BIOGENIX

POLICY PROCEDURE FOR INCIDENT REPORTING

	NAME	DESIGNATION	SIGNATURE	DATE
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1. TABLE OF CONTENT

2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3. REVIEW HISTORY

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1	1.0				

4. POLICY STATEMENT

Identification and control of Non conformities are done as per following procedure.

5. PURPOSE

The purpose of this procedure is to establish an incident reporting and a documenting system to identify and provide notification of incidents or events that have occurred involving patients, visitors, staff, equipment, facilities or grounds which are likely to give rise to potential liability, affect the quality of patient care or affect safety in the facility.

This procedure is developed and implemented based on ISO 15189:2012 Medical Laboratory Requirement for Quality and competence Clause number: 4.13(l-m)/ 4.14.6 and HAAD Standard for Adverse Events Management and Reporting: HAAD/EMR/01/2011. BIOGENIX laboratory has an active incident reporting system (procedure, process, forms, documentation, etc) in place.

The effective reporting and management of incidents at BIOGENIX laboratory is essential for the delivery of high quality, safe, patient care. This also ensures the health, safety and wellbeing of staff, contractors and visitors.

BIOGENIX laboratory emphasizes that incident reporting is a shared responsibility of all staff and is therefore part of every member's role and responsibility, where mistakes and untoward occurrences are identified quickly and acted upon in a positive and constructive way.

The incident reporting system document that the following events involving patients, clients, staff and visitors are reported promptly and action taken as necessary: Clinical Incidents, Health incidents, Patient Falls, Near Misses, Personal Accidents & Dangerous Occurrences, Violence, Abuse & Harassment incidents, Fire Incidents, Security Incidents, and Other incidents

6. SCOPE

6.1. This procedure relates to all staff as well as anyone working on, or using, BIOGENIX laboratory premises, e.g. service users, visitors, contractors, staff.

6.2. TARGET AUDIENCE:

- 6.2.1. BIOGENIX Management
- 6.2.2. BIOGENIX Staff

7. DEFINITIONS

7.1. Incidents or Accidents: An event that harms, or has the potential to harm. This may give rise to actual or possible personal injury, to patient, visitor, or staff dissatisfaction, or to property loss

or damage. This includes adverse clinical events (an event or omission arising during the delivery of clinical care and causing physical or psychological injury to a patient).

This also includes an injury sustained by a staff member during the course of their work or an injury sustained as a result of a physical act of violence done to a person at work.	Occupational Injury
Any unintended or unexpected incident that could have or did lead to Harm for one or more patients	Patient safety Incident
Anything that has the potential to cause injury, damage or loss.	Hazard
An incident, which if it did not cause injury or damage this time, Could do so if it happened again.	Near miss
Any disease or medical condition that may have resulted from a Work-related activity. This is required to be supported by a sickness Certificate from a suitably qualified medical practitioner (i.e. a General Practitioner) or from an Occupational Health physician e.g. for work related illnesses such as TB , Sharps injury.	Work-related illness
Any accident, no matter how small, which did or could have Adversely, affected any person. This does not include any incident Caused deliberately. Examples, needle stick injury from taking a Blood sample, slip on wet floor, caught finger in filing cabinet.	Personal accident
Any incident involving verbal abuse, unsociable behavior, racial or sexual harassment, physical assault, or self-harm, whether or not Injury results	Violence, Abuse or Harassment
Any case of known or suspected work or environment related ill health (for example, infection, headaches, dermatitis, minor ailments	ill Health

