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## Economic Commission for Europe

### Inland Transport Committee

#### Working Party on the Transport of Dangerous Goods

Joint Meeting of the RID Committee of Experts and the

Working Party on the Transport of Dangerous Goods

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Item 2 of the provisional agenda

Tanks

5 September 2022

### **Accreditation of inspection bodies for the purpose of authorisation and surveillance of in-house inspection services**

#### **Further information on clauses in EN ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements**

##### **Transmitted by the Government of the United Kingdom**

1. Further to ECE/TRANS/WP.15/AC.1/2022/30 on the accreditation of inspection bodies for the purpose of authorisation and surveillance of in-house inspection services, clauses 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10 and 9.1 to 9.4 and 9.6 of EN ISO/IEC 17021-1:2015 *Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements* are set out in the annex below for ease of reference when this item is discussed in the September 2022 session of the Joint Meeting.
2. Currently inspection bodies are accredited according to standard EN ISO/IEC 17020:2012 (except clause 8.1.3) for the purpose of performing inspections, but no accreditation is required of inspection bodies for the purpose of authorisation and surveillance of an in-house inspection service when used by a manufacturer. Furthermore, new 1.8.6.2.3.1 in the 2023 editions of RID and ADR requires the competent authority that approved an inspection body for such activities to ensure the monitoring of those activities.
3. Reference in new 1.8.6.2.1 and 1.8.6.3.1 to relevant clauses in EN ISO/IEC 17021-1:2015, to provide for the accreditation of inspection bodies for the purpose of authorisation and surveillance of in-house inspection services, would facilitate the monitoring of those activities in a manner which would be equivalent to that required for the purpose of performing inspections, thus satisfying the obligations of the competent authority to ensure that whatever the activities of an inspection body those activities are properly monitored.

## Annex

### **Clause 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10 and 9.1 to 9.4 and 9.6 of standard EN ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements**

#### 7. Resource requirements

##### 7.1 Competence of personnel

###### 7.1.1 General considerations

The certification body shall have processes to ensure that personnel have appropriate knowledge and skills relevant to the types of management systems (e.g. environmental management systems, quality management systems, information security management systems) and geographic areas in which it operates.

###### 7.1.2 Determination of competence criteria

The certification body shall have a process for determining the competence criteria for personnel involved in the management and performance of audits and other certification activities. Competence criteria shall be determined with regard to the requirements of each type of management system standard or specification, for each technical area, and for each function in the certification process. The output of the process shall be the documented criteria of required knowledge and skills necessary to effectively perform audit and certification tasks to be fulfilled to achieve the intended results. Annex A specifies the knowledge and skills that a certification body shall define for specific functions. Where additional specific competence criteria have been established for a specific standard or certification scheme (e.g. ISO/IEC TS 17021-2, ISO/IEC TS 17021-3 or ISO/TS 22003), these shall be applied.

NOTE : The term “technical area” is applied differently depending on the management system standard being considered. For any management system, the term is related to products, processes and services in the context of the scope of the management system standard. The technical area can be defined by a specific certification scheme (e.g. ISO/TS 22003) or can be determined by the certification body. It is used to cover a number of other terms such as “scopes”, “categories”, “sectors”, etc., which are traditionally used in different management system disciplines.

##### 7.2 Personnel involved in the certification activities

7.2.4 The certification body shall have processes for selecting, training, formally authorizing auditors and for selecting and familiarizing technical experts used in the certification activity. The initial competence evaluation of an auditor shall include the ability to apply required knowledge and skills during audits, as determined by a competent evaluator observing the auditor conducting an audit.

NOTE : During the selection and training process described above desired personal behaviour can be considered. These are characteristics that affect an individual’s ability to perform specific functions. Therefore, knowledge about the behaviour of individuals enables a certification body to take advantage of their strengths and to minimize the impact of their weaknesses. Desired personal behaviour that is important for personnel involved in certification activities is described in Annex D [of EN ISO/IEC 17021-1:2015].

7.2.5 The certification body shall have a process to achieve and demonstrate effective auditing, including the use of auditors and audit team leaders possessing generic auditing skills and knowledge, as well as skills and knowledge appropriate for auditing in specific technical areas.

7.2.8 The group or individual that takes the decision on granting, refusing, maintaining, renewing, suspending, restoring, or withdrawing certification, or on expanding or reducing the scope of certification, shall understand the applicable standard and

certification requirements, and shall have demonstrated competence to evaluate the outcomes of the audit processes including related recommendations of the audit team.

