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1.0 Purpose

This SOP describes the issuance, use, review, and archiving of equipment logs used at the BDP.

2.0 Scope

This SOP applies to the issuance, use, review, and archiving of logs for equipment associated with the manufacture, testing, and storage of materials that require a chronological record of use, cleaning, and maintenance. This SOP does not apply to Process Analytics/Quality Control (PA\QC) Solution Logs, MMIC Inventory Logs, or to Facility Cleaning which are governed by other SOPs.

3.0 Authority and Responsibility

3.1 The Quality Engineering/Validation Manager, Biopharmaceutical Quality Assurance (BQA) has the authority to define this procedure.

3.2 BQA Documentation (BQAD) is responsible for issuing, tracking, reporting status of, and archiving completed logs.

3.3 It is the responsibility of Biopharmaceutical Development Program (BDP) staff to request equipment logs from BQA, specifying the equipment number and location.

3.4 Supervisors/Managers are responsible for auditing equipment logs for accuracy and completeness. This includes ensuring that maintenance technicians (both FME and outside vendors) document work in the log according to Sections 6.5 of this SOP. Supervisors/Managers are also responsible for assuring that they or their designee is familiar with the Preventive Maintenance (PM) schedule and activities and the equipment calibration due dates.

3.5 Employees that are responsible for equipment logs or making entries into equipment logs must read and understand ***SOP 21409 - Good Documentation Practices*** and complete the GMP training modules on “Documentation and Recordkeeping” and “Equipment.”

3.6 BQA Engineering/Validation (or designee) (BQAE) is responsible for periodic review of active logs and final review of completed logs as indicated in this SOP.

3.7 BQA is responsible for quality oversight of this procedure.

4.0 Equipment Which Requires Logs

4.1 Equipment used in or supporting the manufacture, testing, and storage of materials that require a record of traceability shall have a log. Guidance on requirements for equipment logs is given below.

4.1.1 GLP and CGMP processing or support equipment that requires preventive maintenance, calibration, or is in product contact requires logs, with the following exceptions:

- Product-contact disposables.
- Fittings and components including flex lines.
- Pipettors and pipettes (these are part of the calibration program).
- Weight sets (these are part of the calibration program).

4.1.2 GMP books will receive green back covers to denote the GMP nature of these books.

4.2 Non-CGMP or R&D Equipment Logs

4.2.1 Equipment that does not support GLP or CGMP activities are NOT REQUIRED to have associated logs EXCEPT in the cases listed in Section 4.3.

4.2.2 R&D logs do not require biennial review by BQAE.

4.2.3 R&D logbooks will receive blue back covers to denote the non-CGMP nature of these books.

4.3 The following equipment has been identified as having high potential impact on product as well as personnel safety. These types of equipment shall have logs regardless of whether they support CGMP activities. The logs shall be used to record the information listed below, at a minimum.

4.3.1 Steam Sterilizers (autoclaves including those for waste inactivation)

- Date and cycle details (type, duration, sterilization setpoint). For GLP and CGMP validated sterilizers, include load description, cycle code, and cycle number.
- Comments regarding cycle performance (this section is used to document anything that occurred during a run that was unexpected or “out of the ordinary”).
- Calibration activities.
- Cleaning and preventive maintenance activities.
- Validation activities (if applicable) and/or routine checks with biological indicators.

4.3.2 Biological Safety Cabinets

- Date and activity, including cell line/organism(s) processed.
- Certification activities.
- Preventive maintenance activities.
- Cleaning activities, including disinfectant used and, if GMP, disinfectant release number.

4.3.3 Centrifuges

- Date and activity, including material/organism(s) processed.
- Cycle details See ***SOP 19102 - Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges.***
- Comments regarding cycle performance (this section is used to document anything that occurred during a run that was unexpected or “out of the ordinary”).
- Calibration activities.
- Preventive maintenance activities.
- Cleaning activities, including disinfectant used and disinfectant release number.

4.4 Methods of maintaining equipment logs not described in this SOP may be acceptable with approval from BQAE. BQAE will add a note to the front of the log documenting the acceptability of the alternate method.

5.0 Requesting, Compiling, Maintaining and Archiving Equipment Logs

5.1 Requesting Logs

5.1.1 Employees need to submit a request through the BDP App online request system by going to *Equipment* and then *Request Log*. Once submitted an automated email is sent to the BQAD Outlook In Box and a copy is sent to the employee's supervisor/manager.

