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ANCILLARY DIVISION APPROVAL MATRIX		Section / Department **LABORATORY SECTION**
Policy Title: **POLICY ON REPORTING, INVESTIGATION AND ANALYSIS OF INCIDENTS, ADVERSE EVENTS AND OTHER RELATED PROCESSES**		Page **1** of **5**
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I. INTRODUCTION

"Primum non nocere" – first do no harm, is one of the basic principles of Medical Ethics. However, the goal of Medicine is not only to "do no harm" to patients, nonmaleficence, but to do what is good or beneficial to them, beneficence. With the presence of the human factor in the various fields of Medicine, including Laboratory Medicine, the possibility of error cannot be ignored. Yet, with the proper investigations and analysis of these events, the correction and improvement of systems and processes can provide a culture of safety in patient care for health institutions.

II. OBJECTIVES

The primary aim of this policy is to promote safe patient care by providing guidelines in the reporting, investigation and analysis of complaints and to use the findings of these events in improving current policies and procedures of the Laboratory.

III. PRINCIPLE

"To Err is Human", but the major message is that "the cause of medical errors and preventable deaths was not careless or incompetent people but bad systems"8 . Therefore, there is a need to move away from the approach of finding somebody to blame for medical errors to an approach where the reporting of patient care events is a reflection of the cooperation and teamwork of the laboratory staff and the hospital as a whole whose main goal is patient safety.

Latest studies recommend the Root-Cause-Analysis approach in investigating

and analyzing patient safety events. The approach focuses on “design or system failure, not individual fault”. Thereby, repetitive mistakes can be avoided if we speak up, analyze the situation, fix something and monitor whether our action makes a difference.

IV. PATIENT SAFETY

The main aim of handling complaints and analyzing unfortunate incidence is patient safety. Patient safety is defined as, “the prevention of errors and adverse effects to patients associated with health care”11

A. Patient Safety Event A patient safety event is an event, incident or condition that could have resulted or did result in harm to a patient.12 The following are considered as patient safety events

1. Adverse Event – is a patient safety event that resulted in harm to the patient.
2. No-Harm Event – a patient safety event that reaches the patient but does not cause harm. 3. Close-call/ Near-miss/ Good Catch- a patient safety event that did not reach the patient. 4. Hazardous/Unsafe Condition(s) – a circumstance (other than a patient’s own disease process or condition) that increases the probability of an event..

B. Sentinel Event A sentinel event is a patient safety event (not primarily related to the natural course of the patient’s illness and underlying condition) that reaches the patient and results in any of the following:

- Death
- Permanent Harm
- Severe Temporary Harm14

V. REPORTING OF PATIENT SAFETY EVENTS

Patient Safety Events involving the Laboratory Section may be identified by the laboratory staff, other hospital staff and patients or their relatives. Events should be reported the soonest possible time but preferably within 72 hours after the incident. The report should be addressed to the Pathologist of the Laboratory Department thru the Chief Medical Technologist.

VI. INVESTIGATION OF REPORTS

A. Investigating Team

The Pathologist and Head Medical Technologist shall head and create the team that shall investigate and analyze any patient safety event that is reported. The Pathologist can also request other experts outside the Laboratory (e.g. Chief of Clinics, Admin officer or Physician on duty) to attend the meetings on an incident for professional opinions and feedback should the need arise.

B. Investigation Procedure

1. The team should request all parties involved in the patient safety event to submit an incident report narrating the sequence of events that has occurred.
2. The team must analyze the reports and investigate to arrive at a resolution by answering the following questions:

A. What happened?

The team must review the following in light of the event that has occurred

(1) Rules, Policies and Procedures that apply to the event and consider if it is updated to the current needs and situations the laboratory is facing.

(2) Safeguards – if there are present safeguards that could have prevented the event from happening or if these safeguards are still applicable to what is needed at hand

(3) Environment – to check if factors such as design of the area

where it occurred and the environmental culture were contributory to the occurrence of the event. A risk assessment should also be made.

(4) Equipment – if equipment is a contributing factor in the occurrence of the event.

(5) Information Technology – to check if the design of the current information system is still applicable to the event and if the staff involved has been properly trained in the technology that was used.

(6) Fatigue and Scheduling – fatigue must be considered since there is a human factor involved. The staffing pattern must also be investigated and correlated to the occurrence of the incident.

(7) Training – the team must ask if the personnel involved have been properly trained for the procedure leading to the event.

(8) Communication – the team must also investigate if there was miscommunication or lapse in the communication system that could have caused the incident to happen.

B. Why did it happen?

The team must be able to establish the link between the incident and the surrounding circumstances that have led to the event. All contributing factors that have been mentioned above must be taken into consideration. Generalities and finger pointing must be avoided

C. **What actions can be taken to avoid it from happening again?**

(1) An action plan must be developed to prevent the incident from happening again in order to make the patient care given safer.

(2) The plan must be able “to get people to interact with the system more effectively”

D. **How will we know if the plan has been effective**?

The team must establish a set criterion if the rectifying actions taken has been effective in addressing the root cause of the incident.

E. **FINDINGS AND RECOMMENDATIONS**

The findings and recommendations of the team should be included as reference in the revision and amendments of Laboratory policies and procedures. All parties involved shall be given a copy of the team's findings and recommendations. Responsible Authority: The Pathologist, Chief Medical Technologist, Laboratory Section Heads are the personnel responsible for this document including any change, correction or update.

ANNEX A: Laboratory Occurrence Management Form (Incident Report)