

STANDARD OPERATING PROCEDURE Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR PERSONNEL SAFETY


CHAPTER: 1 - ADMINISTRATION AND QUALITY OVERSIGHT

SOP #: SF-1-7.12

SUPERSEDES SOP #: N/A

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AUTHORED BY:  DATE: 11-7-22
Indiana CTSI SSF Staff

APPROVAL:  DATE: 11-10-2022
Indiana CTSI SSF Director

QA APPROVAL:  DATE: 11.10.2022
Quality Compliance Specialist

1. REVISION

1.1. Significant changes incorporated in this version include:

- 1.1.1. References to “laboratory” have been changed to “facility” throughout.
- 1.1.2. Step 4.2 added to direct that use of C158A by other laboratory groups assigned that space is outside the scope of this SOP.
- 1.1.3. Step 4.3 added to direct that monitoring and maintenance of safety equipment in R3-C158A and R3-C158C (Special Handling Room) is outside the scope of this SOP.
- 1.1.4. Step 5.3 added to include Personal Protective Equipment.
- 1.1.5. Update EHS website address in Steps 6.1.1 and 8.1.
- 1.1.6. Section 6.3 revised to remove monitoring and maintenance of C158A and C158C eyewash stations from the SSF scope; direct that personnel are required to be familiar with the locations and use of the eyewashes and safety showers per IU EHS directives; and denote where eye wash stations and the safety shower are located.
- 1.1.7. Step 6.3.2.1 clarified to direct that SSF personnel maintain adequate supply of applicable PPE for use in SSF facilities.
- 1.1.8. Section 9 revised to reflect change to Appendix A and renaming of Appendix E.
- 1.1.9. Eliminated Appendix A: Eyewash Maintenance & Test Record Log. Appendix A is now Intentionally Blank.
- 1.1.10. Appendix B revised to reflect reduced tasks resulting in exposure.
- 1.1.11. Appendix C revised to replace all references to “laboratory” with “facility”.
- 1.1.12. Appendices D & E revised to reflect that:
 - 1.1.12.1. Use of C158A by other laboratory groups assigned that space is removed from the scope of SSF SOPs.
 - 1.1.12.2. Monitoring and maintenance of safety equipment in C158A and C158C is removed from the scope of SSF SOPs.
- 1.1.13. Appendix D revised to:
 - 1.1.13.1. Reflect that PPE is not required in C158A, C158C, or C160A by SSF directives, since these spaces are outside the scope of SSF SOPs.

- 1.1.13.2. Correct that PPE was previously mandated in C160A in error, since C160A was not a validated SSF facility.
- 1.1.13.3. Correct that PPE was previously erroneously designated applicable in the mechanical room adjacent to TK 246 and outside the northern TK 246 door.
- 1.1.14. Appendix E revised to reflect that open manipulation of specimens is not conducted in SSF spaces. Revision date revised in title of Appendix E.
- 1.1.15. Appendix G revised to remove R3-C158
- 1.1.16. Appendix H revised to reflect new EHS website and that personnel are required to be familiar with the locations and use of the eyewashes and safety showers per IU EHS directives.

2. PURPOSE

- 2.1. This Standard Operating Procedure (SOP) defines the procedures used in the Indiana CTSI Specimen Storage Facility (SSF) to provide biologic safety for all personnel in the SSF. The SSF meets the safety requirements of IUPUI Environmental Health and Safety (EHS).

3. PRINCIPLE

- 3.1. Personnel safety must be an overarching focus for facility management and staff. All human blood, body fluids, and tissue are assumed to carry blood borne pathogens and, therefore Universal Precautions must be Standard Practice for the SSF. Policies and procedures are defined to manage safety practices such that disruption to workflow is minimized while all applicable safety requirements are satisfied.

