INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: Quality Management

CHAPTER: 1-Administration and Quality Oversight

SOP #: SF-1-8.06

SUPERSEDES SOP#: N/A

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1. REVISION
   1.1. Significant changes incorporated include:
      1.1.1. Section 3.2 added to define personnel executing the QA/QMS system.
      1.1.2. Step 3.7 revised to define that the auditor is *not* required to be familiar with the specific work being reviewed, but the auditor cannot be directly involved in the performance of procedures being audited.
      1.1.3. To align with Section 3.2 revisions and current practices, **Step 4.1** was revised to define that scope of procedure is limited to internal audits performed by a QC *Consultant* and/or performed by SSF *QC personnel* to determine compliance with ISBER guidelines and SSF SOPs by SSF Personnel.
      1.1.4. To align with current practices, **Step 6.4** was revised to define that document control audits are performed by the QC Consultant(s), since SSF Operations personnel are responsible for document control.
      1.1.5. Section 13 Appendix A table revised to reflect:
         1.1.5.1. Corrected SF-2-3 name
         1.1.5.2. Addition of SF-3-3 and SF-3-10
         1.1.5.3. Name changes of SF-3-9 and SF-3-15
      1.1.6. Appendix A updated as follows:
         1.1.6.1. Added SF-1-4 Appendices P & Q, Annex IV Freezer Room maps (page 1, item 3), to reflect the addition of Annex IV
         1.1.6.2. Add OOS Appendix F (page 4, item 2)
         1.1.6.3. Remove specificity of itemizing freezer rooms on page 4, item 5 and page 6, item 4, referring to "freezer rooms" instead.
         1.1.6.4. Added TK 252 to SF-2-2 (page 7, item 6)
         1.1.6.5. Moved Charts up to be referenced under SF-3-1 Appendix A in page 13, item 1.
         1.1.6.6. Added SF-1-4 Appendices Q and P & SF-3-16 Appendix F for TK facility (Item 11, page 14)

1.1.6.7. Added SF-3-2 Appendix F (page 15, item 7) for TK 252
1.1.6.8. Added SF-1-4 Appendix P (page 15, item 8) for TK 252
1.1.6.9. Added SF-3-3 and SF-3-10 in the Miscellaneous Equipment Section
1.1.6.10. Revised SF-3-9 and SF-3-15 sections to reflect new SOP titles
1.1.6.11. Revised SF-3-9 section to reflect Appendix titles
1.1.6.12. Revised SF-3-9 section to reflect that Management Review is not required on any SF-3-9 Appendices (page 18)
1.1.6.13. Revised SF-3-15 item 1 (page 19) to reflect that bi-annual certification is not always provided by Drager.

1.1.7. Appendix C and Appendix D revised to reflect:
1.1.7.1. Addition of SF-3-3 and SF-3-10
1.1.7.2. Name changes of SF-3-9 and SF-3-15

2. PURPOSE

2.1. This Standard Operating Procedure (SOP) describes the procedure that is followed by quality assurance personnel to ensure that SSF practices meet ISBER recommendations and comply with SSF SOPs.

3. PRINCIPLE

3.1. The Indiana CTSI Specimen Storage Facility (SSF) is committed to providing a storage facility for Principal Investigators performing bio-banking activities that satisfy all applicable "best practice recommendations." ISBER defines Quality Assurance as: "…an integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process, or item, is of the type and quality needed for the project." ISBER recommends that each repository have a Quality Assurance Program/Quality Management System (QA/QMS) or adhere to a QA program of an associated organization. The QA program describes the storage facility's commitment to Quality Assurance, describes the approach used to ensure that the requirements of the QA program are met, and defines the methods used to review procedures and records to assess the efficacy and quality of repository operations.

3.2. The QA/QMS system is executed by QA Personnel, consisting of QC Consultant(s) and SSF QC Personnel.
3.2.1. SSF QC Personnel include the SSF QA Specialist and SSF personnel as assigned by SSF Management.
3.2.2. QC Consultant and QA Specialist roles are defined in SF-1-3, SOP for Organization: Directorship, Staffing, Oversight Committee.

3.3. Personnel performing quality assurance functions for the SSF are not required to have responsibilities limited solely to quality assurance.

3.4. Internal System/equipment audits are conducted minimally four times per year, but the interval between audits is not further defined and may vary dependent upon the needs of the SSF and the auditor's availability. At the discretion of the auditor and SSF Management, site visits may be limited to occur three times per year with an additional audit to consist only of a review of documentation for the systems subject to audit.

3.5. QA personnel are responsible for assuring compliance with all SOPs, policies and regulatory requirements.

3.6. QA personnel are responsible for inspecting and approving specimen management and storage practices within the SSF.

3.7. QA personnel are responsible for managing audits which cover the implementation of all SOPs that govern the repository. The individual conducting the audit cannot be directly involved in the performance of procedures being audited.

