



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Responding to Alarms
SOP Number: 21503
Revision: 06

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1. PURPOSE

The purpose of this procedure is to specify the actions to take in response to alarms on utility and process equipment used in the manufacture, processing, or storage of GMP materials and/or products. Alarms may occur at the local equipment panel, on the [REDACTED] Supervisory Control and Data Acquisition (SCADA) system as viewed locally or remotely, or via some other means. This procedure applies to normal and after-hours response.

2. SCOPE

This procedure applies to personnel who respond to alarms (BDP, FME, Security), for BDP equipment and spaces associated with the manufacturing, processing, and storage of GMP products. The primary facility involved is the [REDACTED].

3. RESPONSIBILITIES

3.1 Manager / Quality Engineering and Validation

- Defines procedure

3.2 Facility Management

- Implements or designates procedure
- Maintains equipment records

3.3 Personnel

- Performs procedure
- Records data

3.4 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight

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4. PROCEDURE

- 4.1 When an alarm is detected for a piece of equipment, notify the equipment or area “owner”. There is contact information on each laboratory door and the MEF database will denote an equipment owner. If this information is not known or there is no response, contact the BDP Facility Manager.
- 4.2 The individual who responds may correct the condition if they have the proper training and expertise. Circumstances will vary widely, and no one should place equipment, product, or their own safety at risk. Some corrections may be straightforward, such as shutting an open refrigerator door.
- 4.3 Any corrective action must be conveyed to the equipment owner. BDP or FME staff should make logbook entries documenting actions taken by them or by security. Security staff is not expected to make entries and any action taken by them will be recorded by the equipment owner.
- 4.4 The SCADA system is configured to notify designated staff via email or text message for “active” (currently in alarm) alarms. Notification will continue on an hourly basis until the condition is corrected or the alarm inactivated by authorized staff.
 - 4.4.1 Staff should be familiar with the equipment location and MEF/description or have a listing of alarm points and equipment IDs and locations available to assist them. This will allow staff, particularly when away from the facility afterhours, to know which equipment is critical.
 - 4.4.2 Staff who use/own the equipment are expected to Reply All to the email with a directive so that others who receive the emails know if actions are being taken. Some alarms occur as part of normal usage as in the case of placing a large mass within a freezer or performing inventory. Alarm events, and their cause, when known should be noted in the equipment log. Local alarms are acknowledged at the equipment and most remote alarms are acknowledged via SCADA.
 - 4.4.3 The BDP Facility Manager, Manufacturing Director, Quality Engineering and Validation Manager, and other designated staff which should include key equipment users and owners receive SCADA alarms. The BDP Facility Manager or designee is the primary contact [REDACTED] security for after-hours alarms.

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- 4.4.4 For after-hours alarm calls, the BDP Facility Manager or designee will be the main person to determine the appropriate response or appropriate persons to contact depending on the criticality of the alarm. The owner should notify the BDP Facility Manager if the after-hours alarm is not critical. This will prevent unnecessary efforts and correspondence.
- 4.4.5 Do not rely on after hours notification by [REDACTED] security for all alarm conditions.
- 4.4.6 Alarms can be reviewed by accessing the SCADA system or by email/text alerts from SCADA. Access into SCADA will allow visibility of more detail including real time monitoring of most variables such as pressure or temperature.
- 4.5 Response if the situation cannot be corrected by the first responder or equipment owner.
 - 4.5.1 Additional steps During normal working hours - place a trouble call through the BDP Facility Manager or designee.
 - 4.5.2 After normal working hours - Call the [REDACTED] Security Desk [REDACTED]. Security will contact FME on call personnel to investigate the alarm if it is critical in nature and cannot wait until the next workday to be addressed. A work order will be issued as needed.
 - 4.5.3 For controlled temperature storage units, stored materials may require relocation to another unit. Ensure that the unit where materials are transferred meets the same temperature range and whenever possible the same validation status. Detail the actions taken in the corresponding equipment logs.
 - 4.5.4 If the alarm is not critical, as defined by not placing product, equipment, or safety at risk, it may be addressed the next business day. Take means to make others aware of this condition such as notification of security and placing signage.

NOTE: FME's normal scheduled work hours are from 6:45 am to 3:30 pm Monday through Friday. All other hours will be considered "After-hours" conditions, including weekends and holidays.



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4.6 BDP Actions

- 4.6.1 The owner of the equipment should attempt to inform Project Scientists, or other appropriate individuals potentially affected by this situation, and work with them to minimize any additional exposure, if possible, to the alarm condition for sensitive products or projects.
- 4.6.2 The equipment owner should verify pertinent equipment logs are updated with relevant entries according to **SOP 21531 Equipment Logs**. Relevant entries include cause of alarm and any corrective action. Use or access to equipment that causes an alarm should also be noted.
- 4.6.3 Equipment and product impact must be addressed using an Engineering Event per **SOP 21526 Engineering Event Management** and/or writing a deviation per **SOP 21301 Deviations**, as appropriate. Alarms that occur as part of regular usage will not undergo further investigation.
- 4.6.4 GMP systems may require Return to Service per **SOP 21526 Engineering Events and Status placarding**, at the Quality Manager or delegates discretion.

5. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21301	Deviations
21526	Engineering Event Management
21531	Equipment Logs