1. Application

The accreditation regulation applies to all bodies which are or apply for accreditation to certification of Occupational Health and Safety Systems.

2. Validity

The accreditation regulation determines the interpretation of specific conditions in DS/EN ISO/IEC 17021, used with accreditation to certification of Occupational Health and Safety Systems.

The designation "shall" is used all the way through the document in order to state the conditions which are mandatory as they reflect the requirements in DS/EN ISO/IEC 17021. The designation “should” is used to indicate the regulations which the certification body is expected to comply with. Deviation from these is only permitted when the certification body has proven to DANAK that it complies with the requirements in the relevant item in DS/EN ISO/IEC 17021 in a similar way.

The specific regulations in AB 14 are identified with the letter “G” followed by the relevant entry from DS/EN ISO/IEC 17021. After this number follow a consecutive numbering of AB 14’s sub-sections from the entry in question.

3. Accreditation regulation with reference to: DS/EN ISO/IEC 17021

3. Terms and definitions

G. 3 – 1 In addition to the definitions in DS/EN ISO/IEC 17021 the following complies:

Accredited certificate:
A certificate issued by a certification body in accordance with the conditions of its accreditation. The certificate shall contain accreditation mark or other reference to the accreditating body.

Assessment:
All activities related to the certification and surveillance of a company to determine whether the company meets all relevant requirements of the specified standard and whether they are properly implemented. The assessment comprises review of documentation review, audit, preparation and consideration of the audit report and other relevant activities necessary to provide sufficient information.

Non-conformity:
The absence of or the failure to implement and maintain one or more required management system elements, or a situation which, on the basis of objective evidence, raise significant doubt as to the capability of the occupational health management system to achieve the policy and objectives of the company.

The certification body is free to define different grades of deficiency and areas for improvement (e.g. Major and Minor Nonconformities, Observations etc). However, all deficiencies which equate to the above definition of nonconformity should be dealt with as laid down in DS/EN ISO/IEC 17021 item 9.1.11 and 9.1.12.

5.1 Legal and contractual matters

G.5.1 - 1 Compliance with the legislation

The certification body shall ensure and confirm that organisations with a certified management system meet the required compliances with a standard and possible supplementary regulations, and that the system is fully implemented, and that the management system is effective in order to achieve and ensure current compliance with relevant legislation.

G.5.1 - 2 Compliance of legislation is the responsibility of the organisation and the certification body should by sampling from the established management system achieve the confidence that the system ensure this compliance.

This means that the certification body shall have procedures which include and ensure that:

a) knowledge of which regulations are relevant and covers the company should be achieved as soon as possible in a certification/audit process

b) adequate competence in the audit team is allocated in order to perform a fulfilling evaluation of an organisations compliance with legal regulations.

c) the organisation is informed about which type of documentation (descriptions, drawings, approvals, reports, correspondence etc.) as well as staff members should be present during the audit in order to achieve an adequate assessment of the area.

d) a description of the action to be performed by the certification body is available in case of non-compliances or possible non-compliance with a relevant law, and that the organisation is informed of these procedures.

e) the organisation has identified all relevant legal requirements and has established, implemented and maintain procedures for periodic evaluation of compliance with all relevant legal requirements as well as identification of new and/or changed legal requirements.

f) the certification body on basis of a number of samples, document the evaluation of whether the company complies with the legal requirements and if procedures, resources and competence is in place to ensure that the company will be capable of ensure current compliance of relevant legislation.

g) it is required that the organisation can demonstrate compliance with relevant legal requirements by own evaluation prior to issuing certificate. In case the relevant legal requirements are not fulfilled after certification is issued, the organisation shall be asked to carry out corrective actions within a reasonable time limit according to the circumstances. Should the improvements prove not be adequate, the certification must be withdrawn.

h) when a non-compliance with a relevant legal requirement is detected (either by the organisation itself or by the certification body), an evaluation of whether the corrective and preventive actions creates confidence in the organisations way of handling the area, shall be carried out.

