SLOVENSKA AKREDITACIJA

D05-02d4

ASSESSMENT OF CERTIFICATION BODIES

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1 PURPOSE

The purpose of this annex to the D05-02 document is to lay down the scope and methods of assessment that are specific for the assessment of certification bodies and/or different certification schemes. In planning assessment of management system certification bodies, also the data provided by the certification body on the form OB05-83, Review of indicators of MS CB's performance, shall be taken into account.

General instructions for assessments of certification bodies and specific instructions applicable only to certain types of certification bodies and/or particular certification schemes are included.

2 ASSESSMENT FOCUSES

The assessment of certification bodies includes the assessment of the main site of the certification body, or its dislocated sites at which the key activities are performed, and the assessment of the audits being performed at its clients.

2.1 Head office or dislocated sites

In the course of the assessment of the certification body's head office or its dislocated sites, the assessor team shall use, in addition to the general assessment techniques, the following techniques: examination of records, system documents, interviews with the certification body's staff. They shall especially focus on:

- organizational structure of certification body, the appropriate position and composition of the Management Board / mechanism for safeguarding impartiality / committee for safeguarding impartiality (involvement of all parties interested in certification, involvement of specific parties interested in certification of different management systems, balanced representation of interested parties) and the authorities of the Board / mechanism for safeguarding impartiality / impartiality protection / committee for safeguarding impartiality;
- ensuring impartiality of certification activities, identifying risk to impartiality, controlling risks, (ongoing activity, providing information to the Board / mechanism for safeguarding impartiality / impartiality protection committee for safeguarding impartiality / interested parties, top management commitment);
- financial stability, resources;
- appropriate relations and cooperation with clients (access to certification service, appropriate contracts with clients, non-discriminatory treatment of clients);
- ensuring confidentiality;
- proper division of the functions of certification/education/verification/testing/inspection, when several such activities are performed within the same certification body;
- appropriate management of the competence of the staff involved in certification procedures;
- the suitability of the use of different information and communication technologies, rules, procedures, security, protection (IAF MD 4);
- the certification process, and controlling and maintaining records in order to prove efficient implementation of the certification process;
- contents of certificates;
- the assurance of independence at the decision-making level as to grant/refuse/withdraw a certificate, and auditing;

- the suitability of subcontractors, when relevant;
- the performance of certification activities at dislocated sites (key and non-key activities), and relations between them;
- the efficiency of the control system for the sites at which the critical activities are performed, when relevant;
- the performance of conformity assessment procedures abroad;
- accessibility (public accessibility of information);
- making reference to certification and the use of marks (ISO/IEC 17021-1, 8.3.3, IAF Resolutions);
- the implementation of the relevant documents, other guidance documents (D05-10) and
- performing certification by fields/schemes/standards from the scope of accreditation.

2.1.1 Certification body operating certification of products/processes/services

When assessing a certification body operating certification of products/processes/services (hereinafter referred to as certification body for products), the following shall be checked in addition to the list under 2.1 above:

- specifying the certification scheme;
- meeting of sector-specific requirements;
- procedures in different product certification schemes, sampling procedures;
- whether the certification body itself performs auditing, testing, calibration or inspection for the needs of certification, and whether it is competent for the performance of these activities under the requirements of the relevant standards. In the case that the certification body cannot provide an appropriate evidence of its competence for auditing/testing/calibration/inspection, its compliance against the accreditation requirements referring to testing, calibration and inspection activities shall also be checked during the assessment;
- procedures in the case of a multi-site certification procedure (IAF MD 1).

2.1.1.1 Certification bodies operating certification of organic production and processing

The assessment relates to the scope of accreditation for the product categories stated in D05-11. When the certification body certifies activity providers from abroad, the national legislation of the activity provider's country shall be taken into consideration in the assessment, in addition to the relevant EU Regulations. Also, the information obtained by the relevant ministry and the commission shall be taken into consideration in the course of assessments. When accreditation is extended to another product category, the assessment shall be performed at least according to the documentation when the competence of auditors is checked among other things.

Assessment shall include review of the control (systematic, substantive) of all changes of the relevant documents (the Regulation, the Implementing regulations, the national regulations …). Special emphasis shall be placed on interrelationship with the clients and the obligations to report; on competence of the personnel and knowledge of the relevant normative documents (EU and national); on issuing permits for the use of non-organic seed material; on labeling of organic products and foodstuffs, as well as on agricultural economy; group certification (Regulation (EU) 2018/848, Article 36); certification of public catering facilities (national regulation); proper control of the nonconformities found (national regulation); new form of certificate and its filling-out (Regulation (EU) 2018/884, Article 35, national regulation); risk assessment (Regulation (EU) 2018/884, Article 38(2)); sampling (Regulation (EU) 2018/884, Article 38(4), national regulation); the contents of the written record

(Regulation (EU) 2018/884, Article 38(6)); cases of exceptions to the rules of organic production and processing; managing data on exceptions (national regulation); exchange of information with the Ministry, with Food Safety, Veterinary and Plant Protection Administration and with National Agency for Agricultural Markets and Regional Development (list of contractors, permits issued, withdrawn certificates, contractor transitions …); and management of records (Rules on records in the field of organic production and processing of agricultural products and foodstuffs).
When assessing a certification body which performs certification in third countries, the requirements of EA-3/12 M, clause 4 shall be complied with.

2.1.1.2 Certification bodies operating certification of protected agricultural products and foodstuffs, aromatised wine products, grapevine products and spirits

Assessment relates to the scope of accreditation for the product categories stated in D05-11.

2.1.1.3 Certification bodies operating certification of traceability of the origin of wood and other forest products according to PEFC ST 2002:2020

In addition to SIST EN ISO/IEC 17065:2012, the sector specific document PEFC ST 2003:2020 and the relevant requirements of ISO 19011:2018 shall be used in assessing.

In assessment, attention shall be paid to:

- obtaining authorisation for the use of the PEFC trademark from the Institute for Forest Certification – ZCG (national representative of PEFC) – PEFC ST 2003:2020, clause 4.1;
- obtaining the client's written consent on exchange of information about clients with ZCG – PEFC ST 2003:2020, clause 4.5;
- meeting the requirements for auditors and experts (basic education, working experience, auditing experience and specific PEFC recognized training, competences) – PEFC ST 2003:2020, clauses 6.1.1.2, 6.1.2;
- documented procedure of ensuring that the auditors have personal qualities, knowledge and skills in conformity with the requirements of ISO 19011:2018 (7.1, 7.2.1, 7.2.2, 7.2.3.1, 7.2.3.2, 7.2.3.4) - PEFC ST 2003:2020, clause 6.1.1.2;
- meeting the qualification requirements for reviewing documentation and decision-making - PEFC ST 2003:2020, clauses 6.1.1.4, 6.1.2.5;
- providing the relevant information of the client upon registration – PEFC ST 2003:2020, clause 7.2;
- rules for conducting audits (including IAF MD 4), complying with the requirements of ISO 19011:2018 (clause 6.3.2), classification of findings – PEFC ST 2003:2020, clause 7.4;
- documented procedure for specifying the audit time, sampling during audit, documentation – PEFC ST 2003:2020, clause 7.4;
- documented procedure for auditing organizations with several locations, sampling of locations - PEFC ST 2003:2020, clause 7.4, Appendix 3;
- the contents of audit report – PEFC ST 2003:2020, clause 7.4.11, Appendix 4;
- the decision-making rules – PEFC ST 2003:2020, clause 7.6;
- certification documents, contents, validity – PEFC ST 2003:2020, clause 7.7, reference to PEFC mark, information on locations;
- informing ZCG about any change in the scope of the certificate, termination, withdrawal of certificate - PEFC ST 2003:2020, clause 7.7.7;

- complaint management and informing relevant parties (PEFC Council, ZCG) about the received complaints, solved complaints and appeals - PEFC ST 2003:2020, clause 7.13;
- the way of performing regular surveillance, frequency – PEFC ST 2003:2020, clause 7.9.;
- compliance with the requirements of the standard and IAF MD 2 in case of certificate transfer.

