Title	**Guidelines for the accreditation of Bodies operating certification of quality management systems (QMS) in the sector of medical devices (MDs)**
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The Director of Department	The Director of Department	The General Director	2014-11-01

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INTRODUCTION

Following the issue of IAF MD 8 and IAF MD 9, ACCREDIA decided to set up a working group for the revision of RT-20, providing interpretations aimed at an improved specification and support for the requirements which are applicable to the process of certification in the sector of medical devices.
For easier consultation, the document is structured in line with the requirements of the standard UNI CEI EN ISO 17021:2011. It also follows the progressive numbering of the IAF Guide (MD + paragraph of the standard: additional IAF MD9 requirement; DT + paragraph of the standard: additional ACCREDIA requirement).
The document provides details and comments where applicable and necessary, in accordance with the requirements of the standard, setting out a reference for the conformity of CABs in order to obtain and maintain accreditation from ACCREDIA, relating to the issue of specific certification.

1 SCOPE AND FIELD OF APPLICATION

The field of application of the present document is the accreditation of bodies operating the certification of quality management systems (QMS) in the sector of medical devices – MDs. The term is defined below (see article 1 of the Directive 93/42/CEE et seq.):

Medical device: an instrument, piece of equipment, installed system, substance or other product, used either alone or in combination (including IT software used for correct functioning) and intended by the manufacturer for human use in matters concerning diagnosis, prevention, controls, therapy, treatment of illness; for diagnosis, controls, therapy, treatment or compensation of a wound or handicap; for study, substitution or modification of the anatomy or for a physiological process; for conception interventions – a product which does not play a principal part – on or in the human body, with pharmacological or immunological means or by means of a metabolic process, but whose function can be aided by such means.
Regarding the correct attribution of the field of application for inclusion in the certificate, see § 3 “Definitions”.

2 NORMATIVE REFERENCES

2.1 STANDARDS AND REGULATIONS APPLICABLE FOR ACCREDITATION

The following documents are applicable:

- **UNI CEI EN ISO/IEC 17021 -** Conformity assessment - requirements for bodies providing audits and certification of management systems;
- **IAF MD 9:2011** IAF - Mandatory Document for the Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485);
- **IAF MD 5:2013** - IAF Mandatory Document for Duration of QMS and EMS Audits;
- **ISO/IEC 17000:2004** - Conformity assessment – vocabulary and general principles;
- **RG-01** – Regulation for the accreditation of certification bodies (current revision);
- **RG-09** - Regulation for the use of the ACCREDIA mark (current revision);
- **UNI EN ISO 19011:2012** – Guideline for management system audits.

2.2 STANDARDS AND REGULATIONS APPLICABLE FOR CERTIFICATION

- **ISO 13485 Medical devices – Quality management systems; and normative references.**

3 DEFINITIONS

The definitions given in the following standards are applicable for management systems:

3.1 UNI EN ISO 9001:2008, § 3;
3.2 UNI EN ISO 9000:2005;
3.3 UNI CEI EN ISO 17021:2011, § 3;
3.4 UNI CEI EN ISO 13485:2012, § 3;
3.5 IAF MD 9, § 3.

In case of conflict the standard indicated in number 3.3 of the above list prevails

4 PRINCIPLES

4.1 General

No additional requirement.

4.2 Impartiality

DT 4.2.4 In the risk analysis the CAB shall give evidence of having taken into consideration the risks deriving from the application of additional requirements contained in IAF MD 9, identifying them and the instruments used for reducing or eliminating them [see also § DT 5.2 below].

4.3 Competence

No additional requirement.

4.4 Responsibilities

DT 4.4.1 in the case of accidents related to MD(s), the CAB shall record the evidence of the assessment performed concerning the notification to the competent authorities and the correct management of the situation by the organization in question.

4.5 Trasparency

No additional requirement.

4.6 Confidentiality

No additional requirement.

4.7 Rapid and effective response to complaints

No additional requirement.

5 GENERAL REQUIREMENTS

5.1 Legal and contractual matters

No additional requirement.

5.2 Management of impartiality

DT 5.2 Regarding ACCREDIA's position concerning the question posed with regard to the threat to impartiality deriving from the use of auditors who have been part of organizations such as those indicated in point 5.2 c) iii of IAF MD 9 and with reference to the preceding point DT 4.2.4, the CAB shall give evidence of a thorough evaluation of the items under examination, providing all the necessary support evidence.

5.3 Responsibilities and financial resources

No additional requirement.

6 STRUCTURAL REQUIREMENTS

No additional requirement.