4. SCOPE

- 4.1. The SOP applies to personnel working within the SSF, and it is the responsibility of SSF personnel to assure that non-SSF staff comply with this SOP. This SOP defines practices applicable to standard facility hazards (biologics, chemicals, flammables, and toxins) excluding practices specifically related to the potential hazards of liquid nitrogen, which are managed through SOP SF-2-2, Liquid Nitrogen System and Liquid Nitrogen Freezer Room Operations.
- 4.2. Use of C158A by other laboratory groups assigned that space is outside the scope of this SOP.
- 4.3. SSF Monitoring and maintenance of safety equipment in R3-C158A and R3-C158C (Special Handling Room) is outside the scope of this SOP.
- 4.4. Annex IV Room TK 258 (M10 BiOS Room) is outside the scope of this SOP per the IU Genetics Biobank (IUGB).

5. MATERIALS

- 5.1. Bleach
- 5.2. Ethanol
- 5.3. Personal Protective Equipment (PPE) as described in facility-specific SOPs

6. PROCEDURE

Note: IUPUI mandated safety forms are included in appendices and represent current version at date of SOP sign-off. Revised forms (as applicable) will be inserted at each annual review.

6.1. IUPUI Policies

- 6.1.1. The IUPUI safety policies are maintained in the IUPUI Safety Manuals - Handbooks - Guidelines accessible at <https://protect.iu.edu/environmental-health/index.html>
- 6.1.2. Training – SSF complies with IUPUI requirements for both initial and on-going safety training.
- 6.1.3. SSF Management will review the safety practices as described in the **Indiana University BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN (August 2004 or current)**, and the results are documented per Appendix C on an annual basis.

6.1.4. Required IUPUI Safety documents (Appendices B and D) are reviewed to determine whether updates are warranted, and the results are documented per Appendix C on an annual basis. Additionally, these documents may be updated as needed as described in the Indiana University **BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN** (August 2004 or current). Corresponding appendices are to be replaced with the current versions when updates are required.

6.2. A copy of the following Safety Procedures are maintained in the SSF:

6.2.1. Facility Specific Safety practices. (Appendix E)

6.2.2. SSF Phone Tree (Template and instructions for use are contained in Appendix F)

6.2.2.1. Updates to the Phone Tree are incorporated as necessary.

6.2.2.2. The current version date is recorded on the Phone Tree.

6.3. Safety Equipment/Personal Protective Equipment

Easily accessible eyewash fountains and safety showers are provided in areas where chemicals and biologicals are handled. Per IU EHS directives, all personnel are required to be familiar with the locations and use of the eyewashes and safety showers.

6.3.1. Safety Equipment

6.3.1.1. R3-C158A: Eyewash station, emergency shower

6.3.1.2. R3-C158C: Eyewash station

6.3.2. Personnel Protective Equipment

6.3.2.1. SSF personnel maintain adequate supply of applicable PPE for use in SSF facilities. (Appendix E)

6.4. SSF Procedures

6.4.1. The SSF has posted the current facility specific practices (Appendix E)

6.4.1.1. Applicable Biosafety precautions are identified for specimens accepted in the SSF. If precautions above BL2 or Universal Precautions are required, applicable safety policies will be developed, added to this SOP as an Appendix (Appendix C sub-appendices) and disseminated

6.4.2. If SF-1-4 Appendix A: (Template for SSF Storage Space Request) indicates the presence of radioactive material, documentation from the PI must be obtained assuring that the specimens do not contain radioactivity other than that occurring as a result of research protocols approved by IUPUI Radiation Safety Office (RSO) for using the following isotopes: C-14, Ca-41, Ca-45, F-18, Tc-99m, and H-3.

6.4.2.1. If such documentation is obtained, samples do not require consideration above Universal Precautions (See Appendix G: Radiation Safety Process and Procedures for Specimen Processing Staff).

6.4.2.2. If such documentation is not available, samples are not accepted into the SSF without written approval by the IUPUI Radiation Safety Office.