2.1.1.4 Certification bodies operating certification of Qualified Trust Service Providers and Trust Service Components from Regulation (EU) No 910/2014, having regard to ETSI EN 319 403-1, V2.3.1 (2020-06)

To the basic requirements provided in SIST EN ISO/IEC 17065, the requirements of sector specific document, standard ETSI EN 319 403-1, V2.3.1: "*Electronic Signatures and Infrastructures (ESI); Trust Service Provider Conformity Assessment – Part 1: Requirements for conformity assessment bodies assessing Trust Service Providers*", shall be added in assessment.

In assessment, attention shall be paid to:

- correct assessment of all those activities of the certification body (CAB) that could compromise impartiality in the field of trust services (ETSI EN 319 403-1, V2.3.1, 4.2.1);
- appropriate management of the CAB personnel involved in the process of trust service providers (TSP) certification, including all levels of the process (examination of application, audit, review and decision-making), and adequateness of their training (ETSI EN 319 403-1, V2.3.1, 6.1. and 6.2);
- adequateness of CAB's processes, which should take into consideration the relevant TSP-specific standards and statutory provisions (ETSI EN 319 403-1, V2.3.1, 7.1);
- adequateness of CAB's processes and procedures for reviewing applications for certification (ETSI EN 319 403-1, V2.3.1, 7.3);
- adequateness of audit procedures with focus on the correctness of estimation as to the scope of audit, competences of auditors, auditing methodology, audit time, adequateness of selecting sites in multi-site cases, reporting method, and performance of audits (first instance audit, second instance audit), and frequency of carrying out audits (ETSI EN 319 403-1, V2.3.1, 7.4);
- adequateness of decision-making procedures on certification (ETSI EN 319 403-1, V2.3.1, 7.6);
- adequateness of procedures regarding certification documentation (ETSI EN 319 403-1, V2.3.1, 7.7);
- adequateness of procedures regarding public availability of information on certified TSPs (ETSI EN 319 403-1, V2.3.1, 7.8);
- adequateness of periodic surveillance and re-certification procedures of certified TSPs (ETSI EN 319 403-1, V2.3.1, 7.9 and Regulation (EU) No 910/2014, Article 20/1);
- adequateness of controlling changes that affect TSP's certification (ETSI EN 319 403-1, V2.3.1, 7.10);
- adequateness of controlling the use of the EU trustmark (Regulation (EU) No 910/2014, Article 23).

The assessment shall also find out whether the CAB performs proper audits, and also comply with the requirements of the Regulation (EU) No 910/2014. These can be divided into general requirements (common to all types of trust services) and specific, which are specified for individual types of trust services (the requirements are presented in *Table 1* below).

Table 1: Requirements of Regulation eIDAS regarding individual types of trust services

Trust Service	Requirements in Regulation eIDAS (910/2014)
Qualified electronic signature: creating, verifying and confirming validity, retention	Art. 3/16 a) and c), Art. 3/12, Art. 28, Art. 33, Art. 34, Annex I
Qualified electronic stamp: creating, verifying and confirming validity, retention	Art. 3/16 a) and c), Art. 3/27, Art. 38, Art. 40, Annex III
Qualified electronic time stamp	Art. 3/16 a) and c), Art. 3/34, Art. 42
Qualified electronic registered delivery service	Art. 3/16 a) and c), Art. 3/37 Art. 44
Qualified website authentication certificate	Art. 3/16 b), Art. 3/39, Art. 45, Annex IV

2.1.1.5 Certification bodies operating quality system certification in fusion welding of metallic materials according to SIST EN ISO 3834

Certification bodies for quality system certification in fusion welding of metallic materials according to SIST EN ISO 3834 may perform certification:

- according to ISO 9001 and EN ISO 3834, Part 2, 3 or 4, with the relevant accreditation being to SIST EN ISO/IEC 17021-1 for quality systems;
- independently, according to EN ISO 3834, Part 2, 3 or 4, with the relevant accreditation being to SIST EN ISO/IEC 17065 for the appropriate scheme.

In assessing a certification body for quality system in fusion welding of metallic materials according to SIST EN ISO 3834, the requirements of EA-6/02M shall be complied with.
Regardless of the type of accreditation, attention in assessing shall be paid to:

- determining the scheme and obligatory contents of the scheme;
- requirements for auditors and experts (in accordance with EA-6/02, 4.1, 4.6, 5);
- the competence evaluation process for auditors and experts (in accordance with EA-6/02);
- requirements regarding the process (EA-6/02, 6);
- requirements regarding validity of the certificate (different for SIST EN ISO/IEC 17021-1 and SIST EN ISO/IEC 17065);
- requirements regarding surveillance and re-certification (different for SIST EN ISO/IEC 17021-1 and SIST EN ISO/IEC 17065).

2.1.2 Certification body operating certification of persons

In assessing a certification body for persons, the following shall be checked in addition to that mentioned under 2.1:

- specification of pre-conditions for acceding to certification;
- relation with training activity in the field of certification, when relevant, and assurance of impartiality;
- certification of "own" personnel;
- assurance of adequate conditions for certification;

- whether the certification body performs testing, calibration or inspection for the requirements of certification by itself and whether it is qualified for such activities according to the requirements of the relevant standards. If the certification body possesses no adequate evidence of competence for testing/calibration/inspection, the assessment shall likewise comprise of conformity with the requirements for accreditation which apply to the testing, calibration and inspection activities;
- assurance of safety throughout the certification procedure (test materials, cheating); and
- control of certification scheme (development, approval and maintenance of certification scheme, monitoring changes).