i) an organisation which are not in compliance with relevant legislation, in such case has a documented agreement with the relevant authority about a plan in order to achieve compliance, and that this plan has the priority necessary in the management system. The Certification body shall verify implementation of such plans by audit.

j) in case the certification body or possible other parties (with less knowledge of the actual conditions) are able to raise reasonable doubt about full compliance with the legislation regarding a specific area in an audited/certified organisation, the certification body's assessment and background for the conclusion on specific conditions shall be documented thoroughly in the audit report, check lists or notes from the assessment.

k) if by inquiries/complaints or in case doubt is raised by other means, concerning a certified organisations compliance with the legislation, a documented evaluation of which type of reaction is necessary in order to regain confidence in the certificate and the certification system, is carried out. Possible reactions can include that the case be examined by request to the organisation, new/extraordinaire audit, a note filed on the case regarding follow-up and the next ordinary audit etc.

7.1 Competence of management and personnel

G.7.1.1 - 1 The certification body shall have procedures which ensures knowledge of the technical progress and possible legal initiatives relevant for occupational health management within the relevant technical area.

G.7.1.2 - 1 The certification body shall have an effective system for analysing the competences available within occupational health management in accordance with the area of activities of the certification body.

G.7.1.2 - 2 Regarding evaluation of type of company and complexity of occupational health, see appendix 1.

G.7.1.3 - 1 The certification body shall be able to demonstrate that a competence analysis of the requirements for each of the relevant technical areas has been carried out (evaluation of expertise in connection with identified needs) prior to the contract review. In particular the certification body shall demonstrate competences to carry out the following activities:

a) identification of the significant occupational health impacts within the specific technical area

b) definition of the competences necessary at the certification body' in order for them to carry out certification relating to the relevant technical area and the connected occupational health conditions

7.2 Personnel involved in the certification activities

G.7.2.1 - 1 The certification body shall be able to demonstrate competence to perform the following activities for the companies for which it certifies their occupational health management system:

a) define the areas of activities and relevant significant occupational health conditions

b) confirm that the typical occupational health conditions occurring through the line of activities in the company, comprises with the above mentioned.

c) Confirm presence of the required competence.

9. Process requirements

9.1 General requirements

G.9.1.1 - 1 Audit plan

The certification body shall inform the company that registration (including all registrations of accidents, breaking of rules or laws and relevant correspondence with authorities) upon which the company base its assessment of compliance with legal requirements, can be necessary at an audit (stage 1) and a detailed assessment can be required by audit (stage 2).

G.9.1.3 - 1 Selection of audit teams

The certification body shall have criteria for selection of audit team. These criteria shall ensure appropriate levels of competence with regards to:

a) knowledge of occupational health management systems

b) understanding of the requirements for occupational health management systems

c) understanding of occupational health issues

d) technical knowledge of the activity to be audited

e) management system audit competencies

f) knowledge of possible legal requirements in connection with the activities or occupational health management system of the company

G.9.1.4 - 1 Audit time

The certification body shall have procedures for determining the time needed in order to cover all relevant elements of the audit (stage 1 and 2 according to the description of audit method below) taking into account, where relevant, the factors below:

a) results and reports from internal audit and the occupational health management systems

b) results of management review

c) maturity of the management systems

d) the level of knowledge of the company

e) the size of the company and possible changes in the company etc.

f) complexity of the company according to appendix 1

g) complexity of registration systems and possible integration with other management systems

h) any shift working

i) variation in working practices

j) the extent of uniform routines

k) variations in the activities of the company

l) number of rules regarding occupational health in relevance to the activities of the activities of the company

m) the views from interested parties

The process of the certification body shall secure that the allocated time for occupational health audit follow IAF's guidelines (IAF MD-documents) for "EMS Auditor time" in combination with use of the categorisation of complexity as listed in appendix 1.

G.9.1.5 - 1 Multi-site

Should a company carry out activities under the control of a single management system which operates across a number of geographical locations, certificates can be issued covering multiple sites provided that each site included in the scope of the certificate has been either

a) individually audited by the certification body or

b) is included in a sample based approach (see below).

