Assemble as a team

Read the case study

Identify hearsay not supported by the evidence

Identify objective evidence

As a team, discuss which section of the standard might apply to the objective evidence

Was there a non-conformity?

Was there another non-conformity?

Record the specific clause number and requirement violated

No

Yes

Proceed to the next case study
1. The competence requirements for Deane Enterprises requires that all Managers must have at least a Bachelor’s degree or 7 years experience as a manager at a midsize electronic component manufacturer. When requesting the records to verify Ed Dunner, the Human Resource Manager could not locate the records.

Objective Evidence: ________________________________________________________________

Was there a non-conformity? ☐ No ☐ Yes

If YES, specify the clause number(s) of the violation(s) and the correlating statement
Violation of Clause _____________ Stating______________________________________________
Violation of Clause _____________ Stating______________________________________________

2. Dirty rags, empty containers and clutter was identified around the assembly area. A guard for the saw blade was also removed to allow the operator a quicker access to cut a groove in the part before assembly. Customer complaints indicated that contamination was a concern and has been a warranty issue. The operator indicated that a clean up crew usually cleans the work area on a monthly basis.

Objective Evidence: ________________________________________________________________

Was there a non-conformity? ☐ No ☐ Yes

If YES, specify the clause number(s) of the violation(s) and the correlating statement
Violation of Clause _____________ Stating______________________________________________
Violation of Clause _____________ Stating______________________________________________

3. While auditing in the Receiving and Inspection department, the auditor asked the supervisor how he or his area inspected Incoming Product. The supervisor immediately produced a company instruction sheet indicating 10 steps with check-off for the inspection of incoming product. The auditor asked the supervisor if this was the most current version of the instruction. Yes, said the supervisor, it is dated 2 months ago, it is current. The auditor asked for evidence that it was current with the document control listing. The Document Control clerk produced an up to date list only to find that the Incoming Product instruction was changed a month before. The supervisor stated to the auditor that it really didn’t matter, we check everything anyway and Management doesn’t have a problem with this.

Objective Evidence: ________________________________________________________________

Was there a non-conformity? ☐ No ☐ Yes

If YES, specify the clause number(s) of the violation(s) and the correlating statement
Violation of Clause _____________ Stating______________________________________________
Violation of Clause _____________ Stating______________________________________________
4. While in a mail order fulfillment center, the auditor notices that a laminating machine is shut down. Upon inquiring, the area manager stated that line had been down for over a week awaiting a finishing roll that is out for repair. The manager also commented that they were swamped because customer orders were backed up, customers were beginning to complain and the re-finished roll was not scheduled for another week. When asked if there was an equipment maintenance schedule, the response was that their maintenance supervisor claims that a PM schedule is not required by the ISO standard and their policy is to “Fix When Broke.”

**Objective Evidence:** ____________________________

__________________________________________________________________________

__________________________________________________________________________

__________ □ No □ Yes

If YES, specify the clause number(s) of the violation(s) and the correlating statement

Violation of Clause _____________ Stating ________________________________

Violation of Clause _____________ Stating ________________________________

5. While auditing the project manager for an insurance disability company seeking ISO certification, the auditor was reviewing the file for a recently launched program for one of the company's clients. The file only contained four workbooks and the auditor asked for any other additional project plans and design review records that might be available. The response was that the company had excluded Design and Development in their certification scope and as such was not design responsible. Besides, he mentioned, new programs have always been worked out by informal discussions between the project team, sales and production fulfillment.

**Objective Evidence:** ____________________________

__________________________________________________________________________

__________________________________________________________________________

__________ □ No □ Yes

If YES, specify the clause number(s) of the violation(s) and the correlating statement

Violation of Clause _____________ Stating ________________________________

Violation of Clause _____________ Stating ________________________________

6. Assigned to audit a community technical high school for recertification to ISO 9001, the audit team leader was reviewing management review records and she noticed a requirement to review the quality policy for continuing suitability. However, the action item column next to the requirement was marked “n/a.” She asked the management representative about this and the reply was that the quality policy was authored by the community school board. The item is reviewed at the technical high school management review meeting, but since they are not empowered to make a change, a “n/a” was notated. The other review requirements were completed as required.

**Objective Evidence:** ____________________________

__________________________________________________________________________

__________ □ No □ Yes

If YES, specify the clause number(s) of the violation(s) and the correlating statement

Violation of Clause _____________ Stating ________________________________

Violation of Clause _____________ Stating ________________________________
Two internal auditors for a small engineering construction company were assigned to audit management review. In preparation for their audit, the auditors reviewed the past two yearly surveillance audit reports from the company’s certifying body and management review reports conducted January 14, 2005, February 5, 2006 and March 22, 2007. No other reports were found in the files. The objective evidence did not support Management Review being conducted on a quarterly basis as defined in the Management System Manual. Also, the follow-up action items listed in the Management Review minutes for the 2005 and 2006 reports were not reflected as input items in the subsequent review reports. During the interview with the management representative, the auditors were told not to be concerned; the registrar had determined that the company’s QMS was in conformance with ISO 9001 and there was no need for an audit finding. The MR did instruct them to write up their observation about the quality manual. Both auditors worked in the quality department.

**Objective Evidence:**
_____________________________________________________________________________________________
_____________________________________________________________________________________________
_____________________________________________________________________________________________

Was there a non-conformity? ☐ No ☐ Yes

If YES, specify the clause number(s) of the violation(s) and the correlating statement

Violations of Clause _______________  Stating ________________________________

Violations of Clause _______________  Stating ________________________________