2.1.3 Certification body operating certification of management systems

When assessing a certification body for certification of management systems, the following shall be checked in addition to that mentioned under 2.1:

- the procedure of including entities operating on behalf of accredited management systems certification bodies (IAF MD 23);
- the procedure of defining the requirements for the competence (knowledge, experience, skills) of the staff taking part in conducting and carrying out audits and certification (for all types of management systems, for any technical field and for any function in certification process), and the results of implementation of the procedure (ISO/IEC 17021-1:2015, 7.1.2, (Annex A); ISO 50003:2021, clause 7.2; IAF MD9, (Annex B, Annex C); ISO/TS 22003:2013, 7.1);
- determining requirements for staff based on HLS MS standards (process approach, risk-based thinking, identifying risks and opportunities, stakeholder needs and expectations, leadership and commitment, organization context, communication, documented information) (ISO/IEC 17021-1 and other sector specific standards, IAF MD 9, Annex B, Annex C);
- the procedure of initial competence evaluation, regular monitoring of competence of the staff taking part in conducting and carrying out audits (ISO/IEC 17021-1:2015, 7.1.3; ISO/TS 22003:2013, 7.1; IAF MD 9, Annex B, Annex C);
- the procedure of selecting and appointing the auditor team (selection criteria) (ISO/IEC 17021-1:2015, 9.2.2);
- the procedure and criteria of appointing the effective number of personnel (IAF MD 5, ISO 50003:2021, clause 9.1.4.4, Annex A);
- process of determining the degree of integration of management systems, approach (standard, extended) in planning and implementation of integrated audits (IAF MD 11);
- the procedure of defining the audit time, decreasing and increasing the audit time (appropriateness of criteria, compliance with criteria) (ISO/IEC 17021-1:2015, 9.1.4; ISO 50003:2021, clause 9.1.4, Annex A; ISO/TS 22003:2013, 9.1.4; IAF MD 5; IAF MD 9 (Annex D); IAF MD 11);
- drawing up an audit programme for the complete certification cycle, indicating audit activities (ISO/IEC 17021-1:2015, 9.1.3);
- defining the audit plan and objectives (certification body), scope of audit (integrated, combined …, participants' roles) and audit criteria as well as reporting on achievements (ISO/IEC 17021-1:2015, 9.2.3; ISO 50003:2021, clause 9.2);
- conducting the opening and closing meeting, attendance (ISO/IEC 17021-1:2015, 9.4.2, 9.4.7, IAF MD 22);
- the auditors' competence, especially when the certification of environmental management and health and safety at work is concerned in the fields where the clients' representativeness is poor,

and the audit is carried out less frequently. The frequency of assessing the adequateness of maintenance of auditors' competence in individual fields shall be adapted by the assessor to the speed of development of techniques, technologies and systems … for individual fields (e.g., the fields of EAC 19, EAC 33, EAC 3, EAC 12, EAC 13 will need more frequent assessment of the proper maintenance of competence);

- the procedure of specifying the audit findings and remedying the nonconformities (IAF MD 9, item 9.4.5);
- the procedure of evaluating the efficiency of corrections and corrective actions (ISO/IEC 17021-1:2015, 9.4.10);
- the completeness of audit report (ISO/IEC 17021-1:2015, 9.4.8);
- the procedures in the "multi-site" certification procedure (IAF MD 1; IAF MD 5; IAF MD 9 (MD 9.1.5); ISO/IEC 17021-1:2015, 9.1.5; ISO 50003:2021, clause 9.1.5, Annex B; ISO/TS 22003:2013, 9.1.5);
- the procedures of the two-stage audit (ISO/IEC 17021-1:2015, 9.3.1; ISO/TS 22003, 9.2.3.1; ISO 50003:2021, clause 9.3);
- the introduction of risk-based approach;
- the procedure in the event of transfer of certificate from another certification body (ISO/IEC 17021-1:2015, 9.5.2.2, IAF MD 2);
- carrying out remote audits (IAF MD 4, IAF MD 5);
- auditing the scope of certification in the case of the organisation outsourcing a part of its functions (IAF MD5);
- informing the clients of the presence of SA at witnessing and its policy in the case they refuse witnessing (inclusion in the contract with the client, possible sanctions); and
- special audits (ISO/IEC 17021-1:2015, 9.6.4, IAF MD 9, item 9.6.4.2).

2.1.3.1 Certification of food safety management systems to ISO 22000:2018

The assessment relates to the scope of accreditation classified according to the categories specified in D05-11 (the same as in ISO/TS 22003:2013, Annex A).

In assessing a food safety management certification body, attention shall be paid to:

- specific requirements for the competence – ISO/TS 22003:2013, 7.1, Annex C, education and work experiences of the staff taking part in certification procedures and their documentation with regard to category and sub-category (ISO/TS 22003:2013, 7.1 – 7.3);
- specific competence for sub-categories, for the field of animal food;
- definition of the scope of certification (ISO/TS 22003:2013, 9.1, Annex A); nothing indicating to product specifics ("organic" or name of product) should be stated;
- correct choice of time (season, time, day) for carrying out the audit (ISO/TS 22003:2013, 9.1.2);
- the availability of competent auditors for individual sub-category;
- the existence of at least one active client of the certification body for individual category for which it seeks to obtain accreditation;
- the contents of the report, suitability of recommendations specified (ISO/TS 22003:2013, 9.1.8, ownership of the report); and
- correct definition of duration of the audit (ISO/TS 22003:2013, 9.1.4, 9.1.5, Annex B).

2.1.3.2 Certification of environmental management systems to ISO 14001:2015

The assessment relates to the scope of accreditation defined by fields of activity as specified in D05-11 (the same as in IAF ID 1).

In assessing a certification body for environmental management systems, attention shall be paid to:

- the definition of the requirements for competence for each function in the certification process and for each EMS field in accordance with ISO/IEC 17021-2:2016;
- competence of the auditors: general competence according to EN ISO/IEC 17021-1:2015, 7, and specific EMS knowledge according to ISO/IEC 17021-2, 5.1–5.15, complying with the requirements for new knowledge (life cycle, waste, space);
- the definition of the requirements for competence of the auditor team in environmental aspects for individual EMS fields according to ISO/IEC 17021-2, 6.1–6.8, taking into consideration the knowledge of monitoring and measurement in individual fields;
- the definition of the requirements for other personnel according to ISO/IEC 17021-2, 7.1–7.3.

2.1.3.3 Certification of management systems to ISO 9001:2015

The assessment relates to the scope of accreditation defined by fields of activity as specified in D05-11 (the same as in IAF ID 1).

In assessing a certification body for management systems, attention shall be paid to:

- the definition of the requirements for competence for all functions in the certification process in accordance with ISO/IEC 17021-1, Table A1, and ISO/IEC 17021-3, 4;
- competence of the auditors: general competence according to EN ISO/IEC 17021-1:2015, 7, and specific knowledge according to ISO/IEC 17021-3:2017, 5; complying with the requirements for new knowledge (role of management, process approach, risk-based thinking, organizational context);
- the definition of the requirements for other personnel according to ISO/IEC 17021-3:2017, 6.

2.1.3.4 Certification of management system to the End-of-Waste regulations (Regulation (EU) No. 333/2011 (scrap metals), Regulation (EU) No. 715/2013 (copper scrap) and Regulation (EU) No. 1179/2012 (glass cullet))

In assessing a certification body for management systems to the End-of-Waste regulations, the following shall be verified, in addition to all other requirements for certification bodies operating certification of quality systems to ISO 9001:

- the implementation of the respective regulation – Regulation (EU) No. 333/2011; Regulation (EU) No. 715/2013 and/or Regulation (EU) No. 1179/2012;
- the specific competence of the auditors for auditing to the End-of-Waste regulations (knowledge of the specifications for classification of scrap; acceptability of input materials, potential impurities; surveillance of waste acceptability, processing procedures and techniques; monitoring the quality of scrap metal; monitoring of radioactivity; acceptability of manufacturer's personnel training; definition of conformity statement, Annex I);
- the frequency of carrying out audits.

