

IR-4 Advisory #2006-01 (Dec. 22, 2006)

Title: Inventory and Transfer of GLP Raw Data and Other Records to IR-4 Headquarters (HQ)

Issue/

Question: What documentation and data security mechanisms are needed when transferring raw data (other than Field Data Books) and other GLP records from IR-4 test sites to IR-4 HQ?

Background:

Original GLP data, SOPs and other applicable GLP records (facility or study related) are periodically transferred from IR-4 test sites (field and lab) to IR-4 HQ for archival (Field Data Books are routed directly to the Regional/ARS Field Coordinator). When received at HQ, the materials come with various forms of chain of custody and inventory records, or none at all. In order to check in the materials and maintain chain of custody, an inventory is generated at HQ so we have a record of what was received. But, without an inventory from the sender, we do not know if all documents intended to be transferred were actually received.

Resolution:

Transfer of GLP raw data and related GLP records should be done in an organized, traceable, secure and well documented fashion. An inventory of the materials being transferred must be generated and chain of custody verified at point of origin and at the receiving location. The sender will receive verification of the completed shipment. Any discrepancies or problems will be addressed prior to document storage at HQ.

Before shipping, be certain to make and keep a copy of all materials being transferred, including the inventory and chain of custody. The IR-4 Raw Data/Documents Transfer Form (see Attachment A as an example) can be used to document inventory and chain of custody information (see Attachment B as an example inventory).

Because handling of data is an element to be addressed in SOPs, any data transfer procedures specific to a test site should be detailed in a site-specific SOP, which should be sent to the Regional/ARS Field/Lab Coordinator, as appropriate, for approval.

Transfer to IR-4 HQ can be by hand or through a courier service, and should be addressed to the Registrations Manager. If a courier service is used, the documentation should include the identity of the courier service and the tracking number provided by the service so that packages can be traced if necessary. Raw data and GLP related records should not be transferred using regular, non traceable US postal service mail, but by certified mail or other traceable mechanism. Materials should be packaged appropriately to protect them during transport.

(If you have any questions, please contact your Regional/ARS Field/Lab Coordinator or HQ QA for further guidance.)

ATTACHMENT B

(EXAMPLE INVENTORY)

Inventory for Data, Documents and/or Facility Files sent to IR-4 HQ

IR-4 test site location: _____

<u>Items</u>	<u># of Pages*</u>
Record of Data in Archive – inventory for 1997-2003	12
Calibration of Hobo loggers – 2005	15
Organization charts (2004-2006)	3
Maintenance log forms – 2004	
VWR digital humidity/temperature meter	2
Kenmore freezer	2
Hobos – 18161-18164, 18166, 18168	10
Turbo meter	2
Taylor soil probe	2
Hobo Standardization records, 2004	15
Pesticide Inventory (2/5/2004)	2
SOP originals, dated 6/3/02	35
Modular building floor plan, 5/9/05	2
Job description (7/28/99), training, and CVs (4/4/05, 3/18/05) for _____	5
Job description (2/25/02), training, and CV (4/19/02) for _____	7

***# of pages is desired, but not required**