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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 2

GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING ENVIRONMENTAL LABORATORIES

Module 1: General Requirements

TNI Standard

COMMITTEE CONTROLLED COPY

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PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Laboratory Accreditation Body Expert Committee. The TNI Board of Directors wishes to thank these committee members for their efforts in preparing this Standard as well as those TNI members who offered comments during the voting process.

It is conformant with the requirements of ISO/IEC 17011:2017(E), and includes applicable clauses from that international standard. The ISO clauses are provided *in italics.* Additional TNI text is provided in a normal font.

This Standard may be used by any organization that wishes to implement a program for the accreditation of environmental laboratories.

Section numbers and language merged into this Module from Module 3 “On-Site Assessment” is denoted by SINGLE-UNDERLINE (_____).

Additional language proposed during the Expert Committee’s review is denoted by DOUBLE-UNDERLINE (xxxx).

Language proposed for deletion during the Expert Committee’s review is denoted by STRIKE-THROUGH (~~xxxx~~).

NOTE: Some language in this document may be denoted both by single-underline and strike-through.

VOLUME 2, MODULE 1
General Requirements
Table of Contents

1.0 INTRODUCTION, SCOPE, AND APPLICABILITY 1

2.0 NORMATIVE REFERENCES 1

3.0 TERMS AND DEFINITIONS 2

4.0 GENERAL REQUIREMENTS 7
4.1 Legal Entity 7
4.2 Accreditation Agreement 7
4.3 Use of Accreditation Symbols and Other Claims of Accreditation 8
4.4 Impartiality Requirements 9
4.5 Financing and Liability 12
4.6 Establishing Accreditation Schemes 12

5.0 STRUCTURAL REQUIREMENTS 13

6.0 RESOURCE REQUIREMENTS 15
6.1 Competence of Personnel 15
6.2 Personnel Involved in the Accreditation Process 18
6.3 Personnel Records 20
6.4 Outsourcing 20

7.0 PROCESS REQUIREMENTS 21
7.1 Accreditation Requirements 21
7.2 Application for Accreditation 21
7.3 Resource Review 22
7.4 Preparation for Assessment 22
7.5 Review of Documented Information 25
7.6 Assessment 25
7.7 Accreditation Decision-Making 29
7.8 Accreditation Information 31
7.9 Accreditation Cycle 34
7.10 Extending Accreditation 35
7.11 Suspending, Withdrawing, or Reducing Accreditation 35
7.12 Complaints 37
7.13 Appeals 38
7.14 Records on Conformity Assessment Bodies 39

8.0 INFORMATION REQUIREMENTS 39
8.1 Confidential Information 39
8.2 Publicly Available Information 40

VOLUME 2, MODULE 1

General Requirements

Table of Contents cont.

9.0 MANAGEMENT REQUIREMENTS 41
9.1 General 41
9.2 Management System 42
9.3 Document Control 42
9.4 Records Control 43
9.5 Nonconformities and Corrective Actions 43
9.6 Improvement 43
9.7 Internal Audits 43
9.8 Management Reviews 44

Annex A (Informative) REQUIRED KNOWLEDGE AND SKILLS FOR FUNCTIONS IN THE ACCREDITATION PROCESS 46

Table A1 TABLE OF KNOWLEDGE AND SKILLS 46

VOLUME 2, MODULE 1

General Requirements

1.0 SCOPE *(ISO/IEC 17011:2017(E), Clause 1)*

This document specifies requirements for the competence, consistent operation, and impartiality of accreditation bodies assessing and accrediting conformity assessment bodies.

NOTE: In the context of this document, activities covered by accreditation include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation, and verification.

In this document, the following verbal forms are used:

- *"shall" indicates a requirement;*

- *"should" indicates a recommendation;*

- *"may" indicates a permission;*

- *"can" indicates a possibility or a capability.*

This TNI Standard is intended as an application of *ISO/IEC 17011:2017(E)* Conformity Assessment - Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies, for the purposes of accrediting environmental testing laboratories. The ISO/IEC clauses are provided in *italics*, with the additional TNI clauses in normal font.

Users of this Standard should make the following substitutions and recognize that the context may require minor variations to these terms:

For this term:	*Substitute this term:*
Conformity Assessment Body (CAB)	Laboratory

Unless the contrary is clearly indicated, all references to singular nouns include the plural noun, and all references to plural nouns include the singular.

Some clauses in this Standard contain notes. The notes are used to explain a particular requirement or to provide clarifying examples. The notes do not supersede or modify requirements of the Standard and do not convey any additional requirements.

2.0 NORMATIVE REFERENCES *(ISO/IEC 17011:2017(E), Clause 2)*

The following referenced documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, Conformity assessment — Vocabulary and general principles

Note: ISO/IEC Guide 99, International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM, latest edition), may also be used as a reference.

3.0 TERMS AND DEFINITIONS *(ISO/IEC 17011:2017(E), Clause 3)*

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

-- ISO Online browsing platform: available at https://www.iso.org/obp

-- IEC Electropedia: available at http://www.electropedia.org

3.1 Accreditation *(ISO/IEC 17011:2017(E) Clause 3.1)*

Third-party attestation related to a conformity assessment body (3.4) conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

[SOURCE: ISO/IEC 17000:2004, 5.6]

3.2 Accreditation Body *(ISO/IEC 17011:2017(E) Clause 3.2)*

Authoritative body that performs accreditation (3.1).

NOTE 1 to entry: The authority of an accreditation body is generally derived from government.

[SOURCE: ISO/IEC 17000:2004, 2.6]

3.3 Accreditation Body Logo *(ISO/IEC 17011:2017(E) Clause 3.3)*

Logo used by an accreditation body (3.2) to identify itself.

3.4 Conformity Assessment Body (CAB) *(ISO/IEC 17011:2017(E) Clause 3.4)*

Body that performs conformity assessment activities and that can be the object of accreditation (3.1).

NOTE 1 to entry: Whenever the word "conformity assessment body" is used in the text, it applies to both the applicant and accredited conformity assessment bodies, unless otherwise specified.

[SOURCE: ISO/IEC 17000:2004, 2.5 modified – The words "and that can be the object of accreditation" have been added, and the Note to entry has been added.]

NOTE 2: This module is concerned with conformity assessment bodies (CAB) commonly known as laboratories providing services in a fixed or mobile setting. The on-site assessment of field sampling and measurement organizations is detailed in *TNI Field Sampling and Measurement Organization Sector, Volume 2.* [from V2M3]

3.5 Conformity Assessment Activity *(ISO/IEC 17011:2017(E) Clause 3.5)*

Activity conducted by a conformity assessment body (3.4) when assessing conformity.

NOTE 1 to entry: In the context of this document, activities covered by accreditation (3.1) include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes

and services, provision of proficiency testing, production of reference materials, and validation and verification. For simplicity, these are referred to as conformity assessment activities being performed by conformity assessment bodies.

3.6 Scope of Accreditation *(ISO/IEC 17011:2017(E) Clause 3.6)*

Specific conformity assessment services for which accreditation (3.1) is sought or has been granted.

(~~See~~ also called Field of Accreditation)

Fields of Accreditation are those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

3.7 Flexible Scope of Accreditation *(ISO/IEC 17011:2017(E) Clause 3.7)*

Scope of accreditation (3.6) expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body (3.4) as confirmed by the accreditation body (3.2).

NOTE to entry: Flexible scopes of accreditation are not applicable to this TNI Standard.

3.8 Accreditation Scheme *(ISO/IEC 17011:2017(E) Clause 3.8)*

Rules and processes relating to the accreditation (3.1) of conformity assessment bodies to which the same requirements apply.

NOTE 1 to entry: Accreditation scheme requirements include, but are not limited to, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17025, ISO/IEC 17024, ISO 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189, and ISO 14065.

NOTE 2 to entry: For The NELAC Institute's Environmental Laboratory Sector (ELS) standards, the accreditation scheme requirements include Volume 1, "Management and Technical Requirements for Laboratories Performing Environmental Analysis" and Volume 2, "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories."

3.9 Accreditation Activity *(ISO/IEC 17011:2017(E) Clause 3.9)*

Individual operational tasks of the accreditation process (3.11).

NOTE 1 to entry: See Clause 7.

3.10 Impartiality *(ISO/IEC 17011:2017(E) Clause 3.10)*

Presence of objectivity.

NOTE 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the accreditation body (3.2).

NOTE 2 to entry: Other terms that are useful in conveying the element of impartiality include "independence," "freedom from conflicts of interest," "freedom from bias," "lack of prejudice," "neutrality," "fairness," "open-mindedness," "even-handedness," "detachment," "balance."

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified – The words "certification body" have been replaced by "accreditation body" in Note 1 to entry.]

3.11 Accreditation Process *(ISO/IEC 17011:2017(E) Clause 3.11)*

Activities from application through to granting and maintenance of accreditation (3.1) as defined by the accreditation scheme (3.8).

3.12 Accreditation Symbol *(ISO/IEC 17011:2017(E) Clause 3.12)*

Symbol issued by an accreditation body (3.2) to be used by accredited conformity assessment bodies to indicate they are accredited.

3.13 Accreditation Decision *(ISO/IEC 17011:2017(E) Clause 3.13)*

Decision on granting (3.14), maintaining (3.15), extending (3.16), reducing (3.17), suspending (3.18), and withdrawing (3.19) accreditation (3.1).

3.14 Granting of Accreditation *(ISO/IEC 17011:2017(E) Clause 3.14)*

Awarding accreditation (3.1) for a defined scope of accreditation (3.6).

3.15 Maintaining Accreditation *(ISO/IEC 17011:2017(E) Clause 3.15)*

Confirming the continuance of accreditation (3.1) for a defined scope.

3.16 Extending Accreditation *(ISO/IEC 17011:2017(E) Clause 3.16)*

Adding conformity assessment activities to the scope of accreditation (3.6).

3.17 Reducing Accreditation *(ISO/IEC 17011:2017(E) Clause 3.17)*

Canceling part of the scope of accreditation (3.6).

3.18 Suspending Accreditation *(ISO/IEC 17011:2017(E) Clause 3.18)*

Putting temporary restrictions in place for all or part of the scope of accreditation (3.6).

3.19 Withdrawing Accreditation *(ISO/IEC 17011:2017(E) Clause 3.19)*

Canceling accreditation (3.1) for the full scope.

3.20 Complaint *(ISO/IEC 17011:2017(E) Clause 3.20)*

Expression of dissatisfaction, other than appeal (3.21), by any person or organization, to an accreditation body (3.2), relating to the activities of that accreditation body or of an accredited conformity assessment body (3.4), where a response is expected.

[SOURCE: ISO/IEC 17000:2004, 6.5, modified – The words "to a conformity assessment body or accreditation body, relating to the activities of that body" have been replaced by "to an accreditation body, relating to the activities of that accreditation body or of an accredited conformity assessment body."]

3.21 Appeal *(ISO/IEC 17011:2017(E) Clause 3.21)*

Request by a conformity assessment body (3.4) for reconsideration of any adverse accreditation decision (3.13) related to its desired accreditation (3.1) status.

3.22 Assessment *(ISO/IEC 17011:2017(E) Clause 3.22)*

Process undertaken by an accreditation body (3.2) to determine the competence of a conformity assessment body (3.4), based on standard(s) and/or other normative documents and for a defined scope of accreditation (3.6).

~~NOTE 2: Accreditation bodies perform the following types of on-site assessments:~~

~~a) Initial assessments: These are comprehensive and involve reviewing all key activities performed by a CAB applying for accreditation for the first time. Initial assessments are announced.~~

~~b) Reassessments: These are similar in scope to initial assessments except that the experience gained during previous assessments may be taken into account.~~

~~c) Surveillance on-site assessments: These are less comprehensive than reassessments and occur as needed in between an initial assessment and a reassessment or between reassessments.~~

~~d) Follow-up assessments: These are undertaken to verify effective implementation of corrective actions.~~

~~e) Extraordinary assessments: These are conducted as a result of complaints or changes such as ownership, key personnel, location, scope of accreditation, or other matters that may affect the ability of a CAB to fulfill accreditation requirements.~~
(from V2M3, 3.7)

3.23 Reassessment *(ISO/IEC 17011:2017(E) Clause 3.23)*

Assessment (3.22) performed to renew the accreditation (3.1) cycle.

3.24 Assessment Technique *(ISO/IEC 17011:2017(E) Clause 3.24)*

Method used by an accreditation body (3.2) to perform an assessment (3.22).

