Changes in Grey

**Incident Management Plan and Incident Investigation Report Form**

**Purpose:** The Purpose of this Incident Management Plan is to provide Bioreach Laboratories with a process for the investigation of reported events to determine the presence of situations that have the potential to cause harm or injury to staff and patients. Investigation of Incidents or near misses can help protect staff and patients from future events. The ultimate goal of Incident management is to prevent future events and improve safety in the laboratory.

**Definition of Incident:** An incident is an event that may result in or has the potential to result or has resulted in, death or serious adverse outcomes for either patients or laboratory staff. Situations that could have resulted in injury and do not represent a systemic problem with potential for recurrence but did not because of some type of intervention are managed as quality assessment reviews and are investigated via the Bioreach Monthly Quality Assurance review.

**Types of Incidents:**

Events or activities that are considered incidents include the following:

* Misidentification of patient specimens or reports.
* Performing testing on the wrong patient.
* Errors in Laboratory policy adherence that result in errors that require corrected reports.
* Systemic non-compliance with established laboratory policies and procedures.
* Repeated failures in safety procedures.
* Recurrent complaints about phlebotomy.
* Accidents or improper disposal of contaminated waste causing injury.
* Sentinel Events resulting in the Death or serious injury (unexplained or unexpected), such as Medication error leading to death of the patient believed to be due to incorrect lab results.
* Other catastrophic events.

**Process for Incident Investigation:** Each incident should be reviewed on a case-by-case basis and discussed promptly so that the causes can be identified, and the problem addressed immediately. The following process should be used for incident investigation:

1. Staff who witness or become aware of an incident should report the occurrence to the laboratory director, manager, or lead tech within 24 hours of discovering the potential incident. Facts related to the incident should be documented on an Incident Management Investigation Form and any materials involved in the incident should be retained.
2. The Laboratory Director or Laboratory Supervisor will determine if any outside agency reporting requirements apply to the incident.
3. The Bioreach Emergency Operations Policy 1.13 should be referred to for any disaster incidents, power outages, fires or natural disasters.
4. Patient injuries or errors in reporting will be reported to the ordering physician. There may be a need to notify affected patients to reevaluate their medical care.
5. The Laboratory Director or Laboratory Supervisor will perform the evaluation and investigation of the incident and complete the Incident Investigation Report.
   1. The individual conducting the investigation must have the authority to recommend changes in policy, process, and procedure to effectively resolve and prevent a recurrence of the incident.
   2. The investigator will analyze the impact of the incident during the time prior to the initial report of the incident, during the investigation of the incident, and for future testing. Testing may be suspended until the true cause of the incident has been determined and corrected.
   3. The investigator will analyze the root cause of the incident by analyzing what, when, who, where and how the event happened. Root cause analysis determines why the event occurred by repeatedly asking “why” questions until the underlying cause is determined.
   4. The investigator will document the facts, findings, and conclusion on the Incident Management Investigation Form. The report is given to the Laboratory Director for review and approval.
6. Based on the findings, the Laboratory Director, Laboratory Supervisor or Bioreach President will determine the appropriate corrective actions that will be taken to prevent recurrence of the incident. Implementation of corrective actions should proceed in a timely manner.
7. The laboratory should document the date that each corrective action step is completed on the Incident Investigation Report form.
8. The investigation findings and outcome are communicated to the staff.
9. Any necessary policy or procedure revisions or re-training of personnel are to be completed.
10. The Laboratory Director or Laboratory Supervisor will follow up on the corrective actions taken to ensure that they were effective.
11. Laboratory Director is to sign final report.
12. Retain all documentation regarding the incident in the laboratory quality assessment manual for two years.

**Incident Investigation Report Form**

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| **Person Reporting Event** |  |  |

**Reporting Information:** *(Complete all information)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date of Incident** | |  | **Number of Patients Affected** | |
| Date of form: |  | Patient(s): |  |
| Time: |  | Staff: |  |
|  |  | Other(s) |  |

**Event Type:** *(Check all appropriate event types)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sentinel event: Death or Injury to patient or staff |  |  | Needlestick or Bloodborne exposure |  |
| Failures in safety procedure |  | Other catastrophic event (describe) |  |
| FDA Device Errors |  |  |  |

**Patient/Staff Information of Person Affected by Event:** *(Complete all information)*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name: Last | |  | | First | |  | | Middle | |  | |
| D.O.B. | |  | | Patient Identification Number: | | | | | |  | |
| Treatment Date |  | | Current Status  *(circle)* | | Discharged | | Hospitalized | | Deceased | | Unknown |

|  |  |
| --- | --- |
| **Person Responsible for Investigation of Event:** |  |
| **Date of Investigation Report:** |  |
| **Regulatory Agency Notification and Date:** |  |
| **Provider/Customer Notification and Date:** |  |
|  |  |
| **Brief Summary of Incident:** *What happened and how was it handled? What area is affected?* | |

*Attach additional information if necessary, including all applicable laboratory reports*

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| **Report of Investigation Findings:** *What did the root cause investigation and analysis find?*   1. *What factors are involved in the event? (e.g., Human, Equipment, Controllable environment, Uncontrollable external factors)* 2. *What systems or processes underlie these factors? (e.g., Human resource issues, Information Management issues, Emergency & Failure-Mode responses, Leadership issues, Uncontrollable factors)* |

|  |
| --- |
| **Correction Action to be Taken as a Result of Investigation Findings:** *What will you do to prevent reoccurrence of the incident?* |

|  |  |
| --- | --- |
| **Reviewing personnel:** |  |
| **Date of Review of Report:** |  |
| **Necessary Communications to Staff:** |  |
| **Date of Communication Report:** |  |

**Follow-Up Actions to be Taken:** *(Check all appropriate actions)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | No action required |  | *Development of new policy/procedure* |  | *Cease patient testing* |
|  | Communication of findings to staff |  | *Revision of policy/procedure* |  | *Refer patient testing* |
|  | *Staff training and in-service* |  | *Staff competency assessment* |  | *Resume patient testing* |
|  | *Corrective action monitoring* | | | | |
|  | *Corrective action follow-up and review by (date):* | | | | |
|  | *Findings inconclusive – monitor process. Review by (date):* | | | | |
|  | *Information is incomplete; follow up to be completed by (date):* | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Report Submitted by:** |  | **Date:** |  |
| **Report Approved by:** |  | **Date:** |  |