2.1.3.5 Certification of quality systems to ISO 9001 and HACCP

The assessment relates to the scope of accreditation defined by fields of activity as specified in D05-11.

In assessing a quality system certification body to ISO 9001 and HACCP, the following shall be verified, in addition to all other requirements for a quality system certification body to ISO 9001:

- implementation of FAO/WHO Codex Alimentarius, CAC/RCP 1-1969:2003;
- specific competence of the persons involved in certification procedures according to this scheme;
- understanding of the HACCP principles; and
- the frequency of audits.

2.1.3.6 Certification of energy management systems (EnMS) to ISO 50001:2018

The assessment relates to the scope of accreditation defined by categories as specified in the document D05-11.

In assessing an energy management system certification body, attention shall be paid to:

- how the certification body approves the scope and limits of the EnMS;
- the procedure of defining active EnMS staff (ISO 50003:2021, Annex A, A.2);
- compliance with specific requirements for two-stage audit (ISO 50003:2021, clause 9.3);
- reporting (statement of continuous improvement of energy performance – description of evidence in support thereof, not just references);
- defining the complexity of EnMS (ISO 50003:2021, Annex A, A.4);
- sampling in "multi-site" assessment, the rules, sample size, calculation (ISO 50003:2021, Annex B);
- information for reviewing the application;
- identifying the central site (office);
- the requirement to implement nonconformities on all sites of the organisation;
- saving and updating information on the organisation's sites;
- auditing other sites of the organisation, announcing the audit;
- the decision-making process in relation with the nonconformities found;
- during the transitional period check the implementation of audits after the new standard issue (as of February 21, 2020, auditing exclusively according to the new edition of the standard).

2.1.3.7 Certification of management systems for medical devices to ISO 13485:2016

The assessment relates to the scope of accreditation defined by technical fields as specified in the document D05-11 (the same as in IAF MD 8:2020).

In assessing a certification body for medical device management systems, attention shall be paid to:

- how the certification body verifies the organisation's compliance with the legislation relating to safety and realization of a medical device, taking action in the case of non-compliance with the latter requirements, and communication with the Surveillance Authority, when required;
- publicly available information on promotion of medical devices by manufacturers (compliant indication of classifications, purpose of use of medical devices);
- the procedure for first approval of auditors (IAF MD 9, Annex C);

- auditors' competence for sterile medical devices or medical devices for use in sterile conditions (for procedures from Table 1.5, IAF MD 9);
- criteria for auditors' competence for auditing at the sites of manufacturers producing medical device parts and providers of medical device services, and for auditing at the sites of manufacturers producing medical devices (IAF MD 9, Annex B);
- auditors' competence for procedures carried out by the organisation's subcontractor;
- carrying out first-instance audit of a client in the case of C and D category of medical devices (GHTF);
- the procedure of determination of audit time (application of IAF MD 5 in the part relating to QMS, except Table QMS 1, which is replaced by Table D.1 from IAF MD 9); add audit time for national or regional legal requirements and review of procedure documents; audit time in combined audit with ISO 9001 (IAF MD 9, Annex D); audit time in the case of an integrated system (integration with other systems, not with ISO 9001 (IAF MD 11));
- criteria for carrying out short visits, possibility of unannounced visits;
- entitlement to allowance in the case of meeting the requirements of work experience in the field of medical devices;
- scope of certification, in particular when the scope of accreditation is defined as "other than the above-mentioned" (The assessor shall obtain from the certification body a list of medical devices belonging under "other than the above-mentioned", their classification of risks and a brief and concise statement of the intended purpose of use of the medical device. The assessor shall review compliance of accreditation for the Main technical fields indicated in D05-11 (in the case of accreditation of the Main technical field "Parts or services") (IAF MD 9, Annex A)), and
- exchange of information with the legislator (inclusion in the contract with the client).

2.1.3.8 Certification of health and safety at work management system to ISO 45001:2018

The assessment relates to the scope of accreditation defined by fields of activity as specified in D05-11 (the same as in IAF MD 22, Annex B).

In assessing a certification body for health and safety at work management systems, the IAF MD 22 shall be complied with, and attention shall be paid to:

- the legally binding commitments to immediately report to the CAB any serious accidents or violations of the regulations;
- obtaining the necessary information upon application;
- audit time and site determination methodology (IAF MD 5);
- considering OH&S risks;
- multi-site sampling rules;
- active personnel determination procedure (IAF MD 5, also contractor / subcontractor personnel);
- fulfilling legal/contractual requirements (IAF MD 22, Annex A);
- rules in the case of identified derogations from legal requirements, action, informing, decision making;
- carrying out the audit, records;
- specific requirements for competence (ISO/IEC 17021-10, Annex C);
- decision-making procedure when not all of the legal requirements have been met (IAF MD 22, Annex A);
- records of the personnel interviewed, documentation of derogations.

2.1.3.9 Certification of quality management systems in organizations performing healthcare activities according to SIST EN 15224:2017 (identical with EN 15224:2016)

The assessment relates to the scope of accreditation defined by fields of activity as stated in D05-11.

In assessing a certification body for quality system certification in healthcare organizations (the scope of the quality system can be extended to research and training processes in healthcare), attention shall be paid to:

- the definition of the requirements for competence for all functions in the certification process in accordance with ISO/IEC 17021-1, Table A1, and ISO/IEC 17021-3, 4;
- competence of the auditors: general competence according to EN ISO/IEC 17021-1:2015, 7, and specific knowledge according to ISO/IEC 17021-3:2017, 5; specific knowledge in various healthcare services, and complying with the requirements for new knowledge (role of management, process approach, risk-based thinking, organizational context); knowledge and understanding of clinical processes and their risk control;
- the definition of the requirements for other personnel according to ISO/IEC 17021-3:2017, 6; the need for specific knowledge in various healthcare services.

2.2 Witnessing the performance of audits

Witnessing of audits shall be aimed at verifying the efficiency of the certification procedure (appointing the appropriate auditors, correct definition of the audit time), the appropriateness of setting the scope of certification and establishing the competence of auditors (compliance with the audit procedure, demonstration of the appropriate knowledge and understanding of the certification criteria, presence of suitable auditing skills, and ability to audit the fulfilment of the relevant criteria), and at providing a representative sample for the assessment of competence of the certification body.

The assessors shall only observe the audit and shall not influence its proceeding by their actions, or ask questions to the auditee, or express their opinions.

Before starting the witnessing of an audit, the certification body whose audit is to be witnessed shall provide: the report from previous audit; an audit programme with information on auditors and audit sites; information on the competence of the auditors included in the audit to be witnessed; calculation of audit time, when relevant; a description of the client's organisation, activity; and other, i.e. the quality and food safety management manual (HACCP manual, HACCP studies) and a list of OHSAS risks and OHSAS legal requirements for the organization being witnessed. The assessor shall assess the documents provided and adapt the assessment accordingly.

