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Laboratory Employee Incident Investigation and Root Cause Analysis

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document identifies the process to follow for employee incident investigations and root cause analysis in the laboratory.

II. GENERAL INFORMATION:

A. Employees must follow the Corewell Health Human Resources (HR) Employee Health and Safety policy Work Related Injury and Illness for reporting incident events that resulted in employee injury or illness . The on-line reporting form can be found on the Corewell Health Intranet under the "Report a Safety Concern" section, then submit a "Safety Pause". If the employee is unable to report the incident to HR, then the employee's Manager/Supervisor/ designee will access the form and record the injury or illness on behalf of the employee.

B. Corewell Health Laboratory employees must report work place incidents to their Manager/ Supervisor when an injury, illness, possible exposure or near misses has occurred.

C. The incident follow-up investigation and root cause analysis (RCA) focuses on the event, the process and systems involved. It is important to closely examine the event, capturing as many facts as possible. The goal is to eliminate/minimize exposure incidents.

D. The Laboratory Incident Investigation and Root Cause Analysis (RCA) form should be used to document the investigation and RCA . The Manager/Supervisor/designee should include the

involved employee and, if applicable, the campus Laboratory Safety Officer in the analysis, after the employee returns to work duty, following a work place injury or illness.

Note: For patient care/testing sentinel and near miss events, report the incident through the Corewell Health Patient Safety Reporting system (RL Solutions). The Corewell Health Quality department will assist in patient related RCA and process improvement, when appropriate. RL Solutions Quality/Safety Report Instructions

III. DEFINITIONS:

A. Incident - a work related event in which an injury, illness or fatality occurred or could have occurred.

B. Near miss events – an unplanned event that did not result in injury, illness, or damage, but had the potential to do so had the circumstances been slightly different.

C. Non-conforming events - events that do not conform with the organization's established policies, processes, or procedures; with applicable regulatory or accreditation requirements; or have the potential to affect (or have affected) patient safety, employee safety or the efficiency and effectiveness of laboratory operation.

D. Personal Protective Equipment (PPE) - refers to protective clothing, helmets, gloves, face shields, goggles, face-masks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.

E. Root Cause Analysis (RCA) is a quality tool to help aid in the discovering of the underlying cause(s) of the incident. A series of "what, how, where, and why" questions are asked during the investigation.

F. Sentinel Event – Safety event that results in death, permanent harm, or severe temporary harm.

IV. PROCEDURE:

A. **Sentinel event, injury or illness event**: If the employee incident resulted in death, permanent harm, severe temporary harm, the employee's Manager/Supervisor/designee will inform the Corewell Health Laboratory Director, System Quality/Safety Manager, Hospital Safety Director, and HR Employee Health. The employee's Manager/Supervisor/designee will initiate an investigation and root cause analysis (RCA). Refer to the Corewell Health policy: Serious Safety Events.

   1. The incident event must be documented in the HR Employee Health Incident Reporting Safety Pause application. This can be done by the employee's Manager/ Supervisor/designee if the employee is unable to access the form.
   2. The manager/Supervisor/designee will document the incident on the Laboratory Incident Investigation and RCA form.

B. **Non-sentinel event or near miss**: If the incident resulted in a non-sentinel event or a near miss, the Manager/Supervisor/designee will determine the extent of the investigation and follow-up for the incident.

   1. The incident should be documented in the HR Employee Health Incident Safety Pause application. This can be done by the employee's Manager/Supervisor/

designee if the employee is unable to access the form.

2. The Manager/Supervisor/designee may document the employee incident on the Laboratory Incident Investigation and RCA form.
3. The Manager/Supervisor/designee may arrange to include the campus Laboratory Safety Officer to participate in the investigation and RCA along with the involved employee.

C. **Manager/Supervisor/designee documents the following on the Laboratory Incident Investigation and RCA form:**

1. Event Information: Collect event information through discussion with the involved employee. For example, date/time of event, where event occurred, employee(s) who were involved in the incident.
2. Evidence Collection: Any incident evidence should be preserved, if possible. For example, a defective box of gloves.
3. Training Record Review: Review employee training and competency records for the task or procedure related to the incident. For example, if the event involved disposing of chemicals, review the employee's training record for chemical education and disposal.
4. Detailed Description of Incident: Engage in a thorough discussion of the incident event that includes events leading up to, during, and after the incident. Employee should include what device/equipment/action was involved in the task or procedure.
5. RCA: For non-sentinel events, the Manager/Supervisor/designee will determine if a RCA and process improvement is required for the incident. If a RCA and process improvement is deemed appropriate, then the involved employee, and if possible, the campus Laboratory Safety Officer can assist the Manager/Supervisor/designee. The "5 Why-Why technique" along with a series of what, how, and where questions can be asked to determine the underlying cause of the incident.
6. Process Improvement: After the RCA is completed, determine if any process improvements or risk reduction should be implemented to help prevent similar events in the future. The process improvement discussion may include the employee directly involved in the incident, other department employees and the campus Laboratory Safety Officer. The goal is to implement process changes, improve forms, policy change, retraining, or other safety improvements to facilitate a safe working environment and to prevent similar events in the future.
7. Storage of the completed Laboratory Incident Investigation and RCA form: The Manager/Supervisor/designee retains the original copy and a copy is sent to the campus Laboratory Safety Officer and the System Quality/Safety manager.