7 REQUIREMENTS FOR RESOURCES

7.1 Competence of the Direction and of personnel

DT 7.1.1 If the technical area is not among those in Annex A of the present document (scope: different MDs from those in the relative tables), the precise name of the MD shall be defined and its intended use.

7.2 Personnel involved in certification activities

DT 7.2.1 Auditors: Apart from identifying them the CAB shall formalize, in a systems document, the authorizations of the lead auditor, the auditor and the technical expert, with precise reference to the technical areas referred to in Annex A. The authorization shall specify any limitations to activities.

7.3 Use of single external auditors and technical experts

No additional requirement.

7.4 Records of personnel

No additional requirement.

7.5 Outsourcing

No additional requirement.

8 REQUIREMENTS FOR INFORMATION

8.1 Information which is accessible to the public

No additional requirement.

8.2 Documents regarding certification

DT 8.2 For accepted exclusions the table shown on page 4 of the introduction to UNI CEI EN ISO 13485:2012 is valid, including the indications given on point 12.1.

8.3 List of certified clients

No additional requirement.

8.4 Reference to certification and use of marks
No additional requirement.

8.5 Confidentiality
No additional requirement.

8.6 Exchanges of information between the CAB and its clients
No additional requirement.

9 PROCESS REQUIREMENTS

9.1 General requirements

9.1.2 Audit plan

DT 9.1.2.3 c) the audit plan shall include the technical areas which will be audited as referred to in Annex A of IAF MD 9. If these are not set out in the Annex they shall be identified by the CAB, including their exact names and intended use.

9.1.3 Selection and assignment of the audit team

DT 9.1.3.1 Evidence of competence in technical areas shall be recorded, as indicated in § 7.2.1 above.

9.1.4 Determination of the duration of the audit

DT 9.1.4.1 In order to determine the timeframe it is necessary to show and record the factors taken into consideration to decide whether or not to carry out an audit at the organization's sub-contractors in the case of critical processes (e.g. sterilizations, preparation of diagnostic kit and so forth) or complex cases (installation and testing of management of the MD, welding in the MDs etc.) which have or could have influence on the reliability of the MD in terms of quality, safety and effectiveness.

9.2 Initial audit and certification

9.2.1 Initial certification audit

DT 9.2.3 The conditions whereby a conformity assessment of items already assessed during audits performed in the mandatory sector is not repeated shall be explained and recorded. Such evidence shall be made available during the audit 13485 so as to avoid the raising of a finding if the audit times do not correspond with those of the IAF MD9.

DT 9.2.3.1.1 e) During the review of the distribution of resources it will be necessary to assess carefully all the personnel with reference to the declarations made to the CAB in the application for certification or of preliminary information in the case of surveillances or re-certifications, recording the details of distribution in: the personnel of the organizations entrusted with the processes contained in the field of application of the certification, the number of shifts and personnel used per shift, any part-time workers (with indication of tasks assigned), active consultant personnel (e.g. medical consultant for planning activities of the MDs, chemical/biological/biomedical consultant for realization of MDIVD etc.).

9.3 Surveillance activities
No additional requirement.

9.4 Renewal of certification
No additional requirement.

9.5 Special audits
No additional requirement.

9.6 Suspension, withdrawal, or reduction of the scope of application of the certification
No additional requirement.

9.7 Appeals
No additional requirement.

9.8 Complaints
No additional requirement.

9.9 Records regarding clients and applicants for certification
No additional requirement.

10. REQUIREMENTS FOR THE MANAGEMENT SYSTEM OF CBs
No additional requirement.

NOTE: in the annexes below the additional elements are shown in the table with double border lines and with a grey background.

ANNEX A

(Normative)

Technical area medical devices

DT Annex A	In the table, if there is written medical devices "**different from those specified"**, the technical area shall be established keeping the wording of the table (e.g. **IVD medical devices different from those specified)**, indicating the products or categories of product and their intended use

ANNEX B

(Normative)

Typologies of knowledge and competence required for personnel involved in ISO 13485 activities

No additional requirement

For collateral processes related to the production chain of the medical devices, if they are in no way directly involved with the medical device (e.g. transport, storage of packaged and identified MDs – excluding installation and maintenance processes for which the competence is required in the reference technical areas), the competences required of personnel are those related to these specific processes: methods of maintenance of the integrity of identification for the purposes of traceability, verification methods and maintenance of the cold chain, where applicable etc.

ANNEX C

(Normative)

Auditor qualification, training and experience

C.1 Education

No additional requirement

C.2 Work experience

No additional requirement

C.3 Competence of the auditors

See Annex B.