3.8. Practices by clients/investigators outside of SSF personnel are NOT included in this Quality Management Plan.

4. SCOPE
   4.1. The scope of this procedure is limited to internal audits performed by a QC Consultant and/or performed by SSF QC personnel to determine compliance with ISBER guidelines and SSF SOPs by SSF Personnel.
   4.2. External audits are described in SOP SF-1-11 SSF Regulatory and Client/User Audits.
   4.3. Compliance with IU Health & Safety directives is primarily assessed by the IU Department of Environmental Health & Safety (EHS).
5. MATERIALS
   5.1. N/A
6. PROCEDURAL OVERVIEW FOR USING AUDIT TEMPLATES TO CONDUCT AN AUDIT
   6.1. Templates in Appendix A include lists of auditable items grouped by major SSF system/equipment and are identified by a corresponding SOP number/title. Documented Approval of an Audit Template (or revision thereof) is performed as defined in the SOP for Controlled Document Management (SF-1-6).
      6.1.1. Audit templates are continually developed and modified by Quality Assurance personnel (with input from SSF personnel, as needed) as appropriate for SSF systems/equipment and may be utilized in an audit without documented approval before being incorporated into this SOP.
      6.1.2. As soon as practical, incorporate modifications to existing templates and add new templates to Appendix A.
      6.1.3. Audit templates are exempt from the requirement defined in SOP 1-6 indicating that each template have a documented Effective and Obsolete date and are considered “effective” at the time of use.
   6.2. In addition to Point 6.1 above, each SSF System/Equipment Audit template contains sections for documentation of each of the following:
      6.2.1. Audit response due date (typically 30 days after the audit report is submitted)
      6.2.2. A list of corresponding documents to be reviewed in order to assess compliance for the respective audit item
      6.2.3. Summary of auditor’s assessment of the items audited
      6.2.4. Acceptability of received responses intended to address any non-conformances
      6.2.5. Items to be audited which have not been pre-defined
   6.3. Not all items on a template must be reviewed at a given timepoint. Items should be selected so as to ensure multiple aspects of a system are periodically reviewed.
   6.4. Since SSF Operations personnel are responsible for document control, any audit of the document control functions is performed by the QC Consultant(s).
   6.5. The pre-defined lists of auditable items are not intended to limit or restrict the conduct of any audit with regard to both the items being audited and the documents being reviewed.
7. PROCEDURE FOR SYSTEM/EQUIPMENT AUDIT PREPARATION
   7.1. Choose one or more SSF systems/equipment to audit and select the corresponding audit template to further refine the audit scope. Systems/equipment selected for audit (and the respective audit

scope for that system/equipment) are chosen at the discretion of the auditor and may be based on one or more of the following:

7.1.1. Follow-up from prior audit
7.1.2. Number of corresponding deviations or associated observations (direct or data review)
7.1.3. Perceived impact of procedural change
7.1.4. Relevance to pending regulatory or client audits
7.1.5. SSF Management request
7.1.6. Audit history
7.1.7. Length of time since last audit
7.1.8. Random selection

7.2. An example of a quarterly audit schedule is provided as Appendix C.

7.3. The proposed audit scope and proposed timeline for audit conduct is submitted to SSF Management for approval and once approved; (electronic approval is sufficient) the list of required documents is developed as described in Steps 7.6 & 7.7 below.

7.4. If an audit item is not pre-defined on the audit template, provide a brief description of the item to be assessed and indicate which documents are needed to complete the review. The item can be added to the respective template as a pre-defined item at the auditor's discretion.

7.5. Log the audit on the audit log (Appendix B) and record the following as the audit progresses:

7.5.1. Audit initiation date
7.5.2. Name primary auditor
7.5.3. Brief description of audit scope
7.5.4. Audit report submission date
7.5.5. Response due date
7.5.6. Response receipt date (Assumed to be the audit close-out date unless otherwise noted)
7.5.7. Close-Out Date
7.5.8. Requirement to perform follow-up
7.5.9. Follow-up date (as applicable)

7.6. Based on the system/equipment being audited, determine which document forms will be needed to perform the audit and identify the specific documents needed for the review.

7.6.1. Where appropriate, request that a minimum of 3 examples (e.g. 3 months) of each form be provided to ensure that a representative sample is obtained.

7.6.2. Where appropriate, request that the documentation be provided for multiple pieces of the same type of equipment. Use ($\sqrt{n}$ +1) as the ideal number of units to review.

Example A: If the Mechanical Refrigeration Unit Storage Room Operation is the system being audited and the audit consists of a review of the monthly maintenance logs, request that SF-2-1 Appendix B be provided for the months of February, April and May.

Example B: If the Mechanical Refrigeration Unit is the equipment being audited, and the audit consists of a review of the Daily/Weekly/Monthly logs, and there are 25 units, request that SF-3-1 Appendix A/C be provided for the months of March, June and November for 6 different units [($\sqrt{25}$) +1 = 6].

7.7. At least 2 weeks prior to initiation of an audit, make a detailed list of the documents needed to perform the review and submit the request to SSF personnel.

7.7.1. The list may be documented directly on the audit template form for simplicity.
7.7.2. For additional clarity, an estimate of the number of pages of documentation expected from SSF personnel in response to a respective item may be provided by the auditor.

7.7.2.1. If the number of pages of documentation prepared by SSF personnel far exceeds the estimated pages expected figure provided by the auditor, it may be beneficial to discuss the differential with the auditor before providing many more pages than expected by the auditor.

7.7.3. The auditor retains a list of all requested documents.

7.8. SSF personnel perform the following:

7.8.1. Obtain copies of the requested documents and perform a cursory review of the records to determine if any of the following are relevant for the requested documents:

7.8.1.1. Related documents are applicable as indicated on the audit template (i.e. access control records or circular charts)

7.8.1.2. Deviations filed

7.8.1.3. OOS conditions

7.8.1.4. Alarms

7.9. If additional documents are needed by the auditor, the associated documents are copied and provided to the auditor to fulfill the original request.