It is only similar locations where the certification body, neither by contract review nor during the certification phase, has identified inconsistencies in the working environment at the different locations or specific conditions at the individual location with relation to the factors listed in item G.9.1.5 – 7c, which can be included in a sample based approach. In case of several groups of comparable locations, each group can be audited by a sample based approach.

G.9.1.5 - 2 Sample based approach

Certification bodies wishing to use a sample based approach to the assessment of sites with similar activities need to maintain procedures which ensures that the full range of issues below are included in the building of their sampling programme.

G.9.1.5 - 3 Prior to undertaking its first assessment based on sampling the certification body shall provide the methodology and procedures which it employs to DANAK and provide demonstrable evidence of how these take account of the issues below to manage multi-site assessment.

G.9.1.5 - 4 The certification body's procedures shall ensure that the initial contract review identifies, to the greatest extent possible, the difference between sites such that an adequate level of sampling is determined in accordance with provisions c) to e) of G.9.1.5 – 7.

G.9.1.5 - 5 In the event that application of the certification body's procedures results in a smaller sample than would result from the application of the guidance set out below, the certification body shall record the reasons justifying this and demonstrate that it is operating in accordance with its approved procedure.

G.9.1.5 - 6 The minimum number of sites to be visited per audit is:

Certification audit: The size of the sample should be the square root of the number of remote sites ($y=\sqrt{x}$), rounded to the upper whole number.

Surveillance visit: The size of the annual sample should be the square root of the number of remote sites with 0.6 as a coefficient ($y=0.6\sqrt{x}$), rounded to the upper whole number (see however G-9.1.5-7c).

Recertification: The size of the sample shall be the same as for a certification audit. Nevertheless, where the occupational health management system has proved to be effective over a period of three years, the size of the sample could be reduced by a factor 0.8, i.e.: ($y=0.8\sqrt{x}$) rounded to the upper whole number.

G.9.1.5 - 7 Where a company has a number of sites with similar activities covered by a single management system, a certificate may be issued to the company to cover all such sites provided that:

(a) all sites are operating under the same management, which is centrally administered and audited and subject to central management review, and

(b) all sites have been audited in accordance with the internal audit procedure(s), and

(c) a representative sample of sites have been audited by the certification body, taking into account the factors below

- the results and reports of internal audits of the management system on both the single sites and the central location,
- the results of management review,
- maturity of the management system,
- existing knowledge of the company,
- variations in the size of the sites,
- complexity of the management system,
- complexity of the sites,
- any shift working,
- variations in working practices,
- repetitiveness of functions,
- variations in activities undertaken,
- the spread of the company's personnel over the sites,
- essence and extent of activities with impact on the occupational health, extent of the rules which can have significant impact on the company's occupational health activities,
- the views of interested parties.

d) the sample is selective, based on c), above and non-selective and result in a range of different sites being selected, without excluding the random element of site selection,

e) the surveillance programme include visits to the company's head office, be designed in the light of the above factors and, within a reasonable time, covers all the sites of the company in accordance with the certification body's sampling method, (for example 1-2 certification cycles)

f) in the case of a nonconformities being observed either at the head office, or at a single site, of a company with an occupational health certificate covering several sites, the corrective action procedure shall apply to all applicable sites covered by the certificate.

g) audit (stage1) address the company's head office activities to ensure that a single occupational health management system applies across all sites and that a central management at the operational level is operated. The audit (stage 1) should address all the issues outlined in a) to f) above.

G.9.1.10 – 1 The report to the company shall include:

a) Clear identification of the significant documents in the assessed management system,

b) plans of action for occupational health,

c) degree of confidence in the internal audit,

d) a summary of the most important observations, positive as well as negative, regarding the implementation and efficiency of the management system,

e) Conclusions of the audit team.

