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# Purpose:

This SOP defines the procedures and controls for managing incidents regarding the Information Technology systems used in regulated activities.

# SOP Scope:

This SOP applies to all computer-based systems.

# Definition:

Incident: A system related situation reported to the Information Technology department as inhibiting use of one or more system functions.

# Responsibilities

The IT Manager is responsible for

* Implementing the practices for system incident management as specified within this SOP.
* Leading periodic evaluation of incident management effectiveness.

The System Users are responsible for

* Reporting system incidents to the Information Technology department.

# Procedures:

## Incident Recording

1. Each incident reported to the Information Technology department is recorded on an Incident Report form, Attachment A.

| **Incident Report Form Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Incident ID** | Assign a unique incident ID using format YYYYMMDD-nnn.  YYYY = current year  MM = current month  DD = current day  nnn = sequential number, starting at 001 each day |
| **System Name** | Record the name of the system involved in the incident. |
| **Date Reported** | Record the current date. |
| **Reported by** | Record the name of the person reporting the incident. |
| **Contact Information** | Record the telephone number and e-mail address of the person reporting the incident. |
| **Incident Description** | Query the incident reporter for details such as:   * When the incident first occurred * Frequency of incident occurrence * Description of the incident * Description of desired performance * Scenarios and data that causes the incident to occur |
| **User Job Impact** | Determine whether or not the incident reporter is able to perform his/her job prior to incident resolution. Select option:   * **Stopped:** User cannot perform job until incident is resolved * **Impeded:** User’s ability to work is partially impacted by incident. In this scenario, a workaround is available. * **Inconvenienced:** User can continue with job |
| **Recorded by** | Enter the name of the person who recorded the incident. |

1. The person who records the incident delivers the completed Incident Report to IT staff member who is responsible for support of the associated system.

## Incident Investigation

1. The IT staff member responsible for system support records the incident investigation details on the Incident Investigation form, Attachment B.
   1. When multiple incidents require investigation, the incident with the greater user job impact is given priority.
   2. The user who reported the incident is contacted when additional details regarding the incident are needed.

| **Incident Investigation Form Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Incident ID** | Record the Incident ID from the Incident Report form. |
| **System Name** | Record the System Name from the Incident Report form. |
| **Software Version** | Record the version number of the software currently in production. |
| **Investigation Date** | Record the date of the incident investigation. |
| **Number of Users Impacted** | Select the number of users impacted:   * **One**. Incident is limited to a single user (e.g., system access problem) * **Multiple**. Incident impacts more than one user (e.g., system defect) * **All**. Incident impacts all users (e.g., system down) |
| **Area(s) Impacted** | List the department or functions impacted by the incident. |
| **Classification** | Classify the incident at one of the following:   * **System Access** – user is unable to access the system or specific functions within the system * **Software Defect** – a function of the system is not working as intended * **Hardware Problem** – a hardware component of the system is not working as intended. This category includes printers and other attached devices. * **Training** – the user needs assistance with how to use a system function or has made an error in using the system * **Enhancement Request** – the user has an idea for improving the system |
| **Feature Criticality** | For software defects, hardware problems, and training incidents, determine the criticality of the function in the incident report using the process in *SOP System Risk Assessment*. Record the criticality. |
| **Recommended Resolution** | Recommend the resolution to the incident. |
| **Priority for Resolution** | For all reported incidents, except enhancement requests, set the priority for resolution using the Incident Resolution Priority table, below. |
| **Recorded by** | Enter the name of the person who performed the incident investigation. |

**Incident Resolution Priority Table**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **User Job Impact** | | |
|  | **High** | **Medium** | **Low** |
| **High Criticality** | High | High | High |
| **Medium Criticality** | High | Medium | Medium |
| **Low Criticality** | High | Medium | Low |
| **System Access** | High | Medium | Low |

1. When the incident involves a software defect for a high or medium criticality function, the IT staff member responsible for system support sends notification to system users with the following information:
   1. System name
   2. Description of the incident
   3. Areas impacted
   4. Workaround, when one is available
   5. Estimated time until resolution

## Incident Resolution

1. The IT staff member responsible for system support records the incident resolution details on the Incident Resolution form, Attachment C.
   1. When multiple incidents require resolution, the incident with the highest priority for resolution, as noted on the Impact Investigation form, is given priority.

