

Rule for the application of DIN EN ISO/IEC 17011 to the accreditation of conformity assessment bodies

R-17011

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Scope:

This rule specifies, where necessary, the requirements of DIN EN ISO/IEC 17011 .

Pursuant to Section 2 in conjunction with Section 3 (9) Federal Act on Gender Equality, Section 4 (3) Federal Act on Gender Equality is not directly applicable to DAkkS. In the interest of good readability, the generic masculine is also used for function descriptions in this document, so far as a concrete designation by natural gender is not possible in any meaningful way and natural gender is either unimportant or male and female persons are meant equally.

DAkkS rules and other technical specifications must be easily readable and must therefore contain no slashes, which excludes the use of the internal / and duplicate designations (concerning admissibility, see Section 115 Manual for Drafting Legislation).

Also applicable are the further requirements of DIN 820-2:2012-12 Standardisation – Part 2: Presentation of documents (ISO/IEC Directives – Part 2:2011) for the formulation of technical specifications.

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Introduction

DIN EN ISO/IEC 17011:2018 (hereinafter simply 17011) sets out requirements for accreditation bodies and the accreditation procedure. It therefore also has an impact on conformity assessment bodies (CABs). DAkkS adheres to the requirements of 17011 for the purpose of international recognition as a minimum requirement and in order to discharge its duties as a national accreditation body pursuant to Regulation (EC) No. 765/2008. For the purpose of national application, stricter requirements may need to be considered.

For administrative practice, this rule only specifies the requirements of 17011 where necessary, only where specific concerns are to be expected with regard to the accreditation procedure for the CAB. This rule applies only as long as this version of 17011 has the status of a harmonised standard.

With this rule, DAkkS defines no new requirements going beyond the requirements of 17011. Existing requirements are not restricted or withdrawn. Where 17011 allows the accreditation body freedom of action, DAkkS sets out – if necessary and appropriate – the specifics of the normative requirements in this rule. Normative terms or subject matter of 17011 whose interpretation is not unambiguous are specified in greater detail in individual cases as required.

DAkkS assumes a knowledge of the exact requirements of 17011, and the text of the standard is therefore not reproduced. Where applicable, and independently of this rule, international rules of the organisations *European co-operation for Accreditation (EA)*, *International Laboratory Accreditation Cooperation (ILAC)* and *International Accreditation Forum (IAF)*, which themselves specify the requirements of 17011 in greater detail, apply. Here again, DAkkS does not reiterate their content in this rule. Where appropriate, reference is made to these rules at the relevant points. DAkkS generally provides translations of the applicable international rules.

This rule includes only aspects that are applicable to DAkkS as a whole or to all accreditation activities and all types of CABs (level 1). Specific details for individual accreditation activities are the subject of lower-level rules (level 3 and level 4)¹.

The rule is based on the structure of 17011. Sections of 17011 that require no greater detail are omitted.

Further information, in particular explanations of 17011 and its application by DAkkS or information for CABs concerning the accreditation procedure in general can be found in the information sheet M-17011 and on the DAkkS website.

¹ Based on the level structure of the international recognition agreements (see EA-1/06, ILAC R6 and IAF PR 4)

1 Scope

No detailed specific requirements.

2 Normative references

No detailed specific requirements.

3 Terms and definitions

No detailed specific requirements.

4 General requirements

4.1 Legal entity

No detailed specific requirements.

4.2 Accreditation agreement

The statement by the CAB of its intention to conclude a legally enforceable agreement is made by submitting an application for carrying out an accreditation procedure to DAkkS. The application initiates an administrative procedure in accordance with the provisions of VwVfG, the German Administrative Procedures Act. When making the application, the applicant must submit the declarations required in the application form. These declarations include in particular the obligation to meet the requirements of section 4.2 of 17011 which are listed in detail in the application, in addition to regulatory requirements.

In addition, DAkkS may also include further obligations on the part of the applicant arising from the specific accreditation procedure, in particular the assessment and the manner in which measures are implemented, as incidental provisions in the notice on the granting or amendment of accreditation, if these incidental provisions are intended to ensure that the statutory requirements are met (Section 36 (1) VwVfG).

Where DAkkS is operating in third countries outside the scope of Regulation (EC) No 765/2008, an appropriate contractual agreement setting out all binding obligations for the CAB will be concluded.