NOTE 1 to entry: Assessment techniques can include, but are not limited to:
- *on-site assessment;*
- *remote assessment (3.26);*
- *witnessing (3.25);*
- *document review;*
- *file review;*
- *measurement audits;*
- *review of performance in proficiency testing and other interlaboratory comparisons;*
- *validation audits;*
- *unannounced visits;*
- *interviewing.*

3.25 Witnessing *(ISO/IEC 17011:2017(E) Clause 3.25)*

Observation by the accreditation body (3.2) of a conformity assessment body (3.4) carrying out conformity assessment activities within its scope of accreditation (3.6).

3.26 Remote Assessment *(ISO/IEC 17011:2017(E) Clause 3.26)*

Assessment (3.22) of the physical location or virtual site of a conformity assessment body (3.4), using electronic means.

NOTE 1 to entry: A virtual site is an on-line environment allowing persons to execute processes, e.g. in a cloud environment.

3.27 Assessment Programme *(ISO/IEC 17011:2017(E) Clause 3.27)*

Set of assessments (3.22) consistent with a specific accreditation scheme (3.8) that the accreditation body (3.2) performs on a specific conformity assessment body (3.4) during an accreditation (3.1) cycle.

3.28 Assessment Plan *(ISO/IEC 17011:2017(E) Clause 3.28)*

Description of the activities and arrangements for an assessment (3.22).

[SOURCE: ISO 19011:2011, 3.15, modified – The word "audit" has been replaced by "assessment."]

3.29 Accreditation Body Personnel *(ISO/IEC 17011:2017(E) Clause 3.29)*

Internal or external individuals carrying out activities on behalf of the accreditation body (3.2).

3.30 Assessor *(ISO/IEC 17011:2017(E) Clause 3.30)*

Person assigned by an accreditation body (3.2) to perform, alone or as part of an assessment team, an assessment (3.22) of a conformity assessment body (3.4).

3.31 Team Leader *(ISO/IEC 17011:2017(E) Clause 3.31)*

Assessor (3.30) who is given the overall responsibility for the management of an assessment (3.22).

3.32 Technical Expert *(ISO/IEC 17011:2017(E) Clause 3.32)*

Person assigned by an accreditation body (3.2), working under the responsibility of an assessor (3.30), who provides specific knowledge or expertise with respect to the scope of accreditation (3.6) to be assessed and does not assess independently.

NOTE 1 to entry: A technical expert is not expected to have assessor qualifications and training.

3.33 Interested Party *(ISO/IEC 17011:2017(E) Clause 3.33)*

Person or organization with a direct or indirect interest in accreditation (3.1).

NOTE 1 to entry: Direct interest refers to the interest of those who undergo accreditation; indirect interest refers to the interests of those who use or rely on accredited conformity assessment bodies.

NOTE 2 to entry: Interested parties can include the accreditation body (3.2), conformity assessment bodies, their associations and their clients, industry services, trade associations, scheme owners, governmental regulatory bodies or other governmental services, or non-governmental organizations, including consumer organizations.

3.34 Consultancy *(ISO/IEC 17011:2017(E) Clause 3.34)*

Participation in any of the activities of a conformity assessment body (3.4) subject to accreditation (3.1).

EXAMPLE 1: Preparing or producing manuals or procedures for a conformity assessment body.

EXAMPLE 2: Participating in the operation or management of a conformity assessment body.

EXAMPLE 3: Giving specific advice or specific training towards the development and implementation of the management system, operational procedures, and/or competence of a conformity assessment body.

NOTE: Consultancy refers to the position or practice of a qualified person paid for advice and services and does not include information and assistance provided by governmental agencies.

NOTE: It is ~~customary and~~ permissible for assessors to provide instruction or guidance on the ~~meaning of~~ accreditation ~~and method~~ requirements during the ~~on-site~~ assessment process. Offering such instruction and advice does not constitute consultancy. Assessors should not prescribe specific tasks on how to develop or implement management systems or operational procedures to comply with accreditation ~~or method~~ requirements to avoid engaging in consultancy. [from V2M3, 6.10.1]

~~**3.14 Field of Accreditation**~~

~~Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation. (see also Scope of Accreditation).~~

4.0 GENERAL REQUIREMENTS

4.1 Legal Entity *(ISO/IEC 17011:2017(E), Clause 4.1)*

The accreditation body shall be a legal entity, or a defined part of a legal entity such that it is legally responsible for its accreditation activities.

NOTE 1: Governmental accreditation bodies are deemed to be legal entities on the basis of their status within their government.

NOTE 2: An accreditation body that is part of a larger body can operate under a different name.

4.2 Accreditation Agreement *(ISO/IEC 17011:2017(E), Clause 4.2)*

The accreditation body shall establish a legally enforceable arrangement with each conformity assessment body that requires the conformity assessment body to conform to at least the following:

a) to commit to fulfill continually the requirements for accreditation for the scope for which accreditation is sought or granted and to commit to provide evidence of fulfillment. This includes agreement to adapt to changes in the requirements for accreditation;

b) to cooperate as is necessary to enable the accreditation body to verify fulfillment of requirements for accreditation;

c) to provide access to conformity assessment body personnel, locations, equipment, information, documents, and records as necessary to verify fulfillment of requirements for accreditation;

d) to arrange the witnessing of conformity assessment activities when requested by the accreditation body;

e) to have, where applicable, legally enforceable arrangements with their clients that commit the clients to provide, on request, access to accreditation body assessment teams to assess the conformity assessment body's performance when carrying out conformity assessment activities at the client's site;

f) to claim accreditation only with respect to the scope for which it has been granted;

g) to commit to follow the accreditation body's policy for the use of the accreditation symbol;

h) not to use its accreditation in such a manner as to bring the accreditation body into disrepute;

i) to inform the accreditation body without delay of significant changes relevant to its accreditation;

NOTE: Such changes can concern:

- its legal, commercial, ownership, or organizational status;

- the organization, top management, and key personnel;

- resources and location(s);

- scope of accreditation;

- other matters that can affect the ability of the conformity assessment body to fulfill requirements for accreditation.

j) to pay fees as determined by the accreditation body;

k) to assist in the investigation and resolution of any accreditation-related complaints about the conformity assessment body referred to it by the accreditation body.

4.3 Use of Accreditation Symbols and Other Claims of Accreditation

4.3.1 *ISO/IEC 17011:2017(E), Clause 4.3.1*

The accreditation body shall take measures to ensure that the accredited conformity assessment body:

a) fully conforms to the requirements of the accreditation body for claiming accreditation status, when making reference to its accreditation in communication media;

b) does not make any misleading or unauthorized statement regarding its accreditation;

c) upon withdrawal of its accreditation, discontinues its use of any reference to that accreditation;

d) does not refer to its accreditation in a way so as to imply that a product, process, service, management system, or person is approved by the accreditation body;

e) informs its affected clients of the suspension, reduction, or withdrawal of its accreditation and the associated consequences without undue delay.

4.3.2 *ISO/IEC 17011:2017(E), Clause 4.3.2*

When an accreditation body has an accreditation symbol, the accreditation body shall have the legal right to use it and the accreditation symbol shall be legally protected.

4.3.3 *ISO/IEC 17011:2017(E), Clause 4.3.3*

The accreditation body shall have a documented policy governing the use of the accreditation symbol and claims of accreditation status. This policy shall specify as a minimum:

a) requirements for the use and monitoring of the accreditation symbol in combination with any conformity assessment body mark;

b) that the accreditation symbol is not affixed on its own or used to imply that a product, process, or service (or any part of it) has been certified or approved by the accreditation body;

c) requirements for reproduction of the accreditation symbol;

d) requirements for any reference to accreditation;

e) requirements for the use of the accreditation symbol and claims of accreditation status in communication media;

f) that the conformity assessment body only uses the accreditation symbol and claims of accreditation status for the specific activities covered by the scope of accreditation.

4.3.4 *ISO/IEC 17011:2017(E) Clause 4.3.4*

The accreditation symbol shall have, or be accompanied with, a clear indication as to which conformity assessment activity the accreditation is related.

4.3.5 *ISO/IEC 17011:2017(E) Clause 4.3.5*

The accreditation body shall take suitable action to deal with incorrect or unauthorized claims of accreditation status, or misleading or unauthorized use of accreditation symbols and the accreditation body logo.

NOTE: Suitable actions may include requests for corrective action, suspension, withdrawal of accreditation, publication of the transgression and, if necessary, legal action.

4.4 Impartiality Requirements

4.4.1 *ISO/IEC 17011:2017(E) Clause 4.4.1*

Accreditation shall be undertaken impartially.

4.4.2 *ISO/IEC 17011:2017(E) Clause 4.4.2*

The accreditation body shall be responsible for the impartiality of its accreditation activities and shall not allow commercial, financial, or other pressures to compromise impartiality. Where an accreditation body, including a governmental accreditation body, is part of a larger entity, the accreditation body shall be organized so that accreditation is provided impartially.

4.4.3 *ISO/IEC 17011:2017(E) Clause 4.4.3*

The accreditation body shall have top management commitment to impartiality. It shall document and make public an impartiality policy which includes the importance of impartiality in carrying out its accreditation activities, managing conflict of interest, and ensuring objectivity of its accreditation activities.

4.4.4 *ISO/IEC 17011:2017(E) Clause 4.4.4*

All accreditation body personnel and committees who could influence the accreditation process shall act objectively and shall be free from any undue commercial, financial and other pressures that could compromise impartiality. The accreditation body shall require all personnel and committee members to disclose any potential conflict of interest whenever it may arise.

4.4.5 *ISO/IEC 17011:2017(F) Clause 4.4.5*

The accreditation body shall document and implement a process to provide opportunity for effective involvement by interested parties for safeguarding impartiality. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.

4.4.6 *ISO/IEC 17011:2017(E) Clause 4.4.6*

The accreditation body shall have a process to identify, analyze, evaluate, treat, monitor, and document on an ongoing basis the risks to impartiality arising from its activities including any conflicts arising from its relationships or from the relationships of its personnel. The process shall include identification of and consultation with appropriate interested parties as described in 4.4.5 to advise on matters affecting impartiality including openness and public perception.

NOTE 1: Sources of risks to impartiality of the accreditation body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, outsourcing, training, marketing, and payment of a sales commission or other inducement for the referral or new clients, etc.

NOTE 2: One way of fulfilling the consultation with the interested parties is by the use of a committee.

4.4.7 *ISO/IEC 17011:2017(E) Clause 4.4.7*

Where any risks to impartiality are identified, the accreditation body shall document and demonstrate how it eliminates or minimizes such risks and document any residual risk. The demonstration shall cover all potential risks that are identified, whether they arise from within the accreditation body or from the activities of other persons, bodies, or organizations.

4.4.8 *ISO/IEC 17011:2017(E) Clause 4.4.8*

Top management shall review any residual risk to determine if it is within the level of acceptable risk.

4.4.9 *ISO/IEC 17011:2017(E) Clause 4.4.9*

When an unacceptable risk to impartiality is identified and which cannot be mitigated to an acceptable level, then accreditation shall not be provided.

4.4.10 *ISO/IEC 17011:2017(E) Clause 4.4.10*

The accreditation body's policies, processes, and procedures shall be non-discriminatory and shall be applied in a non-discriminatory way. The accreditation body shall make its services accessible to all applicants whose application for accreditation falls within the scope of its accreditation activities as defined within its policies and rules. Access shall not be conditional upon the size of the applicant conformity assessment body or membership of any association or group, nor shall accreditation be conditional upon the number of conformity assessment bodies already accredited.

NOTE: It is not considered discriminatory when an accreditation body refuses services to a conformity assessment body because of proven evidence of fraudulent behavior, falsification of information, or deliberate violation of accreditation requirements.

4.4.11 *ISO/IEC 17011:2017(E) Clause 4.4.11*

The accreditation body and any part of the same legal entity shall not offer or provide any service that affects its impartiality, such as:

a) those conformity assessment activities covered by accreditation which include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification;

b) consultancy.

4.4.12 *ISO/IEC 17011:2017(E) Clause 4.4.12*

In case the accreditation body is linked to a body offering consultancy or undertaking those conformity assessment activities mentioned in 4.4.11 bullet a), the accreditation body shall have:

a) different top management (see 5.7);

b) different personnel performing the accreditation decision-making processes (see Clause 5);

c) distinctly different name, logos, and symbols;

d) effective mechanisms to prevent any influence on the outcome of any accreditation activity.

