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1.0 PURPOSE

1.1 The purpose of this Standard Operating Procedure (SOP) is to define the internal audit process for the Biospecimen Management Core (BMC) area, which takes place on a planned basis over the course of a year.

2.0 SCOPE

2.1 This procedure is applicable to all BMC areas that have quality oversight.

3.0 ROLES AND RESPONSIBILITIES

Role	Responsibilities
BMC Staff	• Receive audit plan • Confirm dates of audit • Provide documents • Complete audit non-conformances • Approve audit report • Provide timely responses to audit findings
Quality Assurance (QA)	• Develop internal audit plan • Conduct audit and complete audit report • Provide audit report to management • Following up on audit responses and action implementation

4.0 REFERENCES AND RELATED DOCUMENTS

Document Number	Title
N/A	International Society for Biological and Environmental Repositories (ISBER) Best Practices – current edition
BMC-SOP-17	Documenting and Managing Corrective and Preventative Actions
BMC-TMP-09	Internal Quality Audit Plan
BMC-TMP-10	Internal Quality Audit Checklist
BMC-TMP-11	Internal Quality Audit Report

5.0 DEFINITION OF TERMS

Term	Definition
Corrective Action Preventative Action (CAPA)	Improvements to a process taken to eliminate or reduce non-conformances or other undesirable outcomes.
Internal Audit Plan	An approved document describing the specific audits to be conducted by QA quarterly for a given year. The plan includes the scope, rationale for the scope, and the planned timing for each audit.
Internal Quality Audit	An independent examination and evaluation of the quality system requirements through assessment of personnel, procedures, processes, and/or products, by individual(s) independent of the function being reviewed. Audits are performed to provide an assessment of a system's internal controls.
Non-Conformance	An unexpected condition or event in which any characteristics do not conform to specifications required and/or stated. This may include failures, deficiencies, defects, deviations, and malfunctions.
Observations	A potential issue that could lead to a non-conformance. This could be considered an opportunity for improvement and does not require immediate corrective action.

6.0 PROCEDURE

6.1 Overview

6.1.1 QA is responsible for planning and implementation of internal quality audits.

6.1.1.1 Creates the internal audit plan.

6.1.1.2 Conducts the audit and completes the audit reports.

6.1.1.3 Reports audit results to management.

6.1.1.4 Performs follow-ups on audit responses and action implementation.

6.2 Internal Audit Plan

6.2.1 QA will determine which processes will be audited for a particular quarter. A schedule will be created (see BMC-TMP-09).

6.2.1.1 Three to four processes and associated procedures will be audited per quarter.

6.2.1.2 Other means for inclusion into the audit plan is as follows:

- Changes to a procedure or process
- Known deviations
- Outstanding corrective actions
- Request by management
- Follow-up from prior audit

6.2.2 QA will complete Internal Audit Checklist, BMC-TMP-10 for procedures being audited.

6.2.3 QA develops Internal Audit Plan based on input from the checklist.

6.2.4 BMC management and QA review and approve the audit plan.

6.3 Conducting an Audit

6.3.1 Based on the system/equipment being audited, QA will determine which documents will be needed to perform the audit and identify the specific documents.

6.3.2 A minimum of three examples of each document will be provided to ensure that a representative sample is obtained.

6.3.3 Two weeks prior to initiation of an audit, a detailed list of documents needed will be requested by QA.

6.3.4 QA reviews documentation related to the audit scope including procedures, records, prior audit results, deviations, and other relevant documentation.

6.3.5 QA observes processes and relevant area activities as appropriate.

6.3.6 QA identifies observations and non-conformances during the audit.

6.3.7 QA uses audit ratings as a means to quantify the audit observations per the following table:

Classification	Definition
Critical	A serious deficiency with company standards, procedures, and/or current regulatory requirements or expectations that will provide an immediate and significant risk to product quality, patient safety or data integrity.
Major	A serious deficiency with company standards, procedures, and/or current regulatory requirements or expectations that will potentially provide an immediate and significant risk to product quality, patient safety or data integrity.
Minor	One that does not meet the criteria for classification of major or critical but is a departure from best practices and requires action(s) to improve the quality and/or efficiency of the systems used.
Recommendations / Comments	Suggestions given on how to improve systems or procedures that may be compliant at this time but if left unattended may become a compliance issue.

6.3.8 Assessments of non-conformances should be supported by at least one example of objective evidence.

6.3.9 Recommendations for performance improvement may be included.

6.4 Audit Reporting

6.4.1 QA prepares a detailed written Internal Audit Report, BMC-TMP-11, of audit observations upon completion of an audit.

6.4.2 QA shares reports with BMC management.

6.4.3 QA discusses audit observations with BMC management to ensure agreement.

6.5 Audit Response

6.5.1 BMC management responds to assessments of non-conformances. The proposed audit response may be developed with or without the collaboration of QA.

6.5.2 BMC management documents the response and submits to QA by the requested date. The final audit response must be reviewed and acknowledged by the BMC Director.

6.5.3 If the response cannot be provided by the request date, a mutually agreeable timeline for completion for the response is determined and documented.

6.5.4 Once received, the auditor reviews the response provided and determines the acceptability of the response. If the response is not acceptable, QA notifies management. If needed, a meeting is arranged to resolve any outstanding items.

6.5.5 Once a mutually agreeable response has been received, the audit is considered to be closed.

6.6 Audit Follow-up

6.6.1 An audit follow-up may be initiated at the discretion of QA in response to any of the following:

- Serious non-compliance issues
- Non-conformances requiring an extended period for resolution
- Instances of recurring non-conformances
- BMC Management request

7.0 APPENDICES

7.1 Not applicable.

8.0 REVISION HISTORY

Revision No.	Section	Change Description/Justification	Date
1.0	All sections	Internal audit was a part of SF-1-08 (Quality Oversight) SOP. It will now be a separate SOP. SF-1-08 will be retired.	03OCT2024 See D-23-08