Massachusetts General Hospital
Department of Biomedical Engineering
Policies and Procedures
Medical Devices Recalls, Alerts, Hazard Notifications, and Risk Bulletins

1. Policy

    1.1. Biomedical Engineering follows the MGH Hazard Notification/Medical Device-Product Recall Policy. This document is supplemental to the hospital policy and describes Biomedical Engineering's internal process for responding to a recall or other medical device-related information notices (recall, hereafter).

2. Roles and Responsibilities

    2.1. Director, Assistant Director, and CE Managers – Responsible for assigning CE resources as needed to implement the action plan developed for the recall.

    2.2. Quality and Safety Manager (QSM) – Responsible for the department's overall response to the recall, including communications with the Product Notification Group (PNG), staff, and manufacturer; action plan; external filing; and, any compliance-related aspects of the recall. The QSM works with the PNG to determine the category of the recall, the level of communication necessary, the locations and owners of affected devices; and, develops an appropriate action plan. For recalls that fall substantially within the OR/Anesthesia environment many of the QSM's communication and coordination responsibilities will be handled by the Anesthesia QA Coordinator and the OR Administration QA Staff Specialist.

    2.3. Clinical Engineer (CE) – Functions as de facto project manager for implementation of the action plan under the direction of the QSM. Responsible for internal project documentation, including device work orders and project completion report, and formulating instructions for technicians.

    2.4. Team Leaders (TL) and Technicians – Responsible for carrying out tasks required by the action plan.

    2.5. Systems Engineering Group – Responsible for generating control numbers and/or work orders as needed. If more than 100 new work orders or control numbers are necessary, Systems Engineering will develop a plan and timeframe for batch generating the new records within 24 hours after being notified and receiving the required information.

    2.6. Operations Manager (OM) – Responsible, in conjunction with the QSM, for responding to recall notifications. The OM also has primary responsibility for maintaining the Recall Master Log (L:\DBEMAIN\Equipment\Recalls\RecallMaster.xls).

3. Notification (see Appendix A)

3.1. Biomedical Engineering receives notification of recalls, alerts, etc. through various sources, including direct mail or email from manufacturers and email from Partners Recall Coordinator or other DTMGs.

3.2. Once any Biomedical Engineering staff member receives any notification that potentially affects equipment managed by the department, they will forward the notification to the QSM and OM, who will document receipt of the notification in the Recall Master Log.

3.3. The QSM and OM will collectively ensure that the equipment database is checked for any affected devices and that department leadership is alerted to the notification. This also applies if the product in question is not in the database but is essentially managed by the department (e.g. monitor mounting arms).

3.4. If no devices are affected by the notification, the QSM or OM will notify the MGH PNG Committee Chair and the Partners Recall Coordinator, and no further action is required by the department.

3.5. If the notification does affect devices managed by the department then the QSM or OM will notify the MGH PNG Committee Chair and the Partners Recall Coordinator as to how many devices are affected, and a brief assessment of the impact. A Clinical Engineer will be assigned to the recall.

3.6. If the notification likely affects devices managed by another Designated Technology Management Group (DTMG), the QSM or OM will forward the notification to the DTMG representative, the MGH PNG Committee Chair and the Partners Recall Coordinator.

4. Initial Response, Immediate Action, and/or Removal of Devices

4.1. The QSM and CE will assess the severity of the recall based on the categories prescribed in the hospital policy and determine if devices need to be immediately removed from service. If immediate removal is required the QSM and CE will:

4.1.1. Create a list of devices with control numbers, serial numbers, and owners and locations.

4.1.2. Work with the PNG Chair to issue a communication to clinical staff, notifying them of the immediate removal and a detailed action plan to follow (see Sec. 6).

4.1.3. Notify department leadership of the impending actions.

5. Communications

The QSM has primary responsibility for communications outside of the department, and can enlist the CE's assistance as needed.

5.1. The QSM will work with the PNG Chair to communicate actions to appropriate staff as needed throughout the recall, and at its conclusion, taking into consideration these guidelines:

5.1.1. Determine the target group (i.e., house-wide communication or specific departments).

5.1.2. Collaborate with the Partners Recall Coordinator for assistance/guidance as needed.

5.1.3. Utilize the appropriate template from PNG (Appendix A in MGH Hazard Notification/ Medical Device-Product Recall Policy).