7.2.10 The certification body shall monitor each auditor considering each type of management system to which the auditor is deemed competent. The documented monitoring process for auditors shall include a combination of on-site evaluation, review of audit reports and feedback from clients or from the market. This monitoring shall be designed in such a way as to minimize disturbance to the normal processes of certification, especially from the client's viewpoint.

## 9. Process requirements

### 9.1 Pre-certification activities

#### 9.1.1 Application

The certification body shall require an authorized representative of the applicant organization to provide the necessary information to enable it to establish the following:

- a) the desired scope of the certification;
- b) relevant details of the applicant organization as required by the specific certification scheme, including its name and the address(es) of its site(s), its processes and operations, human and technical resources, functions, relationships and any relevant legal obligations;
- c) identification of outsourced processes used by the organization that will affect conformity to requirements;
- d) the standards or other requirements for which the applicant organization is seeking certification;
- e) whether consultancy relating to the management system to be certified has been provided and, if so, by whom.

#### 9.1.2 Application review

9.1.2.1 The certification body shall conduct a review of the application and supplementary information for certification to ensure that:

- a) the information about the applicant organization and its management system is sufficient to develop an audit programme (see 9.1.3);
- b) any known difference in understanding between the certification body and the applicant organization is resolved;
- c) the certification body has the competence and ability to perform the certification activity;
- d) the scope of certification sought, the site(s) of the applicant organization's operations, time required to complete audits and any other points influencing the certification activity are taken into account (language, safety conditions, threats to impartiality, etc.).

9.1.2.2 Following the review of the application, the certification body shall either accept or decline an application for certification. When the certification body declines an application for certification as a result of the review of application, the reasons for declining an application shall be documented and made clear to the client.

9.1.2.3 Based on this review, the certification body shall determine the competences it needs to include in its audit team and for the certification decision.

#### 9.1.3 Audit programme

9.1.3.1 An audit programme for the full certification cycle shall be developed to clearly identify the audit activity/activities required to demonstrate that the client's management system fulfils the requirements for certification to the selected standard(s) or

other normative document(s). The audit programme for the certification cycle shall cover the complete management system requirements.

9.1.3.2 The audit programme for the initial certification shall include a two-stage initial audit, surveillance audits in the first and second years following the certification decision, and a recertification audit in the third year prior to expiration of certification. The first three-year certification cycle begins with the certification decision. Subsequent cycles begin with the recertification decision (see 9.6.3.2.3) The determination of the audit programme and any subsequent adjustments shall consider the size of the client, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits.

NOTE 1 : Annex E [of EN ISO/IEC 17021-1:2015] provides a flowchart of a typical audit and certification process.

NOTE 2 : The following list contains additional items that can be considered when developing or revising an audit programme, they might also need to be addressed when determining the audit scope and developing the audit plan:

- complaints received by the certification body about the client;
- combined, integrated or joint audit
- changes to the certification requirements;
- changes to legal requirements;
- changes to accreditation requirements;
- organizational performance data (e.g. defect levels, key performance indicators data);
- relevant interested parties' concerns.

NOTE 3 : If specified by the industry specific certification scheme, the certification cycle can be different from three years.

9.1.3.3 Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.

NOTE : It can be necessary to adjust the frequency of surveillance audits to accommodate factors such as seasons or management systems certification of a limited duration (e.g. temporary construction site).

9.1.3.4 Where the certification body is taking account of certification already granted to the client and to audits performed by another certification body, it shall obtain and retain sufficient evidence, such as reports and documentation on corrective actions, to any nonconformity. The documentation shall support the fulfilling of the requirements in this part of ISO/IEC 17021. The certification body shall, based on the information obtained, justify and record any adjustments to the existing audit programme and follow up the implementation of corrective actions concerning previous nonconformities.

9.1.3.5 Where the client operates shifts, the activities that take place during shift working shall be considered when developing the audit programme and audit plans.

#### 9.1.4 Determining audit time

9.1.4.1 The certification body shall have documented procedures for determining audit time. For each client the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the client's management system.

9.1.4.2 In determining the audit time, the certification body shall consider, among other things, the following aspects:

- a) the requirements of the relevant management system standard;
- b) complexity of the client and its management system;
- c) technological and regulatory context;

- d) any outsourcing of any activities included in the scope of the management system;
- e) the results of any prior audits;
- f) size and number of sites, their geographical locations and multi-site considerations;
- g) the risks associated with the products, processes or activities of the organization;
- h) whether audits are combined, joint or integrated.