G.9.1.10 -2 Reporting to the certification body by the audit team
In order to provide a basis for the certification decision, the certification/registration body will need one or more clear report(s) from the audit team which provide(s) sufficient information to make the decision. To achieve this, the report(s) should meet the general requirements for conformity assessment.

a) Reports from the audit team to the certification/registration body are required as a minimum at the end of audit stages 1 and 2. In combination with information held on file these report(s) should at least contain:

- a description of the audit (stages 1 and 2) including a summary of the document review and the audit (stage 2) including audit days used (including preparation and site audit (stage 1), audit (stage 2) and reporting),
- clarification of nonconformities,
- audit enquiries which have been followed, rationale for their selection, and the methodology employed,
- recommendation by the audit team to the certification body;

b) Surveillance reports should contain, in particular, information on clearing of nonconformities revealed previously and other areas for follow up.

c) Reassessment reports should as a minimum cover, in totality, the requirement of a) above.

9.2.1 - 1 Application

G.9.2.1-1 In order to certify a company's occupational health management system:

a) the management of the activities covered by the occupational health management system should:

- be able to demonstrate responsibility for all occupational health aspects,
- have authority to determine how occupational health policy is implemented and maintained in terms of setting its own objectives and targets, and programmes to meet them
- have authority to allocate appropriate financial and human resources to occupational health control and improvement. This may be within budgets or other constraints. Additional resources for improvements may require the authority of more senior management

b) the interfaces with services or activities not completely in the scope of the occupational health management system (for example sub-contractors) also be addressed within the occupational health management system subject to certification.

c) Additionally, account should be taken of the scope of the company's possible agreements and other commitments when determining the coverage of the certification.

G.9.2.1 - 2 Activities
The activities subject to certification should be clearly identified.

G.9.2.1 - 3 Organisation (Company)
This is typically defined as all land on which the activities under the control of an organisation at a given location are carried out This includes any connected or associated storage of raw materials, by-products, intermediate products, end products and waste material, and any equipment or infrastructure involved in the activities, whether or not fixed. Alternatively, where required by law, definitions laid down in national or local licensing regimes shall apply.

Other definitions may also be used subject to justification.

a) Temporary sites, such as construction sites, are covered under the occupational health management system of the company which has management control over them irrespective of where the sites are located, and may be subject to assessment on a sample basis as part of the certification process to provide evidence of the operation and effectiveness of the system.

b) Where it is not practicable to define a location (e.g. for services), the coverage of the certification should take into account the company's headquarters activities as well as delivery of its services. Where relevant, in special cases, the certification body may decide that the certification audit will be carried out only where the company delivers its services. In such cases the interfaces with its headquarters should be audited.

9.2.2 Review of application

G.9.2.2.4 - 1 The following apply to the audit team as a whole:

All team members should as a minimum be confident with the following:

a) standards for occupational health management or other normative documents

b) general terms for management systems

c) methods to evaluate impacts of occupational health activities

d) principles of audits

G.9.2.2.4 - 2 The following apply to the audit team as a whole:

a) In each of the following areas at least one audit team member should satisfy the certification body's criteria for taking responsibility within the team for
   - leading the team and managing the audit process;
   - management systems and auditing methods;
   - knowledge of occupational health conditions within the specific technical area
   - knowledge of possible specific occupational health requirements in relation to the company's activities

b) the audit team should collectively have experience, training and up to date knowledge of the following:
   - analyses of occupational health conditions within the specific technical area
   - relevant occupational health legislation;
   - procedures to reduce occupational health impact and the use of these procedures in praxis within the specific technical area;

c) the audit team should be competent to trace evidence of failures in the company's occupational health management system back to the appropriate elements of the occupational health management.

d) an audit team may consist of one person provided that this person complies with all the requirements above for an audit.

G.9.2.2.4 – 3 Use of experts

Experts with specific knowledge of special conditions and possible regulations of these, but who do not satisfy all the above criteria, may be part of the audit team. Experts cannot function independently from the auditor.

G.9.2.2.4 - 4 In order to assess the audit team's competence please see DANAK's guideline RL18.

9.2.3 Initial certification audit

G.9.2.3.1 - 1 When the audit (stage 1), including document review, is not conducted by a single person, the certification body should be able to demonstrate how the various team members activities are coordinated.

