| INDIANA Clinical and Translational CTSI Sciences Institute | STANDARD OPERATING PROCEDURE Indiana CTSI Specimen Storage Facility |
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**TITLE:** Organization: Directorship, Staffing, Oversight Committee

**CHAPTER:** 1-Administration and Quality Oversight

**SOP #:** SF-1-3.09

**Issue Date:** 04.27.2022

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**SUPERSEDES SOP#:** N/A

**AUTHORED BY:** _____ **DATE:** 4-25-22
Indiana CTSI SSF Staff

**AUTHORED BY:** _____ **DATE:** 26 APR 2022
Director Indiana CTSI SSF

**QA APPROVAL:** _____ **DATE:** 04.27.2022
Quality Compliance Specialist

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1. REVISION
   1.1. Significant Changes Incorporated in this version include:
      1.1.1. Section 6.4.4 created to define roles of Quality Compliance Personnel and further define the QC Consultant role as employee(s) of Indiana University or contract employees, qualified and appointed by the SSF Director to perform internal QA/QMS oversight duties. Definition of QC Consultant role moved from Section 6.4.3 to Section 6.4.4.
      1.1.2. Appendix A revised to remove SMS Representative, deemed unnecessary by SSF Management and the SSF Oversight Committee, and allow for Purdue and/or Notre Dame Representatives.
      1.1.3. Appendix B revised to add new SOPs and rename existing SOPs to align with currently effective SOPs.

2. PURPOSE
   This Standard Operating Procedure (SOP) describes the personnel of the organization, including the director, management team, oversight committee, technical staff, and consultants. It defines the roles, requirements and responsibilities of each. The SSF provides a management structure for the facility in support of the biorepository and regulatory-controlled specimen storage efforts of multiple principal investigators. This procedure describes the roles of the facility and satisfies guidance set forth in ISBER Best Practices.

3. PRINCIPLE
   The Indiana CTSI Specimen Storage Facility (SSF) is committed to providing a storage facility for Principal Investigators performing bio-banking activities that satisfies current best practices recommendations and meets GLP Regulations and guidances applicable to accepted collections. The SSF strives to provide quality, cost-efficient services to meet the needs of the scientific and medical communities we serve.

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4. SCOPE

The scope of this procedure includes SSF personnel. The specific job duties for personnel are defined via individual training files. Institutional position descriptions are maintained through Human Resources.

5. MATERIALS

N/A

6. PROCEDURE

6.1. Organization Overview: The SSF operates under the overall guidance of the Operations Oversight Committee. The director and/or associate director ensure that policies and procedures developed for SSF operation are consistent with Committee directives.

6.2. **Operations Oversight Committee**

6.2.1. The Operations Oversight Committee (OOC or Committee) provides oversight of the SSF.

6.2.2. The Chair of the Committee must not be SSF Staff or an SSF Director and must be approved by the Clinical and Translational Sciences Institute (CTSI) Director assigned oversight of the SSF. The CTSI is the SSF's funding agency.

6.2.3. The Committee must include at least 3 members in addition to the SSF Director and consists of representatives from biorepositories and regulated storage collections using the SSF. Additional ad hoc consultants may be invited to participate, as deemed necessary by the Committee. Members are appointed by the SSF Director, approved by the Committee, and Committee composition complies with the following CTSI requirements:

6.2.3.1. The majority of voting members are outside of the SSF

6.2.3.2. At least 1 member of the Committee must be outside the CTSI

6.2.3.3. Must include SSF customers

6.2.3.4. Must include at least 1 technical adviser

6.2.3.5. The Committee's findings must be communicated to the CTSI Director and CTSI Oversight Committee at least once per year.

6.2.4. A template for the SSF Organizational chart is provided in Appendix A. Updates to the Organizational Chart are incorporated within one month of receipt of change notification.

6.2.5. Current and obsolete versions of the SSF Organizational chart are maintained in the SSF as defined in Section 9.

6.2.6. A roster of approved personnel for defined roles is defined in the current version of the Organizational Chart. Typical activities expected of individuals are stated; however, these do not supersede responsibilities defined below.

