✓	Test substance records	✓	
✓	Application video	✓	
✓	Box 2: Analytical data 7-1-97 to 8-19-97	✓	
✓	Box 3: Analytical data 8-26-97 to 9-15-97	✓	
✓	Final report	✓	
✓	QA records (in separate envelope)	✓	
Date Received: 10/18/02	Received By/Company: J.Doe/Archives, Inc.		
Condition Received: Good, sealed boxes. 3 boxes received.			