NOTE 1 : Time spent travelling to and from audited sites is not included in the calculation of the duration of the management system audit days.

NOTE 2 : The certification body can use the guidelines established in ISO/IEC TS 17023 for determining the duration of management system audit when documenting these procedures.

Where specific criteria have been established for a specific certification scheme, e.g. ISO/TS 22003 or ISO/IEC 27006, these shall be applied.

9.1.4.3 The duration of the management system audit and its justification shall be recorded.

9.1.4.4 The time spent by any team member that is not assigned as an auditor (i.e. technical experts, translators, interpreters, observers and auditors-in-training) shall not count in the above established duration of the management system audit.

NOTE : The use of translators and interpreters can necessitate additional time.

#### 9.1.5 Multi-site sampling

Where multi-site sampling is used for the audit of a client's management system covering the same activity in various geographical locations, the certification body shall develop a sampling programme to ensure proper audit of the management system. The rationale for the sampling plan shall be documented for each client. Sampling is not allowed for some specific certification schemes, and where specific criteria have been established for a specific certification scheme, e.g. ISO/TS 22003, these shall be applied.

NOTE : Where there are multiple sites not covering the same activity sampling is not appropriate.

#### 9.1.6 Multiple management systems standards

When certification to multiple management system standards is being provided by the certification body, the planning for the audit shall ensure adequate on-site auditing to provide confidence in the certification.

### 9.2 Planning audits

#### 9.2.1 Determining audit objectives, scope and criteria

9.2.1.1 The audit objectives shall be determined by the certification body. The audit scope and criteria, including any changes, shall be established by the certification body after discussion with the client.

9.2.1.2 The audit objectives shall describe what is to be accomplished by the audit and shall include the following:

- a) determination of the conformity of the client's management system, or parts of it, with audit criteria;
- b) determination of the ability of the management system to ensure the client meets applicable statutory, regulatory and contractual requirements;

NOTE : A management system certification audit is not a legal compliance audit.

- c) determination of the effectiveness of the management system to ensure the client can reasonably expect to achieving its specified objectives;

d) as applicable, identification of areas for potential improvement of the management system.

9.2.1.3 The audit scope shall describe the extent and boundaries of the audit, such as sites, organizational units, activities and processes to be audited. Where the initial or re-certification process consists of more than one audit (e.g. covering different sites), the scope of an individual audit may not cover the full certification scope, but the totality of audits shall be consistent with the scope in the certification document.

9.2.1.4 The audit criteria shall be used as a reference against which conformity is determined, and shall include:

- the requirements of a defined normative document on management systems;
- the defined processes and documentation of the management system developed by the client.

## 9.2.2 Audit team selection and assignments

### 9.2.2.1 General

9.2.2.1.1 The certification body shall have a process for selecting and appointing the audit team, including the audit team leader and technical experts as necessary, taking into account the competence needed to achieve the objectives of the audit and requirements for impartiality. If there is only one auditor, the auditor shall have the competence to perform the duties of an audit team leader applicable for that audit. The audit team shall have the totality of the competences identified by the certification body as set out in 9.1.2.3 for the audit.

9.2.2.1.2 In deciding the size and composition of the audit team, consideration shall be given to the following:

- a) audit objectives, scope, criteria and estimated audit time;
- b) whether the audit is a combined, joint or integrated;
- c) the overall competence of the audit team needed to achieve the objectives of the audit (see Table A.1);
- d) certification requirements (including any applicable statutory, regulatory or contractual requirements);
- e) language and culture.

NOTE : The team leader of a combined or integrated audit is expected to have in-depth knowledge of at least one of the standards and an awareness of the other standards used for that particular audit.

9.2.2.1.3 The necessary knowledge and skills of the audit team leader and auditors may be supplemented by technical experts, translators and interpreters who shall operate under the direction of an auditor. Where translators or interpreters are used, they shall be selected such that they do not unduly influence the audit.

NOTE : The criteria for the selection of technical experts are determined on a case-by-case basis by the needs of the audit team and the scope of the audit.

9.2.2.1.4 Auditors-in-training may participate in the audit, provided an auditor is appointed as an evaluator. The evaluator shall be competent to take over the duties and have final responsibility for the activities and findings of the auditor-in-training.

