Effectively Managing Medical Equipment Recalls

According to the FDA, the number of medical device recalls in the U.S. surpassed 3,000 in 2015. This equates to well over 50 safety alerts per week related to medical equipment. As a result of the high number of recalls, healthcare organizations are heavily burdened with the process of removing all affected devices throughout their facilities. The time it takes to locate, repair, remove, or replace equipment introduces a significant health and safety risk to patients and staff.

During recalls, it is imperative that all recalled equipment be immediately removed from service until it is repaired or properly disposed. Here are five steps you can take to ensure safety by effectively managing medical equipment recalls:

1. Be Sure to Receive All Recall Notifications

   The first and most basic step in effective management of recalls is being aware of them. Make sure your organization is subscribing to more than one source of product recall notifications (e.g. FDA, ECRI Institute, manufacturers, distributors, rental companies) and build in redundancy for notification methods. Common methods include Listservs on the FDA website, and email or fax notifications. You should also ensure notifications are being sent to the right people in your organization.

2. Verify the Existence of Recalled Equipment

   The next step is to check if you have any of the items listed in the recall notification. The critical component would be a Computerized Maintenance Management System (CMMS), which would provide this information faster than any paper-based inventory management system. The electronic system can generate a list of affected assets and automatically distribute it to every department that might be affected.

InSites Tip

Create a roles and responsibilities matrix to identify all personnel involved in the recall process. For some hospitals, a small, dedicated team can provide the best support in handling recalls. In other hospitals, a multi-departmental and cross-functional team approach may be more effective. You should also establish a centrally located and easily accessible repository of recall notices. It is helpful to indicate in the responsibilities matrix who has accountability for maintaining the repository.

InSites Value

With the Intelligent InSites solution integrated with your CMMS system, work orders can be generated in InSites to provide staff with an equipment recall task list. InSites also can help with prioritizing equipment retrieval based on real-time status, such as ‘in use with a patient.’
3. Locate and Remove Recalled Equipment

Quickly removing recalled equipment from patient care areas is the highest priority. In many healthcare facilities, this step takes a significant amount of time, as clinical engineers have to search through all places affected equipment might be located. Therefore, it is highly recommended to implement an RTLS-based asset tracking system for immediate locating of recalled equipment anywhere in the facility. Hospital leaders need to prioritize this technology as a solution that directly impacts patient safety.

4. Safeguard the Quarantined Equipment

Once recalled products are removed from the patient care cycle, you need to ensure they are stored in a designated and clearly marked quarantine area until clinical engineering fixes, returns or disposes them as directed in the recall notice. If you do not properly safeguard quarantined products, you are taking the risk of them making their way back to storage areas or even worse – patient rooms.

InSites Value

Using a map view within the InSites solution, staff can immediately find the location of recalled equipment and see which are available or in use with patients.

5. Evaluate the Recall Management Process

After each recall, healthcare organizations should document any problems encountered during the recall process and ways to avoid them in the future. A key performance indicator should be the amount of time elapsed from recall notice to completing all equipment recall tasks required for closure. It is also critical to ensure knowledge transfer regarding recall procedures by documenting the process, providing ongoing training to all staff members, and conducting recall drills to verify the process.

By following the steps described above, healthcare organizations can streamline their medical equipment recall process, making it more complete, reliable, and much faster.

“We conducted many mock recalls so the staff could demonstrate their abilities. We were able to trace to the granularity of specific manufacturer lot numbers. Finding the exact items went from being nearly impossible to locating these items in seconds with RTLS.”

VA Ann Arbor Healthcare System
Intelligent InSites Customer