7. Documentation:

7.1. Safety practice files are retained according to SOP SF-1-6 (SOP for Controlled Document Management).

7.2. Deviations are managed per SOP SF-1-9 (SOP for Deviation Management).

8. REFERENCES:

8.1. IUPUI Policies & Procedures Manual: <https://protect.iu.edu/environmental-health/index.html>

9. APPENDICES:

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

Appendix A: Intentionally Blank (1 page)

- Appendix B: Department/Sub-Unit Exposure Determination List (1 page)
- Appendix C: Annual SSF Managerial Review of Safety Practices (1 page)
- Appendix D: Record of ECP Review/Changes (3 pages)
- Appendix E: Blood Borne Pathogens Safety Procedures: R3-C135 & C156; IB 097/MS-B046 Cage; MS-B037; and TK 246, 250, and 252 (1 page)
- Appendix F: Indiana CTSI SSF Emergency Phone Tree Template (1 page)
- Appendix G: Radiation Safety Process and Procedures for SSF (1 page)
- Appendix H: Collaborating Biobank Training (1 page)

10. COLLABORATING BIOBANK TRAINING DIRECTIVES

- 10.1. CBP comply with Read and Understand training on SOP SF-1-7, SOP for Personnel Safety, by continuing to and reading Collaborating Biobank Training, Appendix H, of this SOP.
- 10.2. CBP comply with directives defined in Appendix H.

Intentionally Blank

Department/Sub-Unit Exposure Determination List

Employment Positions

1. SSF Personnel
2. Non-SSF Personnel Working in the SSF
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Tasks with Potential Exposure

1. Accessing freezers containing specimens
2. Cleaning facility work areas
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Annual SSF Managerial Review of Safety Practices		
Report for the Year: _____		
	Description	By/Date (or N/A)
SECTION I - Evaluation of Changes in technology that eliminate or reduce exposure to bloodborne pathogens.		
<input type="checkbox"/>	No significant changes to technology are available since the last review period. PPE is utilized to minimize exposure	
<input type="checkbox"/>	Significant changes in technology that eliminate or reduce exposure to bloodborne pathogens have been identified since the last review period. All changes are described below in comment section.	
SECTION II - Solicitation of input from non-managerial employees on the jointly implemented SSF Facility-specific Bio-safety Practices		
<input type="checkbox"/>	Annual solicitation of input requested with no changes to SSF Facility-specific Bio-safety Practices having been identified.	
<input type="checkbox"/>	Response to request for input was indicative of necessary changes to SSF Facility-specific Bio-safety Practices which is/are described below in comment section (update Appendix E as necessary).	
SECTION III - Consideration and/or implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure		
<input type="checkbox"/>	No appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure have been identified since the last review period.	
<input type="checkbox"/>	Commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure have been identified and/or implemented since the last review period and are described below in the comment section (update Appendix E as necessary).	
Section IV - Department/Sub-Unit Engineering Controls Evaluation		
<input type="checkbox"/>	No unique engineering controls have been identified since the last review period.	
<input type="checkbox"/>	Unique engineering controls have been identified since the last review period and are available. These controls are described below in the comment section.	
Section V - Record of Exposure Control Plan (ECP) Review/Changes (Refer to Indiana University BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN (August 2004 or current))		
Section VI - SSF Specimen Collection-specific Appendices		
<input type="checkbox"/>	No SSF Specimen collection-specific appendices have been identified since the last review period.	
<input type="checkbox"/>	Needed SSF Specimen collection-specific appendices have been identified since the last review period and modifications to this SOP have been incorporated unless otherwise explained and justified below in the comment section.	
Section VII - Department/Sub-Unit Exposure Determination List Evaluation (Appendix B)		
<input type="checkbox"/>	No changes to the Department/Sub-Unit Exposure Determination List are warranted at this time.	
<input type="checkbox"/>	Needed changes to the Department/Sub-Unit Exposure Determination List have been identified (update Appendix B as necessary)	
Section VIII - Department/Sub-Unit Work Practice Controls Evaluation (Appendix D)		
<input type="checkbox"/>	No changes to the Department/Sub-Unit Work Practice Controls are warranted at this time.	
<input type="checkbox"/>	Needed changes to the Department/Sub-Unit Work Practice Controls have been identified (update Appendix D as necessary).	
Comments:		