4.3 Use of accreditation symbols and other claims of accreditation

4.3.1

DAkkS ensures adherence to the requirements addressed to the CAB by applying and implementing the provisions of Section 6 of the Act on the Accreditation Body (AkkStelleG) and the Regulation on the Accreditation Symbol (SymbolVO). With the granting of accreditation, DAkkS permits the use of the accreditation symbol within the scope of the accreditation. DAkkS informs the CAB of the details governing use of the accreditation symbol by means of a licence agreement or of incidental provisions in connection with the granting of permission for its use. In this context, the minimum requirements of the international rules EA-3/01, ILAC R7, ILAC P8, IAF ML 2 and other EA, ILAC or IAF provisions governing use of the accreditation symbol and other references to the accreditation in their current versions must be observed.

4.3.2

For use of the combined accreditation symbols of EA, ILAC and IAF, the CAB and DAkkS sign sublicence agreements setting out the specific rights of use and obligations with regard to use of these symbols.

4.3.5

Any misuse or irregular use by an accredited CAB will be punished in accordance with the provisions of Section 4 (4) of the Regulation on the Accreditation Symbol and with measures under trademark law and/or accreditation law.

In the event of unauthorised use of the symbol by a third party, DAkkS will also take action against the unauthorised use with claims for injunctive relief and damages under trademark law.

In the event of any unlawful assertion concerning accreditation status, DAkkS will take action on the basis of Section 1a or Section 3 (2) AkkStelleG.

4.4 Impartiality requirements

4.4.5

To ensure the involvement of the “interested parties” and to evaluate the impartiality of DAkkS, DAkkS has established an Advisory Board at the horizontal level. The Advisory Board participates in the analysis of risks to the impartiality of DAkkS and advises it on measures to eliminate or minimise any existing risks.

4.5 Financing and liability

No detailed specific requirements.

4.6 Establishing accreditation schemes

4.6.1

For its accreditations, DAkkS applies the harmonised international standards for conformity assessment. Where applicable, DAkkS applies more detailed specific rules of EA, ILAC and IAF which contain binding requirements for CABs or accreditation bodies as minimum requirements and makes them available in translation into German on the DAkkS website. DAkkS reserves the right to specify existing standards or other requirement documents in greater detail and to publish general or sectoral DAkkS rules for this purpose. If necessary and appropriate, DAkkS publishes additional documents that serve to inform interested parties and are essentially of an explanatory/recommendatory nature. Information on the structure of the DAkkS rules is available on the DAkkS website.

In addition to this rule, which specifies the application of 17011 by DAkkS for all areas and procedures, DAkkS publishes a rule for each accreditation activity in combination with the relevant level 3 standard² (accreditation scheme as per 17011). Where necessary, further rules for the application of 17011 or the applicable level 3 standard can be established for individual subject areas on a sectoral basis.

4.6.2

As a general rule, DAkkS establishes sector committees for the preparation of sectoral application documents³. The interested parties participate in this process in an advisory capacity.

4.6.3

The eligibility of conformity assessment schemes for accreditation is generally determined in a separate scheme evaluation procedure that precedes the accreditation procedure. The decision on eligibility for accreditation is made by an internal DAkkS scheme committee.

If recognition of the conformity assessment scheme by EA is being sought, rule EA-1/22 is applied.

Additional information on the process, the sources of further requirements and the documents to be submitted are available in an information sheet.

5 Structural requirements

No detailed specific requirements.

² Harmonised standard setting out the requirements for CABs for the respective accreditation activities and which is used for the accreditation of CABs. For the level structure of the multilateral recognition agreements, see EA-1/06, ILAC R6 and IAF PR 4.

³ Information sheets and rules. Information on the document types can be found on the DAkkS website.

6 Resource requirements

No detailed specific requirements.

7 Process requirements

7.1 Accreditation requirements

No detailed specific requirements.

7.2 Application for accreditation

7.2.1

Accreditation can only be granted to a legal entity or a specified part of a legal entity. The following are also treated as a legal entity in this sense:

- Associations, insofar as they may be entitled to a right (right to bring their own action)
- Authorities.

Note: The harmonised standards for the individual accreditation activities (e.g. DIN EN ISO/IEC 17025) may result in further restrictions with regard to the possible forms of organisation.

