



nonconformity statements add value

Well-crafted nonconformity statements help companies remove the root causes of hidden or neglected costly problems. Much auditee time and money is wasted chasing auditor comments and recommendations often in the guise of nonconformity statements or observations

So, as part of their auditor improvement service, Quality Management International are offering an eLearning course on their website, www.aworldofquality.com, free of charge.

Each nonconformity statement has three parts. You can learn how to write each part so together the statement defines the problem clearly for the corrective action or problem solving team. You can

also learn how to weigh-up the magnitude of the nonconformity.

Nonconformity, finding or observation; you can find two of these definitions in ISO 19011 the international standard for auditing management systems.

"Nonconformity" means nonfulfillment of a requirement. Note that the requirement does not have to be specified or documented. By the way, processes that fail to fulfill their objectives are ineffective. In most

cases effectiveness equates to conformity. Work that conforms to an ineffective procedure would not conform to the system standard.

A "finding" used to be called an "observation" and is a statement of fact from an audit. The term "observation" used to mean a statement of fact from the audit. ISO changed this term to "finding" in the year 2000 after years of auditors misusing the term "observation".

Some auditors report observations to impose their will or express their opinion about something they do not like. Unfortunately, so as not to upset their auditor, auditees still accept observations instead of conformity

or nonconformity when their auditor is unsure, lazy or opinionated.

have you discovered system nonconformity?

Have you discovered system nonconformity?

When a person, process or product fails to meet a requirement the system is nonconforming in some way.

Notice how auditors do not refer to people as nonconformities! Human factors studies following the investigation of air accidents have also concluded that the system causes human error.

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Even though auditors look for evidence of conformity they find evidence of nonconformity. Usually this is the result of their thorough research, focused sampling, keen listening and observing skills although some auditees may think their auditors are just "lucky"!

On finding evidence of nonconformity discuss the situation with the manager responsible for the area and:

1. **Agree the requirement**
2. **Seek contrary evidence**
3. **Make notes and evaluate evidence**
4. **Reach a conclusion**
5. **Agree the conclusion**

Never agree nonconformity with an operator. For example determine the availability of competent operators in discussion with the supervisor not by asking the operator how they know how to do their job! If an operator was not working in conformity with a documented instruction then ask why. You may find they received verbal instructions from a manager that contradicted the documented instruction.

Seek a manager responsible for that part of the system.

Agree the requirement and the evidence in support of any unusual interpretation of the requirement from the system standard.

Ask the manager for any evidence that may contradict the nonconformity. Update your notes and objectively evaluate whether you have evidence of conformity. Conclude "conformity" or "nonconformity" and discuss the basis for your conclusion with the manager.

Be prepared to consider contrary evidence from the auditee.

purpose of a nonconformity statement

The nonconformity statements inform the auditee how the system has failed to meet a requirement and are the starting points for effective corrective

action. They are the record on which an auditor bases his or her audit conclusions.

Your audit's summary statement will include a conclusion that answers the question posed by the audit objective. Base your conclusions on the audit findings including the positive points and the nonconformities. You are unlikely to recommend selection of a supplier who operates a system with a major or critical nonconformity. You are likely to recommend a supplier using a system with a few minor nonconformities. Notice how even with process and product nonconformities you are identifying the part of the system found to be responsible for the nonconformity. Your clear definition of the problem is essential for the auditee's effective corrective action.

Every nonconformity

statement comprises three parts: the unfulfilled requirement, the supporting evidence and the nature or description of the problem.

Requirements are from the audit criteria, for example:

- Clause reference of system standard
- Auditee's management system
- Auditee manager's statement
- Contract
- Regulation
- Specification

The auditee knows the audit criteria from the beginning of the audit. Do not surprise the auditee with new criteria. These are the client-specified or auditor-recommended requirements necessary to support the audit objective. The requirements (shalls) do not include guidelines (shoulds). Auditors ignore guidelines when reporting conformity or nonconformity. Auditee management may verbally clarify their requirements during the audit and the auditor uses such requirements as audit criteria if within the scope of the audit.

Evidence is verifiable and comes from your

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notes, for example:

- Name or job title of the auditee
- Statements
- Name of the process (and core or support)
- Document references
- Serial numbers
- Sample size
- Time and location
- Description of the possible consequences of the nonconformity

Do not use hearsay as evidence. Your notes will include the evidence of the nonconformity. If not then you need to improve your note-taking during the audit. What you or the audit team has not verified directly is hearsay.

Record your notes so the auditee can later verify the evidence; keep copies to the extent necessary. Do not use a voice recorder, they are intimidating and inefficient. If you sense a blame culture do not to make matters worse by naming operators in your nonconformity statements.

Involve your interviewee in getting an accurate record of their statements and of the possible consequences of the nonconformity. Pay attention to the

unique numbers of machines and devices and to the document and revision letters or numbers. Record sizes of samples take and keep all the records at the time of doing the audit. Be prepared to keep rough notes on paper for later updating of the checklist on your laptop.

Nature is the opposite of the requirement, some broad examples:

- Failure to determine the criteria for the marketing process to be effective
- Failure to monitor and require correction of the design process
- Failure to collect and analyze supplier performance data
- No evidence of repair disposition approval authority
- No evidence of document approval
- No evidence of design validation

Test the evidence against the nature statement. In other words select the requirement, state the opposite of the requirement and see if the evidence supports the nature of the nonconformity. If not, you have the wrong requirement or no nonconformity. The nature of the

nonconformity is a description of the problem. It defines the problem ready for problem solving or corrective action. Alone, these examples may seem broad but with the evidence they become clear.

writing the statement

Inform management of the problem, reach agreement and make notes. Decide if corrective action would add value. If so, prepare statements before the closing meeting. Expect an auditee-challenge if incorrect.