Example C: For the audit described in example B above, SSF personnel copy and review the specified documents requested and determine that one deviation, two OOS conditions and one alarm are applicable for the requested records. All of these documents are copied and provided to the auditor to fulfill the initial request.

7.10. If the number of records requested cannot be provided by the requested date, contact SSF Management and the auditor to determine an appropriate course of action.

7.11. SSF personnel provide the auditor with a copy of the original request to indicate that the requested documents are ready for review.

8. PROCEDURE FOR DOCUMENTING AND REPORTING AUDIT RESULTS

8.1. Perform the procedural observation (as appropriate). Review the requested documents (along with any associated documents provided) and determine the level of conformance of the documentation to SSF/ISBER directives.

8.2. Assessments can be documented directly on the audit template in summary format for submission to SSF Management. Copies of documents supporting any non-conformances may be provided for clarity or alternately, a separate, detailed description of the assessment can be provided to SSF Management.

8.3. Assessments of "non-conformance" should be supported by at least one example of objective evidence.

8.4. Recommendations for performance improvement may be documented in the Observation Summary column at the auditor's discretion, but do not require a response from SSF Management.

8.5. Submit the draft audit report and supporting evidence to SSF Management (electronic submission is acceptable). Retain relevant correspondence to file with the audit report.

8.6. Complete Appendix D once the draft audit report has been reviewed by SSF Management and all clarifications are made and/or discrepancies resolved, the audit report is considered final and Appendix B is updated by QA personnel. The audit response date is calculated from the finalization date of the audit report.

8.7. Once completed, Appendix D is retained by SSF personnel as evidence of the audit summary and close-out.

9. PROCEDURE FOR AUDIT RESPONSE

9.1. SSF Management responds to any assessments of "non-conformance". The proposed audit response may be developed with or without the collaboration of the auditor.

9.2. SSF Management documents the response (and any evidence thereof) and submits the response to the auditor by the requested date. The final audit response must be reviewed and acknowledged by the SSF Director (electronic acknowledgement is acceptable).
9.3. If the response cannot be provided by the request date, a mutually agreeable timeline for completion of the response is determined and documented.
9.4. Once received, the auditor reviews the response provided and determines the acceptability of the response. If the response is not acceptable, the auditor notifies SSF Management. If needed, a meeting is arranged to resolve any outstanding items.
9.5. Once a mutually agreeable response has been received, the audit is considered to be closed. QA personnel document the audit close-out date on Appendix B.
9.6. Once completed, Appendix D is retained by SSF personnel as evidence of the audit summary and close-out.

10. PROCEDURE FOR AUDIT FOLLOW-UP
10.1. An audit follow-up may be initiated at the auditor's discretion in response to any of the following:
10.1.1. Serious non-compliance matters requiring a more intensive review
10.1.2. Non-conformances requiring an extended period for resolution
10.1.3. Instances of recurring non-conformance
10.1.4. SSF Management request
10.2. When audit follow-up is warranted, indicate the need to perform follow-up on the audit template form and in the audit log. Provide a tentative date for the initiation of the audit follow-up.

11. REFERENCES
11.1. ISBER Best Practices – current version

12. DOCUMENTATION
12.1. Completed audit checklists and corresponding responses are retained as described in SOP SF-1-6 (SOP for Controlled Document Management).
12.2. Completed audit checklists and corresponding responses are considered to be confidential documents and are not disclosed without prior approval of the SSF Director and QA.
12.3. Deviations to this SOP are managed per SOP SF-1-9 Deviation Management.

13. APPENDICES

13.1. The current version of each of the following appendices is used to implement this SOP:

Appendix A: Audit Checklist Template (22 Pages)

	SOP ID	SOP Description
1	SF-1-4	Managing Storage Space
2	SF-1-5	Personnel Training
3	SF-1-6	Controlled Document Management
4	SF-1-10	OOS Response & Management
5	SF-1-13	Housing GLP Collections
6	SF-2-1	Mechanical Refrigeration Units Storage Room Operation
7	SF-2-2	LN_2 System
8	SF-2-3	Controlled Access Operations
9	SF-2-4	Alarm System Management & Response
10	SF-3-1	Mechanical Refrigeration Units
11	SF-3-2	Liquid Nitrogen Freezer Units
12	SF-3-3	Sensit P100 Personal O_2 Monitors
13	SF-3-6	Timers
14	SF-3-7	Thermometer
15	SF-3-9	Drager Quick Air Emergency Escape Breathing Apparatus Units
16	SF-3-10	Scott ELSA Emergency Escape Breathing Device
17	SF-3-15	Drager Pac 5500 Personal O_2 Monitor
18	SF-3-16	-80 °C LN_2 Units
19	SF-1-7, 1-9, 1-11, 1-12	Miscellaneous Administrative SOPs
TBD	TBD	Additional as applicable

Appendix B: Audit Log (1 Page)

Appendix C: Quarterly Audit Scheduling Template (1 Page)

Appendix D: Internal Audit Summary Document Template (1 Page)

	SF-1-4 Managing Storage Space Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Storage Request / Master Study Log completed Request Forms entered on study Log Good Documentation Practices followed	SF-1-4 Appendix A & B Deviation Forms		
2	Storage Agreements completed Verify for 3 units that the actual location is as assigned Good Documentation Practices followed	SF-1-4 Appendix D Deviation Forms		
3	Templates for Storage Locations are updated and available	Please provide copies of the current and previous versions of the following templates/appendices: E, F, G, H, I, K, M, P[1], and Q[1]		
4	Training Documentation is complete for Personnel Completing Logs Good Documentation Practices followed	Training records for SOP version in effect		
5	Current form versions being used	Corresponding SOP		
6	*(Define)*			
7				
8				

[1]When effective.