This also applies mutatis mutandis to applicants from third countries.

An application for accreditation is therefore only likely to succeed for a legal entity.

For the following accreditation procedures, the CAB must submit an application to DAkkS:

- Initial accreditation
- Reaccreditation, provided that the existing accreditation is limited
- Amendment of accreditation
- Suspension and withdrawal at own request

If there is no legal requirement for a time limit for accreditations in the statutory area, DAkkS grants accreditations for an unlimited period of time. Scopes with and without time limits cannot be combined in a single accreditation file.

Each application must be in writing, i.e. with the personal signature of an authorised person, or in a manner replacing the written form, i.e. by means of an electronic document with a qualified electronic signature or by De-Mail. The details concerning replacement of the written form are derived from Section 3a of the Administrative Procedures Act. In the non-statutory area, DAkkS can provide for alternative procedures.

7.2.2

Before planning the assessment for initial accreditation, the CAB must provide documents to DAkKS within a specified period of time (Section 3 AkkStelleG). DAkKS determines which documents must be provided by the CAB and publishes information on each accreditation activity on its website. Unless otherwise specified, the documents must be provided in electronic form in the manner specified by DAkKS. The documents shall generally be submitted in German.

After initial accreditation, the CAB must provide the documents to be submitted in full and in their current version for each subsequent surveillance or amendment of the accreditation, and when asked to do so by DAkKS.

7.2.3

If the review of the submitted documents finds that they are incomplete or insufficient, DAkKS will inform the CAB and set a one-off deadline for subsequent correction.

7.3 Resource review

No detailed specific requirements.

7.4 Preparation for assessment

7.4.2

DAkKS determines, within the scope of its discretion, the assessors and where applicable the observers who will participate in the assessment.

The CAB has the ability to raise justified objections against the assignment of individual persons in writing within two weeks of notification of the assessors or observers. Objections within the meaning of Sections 20, 21 VwVfG are included. DAkKS decides on a case-by-case basis whether the objections raised are justified. Legitimate objections will be considered.

DAkKS reserves the right to use suitable interpreters to ensure that communication during the assessment between assessors and staff employed by the CAB is satisfactory. In this way, it can ensure that CAB documents and records can be read, understood and evaluated by the assessors.

7.4.4

For each assessment, DAkkS specifies which assessment techniques are to be used in accordance with 17011 Section 3.24. Assessments undertaken as part of initial accreditations and reaccreditations, reassessments and significant extensions include in principle on-site assessments.

DAkkS specifies the composition of the assessment team for each assessment activity according to the scope to be assessed. When determining the composition, care is taken to ensure that the required competence for the scope to be assessed is available in the assessment team. For initial accreditations, reaccreditations and reassessments, at least two assessors are always used in accordance with the principle of dual control.

7.4.5

DAkkS determines the representative sample to be assessed individually for each assessment according to the scope to be assessed. In addition to the relevant conformity assessment activities and the personnel involved in this respect, DAkkS also makes due allowance for all locations, and in particular those that perform key activities for the CAB. Key criteria for determining the content of the assessment include:

- Results of previous assessment activities
- Information from the annual statement, such as scope of the conformity assessment activities carried out
- Location of the conformity assessment activity carried out (at the premises of the CAB, at different CAB locations, on-site at the client's premises, abroad where applicable)
- Personnel involved (internal – external)
- Risks associated with the conformity assessment activity and other applicable risk factors (see 7.4.6)
- Requirements of scheme owners
- Feedback to DAkkS about the CAB (e.g. complaints, market surveillance, power-conferring authorities)

A lack of orders at the CAB for particular conformity assessment activities is not a reason to exclude those activities from the sample of activities to be assessed.

For the assessment of CAB locations, the following more specific provisions apply:

The main office and other locations at which the CAB carries out key activities are assessed by DAkkS during the initial assessment and each reassessment across the entire scope. The CAB must also inform DAkkS of locations at which it does not carry out key activities, stating specific activities. DAkkS reserves the right to include these locations and the activities carried out at them in the assessment.

For the purpose of this rule, a location (branch office, subsidiary – however denoted) is a part of an organisation, physically separated from the headquarters or main office and subject to the management system in place at the CAB, at which one or more activities within the accreditation are carried out under the technical supervision of the main office. Locations can be physical or virtual places.

