**Identification & Control of Nonconformities Process Table**

| **Step** | **What happens?** | **Who’s responsible?** | **Procedures needed?** | **Pitfalls** |
| --- | --- | --- | --- | --- |
| 1. **A single NCE has occurred** | A problem develops due to a need or requirement that went unfulfilled. |  |  | * A process problem was not identified during quality planning or implementation * Training, communication, and/or competency assessment were insufficient * Problem may no longer be a system’s problem, but an accountability problem * The scope of which problems will be included was never clearly defined, especially the handling of quality control failures during the examination phase |
| 1. **NCE is identified** | Any staff member who recognizes or is made aware of a NCE initiates a report. | All Laboratory Personnel | Reporting a Nonconformity Procedure | * Report not initiated   + Staff was not adequately trained to recognize a NCE   + Staff member chose not to get involved or get someone into trouble * The time between occurrence and identification is extensive * Only *big* events are identified and not the frequent daily work-arounds to process design problems |
| 1. **Remedial action is taken** | Action taken at the time of the occurrence to mitigate its immediate effects by focusing on the consequences of the NCE. Also known as immediate action. | * Necessary action delayed because time was taken to investigate the WHY component at this time * The required action, which exceeded the staff member’s authority, role or level of knowledge, was not further communicated to a level of authority that could address the problem. |
| 1. **NCE is reported** | **A NCE report is generated**  A record of the description and how the NCE was followed-up is completed which includes a detailed *when* component. | * Staff not adequately trained in using the approved template * Documentation includes a lot of emotion * Documentation is insufficient * Approved form is too complicated for use or not easily located * Employee uncomfortable reporting an event or the culture is not safe to do so * Staff has lack of confidence in the usefulness of the NCE process * Missing or incomplete dates and times for   + When the NCE occurred   + When the NCE was detected   + When remedial action was taken |
|  | **NCE report is given to management**  The NCE record is given to the staff member’s immediate supervisor. | * Roles and responsibilities are poorly designed or communicated * Organizational chain poorly communicated during vacations, weekends, or holidays * Assigning responsibility for conducting the investigation when the immediate supervisor available is not the section supervisor * The verbal explanation does not match the written documentation * Missing or incomplete date and time for when the NCE was reported |
| 1. **NCE is investigated** | **The extent of the NCE is determined**  A quick assessment on the overall problem is performed by management. | Section Supervisor | Investigating and Managing an Individual NCE Procedure | * Inadequate or inappropriate decisions are made based on the provided report information * Supervisors not trained in how to perform a quick assessment |
|  | **Tracking number is assigned to NCE**  The individual event is catalogued with a unique tracking number. Upper laboratory management is informed of the NCE within a timely manner. | * Laboratory upper management is not made aware of a significant problem in a timely manner * Too much laboratory upper management oversight spent on minor or insignificant events |
|  | **Investigation is performed**  Specific details surrounding the *what*, *how*, *who* and *where* factors that led to the NCE are gathered. Afterwards, the *why* component is performed to determine the underlying cause of the problem. | * Documents and records needed for investigation are incomplete or absent * Supervisor is insufficiently trained to perform investigation * Supervisor investigating may have played a direct or compounding role in the NCE * Assumes a *name and blame* stance without focusing on system level vulnerabilities * Neglected to investigate instances when the gap between occurrence and detection was extensive overlooking important information regarding laboratory performance * Unable to retrieve previous individual NCE records related to the current investigation * Investigation is unable to answer how was the NCE identified and how did it occur * Drilling deeper to more specific evidence was insufficient regarding *what*, *how*, *who*, and *where* factors |
|  | **Investigation is documented**  Key facts, made visible by probing questions to determine details of what happened, how it happened, and why it happened, are recorded. | * Incomplete investigation * Inadequate information on report * Investigation is delayed making it harder to collect accurate facts or complete details * Report includes judgments |