5.1.4. Current email distribution lists can be used once the target group is identified (i.e., All User Broadcasts, PCS/Associate Chiefs, PCS Nurse Directors, PCS Clinical Nurse Specialists, PCS Operations Managers, MGH Biomedical Engineering Department, Respiratory Department staff who cover for Biomed).

5.1.5. There is a group page to all Resource Nurses which can be accessed via the page supervisor if immediate action is required.

5.2. Communication with the manufacturer should initiate with both the QSM and CE involved, but can be delegated to the CE at the QSM's discretion once the action plan implementation is underway. If the QSM and CE feel that the manufacturer response is inadequate and their timeline for action unacceptable and poses a patient safety risk, they should request to speak with someone from the manufacturer's Regulatory or Safety office, and discuss with department leadership whether to escalate internally.

6. Action Plan Development and Implementation

The QSM and CE will collaboratively perform the following tasks:

6.1. Determine/verify the number of devices in inventory and create list that includes, at a minimum, control numbers, serial numbers, owners, and locations, and other fields as appropriate.

6.2. Develop a preliminary action plan, taking into consideration:
- availability of loaner equipment (with input from team leaders)
- availability of loaner or replacement devices from manufacturer
- impact on hospital operations.

6.3. Schedule a meeting with team leaders to present a written action plan and implementation timeframe to be agreed upon by the QSM, CE, and TLs. The action plan should include:

6.3.1. Explicit steps for technicians to follow when assessing, testing, and/or servicing each affected device.

6.3.2. Details of how the work should be documented, including who is responsible for opening and completing work orders; typically there should be a work order for every device.

6.3.3. Instructions to technicians for handling questions from clinical staff and any information that should be delivered to staff when visiting units.

6.3.4. An agreed upon timeframe for completing the action plan, as well as frequency and method(s) of update through implementation.

6.3.5. A draft of a high-level communication to affected staff in instances where the action plan could substantially impact hospital operations.

6.4. The CE will be responsible for documenting the agreed upon action plan.

6.5. The QSM and CE will work with the PNG Chair to issue a communication to clinical staff with the details of the action plan.

6.6. The CE will monitor the progress of the action plan implementation and will field questions from technicians and TLs as they arise, bringing them to the QSM if necessary.

6.7. Completion of Action Plan

6.7.1. The CE will complete all the actions outlined in Section 7 and ensure removal of any signage.

6.7.2. The QSM will notify the manufacturer, clinical staff, department staff, Recall Coordinator and PNG Chair when the action plan is complete.

7. Documentation of Action Plan

7.1. General Rules

7.1.1. Any manufacturer recall that affects the equipment inventory will be managed and tracked as a project in the equipment management database.

7.1.2. A CE will be assigned to each project as the project Leader. The QSM will be listed as the project Sponsor for all recalls.

7.2. Project Profile

The project profile will include the following information:

Field	Value
Title	include manufacturer, model, nature of recall, class and notification date (Example: *Sigma Spectrum Pump EXPANDED Bearing Recall (Class 1) - 7/6/2011*)
General tab	
Project Type	*Recall*
Start	date of notification
Project Leader	CE assigned (or QSM, if no CE assigned)
Business Unit	none (1)
Cost Center	none (1)
Project/Grant	none (1)
Owner	none (2)
Sponsor	QSM
Institution	*MGH*
URL	None
Comment	description of recall/alert (Example: *Expansion of 9/14/2010 Sigma Spectrum recall (project 2010062); affects s/n 700000 to 794213) primary root causes are bearing quality and contamination leading to loss of grease; bearing malfunction results in lack of tubing closure in pumping mechanism, leading to inaccurate flow conditions)*
Status	update as needed
End	default is 3 months from notification date; update as needed
Reference	project number (assigned by project administrator)
Assets tab	None
Employees tab	additional CEs assigned, if any
Preview tab	None
History tab	None
All WOs tab	TBD (see Section 7.3)
Active WOs tab	TBD (see Section 7.3)
Documents tab	upload a copy of the recall/alert notification

(1) Recalls are typically not funded, and the expectation is that the work associated with each device will be charged to the equipment owner's operating cost center; in other words, there is no "overall" funding information, except in very rare circumstances.