9.2.2.1.5 The audit team leader, in consultation with the audit team, shall assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments shall take into account the need for competence, and the effective and efficient use of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure achievement of the audit objectives.

### 9.2.2.2 Observers, technical experts and guides

#### 9.2.2.2.1 Observers

The presence and justification of observers during an audit activity shall be agreed to by the certification body and client prior to the conduct of the audit. The audit team shall ensure that observers do not unduly influence or interfere in the audit process or outcome of the audit.

NOTE : Observers can be members of the client's organization, consultants, witnessing accreditation body personnel, regulators or other justified persons.

#### 9.2.2.2.2 Technical experts

The role of technical experts during an audit activity shall be agreed to by the certification body and client prior to the conduct of the audit. A technical expert shall not act as an auditor in the audit team. The technical experts shall be accompanied by an auditor.

NOTE : The technical experts can provide advice to the audit team for the preparation, planning or audit.

#### 9.2.2.2.3 Guides

Each auditor shall be accompanied by a guide, unless otherwise agreed to by the audit team leader and the client. Guide(s) are assigned to the audit team to facilitate the audit. The audit team shall ensure that guides do not influence or interfere in the audit process or outcome of the audit.

NOTE 1 : The responsibilities of a guide can include:

- a) establishing contacts and timing for interviews;
- b) arranging visits to specific parts of the site or organization;
- c) ensuring that rules concerning site safety and security procedures are known and respected by the audit team members;
- d) witnessing the audit on behalf of the client;
- e) providing clarification or information as requested by an auditor.

NOTE 2 : Where appropriate, the auditee can also act as the guide.

### 9.2.3 Audit plan

#### 9.2.3.1 General

The certification body shall ensure that an audit plan is established prior to each audit identified in the audit programme to provide the basis for agreement regarding the conduct and scheduling of the audit activities.

NOTE : It is not expected that a certification body will develop an audit plan for each audit at the time that the audit programme is developed.

#### 9.2.3.2 Preparing the audit plan

The audit plan shall be appropriate to the objectives and the scope of the audit. The audit plan shall at least include or refer to the following:

- a) the audit objectives;
- b) the audit criteria;
- c) the audit scope, including identification of the organizational and functional units or processes to be audited;
- d) the dates and sites where the on-site audit activities will be conducted, including visits to temporary sites and remote auditing activities, where appropriate;
- e) the expected duration of on-site audit activities;
- f) the roles and responsibilities of the audit team members and accompanying persons, such as observers or interpreters.

NOTE : The audit plan information can be contained in more than one document.

### 9.2.3.3 Communication of audit team tasks

The tasks given to the audit team shall be defined, and require the audit team to:

- a) examine and verify the structure, policies, processes, procedures, records and related documents of the client relevant to the management system standard;
- b) determine that these meet all the requirements relevant to the intended scope of certification;
- c) determine that the processes and procedures are established, implemented and maintained effectively, to provide a basis for confidence in the client's management system;
- d) communicate to the client, for its action, any inconsistencies between the client's policy, objectives and targets.

### 9.2.3.4 Communication of audit plan

The audit plan shall be communicated and the dates of the audit shall be agreed upon, in advance, with the client.

### 9.2.3.5 Communication concerning audit team members

The certification body shall provide the name of and, when requested, make available background information on each member of the audit team, with sufficient time for the client to object to the appointment of any particular audit team member and for the certification body to reconstitute the team in response to any valid objection.

## 9.3 Initial certification

### 9.3.1 Initial certification audit

#### 9.3.1.1 General

The initial certification audit of a management system shall be conducted in two stages: stage 1 and stage 2.

#### 9.3.1.2 Stage 1

9.3.1.2.1 Planning shall ensure that the objectives of stage 1 can be met and the client shall be informed of any "on site" activities during stage 1.

NOTE : Stage 1 does not require a formal audit plan (see 9.2.3).

9.3.1.2.2 The objectives of stage 1 are to:

- a) review the client's management system documented information;
- b) evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2;
- c) review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;
- d) obtain necessary information regarding the scope of the management system, including:
  - the client's site(s);
  - processes and equipment used;
  - levels of controls established (particularly in case of multisite clients);
  - applicable statutory and regulatory requirements;
- e) review the allocation of resources for stage 2 and agree the details of stage 2 with the client;
- f) provide a focus for planning stage 2 by gaining a sufficient understanding of the client's management system and site operations in the context of the management system standard or other normative document;



- g) evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2.

