*NOTE: This requirement is not intended to imply that all "unacceptable" specimens be discarded or not analyzed. For example, if an unacceptable specimen is received, there must be a mechanism to notify the requesting researcher, and to note the condition of the specimen on the report. For example, many semen specimens are sub-optimal; all specimens should be evaluated and unusual properties noted. The biorepository may wish to record that a dialogue was held with the requesting researcher.*

**BAP.03100 Relabeling** **Phase II**

**The biorepository has a defined process for relabeling of a biospecimen and/or aliquots.**

*NOTE: Circumstances under which relabeling may occur may include, but are not limited to: a) inadvertent duplication of ID from internal or external sources; b) full de-identification; c) replacement of a label (eg, original label has fallen off).*

**Evidence of Compliance:**
- ✓ Records, including reason for relabeling

**BAP.03700 Retrieval Procedures** **Phase II**

**All specimen retrieval procedures ensure specimen integrity.**

*NOTE: The integrity of the biospecimen must be maintained throughout the retrieval process.*

**BAP.03800 Paraffin Embedding and/or Fixation QC** **Phase II**

**The biorepository has a process for paraffin embedding and/or fixation that includes quality checks at a defined frequency (eg, 24 hours/48 hours).**

*NOTE: This requirement applies only to biorepositories that perform their own fixation and embedding and are not a part of a CAP-accredited laboratory.*

**Evidence of Compliance:**
- ✓ Records of quality checks

## DNA/RNA EXTRACTION/AMPLIFICATION

## Inspector Instructions:

| | |
|---|---|
|   | • Sampling of nucleic acid extraction and amplification policies and procedures<br>• Sampling of nucleic acid measurement records<br>• Records of nucleic acid integrity and purity assessment<br>• Records of internal controls<br>• Sampling of specimen processing, handling, aliquoting, and storage policies and procedures |
|   | • Nucleic acid amplification procedures for proper physical containment and procedural controls to prevent carryover<br>• Observe quantitation and quality control assessments |