When witnessing/assessing the performance of auditor team, the assessors shall closely monitor (ISO/IEC 17021-1:2015, 9.4):

- the performance/mutual co-operation of the members of auditor team (including observers, interpreters …), team leading (controlling changes in plan);
- the knowledge of auditing/verification procedures and techniques;
- the way of communicating with the client (initial (contents), closing meeting (contents, attendance list), control of contingencies);
- the capability of obtaining substantial evidence (asking proper questions and focusing on the important requirements);
- the knowledge of the certification requirements (for a product/product group and the requirements for conformity of a product/product group, knowledge of specific requirements for certification of

different management systems, knowledge of the national environmental requirements; knowledge of the requirements for the competence of the client's staff and the requirements for the competence of certified staff);

- the reporting of findings (correct definition of a finding; nonconformities shall not be reported in terms of possibilities for improvement; a finding shall refer to the criterion and the evidence);
- coordination of different opinions regarding findings; any disagreements should be recorded; and
- the duration, appropriateness of the audit programme (relevance of sites, coverage of the scope).

Within two weeks after the conclusion of the audit, which was witnessed by SA assessors, the certification body shall submit to SA its report prepared for the management of the auditee organisation. The assessor team shall prepare a report on witnessing the audit (form OB05-43), which shall include information on implementation of the certification procedure, on the audit carried out, the performance and competence of the auditor team, and also information on evaluation of the contents of the subsequently sent report. Particular attention should be paid to the contents of the report (nonconformities shall not be reported in terms of possibilities for improvement; findings shall refer to the criterion and the evidence, conclusions, declarations of conformity …) (ISO/IEC 17021-1:2015, 9.4.8).

When witnessing an audit, the assessors shall assess the performance of the complete auditor team.

When possible, the assessors shall inform the auditors of the witnessing results immediately after the audit in the company has been completed, but without the presence of the auditee.

Note: The certification body's client shall be responsible for the safety of assessors while witnessing the audit and shall inform all the participants of the measures taken. Should SA's assessors perceive potential risk of damage during the course of the audit, they shall take immediate action and request to meet with the lead auditor.

In the event that, prior to the assessment, the certification body has not yet performed certification from the scope of accreditation, the continuation of the certification procedure shall be assessed in at least one of the observed procedures, or an assessment of the confirmation of the acceptability of corrective actions and decisions shall also be performed. The results shall be entered in OB05-43.

3 SCOPE OF THE ASSESSMENT (IN RELATION TO THE OVERALL SCOPE OF THE CERTIFICATION BODY'S ACCREDITATION)

3.1 Vertical audits

3.1.1 Certification body operating certification of management systems

At the initial assessment of a certification body for management systems, at least four procedures of certification for each management system (management system standard) shall be assessed through vertical audits, as follows:

- ISO 9001 – the selection shall be made from among the most critical or complex groups of sectors (IAF MD 5) from the scope of accreditation;
- ISO 14001 – the selection shall be made from among the most critical or complex groups of sectors (IAF MD 5) from the scope of accreditation;
- ISO 50001 – the selection shall be made from among the clients with high (e.g. (IAF ID1) 1, 3, 7, 11, 13, 15, 20, 21, 22 …) or complex energy usage (e.g. (IAF ID1) 2, 10, 12, 17, 25);
- ISO 22000 – the selection shall be made from among the clients with high level of risk to food safety;

- OHSAS – the selection shall be made from among the clients with high/higher level of risk to health and safety at work, or where hazardous substances, possibility of explosion or high physical burdens are present (IAF MD 5, Annex C, Table OH&SMS 2);
- ISO 13485 – the selection shall be made from among the clients with medical devices with high level of risk (GHTF, Category C and D);
- EN 15224 – the healthcare activities with a higher risk to the patient's health shall be selected.

For certification schemes which are a combination of the basic scheme (management system standard) and additional requirements, at least one certification procedure shall be assessed through vertical audit in initial assessment and in re-assessments of the management system certification body.

The selection shall also include cases of multi-site organisations, cases involving transfer of certificates, and cases of certification procedures carried out abroad, as well as initial audits, surveillance audits and integrated audits.

Vertical audits for each management system shall be carried out during regular surveillance visits, as planned in the Witnessing and Vertical Audits Plan. Upon changing the Vertical Audits Plan, it should be taken into account that all the IAF ID sectors/groups/technical fields for each management system within the scope of accreditation shall be examined within one accreditation cycle, when not looked at earlier during the witnessing of audits. Changes shall be recorded, as appropriate, in the form Witnessed and Vertical Audits Plan.

In vertical audit, attention should also be paid to the following:

- how the findings and conclusions are presented (nonconformities shall not be reported in terms of possibilities for improvement; findings shall refer to the criterion and the evidence) (ISO/IEC 17021-1:2015, 9.4.5); and
- documentation of verification of the efficiency of corrections and corrective actions (ISO/IEC 17021-1:2015, 9.4.10).

3.1.2 Certification body operating certification of products/processes/services

In a certification body for products, the assessors shall assess through vertical audits, at the initial assessment and re-assessments for individual scheme, the representative part of certification procedures for those products, services or processes that are more critical in terms of protection of health of people, animals, nature, and protection of property. The selection shall also include cases of multi-site organisations, cases of certification procedures carried out abroad, as well as initial audits and surveillance audits.

Regular surveillance visits shall include at least one vertical audit for each certification scheme, so that all the sectors/groups within the accreditation schemes are examined in one accreditation cycle. A comprehensive review of the vertical audits carried out shall be documented in the Witnessed and Vertical Audits Plan.

In certification bodies for **organic production and processing**, vertical audits shall comply with the provisions from EA-3/12 tables.

At the initial assessment of certification bodies for **protected agricultural products and foodstuffs**, **aromatised wine products, grapevine products and spirits**, a representative part of the certification procedures, or at least one procedure in the field of agricultural products and foodstuffs and in the field of

wine products and spirits shall be examined. At least one example for each category from the scope of accreditation shall be looked at through vertical audit within one accreditation cycle.

3.1.3 Certification body operating certification of persons

At the initial assessment and re-assessment of a certification body for persons, a representative number of procedures for individual groups, methods, levels of persons' competence and procedures carried out at different sites, shall be assessed through vertical audits.

At least one vertical audit shall be carried out for individual certification scheme during regular surveillance all by considering the above criteria for selection and making sure that all the groups from the scheme included in the scope of accreditation have been examined in one accreditation cycle.

When selecting cases for vertical audit, the planned assessments of audit performance shall be taken into account so that an even representation of the accredited activity is provided in the sample under assessment. A comprehensive review of the vertical audits carried out shall be documented in the Witnessed and Vertical Audits Plan.

3.2 Witnessing audits

3.2.1 Certification body operating certification of management systems

In initial assessment or extension of accreditation for management systems according to ISO 50001, ISO 9001, ISO 14001 and ISO 45001, the activities in **bold print** or those under the heading "Critical Code" in the tables below require obligatory witnessing before grant of accreditation.

