

Writing Clear and Concise Non-conformances (NCs)

About Qdot

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Qdot managed by a team of experienced professionals, is committed to promote quality & excellence culture in GCC (UAE, QATAR, KSA, Oman, Kuwait, Bahrain)by providing below mentioned services.

Management System Services

- ISO 9001, ISO 14001, ISO 45001, HACCP, ISO 22000, FSSC 22000, BRC GS, Halal, ISO 22716 (GMP),Organic Certification, ISO 27001, ISO 41001, ISO 37001, ISO 50001, ISO 55001, ISO 17020 & ISO 17025 etc

Training Services

- IRCA Approved Lead Auditor
- Awareness & Trainings on ISO Standards

Product Registration

- SABER, SQM, SFDA, CITC, IECEE, ECAS, EQM, RoSH, EESL, SLCP, G-Mark etc

Social Compliance

- SEDEX, SA 8000, amfori BSCI, ISO 26001, WRAP, GRLI, ESG, CTPAT etc



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AGENDA

- Writing Non-conformances (NC) Analysis
- Parts of a Non Conformance
- Making it clear.
- Accepting NC Responses
- Different Scenarios



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DESCRIPTION	NC./OBS.
i. Updated and controlled Organogram of the division was not available. ii. Job Description of Asst. Supervisor Production was not available.	Maj.NC-01
i. A competence criterion for hiring of Asst. Supervisor Lab was not followed. Criteria defined as B.Sc/F.Sc, whereas individual holds neither of the degrees, and was a diploma holder. ii. Evolution of training effectiveness was not carried out.	Maj.NC-02
i. Review and closing status of OTPs 2011-13 was not available. ii. Approved OTPs for 2012-13 were not available.	Maj.NC-03
i. Format of production plan was not controlled. ii. Documents were not available with users at most of the points.	Maj.NC-04
Work Instructions for Boiler/Boiler Operator were not available.	Maj.NC-05



DESCRIPTION	NC./OBS.
Updated & approved organogram is not available.	Major NC
Updated & approved OTP's not available.	Major NC
Work instructions/operating procedures & safety instructions are not available for Diesel Tank.	Minor NC
Door is missing for Cooling Tower # 4.	OBS
Motor cover not found on pump # 9 (ENG-WRK-M-32).	OBS
Wires are not proper insulated @ cooling tower section & water softener plant.	OBS
Electric panel lock does not exist at Boiler Section.	OBS

Non-conformance Report Writing

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And the client says:

- I don't have a clue what you are saying or what you are talking about.....???
- Why is this an NC?
- What requirement is violated?



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NC Writing Analysis

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From analysis of data collected from witness audits, NC writing has been identified as one of the more significant concerns.

Identified weaknesses were:

- The NC as written was “incident specific” and did not address the system issues
- The NC as written could not be understood by the organization after the audit was completed; and not understandable at later date.
- The NC did not identify the actual requirement being offended.
- The NC did not identify the supporting objective evidence.
- Poor CA and root cause analysis accepted by the auditor.
- Corrective actions were not verified at NC closure.



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Writing Process Non-conformances

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- NCs must be clearly written.
- Should address the **process/system** which is deficient.
- Objective evidence gathered should identify which **process** is deficient.
- What is the **process**?
 - You must understand the process to verify conformance or non-conformance.



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HOW DEEP SHOULD YOU GO!----INTO THE PROCESS

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- Evaluate the process thoroughly.
- Avoid “tunnel vision”.
- Ensure objective evidence supports conformance or non-conformance of the process.
- Gather enough objective evidence to support your final decision.
- Adequate “sampling” of objective evidence.
 - Repeatability of objective evidence which indicates the process is not working.
 - indication of consistent process failure.

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Three Distinct Parts of An NC

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An audit NC should have three distinct parts:

The requirement, or specific reference to the requirement.

If you cannot identify a requirement, then you cannot raise a non-conformance.

A clear statement of the non-conformance.

What requirements has been breached

And finally, objective evidence that supports the statement of non-conformance; based on the requirement.