	SF-1-5 Personnel Training Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Prerequisite Training & Signature Form is complete for individual. Good documentation practices followed	SF-1-5 Appendix A		
2	SSF Training Plan is complete for individual and updated minimally on an annual basis Good documentation practices followed	SF-1-5 Appendix B		
3	Read & Understand Training Forms are completed prior to individual performing SOP-defined activities. *(*Performance verified in multiple Templates)* Good documentation practices followed	SF-1-5 Appendix C		
4	Technical Training Forms are completed prior to individual performing SOP-defined activities. *(*Performance verified in multiple Templates)* Good documentation practices followed	SF-1-5 Appendix D *(As defined in Appendix G)*		
5	Individual documents re-training prior to performing activities which they have not performed in the previous calendar year. Good documentation practices followed	SF-1-5 Appendix C SF-1-5 Appendix D		
6	Retraining requirements defined in CAPAs and deviations are appropriately documented for appropriate individuals. Good documentation practices followed	SF-1-5 Appendix C SF-1-5 Appendix D		
7	Individuals signing as "trainers" are qualified as such per current version of SF-1-5 Good documentation practices followed	SF-1-5 Appendix C SF-1-5 Appendix D		
8	Seminar Training Forms are appropriately completed Good documentation practices followed	SF-1-5 Appendix E		
	(Define)			

	SF-1-6 Controlled Document Management Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Table of Contents accurately reflects contents of each manual. Effective dates listed in Table of Contents accurately reflect dates listed on corresponding SOPs Good Documentation Practices followed	Various		
2	Electronic copies of Active SOPs are available	Various		
3	Original SOPs are maintained in the SSF Operations Office	Various		
4	Official copies of SOPs are appropriately identified	Various		
5	Obsolete SOPs and forms (as applicable) are appropriately identified, archived and accompanied by a completed Change Control form Change Control form is completed accurate, and approved Good Documentation Practices followed	SF-1-6 Appendix C		
6	Form versions in Form Logbook accurately reflect form versions in approved SOPs	Various		
7	Effective Templates contain and effective date Obsolete Templates are appropriately archived and contain both an effective and obsolete date.	Various		
8	Postings accurately reflect the version contained in the current SOP.	Various		
9	Archived documents not stored in archive location have been appropriately logged out and can be produced (as applicable) by identified individual.	SF-1-6 Appendix B		
10	Training Documentation is complete for personnel performing document control activities Training Documentation is complete for personnel completing forms and logs Good Documentation Practices followed	Training records for SOP version in effect		
11	Current & archive records for the following are appropriately stored, identified and organized as defined in the current version of SF-1-6: Facility, Equipment, Training, Deviations, Audits,	Various		
12	*(Define)*			
13				

	SF-1-10 OOS Response & Management Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	OOS Occurrence Log completed as appropriate Review completed Good Documentation Practices followed	SF-1-10 Appendix C		
2	OOS Response Logs completed as appropriate Management Review completed Good Documentation Practices followed	SF-1-10 Appendix A SF-1-10 Appendix F Deviation Forms		
3	OOS Specimen relocation Record completed as appropriate Good Documentation Practices followed	SF-1-10 Appendix B Deviation Forms		
4	Corresponding Alarm Reports are printed as appropriate. All alarm logs contain an adequate description of the response per SF-2-4 Good Documentation Practices followed	Alarm Reports		
5	Personnel completing the logs for which access to freezer rooms was required are authorized to access as defined in SF-2-3	SF-2-3 Appendix B Deviation Forms		
6	Training Documentation is complete for Personnel completing logs Good Documentation Practices followed	Training records for SOP version in effect		
7	Current form versions being used	Corresponding SOP		
8	*(Define)*			
9				
10				

	SF-1-13 SOP For Housing GLP Collections Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Access Authorization is complete for each GLP unit and is posted on respective unit. Effective Date is assigned GLP Director Approval (or designee) completed Obsolete Access authorizations (if applicable) contain a "date retired" and SSF Director's signature. Good Documentation Practices followed	SF-1-13 Appendix A SF-1-4 Appendix A SF-1-4 Appendix D Deviations		
2	GLP Monitoring log is completed for each defined parameter Personnel completing logs are listed on the respective access authorization list. OOS values addressed Alarm records generated and contain appropriate documentation as defined in SF-2-4 Management Review completed Good Documentation Practices followed	SF-1-13 Appendix A SF-1-13 Appendix B SF-1-10 Appendix A SF-1-10 Appendix B SF-1-4 Appendix D Deviations Alarm Records		
3	GLP Supplementary Requirements Reporting Forms completed as applicable. Signatory approvals completed. Supplementary Requirements have been implemented as applicable. Good Documentation Practices followed	SF-1-13 Appendix B SF-1-13 Appendix C Deviations		
4	Training documentation is complete for Personnel completing logs Good Documentation Practices followed	Training records for SOP version in effect		
5	Current form versions being used	Corresponding SOP		
6	*(Define)*			
7				