Then accreditation cycles follow (three consecutive surveillances and a re-assessment).

During the first five years after granting the accreditation for management systems according to ISO 9001, ISO 14001 and ISO 45001, at least one witnessing of the activity from each technical group for each management system shall be carried out.

In other management systems, witnessing is considered to be planned so that each activity is witnessed at least once in an accreditation cycle, unless otherwise specified.

In making the selection, the criteria from IAF MD 17 and other sector-specific documents shall be complied with, in addition to the directions for individual schemes specified below.

When a technical group has 1 critical code only, the witnessing of the audit shall be carried out at that critical code for the purpose of granting accreditation for all IAF codes in that group. Witnessing of the activities in the critical code area is mandatory in initial assessment or in extension of accreditation.

When a technical group has more than 1 critical code, witnessing shall be carried out in the following way:

a) when all critical codes are delimited by "and", witnessing shall be carried out for all the stated critical codes prior to granting accreditation, and accreditation may be granted for all non-critical IAF codes in the technical group;

b) when some of the critical codes are delimited by "or", one witnessing shall be carried out from among those delimited by "or", and accreditation may be granted for both the critical codes and the other non-critical IAF codes.

In the case that a certification body seeks to obtain accreditation for the non-critical IAF codes from the technical group only, at least one witnessing for individual technical group for each management system shall be carried out.

In a quality management system, environmental management system and occupational health and safety system, when the certification body seeks to obtain accreditation for the non-critical IAF codes only, the audits from the highly complex activity groups with respect to the specific risks (IAF MD 5) of the scope applied for shall be selected.

In energy management system, when the certification body seeks to obtain accreditation for a technical field not comprising activities in bold print, the audits in a client with at least average complexity (calculated to ISO 50003:2021, Annex A, A.4) within the technical field shall be selected. Audits can be combined.

The rules of selection for witnessing in food safety management system scheme to ISO 22000 are specified under 3.2.1.8.

In the case of "combined" schemes (End-of-Waste, ISO 9001 with HACCP …) at least one audit shall be witnessed in initial assessment and re-assessment, and the witnessing in the combined scheme shall also be taken into account *mutatis mutandis* in witnessing the certification according to the basic scheme.

At least one of the planned witnessed audits within the context of an accreditation cycle should be (if possible) an initial audit (first and second level).

Audits can be integrated.

When the certification body demonstrates sufficient experience and improvements in performing audits, any of the planned witnessing may be replaced by a different way of assessment in order to make sure that every group/technical field/cluster in individual scheme is witnessed during two consecutive accreditation cycles. SA shall document the reasons for deviation from the basic principles of planning witnessing.

In the case of significant changes in certification body (auditor training process, change of auditing procedure, results of witnessing, change of personnel, …) the Witnessing and Vertical Audits Plan shall be revised, and the frequency of witnessing changed.

3.2.1.1 Certification body for quality systems

The scope of accreditation for a quality systems certification body is divided into 39 activities (IAF ID 1), which are classified, *mutatis mutandis,* by the nature of activity, the relevant legislation, technical details of the process and the required competence of auditors, into the following groups:

Technical Group (QMS)	**IAF Code**	**IAF ID 1 Description of economic sector/activity**	**Critical Code**
Food	1	Agriculture, forestry and fishing	**3**
	3	Food products, beverages and tobacco	
	30	Hotels and restaurants	
Mechanical	17	Basic metals and fabricated metal products	**22 or 20**
	18	Machinery and equipment	
	19	Electrical and optical equipment	

Technical Group (QMS)	IAF Code	IAF ID 1 Description of economic sector/activity	Critical Code
	20	Shipbuilding	
	22	Other transport equipment	
Paper	7	(limited to) Paper products	**9**
	8	Publishing companies	
	9	Printing companies	
Minerals	2	Mining and quarrying	**2 or 15**
	15	Non-metallic mineral products	
	16	Concrete, cement, lime, plaster, etc.	
Construction	28	Construction	**28**
	34	Engineering services	
Goods production	4	Textiles and textile products	**5 or 14**
	5	Leather and leather products	
	6	Wood and wood products	
	14	Rubber and plastic products	
	23	Manufacturing not elsewhere classified	
Chemicals	7	(limited to) Pulp and paper manufacturing	**12**
	10	Manufacture of coke and refined petroleum products	
	12	Chemicals, chemical products and fibres	
Supply	25	Electricity supply	**26**
	26	Gas supply	
	27	Water supply	
Transport & Waste management	24	Recycling	**24**
	31	Transport, storage and communication	
	39	Other social services	
Services	29	Wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods	**37 or 33**
	32	Financial intermediation; real estate; renting	
	33	Information technology	
	35	Other services	
	37	Education	
	36	Public administration	
Nuclear	11	Nuclear fuel	**11**
Pharmaceutical	13	Pharmaceuticals	**13**
Aerospace	21	Aerospace	**21**
Health	38	Health and social work	**38**

3.2.1.2 Certification body for certification of systems to End-of-Waste regulations

The witnessing plan shall ensure that at least one audit to individual regulation is witnessed within the framework of one accreditation cycle.

3.2.1.3 Certification body for certification of quality systems to ISO 9001 and HACCP

The witnessing plan shall ensure that at least one audit to this scheme is witnessed within the framework of one accreditation cycle.

3.2.1.4 Certification body for environmental management systems

The scope of accreditation for an environmental management systems certification body is divided into 39 activities (IAF ID 1), which are classified, *mutatis mutandis*, by the nature of activity, the relevant legislation, technical details of the process and the required competence of auditors, into the following groups:

Technical group (EMS)	**IAF Code**	**IAF ID 1 Description of economic sector/activity**	**Critical Code**
Agriculture, forestry and fishing	1	Agriculture, forestry and fishing	**1**
Food	3	Food products, beverages and tobacco	**3**
	30	Hotels and restaurants	
Mechanical	17	(limited to) Fabricated metal products	**20 or 21**
	18	Machinery and equipment	
	19	Electrical and optical equipment	
	20	Shipbuilding	
	21	Aerospace	
	22	Other transport equipment	
Paper	7	(limited to) Paper products	**9**
	8	Publishing companies	
	9	Printing companies	
Construction	28	Construction	**28**
	34	Engineering services	
Goods production	4	Textiles and textile products	**4 and 5**
	5	Leather and leather products	
	6	Wood and wood products	
	23	Manufacturing not elsewhere classified	
Chemicals	14	Rubber and plastic products	**7 and 10 and 12 and 13**
	7	(limited to) Pulp and paper manufacturing	
	10	Manufacture of coke and refined petroleum products	
	12	Chemicals, chemical products and fibres	
	13	Pharmaceuticals	
	15	Non-metallic mineral products	
	16	Concrete, cement, lime, plaster, etc.	
	17	(limited to) Base metals production	
Mining and quarrying	2	Mining and quarrying	**2**
Supply	25	Electricity supply	**25 or 26**
	26	Gas supply	
	27	Water supply	