G.9.2.3.2 - 1 Certification audit (Stage 2)

a) On basis of the findings of the audit (stage 1) the certification body shall draft an audit plan for the conduct of the audit (stage 2)

b) Certification audit (stage 2) shall aim at verifying the implementation of all elements in the requirements (except for those which were confirmed implemented at stage 1) with particular focus on the company's:

- identification and description of the company's occupational health aspects
- Evaluation and identification of significant occupational health impact as well as priority of areas to improve preventive actions;
- Procedures to ensure compliance with legal and other requirements
- targets derived from the evaluation process;
- performance monitoring, measuring, reporting and reviewing against the objectives and targets;
- identification and evaluation of nonconformities and completion of corrective/preventive actions
- internal audit and management review;
- management responsibility for the occupational health policy;
- links between policy, activities and their associated occupational health impacts, objectives and targets, responsibilities, programmes, procedures, performance data, internal audit and review.

G.9.2.3.2 - 2 Assessment of the Internal Audit

a) The extent of the audit (stage 2) may be influenced by the degree to which reliance can be placed on the company's internal audit. At the audit (stage 1) the certification body should determine, through detailed analysis, the reliance it can place on the results of the internal audit. Records of the internal audits should be sufficiently comprehensive to provide data that can be validated by the certification body to confirm the effectiveness of the audit process. The certification body should be able to demonstrate the basis for determining the extent of its own audit (stage 2) to DANAK.

b) On basis of sample based approach the certification body should confirm the overall reliability of the internal audit

c) The certification body should do this, in particular, by seeking objective evidence of:

- competence, experience, training and independence of auditors
- auditing procedure and methodology, in particular the extent of the audit
- standards relevant for the audit
- resources available for the audit
- organisation of the audit
- checks and verifications performed
- audit findings, including reports and records
- management of audit follow-up
- timeliness and effectiveness of corrective action

d) By certification on sample based approach (Multi-site), which partly is based on a well-functioning internal audit, the above mentioned issues should be well documented.

e) Internal audit programmes should address the essentiality of the various areas of the company's activities.

G.9.2.3.2 - 3 Recording and evaluation of occupational health aspects and control of those deemed significant

a) In order to provide confidence that companies are consistent in establishing and maintaining procedures for the identification, examination and evaluation of occupational health aspects and their associated impacts, certification bodies' procedures should reflect the following factors:

- it is the task for the company to define the criteria by which occupational health aspects and their associated impacts are identified as significant, and to develop one or more procedures for doing this;
- it is the task for the certification body to assess that the procedure(s) by which the company determines which occupational health aspects and their associated impacts are significant, sound and adhered to;
- the certification body should identify to the company for its action any inconsistencies between the company's policy, objectives and targets and its procedure(s) or the results of their application.

b) The certification body should establish whether the procedures employed in the analysis of significance are sound and properly implemented. It shall verify that an occupational health aspect or associated impact which is identified as being significant is managed within the system. This may entail assessment of combinations of the following:

- investigation and development of opportunities for further improvement;
- programmes for planned improvement;
- controls to maintain the effectiveness of the occupational health management system.

c) Significant occupational health aspects and their associated impacts are not necessarily confined to a single geographical location. They may also include other aspects of a company's activities, products or services that it can control and over which it can be expected to have an influence. In particular, these may include any activities of suppliers, customers or related company's which create additional occupational health aspects.

G.9.2.3.2 - 4 Recording and evaluation of continual improvement and prevention of occupational health impacts

In order to provide confidence that companies have processes in place for achieving continual improvement and prevention of occupational health, the certification bodies' procedures shall reflect the following factors:

a) it is a task for the company to define the means by which its policy commitment to continual improvement and to initiate activities for doing this and for measuring progress in this regard;

b) it is a task for the certification body to assess that the company's processes and criteria are sound and adhered to;

c) the certification body should identify to the company for its action any inconsistencies between the company's policy, objectives and targets and its processes or the result of their application.

G.9.2.3.2 - 5 Occupational health management system documentation

The documentation required by the normative basis should describe the occupational health management system and make clear the relationship to any other related management system in operation in the company or having an influence on the occupational health management system subject to certification. It is acceptable to combine the documentation for occupational health and other management systems (such as for quality, environment and energy) as long as the components of the occupational health management system can be clearly identified together with the appropriate interfaces to the other systems.

