Environmental storage areas (eg, freezers and refrigerators) have their own unique identifier that includes a defined convention for numbering shelves, racks, boxes, and the location within each container.

BAP.13150 Missing Specimen - Inventory Update **Phase II**

If a specimen is missing, inventory is updated to reflect that the specimen cannot be located.

SAMPLE MANAGEMENT

Inspector Instructions:

	• Sampling of sample distribution records
	• Sample being removed from inventory
	• What is the process if a sample entered into the inventory system cannot be located? • What are you looking for when performing a sample pre-distribution quality check? • How do you ensure personnel are available to receive shipments?
	• Select a specimen that was shipped and review the audit trail for the specimen

BAP.13200 Shipment Acceptance Confirmation **Phase II**

Recipients are notified before shipping to ensure that appropriate personnel are available to receive the shipment.

BAP.13300 Shipping Tracking Criteria **Phase II**

Tracking information for shipment of specimens includes the following, as applicable.

1. **Invoice/tracking number**
2. **Recipient/source**
3. **Date of shipment or receipt**
4. **Courier name and ID# for each package**
5. **Sample description**
6. **Number of samples shipped/received**
7. **Study name/number**

8. **Shipping conditions (eg, dry ice, ambient temperature)**
9. **Key investigators identification**
10. **Confirmation of receipt**
11. **Any discrepancies from manifest and actual shipment**
12. **Specimen damage**

BAP.13400 Specimen/Shipping Manifest Linkage **Phase II**

Specimens are labeled with a unique identifier and/or code.

NOTE: The intent of this requirement is to ensure that specimens arrive with accurate manifest of the contents of the shipping container.

BAP.13500 Reconciliation of Discrepancies **Phase II**

When specimens are retrieved from storage, any discrepancies found are recorded and reconciled prior to distribution.

BAP.13600 Pre-Distribution QC **Phase II**

A quality check is performed prior to distribution.

NOTE: Quality checks may include, but are not limited to, gross observations, labeling accuracy, condition of specimens, weight, and verification that storage temperature is appropriate for the shipping temperature.

RECORDS

Inspector Instructions:

READ

- Policy for record retention
- Policy for disposition of specimen and data
- Sampling of disposition records from the last 2 year period

BAP.13740 Record Retention - Biorepository **Phase II**

The biorepository specifies the length of time in which all records, paper and/or electronic, are retained.

NOTE: The length of time will depend on the nature of the record and is determined by the biorepository. The records include, but are not limited to, equipment maintenance and repair records, clinical and patient information, and records pertaining to closed collections.

BAP.13750 Disposition of Specimens, Data and Regulatory Documents **Phase II**

The biorepository complies with the regulations that govern the biorepository for the disposition of specimens, data, and related regulatory documents.

NOTE: Reasons for disposition may include, but are not limited to:
1. *Transfer or termination of collection*
2. *End of funding period*