**Nonconformance and Corrective Action: A Comprehensive Overview**

**Introduction**

Nonconformance (NC) and Corrective Action (C/A) are fundamental components of a robust Quality Management System (QMS), yet they are frequently misunderstood. While interconnected, NCs and C/As possess distinct characteristics. This document clarifies their definitions, responsibilities, appropriate application, and documentation/correction procedures.

**What are Nonconformances and Corrective Actions?**

***What is a Nonconformance?*** A nonconformance is any instance where a requirement is not met. Within a QMS, these requirements can be contractual, regulatory, or internally defined, pertaining to product attributes (e.g., welding, dimensions, materials) or procedural adherence (e.g., form completion, process timeframes, training).

***What is a Corrective Action?*** AISC defines a corrective action as "the action or actions undertaken to identify and eliminate the root cause of a service or process *nonconformance* to prevent its recurrence. Corrective action is not the *repair* or *rework* of a *nonconformance*.” Thus, a Corrective Action is an in-depth investigation to uncover the fundamental reasons behind an issue.

**Who is Responsible?**

***Who documents a Nonconformance?*** The QMS should specify who is responsible for capturing NCs. Typically, this is the individual who first identifies the nonconformance (e.g., Production Operator, QC Inspector, Quality Auditor).

***Who documents a Corrective Action?*** Corrective Actions are usually documented and managed by Management personnel (e.g., QA Manager, Production Manager). This elevation ensures an evaluation of the cost-effectiveness of the C/A process (investigation, repair/rework, follow-up).

**When are They Appropriate?**

***When to document a Nonconformance?*** The most effective QMS practices document all identified nonconformances promptly, regardless of their severity. While all NCs should be recorded for data analysis and trend identification, the level of documentation should be proportionate to the issue's significance and the required correction effort. Minor issues corrected quickly may only require a simple notation, while more significant issues might necessitate a formal NC Report and potentially Management approval.

***When to initiate a Corrective Action?*** A Corrective Action is typically initiated for recurring nonconformances or a significant single nonconformance that could lead to substantial future failures if not thoroughly addressed to prevent recurrence. Repetitive minor issues can indicate a systemic process breakdown warranting a C/A to identify the root cause. Similarly, a critical "Major" nonconformance necessitates a C/A to prevent more costly future failures. These situations justify the time, resources, and attention involved in a comprehensive C/A to determine and eliminate the root cause.

**How are They Handled?**

***How to document and correct a Nonconformance?*** All NCs should be documented, as the collected data is valuable for identifying trends. However, the QMS should differentiate between minor and major issues in terms of documentation. Minor, immediately corrected issues can be noted on inspection reports. More significant issues requiring time for repair or Management approval may require a formal NC Report. The level of documentation should align with the expected corrective action.

***How to document and correct a Corrective Action?*** Corrective Actions follow a more formal process than nonconformance correction. Each C/A is typically documented on a dedicated C/A Form and involves a root cause analysis. Once the root cause is identified, an action is implemented to address it and prevent recurrence. A follow-up action, conducted after a defined period (e.g., 2 weeks), is crucial to verify the effectiveness of the implemented corrective action in eliminating the root cause and preventing future similar issues. If the follow-up reveals the action was insufficient, the Root Cause Analysis phase is revisited for further investigation and action.

**Important Considerations:**

A well-executed Corrective Action is often an extensive and resource-intensive process involving multiple individuals. Therefore, it is not recommended for every nonconformance.

Note: The Corrective Action process can also be applied to identify and replicate positive trends within a company, such as achieving goals, improving workforce training and retention, or increasing profits. By analyzing the factors contributing to these successes, the C/A model can drive continuous improvement efforts.