| **Incident Resolution Form Instructions** | |
| --- | --- |
| **Information** | **Instruction** |
| **Incident ID** | Record the Incident ID from the Incident Report form. |
| **System Name** | Record the System Name from the Incident Report form. |
| **Reason for Incident Closure** | Record the reason that the incident is being closed.   * + **Duplicate.** Record the original Incident ID   + **Enhancement Request**. Enter the request in the enhancement tracking log the record the associated tracking ID.   + **Resolved** |
| **Closure Date** | Record the date of incident closure. |
| **Resolution Activity** | For resolved incidents, document the activities that were performed to achieve resolution. |
| **Resolution Effectiveness Verification** | For resolved incidents, contact the system user who reported the problem to ensure that the resolution met his/her expectations. After verification of resolution effectiveness, sign and date the Incident Resolution form. |
| **Probable Cause of Incident** | For resolved software defects, hardware problems, and training incidents, record the probable cause of the incident. For example:   * Hardware configuration error for printer ‘X’ * Inadequate functional specifications for feature ‘Y’ * Inadequate user training for feature ‘Z’ |
| **Software Version of Resolution** | For resolved software defects, identify the software version that was implemented to correct the defect. |
| **Preventive Action** | For resolved incidents for functions with High Criticality, identify one or more actions that are needed to prevent the same or similar incident from occurring. For example:   * Update SOP for configuration of printer ‘X’ to include steps … * Train IT personnel responsible for writing functional specifications on how to …. * Add examples of how to use feature ‘Z’ to training manual…. |
| **Due Date** | When a preventive action is identified, enter the associated due date. |
| **Responsibility** | When a preventive action is identified, enter the name of the person responsible for completing the action. |
| **Recorded by** | Enter the name of the person who resolved the incident. |

1. If a user notification was sent during an incident’s investigation, upon resolution of the incident, the IT staff member responsible for system support sends system users notification of resolution.

## Incident Record Retention

1. Records are retained for all incidents. Records include:
   1. Incident Reports
   2. Incident Investigations
   3. Incident Resolutions
   4. Incident Management Effectiveness Review Logs
2. Incident records are retained for the same period of time as the associated electronic records generated by each system.

## Periodic Incident Management Effectiveness Reviews

1. Each system’s incident management effectiveness is reviewed per this schedule:

|  |  |  |
| --- | --- | --- |
| **Incident Management Effectiveness Review Schedule** | | |
|  | **First 3 Months** | **Life of System** |
| **High Criticality** | Monthly | Every 6 Months |
| **Medium Criticality** | Monthly | Annually |
| **Low Criticality** | Monthly | N/A |

1. For each system, per the schedule above, the IT Manager collects all of the Incident Reports, Incident Investigations, and Incident Resolutions created since the last incident management effectiveness review.
2. The IT Manager reviews the documentation for:
   1. Prompt incident investigation in alignment with severity of user job impact
   2. Prompt incident resolution in alignment with assigned priority
   3. Completion of preventive actions according to documented due dates
   4. Frequent reporting of the same or similar probable causes indicating the need to implement general, preventative actions
3. Results of the incident management effectiveness review are recorded in the Incident Management Effectiveness Review Log, Attachment D.
4. Actions to correct or mitigate any negative findings are also recorded in the log.
5. The IT Manager indicates confirmation of all findings, corrections, and mitigations by signing the Incident Management Effectiveness Review Log.

**References:**

Eudralex Volume 4, Annex 11: Computerised Systems

Good Practices for Computerised Systems in Regulated “GxP” Environments, PIC/S, September, 2007

21 CFR Part 820, Quality System Regulation, FDA, April 1, 2007

# ATTACHMENT A: Incident Report

|  |  |
| --- | --- |
| **Incident ID** |  |
| **System Name** |  |
| **Date Reported** |  |
| **Reported by** |  |
| **Contact Information** |  |
| **Incident Description** |  |
| **User Job Impact** | *Please check one:*  Stopped: user cannot perform job until incident resolved  Impeded: user’s ability to work is partially impacted by incident  Inconvenienced: user can continue with job |
| **Recorded by** |  |

# ATTACHMENT B: Incident Investigation

|  |  |  |
| --- | --- | --- |
| **Incident ID** |  | |
| **System Name** |  | |
| **Software Version** |  | |
| **Investigation Date** |  | |
| **User Impact** | **Number of Users Impacted** | One  Multiple  All |
| **Area(s) Impacted** |  |
| **Classification** | System Access  Software Defect  Hardware Problem | Training  Enhancement Request |
| **Feature Criticality** | High Criticality  Medium Criticality  Low Criticality  N/A - system access or enhancement request | |
| **Recommended Resolution** |  | |
| **Priority for Resolution** | High Priority  Medium Priority  Low Priority  N/A - enhancement request | |
| **Investigated by** |  | |

# ATTACHMENT C: Incident Resolution

|  |  |
| --- | --- |
| **Incident ID** |  |
| **System Name** |  |
| **Reason for Incident Closure** | Duplicate of Incident \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Enhancement Request tracked as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Resolved |
| **Closure Date** |  |
| *Complete next section for all Resolved Incidents* | |
| **Resolution Activity** |  |
| **Resolution Effectiveness Verification** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature Date |
| *Complete next section for all Resolved Software Defects, Hardware Problems, and Training Incidents* | |
| **Probable Cause of Incident** |  |
| *Complete next section for all Resolved Software Defects* | |
| **Software Version of Resolution** |  |
| *Complete next section for all Resolved Incidents for functions with High Criticality* | |
| **Preventive Action** |  |
| **Due Date** |  |
| **Responsibility** |  |
| **Resolved by** |  |

# ATTACHMENT D: Incident Management Effectiveness Review Log

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **System Name** | **Review Date** | **Review Findings** | **Correction or Mitigation** | **Reviewed by**  **Name/Signature/Date** |
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