NOTE ~~3~~: An accreditation body and related bodies within a Government department or entity might not have a distinctive name, logo and/or symbol. [from V2M1, 4.3.7]

4.4.13 *ISO/IEC 17011:2017(E) Clause 4.4.13*

The accreditation body's activities shall not be presented as linked with consultancy or other services that pose an unacceptable risk to impartiality. Nothing shall be said or implied that would suggest that accreditation would be simpler, easier, faster, or less expensive if any specified person(s) or consultancy were used.

NOTE: Accreditation bodies can carry out, for example, the following duties that are not considered a risk to impartiality:

- Arranging and participating as a lecturer in training, orientation, or educational courses, provided that these courses confine themselves to the provision of generic information that is freely available in the public domain, i.e., they cannot provide specific solutions to a conformity assessment body in relation to the activities of that organization;

- Adding value during assessments, e.g., by identifying opportunities for improvement as they become evident during the assessment without recommending specific solutions;

- Advising other accreditation bodies on development of accreditation process;

- Advising scheme owners on accreditation requirements, including requirements within relevant conformity assessment standards.

~~4.4.14 The accreditation body also shall require accredited CAB's to maintain impartiality and integrity.~~ [from V2M1, 4.3.3.1]

~~4.4.15 Unless required by applicable regulations, accreditation bodies and their contractors shall confine their requirements, assessments and decision making process for an accredited CAB to those matters specifically related to the fields of accreditation being sought or maintained by a CAB.~~ [from V2M1, 4.3.8]

4.5 Financing and Liability

4.5.1 *ISO/IEC 17011:2017(E) Clause 4.5.1*

The accreditation body shall have the financial resources, demonstrated by records and/or documents, required for the operation of its activities. The accreditation body shall have a description of the source(s) of its income.

4.5.2 *ISO/IEC 17011:2017(E) Clause 4.5.2*

The accreditation body shall evaluate the risks arising from its activities and have arrangements to cover liabilities arising from its activities.

4.6 Establishing Accreditation Schemes

4.6.1 *ISO/IEC 17011:2017(E) Clause 4.6.1*

The accreditation body shall develop or adopt accreditation schemes. The accreditation body shall document the rules and processes for its accreditation schemes referring to the relevant International Standards and/or other normative documents.

4.6.2 *ISO/IEC 17011:2017(E) Clause 4.6.2*

The accreditation body shall ensure that any guidance, application, or normative documents it uses have been developed by committees or persons possessing the necessary competence and with participation of appropriate interested parties. These documents shall not contradict or exclude any of the requirements included in the relevant international standards and/or other normative documents.

NOTE 1: Where international application or guidance documents are available, these can be used.

NOTE 2: The accreditation body can adopt and/or develop application or guidance documents, normative documents, and/or participate in their development.

4.6.3 *ISO/IEC 17011:2017(E) Clause 4.6.3*

The accreditation body shall have a policy and documented procedures to determine the suitability of the conformity assessment schemes and standards for accreditation purposes.

4.6.4 *ISO/IEC 17011:2017(E) Clause 4.6.4*

The accreditation body shall establish, document, implement, and maintain a process for developing and extending its accreditation schemes. The following shall be considered:

a) feasibility of launching or extending an accreditation scheme;

b) analysis of its present competence and resources;

c) accessing and employing expertise;

d) the need for application or guidance documents;

e) training of accreditation body personnel;

f) implementation or transition arrangements;

g) views of interested parties.

4.6.5 *ISO/IEC 17011:2017(E) Clause 4.6.5*

Before an accreditation body discontinues an accreditation scheme in part or in full, at least the following shall be considered:

a) views of interested parties;

b) contractual duties;

c) transition arrangements;

d) external communication regarding the discontinuation;

e) information published by the accreditation body.

5.0 Structural Requirements

5.1 *ISO/IEC 17011:2017(E) Clause 5.1*

The accreditation body shall be structured and managed so as to safeguard impartiality.

~~NOTE 1~~: ~~In all cases, accreditation bodies are governmental organizations at the territory, state or federal levels.~~

~~NOTE 2:~~ ~~A territorial, state or federal entity may designate the appropriate agencies or departments as its designated accreditation body for the fields of accreditation for which recognition is being sought.~~ [from V2M1, 4.2.1]

5.2 *ISO/IEC 17011:2017(E) Clause 5.2*

The accreditation body shall document its entire organizational structure, including lines of authority and responsibility.

5.3 *ISO/IEC 17011:2017(E) Clause 5.3*

If the accreditation body is part of a larger entity, the accreditation body shall be identified.

5.4 *ISO/IEC 17011:2017(E) Clause 5.4*

The accreditation body shall have a description of its legal status, including the names of its owners if applicable, and, if different, the names of the persons who control it.

5.5 *ISO/IEC 17011:2017(E) Clause 5.5*

The accreditation body shall have authority and be responsible for its accreditation decisions, which shall not be subject to approval by any other organization or person.

5.6 *ISO/IEC 17011:2017(E) Clause 5.6*

The accreditation body shall document the duties, responsibilities, and authorities of top management and other personnel associated with the accreditation body who are involved in the accreditation process.

5.7 *ISO/IEC 17011:2017(E) Clause 5.7*

The accreditation body shall identify the top management having overall authority and responsibility for each of the following:

a) development of policies relating to the operation of the accreditation body;

b) supervision of the implementation of the policies, processes, and procedures;

c) supervision of the finances of the accreditation body;

d) development or adoption of activities for the schemes for which it provides accreditation;

e) decisions on accreditation;

f) performance of assessments and accreditation processes;

g) responding to complaints and appeals in a timely manner;

h) contractual arrangements;

i) provision of adequate resources;

j) delegation of authority to committees or individuals, as required, to undertake defined activities on behalf of top management;

k) safeguarding of impartiality.

NOTE: In the case of an accreditation body within a government department or entity, top management refers to the management of the organizational unit (and not the department or entity) having authority and responsibility for the accreditation program. [from V2M1, 4.2.5]

5.8 *ISO/IEC 17011:2017(E) Clause 5.8*

The accreditation body shall have formal rules for the appointment, terms of reference, and operation of committees that are involved in the accreditation process, and shall identify the interested parties participating.

6.0 RESOURCE REQUIREMENTS

6.1 Competence of Personnel

6.1.1 General (*ISO/IEC 17011:2017(E) Clause 6.1.1)*

The accreditation body shall have processes to ensure its personnel have appropriate knowledge and skills relevant to the accreditation schemes and geographic areas in which it operates.

6.1.2 Determination of Competence Criteria

6.1.2.1 *ISO/IEC 17011:2017(E) Clause 6.1.2.1*

The accreditation body shall have a documented process for determining and documenting the competence criteria for personnel involved in the management and performance of assessments and other accreditation activities. Competence criteria shall be determined with regard to the requirements of each accreditation scheme and shall include the required knowledge and skills for performing accreditation activities.

6.1.2.2 *ISO/IEC 17011:2017(E) Clause 6.1.2.2*

The accreditation body shall ensure the assessment team, and the accreditation body personnel who review documents, review assessment reports, and make accreditation decisions, demonstrate knowledge of the following:

- assessment principles, practices, and techniques;

- general management system principles and tools.

6.1.2.3 *ISO/IEC 17011:2017(E) Clause 6.1.2.3*

The accreditation body shall ensure the assessment team, and accreditation body personnel who review applications, select assessment team members, review documents, review assessment reports, make accreditation decisions, and manage accreditation schemes, demonstrate knowledge of the following:

- accreditation body's rules and processes;

- accreditation and accreditation scheme requirements and relevant guidance and application documents;

- conformity assessment scheme requirements, other procedures, and methods used by the conformity assessment body.

6.1.2.4 *ISO/IEC 17011:2017(E) Clause 6.1.2.4*

The accreditation body shall ensure the assessment team, and accreditation body personnel who review assessment reports, make accreditation decisions, and manage accreditation schemes, demonstrate knowledge of risk based assessment principles.

6.1.2.5 *ISO/IEC 17011:2017(E) Clause 6.1.2.5*

The accreditation body shall ensure the assessment team, and accreditation body personnel who review documents, review assessment reports, make accreditation decisions, and manage accreditation schemes, demonstrate knowledge of general regulatory requirements related to the conformity assessment activities.

6.1.2.6 *ISO/IEC 17011:2017(E) Clause 6.1.2.6*

The accreditation body shall ensure the assessment team demonstrates the following knowledge and skills:

- *knowledge of practices and processes of the conformity assessment body business environment;*

- *communication skills appropriate to interact with all levels within the conformity assessment body;*

- *note-taking and report-writing skills;*

- *opening and closing meeting skills;*

- *interviewing skills;*

- *assessment-management skills.*

~~NOTE 2~~: ~~Assessors that are able to communicate effectively through a translator or interpreter are considered to have complied with this requirement.~~ [from V2M3, 4.2.7]

6.1.2.7 *ISO/IEC 17011:2017(E) Clause 6.1.2.7*

The accreditation body shall ensure the accreditation body personnel who review documents demonstrate note-taking and report-writing skills.

6.1.2.8 *ISO/IEC 17011:2017(E) Clause 6.1.2.8*

The group or individual that makes the accreditation decisions shall understand the applicable accreditation scheme requirements and shall have competence to evaluate the outcomes of the assessment, including where appropriate related recommendations of the assessment team.

NOTE: Annex A summarizes 6.1.2.2 to 6.1.2.8.

6.1.2.9 *ISO/IEC 17011:2017(E) Clause 6.1.2.9*

Where additional specific competence criteria have been established for a specific accreditation scheme, these shall be applied.

6.1.2.9.1 An assessor shall hold at least a Bachelor's degree in a scientific discipline or have commensurate experience acquired by having performed verified assessments of environmental CABs (see 6.1.3.2.1). An accreditation body that chooses to evaluate an assessor's educational qualifications using the "commensurate experience" allowance shall have documented procedures for evaluating what constitutes commensurate experience. These procedures must define how this practice is applied within the organization and document the decision-making process used to approve the assessor. [from V2M3, 4.2.3]

6.1.2.9.2 An assessor shall complete and pass assessor training courses that include obtaining a passing score on the written examination at the conclusion of the course. These training courses shall include, but not be limited to:

(a) TNI proficiency testing and quality management systems assessment training (specifically, TNI ELS Volume 1, Modules 1 and 2);

(b) TNI technical module assessment training (e.g., TNI ELS Volume 1, individual Modules 3 through 7); and

(c) Technical discipline assessment training as required by the Accreditation Body for the accreditation scheme(s) supported.

NOTE: Examples of technical discipline assessment training could include the U.S. EPA Safe Drinking Water Act Certification Officers training courses in Microbiology, Inorganic Chemistry, and Organic Chemistry; or technical assessment training courses approved and offered by The NELAC Institute (TNI).

6.1.2.9.3 An assessor shall complete on-going refresher training that includes any revisions to the TNI ELS Volume 1 Standard, plus any additional refresher training as required by the Accreditation Body.

NOTE: The Accreditation Body may require a written examination with a passing score as evidence for the ongoing (refresher) training of its assessors.

~~An assessor shall have completed and attained a passing score on the written examination of courses approved by the employing accreditation body on assessing quality systems and all technical disciplines comprising a technology or combination of method and technology that the assessor will assess.~~

~~NOTE: Technical disciplines applicable to the environmental sector include microbiology, toxicity testing, inorganic non-metals, metals, organics, asbestos, and radiochemistry, and field activities.~~ [from V2M3, 4.2.4]

6.1.2.9.4 ~~Assessors shall sign qualification statements attesting the assessors meet the education and training required by this Standard. Accreditation bodies shall provide those statements to CABs upon request.~~ [from V2M3, 4.3.2]

6.1.3 Competence Management

6.1.3.1 *ISO/IEC 17011:2017(E) Clause 6.1.3.1*

The accreditation body shall:

a) establish and implement a documented process for the initial evaluation, and on-going monitoring of all personnel involved in accreditation processes;

b) ensure that its evaluation methods are effective to demonstrate competence of accreditation body personnel;

c) prior to undertaking accreditation activities, authorize personnel to perform those activities of the accreditation process.

6.1.3.2 *ISO/IEC 17011:2017(E) Clause 6.1.3.2*

The accreditation body shall have documented processes for selecting, training, and formally authorizing assessors. The accreditation body shall have documented processes for selecting and authorizing technical experts and familiarizing them with relevant requirements and procedures used in the accreditation process. The initial competence evaluation of an assessor shall include determining the ability to apply required knowledge and skills during assessments.

NOTE: One method of evaluating as assessor is to have competent individuals observing the assessor conducting an assessment.

