Raad voor Accreditatie (Dutch Accreditation Council RvA)

Specific Accreditation Protocol for Certification of Quality Management Systems in accordance with ISO 9001

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A Specific Accreditation Protocol (SAP) describes the assessment service for a specific accreditation. It should be read in conjunction with the generic RvA regulations and policy documents.
A current version of the SAP is available through the website of the RvA. (www.rva.nl).

Content

INTRODUCTION

This SAP should be read in conjunction with SAP-C000, only additional or deviating aspects will be listed in this SAP. This means that some numbers in this SAP may be missing (if all information is already contained in SAP C000).

1 Relevant documents

1.2 Additional standards

- ISO/IEC 17021-3 Conformity assessment — Requirements for bodies providing audit and certification of management systems. Part 3: Competence requirements for auditing and certification of quality management systems.

1.3 Additional documents

- RvA-T041; Implementation of ISO 9001:2015 and 14001:2015.

1.5 Documents related to the conformity assessments to be carried out

Certification bodies (CB) certify against:

- ISO 9001, Quality management systems – Requirements.

2 Scope of accreditation

An accreditation for ASRP (see IAF MD3) will be mentioned explicitly in the scope of accreditation.

Under ISO 9001 certification, it is possible to include several co-notations in the scope (these require a specific extension of scope assessment):

- ISO 3834-2 “Quality requirements for welding. Fusion welding of metallic materials. Comprehensive quality requirements”;
- AQAP 2110, Nato Quality Assurance requirements for design, development and production;
- AQAP 2120, Nato Quality Assurance requirements for production;
- AQAP 2130, Nato Quality Assurance requirements for inspection and test
- Certificatieschema Contractcatering;

3 Accreditation assessments

3.2 The nature and content of the assessments

3.2.1 Initial assessments and extensions of scope

The content and extent of the assessment shall at least ensure the following:

During the office assessment, the team samples the files of clients and personnel to cover the scope for which accreditation is sought. At least 1 client and 1 personnel competence file per IAF sector requested shall be reviewed completely, unless more than 10 IAF sectors have been requested, in which case sectors may be omitted in the sample. This is to be determined by the Lead Assessor, who should apply the following guidelines:

- Only the less complex sectors should be omitted (i.e. not the critical codes, as identified in the table of annex 1);
- Dossiers from each of the clusters (see annex 1) should have been assessed (i.e. the sample should be representative for the scope requested);
- Sectors, which are included in the program for witnessing, may be excluded;
- In total, more than 10 certification dossiers shall be assessed.

The above is also applicable for extensions of the scope.

For the selection of audits to be witnessed, the rules from paragraph 3.2.3 apply.

3.2.2 Surveillance and reassessments

The implementation of the ISO 9001 certification system shall be verified during each surveillance assessment of the RvA. The files reviewed (this includes personnel files and certification files) during the subsequent surveillances and the reassessment in a four years period (accreditation cycle) shall cover all the IAF codes mentioned in annex 1 for which the CB is accredited.

The application of IAF MD1 (multisite), IAF MD3 (ASRP) and IAF MD4 (CAAT) shall be verified at least once during the accreditation cycle, when applicable.

The functioning of the impartiality committee of the body is reviewed in-depth at least once during the accreditation cycle. The RvA Team Leader may determine the method, which may include an interview (face-to-face, or telephone conversation) with a representative (non-CAB) of the Committee, or the attendance to (part of) one of their meetings.

For each accreditation cycle (surveillances and reassessment), the number of witnesses will be determined based on rules in paragraph 3.2.3.

3.2.3 Witnessing

General remarks

At least two weeks before the witnessing the RvA team shall be provided with:

- Documented information (e.g. Quality Manual) of the organization to be audited and an extended description of the organization, specifying its activities, structure and top level procedures (i.e. it is not necessary to submit the entire documented system, but the procedures on a higher level so that the RvA assessor can obtain a reasonable picture of the audit client and its system);
- A description of the most critical quality aspects of the products of the client (e.g. the output (records/procedures) of the organization to be audited related to their determination of requirements related to the product/services as required by ISO 9001 clause 8.2.2);
- The records of the CB's contract review for this organization (including qualification records for the auditors used);
- In case a surveillance or recertification audit is witnessed, a copy of the ISO 9001 certificate issued by the CB;
- The report of the CB's pre-assessment or stage 1 assessment of the organization's QMS (or other latest report) and the audit plan (or the totality of documents, consistent with the requirements of ISO/IEC 17021-1, cl. 9.2.3.2).

Besides the SAP-C000 considerations for selection of audits to be witnessed, during an accreditation cycle, at least a quarter (with a minimum of 1) of the audits to be witnessed should include design control (clause 8.3 of ISO 9001:2015).

Selection of witness audits

In line with IAF MD17, all the IAF codes (see IAF ID1) have been merged into a series of technical clusters as appropriate for QMS certification (see annex 1). For each of these clusters, critical codes have been identified.

