Raad voor Accreditatie (Dutch Accreditation Council RvA)

Specific Accreditation Protocol for Certification according to EN ISO 13485

Document code:	**RvA-SAP-C021-UK** **Version 3, 14-9-2018**

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

0 Introduction

This specific accreditation protocol should be read in conjunction with the SAP-C000; only additional deviating aspects are mentioned in this SAP. This means that paragraph numbers in this SAP are missing if the information already is in SAP-C000.

1 Relevant documents

1.1 Accreditation standard

- EN ISO/IEC 17021-1, Conformity assessment — Requirements for bodies providing audit and certification of management systems.

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.

1.4 Additional documents (indirectly applicable)

- ISO 14971, Medical devices – Application of risk management to medical devices

1.5 Documents related to the conformity assessment to be carried out

Certification bodies certify against:

- EN ISO 13485; Medical devices — Quality management systems — Requirements for regulatory purposes

2 Scope of accreditation

In accordance with the requirements of IAF MD8, the scope of accreditation for EN ISO 13485 is granted per technical area corresponding to the directives concerning medical devices.
These have been listed in Annex 1. Please note that the Annex (in line with IAF MD9) indicates both “Main Technical Areas” (the dots) and “Technical Areas” (the dashes).

3 Accreditation assessments

3.1 Documents to be submitted

In line with the requirements of IAF MD 8 (7.14.3), additional to the documents mentioned in the relevant application form and the annex to RvA-BR005, the documents to be submitted shall include concerns, opinions and feedback received from Regulatory Authorities on the performance of the CB, pertaining to the scope of accreditation.

3.2 The nature and content of the assessments

In addition to the generic rules for the type and content of RvA assessments as defined in RvA-BR002, RvA-BR005 and SAP-C000, for this specific accreditation the requirements from the following table

apply. The type, extent and content of the assessment depend on the requested scope of accreditation, other accreditations possibly existing and the functioning of the CB in the past (where relevant).

Assessment method	Pre-assessment	Initial assessment	During the Accreditation cycle	Scope extension [1)]
Document assessment	√			√
On site Office assessment	√ (optional)	√ At least one certification file and one personnel file per Technical area	√ (annually) At least one certification file and one personnel file per Main technical area during the accreditation cycle and at least one certification file per Technical area during two successive accreditation cycles	√ At least one certification file and one personnel file per Technical area
Witnessing		See policy concerning witnessing (3.2.3)	See policy concerning witnessing (3.2.3)	See policy concerning witnessing (3.2.3)

[1)] Based upon the requested scope extension (form RvA-F105), the RvA will determine how the assessment of the extension will be conducted.

3.2.1 Reassessments and surveillance

In line with the requirements of IAF MD 8 (7.11.2), the RvA surveillance on-site office assessments shall be conducted at least once a year. Surveillance and reassessment will include on-site assessment as well as witnessing. The witnessing program shall ensure, as a minimum, one audit from each of the Main Technical Areas (shown in Annex 1 of IAF MD8) in the scope of accreditation within an accreditation cycle. The sampling for witnessing will give priority to higher risk areas.

3.2.2 Scope extension

The assessment by the RvA in case of an application for an additional technical area shall include at least the defined requirements for competence in that sector, records of the qualification process of auditors for that sector, and a complete certification and personnel file in that sector.

3.2.3 Policy concerning witnessing

In line with the requirements of IAF MD8 (7.5.6) the samples for witnessing of audits shall include an audit of the higher risk class of the Technical Areas covered under the scope of accreditation. The witnessing program shall ensure, as a minimum, one audit from each of the Main Technical Areas (shown in Annex 1 of the MD8) under the scope of accreditation.

The experience of the CB recognized for one or more medical device regulatory scheme(s), among other factors, will be considered in the witnessing schedule. Typical regulatory schemes are: Medical Device Directive (MDD - 93/42/EEC), Active Implantable Medical Devices Directive (AIMD - 90/385/EEC), Medical Device Regulation (EU) 2017/45, In-Vitro Diagnostic Devices Directive (IVD -

98/79/EEC) / In-Vitro Diagnostic Devices Regulation (EU) 2017/746, and also the Canadian Medical Devices Conformity Assessment System (CMDCAS) and the Therapeutic Goods Administration, Therapeutic Goods Regulations by Australia.