6.1.3.2.1 Before an assessor is allowed to perform unsupervised assessments for an accreditation body, the assessor shall have performed a minimum number of assessments under the supervision of an assessor whose competence has been qualified by the accreditation body. The qualified assessor shall observe the candidate assessor performing:

a) at least one assessment, for those assessors that have previous documented experience performing environmental CAB assessments; or

b) at least two assessments, for those assessors that have no documented experience performing environmental CAB assessments.

NOTE: A qualified assessor may evaluate the ability of an assessor to perform unsupervised assessments by: direct observation, observing the assessor perform an assessment in its entirety; or by limited observation, observing the assessor performing parts of an assessment and allowing the assessor to conduct some parts of the assessment independently.

c) The supervising qualified assessor shall document his or her conclusions to the accreditation body employing the candidate assessor. The accreditation body shall use the qualified assessors' conclusions to determine if an assessor candidate may perform unsupervised assessments or if additional supervised assessments beyond the minimum specified in this Standard are required to qualify the candidate assessor. [from V2M3, 4.2.5]

6.1.3.3 *ISO/IEC 17011:2017(E) Clause 6.1.3.3*

The accreditation body shall identify training needs and shall provide access to specific training to ensure all personnel involved in accreditation processes are competent for the accreditation activities they perform.

6.1.3.4 *ISO/IEC 17011:2017(E) Clause 6.1.3.4*

There shall be a documented process for monitoring competence and performance of all personnel involved in the assessment activities based on the frequency of their involvement and the level of risk linked to the accreditation activities they perform. In particular, the accreditation body shall review and record the competence of its personnel taking into account their performance in order to take any necessary corrective action.

6.1.3.5 *ISO/IEC 17011:2017(E) Clause 6.1.3.5*

The accreditation body shall monitor each assessor considering each accreditation scheme for which the assessor is authorized. The documented monitoring process of assessors shall include a combination of on-site evaluation, review of assessment reports, and feedback from personnel, conformity assessment bodies, or from other interested parties.

6.1.3.6 *ISO/IEC 17011:2017(E) Clause 6.1.3.6*

Each assessor shall be observed during an assessment at regular intervals. This shall be at least every three years, unless there is sufficient supporting evidence that the assessor is continuing to perform competently. If the interval is extended, justification shall be made.

6.1.3.7 The accreditation body shall maintain records for assessing and monitoring for all assessors.

6.2 Personnel Involved in the Accreditation Process

6.2.1 *ISO/IEC 17011:2017(E) Clause 6.2.1*

The accreditation body shall have access to a sufficient number of competent personnel to manage and support all its accreditation functions for all accreditation schemes.

6.2.2 *ISO/IEC 17011:2017(E) Clause 6.2.2*

The accreditation body have enforceable arrangements requiring all personnel to conform to applicable

policies and implement processes as defined by the accreditation body. The arrangements shall address aspects relating to confidentiality and impartiality and shall require all personnel to notify the accreditation body of any existing, prior, or foreseeable relationships which may compromise impartiality.

6.2.2.1 Assessors and experts shall conform to professional and ethical standards of conduct. Assessors and experts shall:

a) have no interests at play other than those of the accreditation body during the entire accreditation process;

b) act impartially and not give preferential treatment to any organization or individual;

c) provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, and disability;

d) not use their position for private gain;

e) not solicit or accept any gift or other item of monetary value from any CAB, CAB representative or any other affected individual or organization doing business with, or affected by, the actions of the assessor's employer or accreditation body;

f) not hold financial interests that conflict with the conscientious performance of their duties;

g) not engage in financial transactions using information gained through their positions as assessors to further any private interest;

h) not seek or negotiate employment or attempt to arrange contractual agreements with a CAB that would conflict with their duties and responsibilities as assessors;

i) not knowingly make unauthorized commitments or promises of any kind purporting to bind an accreditation body; and

j) attempt to avoid any actions that could create the appearance that they are violating any of the standards of professional conduct outlined here. [from V2M3, 4.4.2]

6.2.2.2 The accreditation body shall require assessors employed directly or under contract to affirm this commitment before they participate in their first assessment for the accreditation body or whenever the rules of the accreditation body pertaining to the accreditation of CABs change. [from V2M3, 4.1.5]

6.2.2.3 Before conducting an assessment, an assessor shall sign statements certifying the assessor has no conflict of interest with the CAB to be assessed and provide such statements, upon request, to the CAB. [from V2M3, 4.3.3]

~~NOTE: Assessors are employed by or on behalf of accreditation bodies to determine the competence of a CAB in meeting this Standard. The initial accreditation of a CAB is based primarily on the findings and observations of assessors. In many accreditation bodies, assessment team members can also be responsible for deciding the accreditation status of a CAB.~~ [from V2M3, 4.3.5]

6.2.3 *ISO/IEC 17011:2017(E) Clause 6.2.3*

The accreditation body shall give assessors and technical experts access to an up-to-date set of documented procedures giving assessment instructions and all relevant information on the accreditation processes.

6.2.3.1 ~~Length of Assessment~~

Accreditation bodies shall assign an adequate number of assessors to complete an assessment within a reasonable period.

NOTE: The length of an ~~on-site~~ assessment is determined by the scope of accreditation of a CAB, the number of assessors in an assessment team, the size of a CAB, the number of findings encountered during the previous assessment, and the cooperativeness of the CAB staff. [from V2M3, 6.7]

6.3 Personnel Records *(ISO/IEC 17011:2017(F) Clause 6.3)*

The accreditation body shall maintain records, including qualifications, training, competence, results of monitoring, experience, professional status, and professional affiliations for personnel managing or performing accreditation activities.

~~NOTE: These records are available to outside parties, upon request, subject to the rules of confidentiality of personnel records and the open records laws of an accreditation body.~~ [from V2M3, 4.3.1]

6.4 Outsourcing

6.4.1 *ISO/IEC 17011:2017(E) Clause 6.4.1*

The accreditation body shall itself normally undertake the accreditation activities.

6.4.1.1 ~~An accreditation body shall not delegate authority for granting, maintaining, suspending or revoking a CAB's accreditation to an outside person or body.~~ Portions of the accreditation process may be contracted out; however, the authority to grant, maintain, suspend or revoke accreditation shall remain with the accreditation body. [from V2M1, 4.2.2.1]

6.4.2 *ISO/IEC 17011:2017(E) Clause 6.4.2*

Accreditation decisions shall not be outsourced. The person(s) assigned by the accreditation body to make an accreditation decision shall be employed by, or shall be under enforceable arrangements with, the accreditation body.

6.4.3 *ISO/IEC 17011:2017(E) Clause 6.4.3*

The accreditation body shall describe the conditions under which outsourcing may take place and when applicable shall have a documented procedure for outsourcing.

6.4.4 *ISO/IEC 17011:2017(E) Clause 6.4.4*

The accreditation body shall have an enforceable arrangement covering the outsourcing arrangements, including confidentiality and conflicts of interest, with each body that provides outsourced services.

6.4.5 *ISO/IEC 17011:2017(E) Clause 6.4.5*

The accreditation body shall:

a) take responsibility for all activities outsourced to another body;

b) ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of the accreditation body and also to the applicable provisions of this document, including competence, impartiality, and confidentiality;

c) obtain the consent of the conformity assessment body to use a particular provider of any outsourced parts of the assessment.

6.4.6 *ISO/IEC 17011:2017(E) Clause 6.4.6*

The accreditation body shall have a documented process for the approval and monitoring of all bodies that provide outsourced services used for accreditation processes, and shall ensure that records of the competence of all personnel involved in accreditation processes are maintained.

NOTE 1: Where the accreditation body engages individuals or employees of other organizations to provide additional resources and expertise, the use of these individuals does not constitute outsourcing provided they are individually contracted to operate under the accreditation body's management system (see 6.2.2).

NOTE 2: Mutual recognition arrangements based on this document can fulfill some of the requirements in 6.4.4, 6.4.5, and 6.4.6.

~~NOTE: External individual assessors and experts become part of the accreditation body assessment team and using them in this manner is not considered subcontracting. Hiring an external organization to perform entire assessments on behalf of an accreditation body is considered subcontracting.~~ [from V2M3, 6.2]

7.0 PROCESS REQUIREMENTS

7.1 Accreditation Requirements *(ISO/IEC 17011:2017(E) Clause 7.1)*

The general requirements for accreditation of conformity assessment bodies shall be those set out in the relevant International Standards and/or other normative documents for the operation of conformity assessment bodies.

7.2 Application for Accreditation

7.2.1 *ISO/IEC 17011:2017(E) Clause 7.2.1*

The accreditation body shall require an authorized representative of the applicant conformity assessment body to make a formal application that includes the following:

a) general features of the conformity assessment body, including legal entity, name, address(es), legal status, and human and technical resources;

b) general information concerning the conformity assessment body such as its relationship in a larger corporate entity if any, addresses of all its physical location(s), and information on activities conducted at all locations including virtual site(s);

c) a clearly defined scope of accreditation as defined in 7.8.3 for which the conformity assessment body seeks accreditation, including limits of capability where applicable;

d) a commitment to continually fulfill the requirements for accreditation and the other obligations of the conformity assessment body.

NOTE 1: Accreditation Bodies may require additional information about the conformity assessment body in the formal application.

NOTE 2: The applicant conformity assessment body could be a mobile laboratory as well as a conformity assessment body in a fixed location.

7.2.2 *ISO/IEC 17011:2017(E) Clause 7.2.2*

The accreditation body shall require the applicant conformity assessment body to provide information demonstrating that the accreditation requirements are addressed prior to commencement of the assessment.

7.2.3 *ISO/IEC 17011:2017(E) Clause 7.2.3*

The accreditation body shall review the information supplied by the conformity assessment body to determine the suitability of the application for accreditation to initiate an assessment.

7.2.4 *ISO/IEC 17011:2017(E) Clause 7.2.4*

At any point in the application or initial assessment process, if there is evidence of fraudulent behavior, if the conformity assessment body intentionally provides false information, or if the conformity assessment body conceals information, the accreditation body shall reject the application or terminate the assessment process.

7.2.5 *ISO/IEC 17011:2017(E) Clause 7.2.5*

Where the accreditation body conducts a preliminary visit before the initial assessment, it shall be conducted with the agreement of the conformity assessment body. The accreditation body shall have clear rules for the conduct of preliminary visits and shall exercise due care to avoid consultancy.

7.3 Resource Review

7.3.1 *ISO/IEC 17011:2017(E) Clause 7.3.1*

The accreditation body shall review its ability to carry out the assessment of the applicant conformity assessment body, in terms of its own policy and procedures, its competence, and the availability of personnel suitable for the assessment activities and decision making.

7.3.2 *ISO/IEC 17011:2017(E) Clause 7.3.2*

The review shall also include the ability of the accreditation body to carry out the initial assessment in a timely manner. Where the initial assessment cannot be conducted in a timely manner, this shall be communicated to the conformity assessment body.

7.3.3 The accreditation body shall determine if a conformity assessment body in a mobile setting qualifies for accreditation as part of a parent fixed-based conformity assessment body's accreditation. The presence or absence of a common management system, ownership / management, technical oversight, and the scope of accreditation as requested in the accreditation application shall be included in making the determination.

7.4 Preparation for Assessment

7.4.1 *ISO/IEC 17011:2017(E) Clause 7.4.1*

The accreditation body shall appoint an assessment team consisting of a team leader and, where required, a suitable number of assessors and/or technical experts for the scope to be assessed. When selecting the assessment team, the accreditation body shall ensure that the expertise brought to each assignment is appropriate. In particular, the team as a whole:

a) shall have appropriate knowledge of the specific scope of accreditation;

b) shall have understanding sufficient to make a reliable assessment of the competence of the conformity assessment body to operate within its scope of accreditation.

~~The accreditation body shall have documented procedures for assigning assessors to CABs. Such procedures shall consider the scope of accreditation and the complexity of operations of the CABs.~~ [from V2M3, 4.1.2]

7.4.2 *ISO/IEC 17011:2017(E) Clause 7.4.2*

The accreditation body shall inform the conformity assessment body of the names of the members of the assessment team and any observers, and the organization(s) they belong to, sufficiently in advance to provide the conformity assessment body the opportunity to lodge an objection to the appointment of any particular team members or observers with supporting justification. The accreditation body shall have a policy for dealing with such objections.

7.4.2.1 ~~Although most assessments are announced, accreditation~~ Accreditation bodies shall have authority to conduct announced or unannounced assessments. [from V2M3, 6.13.4]

7.4.2.2 The accreditation body need not notify the conformity assessment body of the names of the assessment team for unannounced assessments.