Next to the office audit activities (where all IAF codes shall be sampled), the following witness selection rules apply for the granting and extension of accreditation of QMS certification to guarantee the appropriate coverage of the applicant scope:

- if a technical cluster has only 1 critical code, RvA shall perform a witnessing activity in this critical code to grant accreditation for all the IAF codes in that cluster - e.g. cluster Food, with 1 witnessing activity in IAF code 03, RvA can grant accreditation in the other IAF codes (01 and 30) of that cluster;
- if a technical cluster has more than 1 critical code, RvA shall perform at least a witnessing activity in one of the critical codes that are identified with an "or" (on the "Critical code" column); e.g. in cluster Mechanical, with 1 witnessing activity in IAF code 20 or 22, RvA can grant accreditation in the other IAF codes (17, 18, 19, 20 or 22) of that technical cluster;
- if it is not possible to perform a witnessing activity in the IAF code/s identified as critical, RvA can agree with the CB on one of these two options:

- RvA can grant accreditation only in the non-critical IAF code/s of the technical cluster for one of which a witnessing activity is performed (e.g. Food cluster - with 1 witnessing activity in IAF code 30, RvA can grant accreditation for both IAF code 30 and 01), or
- RvA can grant accreditation in all the codes of the cluster, performing an office activity in the critical code/s, but under additional conditions:
  - that the CB has demonstrated its competence on a documental basis in all the codes of the cluster; and
  - that the witnessing activity in the critical code/s takes place before any certificate in the critical code/s based on accreditation is issued.
    However, in such cases, if the result of the witnessing activity is negative, RvA shall consider reducing the scope of accreditation.

If the CB wants to be accredited only in one or more non-critical IAF codes, a minimum of one witness audit is required in each cluster with non-critical IAF codes.

In the initial accreditation cycle (meaning from 1st surveillance to the 1st reassessment), RvA shall perform at least one witnessing activity in each technical cluster. This programme will continue until the CB has demonstrated sufficient experience and performance for an enhanced programme. When this happens, RvA shall perform at least one witnessing activity in each technical cluster, during two successive accreditation cycles. This shall be complemented with other assessment activities to guarantee that each technical cluster is assessed at each cycle. RvA shall justify why the witnessing programme was reduced. Normally, the witnessing frequency established for a 1st cycle would be reinstated if significant changes occur in the CBs' auditor qualification process, auditing practices or results and audit personnel.

4 Specific issues for the RvA assessment

The RvA shall in particular focus on the following issues during the assessment of CB's for ISO 9001 certification:

- Calculation of man days for audits following the principles described in IAF MD5. For each calculation the rationale shall be recorded in the file.
- Impartiality committee: composition and operation.
- Managing threats to impartiality as explained in cl. 5 of ISO/IEC 17021. In case the CB has a relation with a consultancy body, the RvA may decide to verify files of this consultancy body to verify the effectiveness of measures taken to prevent linkage between the two activities.
- Management of competence as explained in ISO/IEC 17021-1, cl. 7 and IAF MD10.

5 Other information

In case accreditation is requested for specific schemes related to ISO 9001, RvA may have published specific accreditation protocols. This can be verified at the RvA website.

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6 Changes with regard to the previous version

In comparison with version 1 dated 11 November 2013 the following significant changes have been made:

- Alignment with SAP-C000 and SAP-C005;
- Updating with respect to issue of ISO 9001: 2015 and ISO/IEC 17021-1:2015;
- Updated number and selection mechanisms for witnessing due to application of IAF MD17

Annex 1: Scope clusters

Technical cluster	IAF code	Description of economic sector/activity, according to IAF ID1	Critical code(s)
Food	1	Agriculture, forestry and fishing	3
	3	Food products, beverages and tobacco	
	30	Hotels and restaurants	
Mechanical	17	Basic metals and fabricated metal products	22 or 20
	18	Machinery and equipment	
	19	Electrical and optical equipment	
	20	Shipbuilding	
	22	Other transport equipment	
Paper	7	Limited to “Paper products”	9
	8	Publishing companies	
	9	Printing companies	
Minerals	2	Mining and quarrying	2 or 15
	15	Non-metallic mineral products	
	16	Concrete, cement, lime, plaster, etc.	
Construction	28	Construction	28
	34	Engineering services	
Goods production	4	Textiles and textile products	5 or 14
	5	Leather and leather products	
	6	Wood and wood products	
	14	Rubber and plastic products	
	23	Manufacturing not elsewhere classified	
Chemicals	7	Limited to “Pulp and paper manufacturing”	12
	10	Manufacture of coke and refined petroleum products	
	12	Chemicals, chemical products and fibres	
Supply	25	Electricity supply	26
	26	Gas supply	
	27	Water supply	
Transport & Waste management	24	Recycling	24
	31	Transport, storage and communication	
	39	Other social services	
Services	29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	33 or 37
	32	Financial intermediation; real estate; renting	
	33	Information technology	
	35	Other services	
	36	Public administration	
	37	Education	

Technical cluster	IAF code	Description of economic sector/activity, according to IAF ID1	Critical code(s)
Nuclear	11	Nuclear fuel	11
Pharmaceutical	13	Pharmaceuticals	13
Aerospace	21	Aerospace	21
Health	38	Health and social work	38

Annex 2: Answers on questions of stakeholders

Throughout the development process of this Specific Accreditation Protocol (SAP), several questions were raised that could not be properly addressed in the revised text of the SAP. Some of these have been included in this Annex.