Surveillance activities between initial assessment and reassessment or between successive reassessments must include the main office, but not all locations with key activities. DAkkS determines the locations to be assessed, the activities to be assessed and the extent of the assessment activities on a case-by-case basis, with due regard to the findings of the risk assessment.

For all CAB types, the key activities include the activity in the functional approach as per DIN EN ISO/IEC 17000 and the following activities:

- Formulation of basic arrangements (business policy/control of accreditation)
- Development and approval of processes and procedures at the CAB
- Application review and/or contract review
- Planning of conformity assessments (this does not mean for example the preparation of a specific audit plan)
- Review or recognition regarding the results of the conformity assessment outside the functional approach
- Handling of appeals and procedure for hearings related to statements of conformity

The key activities for the specific accreditation activities are set out in the relevant rules for the level 3 standards⁴.

For the assessment of locations abroad, DAkkS takes into account Regulation EC 765/2008 and the applicable EA, ILAC or IAF rules.

In its selection of the sample to be assessed, DAkkS makes allowance for activities of the CAB that are carried out from mobile facilities or on-site at the premises of the client of the CAB.

7.4.6

The risk assessment is compiled and reviewed exclusively by DAkkS staff at the same time as preparation of the accreditation decision and is updated if necessary. This is done on the basis of the information available from the CAB, the objective evidence and the findings from the accreditation procedure. This can include for example results from the assessments, the evaluation of corrective actions or surveillance activities, and information about the scope and type of the conformity assessment activities of the CAB.

⁴ Harmonised standards that specify requirements for CABs and are used for the accreditation of CABs.

To assess the risk, DAkkS collects the CAB's objective risk factors, as explained below. Each risk factor is assigned to either the risk of error occurrence or the risk of error impact. In its selection of the risk factors, DAkkS is guided by section 2.2 of EA document EA-2/19 INF:2020 *"List of risks for accreditation processes and operation of national accreditation bodies"*.

The following are among the risk factors assessed by DAkkS in the area of risk of error occurrence:

- Number of different subject areas covered by an accreditation
- Number of conformity assessment procedures or schemes used
- Number of activities carried out abroad
- Number of locations
- Number of employees
- Accreditation with a flexible scope (e.g. for category I and II and for scopes with variability)
- Intensive use of external equipment by the CAB for conformity assessment activities
- Performance of activities within complex CAB group structures
- Presence of integrity risks due to digital business processes
- Use of remote techniques for conformity assessment activities to a significant degree
- The technical area of the conformity assessment activity is in its nascency or is currently undergoing major change
- The conformity assessment statement is based on results reported by third parties (subcontracting and the use of external personnel are expressly not covered by this)
- Regular use of significant numbers of external personnel in conformity assessment activities
- Number and importance of nonconformities
- Handling of identified nonconformities
- Adherence to deadlines set by DAkkS
- Significant reorganisations or relocations
- Frequent staff turnover, particularly in key positions
- Large scale subcontracting
- Significant dependence of the result of the conformity assessment on procured consumables/reagents/tools/test kits
- Experience of the body, period of accreditation since initial accreditation
- Maturity of the QM system

The following are among the risk factors assessed by DAkkS in the area of risk of error impact:

- Complexity of the procedures used, e.g. many sub-steps, need to take many different requirements into account
- Presence of integrity risks, e.g. increased risk of fraudulent behaviour in the area
- Potential for personal injury as a result of an incorrect conformity assessment
- Potential for major property damage as a result of an incorrect conformity assessment
- Potential for damage to the image of the CAB or DAkkS as a result of an incorrect conformity assessment
- Potential for high financial losses as a result of an incorrect conformity assessment for which the CAB may be held liable
- Stability of the results of the conformity assessment, e.g. large measurement uncertainties
- Large number of results reports compared to other CABs working in the same area
- Conformity assessment statement for a period in the future
- Multiple reuse of results reports for further decisions
- High susceptibility of the examination procedures used to individual influencing factors
- Procedures used in the evaluation activity, e.g. primarily by audit or by means of other procedures
- Significant recent change in the number of results reports

Depending on the applicable risk factors, DAkkS determines the scope of assessment⁵, the depth of assessment⁶ and the applicable focal points for the ensuing accreditation cycle by the relevant qualified personnel.