~~NOTE: Accreditation bodies may conduct unannounced assessments. The requirement to notify the CAB in advance of the names of the members of the assessment team does not apply to unannounced assessments. An unannounced assessment should not be used by an accreditation body to appoint a known objectionable assessment team. The policy established for dealing with objections from a CAB to the appointment of an assessor or expert to the assessment team should specify the type of objections under which an accreditation body may consider assigning a different assessor or expert. When assembling a team for an unannounced assessment, accreditation bodies should consider previous objections to an assessor made by the CAB. A CAB retains the right to raise an objection to an assessor or expert at the time of the unannounced assessment but should not raise objections to avoid or delay an unannounced assessment.~~ [from V2M3, 6.3.3]

~~The CAB shall have the right to exclude a third party assessor if there is a conflict of interest.~~ [from V2M1, 7.4.2.1]

7.4.2.3 ~~Accreditation bodies have authority to conduct unannounced assessments. Initial on-site assessments are announced.~~ [from V2M3, 5.2]

~~NOTE: Accreditation bodies may conduct unannounced assessments. The requirement to notify the CAB in advance of the names of the members of the assessment team does not apply to unannounced assessments. An unannounced assessment should not be used by an accreditation body to appoint a known objectionable assessment team. The policy established for dealing with objections from a CAB to the appointment of an assessor or expert to the assessment team should specify the type of objections under which an accreditation body may consider assigning a different assessor or expert. When assembling a team for an unannounced assessment, accreditation bodies should consider previous objections to an assessor made by the CAB. A CAB retains the right to raise an objection to an assessor or expert at the time of the unannounced assessment but should not raise objections to avoid or delay an unannounced assessment.~~ [from V2M3, 6.3.8]

~~NOTE 3: Proficiency testing can occur and be administered by assessors during an on-site assessment of a CAB.~~ [from V2M1, 7.11.3]

7.4.3 *ISO/IEC 17011:2017(E) Clause 7.4.3*

The accreditation body shall clearly define the assignment given to the assessment team.

7.4.4 *ISO/IEC 17011:2017(E) Clause 7.4.4*

The accreditation body shall establish documented procedures to assess the competence of a conformity assessment body to perform all activities in its scope of accreditation irrespective of where these activities are performed. These procedures shall describe the manner in which the scope of an applicant or an accredited conformity assessment body is covered through the use of a combination of on-site assessments and other assessment techniques sufficient to provide confidence in the conformity with the relevant accreditation criteria.

~~NOTE 2: Each fixed-base branch or subsidiary of a CAB with multiple locations is customarily accredited separately by accreditation bodies and requires separate initial assessments. Mobile facilities of fixed-base CABs or mobile facilities not directed by or attached to a fixed-base CAB may be required to maintain distinct accreditations by different accreditation bodies and may require separate initial assessments.~~ [from V2M3, 6.3.6]

~~NOTE: Each fixed-base branch or subsidiary of a CAB with multiple locations is customarily accredited separately by accreditation bodies and requires separate surveillance and reassessments. Mobile facilities of fixed-base CABs or mobile facilities not directed by or attached to a fixed-base CAB may be required to maintain distinct accreditations by different accreditation bodies and may require separate surveillance and reassessments.~~ [from V2M3, 6.3.7]

7.4.5 *ISO/IEC 17011:2017(E) Clause 7.4.5*

The procedures shall ensure that the assessment team assesses the performance of a sample of the conformity assessment activities representative of the scope of accreditation. The assessment shall cover a sample of locations and personnel to determine the competence of the conformity assessment body to perform the activities covered by its scope of accreditation.

~~NOTE: Accreditation bodies should establish procedures for selecting systems, methods and analytical activities that will be observed during an on-site assessment based on the accreditation scope and complexity of the CAB to be assessed. Assessors should strike a balance between thoroughness and practicality while determining the extent to which CABs meet this Standard. The examination of the systems, processes and procedures of the CAB should give a general sense of its past and present capabilities to perform work of known and documented quality.~~ [from V2M3, 6.3.5]

7.4.6 *ISO/IEC 17011:2017(E) Clause 7.4.6*

In selecting the activities to be assessed, the accreditation body shall consider the risk associated with the activities, locations, and personnel covered by the scope of accreditation.

7.4.7 *ISO/IEC 17011:2017(E) Clause 7.4.7*

The accreditation body shall develop an assessment plan to cover the activities to be assessed, the locations at which activities will be assessed, the personnel to be assessed where applicable, and the assessment techniques to be utilized, including witnessing where appropriate or applicable. The accreditation body shall justify where witnessing is not appropriate or applicable.

7.4.7.1 At a minimum, the assessment plan and the assessment activities at the conformity assessment body's location(s) must include all analytes and test methods for which the conformity assessment body seeks to obtain or maintain accreditation for regulated drinking water contaminants, for compliance with the United

States Environmental Protection Agency's Safe Drinking Water Act.

7.4.8 *ISO/IEC 17011:2017(E) Clause 7.4.8*

The accreditation body shall confirm, with the conformity assessment body, the date(s) and plan for the assessment.

7.4.9 *ISO/IEC 17011:2017(E) Clause 7.4.9*

The accreditation body shall ensure that the assessment team is provided with the appropriate requirements documents, previous assessment records, if applicable, and the relevant documents and records of the conformity assessment body.

7.5 Review of Documented Information

7.5.1 *ISO/IEC 17011:2017(E) Clause 7.5.1*

The assessment team shall review all relevant documented information supplied by the conformity assessment body to evaluate its system for conformance with the relevant standard(s) and other requirements for accreditation.

7.5.2 *ISO/IEC 17011:2017(E) Clause 7.5.2*

The accreditation body can decide not to proceed with further assessment based on the review of the documented information. In such cases, the results with their justification shall be reported in writing to the conformity assessment body.

NOTE: ~~The assessment team assigned to the CAB usually makes a recommendation to the accreditation body to not proceed with an initial assessment when it encounters significant nonconformities during document and record review.~~ Accreditation bodies should inform CABs of a cancellation of an ~~initial on-site~~ assessment ~~for those conditions~~ as soon as feasible. ~~For other types of assessments, nonconformities found while reviewing documents and records before an on-site assessment would not result in cancellation of an on-site assessment.~~ [from V2M3, 6.4.2]

7.6 Assessment

7.6.1 *ISO/IEC 17011:2017(E) Clause 7.6.1*

The assessment body shall have documented procedures for describing the assessment techniques used, the circumstances in which they are to be used, and the rules for determining assessment durations. The procedures shall include how the accreditation body will report the assessment findings to the conformity assessment body.

7.6.2 *ISO/IEC 17011:2017(F) Clause 7.6.2*

For an assessment, whether performed on-site or remotely, the assessment team shall commence the assessment with an opening meeting at which the purpose of the assessment and accreditation requirements are clearly defined, and the assessment plan as well as the scope for the assessment are confirmed.

7.6.2.1 Attendance at the opening conference shall be documented ~~in sheets or forms provided by the assessment team.~~ [from V2M3, 6.8]

~~NOTE: Additional items that may be covered or addressed during an opening meeting include: identification of records and operating procedures to be examined and the responsible CAB~~

~~individuals that will provide the assessment team with the necessary documentation, procedures to be followed when a CAB claims information to be confidential business information (CBI), and safety procedures that the CAB may think necessary for the protection of the assessment team.~~

7.6.3 *ISO/IEC 17011:2017(E) Clause 7.6.3*

The assessment team shall conduct the assessment based on the assessment plan.

7.6.3.1 If the assessment plan is not followed, the assessment report shall document any changes and include justification for those changes.

7.6.3.2 ~~Documents Provided to CAB~~

The assessment team shall provide or make available the following types of documents before a scheduled announced ~~on-site~~ assessment or before the conclusion of the on-site portion of the CAB assessment:

~~a) Assessment Confidentiality Notice: a document advising the CAB that it has the right to declare information gathered during an assessment as confidential business information according to procedures established by the accreditation body or to restrict access to information requested during an assessment when such information directly affects national security.~~

~~b) Checklists: any standard forms that the assessment team will use to evaluate conformance with this Standard or to document assessment findings.~~

a) ~~d)~~ Notice of Announced Assessment: an appointment letter, electronic mail message or a published schedule informing the CAB about an upcoming assessment and identifying members of the assessment team with sufficient time to allow for potential objections from a CAB to members assigned to the assessment team.

b) ~~c)~~ Assessment Appraisal Form: a document used by the accreditation body to obtain feedback from CABs about the adequacy and the effectiveness of the assessment process, including the performance of the assessment team. [from V2M3, 6.5]

7.6.3.3 It is possible that during an ~~on-site~~ assessment, assessors or CAB personnel become aware of previously unforeseen conflicts of interest. When this happens, the assessment team leader ~~lead assessor~~ shall consult with the accreditation body, as soon as practicable, to determine how to proceed. The accreditation body shall take action to ensure that the assessment can proceed without compromising its integrity and impartiality or shall request that the assessment team terminate the assessment. If it is necessary to appoint a new assessment team, the accreditation body shall appoint it as soon as practicable without jeopardizing the CAB's request for accreditation. [from V2M3, 4.3.4]

7.6.3.4 ~~NOTE:~~ Assessment team members shall have the authority to conduct interviews with any or all CAB staff. [from V2M3, 6.9.2]

7.6.4 *ISO/IEC 17011:2017(E) Clause 7.6.4*

The assessment team shall analyze all relevant information and objective evidence gathered prior to and during the assessment to determine the competence of the conformity assessment body as determined through its conformity with the requirements for accreditation.

7.6.4.1 During the assessment, sufficient information may become available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false

statement on a report. This information must be carefully documented since further action may be necessary. In the event that evidence of improper and/or potentially illegal activities have or may have occurred, the assessment team shall present such information to the accreditation body for appropriate action(s). These issues, at the discretion of the accreditation body, may or may not be subjects or issues at the closing conference. However, the assessor shall continue to gather the information necessary to complete the accreditation assessment. [NOTE: from 2003-NELAC, section 3.6.2]

7.6.4.2 ~~While on site, assessment teams may become aware that a CAB may be in violation of an environmental law or regulation. The assessment team shall present this information and any associated documentation to the accreditation body for appropriate action.~~

~~NOTE: Some assessment teams have the ability to act as enforcement agents for their accreditation bodies.~~ [from V2M3, 4.4.3]

7.6.5 *ISO/IEC 17011:2017(E) Clause 7.6.5*

Where the assessment team cannot reach a conclusion on a finding, the team shall refer back to the accreditation body for clarification.

7.6.6 *ISO/IEC 17011:2017(E) Clause 7.6.6*

The accreditation body's documented reporting procedures shall require the following.

a) For an assessment, whether performed on-site or remotely, a meeting shall take place between the assessment team and the conformity assessment body at the end of the assessment. At this meeting, the assessment team shall report on the findings identified during the assessment and detail in writing any nonconformities. An opportunity shall be provided for the conformity assessment body to seek clarification on the findings including the nonconformities, if any, and their basis.

(1) ~~NOTE:~~ The accreditation body shall be considered to have satisfied this requirement by having the assessment team ~~may only~~ provide a preliminary written or oral report at the closing meeting. Final ~~because all final~~ determinations of findings are subject to the approval of the accreditation body. [from V2M3, 6.11.1(b)]

(2) Attendance at the closing conference shall be documented ~~in sheets or forms provided by the assessment team.~~ [from V2M3, 6.11.1(a)]

~~The assessment team shall provide only preliminary determinations of potential findings and shall inform the CAB that final determinations concerning the number, nature and extent of assessment findings shall be made by the accreditation body after reviewing reported findings.~~ [from V2M3, 6.11.1(b)]

b) A written report on the outcome of the assessment shall be provided to the conformity assessment body without undue delay and within a defined timeframe. This assessment report shall contain comments on competence as determined through conformity, the scope assessed, and shall identify nonconformities, if any, to be resolved in order to conform to all of the requirements for accreditation. Comments on competence as determined through conformity included in the assessment report shall be adequate to support the conclusions arising from the assessment. The team's observations on areas for possible improvement may also be presented to the conformity assessment body but shall not recommend specific solutions.

(1) The accreditation body ~~or its authorized representative~~ shall present to the CAB within thirty calendar days of the last day of the ~~on-site~~ assessment a final assessment report ~~identifying all confirmed findings~~. [from V2M3, 6.12.2]

(2) The assessment report shall contain the following minimum contents:

- Assessment Date(s)

- Laboratory Name and Physical Address

- Laboratory ID Number (as assigned by the Accreditation Body)

- Scope of Accreditation Matrices that were assessed

- Test Methods that were assessed, including preparation methods when separate or different from the analytical method

- Key Laboratory Personnel (e.g., technical manager, QA officer, etc.)

