

Consolidated version of

The Swedish Board for Accreditation and Conformity Assessment's (SWEDAC) Regulations and General Guidelines for Accredited Bodies that Certify Management Systems

The translation includes the following amendment STAFS 2012:2

Scope

1 § These regulations apply to bodies that are accredited or bodies applying for accreditation by SWEDAC to certify management systems for:

1. occupational health and safety (henceforth called OH&S),
2. energy,
3. information security,
4. quality,
5. food safety, or
6. environment.

These regulations are a supplement to SWEDAC's Regulations (STAFS 2007:7) and General Guidelines for Accreditation.

For some of the application fields, the regulatory authorities or SWEDAC in consultation with the regulatory authorities, have issued more detailed special regulations that supplement these regulations. (STAFS 2008:6)

Definitions

2 § These regulations use the definitions given in:

1. ISO/IEC 17021:2006 - *Conformity assessment – Requirements for bodies providing audit and certification of management systems*,
2. ISO/IEC 27006:2007 - *Information technology - Security techniques - Requirements for bodies providing audit and certification of information security management systems*, and
3. ISO/TS 22003:2007 – *Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems*. (STAFS 2008:6)

Requirements in standards and other documents

3 § Accredited certification bodies that certify management systems for OH&S, energy, quality and environment shall fulfil the requirements set out in ISO/IEC 17021:2006.

4 § Accredited certification bodies that certify information security management systems shall fulfil the requirements set out in the standards ISO/IEC 17021:2006 and ISO/IEC 27006:2007. (STAFS 2008:6)

5 § Accredited certification bodies that certify food safety management systems shall fulfil the requirements set out in ISO/IEC 17021:2006 and the document ISO/TS 22003:2007. (STAFS 2008:6)

6 § Accredited certification bodies that certify management systems shall also fulfil the requirements in the guidelines, regarding the application of the aforementioned standards and documents, which are published by the European Co-operation for Accreditation (EA) and the International Accreditation Forum (IAF). The current list of guidelines that are mandatory to fulfil are found in *appendix 1* to these regulations. (STAFS 2008:6)

7 § Normative documents, according to which certification under accreditation may be performed, must be one of the following kinds of document:

1. a national or international standard for management systems,
2. a standard in accordance with the above in combination with interpretative documents,
3. other kinds of document

that are unambiguous, available to the public and approved by SWEDAC and other interested parties involved.

Application for accreditation

8 § The application shall detail the proposed accreditation scope in the form of normative documents and sectors (industry sectors). The certification body shall have procedures to analyse the competence needs and to ensure their competence for the accreditation scope applied for. The result of the certification body's evaluation of available competence for each accreditation scope shall be enclosed with this application.

Assessment before the decision on accreditation and surveillance

9 § A certification body shall, in connection to new accreditation, provide SWEDAC with the opportunity of participating as an observer as part of accreditation assessment for at least two certifications, carried out in accordance with the procedures of the certification body.

An accredited certification body shall give SWEDAC the opportunity to participate as an observer of certifications as part of the annual surveillance.

Withdrawal of accreditation

10 § If an accredited certification body fails to comply with the conditions for accreditation, SWEDAC, by virtue of the Act (1992:1119) on Conformity Assessment, may decide to suspend the right of the certification body to cite

accreditation for a limited time, until it once more fulfils the accreditation conditions.

If the accredited certification body in accordance with the above is not allowed to issue new certificates, the certification body shall still carry out surveillance and other commitments concerning previously issued certificates in accordance with its regular plans.

Use of the accreditation mark and other references to accreditation

11 § An accredited certification body may provide a company that has received certification for its management system the right to reproduce the accreditation mark along with the certification body's name or mark. The certification body shall follow up to ensure that these marks are used in accordance with the applicable regulations.

12 § An accredited certification body that provides companies with the right to reproduce the accreditation mark in accordance with 11 § shall ensure that the mark is not used in any way or under any conditions that could lead to misunderstanding about the scope or content of accreditation.

If the certification body is made aware of the fact that the accreditation mark is being used in violation to the first paragraph, the body shall demand immediate rectification and inform SWEDAC of what has occurred.

The certification body shall ensure that the accreditation mark, granted in accordance with 11 §, is not used once the certification has ceased to apply.

13 § If a company's management system is certified, and this certification also includes laboratory activities, the accreditation mark may only be used on laboratory reports if the laboratory is accredited.