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Statement of the NC

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- Should be self-explanatory and related to the process.
- Be unambiguous and concise.
- Not be a restatement of the audit evidence.
- Record the requirement against which the NC was detected.
 - If possible, write out the exact text of the requirement.
- The audit evidence must support the audit finding.
 - The evidence must be specific to the violated requirement.
 - Evidence must be traceable to the NC



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Examples of **POOR** NC Statements

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- Example: **Production Plan format was not controlled.**

(THIS GIVES ONLY A BRIEF INDICATION OF THE PROBLEM)

AND ALSO

- The statement does not give the auditee any indication that there is a system/process failure.
- It appears as a single instance.
- It does not identify the actual requirement being offended-actually, it incorrectly states the requirement.
- As written, the auditee could easily assume the NC was a single incident and take action **ONLY** related to the two pieces of calibrated equipment.

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Controlled & Un-Controlled

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Making it Clear

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- Changing the structure and the way the NC is written can assist in getting the auditee to address the “root cause” of why the production plan document was not controlled.
- The NC must highlight the issue that there is a system/process failure vs a single incident failure.
- Thus, the corrective action and root cause should be focused towards system/process failure, not the observed incident.



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NC Statement “TIPS”

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TIPS:

- The statement of NC should be as generic as possible to help direct the auditee to the system’s issue... instead of the specific incident.
- Keep the “specific details” in the objective evidence area, if at all possible.
- The NC statement should include enough details so that the auditee can respond to exactly what the auditor found.....even years later.



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What it Should be?

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Production Plan format was not controlled.

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Examples of **POORLY** Written NCs

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Non-conformance states:

- A required torque test was not being performed.

Non-conformance states:

- No preventative action records exist.

(This would equate to an absence of a quality management system element.)

Neither NC statement tells the client what went wrong...what requirement is breached?



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Writing of NC Statements

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■ Standard Requirement:

- Quote appropriate standard clause, work instruction, procedure/process or system requirement

■ Non-conformance:

- Clearly define and document the systemic failure within the non-conformance.
- Ensure the client understands the exact nature of the non-conformance.
- Too many words could mislead the client.



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Writing of NC Statements

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■ Objective Evidence:

- What objective evidence is/was used to indicate a non-conformance existed?
- What record, document, procedure was used to verify existence of a non-conformance



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Accepting Closure of CAR Responses

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The auditee's corrective action response should cover three areas, as a minimum:

Containment of the current situation and identified systemic failure.

Action to control or mitigate a problem; could includes correction, corrective action.

Root cause analysis as to why the system failed.

Finally, a systemic corrective action to prevent a recurrence of a failure in the system/process (could be preventive action may apply here.)

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Corrective Action Acceptance/ Closure

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- Does CA response address system process NC?
- Is Root Cause adequate?
- You must know and understand the process to accept the CA and root cause.
- Does client's response ensure no re-occurrence?



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Scenario-1

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- During an audit, you read the Management Review procedure. It states they have defined measurable objectives for productivity, Customer satisfaction, and quality. When you ask to see the measures looked at during a management review meeting, the Plant Manager hands you a 3 inch pile of papers. As you go through the information, you notice there are plenty of charts, graphs, and pivot tables. Seems like this place measures everything they possible can, but there are no goals listed or explanations for trends going in the wrong direction.
- The Plant Manager understands each chart and is clearly involved, but when asked how he uses them to drive improvement, or how he knows if he is meeting his goals, he has no answer.