- Laboratory personnel interviewed at the time of the assessment

- For each nonconformity reported, the specific Standard citation, regulatory requirement, or test method section where the observed laboratory activity is not in conformance

(3) If the report is not issued by the accreditation body itself, the accreditation body shall develop and implement procedures to outsource the issuance of assessment reports to conformity assessment bodies, as described in clause 6.4.

c) If the report on the outcome of the assessment [see bullet (b) above] differs from the outcome delivered at the close of the assessment [see bullet (a) above], the accreditation body shall provide an explanation to the assessed conformity assessment body, in writing.

d) If additional nonconformities are identified after the assessment is concluded, these nonconformities shall be communicated to the laboratory in writing.

7.6.7 *ISO/IEC 17011:2017(E) Clause 7.6.7*

The accreditation body shall be responsible for the content of all its assessment reports.

7.6.7.1 The accreditation body shall develop procedures for the review and approval of assessment reports. If the accreditation body finds that any portion of the report issued to the conformity assessment body requires amendment, the accreditation body shall issue an amended report to the conformity assessment body and explain why an amended report is being issued. Issuing an amended report does not reset the timeline for a conformity assessment body to provide a plan of corrective action, as required in clause 7.6.8.1, for the portions of the report that are not amended.

7.6.7.2 ~~Only accreditation bodies are allowed to release assessment reports initially. An assessment report shall not be released to the public by an accreditation body until the report has been provided to the CAB, and until the findings of the assessment and the associated corrective actions have been finalized~~.

NOTE: ~~The on-site assessment process concludes when a CAB addresses all findings in the on-site assessment report to the satisfaction of the accreditation body.~~ [from V2M3, 6.12.6]

7.6.8 *ISO/IEC 17011:2017(E) Clause 7.6.8*

When nonconformities are identified, the accreditation body shall define time limits for correction and/or corrective actions to be implemented. The accreditation body shall require the conformity assessment body to provide an analysis of the extent and cause (e.g. root cause analysis) of the nonconformities and to describe within a defined time the specific actions taken or planned to be taken to resolve the

nonconformities.

7.6.8.1 The accreditation body shall require the CAB to ~~shall~~ provide to the accreditation body a plan of corrective action to address nonconformities ~~findings~~ in the assessment report within thirty calendar days from its receipt. The accreditation body shall require the CAB to provide the date for implementation of corrective action as part of the response.

~~NOTE: Customarily, a CAB that does not address all findings satisfactorily within two responses is scheduled for a follow-up evaluation or is subject to administrative procedures that deny accreditation to the CAB or that reduce its scope of accreditation.~~ [from V2M3, 6.12.4]

7.6.8.2 The accreditation body shall require the CAB's implementation of each corrective action to be due as specified in the submitted corrective action plan or as specified in the accreditation body's policy.

7.6.9 *ISO/IEC 17011:2017(E) Clause 7.6.9*

The accreditation body shall ensure that the responses of the conformity assessment body to resolve nonconformities are reviewed to determine if the actions are considered to be sufficient and appropriate. Where the conformity assessment body's responses are found not to be sufficient, further information shall be requested. Additionally, evidence of effective implementation of actions taken may be requested, or a follow-up assessment may be carried out to verify effective implementation of corrective actions.

NOTE: The accreditation body should ~~may~~ consult with the assessment team while reviewing CAB responses to nonconformities and before arriving at decisions on the accreditation status of a CAB. [from V2M3, 6.12.7]

7.6.10 The accreditation body shall inform the conformity assessment body in writing within 30 calendar days of receipt if any proposed corrective actions are considered insufficient or inappropriate.

7.6.11 If the accreditation body allows the conformity assessment body to submit additional or amended responses to correct any unresolved nonconformities, the accreditation body shall issue the report detailing the unresolved nonconformities that require additional or amended responses within thirty calendar days. The accreditation body shall review those additional or amended responses within thirty calendar days of receipt.

7.6.12 If any proposed or revised submittals are considered insufficient or inappropriate to resolve the nonconformity(ies), the accreditation body shall implement its procedures to deny, suspend, withdraw, or reduce accreditation for the Scope of Accreditation that is affected (clause 7.7).

7.6.13 When the last day of the thirty calendar day timeframes specified in clauses 7.6.6(b)(1), 7.6.10, or 7.6.11 occurs on a non-business day, the required accreditation body actions performed on the next business day shall be considered to meet the timeframe requirements. Any other extensions to the timeframe requirements shall be justified by prevailing statutory regulations or by documented, exceptionally permitted reasons for the delay. The accreditation body shall communicate such extensions to the conformity assessment body with information on the expected date of completion.

7.6.14 Persistent failure by the accreditation body to meet the requirements within the timeframes specified in clauses 7.6.6(b)(1), 7.6.10, 7.6.11, and 7.6.13 shall necessitate the accreditation body to implement the management system requirements in clause 9.5.

7.7 Accreditation Decision-making

7.7.1 *ISO/IEC 17011:2017(E) Clause 7.7.1*

The accreditation body shall describe its process for all types of accreditation decisions.

7.7.2 *ISO/IEC 17011:2017(E) Clause 7.7.2*

The accreditation body shall ensure that each decision on granting, maintaining, extending, reducing, suspending, and withdrawing accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment. However, where maintaining is not related to a reassessment (see 7.9.4) and there is no modification to the scope, or where the reduction, suspension, or withdrawal is requested by the conformity assessment body, then the accreditation body can implement a process which does not require an independent decision.

7.7.3 *ISO/IEC 17011:2017(E) Clause 7.7.3*

The information provided to the accreditation decision-maker(s) for review shall include the following:

a) unique identification of the conformity assessment body;

b) date(s) and type(s) of assessment(s) (e.g. initial, reassessment);

c) name(s) of the assessor(s) and, if applicable, technical expert(s) involved in the assessment;

d) unique identification of all locations assessed;

e) scope of accreditation that was assessed;

f) the assessment report(s);

g) a statement on the adequacy of the organization and procedures adopted by the conformity assessment body to give confidence in its competence, as determined through its fulfillment of the requirements for accreditation;

h) sufficient information to demonstrate the satisfactory response to all nonconformities;

i) where relevant, any further information that may assist in determining the competence of the conformity assessment body as determined through conformity with requirements;

j) where appropriate, a recommendation as to the accreditation decision for the proposed scope.

7.7.4 *ISO/IEC 17011:2017(E) Clause 7.7.4*

The accreditation body shall, prior to making a decision, be satisfied that the information is adequate to decide that the requirements for accreditation have been fulfilled.

7.7.5 *ISO/IEC 17011:2017(E) Clause 7.7.5*

The accreditation body shall, without undue delay, make the accreditation decision on the basis of an evaluation of all information received and any other relevant information. Without undue delay, the conformity assessment body shall be notified in writing of the decision including justification where relevant.

7.7.5.1 ~~Denial of Accreditation~~ Reasons to deny an initial application shall include, but are not limited to:

7.7.5.1.1 failure to submit a completed application;

7.7.5.1.2 failure to pay fees;

7.7.5.1.3 failure of CAB staff to meet the personnel qualifications of education, training, and experience as required by the Standard;

7.7.5.1.4 failure to successfully analyze and report proficiency testing samples as required;

7.7.5.1.5 failure to respond to an assessment report from an ~~on-site~~ assessment with a corrective action report as required;

7.7.5.1.6 failure to implement the corrective actions detailed in the corrective action report within the required time frame;

7.7.5.1.7 failure to implement a quality system as defined in TNI Environmental Laboratory Sector Volume 1, Module 2 "Management and Technical Requirements for Laboratories Performing Environmental Analysis";

7.7.5.1.8 ~~failure to pass required on-site assessment(s);~~

7.7.5.1.8 ~~9~~ misrepresentation of any fact pertinent to receiving or maintaining accreditation; ~~and/or~~

7.7.5.1.9 ~~10~~ denial of entry during normal business hours for an ~~on-site~~ assessment; and/or ~~.~~

7.7.5.1.10 failure to provide documents requested by the accreditation body for review in a timeframe requested by the accreditation body prior to the assessment.

7.7.5.2 No CAB's accreditation shall be denied without the right to due process. [from V2M1, 7.5.6]

7.7.6 *ISO/IEC 17011:2017(E) Clause 7.7.6*

Where the accreditation body uses the results of an assessment already performed by another accreditation body, it shall have assurance that the other accreditation body was operating in accordance with the requirements of this document.

NOTE: An accreditation body would not be required to accept or recognize the primary accreditation of the CAB if the accreditation body has a legal action that precludes the accreditation body from granting any accreditation to a particular CAB for a specific scope of accreditation ~~, in recognizing the accreditation granted by another accreditation body, which has a law or decision resulting from a legal action, the legal effect of which precludes the accreditation body from granting any accreditation to a particular CAB, would not be required to accept the accreditation of this CAB~~. [from V2M1, 7.5.2]

7.8 Accreditation Information

7.8.1 *ISO/IEC 17011:2017(E) Clause 7.8.1*

The accreditation body shall provide information on the accreditation to the accredited conformity assessment body that shall identify the following:

a) the identity and, where relevant, the accreditation body logo;

b) the name of the accredited conformity assessment body and the name of the legal entity, if different;

c) scope of accreditation;

d) locations of the accredited conformity assessment body and, as applicable, the conformity assessment activities performed at each location and covered by the scope of accreditation;

e) the unique accreditation identification of the accredited conformity assessment body;

f) the effective date of accreditation and, if applicable, its expiry or renewal date;

g) a statement of conformity and a reference to the international standard(s) and/or other normative document(s), including issue or revision used for assessment of the conformity assessment body.

NOTE: The information can be provided in an accreditation certificate or other suitable means (e.g. electronic media).

7.8.2 *ISO/IEC 17011:2017(E) Clause 7.8.2*

The effective date of accreditation shall be the date of or a date after the accreditation decision.

7.8.3 *ISO/IEC 17011:2017(E) Clause 7.8.3*

NOTE: In the context of this Volume in TNI's Environmental Laboratory Sector standards, only clause 7.8.3(d) is applicable. Clause 7.8.3(e) is applicable to Volume 4 in this Sector.

The scope of accreditation shall, at least, identify the following:

a) For certification bodies:

- *the type of certification (e.g. management systems, products, processes, services, or persons);*

- *certification scheme(s);*

- *the standards, normative documents, and/or regulatory requirements to which management systems, products, processes, and services, or persons are certified, as applicable;*

- *industry sectors, where relevant;*

- *product, processes, service, and persons categories where relevant.*

b) For inspection bodies:

- *the type of inspection body (as defined in ISO/IEC 17020);*

- *inspection schemes, where relevant;*

- *the field and range of inspection for which accreditation has been granted;*

- *the regulations, inspection methods, standards, and/or specifications containing the requirements against which the inspection is to be performed, as applicable.*

c) For calibration laboratories:

- *the calibration and measurement capability (CMC) expressed in terms of:*

  - *measurand or reference material;*

  - *calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;*

  - *measurement range and additional parameters where applicable, e.g. frequency of applied voltage;*

  - *measurement uncertainty.*

d) For testing laboratories (including medical laboratories):

- materials or products tested;

Matrix

- component, parameter, or characteristic tested;

Analyte

- tests or types of tests performed and, where applicable, the techniques, methods, and/or equipment used.

Technology / Method

e) For proficiency testing providers:

- schemes that the proficiency testing provider is competent to provide;

- type of proficiency testing items;

- the measurand(s) or characteristic(s) or, where appropriate, the type of measurand(s) or characteristic(s) that are to be identified, measured, or tested.

f) For reference material producers:

- types of reference materials (certified reference material, reference material, or both);

- the reference material matrix or artefact;

- the property/properties characterized;

- the approach used to assign property values.

g) For validation and verification bodies:

- identification of the activity (validation or verification or both);

- the standards, normative documents, and/or regulatory requirements to which validation or verification or both is to be performed, as applicable;

- validation and/or verification scheme where relevant;

- industry sector where relevant.

h) For other conformity assessment bodies:

- the specific conformity assessment activities the conformity assessment body is accredited for;

- the standards, normative documents, and/or regulatory requirements containing the requirements against which the conformity assessment activity is to be performed, as applicable;

- conformity assessment scheme, where relevant;

- industry sector, where relevant.

7.8.4 *ISO/IEC 17011:2017(E) Clause 7.8.4*

When the accreditation body uses a flexible scope of accreditation, it shall have documented procedures on how it addresses and manages flexible scopes. The procedure shall include how the accreditation body addresses 7.8.3 bullets (a) to (h), including specifying how the information required for bullets (a) to (h) shall be maintained and made available on request.

