Do not open this booklet until asked to do so by the examiner:

IAS Lead Assessor Course

Final Exam #1

1. Course Details

Date: _____ Venue (or Online): _____

Instructor Name(s): _____

Participant Name taking the Exam: _____

2. Instructions

1. Complete the identifications needed above before the exam start time. If you are having difficulty doing so, please inform the examiner. The exam time will not start until all participants have completed the Course Details section.
2. You are allowed to use all course notes taken during the course, as reference materials for this exam. You are allowed to use all course notes delivered to you, as reference materials during this exam.
3. You are not to discuss any of the material with any person from the start time of the exam until the last person has left the examination room.
4. You may use pencil and eraser to write your answers in the spaces provided.
5. All participants are allowed 120 minutes to complete this exam.
6. The following grades are assigned to each of the four sections of this exam. **Apportion your time accordingly.**

Examination Section	Section Title	Total Possible Marks	Marks Obtained	Examiner Initials
Section 1	Multiple choice	10		
Section 2	Short answer	20		
Section 3	Long answer	30		
Section 4	Findings classification	40		
Total				

3. Section 1 – Worth 10 Marks

4. Each question is worth 1 mark

Circle the correct answer for each question in this Section. There is only **one** correct answer for each question.

1.1 ISO/IEC 17025 contains the following types of requirements:

a. Management system and Process requirements
b. Management and organizational requirements
c. Quality system and technical requirements
d. Leadership and management requirements

1.2 Accreditation bodies conduct assessments:

a. Against ISO/IEC 17025 alone
b. Against ISO 9001 alone
c. Against ISO/IEC 17011 and ISO/IEC 17025
d. Against ISO/IEC 17025 and other AB requirements documents

1.3 The Principle of “Capacity” is described as:

a. The people with the skills and knowledge,
b. The environment with the facilities and equipment
c. The quality control and the procedures
d. All of the above.

1.4 Only one of the following statements is correct. Circle the correct one.

a. AB05 describes the AB Policy on Traceability
b. AB07 describes the AB Policy on Root Cause Analysis
c. Assessors should use AF01 to document a proposed assessment schedule.
d. AF13 describes the AB Policy on the use of IT in an accredited laboratory.

1.5 Traceability includes three components for every step in the traceability chain:

a. Uncertainty, calculation, documentation
b. Calibration, uncertainty, traceability
c. Documentation, registration, reference to the SI
d. Calibration, uncertainty, competence

1.6 A laboratory seeking accreditation must complete a set of responses to required actions that contains the following information found on AF08 – Assessment Finding Form:

a. Description of the action taken and the expected time of implementation.
b. Description of the action to be taken and who will implement it.
c. Description of the action that was taken and reference to evidence of implementation.
d. Desired timeline for the implementation of the action to be taken and its description.

1.7 Documents and records acquired or created during an assessment:

a. Are to be returned to the laboratory.
b. Are to be retained for future reference by the assessors.
c. Are to be returned to the AB
d. Are to be returned to the laboratory and/or the AB, as appropriate.

1.8 Laboratories may dispute AB assessment report findings:

a. On appeal to the AB Board
b. With the concurrence of the Technical Review Panel
c. Within 10 days of the receipt of the report
d. At any time after the presentation of the assessment report.

1.9 Washup meetings can be held:

a. Before the opening meeting
b. Before the onsite visit
c. At the end of any day or at the beginning of the next
d. After the closing meeting.

1.10 Once a non-conforming condition is observed by the assessor, they should first:

a. Determine the level of blame to be assigned to the person responsible for the process
b. Find as many non-conformances as possible associated to the process under review
c. Understand the process under review as it is understood by the person being interviewed
d. Record the observation, the requirement, and the evidence that is available for examination

Section 2 – Worth 20 Marks

Each question is worth 5 marks

Each question in this Section asks for a list of things (considerations, components, etc). There are five "bullets" under each question. The correct response for each question will have more than 10 possible answers. Each bullet is worth one mark. **Note**: Any five correct answers are acceptable.

2.1 Provide the **document number** and **name** of five AB requirements documents provided as samples on this course, besides ISO/IEC 17025:

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_____

_____

_____

_____

2.2 Name five required **agenda items** for an **assessment closing meeting as described in AS02 from the Assessor Toolkit:**

_____

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_____

2.3 Name five of the **attachments** listed on the AB Assessment report at the end of **an assessment**:

_____

_____

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2.4 Name five of the list of post assessment activities that should be completed by an assessor after an assessment visit:

_____

_____

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_____

_____

Section 3 – Worth 30 Marks

Each question is worth 15 marks

Each question in this Section requires a descriptive and narrative answer. Each answer is to contain the following:

- Identification of the issue at the core of the problem / question (5 marks)
- Identification of the approach used to resolve the issue or address the problem (5 marks),
- Identification of the documents or references describe the actual requirement (5 marks)

3.1 As part of its customer service, a laboratory does have staff that will go to sites and do sampling, and then submit samples to the laboratory for analysis. During the assessment of soil methods, the assessor notes that the uncertainty of the sampling is not incorporated into the estimate of measurement uncertainty of the test result. The laboratory argues that this is not necessary, and is undue work for the laboratory.