If known in advance, the applicable risk factors are also taken into account in the assessment for the initial accreditation.

In addition, a new risk assessment for specific reasons is also possible. This includes for example any risk-relevant extension. DAkkS informs the CAB of the risk assessment or updated risk assessment after completion of the accreditation decision, including the relevant risk factors.

⁵ Scopes that will be assessed (selection from the accredited scope and locations as per the current certificate annex, as well as focal points with regard to the normative requirements of the applicable level 3 standard)

⁶ Required samples including witness activities for the defined scope of assessment

7.4.8

When arranging assessment dates and dates for witnessing activities, the CAB must ensure that the assessment can be carried out within the maximum periods specified by DAkkS. Exceeding deadlines can lead to the reduction of accreditation.

To ensure that it runs smoothly, the CAB must play its part in the concrete planning of the assessment (including time scheduling, availability of required personnel, realisation of witnessing of specific conformity assessment activities, where relevant facilitation of witness audits at the premises of clients of the CAB).

In the event that dates for assessments for the surveillance of accreditation are not arranged within the prescribed period as a result of a lack of cooperation on the part of the CAB, DAkkS will set appropriate dates. For assessments linked to an application, DAkkS may also reject the application.

The provisions of section 7.4.8 do not apply to extraordinary surveillance measures.

7.5 Review of documented information

No detailed specific requirements.

7.6 Assessment

7.6.6 b)

The main results of the assessment are documented in the form of partial assessment reports and nonconformities. DAkkS discusses these nonconformities in detail with the CAB in the closing meeting and provides a copy of the documentation. The CAB is invited to speak at the closing meeting and is given the opportunity to deliver an opinion on the findings. The partial assessment reports are sent independently of the processing of corrective actions, usually within six weeks of the assessment. The CAB has the ability to again express an opinion on the reports within two weeks of them being sent.

7.6.8

The following are the maximum periods for the processing of nonconformities and implementation of any corrective actions:

- Assessment for initial accreditation: Up to four months
- All other assessments: Up to two months.

Depending on the nature and importance of the nonconformities, shorter periods for the implementation of appropriate corrective actions may be specified, except in the case of the initial assessment. The deadlines to be met are documented in each nonconformity report.

7.6.9

If, in the view of DAkkS and its assessors, the feedback from the CAB on the nonconformities is insufficient and the CAB fails to rectify the nonconformities in question, DAkkS will immediately initiate measures to reduce, suspend or withdraw the accreditation.

7.7 Accreditation decision-making

No detailed specific requirements.

7.8 Accreditation information

7.8.3

Irrespective of the prescribed minimum with regard to accreditation information, DAkkS defines specifications, in the interests of uniformity, for the content and formal design or presentation of the scopes.

7.8.4

In the accreditation schemes, DAkkS specifies the accreditation activities and scopes for which accreditation with a flexible scope is possible and what degree of flexibility is available. The accreditation of flexible scopes is subject to the following general conditions:

- The requirements of EA rule EA-2/15 must be met
- The form and manner of presentation of the flexible scopes in the certificate or certificate annex is specified by DAkkS for the purposes of uniformity and comparability
- The presentation of the flexible scopes must be described in the certificate or certificate annex in a manner that ensures that the content and limits of the flexibility are clearly recognisable
- All forms of flexibility of the scope of accreditation are associated with specific requirements and require specific competence on the part of the CAB, as well as an obligation to make the procedures or activities carried out or offered within the flexible scope publicly available. In the assessment planning undertaken by DAkkS, a flexibly accredited scope is given due regard as a risk factor during surveillance of the CAB
- For an accreditation with a flexible scope, DAkkS may limit its flexibility if the CAB does not make use of the flexibility granted over an extended period of time
- DAkkS reserves the right to reduce accreditations granted with a flexible scope if the CAB extends the scope of its accreditation beyond the limits of the flexibility granted
- Sectoral arrangements and information on the accreditation of flexible scopes are set out in lower-level rules where required. Supplementary information on this topic may be included in information sheets

7.9 Accreditation cycle

7.9.1

The DAkkS accreditation cycle starts on the day of the accreditation decision⁷ and is a maximum of five years for accreditations with and without time limits.

