INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR TIMER MAINTENANCE

CHAPTER: 3-Equipment

SOP #: SF-3-06.03

SUPERSEDES SOP #: N/A

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APPROVAL: _____ DATE: 10/19/2020
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1. REVISION
   1.1. Significant revisions incorporated in this version include:
      1.1.1. Updated Indiana CTSI logo.
      1.1.2. Section 3 and 4 references to "laboratory" were replaced with "facility" since the SSF ceased processing operations and doesn't use its assigned laboratory space for processing functions.
      1.1.3. Removed reference to DNA extraction in section 3.1 as the SSF no longer provides this service.
      1.1.4. Added Section 10 Collaborating Biobank Training Directives for consistency with SF-1-01 Writing, Reviewing, and Approving SOPs.
      1.1.5. Minor grammatical and formatting changes made throughout.

2. PURPOSE
   2.1. This Standard Operating Procedure (SOP) defines the procedures used in the Indiana CTSI Specimen Storage Facility (SSF) for maintaining and operating timers in a manner which complies with all appropriate regulatory and protocol specific requirements.

3. PRINCIPLE
   3.1. Accurate timing is essential to various steps of many different facility protocols. An appropriately calibrated timer is often utilized to provide such accuracy. The Indiana CTSI Specimen Storage Facility (SSF) uses and maintains timers which are NIST-traceable so that procedural directives may be followed with appropriate precision and accuracy. Any standard NIST-traceable timer capable of measuring intervals in seconds is suitable for the purposes of the SSF.

4. SCOPE
   4.1. The SOP applies to all SSF staff and is intended to outline maintenance and documentation procedures used within the facility to ensure that timers perform with reliable precision and accuracy.

5. MATERIALS
   5.1. Appropriate batteries
   5.2. Soapy water
   5.3. 10% bleach solution (made fresh each day of use)
   5.4. Paper towels

6. PROCEDURE
   6.1. EQUIPMENT INTAKE
      6.1.1. Place the timer in service by documenting the information as follows (see Appendix A Timer Log):
         6.1.1.1. SSF TIMER ID
            6.1.1.1.1. Assign an SSF TIMER ID for the timer in the format "SF Timer-X" where "X" is the next available sequential numerical value. For example, a new timer would be assigned the SSF TIMER ID "SF Timer-5" if the last timer that was placed into service was "SF Timer-4."
            6.1.1.1.2. The SSF TIMER IDs are NOT reused if a timer is placed out of service.
         6.1.1.2. Date in Service
         6.1.1.3. Manufacturer
         6.1.1.4. Model
         6.1.1.5. Serial Number
         6.1.1.6. Receipt of NIST Traceability (retain in equipment file)
         6.1.1.7. Recalibration due date (i.e., expiration date of equipment)
         6.1.1.8. Date out of Service and Reason

   6.2. OPERATION
      6.2.1. For a single channel timer, set the desired time by pressing the MIN and SEC buttons, or their equivalents, so that it reads on the digital display.
      6.2.2. For multiple channel timers, choose one channel and then set the desired time by pressing the MIN and SEC buttons, or their equivalents, so that it reads on the digital display. Alternatively, choose multiple channels to set the desired times if multiple times need to be kept.
      6.2.3. Push the START/STOP button, or equivalent.
      6.2.4. Reset timer when timer goes off.
      6.2.5. Refer to manufacturer documentation for additional details.

   6.3. FUNCTION VERIFICATION
      6.3.1. There is no defined function verification procedure indicated for timers.

   6.4. CLEANING
      6.4.1. Clean with warm soap solution and 10% bleach solution as needed.

   6.5. MAINTENANCE
      6.5.1. Routine

6.5.1.1. Replace batteries with appropriate sized batteries as necessary.

6.5.1.2. NIST traceable timers can be in service until recalibration is due or obvious function failure is noted.

6.5.1.3. When the recalibration date is approaching, a new timer will be ordered to replace the existing timer.

6.5.1.4. The expired timer will be retired.

6.5.1.5. Document the details of timer service on Appendix A.

6.5.2. Non-Routine

6.5.2.1. If the timer begins malfunctioning or becomes inoperable, retire the unit and order a replacement.

6.5.2.2. Record actions and date retired on Appendix A.

6.6. CALIBRATION

6.6.1. Re-calibration of the timers will not be performed. The units will be replaced when their calibration dates expire.

7. REFERENCES

7.1. N/A

8. DOCUMENTATION

8.1. Maintenance logs are submitted for review by SSF Management upon retirement of the equipment and are maintained per SF-1-6 Controlled Document Management SOP.

8.2. All Deviations are managed per the SF-1-9 Deviation Management SOP.

9. APPENDICES

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

APPENDIX A – Timer Log (1 page)

10. COLLABORATING BIOBANK TRAINING DIRECTIVES

10.1. N/A

Appendix A

Timer Log:

SSF TIMER ID	Date in Service	Manufacturer	Model	Serial Number	NIST Certificate Received? (yes/no)	Calibration Due Date	Initials/ Date	Date Retired	Reason	Initials/ Date	Reviewed By:
									☐Expired ☐Defective ☐Other		
									☐Expired ☐Defective ☐Other		
									☐Expired ☐Defective ☐Other		
									☐Expired ☐Defective ☐Other		
									☐Expired ☐Defective ☐Other		
									☐Expired ☐Defective ☐Other		
									☐Expired ☐Defective ☐Other		
									☐Expired ☐Defective ☐Other		

Comments: