

# NONCONFORMITY REVIEW AND ROOT CAUSE ANALYSIS

## Clause 10.1.1(b) – Evaluation of Causes and Potential Occurrence Elsewhere

**Operational criterion:** Ketidaksesuaian ditinjau secara sistematis. Akar penyebab ketidaksesuaian ditentukan menggunakan metode yang ditetapkan. Organisasi mengevaluasi apakah ketidaksesuaian serupa ada atau berpotensi terjadi di tempat lain.

**Purpose:** To provide traceable evidence of nonconformity review, root cause analysis, review of similar cases or potential occurrence elsewhere, corrective action, and verification of non-recurrence.

### FORM 1. ROOT CAUSE ANALYSIS (RCA)

|                    |  |                    |                                                                                                                                                  |
|--------------------|--|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| RCA No.            |  | Date               |                                                                                                                                                  |
| Unit/Process       |  | Source of Finding  | <input type="checkbox"/> Internal Audit <input type="checkbox"/> Complaint<br><input type="checkbox"/> Monitoring <input type="checkbox"/> Other |
| Clause/Requirement |  | Responsible Person |                                                                                                                                                  |

#### A. Description of Nonconformity

Nonconformity statement:

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Objective evidence:

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Immediate impact/consequence:

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Immediate correction taken (if any):

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B. Root Cause Analysis Method: ☐ 5 Whys ☐ Fishbone ☐ Other: \_\_\_\_\_

#### 5 Whys Worksheet

| Level | Question / Why?     | Answer / Evidence |
|-------|---------------------|-------------------|
| Why 1 | Why did this occur? |                   |
| Why 2 | Why did this occur? |                   |
| Why 3 | Why did this occur? |                   |
| Why 4 | Why did this occur? |                   |
| Why 5 | Why did this occur? |                   |

#### Fishbone Analysis Worksheet

| Category                 | Potential Cause | Evidence / Verification |
|--------------------------|-----------------|-------------------------|
| People                   |                 |                         |
| Process / Method         |                 |                         |
| Technology / Equipment   |                 |                         |
| Material / Input         |                 |                         |
| Environment              |                 |                         |
| Management / Measurement |                 |                         |

Verified root cause:

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Basis/evidence confirming the root cause:

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## FORM 2. NONCONFORMITY EVALUATION CHECKLIST

| No. | Evaluation Item                                                                               | Yes                      | No                       | N/A                      | Evidence / Notes |
|-----|-----------------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|------------------|
| 1   | Has the nonconformity been clearly defined against a requirement or criterion?                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 2   | Has objective evidence supporting the nonconformity been recorded?                            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 3   | Has the affected process/unit and scope been identified?                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 4   | Has the immediate impact or consequence been evaluated?                                       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 5   | Has an immediate correction/containment action been taken where necessary?                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 6   | Has the need for root cause analysis been evaluated?                                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 7   | Has a defined RCA method (e.g., 5 Whys/Fishbone) been applied?                                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 8   | Has the identified root cause been supported by evidence?                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 9   | Has the possibility of recurrence in the same process been evaluated?                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 10  | Has the existence or potential occurrence of a similar nonconformity elsewhere been reviewed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 11  | Have corrective actions addressing the verified root cause been determined?                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 12  | Have responsibility and completion target dates been assigned?                                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |
| 13  | Has the effectiveness/non-recurrence of corrective action been planned for verification?      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |                  |

### FORM 3. REVIEW OF SIMILAR CASES / POTENTIAL OCCURRENCE ELSEWHERE

This review documents whether the same or a similar nonconformity exists, or could potentially occur, in other units, processes, locations, or activities.

| No. | Unit / Process / Location Reviewed | Similar Condition Found?                                 | Potential to Occur?                                      | Evidence Reviewed | Required Action / Decision | Responsible Person |
|-----|------------------------------------|----------------------------------------------------------|----------------------------------------------------------|-------------------|----------------------------|--------------------|
| 1   |                                    | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |                   |                            |                    |
| 2   |                                    | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |                   |                            |                    |
| 3   |                                    | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |                   |                            |                    |
| 4   |                                    | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |                   |                            |                    |
| 5   |                                    | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |                   |                            |                    |
| 6   |                                    | <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No |                   |                            |                    |

Summary of review findings:

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Trend/pattern identified (if any):

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Decision on organization-wide or cross-unit action:

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### FORM 4. CORRECTIVE ACTION AND VERIFICATION RECORD

| No. | Verified Root Cause | Corrective Action | PIC | Target Date | Completion Evidence | Effectiveness / Non-recurrence Verification | Status                                                           |
|-----|---------------------|-------------------|-----|-------------|---------------------|---------------------------------------------|------------------------------------------------------------------|
| 1   |                     |                   |     |             |                     |                                             | <input type="checkbox"/> Open<br><input type="checkbox"/> Closed |
| 2   |                     |                   |     |             |                     |                                             | <input type="checkbox"/> Open<br><input type="checkbox"/> Closed |
| 3   |                     |                   |     |             |                     |                                             | <input type="checkbox"/> Open<br><input type="checkbox"/> Closed |
| 4   |                     |                   |     |             |                     |                                             | <input type="checkbox"/> Open<br><input type="checkbox"/> Closed |

**Verification conclusion:** ☐ Effective – no recurrence detected ☐ Partially effective – further action required ☐ Not effective – RCA/action must be revised

Verification evidence / notes:

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### AUTHORIZATION

| Prepared by / Process Owner | Reviewed by / Internal Auditor or QA | Approved by / Authorized Officer |
|-----------------------------|--------------------------------------|----------------------------------|
| Name:                       | Name:                                | Name:                            |
| Signature:                  | Signature:                           | Signature:                       |
| Date:                       | Date:                                | Date:                            |

**Expected evidence:** Root cause analysis report (5 Whys/Fishbone), completed nonconformity evaluation checklist, documented review of similar cases/potential occurrence elsewhere, corrective action records, and verification of effectiveness/non-recurrence.