Such as headaches) potentially caused by inadequate lighting, known or suspected hospital acquired infections, dermatitis and latex allergy.	
Any incident, no matter how small, involving fire or fire warning Systems (including false alarms). Example, false alarms, actual fires caused accidentally or willfully, involving injury or no injury.	Fire Incident
Any untoward incident involving theft, loss or other damage to organizational or personal property, intrusions, false alarms (but not fire alarms), absconded patients and other security incidents. Examples -, burglary, petty theft, fraud.	Security Incident
An occurrence that is not consistent with the professional standards of care of the patient or the routine operation or policies and Procedures of the organization.	Clinical Variance
An occurrence that may involve persons, machine/equipment failure or misuse, security breaches and violence, or fallen due any instinctive or extinctive reason	Non Clinical Variance
A sentinel event is an unexpected occurrence involving death or Serious physical or psychological injury or the risk thereof. Serious, as per HAAD sentinel event policy and definition.	Sentinel Event

8. ACRONYMS

8.1. SE- Sentinel event

8.2. RCA- Root Cause Analysis

9. RESPONSIBILITIES

9.1. All staffs comply with the procedure requirement; Management of BIOGENIX laboratory is responsible for ensuring that this procedure is disseminated to the BIOGENIX Laboratory staffs.

10. PROCEDURE

10.1. The quality manager provides orientation to all BIOGENIX laboratory Staff on the procedure for their better understanding, reporting and, documenting (Incident reporting form, etc) incidents in the center.

10.2. For incidents involving patients, the person completing the incident report form is the individual who witnessed, first discovered, or is most familiar with the incident. Each section of the form is completed.

10.3. The report immediately presented to the lab director who investigate and recommend corrective action. The description of the incident is a brief narrative which consists of an objective description of the facts. It includes the writer's judgment as to the cause of the event. Quotes used where applicable with witnessed incidents, e.g., "Patient states..." The name of any witnesses is included on this report. The name of the employee directly involved in the incident is recorded in the witness space as well, if the employee is not the reporter.

10.4. The quality manager identifies and monitor risk areas with the staff involved in the incident and report to lab director with appropriate preventative action. Staff who involved in the incident is reassured that the management of BIOGENIX laboratory adopts a blame-free culture.

10.5. The incident report form is completed no later than the end of the shift during which the incident occurred or discovered to have occurred.

10.6. All incidents involving visitors are reported to the quality manager. A visitor who has sustained an injury while in the BIOGENIX laboratory is escorted by a staff member to the nearby hospital Emergency Service for medical attention. If the injured person refuses medical attention, this is noted on the Report of incident form.

10.7. The incident report form is an administrative document not part of the medical record.

10.8. Report of incidents and or near misses are documented by using the same incident reporting system;

10.9. Management of the BIOGENIX have designated quality manager who is responsible that the information (regarding the incident) is collated and trends produced, the recording of incident data is a confidential process therefore the data is secured and ensure access to only those with approved access such as quality manager, lab director. Each incident is reviewed by quality manager along with Lab Director who provides advice and recommends corrective actions as and when necessary.

10.10. The lab director and quality manager analyze incidents and classified the incident.

10.11. All incidents including near misses are investigated by the lab staff and reported to Quality manager with timeline. Also communicated to all the staff for lesson learnt which helps to reduce risk in future and improve systems.

10.12. It is essential that all incidents and near misses are handled in a confidential manner to ensure that patients/clients and staff are supported and treated respectfully.

10.13. All the track and trend is maintained by quality manager with corrective and preventive actions.

10.14. Root Cause Analysis:

Root cause analysis is conducted for the near miss incidents. The root cause analysis is conducted for serious events and incidents repeated. The lab staff conducts RCA with quality manager. The report of the analysis is discussed with the lab director for the corrective and preventive action. The quality manager is responsible to review action plan and to see all the gaps are closed. The track and trend on all incidents is maintained and presented to management

11. CROSS REFERENCE

11.1 HAAD standard for clinical Laboratory

11.2 ISO 15189:2012 Medical Laboratories –Requirement For Quality And Competence.

11.3 Adverse Events Management and Reporting: HAAD/EMR/01/2011

12. RELEVANT DOCUMENTS & RECORDS

12.1 BG/REC/GEN/002 Incident Reporting Form