	SF-2-1 Mechanical Refrigeration Units Storage Room Operations Audit Template			
	QA Signature/Date		Response Due:	
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Monthly Room Maintenance Log completed Management Review completed Good Documentation Practices followed	SF-2-1 Appendix B Deviation Forms		
2	Monthly Room HVAC Monitoring Log completed OOS values addressed Alarm records generated and contain appropriate documentation as defined in SF-2-4 Management Review completed Good Documentation Practices followed	SF-2-1 Appendix C SF-1-10 Appendix A SF-1-10 Appendix B Alarm Reports Deviation Forms		
3	Digital NIST Thermometers used to record temperatures have been appropriately calibrated	SF-3-7 Appendix A SF-3-7 Appendix B Deviation Forms		
4	Personnel completing those logs for which access to MRU freezer rooms is required are authorized to access those areas as defined in SF-2-3	SF-2-3 Appendix B Deviation Forms		
5	Training Documentation is complete for Personnel completing logs Good Documentation Practices followed	Training records for SOP version in effect		
6	Current form versions being used	Corresponding SOP		
7	Any alarms generated for the Mechanical Refrigeration Storage Room are printed automatically and contain an adequate description of the response as defined in SF-2-4	Alarm Reports Deviation Forms		
8	*(Define)*			
9				

	SF-2-2 Liquid Nitrogen System Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Daily Use Log completed OOS Values addressed Alarm records generated and contain appropriate documentation as defined in SF-2-4 Management Review completed Good Documentation Practices followed	SF-2-2 Appendix C SF-1-10 Appendix A SF-1-10 Appendix B Deviation Forms Alarm Records		
2	Post-Fill Log completed OOS values addressed Alarm records generated and contain appropriate documentation as defined in SF-2-4 Good Documentation Practices followed	SF-2-2 Appendix E Deviation Forms Alarm Records		
3	Quarterly Assessment completed OOS Values addressed Management Review completed Good Documentation Practices followed	SF-2-2 Appendix B1 Deviation Forms		
4	Annual Valve Assessment completed OOS Values addressed Management Review completed Good Documentation Practices followed	SF-2-2 Appendix B2 Deviation Forms		
5	Expected Use Range Calculation completed Spreadsheet calculations performed per Appendix D Management Review completed X2 (Data + Formulas) Good Documentation Practices followed	SF-2-2 Appendix D (Associated spreadsheet) Deviation Forms		
6	Personnel completing those logs for which access to TK 252 and/or R3-C156 is required are authorized to access TK 252 and/or R3-C156 as defined in SF-2-3	SF-2-3 Appendix B Deviation Forms		
7	Training Documentation is complete for Personnel completing logs Good Documentation Practices followed	Training records for SOP version in effect		

	SF-2-2 Liquid Nitrogen System Audit Template Cont.			
	Item	Documents Requested	Observation Summary	Response Acceptable
8	Current form versions being used	Corresponding SOP		
9	OOS Values documented as appropriate Any alarms generated for the LN_2 System/Low O_2 monitors are printed automatically and contain an adequate description of the response as defined in SF-2-4	SF-1-10 Appendix A Alarm Records Deviation Forms		
10	Appendix F (page 2 of the template) is completed with current contact information, and has an effective date. Obsolete versions of the template are marked with an obsolete date and do not have dates that overlap with any other version.	SF-2-2 Appendix F		
11	LN_2 Weekly System Check and O_2 Cylinder Gauge Readings for E-stop are completed OOS values addressed Management review is completed Good Documentation Practices followed	SF-2-2 Appendix G		

	SF-2-3 Controlled Access Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Controlled Access Change Forms are completed for all personnel as appropriate (authorize/rescind) Individual requesting change is authorized Updated Access Authorization Reports are attached to change forms and are appropriately reviewed. Good Documentation Practices followed	SF-2-3 Appendix B SF-2-3 Appendix E SF-1-5 Appendix A Access Authorization Reports Deviation Forms		
2	Visitor Log is completed as appropriate Good Documentation Practices followed	SF-2-3 Appendices D Deviation Forms		
3	Access by SSF personnel with forgotten cards is documented 1X per day on the visitor log. Good Documentation Practices followed	SF-2-3 Appendix D Deviation Forms		
4	Access by SSF personnel with lost cards is documented 1X per day on the visitor log. Access for the lost card is revoked and documented on the Access Change Form. Good Documentation Practices followed	SF-2-3 Appendix B Access Authorization Reports, SF-2-3 Appendix D Deviation Forms		
5	Emergency access (forced entries) is documented as a deviation Good Documentation Practices followed	Deviation Forms		
6	Training Documentation is complete for Personnel with access (as appropriate) Good Documentation Practices followed	Training records for SOP version in effect		
7	Current form versions being used	Corresponding SOP		
8	Appendix E is completed by authorized individuals for granting/rescinding access authorizations changes for Collaborating Biorepository personnel. Good Documentation Practices followed	SF-2-3 Appendix E		