NOTE : If at least part of stage 1 is carried out at the client's premises, this can help to achieve the objectives stated above.

9.3.1.2.3 Documented conclusions with regard to fulfilment of the stage 1 objectives and the readiness for stage 2 shall be communicated to the client, including identification of any areas of concern that could be classified as a nonconformity during stage 2.

NOTE The stage 1 output does not need to meet the full requirements of a report (see 9.4.8).

9.3.1.2.4 In determining the interval between stage 1 and stage 2, consideration shall be given to the needs of the client to resolve areas of concern identified during stage 1. The certification body may also need to revise its arrangements for stage 2. If any significant changes which would impact the management system occur, the certification body shall consider the need to repeat all or part of stage 1. The client shall be informed that the results of stage 1 may lead to postponement or cancellation of stage 2.

#### 9.3.1.3 Stage 2

The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's management system. The stage 2 shall take place at the site(s) of the client. It shall include the auditing of at least the following:

- a) information and evidence about conformity to all requirements of the applicable management system standard or other normative documents;
- b) performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document);
- c) the client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;
- d) operational control of the client's processes;
- e) internal auditing and management review;
- f) management responsibility for the client's policies.

#### 9.3.1.4 Initial certification audit conclusions

The audit team shall analyse all information and audit evidence gathered during stage 1 and stage 2 to review the audit findings and agree on the audit conclusions.

### 9.4 Conducting audits

#### 9.4.1 General

The certification body shall have a process for conducting on-site audits. This process shall include an opening meeting at the start of the audit and a closing meeting at the conclusion of the audit.

Where any part of the audit is made by electronic means or where the site to be audited is virtual, the certification body shall ensure that such activities are conducted by personnel with appropriate competence. The evidence obtained during such an audit shall be sufficient to enable the auditor to take an informed decision on the conformity of the requirement in question.

NOTE : "On-site" audits can include remote access to electronic site(s) that contain(s) information that is relevant to the audit of the management system. Consideration can also be given to the use of electronic means for conducting audits.

#### 9.4.2 Conducting the opening meeting

A formal opening meeting, shall be held with the client's management and, where appropriate, those responsible for the functions or processes to be audited. The purpose of the opening meeting, usually conducted by the audit team leader, is to provide a short

explanation of how the audit activities will be undertaken. The degree of detail shall be consistent with the familiarity of the client with the audit process and shall consider the following:

- a) introduction of the participants, including an outline of their roles;
- b) confirmation of the scope of certification;
- c) confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management;
- d) confirmation of formal communication channels between the audit team and the client;
- e) confirmation that the resources and facilities needed by the audit team are available;
- f) confirmation of matters relating to confidentiality;
- g) confirmation of relevant work safety, emergency and security procedures for the audit team;
- h) confirmation of the availability, roles and identities of any guides and observers;
- i) the method of reporting, including any grading of audit findings;
- j) information about the conditions under which the audit may be prematurely terminated;
- k) confirmation that the audit team leader and audit team representing the certification body is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails;
- l) confirmation of the status of findings of the previous review or audit, if applicable;
- m) methods and procedures to be used to conduct the audit based on sampling;
- n) confirmation of the language to be used during the audit;
- o) confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;
- p) opportunity for the client to ask questions.

#### 9.4.3 Communication during the audit

9.4.3.1 During the audit, the audit team shall periodically assess audit progress and exchange information. The audit team leader shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.

9.4.3.2 Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the audit team leader shall report this to the client and, if possible, to the certification body to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The audit team leader shall report the outcome of the action taken to the certification body.

9.4.3.3 The audit team leader shall review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the certification body.

#### 9.4.4 Obtaining and verifying information

9.4.4.1 During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be obtained by appropriate sampling and verified to become audit evidence.

9.4.4.2 Methods to obtain information shall include, but are not limited to:

- a) interviews;
- b) observation of processes and activities;
- c) review of documentation and records.

#### 9.4.5 Identifying and recording audit findings

9.4.5.1 Audit findings summarizing conformity and detailing nonconformity shall be identified, classified and recorded to enable an informed certification decision to be made or the certification to be maintained.

9.4.5.2 Opportunities for improvement may be identified and recorded, unless prohibited by the requirements of a management system certification scheme. Audit findings, however, which are nonconformities, shall not be recorded as opportunities for improvement.