6.2.7. **Operations Oversight Committee Role**

6.2.7.1. Ensures SSF compliance with CTSI directives

6.2.7.2. Meets at least annually to discuss, at minimum, the following *non-SOP defined* topics:

6.2.7.2.1. Core utilization

6.2.7.2.2. Core quality assessment / user satisfaction survey, conducted per ATP guidelines

6.2.7.2.3. User fees, calculated by the CTSI and the SSF Director and approved by Indiana University

6.2.7.2.4. Suitability of new services and equipment purchases

6.2.7.2.5. Funding opportunities (Core equipment grants, Core Pilot grants, etc.)

6.2.7.3. Review is documented on the non-SOP defined CTSI Core Advisory Committee Form, stored in the SSF Management Office.

6.3. **The SSF Management Team Personnel:** The SSF Management Team consists of the following personnel: Director, Associate Director, Operations Manager and Facility Manager.

6.4. **SSF Personnel**

    6.4.1. **Director:** The director of the SSF is qualified by training and experience to manage SSF activities. The director role may be filled by either the primary director or designated alternate.

        6.4.1.1. The Director implements policies of the organization and is responsible for facility operations, including compliance with current national, state and local regulations; and current best practice guidances.

        6.4.1.2. The director will provide the SSF Oversight Committee with access to all facility policies.

            6.4.1.2.1. The director will provide summaries of SSF facility activities, including fiscal management, to the SSF Oversight Committee for their review. The summaries will be provided at least twice each year.

            6.4.1.2.2. The director, with input from the SSF Oversight Committee, will establish SSF storage and monitoring recharge rates for CTSI users. Rates must be approved by Indiana University.

            6.4.1.2.3. The director, with input from the SSF Oversight Committee, will establish external storage and monitoring charge rates for non-CTSI users. Rates must be approved by the IU School of Medicine.

            6.4.1.2.4. The Director is the person with overall responsibility for management of the facility. The Director:

                6.4.1.2.4.1. Makes recommendations for cost-recovery and operations consistent with short and long-term financial goals.

                6.4.1.2.4.2. Ensures that an adequate policy is in place for secure controlled storage for specimens stored in the facility.

                6.4.1.2.4.3. Serves as a liaison to key users.

            6.4.1.2.5. The Director constructs and maintains an organizational structure that delineates the functional relationships within the facility.

            6.4.1.2.6. Candidates for the supervisory and technical staff for the facility are approved by the Director.

            6.4.1.2.7. The Director approves and maintains SSF job duties, defines qualifications, and documents staff responsibilities.

            6.4.1.2.8. The Director ensures that SSF personnel responsible for performing facility activities are adequate in number and experience, and are assigned responsibilities commensurate with their capabilities.

            6.4.1.2.9. The Director is responsible for developing and reviewing employee training programs.

        6.4.1.3. The Director or other responsible party ensures that a Quality Assurance (QA) Program (also termed a Quality Management System or QMS) is in place to ensure that the facility conforms to applicable regulatory guidances and directives and SSF standard operating procedures (SOPs).

        6.4.1.4. The Director requires regular, documented, internal reviews or audits to ensure compliance with the facility SOPs and regulations.

    6.4.2. **Associate Director:** Approved by the Operations Oversight Committee as qualified to fulfill director responsibilities in the absence of, or in conjunction with, the director. At the discretion of the Director, signatory authority may be assigned to the Associate Director.

6.4.3. **Operations and Facility Managers**

NOTE: Operations Manager and Facility Manager roles may be filled by the same individual dependent upon staffing needs, and the following assigned duties may be performed by either the Operations Manager or Facility Manager. Certain duties and responsibilities as referenced in SSF SOPs may also be fulfilled by assigned technical personnel, except as noted below, where delegation to technical personnel is not permitted.

Any SSF SOP which expressly prohibits the delegation of duties of the Operations / Facility Manager supersedes this SOP. It is the responsibility of the SSF Operations / Facility Manager and SSF Director that delegated duties are performed in accordance with the applicable SOP.

**Operations Manager**

6.4.3.1. Possesses sufficient educational background, experience, and training to assure that assigned tasks are performed in accordance with the facility's established procedures. (Delegation not applicable.)

6.4.3.2. Manage the day-to-day scientific operations of the SSF in compliance with SSF SOPs.

6.4.3.3. Serve as liaison between the Principal Investigators of the Biorepositories sharing SSF non-critical spaces, IUSCC Tissue Bank and IUGB, and other Principal Investigators storing samples in the SSF. Provide leadership, guidance, support, and mentoring for coordinators, technicians, and medical staff, including training and performance management as required.