5.1.1.1 Users will ensure that new logs are obtained from BQA before the current log is completed. Allow **2-4 weeks** for processing of requests for new logs.

5.1.1.2 Multiple pieces of identical equipment, such as chromatography columns, TFF filter holders, etc., may share an equipment log if located near each other. Some logbooks may require the use of two different forms. The format of logs of this type will be individually tabbed sections for each unique equipment ID. Please make note of this in the comments section of the request in Step 5.1.1 above.

5.1.2 BQA assigns each requested log a new sequential number from the Equipment Logbooks database and enters the information provided in the email request into the database. The sequential number is derived as follows: "EL" for Equipment Logbook, the Year issued in "YYYY" format, and the four-digit sequential number for the log issued in the given year. Example: EL-2023-0001 for the first log of 2023.

5.2 Compiling Logs

5.2.1 The first page of the equipment logbook is the title page with specific information regarding the equipment logbook, e.g.:

Biopharmaceutical Development Program
pH Meter

MEF 79040, SOP 12345
Equipment Logbook – EL-2023-0021

Building ATRF, [redacted]
Technical Operations – Purification

Issued 03/01/23

This is a GMP piece of equipment.
Record all use of equipment in this logbook.

5.2.2 The second page is the QA Review page.

BQA Logbook Review History

For Use by BQA (or Designee) Only		
Date Reviewed	**Reviewed by**	**Next Review Date**

5.2.3 The log form content pages follow and are numbered sequentially by BQA. The form to be used is indicated on the Log Book Request.

5.2.3.1 Several “generic type” log book forms are included in this SOP. Refer to attached Forms 21531-04, Date/Time/Activity Log, 21531-05, Date/Time/Temperature/Activity Log, and 21531-06 Chemical Fume Hood Log)

5.2.3.2 Refer to equipment specific SOPs for specified equipment log forms.

5.2.4 BQA binds the log and notifies the requestor that the log is ready.

5.2.5 If an SOP Form is revised that is used in existing equipment logbooks, the logbook by default will not require updating. The next issued log will use the updated form. QA will determine if existing logbooks require updating as part of the form revision process and make this notation in MasterControl. Revisions that are primarily for formatting or other non-critical changes as determined by QA are those that do not require immediate recall and updating.

NOTE: The reviser should notify other equipment owners who use the same form and collaborate with them to ensure revisions work for all parties. BQAD can provide some details on others who use the form.

5.3 Maintaining Logs

5.3.1 The log must be kept near the piece of equipment. This could be on a table with the equipment, on a shelf next to the equipment, in a case attached to the equipment, or if appropriate, on the top or side of the equipment. BDP personnel, FME technicians, and trained vendors must be able to easily locate the logbook for entries when using or performing work on the equipment.

5.3.1.1 **If equipment logs are not located close to the equipment, the equipment shall be labeled to indicate the log’s location.**

5.3.2 Entries are made in the logs as specified by the guidelines in Section 6.0 of this SOP.

5.3.3 If the way the equipment is used changes significantly or if its location is changed, then an entry should be made in the logbook explaining the change.

5.3.4 Periods of equipment inactivity or non-use.

5.3.4.1 When equipment may not be needed for some time, an entry may be made in the logbook to indicate that the equipment is “idle”. The designation of idle is not applicable to equipment in constant use such as CTUs that contain materials or for utilities or other equipment that is powered on constantly.

5.3.4.2 Logbooks must be reviewed at their established frequency if the equipment logbook does not have a previous entry of idle.

5.3.4.3 It is suggested that the logbook be reviewed at the completion of a production campaign to reduce the likelihood of exceeding the review interval.

5.3.4.4 Equipment not in use may be made inactive in the calibration system per ***SOP 21508 – Equipment Calibration Program*** if it is known that it will not be used for extended periods. This status should also be recorded in the logbook.

5.3.4.5 A reviewer may also indicate during their review entry that the equipment is idle.

5.4 Reviewing Logs

5.4.1 Each Manufacturing and Utility log is reviewed monthly at a minimum.

5.4.2 Each Development and Process Analytics\Quality Control log is reviewed every three months at a minimum.

5.4.3 Pages are reviewed by the Supervisor/Manager or designee who has been trained on ***SOP 21409 – Good Documentation Practices***.

5.4.3.1 Supervisors/Managers or designees may indicate their review on the next available entry line on an incomplete page. The review does not need to wait until the time the page is complete and be documented at the end of the page.

