1. What is the definition of a finding?

- A required corrective action
- An auditor's personal opinion
- A regulatory citation
- **A factual statement based on objective evidence collected during the audit**

2. What is the difference between a nonconformity and an observation?

- Only nonconformities appear in the report
- An observation is more serious than a nonconformity
- They are the same thing
- **A nonconformity is a failure to meet a specified requirement; an observation is a noted condition that may not be a formal nonconformity but warrants attention**

3. In which context is 'noncompliance' more commonly used?

- Marketing communications
- Internal audits only
- **Regulatory audits**
- Supplier audits only

4. What makes a result reportable?

- The auditee disagrees with the auditor's preference
- The auditor has seen it done differently elsewhere
- It is interesting to the auditor
- **It is supported by objective evidence and tied directly to a requirement (standard, procedure, regulation, or contract)**

5. Which classification represents an immediate threat to product safety, compliance, or user health?

- **Critical**
- Major
- Opportunity for Improvement
- Minor

6. What characterizes a minor nonconformity?

- A regulatory violation
- **An isolated issue with low risk that does not significantly affect outcomes**
- An immediate threat to safety
- A systemic failure across the organization

7. What structure is recommended for writing valid audit findings?

- Cause → Solution → Recommendation
- Auditee → Auditor → Manager
- Observation → Opinion → Conclusion
- **Requirement → Condition → Evidence**

8. Which is a sequencing approach for presenting audit results?

- By auditor preference only
- By date and time stamp only
- **By severity, by process or requirement, or by audit trail**
- By auditee request only

9. Scenario: An auditor sees a process they would have run differently, but the auditee's procedure does not violate any standard. Should this be a finding?

- Only if it is a minor finding
- Yes, but only if the auditee agrees
- Yes, anything an auditor disagrees with should be a finding
- **No, auditor preference is not a basis for findings**

10. What should auditors avoid when writing the audit report?

- **Recommending specific corrective actions or implying disciplinary decisions**
- Citing the requirement
- Including objective evidence
- Using neutral language

QUIZ 8.2 — ANSWERS & RATIONALES

1. A factual statement based on objective evidence collected during the audit - Findings are factual statements based on objective evidence. They are the broad category that includes nonconformities and observations.

2. A nonconformity is a failure to meet a specified requirement; an observation is a noted condition that may not be a formal nonconformity but warrants attention - Nonconformities tie directly to a violated requirement. Observations note conditions that may not violate a requirement but warrant attention.

3. Regulatory audits - Noncompliance is often used interchangeably with nonconformity but is more common in regulatory contexts where audits relate to regulations.

4. It is supported by objective evidence and tied directly to a requirement (standard, procedure, regulation, or contract) - Reportable findings must be tied to a specific requirement and supported by objective evidence. Personal opinions are not reportable.

5. Critical - Critical nonconformities are immediate threats requiring urgent response. They are often show-stoppers.

6. An isolated issue with low risk that does not significantly affect outcomes - Minor nonconformities are isolated, low-risk issues that do not significantly affect product or process outcomes.

7. Requirement → Condition → Evidence - Findings follow Requirement → Condition → Evidence. Each element supports the next, and skipping any one weakens the finding.

8. By severity, by process or requirement, or by audit trail - Three common sequencing approaches: by severity (most critical first), by process or requirement (organized by clause), or by audit trail (in audit order).

9. No, auditor preference is not a basis for findings - Findings must be tied to a specific requirement violation. Auditor preference, opinion, or industry experience is not a basis for findings.

10. Recommending specific corrective actions or implying disciplinary decisions - Auditors observe and report. Recommending solutions or assigning blame can create liability and falls outside the audit's role.