

Standard Operating Procedure

SOP-IT-009: Incident Response

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| Document ID: | SOP-IT-009 | Version: | 1.0 |
| Effective Date: | YYYY-MM-DD | Review Date: | YYYY-MM-DD |

1. Purpose

This SOP defines the technical response procedures for IT security incidents and system failures.

2. Scope

This SOP applies to all IT security incidents, system outages, and technical emergencies.

3. Incident Response Phases

Phase 1: Detection & Analysis

- Automated monitoring alerts (CloudWatch, Datadog)
- User reports via GitHub Issues or Slack
- Initial triage by SRE on-call

Phase 2: Containment

- Isolate affected systems
- Preserve evidence (logs, snapshots)
- Activate incident response team if P1

Phase 3: Eradication & Recovery

- Root cause identification
- Apply fixes via emergency change process
- Restore services from backups if needed

Phase 4: Post-Incident

- Post-mortem report (within 48 hours)
- CAPA if quality impact (SOP-IT-005)
- Update runbooks and monitoring

4. Communication Protocol

- P1 incidents: Notify Quality Manager within 1 hour
- Status updates: Every 2 hours during active incident

- All stakeholder communication via Slack #incidents channel

5. Documentation Requirements

- **Incident timeline with timestamps**
- Actions taken and by whom
- Root cause analysis
- Lessons learned and preventive measures

6. Approvals

This document requires electronic signature approval via DocuSign (21 CFR Part 11 compliant).

| Role | Name | Signature & Date |
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