(2) Recalls are equipment-centric, not owner-centric, so there is no single owner to associate with the project.

7.3. Work Orders

7.3.1. Every device affected by the recall will have a work order assigned to it, so that there is a "set" of work orders encompassing the recall. Progress on the project will be tracked via completion of these work orders; when all the work orders are completed then the project is complete.

7.3.2. The CE will open a work order of type Recall for every Active/In Use device affected by the recall. All work orders should be linked to the project via the Project/Task field in the work order General tab. If more than 100 work orders need to be opened, the CE will provide the necessary information to Systems Engineering to process a batch opening.

7.3.2.1. Inactive, Missing, and Retired Devices

Work orders should generally not be opened in advance for Inactive, Missing, and Retired devices that are affected by recalls. Inactive devices should be reviewed individually; effort should be made to locate the devices and mitigate them, and work orders created manually as needed so their Inactive status can be maintained. Missing and Retired devices should have their equipment profiles annotated as per Sec. 7.4.3 at the start of the recall.

7.3.3. The Req or Problem field in the work order should include instructions on what needs to be done to the device in order to satisfy the recall.

7.3.4. If the affected equipment does not have control numbers (e.g. mounting arms) then unclassified work orders shall be used to document the work.

7.3.5. If there are no substantive actions required in the action plan (i.e. if it is merely a notification or a change in practice), then this shall be documented under a single unclassified work order, making note of the affected manufacturer/model profile.

7.4. Completing the Project

7.4.1. Ideally the project will be completed once every device affected by the recall has been located and any required assessment, inspection, testing or corrective action has been performed. In practice, however, there will be instances when some devices affected by the recall cannot be located after a thorough search.

7.4.2. The project cannot be completed until all devices affected by the recall have either been located, or (re)classified as Missing per the rules of the Medical Equipment Management Program. In either case, all device-related work orders must be completed before the project can be completed.

7.4.3. For devices that cannot be located, they should be reclassified as Missing once the MEMP criteria have been satisfied, and the corresponding recall work orders subsequently completed by the project leader.

7.4.3.1. Work Orders

The Reason should be manually changed to “Data Management” and the following text should be included in the Work Done section.

THIS WORK ORDER WAS CREATED AS PART OF A RECALL. THE DEVICE WAS THOROUGHLY SEARCHED FOR BUT WAS NOT FOUND AND WAS RECLASSIFIED AS “MISSING” PER THE MEMP. IF YOU FIND THIS DEVICE NOTIFY YOUR SUPERVISOR, DO NOT RETURN THE DEVICE TO SERVICE. SEE PROJECT <PROJECT NUMBER> FOR MORE INFORMATION.

7.4.3.2. Equipment Profiles

The device’s equipment profile should be updated with this note in the Comments section:

THIS DEVICE IS PART OF A RECALL AND REQUIRES MITIGATION. THIS DEVICE WAS THOROUGHLY SEARCHED FOR BUT WAS NOT FOUND AND WAS RECLASSIFIED AS “MISSING” PER THE MEMP. IF YOU FIND THIS DEVICE NOTIFY YOUR SUPERVISOR. DO NOT RETURN THE DEVICE TO SERVICE. SEE PROJECT <PROJECT NUMBER> FOR MORE INFORMATION.