9.4.5.3 A finding of nonconformity shall be recorded against a specific requirement, and shall contain a clear statement of the nonconformity, identifying in detail the objective evidence on which the nonconformity is based. Nonconformities shall be discussed with the client to ensure that the evidence is accurate and that the nonconformities are understood. The auditor however shall refrain from suggesting the cause of nonconformities or their solution.

9.4.5.4 The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, and unresolved points shall be recorded.

#### 9.4.6 Preparing audit conclusions

Under the responsibility of the audit team leader and prior to the closing meeting, the audit team shall:

- a) review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities;
- b) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process;
- c) agree any necessary follow-up actions;
- d) confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence).

#### 9.4.7 Conducting the closing meeting

9.4.7.1 A formal closing meeting, where attendance shall be recorded, shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting, usually conducted by the audit team leader, is to present the audit conclusions, including the recommendation regarding certification. Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.

NOTE : "Understood" does not necessarily mean that the nonconformities have been accepted by the client.

9.4.7.2 The closing meeting shall also include the following elements where the degree of detail shall be consistent with the familiarity of the client with the audit process:

- a) advising the client that the audit evidence obtained was based on a sample of the information; thereby introducing an element of uncertainty;

- b) the method and timeframe of reporting, including any grading of audit findings;
- c) the certification body's process for handling nonconformities including any consequences relating to the status of the client's certification;
- d) the timeframe for the client to present a plan for correction and corrective action for any nonconformities identified during the audit;
- e) the certification body's post audit activities;
- f) information about the complaint and appeal handling processes.

9.4.7.3 The client shall be given opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to the certification body.

#### 9.4.8 Audit report

9.4.8.1 The certification body shall provide a written report for each audit to the client. The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by the certification body.

9.4.8.2 The audit team leader shall ensure that the audit report is prepared and shall be responsible for its content. The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made and shall include or refer to the following:

- a) identification of the certification body;
- b) the name and address of the client and the client's representative;
- c) the type of audit (e.g. initial, surveillance or recertification audit or special audits);
- d) the audit criteria;
- e) the audit objectives;
- f) the audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit;
- g) any deviation from the audit plan and their reasons;
- h) any significant issues impacting on the audit programme;
- i) identification of the audit team leader, audit team members and any accompanying persons;
- j) the dates and places where the audit activities (on site or offsite, permanent or temporary sites) were conducted;
- k) audit findings (see 9.4.5), reference to evidence and conclusions, consistent with the requirements of the type of audit;
- l) significant changes, if any, that affect the management system of the client since the last audit took place;
- m) any unresolved issues, if identified;
- n) where applicable, whether the audit is combined, joint or integrated;
- o) a disclaimer statement indicating that auditing is based on a sampling process of the available information;
- p) recommendation from the audit team
- q) the audited client is effectively controlling the use of the certification documents and marks, if applicable;

r) verification of effectiveness of take corrective actions regarding previously identified nonconformities, if applicable.

9.4.8.3 The report shall also contain:

a) a statement on the conformity and the effectiveness of the management system together with a summary of the evidence relating to:

- the capability of the management system to meet applicable requirements and expected outcomes;
- the internal audit and management review process;

b) a conclusion on the appropriateness of the certification scope;

c) confirmation that the audit objectives have been fulfilled.

9.4.9 Cause analysis of nonconformities

The certification body shall require the client to analyse the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities, within a defined time.

9.4.10 Effectiveness of corrections and corrective actions

The certification body shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The certification body shall verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities shall be recorded. The client shall be informed of the result of the review and verification. The client shall be informed if an additional full audit, an additional limited audit, or documented evidence (to be confirmed during future audits) will be needed to verify effective correction and corrective actions.

NOTE : Verification of effectiveness of correction and corrective action can be carried out based on a review of documented information provided by the client, or where necessary, through verification on-site. Usually this activity is done by a member of the audit team.

9.6 Maintaining certification

9.6.1 General

The certification body shall maintain certification based on demonstration that the client continues to satisfy the requirements of the management system standard. It may maintain a client's certification based on a positive conclusion by the audit team leader without further independent review and decision, provided that:

a) for any major nonconformity or other situation that may lead to suspension or withdrawal of certification, the certification body has a system that requires the audit team leader to report to the certification body the need to initiate a review by competent personnel (see 7.2.8), different from those who carried out the audit, to determine whether certification can be maintained;

b) competent personnel of the certification body monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

9.6.2 Surveillance activities

9.6.2.1 General

9.6.2.1.1 The certification body shall develop its surveillance activities so that representative areas and functions covered by the scope of the management system are monitored on a regular basis, and take into account changes to its certified client and its management system.