C.4 Development and maintenance of competence

C.4.1 Continuous professional development

DT C.4.1	Such activities shall be recorded in the CV or, if undertaken on behalf of the CAB, on a specific document (e.g. personnel file). Attestations of activities undertaken shall be made available with indications of any courses successfully completed (where applicable). In cases of personal study the auditor shall provide a self-attestation in accordance with DPR 445/2000, with details of the activities.

C.4.2 Advanced training for auditors

DT C.4.2	Advanced training activities shall be recorded in the CV or, if undertaken on behalf of the CAB, on a specific document (e.g. personnel file). All important aspects of such activities shall be made available, indicating, as well as the period in question, also the organization where they took place. In the absence of original documents attesting these activities, self-declaration is required in accordance with DPR 445/2000

ANNEX D
(Normative)

Table D.1
Relation between effective number of personnel and audit duration (only for the initial audit)

Factors used to determine the audit duration

No additional requirement

11. RELATION WITH THE STANDARD ISO 9001

In cases only of certification, in accordance with UNI CEI EN ISO 13485, for determining the audit times the contents of Table D.1 of Annex D are applicable. For periodical surveillance and renewal of certification, as for factors which may add to or reduce the audit time, the document IAF MD 5 is applicable. It is also necessary to take into consideration the additional factors set out in Annex D.
In cases of combined ISO 13485 and ISO 9001 certification, it is necessary to indicate in the audit plan the additional requirements of ISO 9001 for assessment on the basis of information in Appendix B of the standard on the MD.

11.1 Case A: Organization without certification

Activities	Times
A1 – the organization seeks certification against UNI EN ISO 13485 and UNI EN ISO 9001	
Granting UNI CEI EN ISO 13485 + UNI EN ISO 9001 – with identical field of application	The times contained in the table IAF MD 9:2011 are applicable with an increase of 0.5 audit days for complex situations
Subsequent assessments	The times of the subsequent assessments are those set out in Table IAF MD 9:2011

A2 – the organization seeks certification against UNI EN ISO 13485	
Granting against UNI CEI EN ISO 13485	The times are those set out in Table IAF MD 9:2011
Subsequent assessments	The subsequent times are those set out in Table IAF MD 9:2011

11.2 Case B: Organization already possessing UNI EN ISO 9001 certification

Document review: to be performed before the audit due to the fact that the CAB must be sure that the organizations QM has applied correctly UNI CEI EN ISO 13485.

Activities	Times
B1 – The organization seeks certification against UNI EN ISO 13485 and decides to maintain UNI EN ISO 9001, with same field of application	
Granting against UNI CEI EN ISO 13485	In general this is done to coincide with renewal against UNI EN ISO 9001, considering the renewal assessment times as in the Table IAF MD 9:2011. If a document review is not performed before the assessment the duration of a certification audit will be as described in IAF MD 9:2011.
Subsequent assessments	The subsequent audit times, valid for both standards, are those given in the Table IAF MD 9:2011.

11.3 Case C:

C1 – the organization, as defined in cases A) and B), markets MDs or delivers services and conducts activities related to MDs (assistance, maintenance, transport, logistics)	
Initial assessment	The assessment times are those given in the Table IAF MD 9:2011.
Subsequent assessments	The subsequent assessment times are those given in the Table IAF MD 9:2011.

This case includes organizations which are not manufacturers in accordance with the directives regarding MDs. If an organization operates within the OBL regime, or if it designs or produces MDs for third parties, the requirements of the manufacturers are applicable (therefore cases A and B are applicable), with reductions (if any) to be calculated on a case-to-case basis, according to their involvement.

12. FURTHER REQUIREMENTS

12.1 Exclusions/ Non-applicability

In cases of certification for the purposes of CE marking, the following table shows exclusions which are not permitted, in order to conform with UNI CEI EN ISO 13485.