Special regulations for accredited bodies that certify OH&S management systems

14 § An accredited certification body shall ensure that organisations that apply for certification follow the applicable laws and other requirements relating to the OH&S. In addition, organisations that have or are applying for certification must draw up, introduce and maintain procedures in order to:

1. identify and have access to applicable laws and other requirements affecting the organisation and which are connected to the OH&S factors of the organisation,
2. decide how the requirements apply to the organisation's OH&S factors,
3. carry out risk assessments, and
4. regularly evaluate and document that applicable laws and other requirements are being followed.

15 § An accredited certification body shall ensure that the organisation applying for certification has a documented OH&S policy and a documentation level for governing and reporting documents that is sufficient to verify conformity with the current normative documents.

An accredited certification body shall ensure that the organisation maintains procedures for governing and handling of governing and reporting documents. (STAFS 2008:6)

Written documentation of the OH&S policy, procedures, task distribution and follow-up of OH&S work must exist even if the number of employees is less than ten.

16 § Employee representatives shall be provided with the opportunity to contribute during certification and follow-up audits.

Miscellaneous

17 § Certifications issued prior to the accreditation decision may be given validity as certification under accreditation if the certification body reviews the certifications in accordance with the conditions applicable to accreditation. Such reviews shall be documented.

18 § If an accredited certification body becomes aware of circumstances that imply that a certified organisation or an organisation seeking certification is judged untrustworthy for the task it has been certified or applying for certification, then the certification body shall consider whether there is reason to abort the certification process or withdraw the issued certificate. These circumstances also relate to conditions that do not relate to the current nature of the certification standard.

19 § In individual cases and if special circumstances so require, SWEDAC may grant dispensation from these regulations.

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1. These regulations come into force on 1 June 2007, on which date the Board's regulations (STAFS 2002:1) for Accredited Bodies that Certify Information Security Management Systems will cease to apply.
 2. Older SWEDAC's Regulations (STAFS 2002:3) for Accredited Bodies that Certify Quality Management Systems, (STAFS 2004:5) for Accredited Bodies that Certify Environmental and/or Energy Management Systems and (STAFS 2005:12) for Accredited Bodies that Certify OH&S Management System still apply for situations that refer to the time before these regulations come into force.
 3. STAFS 2002:3, STAFS 2004:5 and STAFS 2005:12 and STAFS 2005:13 will cease to apply on 15 September 2008. (STAFS 2008:6)

On behalf of SWEDAC

HANS-ERIC HOLMQVIST

Roland Jonsson

The following EA and IAF documents apply for accredited certification bodies that certify management systems

1. EA-6/02:2007 – *EA Guidelines on the use of EN 45011 and ISO/IEC 17021 for certification to EN ISO 3834, rev 1,*
2. EA-7/04:2010 – *Legal Compliance as a part of Accredited ISO 14001:2004 certification,*
3. EA-7/05:2008 – *EA Guidance on the Application of ISO/IEC 17021:2006 for Combined Audits, rev 00,*
4. IAF MD 1:2007 – *IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling,*
5. IAF MD 2:2007 – *IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems,*
6. IAF MD 3:2008 – *IAF Mandatory Document for Advanced Surveillance and Recertification Procedures,*
7. IAF MD 4:2008 – *IAF Mandatory Document for the use of Computer Assisted Auditing Techniques (“CAAT”) for Accredited Certification of Management Systems,*
8. IAF MD 5:2009 – *IAF Mandatory Document for Duration of QMS and EMS audits och*
9. EA-3/11 – *Food Safety Management Systems Scope of Accreditation: De krav som avser certifieringsorgan i avsnitt 3 Criteria for including a particular category in the accreditaion scope (STAFS 2011:17) och*
10. IAF MD 9:2011 - *IAF Mandatory Document for the Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485).(STAFS 2012:2)*

Table 1: Scopes within which specific environmental knowledge is required
(STAFS 2008:6)

