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# Management of Nonconforming Laboratory Events; Approved Guideline

This guideline provides an outline and the content for developing a program to manage a health care 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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## Abstract

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

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## Foreword

Although health care 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 the efficiency and effectiveness of work operations.

Nonconforming event management is linked to the health care 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.

**Key Words**

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

# Management of Nonconforming Laboratory Events; Approved Guideline

## 1 Scope

This 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 health care facility; **NOTE:** Adverse events may result from acts of commission or omission (eg, administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment).[1]

**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.[1]

**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.[2]

**corrective action** – action to eliminate the (root) cause of a detected nonconformity or other undesirable situation (modified from ISO 9000).[3]

**examination processes (analytic)** – processes that include all activities for performing the examinations, verifying the reliability of the results, and interpreting the findings (ISO 15189).[4]

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

**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.[5]

**noncognitive error** – failure to accomplish a task that is usually automatic because of a lapse in concentration; **NOTE:** Also referred to as "slips."[2]

**nonconformance** – nonfulfillment of a requirement (ISO 9000)[3]; **NOTE:** Other terms frequently used include: *accident, adverse event, error, event, incident, nonconformity,* and *occurrence*.