

CONTROL OF NONCONFORMING PRODUCT

Standard Operating Procedure

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1. PURPOSE

This procedure defines the process for identifying, documenting, evaluating, and dispositioning nonconforming products, materials, and components. It ensures that nonconforming items are controlled and prevented from unintended use or delivery.

2. SCOPE

This procedure applies to all nonconformities identified in:

- Incoming materials and components
- In-process products and intermediates
- Finished products before release
- Products returned from customers
- Products identified during post-market activities

3. DEFINITIONS

| Term | Definition |
|--------------------|--|
| Nonconformity (NC) | Non-fulfillment of a specified requirement |
| Disposition | Decision on how to handle nonconforming product (rework, scrap, use-as-is, etc.) |
| Containment | Immediate action to prevent further use or distribution of NC product |
| Concession | Permission to use or release product that does not conform to specified requirements |

5.2 RISK-BASED ASSESSMENT

Each nonconformity shall be assessed using the NC Assessment Matrix to determine:

| Classification | Severity | Action Required |
|----------------|----------------------------|---------------------------------------|
| Critical | Patient safety impact | Immediate containment, mandatory CAPA |
| Major | Significant quality impact | Containment, CAPA evaluation required |
| Minor | Limited impact | Standard disposition, CAPA optional |

This sample shows the document structure and first sections. The complete document contains additional sections with detailed procedures, forms, and implementation guidance.

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