	SF-2-3 Controlled Access Audit Template Cont.			
	Item	Documents Requested	Observation Summary	Response Acceptable
8	Appendix E is completed by authorized individuals for granting/rescinding access authorizations changes for Collaborating Biorepository personnel. Good Documentation Practices followed	SF-2-3 Appendix E		
9	Completed Templates comply with SOP Directives- No date overlap Good Documentation Practices followed	SF-2-3 Appendix F		
10	Appendix G is completed appropriately when the monthly Access Control records are reviewed. Good Documentation Practices followed	SF-2-3 Appendix G		
11	Appendix H is completed appropriately when the annual Access Control Records are reviewed. Good Documentation Practices followed	SF-2-3 Appendix H		
12	Appendix K is completed annually for doors listed CFS documentation of performance is attached Good Documentation Practices followed	SF-2-3 Appendix K		
13	Appendix L is completed appropriately, documenting investigation of all door alarms. Good Documentation Practices followed	SF-2-3 Appendix L Deviation Forms		

	SF-2-4 Alarm System Management and Response Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Maintenance & Function Verification Log completed OOS values addressed Management Review completed Good Documentation Practices followed	SF-2-4 Appendix C Deviation Forms		
2	Siemens Alarm System Change Approval Log completed as appropriate Management Review completed Good Documentation Practices followed	SF-2-4 Appendix E Deviation Forms		
3	SSF Siemens Alarm Response Guide completed as appropriate Management Review completed Good Documentation Practices followed	SF-2-4 Appendix F SF-2-1 Change control SF-2-2 Change control SF-3-1 Change control SF-3-2 Change control SF-3-16 Change control Deviation Forms		
4	LN_2 Alarm Testing Worksheet is completed as defined Management Review completed Good Documentation Practices followed	SF-2-4 Appendix J		
4	Mechanical Refrigeration Unit Alarm Testing Worksheet is completed as defined Management Review completed Good Documentation Practices followed	SF-2-4 Appendix K		
6	Siemens Service Report Form is completed and filed as Appropriate	SF-2-4 Appendix L		
7	Alarm Reports are printed as appropriate. All alarm logs contain an adequate description of the response per SF-2-4 Good Documentation Practices followed	Alarm Reports *(Section 6.6.2.3)*		

	SF-2-4 Alarm System Management and Response Audit Template cont.			
	Item	Documents Requested	Observation Summary	Response Acceptable
8	Documentation indicating verification of the Siemens return to normal status is noted for each alarm on the alarm print-out	Alarm Reports *(Section 6.2.3, 6.6.4)*		
9	Confirmation that RENO has sent an e-mail alarm notification each workday following the 7 AM daily auto-reboot of the Siemens Alarm Server exists and is documented on Appendix N. *(Section 6.6.3)*	SF-2-4 Appendix N		
10	Daily review of the Siemens graphic, weekly review of APOGEE Insight Services Startup Parameters, and weekly system backup and transfer is documented on Appendix N. *(Section 6.6.4)* Good Documentation Practices followed	SF-2-4 Appendix N		
11	Training Documentation is complete for Personnel documenting on forms and responding to alarms (as appropriate) Good Documentation Practices followed	Training records for SOP version in effect		
12	Current form versions being used	Corresponding SOP		
13	*(Define)*			

	SF-3-1 Mechanical Refrigeration Units + SF-3-16 -80° C LN_2 Units Audit Template			
	QA Signature/Date		Response Due:	
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Daily/Weekly/Monthly Logs completed OOS values addressed Alarm records generated and contain appropriate documentation as defined in SF-2-4 Charts labeled with dates, Unit ID, tech initials Management Review completed Good Documentation Practices followed	SF-3-1 Appendix A Charts SF-3-1 Appendix C SF-3-16 Appendix A SF-1-10 Appendix A SF-1-10 Appendix B Deviation Forms Alarm Records		
2	Annual Logs completed OOS values addressed Management Review completed Good Documentation Practices followed	SF-3-1 Appendix B Deviation Forms Alarm Records		
3	Biennial Logs completed OOS values addressed Management Review completed Good Documentation Practices followed	SF-3-1 Appendix F Deviation Forms Alarm Records		
4	Semi-Annual and Annual Logs completed OOS values addressed Management Review completed Good Documentation Practices followed	SF-3-16 Appendix B Deviation Forms Alarm Records		
5	Defrost Logs completed OOS values addressed Management Review completed Good Documentation Practices followed	SF-3-16 Appendix D Deviation Forms Alarm Records		
6	Training Documentation is complete for Personnel completing Logs Good Documentation Practices followed	Training records for SOP version in effect		
7	Current form versions being used	Corresponding SOP		

	SF-3-1 Mechanical Refrigeration Units + SF-3-16 -80° C LN_2 Units Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
8	Mechanical Refrigeration Unit Quarterly Temperature Calibration verifications performed OOS values appropriately addressed Management review completed Good Documentation Practices followed	SF-3-1 Appendix D		
9	Mechanical Refrigeration Unit Re-calibration Investigation Forms completed as required Management review completed Good Documentation Practices followed	SF-3-1 Appendix E		
10	Any alarm generated for a mechanical refrigeration unit is printed automatically and contains an adequate description of the response as defined in SF-2-4	Alarm Records		
11	Completed Templates comply with SOP Directives- No date overlap Good Documentation Practices followed	Template Maps (SF-1-4, Appendix F, I, M, P, and Q[1]) SF-3-16 Appendix C SF-3-16 Appendix F		

[1]When effective.