Directive 90/385/CEE	Directive 93/42/CEE	Directive 98/79/CE
No exclusions for Annex II	No exclusions for Annex II	No exclusions for Annexes III and IV
It is possible to exclude point 7.3 of the standard for Annex V (preparation and management of the Technical File, however, remain)	It is possible to exclude point 7.3 of the standard for Annex V	It is possible to exclude point 7.3 of the standard for Annex VII
	Exclusions of points 7.3, 7.5.1 and 7.5.2 of the standard for Annex VI are permitted	

If different exclusions are declared from those indicated it is not possible to attest conformity with UNI CEI EN ISO 13485, and therefore the presumption of conformity is no longer possible.
In all cases the CB shall never allow exclusion or non-application against the following requirements:

Par.	Comment
7.1.	**Planning of product realization** The planning shall be consistent with the outcomes of the risk management, in accordance with UNI CEI EN ISO 14971. The standard takes into consideration the entire life cycle of the MD, so it is improbable that the various organizations can exclude the requirement. The CAB shall verify the existence of the risk analysis document and evaluate its congruity with the specific characteristics of the product.
7.2	**Customer-related processes** In relation to point 7.2.3 “Customer communication”, the CAB shall check that there are procedures of communication regarding both the market surveillance requirements and the management of post-production information (UNI CEI EN ISO 14971).
7.4	**Purchasing** The CAB shall check that there are adequate procedures and/or documented evidence regarding post-sale surveillance requirements of products with respect to the traceability requirements of individual components and/or raw materials.
7.5.3	**Identification and traceability** The CAB shall verify not only the application of the requirement but also the effectiveness of the identification and traceability procedures
7.5.5	**Preservation of product** As for requirement 7.1, regarding the management of risks by means of proper planning of the management system, the requirements concerning logistics are always applicable both for producers and for organizations which market MDs

Any modifications adopted by the organization for the exclusion of requirements shall be evaluated and approved by the CAB and confirmed by the decision-taking body.

With regard to non-exclusion from requirement 7.1 it is recommended to confirm as follows:

- The CAB shall not grant QMS certification to organizations which do not possess the Technical File, if such organization is a producer in accordance with the Directives 90/385/CEE, 93/42/CEE and 98/79/CE.
- During the examination phase of the Technical File can obtain all the necessary indications for describing the organization's productive process related to the nature itself of the organization.
- The CAB shall verify the presence of technical documentation and the management method for organizations producing class I MDs (also on OBL basis).
- Also in the case of organizations responsible only for placing the MD on the market, the CAB shall ensure that the organization is able to manage the activities set out in the Technical File within the timeframe defined by the applicable legislation. Relations with organizations involved principally in processes of planning and production shall be supported by adequate contractual documents.

12.2 Outsourcing

Due to the fact that the standards UNI CEI EN ISO 13485 and UNI EN ISO 9001 require management of outsourcing processes, the CAB is provided with a means for defining the necessity of performing audits on the certified organization's suppliers. Such criteria derive from the European Commission's document "MEDDEV 2.5/3 rev/2 Subcontracting QS" of June 1998.
The audit at the location of the producer's supplier shall be specific, justified and planned. The CAB, before requesting to carry out such audit, shall evaluate as follows:
a) Whether the supplier is substantially involved in the planning and/or production of the MD;
b) Whether the supplier commits himself to supplying one part, one material or one service which might influence the MD with respect to the essential requirements.

If both answers are negative no additional action is necessary by the CAB.

If the answers to a) or b) are affirmative the CAB shall evaluate if there is sufficient evidence of the competence of the supplier in carrying out such activities. Such evaluation shall also take into account the level of control made by the producer with respect to the supplier and the certification (system or product) which the producer holds. If the producer's evidence is insufficient the CAB shall arrange for an audit at the supplier's location or request a re-evaluation.

The CAB is not obliged to carry out audits on the suppliers if another CAB or notified body which is competent in the activities, materials or services which could influence the MD has already performed an audit on the supplier as long as it regards the activities, materials or services related to the MD, on condition that it can evaluate the results of the audit.

12.3 Legislative conformity

The role of the accredited CAB can in no way whatsoever substitute the one of the notified bodies or public control entities or institutions due to the different role covered by the various bodies and to the different significance of the two verifications (conformity with a voluntary standard on the one hand and conformity assessment in accordance with the law on the other).
In line with the general points of UNI CEI EN ISO 13485 and with point MD 4.4.1 of IAF MD 9, the aim of the standard is to demonstrate not only the capability to supply not only MDs regularly and relative services in conformity with the clients' requirements, but also the mandatory applicable ones.
CABs must evaluate the desire and capability of the organization to ensure European and national legislative compliance as a part of certification against UNI CEI EN ISO 13485.

The CAB shall verify that the organization has identified all the legal requirements, making them accessible to the personnel involved and shall establish how these legal provisions are applicable to MDs. This highlights the fact that the organization must know which laws to comply with and that it must verify periodically its adherence and keep the pertinent records.
UNI CEI EN ISO 13485 binds the organization to full legal compliance and any deviation would lead to non-compliance with such requirements.
If, during the audit to evaluate commitment and legal compliance by the organization, the CAB finds any failures which can be related to the certification, it shall raise a nonconformity (NC), the gravity of which will be established in accordance with the reference standard. If the failure reveals a lack of desire or capability of the organizations QMS to meet the requirements, the CAB shall raise a NC of sufficient relevance that certification cannot be issued until it has been resolved.