The CAB must fulfil its obligations to cooperate in a manner that ensures that it is possible to adhere to the accreditation cycle.

7.9.2

To ensure that the assessment programme can be established by DAkkS, each accredited body must provide up-to-date information at one-year intervals on the CAB and the activities carried out within the scope of the accreditation in the form of an annual statement. DAkkS provides templates for this purpose on its website. The CAB must submit the annual statement for the past calendar year for each accreditation file by 31 March.

7.9.3

For the first accreditation cycle, the first surveillance after the initial granting of accreditation must not be later than twelve months after the accreditation date, or 18 months after the last on-site assessment conducted as part of the initial assessment. The first of these eventualities applies. For the following surveillance activities, the intervals are:

- For certification and verification bodies, the regular interval for surveillance is a maximum of twelve months
- For all other accreditation activities, the interval is a maximum of 18 months

The maximum intervals for surveillance of accreditation in the accreditation cycle must be observed. Regular assessments for surveillance of accreditation can be brought forward by DAkkS if required. If a surveillance assessment has been brought forward, DAkkS calculates the following surveillance dates from the date of the assessment that was brought forward. The intervals also apply during the transition from one accreditation cycle to the next.

For an 18-month interval, surveillance always includes the assessment of a sample of the technical scope by a technical assessor or technical expert appointed for the scope to be assessed.

For a surveillance interval of twelve months, surveillance is usually carried out four times between two reassessments. For a surveillance interval of 18 months, surveillance is usually carried out twice between two reassessments. For unlimited accreditations, DAkkS specifies when the reassessment is to take place. The CAB has no automatic right to the maximum period of five years for an accreditation cycle specified by 17011.

⁷ The date of the accreditation notice applies.

As part of the assessment process, the CAB must provide periodic evidence that it has the competence to perform the specific conformity assessment activity.

If the recurring assessment of the activities of the CAB is not possible due to a lack of orders or clients, the CAB must implement appropriate measures to compensate for the lack of orders or clients. Details are set out in the accreditation schemes. If there is no possibility of compensation, it is not possible for DAkkS to confirm competence.

7.9.4

Regardless of the defined interval, DAkkS may bring forward the reassessment at the end of the current accreditation cycle in order to ensure that the subsequent accreditation decision can be made within the current accreditation cycle. The last assessment activity within the framework of reassessment must take place no later than four months before the end of the accreditation cycle.

In terms of scope and procedure, a reassessment is comparable to an assessment for initial accreditation.

For a limited accreditation, an application for reaccreditation must be submitted no later than twelve months before the end of the accreditation cycle.

7.10 Extending accreditation

7.10.1

Extensions can be carried out separately or combined with planned surveillance assessments and carried out at the same time, provided that the CAB has applied for this in due time. The assessment of an extension as part of a planned surveillance assessment cannot be counted towards the duration and scope of the surveillance assessment.

If a CAB wishes to make use of this combination, it must submit the application for extension to scope at least three months before the planned surveillance assessment.

7.11 Suspending, withdrawing or reducing accreditation

DAkkS suspends, reduces or withdraws an accreditation if the CAB is either no longer competent – i.e. no longer satisfies all requirements for accreditation – or has committed a serious breach of duty. Suspension, withdrawal or reduction is effected by means of administrative act or, in third countries, by means of written or electronic notification.

Voluntary suspension, withdrawal or reduction is possible if requested in writing by the CAB and is also by means of administrative act or, in third countries, written or electronic notification.

If immediate measures are required to prevent the suspension, withdrawal or reduction of accreditation, they can be defined by the assessors respectively by DAkkS. The CAB must provide the assessor/DAkkS with evidence of the implementation of defined immediate measures within the period specified for this purpose in the nonconformity report. Immediate measures do not replace a careful analysis of root causes and extent and the definition of appropriate corrective action by the CAB.

7.12 Complaints

No detailed specific requirements.

7.13 Appeals

An appeal is when a CAB or another party requests that a decision announced publicly by DAkkS by administrative act be reviewed in the accreditation procedure. The processing of objections is the responsibility of the DAkkS Appeals Office.

In third countries, the appeals procedure is in accordance with the principles of civil law.

7.14 Records on conformity assessment bodies

No detailed specific requirements.

8 Information requirements

No detailed specific requirements.

9 Management system requirements

No detailed specific requirements.