**Incident Investigation Report Form**

| **Person Reporting Event** |  |  |
| --- | --- | --- |

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

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

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

| Sentinal 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*

| **Report of Investigation Findings:** *What did the true 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):* | | | | |

**Notes/Comments:**

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