What is the real problem here? Cite the requirement in the Standard. (5)

_____

_____

_____

_____

What are the **five things** an assessor should do on discovery of this condition/observation? (5)

_____

_____

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What documents provide guidance on the actual requirement here? (5)

_____

_____

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3.2 During the reassessment of an accredited laboratory, the assessor requests to see the method validation for several methods. The laboratory cannot provide the assessor with any of the QC data that was generated during method validation.

What is the real problem here? Cite the requirement in the Standard. (5)

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What are the **five things** an assessor should do on discovery of this condition/observation? (5)

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What documents provide guidance on the actual requirement here? (5)

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Section 4 – Worth 40 Marks

Each question is worth 10 marks

Each question in this Section requires a written finding, to be developed from the scenario presented. Each finding must contain the following information, all of which can be obtained from the course material:

- Identification of the Assessment Checklist Item against which the finding is raised (1 marks)
- Identification of the clause of ISO/IEC 17025 that governs (2 mark)
- Statement of the condition that has been observed (3 marks)
- Identification of the evidence used to support the observation (2 mark)
- Classification of the finding (Non-Conformance, Potential Non-Conformance, Opportunity for Improvement) (2 marks)

4.1 During an assessment the assessor noted that a simplified test report doesn't include a note that information is available for any of the items listed in section 7.8.2 of ISO/IEC 17025.

The laboratory stated that they don't have the external customers, only internal, which has the same company name and the same address as the laboratory. In addition, clause 7.8.2 states that this information must be on the report unless the laboratory has a valid reason for not doing so.

What is the F04 Assessment Checklist for 17025 Item that states the requirement? (1)

_____

What is the ISO/IEC 17025 Clause (including sub clause) that states the requirement? (2)

_____

How does the Assessor write the comparison of requirement to condition? (3)

_____

_____

_____

What is the evidence that supports the finding? (2)

_____

_____

How should this finding be classified? (3)

Non-Conformance ❑

Potential Non-Conformance ❑

Opportunity for Improvement ❑

Not a Finding ❑

4.2 During the document review, in preparation for a reassessment, the assessor notes that the quality manual stipulates that the laboratory does not do any sampling, so Clause 7.3 of ISO/IEC 17025 is not applicable. External customers submit samples to the laboratory. During the on-site review of the methods, the assessor notes that the laboratory is performing sub-sampling of soil samples received from external customers. The laboratory does not have a procedure for sub-sampling and maintains that Clause 7.3 of the standard is not applicable to the sub-sampling and only applicable if the laboratory is actually in the field, taking samples.

What is the F04 Assessment Checklist for 17025 Item that states the requirement? (1)

_____

What is the ISO/IEC 17025 Clause (including sub clause) that states the requirement? (2)

_____

How does the Assessor write the comparison of requirement to condition? (3)

_____

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What is the evidence that supports the finding? (2)

_____

_____

How should this finding be classified? (3)

Non-Conformance ❑

Potential Non-Conformance ❑

Opportunity for Improvement ❑

Not a Finding ❑

4.3 While assessing an analytical method the assessor asked the laboratory to provide evidence of method validation in accordance with Appendix 2 of the Department of Environment reference method, i.e., 4 samples in triplicate run by the benchmark method and the laboratory method that uses spectroscopy. The laboratory uses a different approach to this method extraction as permitted in section 11.2 of the Department of Environment reference method.

The laboratory stated that they deemed their alternative approach to be the equivalent of the Department of Environment reference method, but did not provide any data that indicated this difference had any impact on results. Additionally, in terms of the performance of their method with respect to the efficiency of their extraction technique, their excellent performance on all PT samples is evidence of robustness of their method.

What is the F04 Assessment Checklist for 17025 Item that states the requirement? (1)

_____

What is the ISO/IEC 17025 Clause (including sub clause) that states the requirement? (2)

_____

How does the Assessor write the comparison of requirement to condition? (3)

_____

_____

_____

What is the evidence that supports the finding? (2)

_____

_____

How should this finding be classified? (3)

Non-Conformance ❑

Potential Non-Conformance ❑

Opportunity for Improvement ❑

Not a Finding ❑

4.4 On a workbench in the sample preparation room, you notice a technician using an old electronic balance on which is affixed a label with the words "Not Calibrated". You record the serial number (No. 916725) of the balance for later reference.

When examining the laboratory equipment records sometime later, you discover that this balance is shown on the list of testing equipment as "Withdrawn from use - Not to be calibrated." During a subsequent conversation with the lab supervisor, it is explained to you that this balance is not used for any accurate work and the technician was probably using it for a task that did not require accurate measurement.

What is the F04 Assessment Checklist for 17025 Item that states the requirement? (1)

_____

What is the ISO/IEC 17025 Clause (including sub clause) that states the requirement? (2)

_____

How does the Assessor write the comparison of requirement to condition? (3)

_____

_____

_____

What is the evidence that supports the finding? (2)

_____

_____

How should this finding be classified? (3)

Non-Conformance ❑

Potential Non-Conformance ❑

Opportunity for Improvement ❑

Not a Finding ❑