5.4.3.2 Reviewers should avoid reviewing their own entries.

5.4.3.3 If no activity has occurred since the most recent review, a new review is not necessary under two conditions

5.4.3.3.1 There is an entry from the user or reviewer in the logbook explaining the reason for inactivity.

5.4.3.3.2 The equipment is “idle”.

5.4.3.4 Routine review of the logbook resumes when activity has been reestablished (such as use in a process or maintenance/cleaning/calibration).

5.4.3.5 Reviewers should use calibration due notifications and be familiar with PM intervals to avoid missing review of PM or calibration entries during idle periods.

5.4.3.6 During idle periods for the equipment, Supervisor/Manager reviews of PM or calibration activities will occur not more than three months from the date work was performed.

5.4.4 GLP and CGMP Logbooks are scheduled for review by Biopharmaceutical Quality Assurance Engineering (BQAE) or their designee at two-year intervals; based on the issue date for the first review and then the review date for subsequent reviews. The logs due for review are posted in the BDP App under *Equipment* and then *Log Reviews*. The application allows users to see logs that are past due and coming due, allows assigning of the review, emailing the equipment owner to coordinate review, and indicating stages of the review process.

5.4.4.1 Logs that are not in routine use may be returned to BQA so that BQA can route the logbook to BQAE or designee for this review. If for some reason the log may not be removed from the in-use location, the reviewer will perform an on-site review of the logbook.

5.4.4.2 During their review, BQAE will monitor compliance to ***SOP 21409 – Good Documentation Practices***, the operational and maintenance SOPs for the equipment, and this SOP. After this periodic review, the log may be archived by BQA, or may be returned to the owner for further use. Specific items to look for are included in the following table. This list is not meant to be inclusive.

Accuracy of entries	**Consistency of entries**	**Legibility of entries**
	Calibration recorded at specified interval.	PM recorded at specified interval
Reviews performed at specified interval	Periods of inactivity documented per 5.3.4	Work Order (WO) numbers recorded where applicable
Proper use of error and correction codes.	Key usage events are recorded.	Outside vendor activity recorded by either vendor or user.

5.4.4.3 The review and any relevant corrections will be documented on Form 21531-02, BQAE Logbook Review Findings. The signed completed form will go to BQAD for filing in the MEF for the equipment.

5.4.4.4 Once BQAE completes the review of a logbook, they will sign the BQA Logbook Review History on the second page of the logbook by entering the Date Reviewed, their signature, and the Next Review Date (two years from the recorded “Date Reviewed”). BQAE or designee will also update the management control system.

5.4.4.5 A follow up review may be performed to verify if remedial measures have been taken prior to the next scheduled BQAE review. If a follow-up review is performed, it is recommended to perform such a review within three months of the initial review.

5.5 Completed logs and logs that are no longer needed are returned to BQA for review by BQAE or designee before being archived using Form 21531-03, Equipment Logbook Return.

5.5.1 BQAE reviews the logbook and works with logbook owners and management to resolve any issues identified during their review.

5.5.2 For partial logs to be retired, BQAE verifies the presence of or makes an entry after the last entry stating, “No other entries will be made in this logbook” or an equivalent statement that is initialed and dated.

5.5.3 BQAE signs the review history table on the second sheet of the logbook, indicates the log is ready for archival, and returns the logbook to BQA to be archived.

5.6 Archival

5.6.1 BQA enters the log information, including archival date (return date), into its equipment log database system. The log is then archived according to ***SOP 21402 – Document Storage and Archival Process.***

6.0 Entries to Logs

6.1 Entries to logs are made according to ***SOP 21409 – Good Documentation Practices***. Entries are made in chronological order.

6.2 At a minimum, as a default requirement, log entries will include a description of cleaning, maintenance, use, and other events. Each entry will include the date and time, product and lot number (as applicable), and the initials of the person performing the event.

6.3 The operation and maintenance SOPs for the equipment provide specific guidance on the entries that should be made.

6.4 Logs are used in addition to other mechanisms for documenting events, such as SOPs, the area clearance system, and Batch Production Records (BPRs). Making entries to logs does not eliminate the need for recording events using other established procedures. Rather, entries to logs provide a chronological record of initiation, calibration, maintenance, use, and cleaning as well as the support information used to complete the documentation associated with those other systems.

6.5 Log Entries for Maintenance Work

6.5.1 Routine maintenance work, including calibration, may be recorded as a generic description of the work, with task number associated (if applicable), the date, time, and technician's initials. If a work order was associated with the work, that number is referenced.