Technical group (EMS)	IAF Code	IAF ID 1 Description of economic sector/activity	Critical Code
Transport & Waste management	24	Recycling	**24 and 39 (limited to NACE 37, 38.1, 38.2, 39)**
	31	Transport, storage and communication	
	39	Other social services	
Services	29	Wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods	**29 or 35 or 36**
	32	Financial intermediation; real estate; renting	
	33	Information technology	
	35	Other services	
	37	Education	
	36	Public administration	
Nuclear	11	Nuclear fuel	**11**
Healthcare	38	Healthcare and social work	**38**

3.2.1.5 Certification body for energy management systems

The scope of accreditation of a certification body for energy management systems is divided into 8 technical fields, as follows:

Technical Field (EnMS)	IAF ID 1	NACE Codes	Description
Industry – light to medium	3	10, 11, 12	Food products, beverages and tobacco
	4	13, 14	Textiles and textile products
	5	15	Leather and leather products
	6	16	Wood and wood products
	7	17.2	**Manufacture of pulp and paper**
	8	58.1, 59.2	Publishing companies
	13	21	Pharmaceuticals
	18	28, 33.12	Machinery and equipment
	19	26, 33.13, 33.14, 95.1	Electrical and optical equipment
	23	31, 32, 33.19	Manufacturing not elsewhere classified
	24	38.3	Recycling
	27	36	Water supply
	28	41, 42, 43	Construction

Technical Field (EnMS)	IAF ID 1	NACE Codes	Description
	29	45, 46, 47, 95.2	Wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods
	30	55, 56	Hotels and restaurants
	31	52, 61	Storage and communication
Industry - heavy	7	17.1	**Manufacture of paper products**
	10	19	**Manufacture of coke and refined petroleum products**
	11	24.46	**Nuclear fuel**
	12	20	**Chemicals, chemical products and fibres**
	13	21	Pharmaceuticals
	15	23 (except 23.5, 23.6)	**Non-metallic mineral products**
	16	23.5, 23.6	**Concrete, cement, lime, plaster, etc.**
	17	24 except 24.46, 25 except 25.4, 33.11	**Basic metals and fabricated metal products**
	18	25.4, 30.4, 33.2	Machinery and equipment
	19	27	Electrical and optical equipment
	20	30.1, 33.15	Shipbuilding
	21	30.3, 33.16	Aerospace
	22	29, 30.2, 30.9, 33.17	Other transport equipment
	28	41, 42, 43	Construction
Buildings	32	64, 65, 66, 68, 77	Financial intermediation; real estate; renting
	33	58.2, 62, 63.1	Information technology
	34	71, 72, 74 except 74.2 and 74.3	Engineering services
	35	69, 70, 73, 74.2, 74.3, 78, 80, 81, 82	Other services
	36	84	Public administration

Technical Field (EnMS)	IAF ID 1	NACE Codes	Description
	37	85	Education
	38	75, 86 (except 86.1), 87, 88	Health and social work
	39	37, 38.1, 38.2, 39, 59.1, 60, 63.9, 79, 90, 91, 92, 93, 94, 96	Other social services
Building complexes	36	84	Public administration complexes
	37	85	Educational complexes
	38	86.1	Hospitals
Transport	1	03	Fishing
	31	49, 50, 51, 53	Transport
Mining	2	05, 06, 07, 08, 09	**Mining**
Agriculture	1	01, 02	Agriculture and forestry
Energy supply	25	35.1	Electricity supply
	26	35.2	Gas supply
	27	35.3	Water supply

3.2.1.6 Certification body for occupational health and safety management systems

The scope of accreditation for occupational health and safety systems certification body is divided into 39 activities (IAF ID 1), which are grouped, *mutatis mutandis*, by the nature of activity into the following groups:

Technical group (OH&SMS)	**IAF Code**	**IAF ID 1 Description of economic activity**	**Critical Code**
Agriculture, forestry and fishing	1	Agriculture, forestry and fishing	**1**
Food	3	Food products, beverages and tobacco	**3**
	30	Hotels and restaurants	
Mechanical	17	(limited to) Fabricated metal products	**20 and 21**
	18	Machinery and equipment	
	19	Electrical and optical equipment	
	20	Shipbuilding	
	21	Aerospace	
	22	Other transport equipment	
Paper	7	(limited to) Paper products	**9**

Technical group (OH&SMS)	IAF Code	IAF ID 1 Description of economic activity	Critical Code
	8	Publishing companies	
	9	Printing companies	
Construction	28	Construction	**28**
	34	Engineering services	
Goods production	4	Textiles and textile products	**[4 (with dyeing) and 5 (with tanning)] or 6**
	5	Leather and leather products	
	6	Wood and wood products	
	23	Manufacture not elsewhere classified	
Chemicals	7	(limited to) Pulp and paper manufacturing	**[7 and 10 and 12 and 13 and 16] or 17**
	10	Manufacture of coke and refined petroleum products	
	12	Chemicals, chemical products and fibres	
	13	Pharmaceuticals	
	14	Rubber and plastic products	
	15	Non-metallic mineral products	
	16	Concrete, cement, lime, plaster, etc.	
	17	(limited to) Basic metals production	
Mining and quarrying	2	Mining and quarrying	**2**
Supply	25	Electricity supply	**25 or 26**
	26	Gas supply	
	27	Water supply	
Transport & Waste management	24	Recycling	**[31 (limited to dangerous goods) and 24] or 39 (limited to NACE 37, 38.1, 38.2, 39)**
	31	Transport, storage and communication	
	39	Other social services	
Services	29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	**29 or 35 or 36**
	32	Financial intermediation; real estate; renting	
	33	Information technology	
	35	Other services	
	37	Education	
	36	Public administration	
Nuclear	11	Nuclear fuel	**11**
Health	38	Health and social work	**38**

3.2.1.7 Certification body for medical device quality management systems

Within the scope of initial assessment, witnessing of at least one audit of medical devices from each main field of medical devices shall be planned, whereby a manufacturer of medical devices with high degree of risk (GHTF, Categories C and D) shall be selected for each main field. In the case of extension to a new main field of medical devices, at least one witnessing shall be carried out. The witnessing plan shall ensure that at least one audit from each main technical field from the scope of accreditation (non-active medical devices, active medical devices (non-implantable), active implantable medical devices, IVD medical devices, sterilization methods for medical devices, devices containing/using special substances/technologies, parts or services …) is witnessed in the context of one accreditation cycle. Groups of products with high degree of risk shall have priority.

3.2.1.8 Certification body for food safety management systems

In this certification body, IAF MD 16 shall be complied with when defining the witnessing of audits. The certification scope shall be grouped in clusters of categories, as follows:

1. Farming (A+B)
2. Food and feed processing (C+D)
3. Retail trade, transport and storage (F+G)
4. Hotel and restaurant services (E)
5. (Bio-)chemical manufacturing (K)
6. Support services (H+I+J).

The grant/extension of accreditation for a category shall not be possible without witnessing at least one audit in the cluster. Priority shall be given to a higher risk sector in assuring safe food. Witnessing is not mandatory for extension to a category within the cluster. Audits from all clusters shall be witnessed during one accreditation cycle.

