

NCE Individual Event Process

Identification and Control of Nonconformities

A single NCE has occurred.

NCE is identified.

- Complaints
- Audits
- Service alerts
- Vendor recalls
- Amended results
- Change of Shift reports
- Supervisory review of quality records

Remedial action is taken.

Immediate action is taken to address the consequences of the problem.

NCE is reported.

- Information to be captured on reporting form:
- Date/time NCE occurred
 - Date/Time discovered
 - Person who discovered NCE
 - Description of NCE
 - Immediate action taken
 - Who was notified

NCE is investigated.

The assigned person determines *who, what, how, and why* things went wrong in the process that led to the NCE.

Risk assessment is performed

NCE is classified according to criteria and course of action is determined.

NCE Log Maintenance Process

Tracking number is recorded on NCE log.

Collective NCE Data Analysis

Management Review Process

No further action is required.

During the investigation of the NCE, an apparent cause was identified.

Short-term correction/containment is required.

Corrective Action (CA) is required.

Single NCE event is closed

NCE event status is updated to closed on NCE log.

