White paper

How Workflow Automation Supports Medical Device Quality Assurance Program Goals: A Manager's Viewpoint

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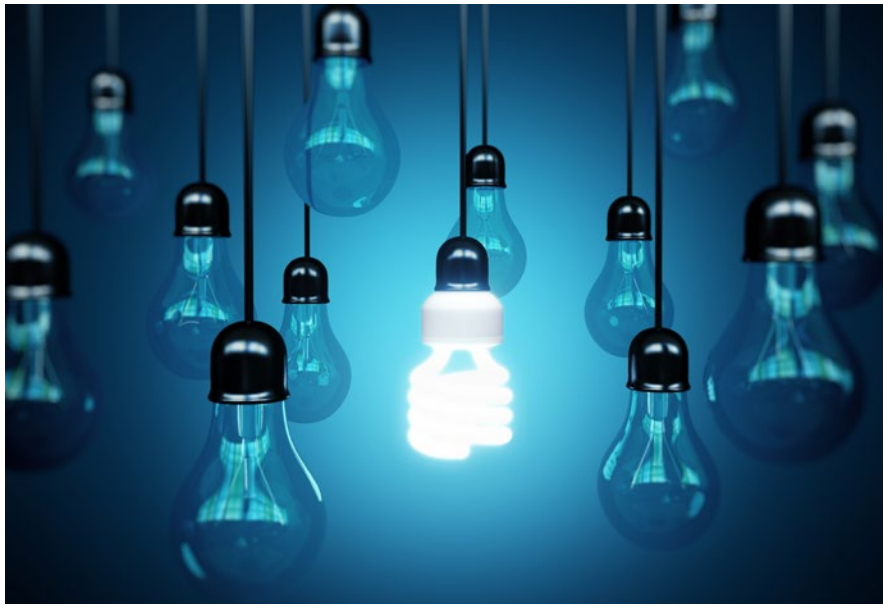

Managing a cost-effective medical device quality assurance program can be daunting. The goals of reducing risk of injury to patients, keeping medical devices properly functioning and available for use, and reducing cost of ownership of the inventory of medical devices and the test instruments needed for maintaining them has been challenging. Keeping biomedical engineers and technicians engaged and motivated to do the work required is also a challenge. This paper will touch on some of these challenges and suggest ways to deal with them more effectively.

What values are expected from periodic testing of medical devices?

1. Reduction of the risk of injury to the patient from faulty medical devices
2. Reduction in cost of ownership of the medical device by
   a. Finding problems sooner while they are less expensive to fix
   b. Time-efficient workflows that are standardized, accommodate the variety of test tools, provide visual guidance about work instructions (where to measure, how to measure, etc.), and reduce sources of human error
   c. Failure analysis to obtain failure rate across failure modes over medical device life cycle
   d. Shorter learning curves for Biomeds (test instruments/tools; medical device function/operation)
3. Increased availability of medical devices in the inventory
   a. Enable and sustain delivery of medical services
   b. Sustain the revenue stream of the medical facility and network
   c. Allow quicker availability for clinical use of new medical devices, and medical devices returned from out-source repair.

Time is money. It has been estimated that more than 50% of the available working hours of the typical Biomed is spent on testing and documentation. Another 30% of the available working hours of the typical biomed has been estimated as being spent finding the medical device asset to be tested. It has also been suggested that medical devices that are maintained using a run-until-fail strategy cost 30% more to keep running than when a program of periodic testing is applied. Part of the savings comes from efficiency. The more time it takes to perform assigned periodic testing of a medical device, the higher the cost of ownership contribution to the medical facility's cost of care. Nevertheless, regulatory requirements prevent the cutting out of important test steps by requiring that the medical device manufacturer's testing procedure be followed, and that the frequency of testing also be followed. So how can the apparent competing values of patient safety and cost of medical device ownership be accommodated? That is the subject of this paper.

The Biomedical or Clinical Engineering department of most medical facilities is charged with the responsibility of keeping an accurate inventory of the medical devices owned or in use within the medical facility. In addition, the proper maintenance of the inventory to ensure minimum performance and safety for clinical use is also the responsibility of the department. To balance reduction of risk of injury to patients who will be connected to these medical devices, and the reduction of cost of ownership of them is not simply about the technology. Testing requires the medical device to be temporarily removed from clinical use. This may mean the interruption of the revenue that could be received by the medical facility (bigger or smaller depending on the category of the medical device and its requirement for use during key clinical procedures). Testing also requires that test procedures and work instructions be followed without ad hoc changes. Because of the innovations in medical devices that save time and improve patient safety during clinical use are also part of the equation, older test instruments may not be able to perform functional testing of the innovation built into newer brands and models of medical devices. This requires keeping the test instruments up to date as well as the test procedures that must be used. New test instruments mean a new learning curve for the Biomed who will use them---slowing down the periodic testing. All this and more cry out for some way to standardize procedures and work instructions, make it easier to keep them up to date, and provide means to shorten learning curves while ensuring that critical data be captured for analysis (e.g., failure modes, failure rates, etc.). How easy or hard is this? It depends.

Standardizing the workflow (test procedure and its work instructions) might seem easy. Just create a document and a worksheet/checklist that has fields for data entry (whether a checkbox for Pass/Fail, or actual measurement values) for the Biomed to follow, right? In what form is the workflow delivered to the Biomed who will be doing the testing? Paper? Spreadsheet? Software? The form of the workflow can either help reduce sources of error or can make errors worse. Who is authorized to change the workflow? Is it delivered all in text? What about those for whom text alone does not completely convey procedure or the work instructions? A truly standardized workflow can only be changed by the authorized person or persons within the department. Standardized, locked-down

workflows prevent tampering, and help ensure that the measurement values collected during testing are statistically sound, thereby making long term trending and other analysis meaningful, valuable, and accurate. Failure mode and failure rate analysis needs this. Adding visual guidance into the work instructions in the form of photographs, or illustrations reduces errors about which test points were used to make the measurement, how to set up the test instrument for the measurement, where lubrication needs to be applied, etc. That ensures not only human error reduction, but efficiency of completing each step in the workflow, irrespective of the Biomed's experience. Of course, when the workflow is automated by software, test instrument interoperability (the set up configuration of the test instrument, and the automatic collection of the measurement into the workflow, and comparison to testing limits) makes the workflow maximally efficient. For test instruments that cannot be made interoperable, the manual entry of measured values that are automatically compared with testing limits make the Pass/Fail determination more objective. What if the available test instruments needed for a particular workflow step are some interoperable and some not? The workflow should be created in such a way as to accommodate manual entry where interoperability is not possible. Efficient workflows reduce the time required to complete, thereby reducing labor while maintaining highly reliable and consistent test results. Time saved can be re-deployed to the next workflow (increasing throughput) or can be applied to in-house repairs and clinician training about the operation of medical devices. Headcount is thereby better managed and increases in headcount can be done at entry-level rather than highly experienced and more costly personnel.

The application of workflow automation to standardized testing, reduce human error, sustain availability of the medical device to maximize the revenue stream, and collection of measurement values that allow accurate failure mode and failure rate analysis reduce the cost of ownership of the medical devices, and drive better choices of more reliable, easier to use medical device replacements.

References

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