|  | **Short-term correction is proposed, if applicable**   * 1)Proposed action that will alleviate the NCE to a manageable level until the root cause of the underlying problem is identified and more definitive action can be taken * 2) Proposed action, which will reduce the risk to a satisfactory level determined by management, will suffice and not require the NCE to undergo long-term corrective action. The event will continue to be monitored and tracked periodically to determine effectiveness of the correction. | * Inadequate understanding of the processes involved * Assumes a *name and blame* stance without focusing on system level vulnerabilities * Low confidence in voicing proposed interim-type solutions * Proposed a cognitive solution (e.g. training or additional supervision) for a non-cognitive-committed error (e.g. distractions or rushing) |
|  | **Feedback is given to reporting staff member**  Feedback on the results of the investigation is provided to staff who reported the NCE. | * Confidentiality is not maintained * Wasting an opportunity to encourage staff members to continue reporting * Lack of feedback and updates to relevant parties can result in a lack of confidence in the usefulness of the NCE process |
|  | **NCE is classified**  The individual event is categorized according to which work processes were involved. | * Poorly selected classifications impede tracking, sorting, and correlating of aggregate data resulting in an inadequate periodic review * Lack of standardization when applying categories to individual NCEs * Classification was done too early resulting in an improperly classified event |
| 1. **Risk assessment is performed** | **Risk-based matrix score is determined and documented**  The risk-based matrix score is quantified by first determining the severity and then the probability of occurrence (frequency) for the NCE. | Quality Manager | Investigating and Managing an Individual NCE Procedure (continued) | * Score did not take into account similar NCEs previously reported to determine a more accurate *frequency* value * Criteria to determine severity and probability is missing or incomplete * A large subjective component is involved when determining the score * When assigning *severity*, the estimation does not take into account the number of affected customers and the magnitude of the problem |
|  | **Risk-based gateway is applied**  Risk-based gateway serves as a filtering system to guide if the NCE should undergo long-term corrective action or periodic monitoring and surveillance. | * Decision matrix is unavailable * A onetime NCE that has a high risk or an NCE that occurs frequently is miscoded * A sentinel event is miscoded |
| 1. **Action is taken:**   **No further action is required.** | For some NCEs, remedial action does solve the problem AND action taken was documented and recorded for periodic monitoring and surveillance. | * Only the symptoms of a noncompliant regulatory or accreditation requirement were handled |
| **7. Action is taken:**  **Short-term correction/containment is required** | The proposed correction mitigates the risk of reoccurrence to a manageable level or prevents the NCE from reoccurring by fixing the problem if the cause of solution is readily apparent. The correction has been documented and recorded to enable periodic monitoring and surveillance. | * With the current process, the date of closure is dependent on when the correction is complete making the interpretation of % closure NCE rate more difficult to monitor and analyze * The correction to contain the NCE at a manageable level was unsuccessful * The issue being monitored reached a significant level without alerting management * Change management process for the correction was inadequate or did not follow established policies, processes, and procedures * There may be agreement that a particular action is needed, but resources or time constraints force a temporary solution. |
| **7. Action is taken:**  **Corrective Action is required.**  **(Corrective Action Process)** | The single NCE must undergo a formal process to uncover the underlying root cause and generate action to prevent the reoccurrence. The selected action must be monitored to ensure its effectiveness. | * Long-term corrective action is chosen for a NCE that has very little impact. * Delay in NCE entering the CA process |
| 1. **NCE is closed** | The date of closure is documented. | * A closed NCE must be reopened. * Record of the individual NCE is incomplete * Updates were not communicated to those who need it or affected by it |
| **Process** | **Purpose** | **Who’s Responsible** | **Commonly Encountered Pitfalls** | |
| **NCE Log Maintenance Process** | Each NCE must be controlled and managed. The control of NCEs is kept current using a database. | Quality Manager | * The log is not maintained and kept current * Individual NCE records not maintained according to retention schedule | |
| **Collective NCE Data Analysis Process** | NCE information is periodically compiled and analyzed to look for trends, shifts, and patterns. The summary data generated is presented to the management review team to enable data-driven decisions regarding prioritization and resource allocation for improvement projects. | Quality Manager | * Electronic database is not periodically backed-up or cannot be retrieved * Database not being maintained in a timely manner * Inability to sort data within the database * Unable to perform an effective search when the process is not fully understood * Definitions of classifications missing or incomplete | |