

# Management of Nonconforming Laboratory Events; Proposed Guideline

*PLEASE*



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Please send your comments on scope, approach, and technical and editorial content to CLSI.

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*COMMENT*

This guideline provides an outline and the content for developing a program to manage a healthcare service's nonconforming events that is based on the principles of quality management and patient safety.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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*Advancing Quality in Healthcare Testing*

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GP32-P

ISBN 1-56238-637-9

Volume 27 Number 13

ISSN 0273-3099

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### Abstract

Clinical and Laboratory Standards Institute document GP32-P—*Management of Nonconforming Laboratory Events; Proposed Guideline* provides a suggested outline and contents for a program to manage a healthcare service's nonconforming events. Such a program is a fundamental component of quality management systems and patient safety.

Clinical and Laboratory Standards Institute (CLSI). *Management of Nonconforming Laboratory Events; Proposed Guideline*. CLSI document GP32-P (ISBN 1-56238-637-9). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007.

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### **Suggested Citation**

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

### **Proposed Guideline**

May 2007

ISBN 1-56238-637-9

ISSN 0273-3099

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## Foreword

Although healthcare continues to make strides in improving patient safety, opportunities for continuous improvement remain. Many of these opportunities present themselves as nonconforming events. The purpose of programs to manage nonconforming events is to identify and characterize problem-prone processes in health care so improvement projects can be prioritized, designed, and implemented.

A nonconforming event management program identifies systematic problems and gains management's commitment to removing the causes. As the words themselves suggest, nonconforming events do not conform with the organization's established policies, processes, or procedures; or with applicable regulatory or accreditation requirements; or have the potential to affect (or have affected) patient safety; or have the potential to affect (or have affected) the efficiency and effectiveness of work operations.

Nonconforming event management is linked to the healthcare organization's risk management program because it provides information on systemic service problems that could pose legal or financial risk issues for the organization.

Nonconforming event management is also linked to quality management; removal of root causes of nonconforming events leads to improved quality, which leads to improved patient safety.

This guideline 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 minimally include the elements of:

- identification and reporting;
- remedial action;
- investigation and documenting;
- classifying;
- analysis and data presentation; and
- management review and referral to process improvement.

## Invitation for Participation in the Consensus Process

An important aspect of the development of this and all CLSI documents should be emphasized, and that is the consensus process. Within the context and operation of CLSI, the term "consensus" means more than agreement. In the context of document development, "consensus" is a process by which CLSI, its members, and interested parties (1) have the opportunity to review and to comment on any CLSI publication; and (2) are assured that their comments will be given serious, competent consideration. Any CLSI document will evolve, as will technology affecting laboratory or healthcare procedures, methods, and protocols; therefore, is expected to undergo cycles of evaluation and modification.

The Area Committee on Quality Systems and Laboratory Practices has attempted to engage the broadest possible worldwide representation in committee deliberations. Consequently, it is reasonable to expect that issues remain unresolved at the time of publication at the proposed level. The review and comment process is the mechanism for resolving such issues.

The CLSI voluntary consensus process is dependent upon the expertise of worldwide reviewers whose comments add value to the effort. At the end of a 60-day comment period, each subcommittee is obligated to review all comments and to respond in writing to all that are substantive. Where appropriate, modifications will be made to the document, and all comments along with the subcommittee's responses will be included as an appendix to the document when it is published at the next consensus level.

## Key Words

Adverse events, incident reporting, nonconformances, nonconformities, patient safety



## Management of Nonconforming Laboratory Events; Proposed Guideline

### 1 Scope

CLSI guideline GP32-P—*Management of Nonconforming Laboratory Events; Proposed Guideline* 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 that do not conform to the service's established policies, processes, and procedures.

This guideline is intended to *supplement, but not replace*, an organization's established risk management or patient safety program.

The guidance provided herein is perhaps best used within an individual clinical service; however, the concepts may be expanded to function in a larger scope, if needed.

In this guideline, the medical laboratory is used for providing examples and appendixes.

### 2 Definitions

**adverse event** – untoward incident, therapeutic misadventure, iatrogenic injury, or other adverse occurrence directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic or other facility; **NOTE:** Adverse events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.).<sup>1</sup>

**close call** – event or situation that could have resulted in an adverse event, accident, injury, or illness; but did not, either by chance or through timely intervention; **NOTE:** Such events have also been referred to as *near-miss* incidents.<sup>1</sup>

**cognitive error** – error made from mistakes in decision-making and problem-solving; **NOTE:** Mistakes typically involve insufficient knowledge, failure to correctly interpret available information, or application of the wrong cognitive rule.<sup>2</sup>

**corrective action** – action to eliminate the (root) cause of a detected nonconformity or other undesirable situation.<sup>3</sup>

**examination processes (analytic)** – processes include all activities for performing the examinations, verifying the reliability of the results, and interpreting the findings.<sup>4</sup>

**latent error** – less apparent failures of organization or design that contributed to the occurrence of errors or allowed them to cause harm to patients.<sup>2</sup>

**near-miss** – used to describe any process variation that did not affect an outcome, but for which a recurrence carries a significant chance of a serious adverse outcome; **NOTE:** Such a “near-miss” falls within the scope of the definition of a sentinel event, but outside the scope of those sentinel events that are subject to review by the Joint Commission under its Sentinel Event Policy.<sup>5</sup>

**nonconformance** – nonfulfillment of a requirement<sup>3</sup>; **NOTE:** Other terms frequently used include: *accident, adverse event, error, event, incident, nonconformity, occurrence.*