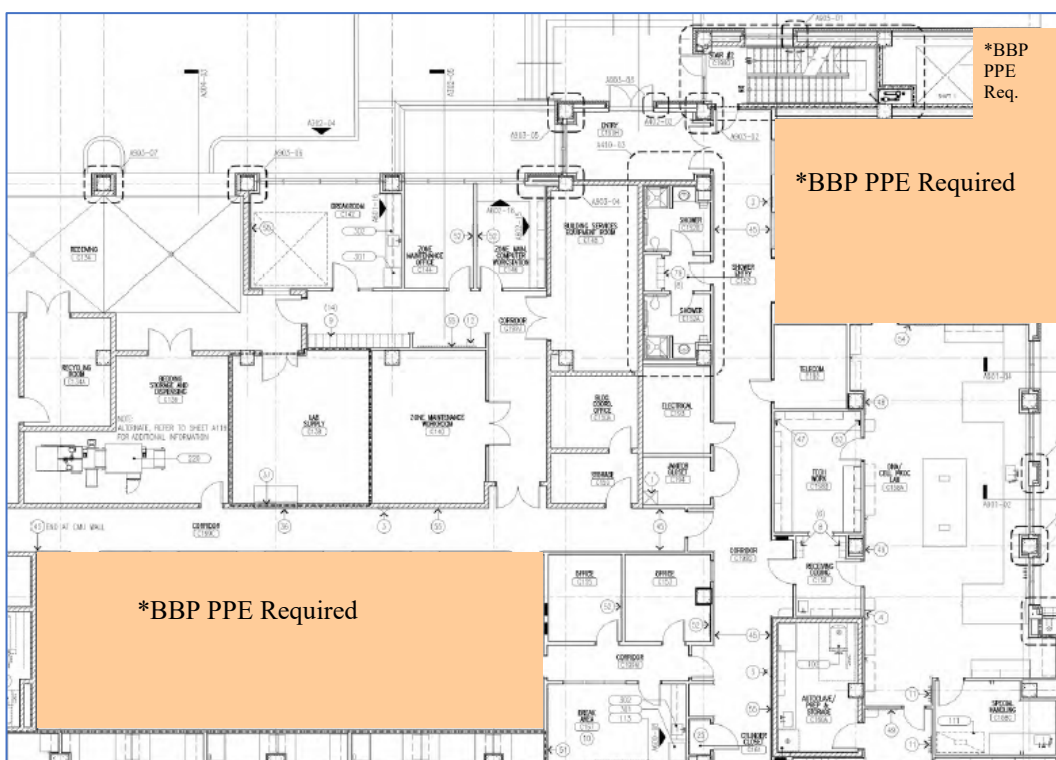
Record of ECP Review/Changes

Department/Sub-Unit Work Practice Controls

Facility-specific safety practices are posted.

- Designation of facility areas for which BBP work is permissible are posted and include: R3-C135 & C156; IB 097/MS-B046 Cage; MS-B037; and TK 246, 250, and 252