6.4.3.4. Implement SOPs for the SSF.

6.4.3.5. Coordinate operational quality assurance practices for the SSF with director and compliance personnel.

6.4.3.6. Implement Quality Improvement processes as applicable.

6.4.3.7. Support collection of data for the cost of storage to support establishing "recovery costs" charged to facility users.

6.4.3.8. Manage contracts and/or agreements, as required, between SSF and biorepository Principal Investigators for specimen storage.

6.4.3.9. Implement invoicing and resource allocation. Assist in development of the budget for services.

6.4.3.10. Serve as an educational resource to laboratory and investigator personnel with regard to appropriate SSF practices.

6.4.3.11. Communicate directly with the Principal Investigators and refer issues regarding operational policies and processes to the Director for referral to the Operations Oversight Committee, as applicable.

**Facility Manager**

6.4.3.12. Possesses sufficient educational background, experience, and training to assure that assigned tasks are performed in accordance with the facility's established procedures. (Delegation not applicable.)

6.4.3.13. Manage the day-to-day storage and facility operations of the SSF in compliance with SSF SOPs.

6.4.3.14. Manage facility validations.

6.4.3.15. Coordinate facility-related quality assurance practices for the SSF with director and compliance personnel

6.4.3.16. Implement Quality Improvement processes as applicable.

6.4.3.17. Support collection of data for the cost of storage to support establishing "recovery costs" charged to facility users.

6.4.3.18. Manage contracts and/or agreements with regard to equipment constraints, as required, between SSF and biorepository Principal Investigators for specimen storage.

6.4.3.19. Provide facility-related data for the purpose of invoicing and resource allocation.

6.4.3.20. Assist in development of the budget for services.

6.4.3.21. Provides facility oversight and coordinates activities to ensure that the facility is maintained and operates as designed.

6.4.3.22. Manages / Directs facility preventive maintenance, calibration, repair, location, and function verification.

6.4.3.23. Provides oversight for all equipment within the SSF Facility (as applicable) and coordinates activities to ensure that the equipment is maintained and operates as designed.

6.4.3.24. Manages / Directs equipment receipt, preventive maintenance, calibration, repair, location, and function verification.

6.4.3.25. Provides oversight for alarm response management to include coordination of all activities related to the alarm response, alarm investigation and for providing notification to applicable parties as warranted.

6.4.3.26. Contributes to procedure development and training as applicable to use, maintenance, and oversight of equipment and facility.

6.4.3.27. Communicate directly with the Principal Investigators on facility matters and refer issues regarding facility policies and processes to the Director for referral to the Operations Oversight Committee, as applicable.

NOTE: Backup personnel are trained to maintain duties requiring specialized training, such as controlled access and storage management, when primary personnel are unavailable. Primary and Backup personnel are denoted on the Indiana CTSI SSF Key Technical Personnel Responsibility Posting (Appendix B) with a "P" denoting personnel assigned a duty as a Primary task and a "B" denoting personnel assigned the duty in a Backup capacity.

6.4.4. **Quality Compliance Personnel**:

6.4.4.1. **Quality Compliance Consultant:** The Office of Research Administration will provide QA/QMS oversight that is independent of facility personnel and management. The Quality Compliance Consultant(s) may be employees of Indiana University or contract employees and are qualified and appointed by the SSF Director to perform internal QA/QMS oversight duties.

6.4.4.2. **Quality Assurance Specialist:**

6.4.4.2.1. Possesses sufficient educational background, experience, and training to assure that assigned tasks are performed in accordance with the facility's established procedures, with focus on quality assurance and auditing tasks. Note: the QA specialist is not responsible for Quality Oversight and is not responsible for the conduct of formal internal audits performed per SOP SF-1-8.

6.4.4.2.1.1. QA tasks are undertaken at the direction of the SSF Director, SSF Facility Manager, and the Quality Compliance Specialist.

6.4.4.2.2. Adheres to policies and procedures as established by the Director.

6.4.4.2.3. Demonstrates competency in operations for which they have received training and to which they are assigned, with focus on quality assurance and auditing tasks.

6.4.4.2.4. Operates within defined organizational structure and reporting relationships for the SSF.

6.4.5. **Technical Staff**

    6.4.5.1. Possesses sufficient educational background, experience, and training to assure that assigned tasks are performed in accordance with the facility's established procedures.