During each witnessing (surveillance, re-assessment) of the certification body, the audit in the cluster 2 shall be witnessed.

Witnessing of categories in other clusters shall be planned so as to witness at least one category in each cluster within the context of accreditation cycle. At least one witnessing in the accreditation cycle shall cover witnessing of audit level 1 and 2.
The above-mentioned shall be the minimum requirements that SA will adapt to the specific situation in individual certification body.

3.2.1.9 Certification body for certification of quality management systems in organizations active in the field of healthcare services according to SIST EN 15224

The scope of certification has been classified into 8 fields of activity in healthcare.

At least two audits to SIST EN 15224 shall be witnessed within the scope of initial assessment. The more critical fields from the point of view of human health shall have priority. The witnessing plan shall ensure that at least one audit from each field of activity being the object of accreditation is witnessed within the framework of one accreditation cycle.

Field of activity
Basic healthcare activity
Activity of specialist outpatient clinics
Hospital activity
Activity of clinics and clinical departments
Public health and related activities
Medical emergency
Pharmacies
Healthcare activity within a social welfare institution

Grant/extension of accreditation to a new field of activity shall not be possible without witnessing at least one audit in the field of activity being the object of extension.

3.2.2 Certification body operating certification of products/processes/services

The initial assessment and the re-assessment of individual scheme of a certification body for products/processes/services shall involve, if not provided otherwise, the witnessing of a representative part of the audits/inspections of those products, services and processes which are more critical in terms of protection of health of humans and animals, protection of nature and protection of property, or at least two audits/inspections at the manufacturers, when possible.

Further planning of witnessing, when not otherwise specified, shall meet the requirement that all the activities from the scope of accreditation shall be witnessed in the context of the accreditation cycle (three consecutive surveillances and reassessment).

In certification bodies for **organic production and processing** in EU Member States, at least one witnessing shall be performed in the context of initial assessment and reassessment in each category of products applied for, and at least one witnessing in the group certification, if that is the case. Additional factors contributing to the definition of the number of witnessing are the criticality of findings and the number of countries in which the certification body is operating, and the number of certificates granted. At least one audit shall be witnessed in each category of products and at least one audit in the group certification within a period of 5 years. Factors referred to in EA-3/12 shall be complied with when determining any additional witnessing. The audits in relation with which the certification body assesses higher risk shall be selected for witnessing; witnessing shall be carried out during the time when the crops are at the site of inspection, and different inspectors shall be witnessed at work. The results of previous witnessing shall be taken into account when making the selection.

In the case of extensions to other categories of products, at least one inspection in each new category shall be witnessed (EA-3/12 M, 3.8).

In certification bodies for **organic production and processing** in third countries, the provisions of EA-3/12, clause 4, shall be complied with.

At the initial assessment of certification bodies for **protected agricultural products and foodstuffs**, **aromatised wine products, grapevine products and spirits**, at least one procedure within the scope of individual category being the object of application shall be witnessed.

In an exceptional case, when the certification body is not in a position to carry out certification procedure because it has not yet acquired the authorization, accreditation may be granted as conditional until the witnessing by SA has been carried out. Should the result of witnessing be negative, a reduction of the scope of accreditation shall follow.

In the case that non-accredited testing is included in the certification procedure, SA shall carry out assessment of the testing laboratory as well.

Within the framework of one accreditation cycle, the procedures for all the accredited categories shall be witnessed, and the non-accredited laboratory shall be assessed at least once.

When the certification body seeks to extend its activity to a new product category, the certification procedure shall be witnessed. Extension inside an already accredited product category can be assessed according to the documentation.

3.2.3 Certification body operating certification of persons

The initial assessment and the re-assessment of a certification body for persons shall involve the witnessing of a representative number of procedures for individual groups, methods, levels of competence of persons, or at least two certification procedures for persons. The site of performing the certification procedure shall also be considered when making the selection.

Regular surveillance shall involve witnessing of at least one audit in the context of individual certification scheme. Witnessing of audits during the surveillance visits shall be carried out according to a programme prepared by the Sector Manager together with the assessors after the conclusion of the initial assessment. It shall be provided for that each group of activities, products, services, processes, and each group of persons from the scope of accreditation has been witnessed between two re-assessments, and that the supervising activity has been witnessed at least once during this time. A multi-site organisation shall be taken into consideration when planning.

The assessor team shall define, for each surveillance, which field from a group of activities, or which auditor they want to witness, all by taking into account the diversity of activities and auditors. If possible, the witnessing of audits should be carried out during the assessment at the certification body's head office, if not, between two surveillance visits.

The share of certificates issued abroad shall also be considered in planning the witnessing of all certification bodies.

4 RECORDS

Each assessor shall note his/her records about the assessment carried out on the assessment checklists (form OB05-78 for certification bodies for products/processes/services; form OB05-60 for certification bodies for persons; form OB05-58 for certification bodies for management systems), so that it is clear what is the scope and which is the assessment method of single system elements against the requirements of the relevant standards and guides for certification bodies, as well as any possible general findings and specific comments, and references to the nonconformities found. The precise defining of field (e.g., IAF ID activity for individual management system, group of persons and the standard, product certification scheme and the standard …) shall be of particular importance for the vertical audits carried out.

A mandatory supplement to the lead assessor’s checklist shall be the form OB05-68 – Cross-border activities of certification body/verifier and a list of foreign locations.

A mandatory supplement to the technical assessor’s assessment checklist is the form OB05-43, “Report on witnessing of audit/verification”. The report shall be prepared separately for each procedure witnessed.

5 CHANGES WITH REGARD TO PREVIOUS REVISION

In item 2.1.1, an element of assessment of certification body for products/processes/services relating to certification scheme has been added.

Item 2.1.1.2 has been added for certification of protected agricultural products and foodstuffs, aromatised wine products, grapevine products and spirits, with instructions for assessment.

Item 2.1.1.5 has been added with directions for assessment in the field of quality system certification in fusion welding of metallic materials according to SIST EN ISO 3834.

Item 2.1.3.9 has been added with directions for assessment in the field of quality management systems certification in organizations performing healthcare activities according to SIST EN 15224:2017.

In item 3.1.1, the principle for selection of vertical audits in EN 15224 has been added.

In item 3.1.2, rules have been added for carrying out vertical audits for organic production and processing and for protected agricultural products and foodstuffs, aromatised wine products, grapevine products and spirits.

In item 3.2.1.7, a rule has been added for extension of accreditation to a new main field of medical devices.

Item 3.2.1.9 has been added specifying the rules for selection of cases for witnessing in the field of certification of quality management systems in organizations performing healthcare activity.

In item 3.2.2, rules have been added for determining examples for witnessing in the field of certification of organic production and processing in third countries, and in certification of protected agricultural products and foodstuffs, aromatised wine products, grapevine products and spirits.

6 TRANSITORY PROVISIONS

N/A.

7 CONTROL OF THE DOCUMENT

A valid document shall be kept in i4 (SA Information System). A clean copy shall be published on SA's website and available in printed form at SA's head office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies of the document shall have an informative character and are not controlled copies. The validity of these documents should be checked in i4 or on SA's website.