	SF-3-2 Liquid Nitrogen Freezer Units Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Daily &/Monthly Logs completed OOS values addressed Alarm records generated and contain appropriate documentation as defined in SF-2-4 Management Review completed Good Documentation Practices followed	SF-3-2 Appendix A SF-1-10 Appendix A SF-1-10 Appendix B SF-1-10 Appendix C Deviation Forms Alarm Records		
2	Semi-Annual, Annual Log completed OOS values addressed Management Review completed Good Documentation Practices followed	SF-3-2 Appendix B Deviation Forms Alarm Records		
3	Training Documentation is complete for Personnel completing logs Good Documentation Practices followed	Training records for SOP version in effect		
4	Current form versions being used	Corresponding SOP		
5	NIST thermometer used for calibration within its calibration period.	NIST certification documentation		
6	Any alarms generated for an LN_2 freezer are printed automatically and contain an adequate description of the response as defined in SF-2-4	Alarm Records Deviation Forms		
7	Completed Templates comply with SOP Directives- No date overlap Good Documentation Practices followed	SF-3-2 Appendix C SF-3-2 Appendix F Deviation Forms		
8	Completed Templates comply with SOP Directives- No date overlap Good Documentation Practices followed	SF-1-4 Appendix E SF-1-4 Appendix P[1] Deviation Forms		

[1]When effective.

	Miscellaneous Equipment SOPs			
	SF-3-3 Sensit P100 Personal O_2 Monitors Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Sensit P100 Personal O_2 Monitor Manufacturer Maintenance Log completed Sensit EU Declaration of Conformity (DoC) completed and appropriately filed Management Review completed Good Documentation Practices followed	SF-3-3 Appendix A Deviation Forms		
2	Sensit P100 Personal O_2 Monitor Weekly and As-Needed Bump Test & Fresh Air Calibration Maintenance Log completed Good Documentation Practices followed	SF-3-3 Appendix B Deviation Forms		
3	Training Documentation is complete for Personnel completing logs Good Documentation Practices followed	Training records for SOP version in effect		
4	Current form versions being used	Corresponding SOP		
5	*(Define)*			

	SF-3-6 Timers Audit Template			
	Item	Documents Requested *	Observation Summary	Response Acceptable
1	SF-3-6 (Timers) Equipment function verification records/calibration records/all maintenance records completed as required Management review documented Training Documentation is complete for Personnel completing logs Good Documentation Practices followed	SF-3-6 Appendix A forms Training records for SOP version in effect		

	SF-3-7 Thermometer Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	NIST Calibration Certificates for units currently in use	Please provide the MS Excel listing of all NIST units currently in service to include documentation of: • Unit Type (Thermometer/Probe) • Unit Model Description • Unit Serial Number • SSF-assigned Unit ID • Calibration Date • Calibration Due date		
2	Thermometer Maintenance Log completed Physically look at 3 thermometers and verify presence on log and accuracy of location Good Documentation Practices followed	SF-3-7 Appendix A Deviation Forms		
3	Thermometer Location Usage Log completed OOS values addressed Management Review completed Good Documentation Practices followed	SF-3-7 Appendix B Deviation Forms		
4	NIST Calibration Log completed OOS values addressed Management Review completed Good Documentation Practices followed	SF-3-7 Appendix C Deviation Forms		
5	Thermometer Calibration Verification Worksheet completed Management Review completed Good Documentation Practices followed	SF-3-7 Appendix D2 Deviation Forms		
6	Training Documentation is complete for Personnel completing logs Good Documentation Practices followed	Training records for SOP version in effect		
5	Current form versions being used	Corresponding SOP		
6	*(Define)*			

	SF-3-9 Drager Quick Air Emergency Escape Breathing Apparatus Units Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Drager Quick Air Emergency Escape Breathing Apparatus Usage Log completed Good Documentation Practices followed	SF-3-9 Appendix A Deviation Forms		
2	Drager Quick Air Emergency Escape Breathing Apparatus Weekly and Monthly Maintenance Log completed for each SSF unit Good Documentation Practices followed	SF-3-9 Appendix B Deviation Forms		
3	Drager Quick Air Emergency Escape Breathing Apparatus Annual / Other Maintenance Log completed for each SSF unit Good Documentation Practices followed	SF-3-9 Appendix C Deviation Forms		
4	Personnel documenting entries in Appendices SF-3-9 B & C are authorized to access C156 as defined in SF-2-3.	SF-3-9 Appendix B SF-3-9 Appendix C SF-2-3 Appendix B Deviation Forms		
5	Training Documentation is complete for Personnel completing Logs Good Documentation Practices followed	Training records for SOP version in effect		
6	Current form versions being used	Corresponding SOP		
7	*(Define)*			
8				
9				

	SF-3-10 Scott ELSA Emergency Escape Breathing Device (EEBD) Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Scott ELSA Emergency Escape Breathing Device Usage Log completed Good Documentation Practices followed	SF-3-10 Appendix A Deviation Forms		
2	Scott ELSA Emergency Escape Breathing Device Weekly and Monthly Maintenance Log completed for each SSF unit Good Documentation Practices followed	SF-3-10 Appendix B Deviation Forms		
3	Scott ELSA EEBD Service Maintenance Log completed for each SSF unit Good Documentation Practices followed	SF-3-10 Appendix C Deviation Forms		
4	Personnel documenting entries in Appendices SF-3-10 B & C are authorized to access TK 252 as defined in SF-2-3.	SF-3-10 Appendix B SF-3-10 Appendix C SF-2-3 Appendix B Deviation Forms		
5	Training Documentation is complete for Personnel completing Logs Good Documentation Practices followed	Training records for SOP version in effect		
6	Current form versions being used	Corresponding SOP		
7	*(Define)*			
8				
9				

