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:

- 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