SNI/NACE code	Economic activity	EA code¹
A 01	Agriculture, hunting and related service activities	01
A 02	Forestry	01
A 03	Fishing and operation of fish hatcheries	01
B 05	Mining of coal	02
B 06	Extraction of crude petroleum and natural gas	02
B 07	Mining of metal ores	02
B 08	Other mining of minerals	02
C 10	Manufacture of food products	03
C 11	Manufacture of beverages	03
C 12	Manufacture of tobacco products	03
C 15.11	Tanning and dressing of leather, fur	05
C 16.1	Sawmilling and planing of wood	06
C 17	Manufacture of paper and paper products	07
C 19	Manufacture of coke, refined petroleum products	10
C 24.46	Nuclear fuel	11
C 20	Manufacture of chemicals and chemical products	12
C 21	Manufacture of pharmaceutical base products and medicine	13
C 22	Manufacture of rubber and plastic products	14
C 23.1-4, C 23.7-9	Manufacture of non-metallic mineral products (except cement, limestone, plaster etc)	15
C 23.5-6	Manufacture of cement, limestone, plaster etc	16
C 24 excl 24.46	Manufacture of steel and metals	17
C 29	Manufacture of vehicles, trailers and semitrailers	22
D 35.1	Electricity supply (power station)	25
D 35.2	Gas supply (gasworks)	26
D 35.3, E 36	Water supply	27
E 37	Sewage	39, part of
E 38.3	Recycling	24
E 39	Slum-clearance, after-treatment of soil and water and also other similar activities	39, part of
F 41	Building construction	28
F 42	Construction work	28
F 43	Specialized building and construction activity	28
H 49	Land transport, transport in pipe systems	31
H 50	Sea transport	31
H 51	Air transport	31
Q 86	Health and social work	38

Comments: specific environmental knowledge refers to eg deeper knowledge of the industrial processes and knowledge of which environmental aspects these processes may cause and also knowledge of different technical solutions and of environmental legislation that regulate the area.

¹ IAF GD 2:2005 – IAF Guidance on the Application of ISO/IEC Guide 62:1996 General Requirements for Bodies Operating Assessment and Certification/ registration of Quality Systems.

Table 2: Scopes within which specific energy knowledge is required
(STAFS 2008:6)

SNI/NACE code	Economic activity	EA code
B 07	Mining of metal ores	02
C 17	Manufacture of paper and paper products	07
C 19	Manufacture of coke products and refined petroleum products	10
C 24.46	Nuclear fuel	11
C 20	Manufacture of chemicals and chemical products	12
C 21	Manufacture of pharmaceutical base products and medicine	13
C 24 excl 24.46	Manufacture of steel and metals	17

Comments: specific energy knowledge refers to eg deeper knowledge of the industrial processes and knowledge of which energy aspects these processes may cause and also knowledge of different energy-saving technical solutions.

Guidelines

These guidelines are general recommendations for the application of regulations, stating how a party may or should act in a certain regard (see 1§ of the Statutory Ordinance [1976:725]).

Guidelines to 1 §

Certification activities in accordance with the Swedish Work Environment Authority's Regulations (AFS 2001:1) on systematic work environment do not restrict the Swedish Work Environment Authority's surveillance in every respect. The Swedish Work Environment Authority may perform surveillance and, when required, apply sanctions or other measures against an organisation even after it has been certified. (STAFS 2008:6)

Guidelines to 3-6 §§

Guidelines on the application of the standards for each field

Current versions of the guidelines can be downloaded from the EA website <www.european-accreditation.org>, the IAF website <www.iaf.nu> and also from the SWEDAC website <www.swedac.se>.

When using the standards and guidelines for certification within the fields of OH&S, energy and food safety, the nomenclature can be adapted to make it relevant to the specific field in question.

Reference to the section in ISO/IEC 17021:2006

Personnel involved in certification activities (section 7.2)

Special knowledge and skills of auditors that audit OH&S management systems

Auditors who audit OH&S management systems should have knowledge and skills in the areas set out below.

1. Methods for evaluating OH&S conditions to ensure that the auditor can review the OH&S management system and formulate suitable audit observations and conclusions. Knowledge and skills in this area should cover
 - a) terminology relating to OH&S
 - b) measurement methods
 - c) surveys and other evaluation tools
2. Knowledge of risk analyses and risk assessments so that the auditor can ask relevant questions and evaluate the company's work in this area.
3. Knowledge of risks of accidents, psychic and social aspects in the OH&S, load ergonomics, chemical OH&S factors, physical OH&S factors, thermal climate and biological factors. Knowledge of the level and extent to which an OH&S factor can be harmful to a human being.

Planning of audits (section 9.1.)

When planning audits, the procedures of the certification body for calculating man-days should follow the guidelines set out in the applicable guidance documents from the EA and IAF.