G.9.2.3.2 - 6 Combining Management Audits

The audit of occupational health management can be combined with audits of other management systems. This combination is possible provided it can be demonstrated that the audit satisfies all requirements for certification of the occupational health management system. The audit plan should identify the roles of each member of the audit team and the criteria each member is to audit. All the elements of an occupational health management system should appear clearly, and be readily identifiable, in the audit reports. The quality of the audit should not be adversely affected by the combination of the audits

9.2.5 Information on granting initial certification

G.9.2.5 - 1 Basis for the decision

The information gathered during the certification process should be sufficient:

a) for the certification body to be able to take an informed decision on certification (or recertification following reassessment);

b) for traceability to be available in the event, for example, of an appeal or for planning for the next audit (possibly by a different team);

c) to ensure continuity.

9.3 Surveillance activities

G.9.3.1 - 1 Surveillance activities - General

The certification body shall be able to adapt its surveillance programme to the occupational health issues related to the activities of the company and justify this programme.

G.9.3.1 - 2 The surveillance programme of the certification body should be determined, taking into account the internal audit programme and the reliability that can be attributed to it. Specific dates for visits may be agreed with the certified company.

G.9.3.2 - 1 As a minimum, surveillance by the certification body should include, on an annual basis, the following considerations:

a) the effectiveness of the occupational health management system with regard to achieving the objectives of the company's policy;

b) an interview with management responsible for the occupational health management system;

c) progress of planned activities aimed at the process of enhancing the occupational health management system to achieve improvements in overall occupational health performance in line with the company's occupational health policy

d) follow up of conclusions resulting from internal audits

e) follow up on nonconformities or complaints since the last assessment

f) the functioning of procedures to ensure compliance with possible relevant legal requirements as well as other regulations committed to.

G.9.3.2 - 2 See G.9.2.5 - 1 and 2 regarding content of audit report.

9.4 Recertification

G.9.4.2 - 1 See G.9.2.5 – 1 to 3 regarding content of audit report.

The Accreditation Regulation comes into force on 29 June 2012. Any differences between the Danish and the English version of this document are not intended, but in case of doubt with respect to the correctness the version in Danish should be consulted.

DANAK, 29 June 2012

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REFERENCES

1. DS/EN ISO/IEC 17021:2011 Conformity assessment - Requirements for bodies providing audit and certification of management systems
2. EA 7/04, April 2010 – rev. 02, EA Guideline, Legal compliance as a part of Accredited ISO 14001:2004 certification.

APPENDICES

Appendix 1: Complexity of the company's occupational health

APPENDIX 1
Complexity of the company's occupational health

The occupational health complexity of the company's is of significance for allocation of audit time in according to G.9.1.4 and in connection with composition of audit team in accordance with RL 18.

The complexity of the branches is divided into respectively high, medium and low. The categorisation is structured in accordance with the Danish Working Environment Authority's 36 guidelines and is based on statistics of working accidents, work related diseases and significant occupational health problems.

Complexity category	**AMV* and Branches**
HIGH	1 Construction work 2 Construction work 3 Completion of construction work 7 Energy and raw materials 8 Installation and repair of machines and equipment 10 Metals and machines 11 Plastics, glass and concrete 13 Transportation 14 Wood and furniture 19 Butcher 20 Foods 21 Police, emergency alert and prisons 23 Water, sewerage and waste 29 Transportation of goods 30 Transportation of passengers 32 24-hour centre and home care
MEDIUM	6 Electronics 9 Chemistry and medicine 12 Textiles and paper 15 Films, media and books 18 Agriculture, forestry and fishing 22 Religious institutions and burial authorities 25 Hotels and camping 27 Cleaning 28 Restaurants and bars 31 Day care 33 Hospitals
LOW	4 Shops 5 Wholesale 16 It and communication 17 Offices 24 Hairdressers and other personal care 26 Culture and sports 34 Doctors, dentists and veterinarians 35 Teaching 36 Universities and research

*) Danish Working Environment Authority's guidelines for occupational health