R3-C135, C156, & C156A



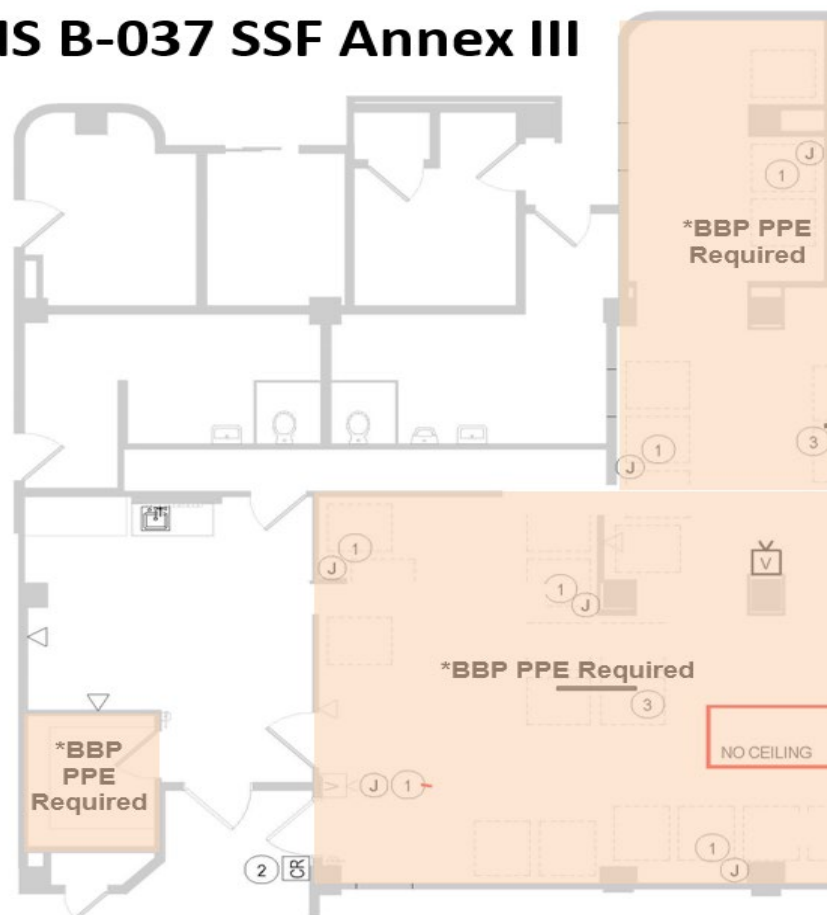
** PPE required only when handling specimens or accessing freezers.*

NOTE: PPE requirements in C158A, C158C, and C160A are defined by the laboratory group operating in those spaces in conjunction with EHS.

IB 097/MS-B046 Cage

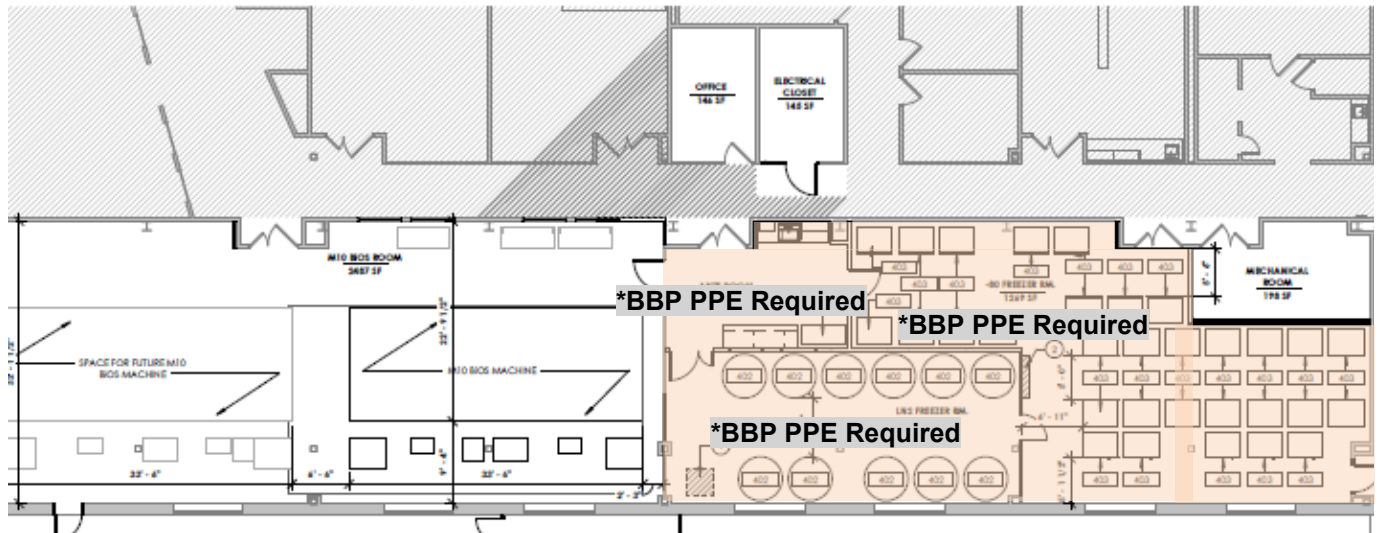


MS B-037 SSF Annex III



* PPE required only when handling specimens or accessing freezers.