If there are any doubts regarding the partial or total applicability of a legal requirement on the part of the organization, the CAB can issue a finding which nevertheless permits the granting of certification if it is sure that this choice is within the objectives of the standard.

12.4 Scope and field of application – technical areas

In setting out the scope or certification the CAB shall refer to factors indicated in Annex A of IAF MD 9; where these factors are not included in the tables of the IAF document (different mandatory documents from those specified above), the exact name of the MD shall be stated and its intended use.
In cases of the delivery of services regarding MDs (logistics, installation, maintenance etc.) as previously indicated is intended to be applicable in cases where the criticality of the process requires specific procedures and competences related to the mandatory documents.

In the certificates issued to organizations it is possible to omit indications concerning technical areas and the EA/IAF sectors.

12.4.1 Distinctions between MD marketing procedures

In creating the scope of certification it should be noted that there is a clear distinction between:

- an organization which markets MDs (sales, marketing or trading) shall manage traceability, complaints, storage of products etc and shall therefore respect, if only partially, some of the provisions of UNI CEI EN ISO 13485;
- an organization which places MDs on the market (this refers also to organizations with OBL contract, and which can be translated, as indicated in the directive “MD - Placing on the market”): the organization shall respect the mandatory factors of a producer in accordance with the Directives on MDs.

The Table below shows (only as examples) some types of fields of application depending on the typology of activity undertaken by the organization:

TABLE 1 – EXAMPLES OF SCOPE/FIELD OF APPLICATION OF CERTIFICATION

	Typology of activity	Standard / field of application
1	Organization which markets [*] MDs (absence of regulatory factors except for traceability, complaints, market recalls)	EN ISO 13485:2012 "Marketing - description as indicated in point 12.4.1"
1a	Organization which places on the market [*] MDs, including logistical factors (absence of regulatory factors except for traceability, complaints, market recalls)	EN ISO 13485:2012 "Marketing and distribution - description as indicated in point 12.4.1"
2	Organization which produces customized MDs (presence of regulatory factors except for traceability, complaints, market recalls)	EN ISO 13485:2012 "Production and placing on the market - description as indicated in point 12.4.1"
3	Organization which places on the market MDs under its own name (with its own CE marking) with outsourced design and/or production. Valid also for OBL possessing the competences required for MDs	EN ISO 13485:2012 "Management of design and marketing - description as indicated in point 12.4.1"
4	Organization which places on the market MDs under its own name (with its own CE MD marking) with internal design and production	EN ISO 13485:2012 "Design, production and placing on the market of - description as indicated in point 12.4.1" *Note: placing on the market may be substituted by other similar definitions when no doubt can be cast on the role of the producer of the organization*
5	Organization which provides services associated with MDs (sterilization, packaging and distribution, installation and technical services etc.)	ISO 13485 :2012 "Design and delivery of services of - description as indicated in point 12.4.1"
6	Organization which produces on behalf of third parties and does not have the responsibilities of the producer in accordance with the reference directives	ISO 13485 :2012 "Production on behalf of third parties - description as indicated in point 12.4.1"

[*] marketing may also take place by means of shops, chemists, e-shops, e-commerce etc:
If organizations undertake activities which are similar to the marketing of products but with a different definition (e.g .retailing – vending machines – resale etc.), it is preferable, if possible and evaluating the organization's activities, that they are among those covered by the directives.

13 BORDERLINE PRODUCTS

This typology of products, for which it is difficult to define the applicable reference standard could, as indicated by the competent authorities, be considered an MD only if its intended use is of a medical nature. This should settle any doubt of the demarcation with products which do not have this purpose, such as cosmetics, pharmaceuticals, herbal products, food supplements, beauty products etc.
For mandatory documents, as for other directives, the decision as to whether a product comes within the definition of a MD is made by the producer using the instruments made available by the directives and sector guides, supported by an adequate rationale and also, where necessary, by the competent authority – especially for class I MDs.
Regarding the competences employed for assessment of the QMS, specific competences should be taken into consideration, at least equal to those of the nearest sector.

For example:
Borderline products with the pharmaceutical sector: GMP pharmaceutical competences and competences in the former EA 13 for the management system.
Borderline products with the cosmetics sector: GMP pharmaceutical competences and competences in the former EA 12 for the management system.