Previous results of witnessing will be taken into account in the witnessing strategy.

All locations where one or more key activities (see RvA-BR003, chapter 7) are performed shall be assessed during the accreditation cycle.

In case of extension of scope, the strategy for the assessment depends on the sector and the scope already accredited. The following guidelines apply:

- In case the requested technical area is for a main technical area (i.e. in another bullet, see Annex 1) the CB is not yet accredited for, a witness shall be included.
- In case the requested technical area is considered to be a higher risk than the ones already accredited, a witness shall be included. The classification of the risk categories for the technical areas is similar to the classification of the medical devices as set down in the medical devices directive 93/42/EEC (annex IX).

4 Specific issues for the RvA assessments

In line with the requirements 4.4.1 and 4.5.1. of IAF MD9, the RvA assessors will check whether the CB verifies that the client organization has evaluated statutory and regulatory compliance and has made agreements with their clients to release audit report information to regulators that recognize EN ISO 13485.

4.1 Initial, surveillance and re-assessments

The specific normative criteria mentioned in IAF MD9 are applicable in addition to the requirements contained in EN ISO/IEC 17021-1.
During the RvA office assessments specific attention will be paid to the following clauses of MD9 which hold additional requirements:

MD 5.2 Management of impartiality
MD 7.1 Competence of personnel
MD 7.2 Personnel involved in the certification process
MD 8.1 Public information
MD 8.2 Certification documents
MD 9.1 Pre-certification activities
MD 9.2 Planning audits
MD 9.3 Initial certification
MD 9.4 Conducting audits
MD 9.6 Maintaining certification

Also, the Annexes A, B, C and D of IAF MD9 are normative for EN ISO 13485 certification/accreditation.

The RvA assessment plans and reports shall refer to these requirements when they will be/have been part of the assessment.

5 Other information

5.1 Transition to EN ISO 13485:2016

On 1 March 2016 the international standard EN ISO 13485:2016 'Medical devices – Quality management systems – requirements for regulatory purposes' has been published. This standard replaces the second edition ISO 13485:2003 and ISO/TR 14969:2004 and it incorporates the Technical Corrigendum ISO 13485:2003/Cor.1:2009 and it supersedes EN ISO 13485:2012.
IAF has decided on a three year transitions period for the implementation of the new version..
This paragraph describes the RvA policy and practices concerning the granting of accreditation for EN ISO 13485:2016 to certification bodies (CB) which are currently accredited for the previous version of EN ISO 13485.

5.1.1 General

Accredited certificates to EN ISO 13485:2016 can only be issued after the CB has been accredited to deliver certification to the new standard, so after the scope is extended with the new standard. For this reason, although normally the RvA accreditation does not indicate the version of standards for which the CB has been accredited, the RvA will indicate on the scope whether accreditation includes certification against the 2003 or the 2016 version. During the transition period, it will do so at the earliest opportunity (e.g. after a regular assessment, or with changes in the scope). This means that when the appendix to the RvA accreditation certificate does not specifically refer to the EN ISO 13485:2016 version, the CB is not yet accredited for the 2016 version. The accreditation for ISO 13485:2003 / EN ISO 13485:2012 will remain valid until the end of the transition period. This will be indicated on the scope of accreditation, by adding the version of the standard.

The fact that significant changes have been introduced in the new standard, resulted in a decision by RvA, that an office assessment and a witness assessment will be part of the scope extension process.

5.1.2 RvA assessment of the scope extension for EN ISO 13485:2016

To start the assessment process the CB should submit an application form for extension of accreditation (RvA-F105). The application should be accompanied by a transition plan, indicating when and how the CB intends to prepare itself and carry out accredited certification against the revised standard. The CB should keep its RvA contact person up to date with relevant changes to the transition plan, i.e. those which may have an impact on the accreditation assessments.

The implementation of the plan will be assessed by the RvA as follows:

- With a document review the RvA assessment team will review the transition plan and verify whether or not the CB has an adequate plan to address the new and changed requirements in its

processes for auditing and qualification of assessors and other staff Based on the plan the RvA will schedule the office assessment to assess the implementation of the plan.