TK 246, 250, and 252



** PPE required only when handling specimens or accessing freezers.*

**December 2022 Jointly Implemented SSF Facility Bio-safety Practices
Blood Borne Pathogens Safety Procedures:**

- **R3-C135 & C156**
- **IB 097/MS-B046 Cage**
- **MS-B037**
- **TK 246, 250, and 252**

SSF Safety Procedures List

1. Only persons who have been advised of the potential hazard may enter the facility.
2. The SSF will adopt/develop a biosafety manual and/or standard operating procedures (SOPs) regarding work conducted in and around areas that have the potential to expose personnel to blood borne pathogens. All personnel working in the affected areas are required to review the manual and pertinent SOPs per SSF training guidelines.
3. A hazard warning sign is posted outside of the freezer rooms. The hazard warning sign identifies the level of infectious agent (e.g. Category B), name and telephone number of the facility director and/or other responsible person and indicates any requirements for entering the freezer rooms.
4. All potentially infectious wastes from the facility are properly decontaminated prior to disposal. Contaminated materials that are to be decontaminated at a site away from the facility are placed in a durable leak-proof container which is closed before being removed from the facility and are stored in a secure location prior to decontamination. Biological waste is appropriately packaged, labeled, and autoclaved by SSF personnel. After autoclaving, waste is removed by Campus Facility Services personnel or placed in outdoor dumpsters by SSF personnel.
5. Personal protective equipment (PPE) is worn to protect eyes, mucous membranes, and skin from contamination. A lab coat and gloves are required PPE while handling specimens and accessing specimen storage in designated work areas. All PPE is to be removed before leaving the facility.
6. Eating, drinking, applying cosmetics, and storing food and drink are prohibited from the facility. Food storage refrigerators and cabinets are located in designated spaces outside of the facility.
7. Personnel must wash their hands (hand sanitizer acceptable) after handling infectious materials and prior to exiting the facility.
8. Spills and accidents which result in potential exposure to infectious materials are immediately reported to SSF Management. SSF Management are to report spills and accidents to the Institutional Biosafety Officer. Spills are cleaned up using 10% bleach. Medical evaluation and treatment are provided by Occupational Health Services.

