SOP: Escalation Procedure for Handling Major Defects or Repeated Non-Conformance

This SOP details the **escalation procedure for handling major defects or repeated non-conformance**, outlining the steps to identify, report, and address significant quality issues promptly. It includes criteria for classification of defects, notification channels, roles and responsibilities for escalation, corrective action implementation, and follow-up verification to prevent recurrence. The goal is to ensure timely resolution of critical problems to maintain product quality, regulatory compliance, and customer satisfaction.

1. Purpose

To establish a standardized escalation process for prompt and effective handling of major defects or repeated non-conformances in products, processes, or systems.

2. Scope

This procedure applies to all employees involved in the identification, reporting, and resolution of major defects or instances of repeated non-conformance within the organization.

3. Definitions

- **Major Defect:** A defect resulting in product failure, compromised safety, regulatory breach, or significant impact on customer satisfaction.
- **Repeated Non-Conformance:** The recurrence of a similar non-conformance in process or product despite previous corrective actions.
- **Escalation:** The process of communicating an unresolved or critical issue to higher management or specialized teams for expedited resolution.

4. Responsibilities

Role	Responsibility
Originator	Identify and report major defects/repeated non-conformance per procedure.
Immediate Supervisor	Assess the report, classify the defect, and initiate escalation if criteria are met.
Quality Assurance (QA)	Review details, confirm classification, coordinate investigation, and recommend corrective actions.
Responsible Department	Implement corrective actions and support investigation.
Management	Make final decisions on critical escalations, resource allocations, and preventive measures.

5. Procedure

5.1 Identification and Classification

1. Detect defect or non-conformance during production, inspection, audit, or from customer feedback.
2. Classify severity according to **Major Defect Criteria**:
    - Regulatory non-compliance
    - Potential safety hazard
    - Repeated similar failures in a short timeframe
    - Customer complaint triggering recall or significant dissatisfaction

5.2 Reporting

1. Complete a **Non-Conformance/Defect Report** immediately via designated system or form.
2. Include relevant details: date, location, affected product/batch, description, evidence, and possible impact.
3. Notify the immediate supervisor and Quality Assurance.

5.3 Escalation Process

1. Supervisor reviews and confirms if the defect meets escalation criteria.
2. If confirmed:
    - Notify QA and affected department heads within **24 hours**.
    - Escalate to management as per the **escalation matrix** below.
3. Document all communications and actions.

5.4 Corrective Action Implementation

1. Root cause analysis led by QA with responsible department.
2. Implement interim containment actions if immediate risk is present.
3. Develop and execute corrective and preventive action plans (CAPA).
4. Monitor and document progress regularly.

5.5 Follow-Up and Verification

1. Verify effectiveness of corrective actions within a defined timeframe (e.g., 30 days).
2. Record outcome in the CAPA system; close issue only after successful verification.
3. Communicate resolution status to all impacted stakeholders.

6. Notification Channels & Escalation Matrix

Escalation Level	Criteria	Contact/Channel	Timeframe
Level 1	Initial detection/first occurrence	Immediate Supervisor, QA	Within 24 hours
Level 2	Confirmed major defect or repeated non-conformance	Department Manager, QA Head	Within 12 hours of confirmation
Level 3	Escalation not resolved at department level or involves regulatory/customer impact	Senior Management, Compliance	Immediate/Within 2 hours of identification

7. Records

- Non-Conformance/Defect Reports
- CAPA Documents
- Escalation Logs
- Verification and Closure Records

8. References

- ISO 9001:2015 â€“ Quality Management Systems
- Internal QMS/Non-Conformance Handling Procedure
- Customer Complaint Handling SOP

9. Revision History

Date	Version	Description of Changes	Approved By
2024-06-15	1.0	Initial release	QA Manager