When the auditing of two management systems is coordinated, the reduction of the audit time (the total number of audit days) may not exceed 30% of the audit time for the activity with the least number of recommended man-days. If more than two management systems are included in a certification audit, the same principle will apply for the additional management systems. The reduction is then divided between the systems in a suitable way. The prerequisite is that management systems are integrated and the planning of the audit must ensure an effective use of the audit time.

Special considerations for OH&S management system audits

In the guidance documents from the EA and IAF the number of man-days is assessed, among others, on factors such as the number of employees and the complexity of the activities. This approach can be used for the OH&S management systems. Special knowledge of OH&S and the rules within the OH&S field is required to decide on the complexity from an OH&S perspective.

The following factors require an increase in the amount of time needed for the audits:

1. the activities contain many different personnel categories or organisational levels, or
2. the activities are complex as far as the OH&S is concerned, with many different risk moments and regulated by many different regulations from the Swedish Work Environment Authority and other authorities.

When auditing 'multisite' activities, the certification body should first receive and review the risk assessments from all units as well as the protocols from the organisation's internal audits before making a decision whether to apply 'sampling' and which selection should then be made. 'Multisite' and 'sampling' are described in detail in the respective guidance document.

Choice of period and form for storage of documents can be based on the risk assessments depending on the nature of activity, needs and possible requirements from authorities. (STAFS 2008:6)

The certification body should analyse how regulations in different statutes regarding secrecy and protection of personal integrity when handling personal data affect its own organisation and take proper measures. (STAFS 2008:6)

Only if, according to law, ordinance or authority's regulations, there is an obligation for the certification body to provide data, deviation from assigner's requirement regarding secrecy can be done. (STAFS 2008:6)

For energy management system audits in combination with environmental management systems, the following applies:

When the audit includes both environmental and energy management systems, the audit time is firstly based on the environmental management system, secondly additional time required for the evaluation of energy management. It is not likely that the additional audit time needed is less than 30% of the estimated time for the environmental management system. The calculations and reasons for the selections made should be documented.

For the information security management system audits, the following applies:

The certification body should have access to the Statement of Applicability. This description should include at least the following:

1. a compilation of all required elements that are relevant and applicable to the organisation's information security management system, and
2. a summary of the risk assessment that forms the basis of the Statement of Applicability.

Handling of nonconformities (section 9.1)

The following applies for the certification of the OH&S management system:

Irrespective of the number of classes of nonconformities that the certification body applies, one class should be related to nonconformities where there is a clear and immediate danger to health and/or safety. These nonconformities should be handled in the following way:

1. the lead auditor informs the company management of the nonconformities and recommends that the activities in the area concerned are stopped and, if so requested, that the organisation should contact the supervisory authority, and
2. the certification body should within a week verify or request to receive verification that the supervisory authority concerned has approved the measures taken by the organisation.

During a certification process, the certificate should not be issued until the acceptable measures have been taken. For surveillance audits/reassessments, action should normally be taken against any nonconformity in accordance with the certification body's procedures at the latest by the time of the next audit.

If there are reasonable grounds as to why action cannot be taken against a nonconformity in accordance with the aforementioned time frame, an action plan with a detailed schedule should be submitted to the certification body. For periodic audits, the certification body verifies that it has agreed with the approved action plan and schedule.

Guidelines to 7 §

The normative documents should primarily be national or international standards. If a different normative document is used, it should be drawn up in consultation with other interested parties. This alternative normative document should be replaced by a national or international standard as soon as such a standard is available.

A normative document must be unambiguous, which means that it should be so detailed and clearly designed that two certification bodies, independent of each other, would arrive at the same results. There is a list of the normative documents that SWEDAC has assessed as fulfilling the requirements on the SWEDAC website <www.swedac.se>.

Interpretative documents can be issued by the regulatory authorities and are available on the SWEDAC website <www.swedac.se>.

Guidelines to 8 §

Accreditation for a specific industry sector implies that the certification body, at management level, has the necessary knowledge to evaluate the competence needed for the specific sector and to compose suitable audit teams. It implies that the

certification body has the necessary competence to administer the certification process and to make correct decisions on certification.

It also implies that the certification body has access to audit personnel that have the necessary competence to perform audits within the main part of the activities within the industry sector. The certification body is always responsible for evaluating its conditions to perform certifications of activities with the conditions applicable for each case.