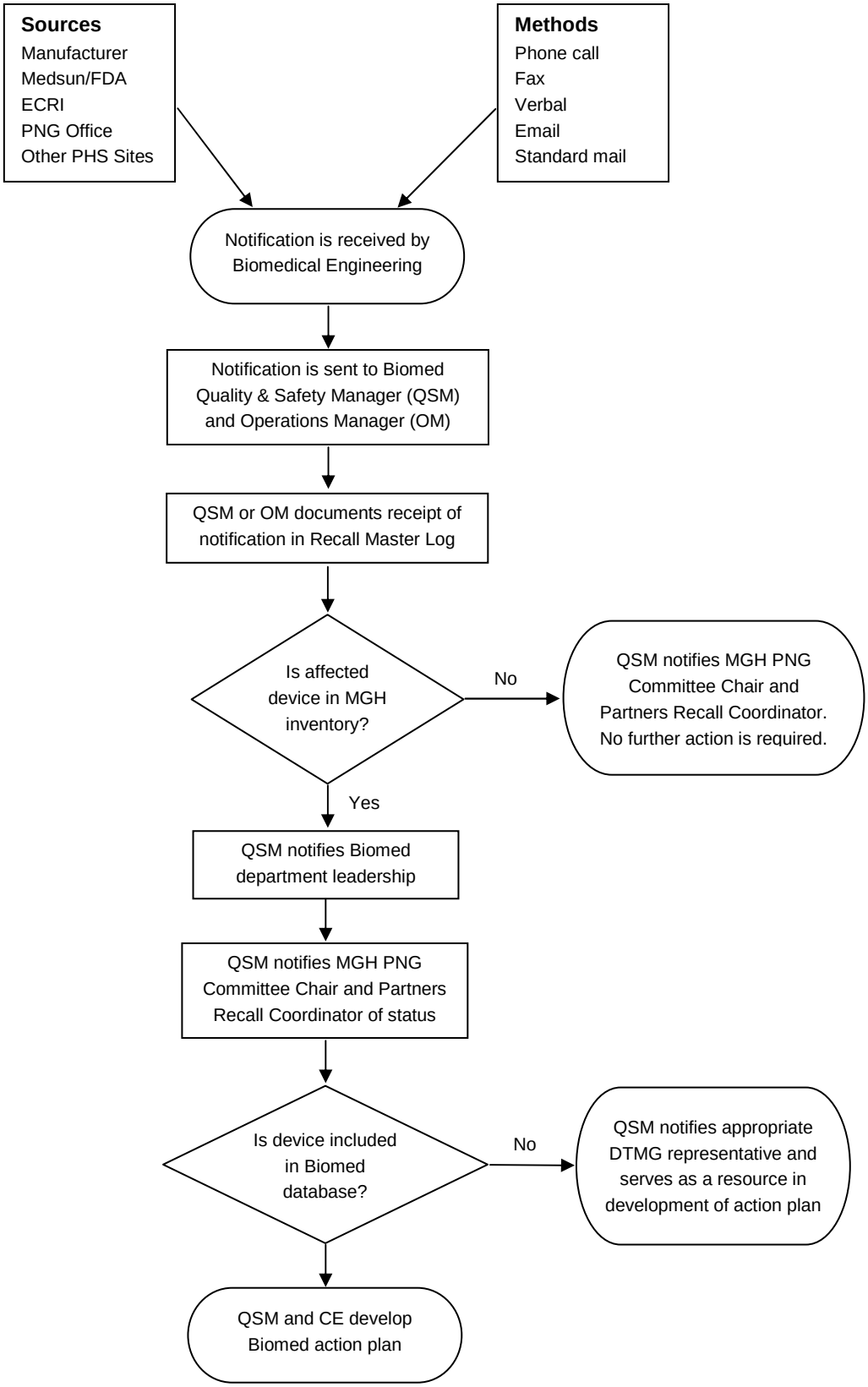
7.5. End-of-project Deliverables

The general guidelines in the document “Engineering Practices – Project Completion” should be followed for recall projects. In addition, every recall project should explicitly include:

- project summary document – describe the nature of the recall, how the corrective action(s) were carried out, any challenges that were encountered during the corrective action phase, any “permanent effects” of the recall (i.e. changes to support operations, clinical practices, etc.)
- list of all classified work orders and corresponding control numbers, including details on any work orders where the corrective action was not performed (i.e. missing devices)
- copies of all pertinent compliance documents.

All deliverables should be stored in the corresponding projects folder (L:\DBEMAIN\Projects\ RECALLS) in a subfolder called “Deliverables”.

Appendix A – MGH Biomedical Engineering Medical Device Recalls/Notification Process



Related Policies:
Hazard Notification/Medical Device-Product Recall (MGH)
Engineering Practices – Project Completion (BME)

Last Revision: 16 January 2013

Last Review: 16 January 2013

L:\DBEMAIN\MGH Policies\Med Device Recalls.pdf