7.9 Accreditation Cycle

7.9.1 *ISO/IEC 17011:2017(E) Clause 7.9.1*

An accreditation cycle shall begin at or after the date of the decision for granting the initial accreditation or decision after reassessment (see 7.9.4) and shall not be longer than five years.

7.9.2 *ISO/IEC 17011:2017(E) Clause 7.9.2*

The accreditation body shall apply an assessment programme for assessing the conformity assessment body activities during the accreditation cycle to ensure that the conformity assessment activities representative of the scope of accreditation at the relevant locations are assessed during the accreditation cycle (see 7.4.4). Factors such as knowledge obtained by the accreditation body about the conformity assessment body's management system and activities and the performance of the conformity assessment body shall be considered by the accreditation body when establishing the assessment programme.

7.9.3 *ISO/IEC 17011:2017(E) Clause 7.9.3*

The assessment programme shall ensure that the requirements of the international standards and other normative documents containing requirements for conformity assessment bodies and the scope of accreditation shall be assessed taking risk into consideration. A sample of the scope of accreditation shall be assessed at least every two years. The time between consecutive on-site assessments shall not exceed two years. However, if the accreditation body determines that an on-site assessment is not applicable, it shall use another assessment technique to achieve the same objective as the on-site assessment being replaced and justify the use of such techniques (e.g. remote assessment).

NOTE: "Other assessment techniques ~~surveillance activities~~" may include~~, among other things,~~ review by the accreditation body of internal audit reports and managerial reviews or continuing demonstration of corrective actions, or proficiency testing performed by the CAB. [from V2M1, 7.7.2]

7.9.4 *ISO/IEC 17011:2017(E) Clause 7.9.4*

Before the end of the accreditation cycle, a reassessment shall be planned and performed taking into consideration the information gathered from assessments performed over the accreditation cycle. The reassessment shall confirm the competence of the conformity assessment body and cover all the requirements of the standard(s) for which the conformity assessment body is accredited. An accreditation decision shall be made after the reassessment.

7.9.4.1 After an initial assessment for accreditation, accreditation bodies shall perform reassessments at intervals of two years plus or minus six months. Once a CAB is accredited, accreditation bodies reserve the right to assess a CAB at any time during the accreditation cycle ~~period~~. [from V2M3, 5.1 & 6.13.3]

7.9.4.2 All requirements specified in clauses 7.4 through 7.6 (inclusive) shall apply to reassessments, including the requirement in clause 7.4.7.1 to comply with the Safe Drinking Water Act.

7.9.4.3 ~~NOTE: A strict timeline defines enforceable deadlines commensurate with the severity of a finding.~~ [from V2M3, 6.13.6]

7.9.5 *ISO/IEC 17011:2017(E) Clause 7.9.5*

The accreditation body may conduct extraordinary assessments as a result of complaints or changes, or other matters that may affect the ability of the conformity assessment body to fulfill the requirements for accreditation. The accreditation body shall advise conformity assessment bodies of this possibility.

NOTE: Examples of changes could include ~~Extraordinary assessments may be performed when accreditation bodies receive complaints about CABs or when CABs experience~~ changes in the CAB's ownership, key personnel, location, and scope of accreditation. [from V2M3, 6.13.8]

7.10 Extending Accreditation

7.10.1 *ISO/IEC 17011:2017(E) Clause 7.10.1*

The accreditation body shall have a documented procedure for extending the scope of accreditation. Based on the risk associated with the activities or locations to be covered in the scope extension, the accreditation body shall define the appropriate assessment technique(s) to apply and consider the corresponding requirements defined in 7.3 to 7.9.

7.10.2 *ISO/IEC 17011:2017(E) Clause 7.10.2*

The accreditation body shall take into account extensions granted when reviewing the assessment programme and planning the subsequent assessment.

7.11 Suspending, Withdrawing, or Reducing Accreditation

7.11.1 *ISO/IEC 17011:2017(E) Clause 7.11.1*

The accreditation body shall have documented procedure(s) and criteria to decide in which circumstances the accreditation shall be suspended, withdrawn, or reduced when an accredited conformity assessment body has failed to meet the requirements of accreditation or to abide by the rules for accreditation or has voluntarily requested a suspension, withdrawal, or reduction.

~~Suspension, Withdrawal or Reduction of Accreditation~~

7.11.1.1 Suspension shall not exceed six months or the period of accreditation, whichever is longer. The purpose of suspension is to allow a CAB time to correct nonconformities ~~deficiencies or an area of non-compliance~~.

7.11.1.2 Subject to applicable laws, regulations and due process requirements, an accreditation body may suspend, withdraw or reduce a CAB's accreditation if the CAB fails to meet the standards for accreditation. The CAB shall retain accreditation for the scope of accreditation, where it continues to meet the requirements of the Standard. Reasons for suspension, withdrawal or reduction shall include but are not limited to:

7.11.1.2.1 if the accreditation body finds, during the ~~on-site~~ assessment, that the public interest, safety or welfare imperatively requires emergency action;

7.11.1.2.2 failure to complete proficiency testing studies as required;

7.11.1.2.3 failure to notify the accreditation body of any changes in key accreditation criteria as referenced in Clauses 4.2 and ~~*ISO/IEC 17011:2004(E) Clause*~~ 7.2.1;

7.11.1.2.4 failure to maintain a Quality System as required;

7.11.1.2.5 failure of the CAB to employ staff that meets qualifications for education, training and experience as required.

7.11.1.2.6 Misrepresentation of any fact pertinent to receiving or maintaining accreditation;

7.11.1.2.7 Denial of entry to an accreditation body's assessment team during normal business hours for the purpose of conducting an ~~on-site~~ assessment;

7.11.1.2.8 Failure to provide documents requested by the accreditation body for review in a timeframe requested by the accreditation body prior to the assessment.
~~Failure to pass an on-site assessment conducted by an accreditation body;~~

7.11.1.2.9 Failure to complete responses or corrective actions from an accreditation body's current or past assessment report(s).

7.11.1.2.10 Failure to pay fees.

7.11.1.3 The accreditation body shall inform the ~~A~~ suspended CAB that it cannot ~~shall not~~ continue to perform conformance assessment services under accreditation auspices for the affected scope of accreditation.

7.11.1.4 The accreditation body shall change the CAB's accreditation status from suspended to accredited when the CAB demonstrates to the accreditation body that it complies with the relevant requirements.

7.11.1.5 ~~A suspended CAB shall not have to reapply for accreditation if the cause/causes for suspension are corrected within six months or before the end of the period of accreditation, whichever is longer.~~

7.11.1.5 ~~6~~ If the CAB fails to correct the causes of suspension within six months after the effective date of the suspension or by the end of the period of accreditation (whichever is longer), the accreditation body shall withdraw or reduce the CAB's accreditation and the CAB is required to reapply for accreditation.

7.11.1.6 ~~7~~ No CAB's accreditation shall be suspended, withdrawn or reduced without the right to due process as set forth by the Accreditation Body. [from V2M1, 7.9.4]

7.11.2 *ISO/IEC 17011:2017(E) Clause 7.11.2*

Where there is evidence of fraudulent behavior, or the conformity assessment body intentionally provides false information or conceals information, the accreditation body shall initiate its process for withdrawal of accreditation.

7.11.3 *ISO/IEC 17011:2017(E) Clause 7.11.3*

The accreditation body shall have a documented procedure and criteria for lifting suspension of accreditation.

7.12 Complaints

7.12.1 *ISO/IEC 17011:2017(E) Clause 7.12.1*

The accreditation body shall have a documented process to receive, evaluate, and make decisions on complaints. The accreditation body shall, where appropriate, ensure that a complaint concerning an accredited conformity assessment body is first addressed by the conformity assessment body.

[covers V2M1, 5.9.1]

NOTE: An independent person, or group of persons, may consist of another group within the accreditation body organization whose responsibility is to handle investigations and appeals. Alternatively, the matter can be addressed by an external group of peers called together for this purpose, and following a documented policy and procedure consistent with this Standard and agreed upon by all participants. [from V2M1, 7.6.2]

7.12.2 *ISO/IEC 17011:2017(E) Clause 7.12.2*

A description of the handling process for complaints shall be available to any interested party.

7.12.3 *ISO/IEC 17011:2017(E) Clause 7.12.3*

Upon receipt of a complaint, the accreditation body shall confirm whether the complaint relates to accreditation activities that it is responsible for and, if so, shall deal with it.

7.12.4 *ISO/IEC 17011:2017(E) Clause 7.12.4*

The handling process for complaints shall include at least the following elements and methods:

a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken in a timely manner.

7.12.5 *ISO/IEC 17011:2017(E) Clause 7.12.5*

The accreditation body shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.12.6 *ISO/IEC 17011:2017(E) Clause 7.12.6*

The accreditation body shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.12.7 *ISO/IEC 17011:2017(E) Clause 7.12.7*

The accreditation body shall be responsible for all decisions at all levels of the handling process for complaints.

7.12.8 *ISO/IEC 17011:2017(E) Clause 7.12.8*

The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved with the activities in question.

7.12.9 *ISO/IEC 17011:2017(E) Clause 7.12.9*

The accreditation body shall give formal notice of the end of the complaint handling process to the complainant.

7.12.10 *ISO/IEC 17011:2017(E) Clause 7.12.10*

Investigation and decision on complaints shall not result in any discriminatory actions against the complainant.

7.13 Appeals

7.13.1 *ISO/IEC 17011:2017(E) Clause 7.13.1*

The accreditation body shall have a documented process to receive, evaluate, and make decisions on appeals.

[covers V2M1, 5.9.1 (and "new" 7.10.3)]

NOTE: An independent person, or group of persons, may consist of another group within the accreditation body organization whose responsibility is to handle investigations and appeals. Alternatively, the matter can be addressed by an external group of peers called together for this purpose, and following a documented policy and procedure consistent with this Standard and agreed upon by all participants. [from V2M1, 7.6.2]

7.13.2 *ISO/IEC 17011:2017(E) Clause 7.13.2*

A description of the handling process for appeals shall be available to any interested party.

7.13.3 *ISO/IEC 17011:2017(E) Clause 7.13.3*

The accreditation body shall be responsible for all decisions at all levels of the handling process for appeals.

NOTE: A governmental accreditation body following its regulatory or statutory due-process administrative procedures is considered to meet this requirement.

7.13.4 *ISO/IEC 17011:2017(E) Clause 7.13.4*

Investigation and decision on appeals shall not result in any discriminatory actions.

7.13.5 *ISO/IEC 17011:2017(E) Clause 7.13.5*

The handling process for appeals shall include at least the following elements and methods:

a) a description of the process for receiving, validating, investigating the appeal, and deciding what actions are to be taken in response to it;

b) tracking and recording appeals, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken in a timely manner.

7.13.6 *ISO/IEC 17011:2017(E) Clause 7.13.6*

The accreditation body receiving the appeal shall be responsible for gathering and verifying all necessary information to validate the appeal.

7.13.7 *ISO/IEC 17011:2017(E) Clause 7.13.7*

The accreditation body shall acknowledge receipt of the appeal, and provide the appellant with progress reports and the outcome.

7.13.8 *ISO/IEC 17011:2017(E) Clause 7.13.8*

The decision to be communicated to the appellant shall be made by, or reviewed and approved by, individual(s) not involved with the activities in question.

7.13.9 *ISO/IEC 17011:2017(E) Clause 7.13.9*

The accreditation body shall give formal notice of the end of the appeals handling process to the appellant.

7.14 Records on Conformity Assessment Bodies

7.14.1 *ISO/IEC 17011:2017(E) Clause 7.14.1*

The accreditation body shall maintain records on conformity assessment bodies to demonstrate that requirements for accreditation have been effectively fulfilled.

7.14.2 *ISO/IEC 17011:2017(E) Clause 7.14.2*

The accreditation body shall have a documented policy and documented procedures on the retention of records. Records of conformity assessment bodies shall be retained at least for the duration of the current cycle plus the previous full accreditation cycle.

~~7.14.3 The accreditation body shall have a policy and procedure for retaining accreditation records for a minimum length of time as required by contractual obligations or pertinent territorial, state or federal laws and regulations.~~ [from V2M1, 7.10.4]

8.0 INFORMATION REQUIREMENTS

8.1 Confidential Information

8.1.1 *ISO/IEC 17011:2017(E) Clause 8.1.1*

The accreditation body shall be responsible through legally enforceable agreements for the management of all information obtained or created during the accreditation process. The accreditation body shall inform the conformity assessment body, in advance, of the information it intends to place in the public domain. Except for information that the conformity assessment body makes publically available, or when agreed between the accreditation body and the conformity assessment body (e.g., for the purpose of responding to complaints), all other information obtained during the accreditation process is considered proprietary information and shall be regarded as confidential.