    6.4.5.2. Adheres to policies and procedures as established by the Director.

    6.4.5.3. Demonstrates competency in operations for which they have received training and to which they are assigned.

    6.4.5.4. Operates within defined organizational structure and reporting relationships for the SSF.

6.4.6. **Consultants**

    6.4.6.1. Technical consultants are utilized periodically to guide policies and procedures. Their role and qualifications shall be documented.

6.4.7. Technical Personnel include Technical Staff and may or may not include the Operations Manager, Facility Manager, and Director, at the Director's discretion.

6.4.8. Appendix B provides a template for Technical Personnel Responsibilities and may be implemented as needed.

7. REFERENCES

    7.1. ISBER Best Practices (Current Version)

    7.2. 21 CFR 58 Good Laboratory Practices, Subpart C, Facilities

8. DOCUMENTATION

    8.1. Documents are retained in the SSF Operation's office per SOP SF-1-6 Controlled Document Management

    8.2. Deviations to this SOP are managed per SOP SF-1-9 Deviation Management
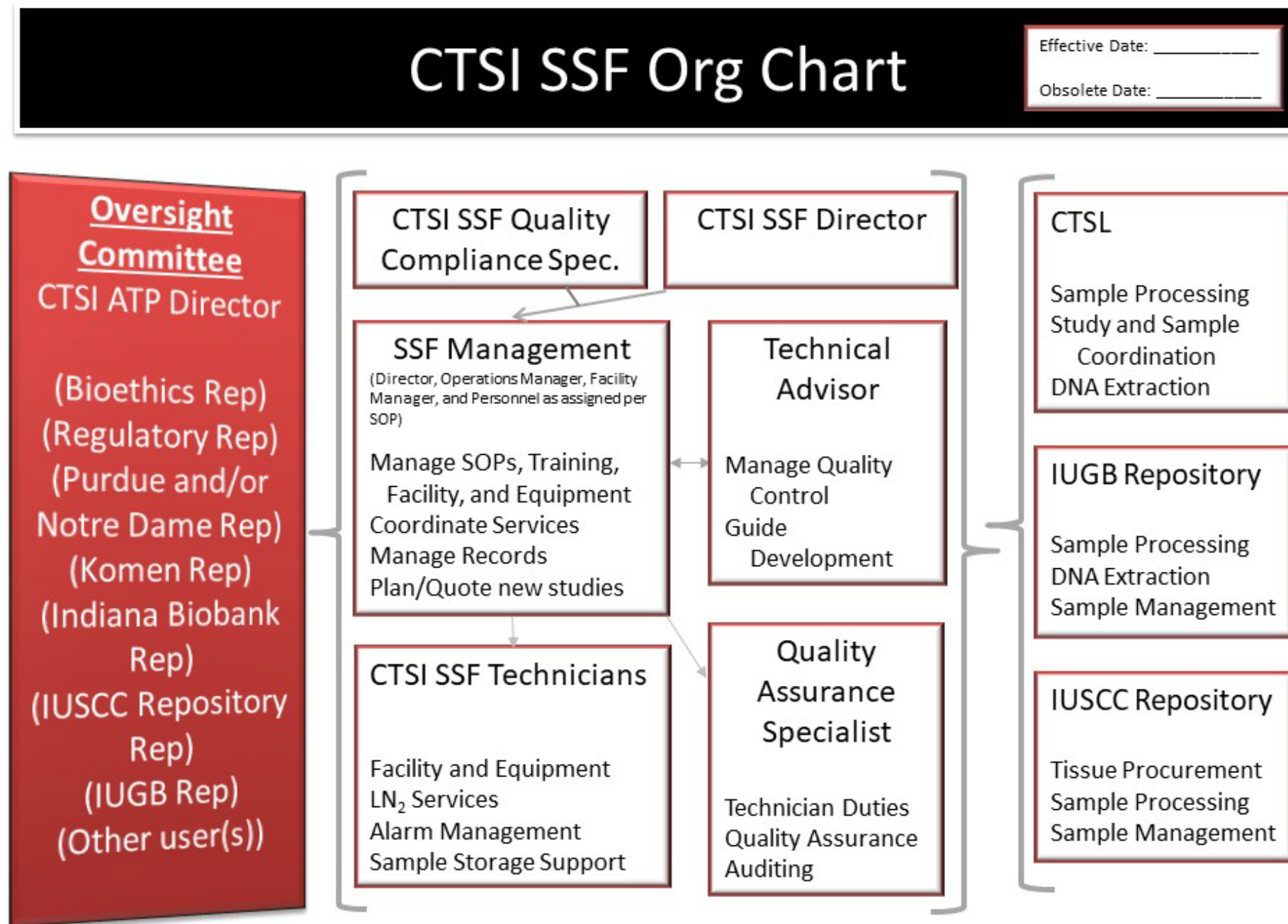
9. APPENDICES