IndianaCTSI SSF EMERGENCY PHONE TREE

Effective Date: _____

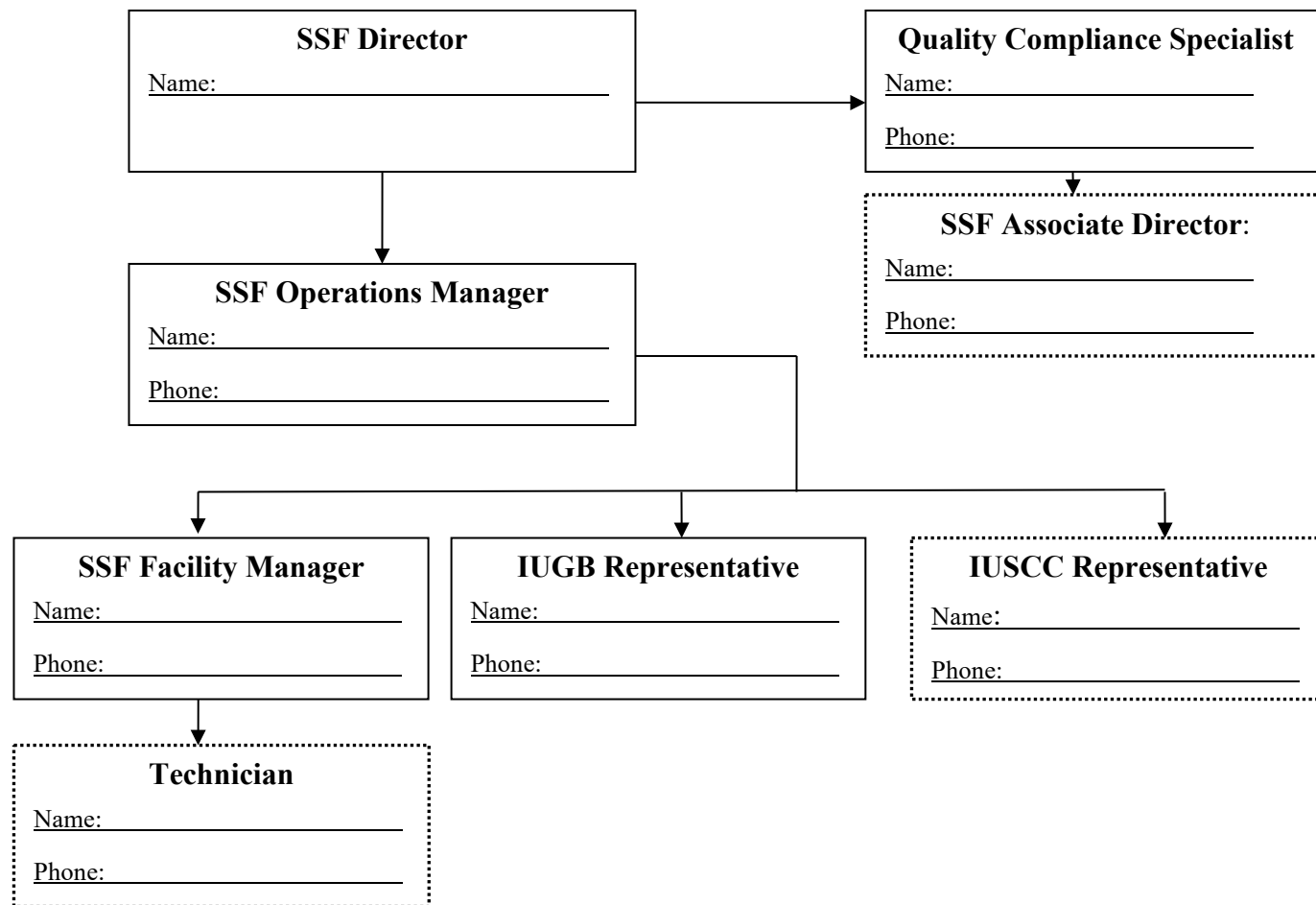
Obsolete Date: _____

Note:

IUPUI Wide emergency notifications are made via IUPUI phone/e-mail notifications. Use of this tree is limited to SSF Specific emergency notifications outside of the Alarm Response notifications.

Responsible individuals are to contact respective personnel as indicated by the directional arrow(s). Proceed to the next contact indicated if the first attempt is unsuccessful.

SSF Personnel are required to respond to the directives relayed.



***RADIATION SAFETY PROCESS AND PROCEDURES
FOR SPECIMEN STORAGE FACILITY***

Scope: This procedure applies to Indiana CTSI Specimen Storage Facility (SSF) staff handling and storing (mechanical or liquid nitrogen freezing equipment) for blood and other body fluids from patients undergoing research protocols approved by IUPUI Radiation Safety Office (RSO) using the following radionuclides: C-14, Ca-41, Ca-45, F-18, Tc-99m, H-3, or other radionuclides as approved by the RSO on an individual basis. The locations for which storage of these samples is permitted without monitoring for radioactivity or performing cleaning practices above standards for Universal Precautions are R3 C135 and C 156; IB 097/MS-B046 Cage; MS-B037; and TK 246, 250, and 252.

Rationale: Exposure to radioactive materials via handling of specimens from patients undergoing radio-labeling studies is a potential safety hazard. While laboratory staff is aware of the potential hazards presented by blood borne pathogens or from certain drugs used in chemotherapy it is important for staff to also be knowledgeable regarding radioactive exposure in order to manage the risk. Everyone is exposed each day to natural background radiation. Persons receive an exposure of about 360 mrem per year from background radiation.