~~NOTE: The confidentiality of documents and records may be challenged in specific instances by public information requests under state or federal laws.~~ [from V2M1, 7.10.2]

8.1.2 *ISO/IEC 17011:2017(E) Clause 8.1.2*

When the accreditation body is required by law or authorized by contractual arrangements to release confidential information, the conformity assessment body shall, unless prohibited by law, be notified of the

information provided.

8.1.3 *ISO/IEC 17011:2017(E) Clause 8.1.3*

Information about the conformity assessment body obtained from sources other than the conformity assessment body (e.g. complainant, regulators) shall be confidential between the conformity assessment body and the accreditation body. The provider (source) of this information shall be confidential to the accreditation body and shall not be shared with the conformity assessment body, unless agreed by the source.

8.1.4 *ISO/IEC 17011:2017(E) Clause 8.1.4*

Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the accreditation body's behalf, shall keep confidential all information obtained or created during the performance of the accreditation body's activities, except as required by law.

8.1.5 ~~Confidential Business Information~~

Accreditation bodies shall have documented procedures for processing and evaluating claims made by CABs of confidential ~~business~~ information ~~(CBI)~~ referencing applicable laws and regulations ~~, the procedures a CAB shall follow to make a claim, the parties that will determine the validity of the claim, and the appeals process to be invoked when a CAB disagrees with the disposition of a claim~~. [from V2M3, 6.6]

8.2 Publicly Available Information

8.2.1 *ISO/IEC 17011:2017(E) Clause 8.2.1*

The accreditation body shall make publicly available through publications, electronic media, or other means, without request, and update at adequate intervals, the following:

a) information about the accreditation body:

1) information about the authority under which the accreditation body operates;

2) a description of the accreditation body's rights and duties;

3) general information about the means by which the accreditation body obtains financial support;

4) information about the accreditation body's activities, other than accreditation;

5) information about international recognition arrangements in which it is involved.

b) information about accreditation process:

1) detailed information about its accreditation schemes, including its assessment and accreditation processes;

2) reference to the documents containing the requirements for accreditation;

3) general information about the fees relating to accreditation;

4) a description of the rights and obligations of conformity assessment bodies;

5) information on procedures for lodging and handling complaints and appeals;

6) information on the use of the accreditation symbol or other claims of accreditation.

8.2.2 *ISO/IEC 17011:2017(E) Clause 8.2.2*

As a minimum, the accreditation body shall make publicly available, without request, information on conformity assessment bodies as described in 7.8.1 and, where applicable, information on suspension or withdrawal of accreditation, including dates and scopes.

NOTE: In exceptional cases, access to certain information can be limited upon the request of the conformity assessment body (e.g. for security reasons).

8.2.3 *ISO/IEC 17011:2017(E) Clause 8.2.3*

The accreditation body shall give due notice of any changes to its requirements for accreditation. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes.

8.2.4 *ISO/IEC 17011:2017(E) Clause 8.2.4*

Following a decision on, and publication of, the changed requirements, the accreditation body shall verify that each accredited body conforms to the changed requirements.

9.0 MANAGEMENT SYSTEM REQUIREMENTS

9.1 General

9.1.1 *ISO/IEC 17011:2017(E) Clause 9.1.1*

The accreditation body shall establish, document, implement, and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document. In addition to meeting the requirements of clauses in this document, the accreditation body shall implement a management system in accordance with option A (see 9.1.4) or with option B (see 9.1.5).

9.1.2 *ISO/IEC 17011:2017(E) Clause 9.1.2*

The accreditation body's management shall establish and document policies and objectives related to competence, consistency of operation, and impartiality. The management shall provide evidence of its commitment to the development and implementation of the management system in accordance with the requirements of this document. The management shall ensure that the policies are understood, implemented, and maintained at all levels of the accreditation body's organization.

9.1.3 *ISO/IEC 17011:2017(E) Clause 9.1.3*

The accreditation body's top management shall assign responsibility and authority for:

a) ensuring that policies and processes needed for the management system are established, implemented, and maintained;

b) reporting to top management on the performance of the management system and any need for improvement.

9.1.4 *ISO/IEC 17011:2017(F) Clause 9.1.4*

Under option A, as a minimum, the management system of the accreditation body shall address the following, as elaborated in 9.2 to 9.8:

- *management system;*
- *document control;*
- *records control;*
- *nonconformities and corrective actions;*
- *improvement;*
- *internal audits;*
- *management reviews.*

9.1.5 *ISO/IEC 17011:2017(E) Clause 9.1.5*

Under option B, an accreditation body that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfillment of this document, fulfills at least the management system section requirements.

9.2 Management System

9.2.1 *ISO/IEC 17011:2017(E) Clause 9.2.1*

The accreditation body shall operate a management system appropriate to the type, range, and volume of work performed. All applicable requirements of this document shall be addressed either in a manual or in associated documents. The accreditation body shall ensure that the manual and relevant associated documents are accessible to its personnel and shall ensure effective implementation of the management system's processes.

9.2.2 *ISO/IEC 17011:2017(E) Clause 9.2.2*

The accreditation body shall continually improve effectiveness of its management system in accordance with the requirements of this document.

9.3 Document Control *(ISO/IEC 17011:2017(E) Clause 9.3)*

The accreditation body shall establish documented procedures to control all documents (internal and external) that relate to its accreditation activities. The procedures shall define the controls needed:

a) to approve documents for adequacy prior to issue;

b) to review and update as necessary and re-approve documents;

c) to ensure that changes and the current revision status of documents are identified;

d) to ensure that relevant versions of applicable documents are available at points of use;

e) to ensure that documents remain legible and readily identifiable;

f) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose;

g) to safeguard, where relevant, the confidentiality of documents.

9.4 Records Control

9.4.1 *ISO/IEC 17011:2017(E) Clause 9.4.1*

The accreditation body shall establish documented procedures to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of its records.

9.4.2 *ISO/IEC 17011:2017(E) Clause 9.4.2*

The accreditation body shall establish documented procedures for retaining records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality arrangements.

9.5 Nonconformities and Corrective Actions *(ISO/IEC 17011:2017(E) Clause 9.5)*

The accreditation body shall establish documented procedures for the identification and management of nonconformities in its own operations. The accreditation body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall cover the following:

a) identifying nonconformities (from complaints, internal audits, or other sources);

b) determining the causes of nonconformity;

c) correcting nonconformities;

d) evaluating the need for actions to ensure that nonconformities do not recur;

e) determining the actions needed and implementing them in a timely manner;

f) recording the results of actions taken;

g) reviewing the effectiveness of corrective actions.

9.6 Improvement *(ISO/IEC 17011:2017(E) Clause 9.6)*

The accreditation body shall establish documented procedures to identify opportunities for improvement and to identify risks and take appropriate actions (see also 4.4).

9.7 Internal Audits

9.7.1 *ISO/IEC 17011:2017(E) Clause 9.7.1*

The accreditation body shall establish documented procedures for internal audits to verify that the accreditation body conforms to the requirements of this document and that the management system is implemented and maintained.

9.7.2 *ISO/IEC 17011:2017(E) Clause 9.7.2*

Internal audits shall be performed normally once a year. An audit programme shall be established, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

9.7.3 *ISO/IEC 17011:2017(E) Clause 9.7.3*

The frequency of internal audits may be reduced if the accreditation body demonstrates that its

management system has been effectively implemented according to this document and has proven stability.

9.7.4 *ISO/IEC 17011:2017(E) Clause 9.7.4*

The accreditation body shall ensure that:

a) internal audits are conducted by competent personnel knowledgeable in accreditation, auditing, and the requirements of this document;

b) internal audits are conducted by personnel different from those who perform the activity to be audited;

c) personnel responsible for the area audited are informed of the outcome of the audit;

d) actions are taken in a timely and appropriate manner;

e) any opportunities for improvement are identified.

9.7.5 ~~One element of the annual internal audit shall be to review the effectiveness of the quality systems required. The internal audit shall include a review of the quality manual and associated written quality procedures. The frequency of internal audits may be reduced if the accreditation body can demonstrate acceptable performance during on-site evaluations. If this audit frequency is extended to a period longer than one year, the accreditation body shall document the frequency in their policies, procedures or quality manual.~~ [from V2M1, 5.7.4]

9.8 Management Reviews

9.8.1 *ISO/IEC 17011:2017(E) Clause 9.8.1*

The accreditation body's management shall establish documented procedures to review its management system at planned intervals to ensure its continuing adequacy and effectiveness in satisfying the relevant requirements, including this document and the stated policies and objectives. These reviews shall be conducted at least once per year.

9.8.2 *ISO/IEC 17011:2017(E) Clause 9.8.2*

Inputs to management reviews shall include current performance and opportunities for improvement related to the following:

a) results of audits;

b) results of peer evaluation where relevant;

c) participation in international activities, where relevant;

d) safeguarding impartiality;

e) feedback from interested parties;

f) new areas of accreditation;

g) trends in nonconformities;

h) status of corrective actions;

i) the status of actions to address risks and opportunities;

j) follow-up actions from earlier management reviews;

k) fulfillment of objectives;

l) changes that could affect the management system;

m) analysis of appeals;

n) analysis of complaints.

9.8.3 *ISO/IEC 17011:2017(E) Clause 9.8.3*

The outputs from the management system review shall include actions related to:

a) improvement of the management system and its processes;

b) improvement of services and accreditation process in conformity with the relevant standards and expectations of interested parties;

c) need for resources;

d) defining or redefining policies, goals, and objectives.

Annex A
(Informative)

Knowledge and Skills for Performing Accreditation Activities

Table A.1 provides a summary of the knowledge and skills required for accreditation body assessment teams and appropriate accreditation body personnel but are informative because they only identify the areas of knowledge for specific accreditation activities.

The competence requirements for each accreditation activity are stated in 6.1.2.2 to 6.1.2.8. Table A.1 gives the reference to the specific requirement.

Table A1 – Table of Knowledge and Skills

	Accreditation Activities				
Knowledge and skills	*Application review including selection of team members*	*Document review*	*Assessment*	*Reviewing assessment reports and making accreditation decisions*	*Management of accreditation schemes*
Knowledge of accreditation body's rules and processes	*X (6.1.2.3)*	*X (6.1.2.3)*	*X (6.1.2.3)*	*X (6.1.2.3)*	*X (6.1.2.3)*
Knowledge of assessment principles, practices, and techniques		*X (6.1.2.2)*	*X (6.1.2.2)*	*X (6.1.2.2)*	
Knowledge of general management system principles and tools		*X (6.1.2.2)*	*X (6.1.2.2)*	*X (6.1.2.2)*	
Communication skills appropriate to all levels within the conformity assessment body			*X (6.1.2.6)*		
Note-taking and report-writing skills		*X (6.1.2.7)*	*X (6.1.2.7)*		
Opening and closing meeting skills			*X (6.1.2.6)*		
Interviewing skills			*X (6.1.2.6)*		
Assessment-management skills			*X (6.1.2.6)*		
Knowledge of accreditation and accreditation scheme requirements and relevant guidance and application documents	*X (6.1.2.3)*	*X (6.1.2.3)*	*X (6.1.2.3)*	*X (6.1.2.3) (6.1.2.8)*	*X (6.1.2.3)*
Knowledge of conformity	*X*	*X*	*X*	*X*	*X*

assessment scheme requirements, other procedures, and methods used by the conformity assessment body	*(6.1.2.3)*	*(6.1.2.3)*	*(6.1.2.3)*	*(6.1.2.3)*	*(6.1.2.3)*
Knowledge of risk based assessment principles			*X (6.1.2.4)*	*X (6.1.2.4)*	*X (6.1.2.4)*
Knowledge of the practices and processes of the conformity assessment body business environment			*X (6.1.2.6)*		
Knowledge of general regulatory requirements related to the conformity assessment activities		*X (6.1.2.5)*	*X (6.1.2.5)*	*X (6.1.2.5)*	*X (6.1.2.5)*

NOTE 1: The required knowledge and skills can be provided collectively by a group of persons involved in the specified accreditation activity.

NOTE 2: Accreditation scheme requirements include ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17025, ISO/IEC 17024, ISO 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189, and ISO 14065.

NOTE 3: Conformity assessment scheme requirements include ISO 9001, ISO 14001, ISO 9096, WADA ISL, and Energy STAR.