
Lab Guidelines & Standards

How to Manage Your Laboratory's Nonconforming Events

Although health care continues to make significant strides in improving patient safety, opportunities for continuous improvement remain, especially in areas involving occurrence management, also known as nonconforming events. By identifying and addressing these types of events, laboratories can elevate health care delivery and bring quality assurance to the next level.

Most nonconforming events are the result of problems with existing processes. Laboratory professionals need to have defined processes to not only report nonconforming events, but also to follow through and determine the causes. Then they can implement process improvement changes, explains Sheila Woodcock, MBA, FCSMLS(D), president of QSE Consulting.

Management of Nonconforming Laboratory Events; Proposed Guideline (GP32-P), published by the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) in May 2007, was designed with this exact purpose in mind. "It is a very important missing link in the CLSI series of quality management documents," said Woodcock, a member of the CLSI committee that developed the document. CLSI is a global, nonprofit organization promoting the development and use of voluntary consensus standards and guidelines within the health care community.

The Need for GP32-P

One of the 12 quality-system essentials in CLSI's guideline, *A Quality Management System Model for Health Care; Approved Guideline—Second Edition (HS1-A2)*, describes the elements of a laboratory nonconforming event management program. However, the guideline gives only brief overviews of these elements, said Lucia Berte, MA, MT(ASCP)SBB,DLM; CQA(ASQ)CMQ, president of *Laboratories Made Better! PC*.

GP32-P will help laboratory professionals to meet requirements of both the International Organization for Standardization's ISO 15189:2003 standard, *Medical laboratories—Particular requirements for quality and competence*, and the College of American Pathologists' Laboratory General Inspection Checklist for medical laboratories to capture, investigate, and follow up on customer complaints and other problems that could (or did) compromise the quality of laboratory service, explains Berte, a member of the CLSI committee that developed the document.

"The idea for creating this document existed for a few years, waiting for someone to take the lead as the primary author," said Woodcock. "Luci [Berte] assumed this role."

Subcommittee members who had set up a laboratory nonconforming event management program or contributed

to the CLSI guideline or ISO standard were sought, Berte explained. Members chose sections to draft and submitted examples of forms used in their programs.

Useful Information for a Broad Audience

GP32-P is intended for use by individuals in any clinical service as an internal program for detecting, documenting, investigating, analyzing, correcting, and following up on events not conforming to the service's established policies, processes, and procedures.¹

Both accrediting bodies and the public at large expect the highest quality of services from health care providers today. "Laboratories must be able to demonstrate how they are continually improving," Woodcock said. "This cannot be achieved without a well-organized program for managing nonconforming events."

Laboratory managers and quality managers should use GP32-P to set up a new nonconforming event management program or strengthen an existing program. "Laboratories don't have to invent a nonconforming event management program," Berte said. "They can benefit from other laboratories' experiences."

GP32-P offers a suggested outline and contents for a nonconforming event management program. The guideline is based on principles of quality management and patient safety. Such programs, at a minimum, include the following elements:

- identification and reporting;
- remedial action;
- investigation and documentation;
- classification;
- analysis and data presentation; and
- management review and referral to process improvement.¹

"As with all of the quality series of documents, this guideline is easy to read and has lots of practical examples and templates in the appendixes," Woodcock noted.

Its applications can be adapted for other clinical areas, such as respiratory therapy, pharmacy, and diagnostic imaging, added Woodcock.

Sections of Particular Interest

Section 5, *Creating a Culture to Discover and Report Nonconforming Events*, discusses the importance of creating the right environment for effective nonconformance management. "A blame-free environment places the focus where it belongs: on the process, not the people," Woodcock said.

For a nonconforming event reporting system to be effective, employees must be willing to report an event in the interest of patient safety, even if it resulted from an inadvertent error. Most errors are unintentional, occur due to system problems, and are easily fixed, Woodcock said. However, tak-

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ing shortcuts can put patients or other staff at risk. Coaching and monitoring are the recommended actions to obtain compliance with correct procedures. Reckless behavior requires more serious intervention in the form of disciplinary action. Implementation of a nonconforming event reporting process must be preceded by staff education about the purpose of the process and training to recognize and report potential nonconforming events.

Section 12, *Management Review and Referral to Process Improvement for Long-term Corrective Action*, explains when a root cause analysis (RCA) should be performed. This is often a source of confusion for laboratory staff, Woodcock said. In addition to the requirement to perform RCA on all sentinel events, it should be performed on recurring nonconforming events and for events considered to have both high severity and high probability for harm. A safety assessment code matrix tool is provided to assist with determining a risk level.

Finally, the appendices provide examples of forms in both paper and electronic formats that can be used for cap-

turing, investigating, classifying, and following up on nonconforming laboratory events, added Berte.

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1. CLSI. *Management of Nonconforming Laboratory Events; Proposed Guideline*. CLSI document GP32-P. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. www.clsi.org.

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The Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) is a global, nonprofit, membership-based organization dedicated to developing standards and guidelines for the healthcare and medical testing community. CLSI's unique consensus process facilitates the creation of standards and guidelines that are reliable, practical, and achievable for an effective quality system.