Review all notes, including team members and:

- State the requirement, evidence and nature
- Check the statement, is it correct, complete and clear?
- Read statements aloud (to detect grammatical errors)

You will have listened to and examined any evidence contrary to the facts of nonconformity. You will have reached agreement and have made excellent notes. You will have access to corrective action request forms from your client or the auditee. Now ask

yourself if the corrective action is likely to add value. If in doubt discuss and agree this with the lead auditor who may apply the 80:20 rule* and elect to merely note the lesser nonconformities in the audit report.

** 80% of the value may come from 20% of the nonconformities!*

The auditee has a right to reject nonconformity statements that are incorrect, incomplete or unclear even if only slightly contrary to the facts.

categorizing nonconformities

Sometimes it is useful to categorize nonconformities. For example you may need to know whether to recommend selection of a supplier. So ask the audit client for the major/minor criteria. More than six examples of the same nonconformity in the same system may for example indicate a chronic problem or major nonconformity. Almost all system and process nonconformities would be minor or isolated implementation problems.

Some failures to fulfill requirements are more serious than others, for example:

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Critical:

- Chronic/repetitive problem
- System breakdown
- Adversely affecting the environment or the customer (core process)

Less critical:

- Isolated implementation problems
- Support process

Write your nonconformity statement only when you are sure that your fellow audit team members did not find contradictory evidence. Write your statement ensuring that it includes the correct requirement, the evidence that substantiates nonfulfillment of the requirement. Ensure it

also describes the nature of the problem.

New auditors may write these three parts separately but experienced auditors tend to write one or two sentences that include all three parts. Ask the auditee (or a colleague on the audit team) to check your nonconformity statement to ensure that it is correct, complete and clear.

You will be reading your statement aloud in the closing meeting. Read it aloud (even to yourself!) before the meeting when you can correct it without losing credibility.

Management acknowledging receipt of the nonconformity statements

You may obtain the signature of a top

manager on a major nonconformity before the closing meeting. This leader can then prepare to demonstrate his or her commitment to prompt and effective corrective action at the closing meeting.

In any case ask the auditee (at least at management representative level) to sign each nonconformity statement to acknowledge receipt. You could ask, "Would you like a copy?" The auditee will answer "yes" and you can respond with "please sign them first". The auditee may get started immediately on determining and removing the root causes. The auditee cannot however claim to have completed the corrective action until

they have evidence of effectiveness.

summary audit report

The auditor's summary report can act as a cover sheet to the nonconformity statements showing the audit objective at the top and audit conclusion at the bottom also identifying the audit team members. It reports the degree of conformity per the audit's criteria, objectives and scope:

- Areas/processes audited (sample)
- Positive points (these are findings also)
- Major/minor nonconformities

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examples

GOOD, BAD AND UGLY AUDIT REPORTS

Nonconformity Statement – Example 1

"In the Instrument Shop, meter serial number 852, used as a standard to calibrate other meters, was due recalibration 2 months ago, on 25 June. It had not been recalibrated."

ISO 9001:2000 - clause 7.6 a)

Notice how the auditor was careful to ascertain the use of meter 852. If the calibration record indicted that the meters overdue calibration resulted in a hazard then this evidence may have changed this to a major nonconformity. Likewise, if calibration is part of the core process.

Nonconformity Statement – Example 2

"Drawing TP 354/88 Issue 4, in use in the Fabrication Shop, had an alteration to a design detail.

There was no evidence that this alteration had Design Department approval, as required by the document control procedure PR-QMS-01(03).

ISO 9001:2000 - clause 4.2.3 b)

Even though this is part of the core process it is still a minor nonconformity unless of course the alteration was to a key characteristic or unapproved alterations were chronic. By the way, this statement is incomplete. It should include a description of the altered design detail.

Nonconformity Statement – Example 3

"The wastewater treatment filters were not replaced every summer as specified in the preventive maintenance plan. Purchasing records and the WW Supervisor indicated that the last filter replacement was 2 summers ago. Failure to maintain the #1 wastewater treatment plant by replacing filters as planned.

ISO 14001:2004 - clause 4.4.6

Again this is part of the core process (even though waste water is a by-product). This is a minor nonconformity. Had it resulted in significant adverse environmental impact then this additional evidence would have made it a major nonconformity.

(the nature part of the nonconformity statements)

- Your conclusion per the audit's objectives.

Do not rewrite the nonconformities in the summary statement.

making a mistake

Mistakes are learning opportunities. Be quick to recognize a factual error. Correct if you can or remove the nonconformity statement from the report and update the audit record. Apologize for your mistake. Lead auditors quickly weigh up the facts and arbitrate decisively.

giving advice

Provide advisory services only if documented as an audit objective. Do not make the audit client pay for advice when they agreed to pay for audit. If required by the audit client to advise during audit then ensure the documented audit objective includes "with consulting" or similar.

Be careful, advice may weaken the system by making it dependent on its auditors. Advice may also disqualify you from independently auditing

that system or part of the system for two years.

Auditees who keep asking the auditor for advice may be providing evidence of their ineffective training or corrective action processes.

conclusion

"Value-added audits" have encouraged some auditors to provide advice on how to conform to the standard or release information that belongs to their other auditees. Doing so fails to protect the customer's intellectual property and makes the system depend too much on its auditor.

Well-crafted nonconformity statements may be the result of value-adding audits. Such audits focus first on the auditee's core process for converting the needs of stakeholders into cash*. Instead of asking "who?" auditees ask "why?" and think system, act on their system and learn from their system.

* Cash or continued funding in the case of a non-profit or government agency

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