D. Communicating the investigation and RCA report: Manager/Supervisor/designee will notify the Laboratory Director, the System Quality/Safety Manager, and the campus Safety Officer about the incident investigation, RCA, and process improvement. The campus Safety Officer should review the event at the Laboratory Safety Committee meeting.

V. REFERENCES:

Occupational Safety and Health Administration Incident Investigation

College of American Pathologists (CAP) Lab General Checklist, Current Version

Attachments

Laboratory Incident Investigation and RCA form.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	5/13/2024
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	5/7/2024
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	5/6/2024
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	5/3/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	5/2/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	5/2/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	5/2/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	5/2/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	5/2/2024
Policy and Forms Steering Committee Approval (if needed)	Christopher Ferguson: Dir, Lab Operations B	5/2/2024
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Operations Directors	Amy Knaus: Dir, Lab Operations C	4/2/2024
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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

Corewell Laboratory

Canton • Dearborn • Farmington Hills • Grosse Pointe • Lenox • Livonia • Royal Oak • Taylor • Trenton • Troy • Wayne

Laboratory Incident Investigation and Root Cause Analysis (RCA) form

Laboratory employee safety incidents include sentinel events, non-sentinel events, possible exposures, or near miss events. Examples include needle sticks/sharps, blood/body fluid splashes/sprays, chemical splash, physical injury, fumes, or events that had the circumstances been slightly different, injury or illness may have occurred.

Manager/Supervisor or designee documents the form with the employee involved in the incident. If possible, also include the campus Laboratory Safety Officer. Supervisor/Manager/designee retains the original form and a copy is sent to the campus Laboratory Safety Officer and the System Quality/Safety manager.

Section A: Information

Questions:	Response:
Date/time of incident	
Location of incident	
Hospital campus where incident occurred:	
Date investigation initiated:	
Supervisor/Manager/designee name:	
Campus Laboratory Safety Officer name (if assisting with investigation/RCA):	
Task or procedure being performed at the time of the incident (i.e. phlebotomy, tissue cutting, waste disposal)	
Are employee's training and competency records complete for the task or procedure related to the incident?	

Section B: Employee information and Incident Description/Injury

Questions:	Response:
Employee's Name:	
Employee's Job title	
Employee's Date of hire	
Length in current position at the time of the incident	
Employee's assigned department (if rotates, the department at the time of the incident)	
Did employee document the incident in the Corewell Health Employee Health and Safety "Employee Health Incident Reporting" online form?	

Questions:	Response:
Type of safety incident (i.e. needle sticks/sharps, blood/body fluid splashes/sprays, chemical, physical injury):	
What type of equipment or device was involved in the incident? Describe any malfunction or defective equipment.	
Personal Protective Equipment (PPE): What type of PPE was the employee using at the time of the incident? Was PPE malfunction involved in the incident? If yes, please explain.	
Was the employee exposed to body fluids other than employee's own? If yes, is the source known? Was the body fluid exposure reported to Employee Health and Safety?	
Did the employee collect any evidence or photos taken to aid in the investigation and RCA? Explain.	

Section C: Detailed Description of Incident
Include relevant events leading up to, during, and after the incident.

Section D: Additional information from employee

In the employee's opinion:	
Did employee have the tools to safely perform the task/procedure? If no, explain.	
Did the employee receive adequate training for the task/procedure involved in the incident? If no, explain.	
Is the written Standard Operating Procedure (SOP) and Policies for the task/procedure related to the incident written clearly? If no, explain.	
Did the employee feel rushed at the time of the incident? If yes, explain.	
What other cause/contributing circumstance was associated with this incident?	
What could be done to prevent a future event?	

Proceed with Sections E – F if a RCA was performed and/or process improvements implemented

Section E: Identify the Root Causes: What caused or allowed the incident to happen?
(Possible contributing factors to consider: availability of information, communication amongst staff, environmental, equipment, facility, human factors, training, policies, staffing)

The root causes are the underlying reasons the incident occurred and are the factors that need to be addressed to prevent future incidents. A common Root Cause Analysis tool is the "5 Why-Why technique". The primary goal of the technique is to determine the root cause of a defect or problem by repeating the question "Why?". Each answer forms the basis of the next question.

Section F: Process Improvement
Implemented actions to prevent future incidents (i.e. process changes, improve forms, policy change, retraining, or other safety improvements)