The following applies for the certification of the OH&S management systems:

Competence areas in the form of sectors should be selected to reflect the key processes and OH&S risks for the sector. Normally classification according to the Swedish Standard for Industrial Classification 2002 (SNI 2002), 2007 (SNI 2007), NACE or IAF GD 2:2005 – *IAF Guidance on the Application of ISO/IEC Guide 62:1996 General Requirements for Bodies Operating Assessment and Certification/registration of Quality Systems* codes (IAF GD 2:2005). (STAFS 2008:6)

The following applies for the certification of the energy management systems:

Competence areas in the form of sectors should be selected to reflect the key processes and energy aspects for the sector. Normally classification according to SNI 2007, NACE or codes according to IAF GD 2:2005 is used.

The competence generally required to perform audits of energy management systems is described in the interpretative documents to the standard. For most sectors, a significant part of the energy consumption is not included in the main process itself. The main part of the energy is used in the energy consumption system of the building (eg ventilation, lighting) and for the production support systems (eg pumps and compressed air) and transport. For these areas, energy aspects are often the same irrespective of the sector. However, some sectors differ from the others due to the fact that a large proportion of their energy consumption is used for the process and they have complicated energy-consuming processes. When auditing within these sectors, which are listed in accordance with the classification in SNI 2007, NACE or IAF GD 2:2005 codes in appendix 2, table 2, specific energy competence for the sector is required. (STAFS 2008:6)

The following applies for the certification of information security management systems:

Competence areas in the form of sectors should be selected to reflect the key processes and risk areas refer to the standard ISO/IEC 27006:2007, Annex A. Normally classification according to SNI 2007, NACE or IAF GD 2:2005 codes are used. (STAFS 2008:6)

The following applies for the certification of food safety management systems:

Competence areas in the form of sectors should be selected to reflect the key production areas and products of the sector, refer to the document ISO/TC 22003:2007, Annex A.

The following applies for the certification of quality management systems:

Competence areas in the form of sectors should be selected to reflect the key processes and products of the sector. Normally classification according to SNI 2007, NACE or IAF GD 2:2005 codes is used. (STAFS 2008:6)

The following applies for the certification of environmental management systems:

Competence areas in the form of sectors should be selected to reflect the key processes as well as the environmental and energy aspects of the sector. Normally classification according to SNI 2007 or IAF GD 2:2005 codes is used.

Generally a broad competence in environmental issues, audit experience, and knowledge of environmental legislation and environmental management systems are required to perform audits and certifications within the environmental area. For some sectors, sector-specific knowledge is required. The sectors, in accordance with the classification in SNI 2007 or IAF GD 2:2005 codes, that are judged to require sector-specific knowledge can be found in appendix 2, table 1. (STAFS 2008:6)

Guidelines to 9 §

As far as accredited certification tasks are concerned, SWEDAC's evaluation in connection with accreditation and surveillance will cover all activities associated with the tasks, such as reviews of contracts, pre-audits, certification audit stages 1 and 2, decisions, issuing of certificates and subsequent follow-up activities.

The certification body should, in connection with the application, and no later than two months before the arranged date of the audit, provide details of planned certification work.

Certification bodies should make sure through its customers that SWEDAC has the opportunity to participate as an observer in audits as part of the accreditation/surveillance assessment. As an observer SWEDAC should be given the opportunity to study the relevant information in advance. Before signing an agreement for a certification task, the certification body should ensure that the client understands these terms.

Guidelines to 15 §

The OH&S management system can be integrated with corresponding management systems for, for example, quality and environment, but no requirements are set for the organisation to be certified within any of these fields. Any certification of an OH&S management system of ships and shipping companies may not come into conflict with existing management systems such as the International Safety Management (ISM) code. The ISM code is regulated through the Swedish Maritime Administration's Regulations (SJÖFS 2002:8) on the Safety Organisation of Shipping Companies and Ships.

Guidelines to 18 §

Examples of the conditions set out in 18 § may be a breach of environmental or OH&S legislation and financial irregularities by an organisation that has a certified quality management system.

In the introductory phase of the certification process and during surveillance, a question about authority intervention and orders should be put to the organisation. The accredited certification body should also consider information from external sources. Procedures for such evaluation should be found in the certification body's quality system and conditions for evaluation should be regulated through an agreements between the certification body and the certified organisation.