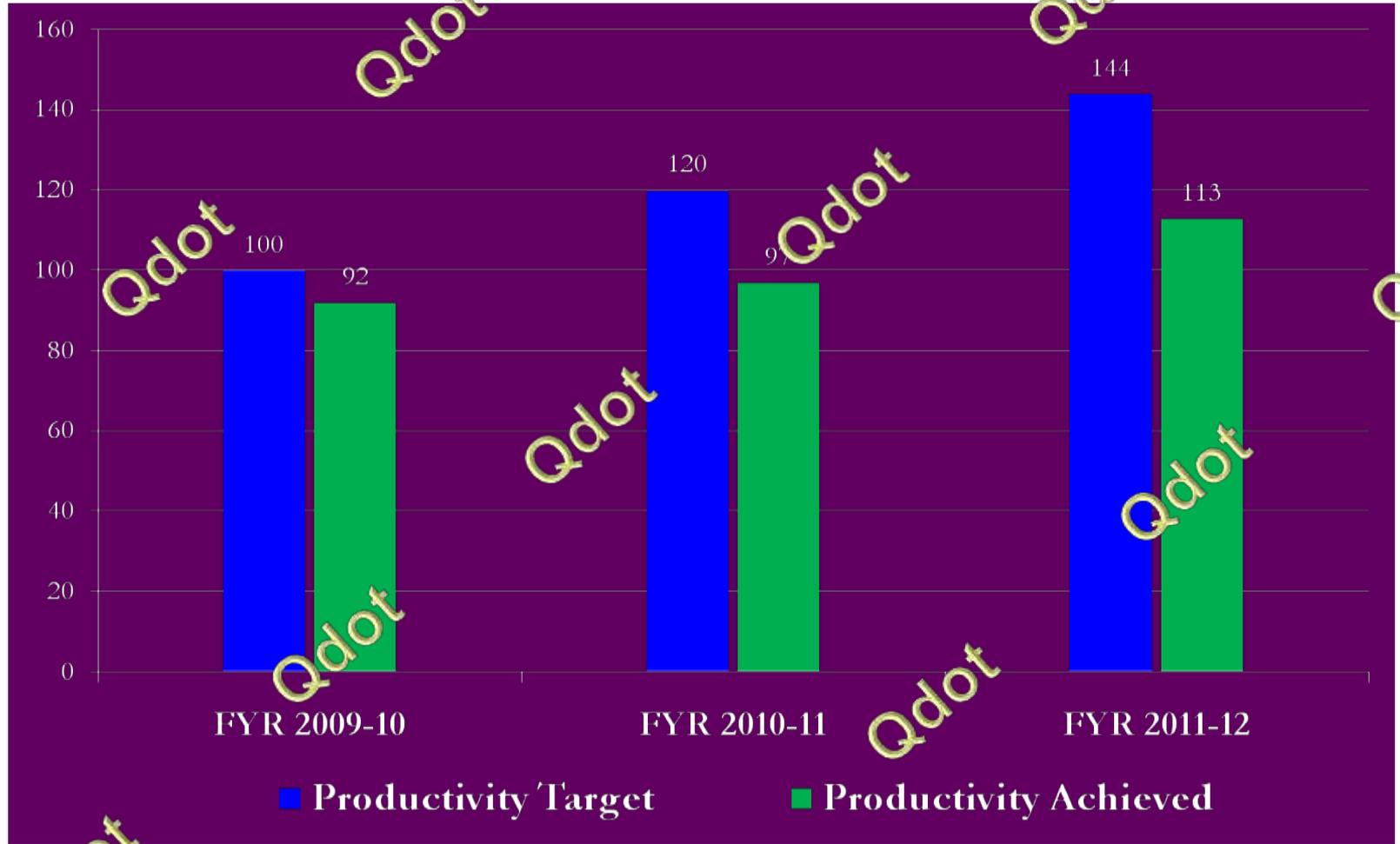


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Productivity



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What should You Do??

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You Should:

- A. Do nothing, the thoroughness of the management review is evidence that it is acceptable. Improvement, although desirable, is not required.
- B. Write an NCR because there has been no improvement and therefore the management review is ineffective.
- C. Write an NCR, as there is no evidence of defined measurable quality objectives as stated in the procedure.



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The Correct answer is **C**:

Write an NC.

Efficient way to write an NC

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Standard Requirement:

- ISO 9001:2008, Clause 5.6.3 (a)
The output from the management review shall include any decisions and actions related to; improvement of the effectiveness of the quality management system and its processes,

Non-Conformance Statement:

- The plant's procedure states that MGR also assess opportunities for continual improvement in the system. But as output of the MGR, nothing assessed as opportunity for improvement in the system.

Objective Evidence:

- Management Review Meeting dtd -----, Page No. ---- & ----



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