- Before the office assessment will be conducted the RvA expects that the CB has carried out an internal audit and management review regarding the new activity. During the office assessment the RvA-team will assess the reports of this internal audit and management review and will also assess the implementation of the plan. During the office assessment the RvA-team will select the audit that will be witnessed.
- During a witness assessment, the assessment team will verify the implementation of the changed procedures and processes.

5.1.3 Granting the scope extension for EN ISO 13485:2016

The non-conformities that are revealed during the scope extension assessment activities will be processed according to policy rule BR004. A positive decision on the extension of the scope will only be taken after all non-conformities that relate to this specific scope have been closed.

If the RvA has not been able to take a positive decision regarding granting accreditation for EN ISO 13485:2016 before 1 March 2019, the accreditation against ISO 13485:2003 / EN ISO 13485:2012 will be withdrawn per 1 March 2019.

5.1.4 Accredited certificates

It should be noted that accredited certificates to the EN ISO 13485:2016 shall be issued only after:

- the RvA has granted accreditation to the CB to deliver certification to the new standard and
- the CB has confirmed by one or more audits that the client complies with all requirements of the new version of the standard.

5.1.5 Annex to the declaration of accreditation

The annex to the declaration of accreditation which was amended to indicate the version of ISO 13485 for which the CB has been accredited (see 5.1.1) will refer to both versions as soon as accreditation for the new version has been granted. On 1 March 2019 the annex will be adjusted and the dates of the versions will be removed, which means that the CB is accredited to the current version, which will then be the EN ISO 13485:2016.

5.2 RvA experts

RvA expertise holder EN ISO/IEC 17021: Corné Cox (corne.cox@rva.nl)
RvA co-ordinator EN ISO/IEC 17021: Carmen Goettsch (carmen.goettsch@rva.nl)
RvA technical expert: Ingrid Grotenhuis (Ingrid.grotenhuis@rva.nl)

6 Changes compared to the previous version of this document

Compared to version 2, dated 6 June 2017, the following significant changes have been made:

- changes due to the update of IAF MD8 and IAF MD9 to the 2017 version, e.g. new elements in chapters 3 and 4, witnessing and office audit frequency and documents to be submitted.
- changes due to the new Technical Areas in table 1.7 of the standard, Main Technical Areas: ‘Parts or services’.
- changes due to the transition to EN ISO/IEC 17021-1:2015.
- ’surveillance’ in the table at 3.2 replaced by ‘accreditation cycle’ due to IAF MD17.

Annex 1: Example of a full scope for EN ISO 13485

Standard / Normative document	Certification scheme*
EN ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes for the scopes: • 1.1 Non-active Medical Devices - General non-active, non-implantable medical devices - Non-active implants - Devices for wound care - Non-active dental devices and accessories - Non-active medical devices other than specified above • 1.2 Active (non-implantable) Medical Devices - General active medical devices - Devices for imaging - Monitoring devices - Devices for radiation therapy and thermo therapy - Active (non-implantable) medical devices other than specified above • 1.3 Active Implantable medical devices - General active implantable medical devices - Implantable medical devices other than specified above • 1.4 In Vitro Diagnostic Medical Devices - Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing - In Vitro Diagnostic Instruments and software - IVD Medical Devices other than specified above • 1.5 Sterilization Methods for medical Devices - Ethylene oxide gas sterilization (EOG) - Moist heat - Aseptic processing - Radiation sterilization (e.g. gamma, x-ray, electron beam) - Sterilization method other than specified above • 1.6 Devices incorporating/utilizing specific substances/technologies - Medical devices incorporating medicinal substances - Medical devices utilizing tissues of animal origin - Medical devices incorporating derivates of human blood - Medical devices utilizing micromechanics - Medical devices utilizing nanomaterials - Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed - Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above • 1.7 Parts and Services - Raw materials - Components - Subassemblies - Calibration services * - Distribution services - Maintenance services - Transportation services Other services

* Organizations providing calibration services should be accredited to ISO/IEC 17025