Why this SAP?

During the EA peer evaluations, it was found that the RvA is not as transparent as it would like to be with respect to indicating the documents, which are relevant for a particular accreditation. In response to these findings, RvA made an inventory for which schemes and activities this is applicable. Thus, it appeared that for a CB, it was not clearly traceable with help of the publicly available documents, which documents are applicable for ISO 9001 certification; this in contrast for instance with EMS, VCA and OHSAS, which schemes all have a SAP document. With this SAP, RvA intends to provide more transparency regarding its operating methods.

Does it change the current operating procedures?

The first version of this SAP did not introduce any significant changes with respect to the current operating methods, however, with the introduction of IAF MD17, the CB may experience changes in the witnessing regime. These will be notified to the CB through their 4-year accreditation programme.

Why does the SAP introduce a link between the number of certificates and the number of files reviewed?

One of the criticisms that RvA has received over the years, relates to the representativeness of the number of certification dossiers reviewed. By more standardising this, RvA intends to prevent some CAB's having almost all of their files reviewed, whereas others only an insignificant number. It should be noted that the prime criterium is still the number of technical areas, i.e. the file review should provide for a reasonable spread over the (clustered) areas as included in the accredited scope.
It is added, that RvA has used the number of certificates for a long time to determine the assessment effort that is required in order to obtain a fair impression of the activities of the CB. With this SAP, RvA intends to make this effort more transparent and open.

How do the numbers (with respect to witness assessments and file reviews) compare with other AB's?

With the notable exception of a few schemes (e.g. food safety management system certification through the use of EA-3/11), this is a topic, which has not yet been standardised or harmonised within IAF or even EA. Each AB is required to develop its own strategy; some will put more emphasis on witnessed assessment, others more on documentation review, others will focus on reviewing certification files at the offices of the CB. It is our impression, that RvA has a fair regime in this respect, which is not stricter or more lenient than that of our colleagues.
Off course, when further international guidelines (EA or IAF) become available, RvA will adapt this SAP to reflect those guidelines, as we have done with the SAP for FSMS certification.

Does this SAP indicate a change of operation with respect to the assessment of technical areas?
No, the RvA has changed its way of assessing technical areas with the introduction of this term in the ISO/IEC 17021 (both in 2006 with further refinement in 2011). This means that RvA reviews how the CB has defined its technical areas, and how it has defined competence criteria for that. Of course, the outcomes of those processes, i.e. the criteria themselves, are reviewed as well (mainly in assessments for extension of scope or initial assessments). Subsequently, RvA reviews whether the CB can demonstrate an effective evaluation process of the competence of the auditors, using the determined competence criteria.

Why does RvA wish to interview a representative of the Committee supervising impartiality?
RvA has started this way of gathering information on the functioning of the Committee about 4 years ago and we have received positive feedback from this approach. The interviews do give more depth to the assessment of impartiality and give an opportunity to give direct feedback to this Committee. The assessments in the interim years (of the meeting minutes) serve to support these interviews.

In case of a witness audit, why does RvA wish to have information about the QMS (e.g. Quality Manual, output from processes of clause 7.2.1) prior to the assessment?
The RvA witnesses an audit to assess the auditor's performance, not to assess the client's MS. Thus, an audit at a client with a poorly functioning MS may result in a good audit (when the client's weaknesses are appropriately identified and consistent findings and audit conclusions are drawn) and vice versa, an audit at a client with a well implemented MS may be a lesser audit (when the auditors omits obligatory audit items, verifies issues superficially, or does not further investigate apparent weaknesses or is being persuaded of conformity without verifying audit evidence).
To enable an auditor to draw these type of conclusions, the RvA assessors is required to have a reasonable insight in the structure of the system and in the most important quality aspects of the client. The time allocated on-site for a certification audit, is just enough to actually perform the audit, and does not allow for preparation on-site (unless this has been planned additionally, i.e. time allocated over and above the guidelines of IAF MD5). The RvA expects its assessors to be able to follow the entire audit and to be able to pinpoint to omissions of the auditors (e.g. by not verifying weaknesses or unclarities). On the other hand, in witness audits, RvA does not wish to interfere by interacting with the client, so a review of the documentation on-site is generally not feasible.
For witnessed surveillance or re-certification audits, this is equally important, because the CB is already familiar with the client and the RvA assessor is not. Therefore, the CB should enable the RvA assessor to prepare properly by ensuring that (the most important parts of) the QMS is available to the RvA 2 weeks prior to the witness.
In order to know, which are the most critical requirements that the CB client's products have to comply with, RvA expects that the information submitted beforehand also includes the client's information on this, with at least their evaluation as required by ISO 9001, clause 7.2.1.