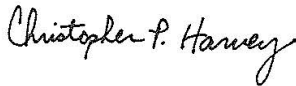
The administration of radioactive materials by the nuclear medicine and PET departments for diagnostic purposes is common. There are several reasons why these patients present a minimal hazard. The primary reason is that the amount of radioactivity (and the related radiation exposure) is small with the material having a short "half-life." This means the radioactivity disappears rapidly. Standard universal precautions (e.g., wearing disposable gloves) will protect laboratory staff from these radiation hazards. Samples from radiolabeled drug study patients carry an even lower level of radioactive isotopes and are considered by IUPUI RSO to not require precautions above those standardly employed for Universal Precautions.

Procedure:

1. The CTSI processing laboratory will NOT specifically identify as radioactive blood samples from studies using radioactive isotopes within the scope stated above.
2. The SSF will utilize Universal Precautions when managing all samples; therefore, no additional precautionary actions are required.
3. Radioactive labeling and radiation monitoring of the storage area is not required.
4. Cleaning per Universal Precautions is adequate.
5. Radiation Safety training for technicians processing these samples is not required.
6. Contact Radiation Safety if you do not understand this procedure or if you have further questions.

For any questions, PLEASE CONTACT: Radiation Safety Office at 317-274-4797 (8 am to 5 pm weekdays, after hours listen for paging instructions)

Approved by:



10/5/2022

Radiation Safety Office Representative

Date



SSF Director

05 OCT 2022
Date

Collaborating Biobank Training

Standard Operating Procedure (SOP) SF-1-7, SOP for Personnel Safety, defines practices applicable to standard facility hazards (biologics, chemicals, flammables, and toxins). Personnel safety must be an overarching focus for all staff. All human blood, body fluids and tissue are assumed to carry blood borne pathogens and, therefore Universal Precautions must be Standard Practice for the SSF. This SOP applies to personnel working within the SSF, and it is the responsibility of SSF and Collaborating Biorepository Personnel (CBP) to assure that untrained staff and visitors comply with this SOP.

SOP Directives apply to all SSF spaces:

- R3-C135 and C156
- MS-B037
- IB 097/MS-B046 Cage
- TK 246, 250, and 252

1. Safety Policies and Procedures

- a. The IUPUI safety policies are maintained in the IUPUI Safety Manuals – Handbooks – Guidelines accessible at <https://protect.iu.edu/environmental-health/index.html>
- b. Training – SSF complies with IUPUI requirements for both initial and on-going safety training.
- c. A copy of the following Safety Procedures are maintained in the SSF:
 - i. Facility Specific Safety practices. (Appendix E)
 - ii. SSF Phone Tree (Appendix F)

2. Safety Equipment

- a. Easily accessible eyewash fountains and safety showers are provided in areas where chemicals and biologicals are handled. Per IU EHS directives, all personnel are required to be familiar with the locations and use of the eyewashes and safety showers.
 - i. R3-C158A: Eyewash station, emergency shower
 - ii. R3-C158C: Eyewash station

3. Personnel Protective Equipment

- a. All facility storage rooms are required to maintain applicable PPE as described for use in facility specific procedures. See Appendix D and Appendix E.

4. Radiation Safety

- a. The SSF will not store specimens that contain radioactivity other than that occurring as a result of research protocols approved by IUPUI Radiation Safety Office (RSO) for using the following isotopes: C-14, Ca-41, Ca-45, F-18, Tc-99m, and H-3.
 - i. Such specimens do not require consideration above Universal Precautions (per Appendix G: Radiation Safety Process and Procedures for Specimen Processing Staff).

5. Additional Appendices Requiring Review:

- a. Appendix D defines where PPE is required in each SSF Facility
- b. Appendix E defines BBP Safety Procedures and is posted at the entrance to each SSF facility
- c. Appendix F is the Emergency Phone Tree posted at the entrance to each SSF facility.