	SF-3-15 Drager Pac 5500 Personal O_2 Monitor Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Personal O_2 Monitor Alarm Maintenance Log completed Production Test Reports completed and appropriately filed Management Review completed Good Documentation Practices followed	SF-3-15 Appendix A Deviation Forms		
2	Training Documentation is complete for Personnel completing logs Good Documentation Practices followed	Training records for SOP version in effect		
3	Current form versions being used	Corresponding SOP		
4	*(Define)*			
5				
6				

	Miscellaneous SOPs (SF-1-7; SF-1-9; SF-1-11; SF-1-12) Audit Template			
	Item	Documents Requested	Observation Summary	Response Acceptable
1	Eyewash logs completed Good Documentation Practices followed	SF-1-7 Appendix A		
2	Personnel observed to comply with Lab Specific Bio-Safety Practices	SF-1-7 Appendix E Deviation Forms		
3	Annual Management Review of Safety Practices Performed. Good Documentation Practices followed	SF-1-7 Appendix C		
4	Emergency Phone Tree Good Documentation Practices followed	SF-1-7 Appendix F		
5	All closed deviations are appropriately filed in SSF Operations Office Personnel completing and approving deviation reports are appropriately trained.	SF-1-9 Appendix A Training records for applicable version(s) of SF-1-9		
6	Audit Log completed as defined in SF-1-11 Auditing Entities have documented entry on SSF Visitor log Good Documentation Practices followed	SF-1-11 Appendix A SF-2-3 Appendix D Deviation Forms		
7	Personnel participating in validation efforts are appropriately trained.	Training records for applicable version(s) of SF-1-12		
8	Current form versions being used	Corresponding SOP		
	(Define)			

	SF-1-14 (Sample Receipt and Release SOP)			
	QA Signature/Date		Response Due:	
	Item	Documents Requested	Observation Summary	Response Acceptable
1	SF-1-14 for SSF Sample Intake and Release has been implemented as defined.	Review of Appendices A and B for a selection of samples received or released after 02.01.2015		

Audit Log **Year:**

	Initiation Date	Auditor	Scope	Report Submission Date	Response Due Date *(~Submit + 30)*	Response Receipt Date	Follow-Up Required? Y* / N * *(If Yes, enter Follow-Up Date)*	Close-Out Date
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

Comments: *(Include reference)*

Quarterly Audit Scheduling Template

Quarter	System/Equipment Description	SOP Reference
Q1, Q2, Q3, Q4	Document Control	SF-1-6
Q1	Mechanical Refrigeration Storage Room	SF-2-1
Q1	LN_2 System	SF-2-2
Q1	Controlled Access	SF-2-3
Q1	LN_2 Freezers	SF-3-2
Q1	Timers	SF-3-6
Q2	Misc	SF-1-7, 1-9, 1-11, 1-12
Q2	OOS Response & Management	SF-1-10
Q2	Mechanical Refrigeration Units	SF-3-1
Q2	-80° C LN_2 Units	SF-3-16
Q3	Training	SF-1-5
Q3	SSF Managed Specimen Intake and Release	SF-1-14
Q3	Alarm System Management & Response	SF-2-4
Q4	Managing Storage Space	SF-1-4
Q4	GLP	SF-1-13
Q4	Sensit P100 Personal O_2 Monitors	SF-3-3
Q4	Thermometer	SF-3-7
Q4	Drager Quick Air Emergency Escape Breathing Apparatus Units	SF-3-9
Q4	Scott ELSA Emergency Escape Breathing Device	SF-3-10
Q4	Drager Pac 5500 Personal O_2 Monitor	SF-3-15

SSF Internal Audit Summary Document

A routine internal audit of the SSF was conducted by: _____

- ❑ **The audit consisted of a site visit on _____**
- ❑ **The audit consisted of a review of documentation for the systems listed below.**
- ❑ **The audit consisted of a site visit on _____ and a review of documentation for the systems listed below:**

SOP Reference	System/Equipment Description	Audit (☑)
SF-1-6	Document Control	
SF-2-1	Mechanical Refrigeration Storage Room	
SF-2-2	LN_2 System	
SF-2-3	Controlled Access	
SF-3-2	LN_2 Freezers	
SF-3-6	Timers	
SF-1-7, 1-9, 1-11, 1-12	Misc	
SF-1-10	OOS Response & Management	
SF-3-1	Mechanical Refrigeration Units	
SF-3-16	-80° C LN_2 Units	
SF-1-5	Training	
SF-1-14	SSF Managed Specimen Intake and Release	
SF-2-4	Alarm System Management & Response	
SF-1-4	Managing Storage Space	
SF-1-13	GLP	
SF-3-3	Sensit P100 Personal O_2 Monitors	
SF-3-7	Thermometer	
SF-3-9	Drager Quick Air Emergency Escape Breathing Apparatus Units	
SF-3-10	Scott ELSA Emergency Escape Breathing Device	
SF-3-15	Drager Pac 5500 Personal O_2 Monitor	
(other –define)	*(other –define)*	

❑ A formal response is required by mm.dd.yy

❑ A formal response is not required.

Signed/Dated: _____

Printed Name: _____