QSE 10: Nonconforming Event Management

Policy	The laboratory identifies, documents, and investigates occurrences (nonconformances); classifies, analyzes, and trends the information they represent; performs remedial/corrective actions; and identifies the need for root cause analysis and process improvement.
Purpose	This policy provides direction for the processes and procedures to effectively detect and resolve problems and to classify problems so that corrective actions aimed at removing root causes and improving processes can be planned and implemented.
Responsibility	The Laboratory Supervisor is responsible for problem resolution and investigations. The Quality Manager and Quality Management Team are responsible for collecting and analyzing occurrence data. The Lead Technologists are responsible for documentation of complaints and problem resolution.
Identifying Occurrences	The laboratory has a means to identify, document, investigate, and respond to complaints from internal/external customers; recalls of materials, equipment, or software; and other nonconforming events.
Investigation and Response to Occurrences	The laboratory has a procedure for identifying, documenting, and investigating occurrences and performing remedial and corrective actions in response to those nonconforming events.
Classifying and Analyzing Occurrence Information	The laboratory has a procedure for classifying and analyzing occurrences, including trending information, so that the portions of the path of workflow with the most important patient-related and costly problems can be identified, corrected, and referred for root cause analysis and process improvement.
Supporting Documents	The following processes support this policy: • Identifying and Documenting Occurrences • Remedial Actions and Investigation of Occurrences • Analyzing Occurrence Information and Referring for Root Cause Analysis and Process Improvement

Process for Identifying and Documenting Occurrences

What Happens	Who's Responsible	Procedures
The laboratory identifies or receives complaints from internal and external customers	• Laboratory Supervisor • Quality Manager • Technicians/Technologists • External Customers	• Communication of Safety and Quality Concerns
The laboratory receives recalls or notification of nonconformances as related to materials, equipment, or software	• Laboratory Supervisor • Laboratory Supply Manager	• Inventory Management • Communication of Safety and Quality Concerns
A nonconforming event is identified from internal/external audits, QC/Calibration/EQA failures, or management reviews	• Laboratory Director • Laboratory Supervisor • Quality Manager • Technicians/Technologists	• Audit-Related SOPs • EQA SOPs • Quality Management • Communication of Safety and Quality Concerns
The occurrence is documented on appropriate electronic or paper-based occurrence report form	• Laboratory Supervisor • Quality Manager • Technicians/Technologists	• Communication of Safety and Quality Concerns
The form is submitted to the designated individual for further action, including remedial/corrective actions, root cause analysis, and process improvement	• Laboratory Supervisor • Quality Manager • Technicians/Technologists	• Communication of Safety and Quality Concerns • Quality Management • Process Improvement • Remedial and Corrective Actions

Process for Remedial Actions and Investigation of Occurrences

What Happens	Who's Responsible	Procedures
Immediate remedial actions are initiated to resolve any immediate concerns related to patient care	• Laboratory Supervisor • Quality Manager • Technicians/Technologists	• Communication of Safety and Quality Concerns • Investigations of Occurrences • Remedial and Corrective Actions
Remedial actions are documented on the occurrence report form	• Laboratory Supervisor • Quality Manager • Technicians/Technologists	• Investigations of Occurrences • Quality Management • Remedial and Corrective Actions
The occurrence is investigated and documentation is completed	• Laboratory Supervisor • Quality Manager • Quality Management Team	• Investigations of Occurrences • Quality Management
Additional corrective or preventive actions are completed and documented	• Laboratory Supervisor • Quality Manager • Quality Management Team • Technicians/Technologists	• Investigations of Occurrences • Quality Management • Technical SOPs • Remedial and Corrective Actions
Occurrence report form is submitted to designated individual for additional occurrence analysis	• Laboratory Supervisor • Quality Manager • Quality Management Team	• Quality Management • Process Improvement

Process for Analyzing Occurrence Information and Process Improvement Referral

What Happens	Who's Responsible	Procedures
Information regarding individual occurrences is entered into an electronic or paper-based database	• Quality Manager • Quality Management Team	• Communication of Safety and Quality Concerns • Occurrence Report Forms • Quality Management • Occurrence Data Analysis • Process Improvement
Occurrences are categorized, tracked, and organized in a manner to facilitate analysis of collective data	• Quality Manager • Quality Management Team	• Occurrence Data Analysis • Quality Management • Process Improvement
Database and occurrence report information are reviewed at regular intervals to identify trends in occurrence information	• Quality Manager • Quality Management Team	• Occurrence Data Analysis • Quality Management • Process Improvement
Management reviews data and allocates resources for root cause analysis and process improvement	• Quality Manager • Quality Management Team • Laboratory Management	• Quality Management • Occurrence Data Analysis • Process Improvement • Allocation of Resources