9.6.2.1.2 Surveillance activities shall include on-site auditing of the certified client's management system's fulfilment of specified requirements with respect to the standard to which the certification is granted. Other surveillance activities may include:

- a) enquiries from the certification body to the certified client on aspects of certification;
- b) reviewing any certified client's statements with respect to its operations (e.g. promotional material, website);
- c) requests to the certified client to provide documented information (on paper or electronic media);
- d) other means of monitoring the certified client's performance.

#### 9.6.2.2 Surveillance audit

Surveillance audits are on-site audits, but are not necessarily full system audits, and shall be planned together with the other surveillance activities so that the certification body can maintain confidence that the client's certified management system continues to fulfil requirements between recertification audits. Each surveillance for the relevant management system standard shall include:

- a) internal audits and management review;
- b) a review of actions taken on nonconformities identified during the previous audit;
- c) complaints handling;
- d) effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);
- e) progress of planned activities aimed at continual improvement;
- f) continuing operational control;
- g) review of any changes;
- h) use of marks and/or any other reference to certification.

#### 9.6.3 Recertification

##### 9.6.3.1 Recertification audit planning

9.6.3.1.1 The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification. A recertification audit shall be planned and conducted to evaluate the continued fulfilment of all of the requirements of the relevant management system standard or other normative document. This shall be planned and conducted in due time to enable for timely renewal before the certificate expiry date.

9.6.3.1.2 The recertification activity shall include the review of previous surveillance audit reports and consider the performance of the management system over the most recent certification cycle.

9.6.3.1.3 Recertification audit activities may need to have a stage 1 in situations where there have been significant changes to the management system, the organization, or the context in which the management system is operating (e.g. changes to legislation).

NOTE : Such changes can occur at any time during the certification cycle and the certification body might need to perform a special audit (see 9.6.4), which might or might not be a two-stage audit.

##### 9.6.3.2 Recertification audit

9.6.3.2.1 The recertification audit shall include an on-site audit that addresses the following:

- a) the effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;

b) demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;

c) the effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s).

9.6.3.2.2 For any major nonconformity, the certification body shall define time limits for correction and corrective actions. These actions shall be implemented and verified prior to the expiration of certification.

9.6.3.2.3 When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the recertification decision.

9.6.3.2.4 If the certification body has not completed the recertification audit or the certification body is unable to verify the implementation of corrections and corrective actions for any major nonconformity (see 9.5.2.1 [of EN ISO/IEC 17021-1:2015]) prior to the expiry date of the certification, then recertification shall not be recommended and the validity of the certification shall not be extended. The client shall be informed and the consequences shall be explained.

9.6.3.2.5 Following expiration of certification, the certification body can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

#### 9.6.4 Special audits

##### 9.6.4.1 Expanding scope

The certification body shall, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit.

##### 9.6.4.2 Short-notice audits

It may be necessary for the certification body to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes, or as follow up on suspended clients. In such cases:

a) the certification body shall describe and make known in advance to the certified clients (e.g. in documents as described in 8.5.1) the conditions under which such audits will be conducted;

b) the certification body shall exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

#### 9.6.5 Suspending, withdrawing or reducing the scope of certification

9.6.5.1 The certification body shall have a policy and documented procedure(s) for suspension, withdrawal or reduction of the scope of certification, and shall specify the subsequent actions by the certification body.

9.6.5.2 The certification body shall suspend certification in cases when, for example:

- the client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system;
- the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies;
- the certified client has voluntarily requested a suspension.

9.6.5.3 Under suspension, the client's management system certification is temporarily invalid.

9.6.5.4 The certification body shall restore the suspended certification if the issue that has resulted in the suspension has been resolved. Failure to resolve the issues that have resulted in the suspension in a time established by the certification body shall result in withdrawal or reduction of the scope of certification.

NOTE : In most cases, the suspension would not exceed six months.

9.6.5.5 The certification body shall reduce the scope of certification to exclude the parts not meeting the requirements, when the certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification. Any such reduction shall be in line with the requirements of the standard used for certification.

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