SOP Title: **Equipment Logs**
SOP Number: **21531**
Revision: **11**

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1. PURPOSE

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

2. 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. RESPONSIBILITIES

3.1 Quality Engineering/Validation Manager / Biopharmaceutical Quality Assurance (BQA)

- Defines procedure
- Performs periodic review of active logs

3.2 BQA Documentation (BQAD)

- Issues equipment logbooks
- Tracks equipment logbooks
- Reports status of equipment logbooks
- Archives completed/returned equipment logbooks

3.3 Supervisors/Managers

- Audits equipment logs for accuracy and completeness.
- Ensures maintenance and repairs are documented according to Sections 7.5 of this SOP
- Assures that they or their designee is familiar with the Preventive Maintenance (PM) schedule and activities and the equipment calibration due dates.

3.4 BDP Personnel / Biopharmaceutical Development Program (BDP)

- Requests equipment logs from BQA, specifying the equipment number and location.
- Makes entries into equipment logs according to **SOP 21409 Good Documentation Practices**
- Prepares equipment logs to archive
- Completes the GMP training modules on "Documentation and Recordkeeping" and "Equipment."
- BQA is responsible for quality oversight of this procedure.

3.5 BQA

- Provides quality oversight

4. DEFINITIONS

- **BDP Equipment Number** – The BDP MEF (Master Equipment File) number or, if one does not exist, the NIH number.
- **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.
- **CTUs** – Controlled Temperature Units.
- **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., "[redacted] Compressed Air System").
- **Form Number** – When the logbook is to be made up of forms bound together, the form used is listed under "Form Number."

  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.

- **Idle** – A period when equipment is not actively in use. The only potential activities for the equipment during such a period are preventive maintenance, calibration, and review.
- **Location** – The building and room where the log will be used or stored when not in use for portable equipment.
- **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.

5. EQUIPMENT WHICH REQUIRES LOGS

5.1 Procedure 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.

5.1.1 GMP 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).

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

5.2 Non-CGMP or R&D Equipment Logs

5.2.1 Equipment that does not support CGMP activities are NOT REQUIRED to have associated logs EXCEPT in the cases listed in Section 5.3.

5.2.2 Non-CGMP/R&D logs do not require biennial review by BQAE.

5.2.3 These logbooks will receive blue back covers to denote the non-CGMP nature of these books.

5.3 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.

5.3.1 Autoclaves (Including those for waste inactivation)

- Date and cycle details (type, duration, sterilization setpoint). 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.

5.3.2 Biological Safety Cabinets

- Date and activity, including cell line/organism(s) processed.
- Certification activities. BDP equipment users are responsible for making/ensuring entries.
- Preventive maintenance activities.
- Cleaning activities, including disinfectant used and, if GMP, disinfectant release number.

5.3.3 Centrifuges (Floor or high-speed units, not needed for low-speed bench units in non-GMP)

- 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.

5.4 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.

6. REQUESTING, COMPILING, MAINTAINING AND ARCHIVING EQUIPMENT LOGS

6.1 Procedure Requesting Logs

6.1.1 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.

6.1.1.1 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.

6.1.1.2 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 6.1.1 above.

6.1.2 BQAD 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-2024-0001 for the first log of 2024.

6.2 Compiling Logs

6.2.1 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-2024-0021

Building [redacted], Room [redacted]

Technical Operations – Purification

Issued 03/01/24

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

6.2.2 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**

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

6.2.3.1 Several “generic type” logbook 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**)

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

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

6.2.5 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.

6.3 Maintaining Logs

6.3.1 The log must be kept near the piece of 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.

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

6.3.2 Entries are made in the logs as specified by the guidelines in Section 7. of this SOP.

6.3.3 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.

6.3.4 Periods of equipment inactivity or non-use.

6.3.4.1 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.

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

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

6.3.4.4 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.

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

6.4 Reviewing Logs

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

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

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

6.4.3.1 Review may be indicated on the next available entry line on an incomplete page. The review does not need to wait until the page is complete and be documented at the end of the page.

6.4.3.2 Reviewers should avoid reviewing their own entries.

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

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

6.4.3.3.2 The equipment is “idle”.

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

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

6.4.3.6 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.

6.4.3.7 Contact BQAE to inactivate calibration or take infrequently used equipment out of service until needed again.

6.4.4 CGMP Logbooks are scheduled for review by 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, indicating stages of the review process, and whether an equipment log is with BQAE for review.

6.4.4.1 Logs that are not in routine use may be provided 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.

6.4.4.2 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 review, the log may be archived by BQA, or returned to the owner for further use. Specific items to look for are included in the following list, which is not meant to be inclusive.

- Complies with **SOP 21409**
- Follows operational/maintenance SOP directives
  - Pattern of entries consistent
  - Key usage recorded
- Calibration captured
- Maintenance/Repair (whether BDP/FME/Vendor/Etc.)
  - PM captured
  - Repair captured
  - WO# included
- Reviews performed at specified intervals
- Periods of inactivity document per 6.4.3.3

6.4.4.3 Review findings and any relevant corrections will be documented on **Form 21531-02 BQAE Logbook Review Findings**. A form is not required if there are no findings. The signed completed form will go to BQAD for filing in the MEF for the equipment.

6.4.4.4 Once BQAE completes the review of a logbook, they will make an entry in the log and 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”).

6.4.4.4.1 Log entry indicates if no findings observed. (As there will not be a corresponding review form.)

6.4.4.4.2 Review form, if required, is reviewed, comments added as needed, and form signed and returned to the reviewer to be finalized and filed in the MEF.

6.4.4.4.3 BQAE or designee updates the management control system (BDP App).

6.4.4.5 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.

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

6.5.1 BQAE reviews the logbook and works with logbook owners and management to resolve issues identified during their review. This review includes all review criteria listed in 6.4.4.2 as well as checking that there are no blank pages or lines.

6.5.2 For partial logs returned, 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.

6.5.3 Once the review is completed and any corrections made, 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 BQAD to be archived.

6.6 Archival

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

7. ENTRIES TO LOGS

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

7.2 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.

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

7.4 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.

7.5 Log Entries for Maintenance Work

7.5.1 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.

7.5.2 Non-routine maintenance work (such as 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**.

7.5.3 If 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.

7.5.4 For work performed by outside contractors, BDP equipment users/owner 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**. Alternatively, 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.

7.5.5 For work performed by FME, BDP equipment owners should verify 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 the needed entry and should notify BQAE of any deficiency for FME retraining consideration.

7.5.6 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.

8. DOCUMENTATION AND RECORDS

8.1 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**.

8.2 **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.

9. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
19102	Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges
21402	Document Storage and Archival Process
21406	Personnel Signature and Initial Verification System
21409	Good Documentation Practices
21508	Equipment Calibration Program
21526	Engineering Event Management
21531-02	BQAE Logbook Review Findings
21531-03	Equipment Logbook Return
21531-04	Date/Time/Activity Log
21531-05	Date/Time/Temperature/Activity Log
21531-06	Chemical Fume Hood Log