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

        Appendix A: Indiana CTSI SSF Organizational Chart Template (1 Page)

        Appendix B: Indiana CTSI SSF Technical Personnel Responsibility (Template) (1 page)

10. Collaborating Biobank training directive

    10.1. N/A

TEMPLATE

# CTSI SSF Org Chart

Effective Date: _____

Obsolete Date: _____

**Oversight Committee**

CTSI ATP Director

(Bioethics Rep)
(Regulatory Rep)
(Purdue and/or Notre Dame Rep)
(Komen Rep)
(Indiana Biobank Rep)
(IUSCC Repository Rep)
(IUGB Rep)
(Other user(s))

**CTSI SSF Quality Compliance Spec.**

**CTSI SSF Director**

**SSF Management**
(Director, Operations Manager, Facility Manager, and Personnel as assigned per SOP)

Manage SOPs, Training, Facility, and Equipment
Coordinate Services
Manage Records
Plan/Quote new studies

**Technical Advisor**

Manage Quality Control
Guide Development

**CTSI SSF Technicians**

Facility and Equipment
$LN_2$ Services
Alarm Management
Sample Storage Support

**Quality Assurance Specialist**

Technician Duties
Quality Assurance Auditing

**CTSL**

Sample Processing
Study and Sample Coordination
DNA Extraction

**IUGB Repository**

Sample Processing
DNA Extraction
Sample Management

**IUSCC Repository**

Tissue Procurement
Sample Processing
Sample Management

**Indiana CTSI SSF Technical Personnel Responsibility**

| Chapter 1: Administration and Quality Oversight | __* | __* | __* | __* | __* | __* |
|---|---|---|---|---|---|---|
| Writing, Reviewing and Maintaining SOPs | | | | | | |
| Facility Overview and Scope of Charge | | | | | | |
| Organization:  Directorship, Staffing, Oversight Committee | | | | | | |
| Managing storage space | | | | | | |
| Personnel Training | | | | | | |
| Controlled Document Management | | | | | | |
| Safety | | | | | | |
| Quality Assurance Oversight | | | | | | |
| Deviation Management | | | | | | |
| Out of Specification Condition and Notification Management | | | | | | |
| Regulatory and Client/User Audit | | | | | | |
| Facility Commissioning and Validation/Revalidation | | | | | | |
| Managing Good Laboratory Practice (GLP) Specimens | | | | | | |
| SSF Managed Specimens Intake & Release | | | | | | |
| **Chapter 2:  Facility** | | | | | | |
| Mechanical Refrigeration Unit Storage Room Operations | | | | | | |
| $LN_2$ System and Freezer Room Operations | | | | | | |
| Controlled Access Operations | | | | | | |
| Alarm System Management and Response (Siemens / Sonicu) | | | | | | |
| **Chapter 3: Equipment** | | | | | | |
| Mechanical Refrigeration Units | | | | | | |
| $LN_2$ Freezers | | | | | | |
| Sensit P100 Personal O2 Monitors | | | | | | |
| Timers | | | | | | |
| Thermometers | | | | | | |
| Drager Quick Air EEBA Units | | | | | | |
| Scott ELSA Emergency Escape Breathing Device | | | | | | |
| Drager Pac 5500 Personal O2 Monitors | | | | | | |
| -80 $LN_2$ Freezer Units | | | | | | |
| **NON-SOP-Managed Processes** | | | | | | |
| SSF Billing | | | | | | |
| Personnel Schedule Coordination | | | | | | |
| IUPUI CFS Repair Management | | | | | | |
| Supply Management | | | | | | |
| RQ Execution | | | | | | |

\*   SSF Personnel identified for Technical Personnel Assignment

"P" denotes Primary personnel assigned to Responsibility.

"B" denotes personnel assigned to Responsibility as Backup to Primary.

Effective_____

Obsolete_____