6.5.1.1 If the work takes more than one day to complete, at least two entries should be made. The first entry will indicate the start of the task and the second would indicate when the task is completed.

6.5.2 Non-routine maintenance work (such because of failure or engineering change) will include details of the activity, such as a description of the failure/change, the reason for the event (if known), any identification numbers of parts affected/replaced, and the date, time, and technician's initials. The Engineering Event (failure or change), work order, or trouble call number associated with the work is referenced. See ***SOP 21526 – Engineering Event Management.***

6.5.2.1 For work performed by outside contractors, BDP staff must ensure that the contractor makes the necessary entries and countersign the entry for any vendor not registered via ***SOP 21406 – Personnel Signature and Initial Verification System***. BDP staff may make the entries on behalf of the contractor using information from staff who witnessed the work, the service ticket, or verbal communications with the contractor.

6.5.2.2 BDP staff should verify if FME has made needed entries to the equipment log (for calibration, repairs, and scheduled PM). If entries are missing or have any errors, BDP staff may make any needed entry and should notify BQAE of any deficiency.

6.5.2.3 For any alteration or reload of software required for testing of the equipment, the log entry will include the description of the software, revision number, and edition date (if applicable), the alteration that was made, why the alteration or reload occurred, and the "as-left" status.

7.0 Documentation

7.1 Logbooks are kept by BQA for a minimum of ten years. Completed or retired logbooks may be sent to off-site storage for archiving according to ***SOP 21402 – Document Storage and Archival Process***

7.2 Form 21531-02, BQAE Logbook Review Findings shall be kept by BQA or at the off-site storage contractor for a minimum of ten years.

8.0 Definitions

8.1 **BDP Equipment Number –** The BDP MEF (Master Equipment File) number or, if one does not exist, the NIH number.

8.2 **Campaign Equipment –** Equipment that is used only for project specific operations during production activities. Such equipment may go for months or years between periods of usage.

8.3 **CTUs** – Controlled Temperature Units.

8.4 **Equipment Type** – The manufacturer's description or suggested use for the equipment in question, such as "freezer," "autoclave," etc. If the log is being used for an equipment system, such as a utility system, that description may be considered the equipment type (i.e., "ATRF Compressed Air System").

8.5 **Form Number** – When the logbook is to be made up of forms bound together, the form used is listed under "Form Number."

8.5.1 Occasionally a form that is in current use in an equipment log will be revised as part of an SOP revision. BQA will notify users if an equipment log needs to be returned because of a revision to an SOP.

8.6 **Idle –** A period when equipment is not actively in use. The only potential activities for the equipment during such a period are preventive maintenance and calibration.

8.7 **Location –** The building and room where the log will be used or stored when not in use for portable equipment.

8.8 **Review Due Date –** The date that the equipment log is due to be returned to BQA for periodic review, if the log is not filled before this date. This date is set two years from the issue date or the date of last review. After this periodic review, the equipment log may be archived by BQA, or may be returned to the owner for further use.

9.0 References and Related Documents

SOP 19102 *Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges*

SOP 21402 *Document Storage and Archival Process*

SOP 21406 *Personnel Signature and Initial Verification System*

SOP 21409 *Good Documentation Practices*

SOP 21508 *Equipment Calibration Program*

SOP 21526 *Engineering Event Management*

Form 21531-02 *BQAE Logbook Review Findings*

Form 21531-03 *Equipment Logbook Return*

Form 21531-04 *Date/Time/Activity Log*

Form 21531-05 *Date/Time/Temperature/Activity Log*

Form 21531-06 *Chemical Fume Hood Log*

Form 21531-07 *Water Sampling Observation Log*

21 CFR 211.67 Equipment Cleaning and Maintenance

a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product

c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in §211.180 and §211.182.

21 CFR 211.68 Automatic, Mechanical, and Electronic Equipment

a) Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.

b) Appropriate controls shall be exercised over computer or related systems in such instances a written record of the program shall be maintained along with appropriate validation data

21 CFR 211.182 Equipment Cleaning and Use Log

A written record of major equipment cleaning, maintenance and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. The persons performing and double-checking the cleaning and maintenance shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

NCI-Frederick Environment, Health, and Safety (EHS) posts information online regarding best and safe practices for equipment including autoclaves, BSCs, and centrifuges.

10.0 Change Summary

[redacted]