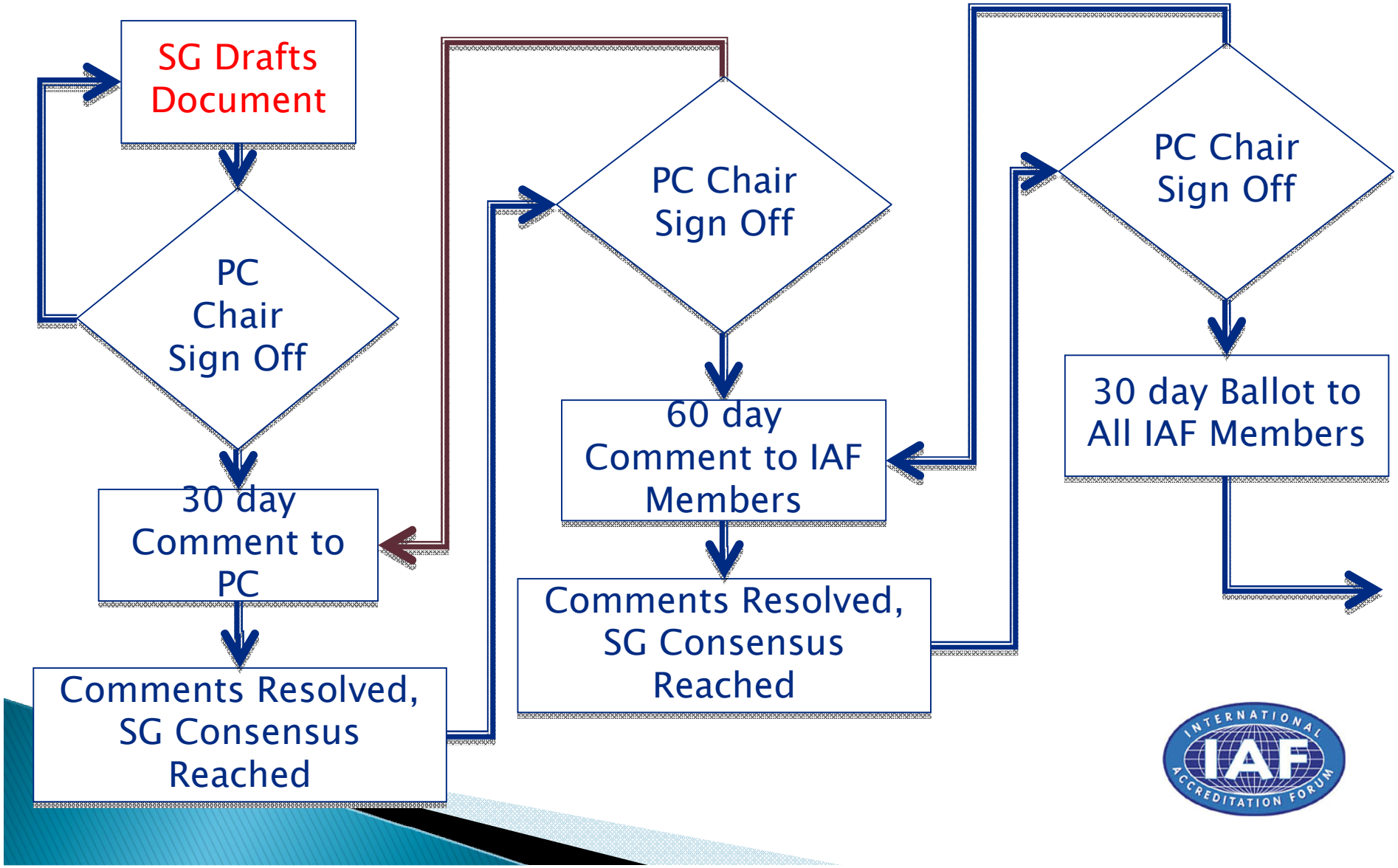
For medical devices

Sub scope provides confidence that conformity assessment results are equivalent

- **ISO 13485 certificates are equivalent**
  - **AB conforms to ISO/IEC 17011 + CB conforms to ISO/IEC 17021 + CB Client conforms to ISO 13485**

- **AB and CB also conform to IAF application documents**
  - **Plus AB conforms to IAF MD 8:2011 Application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485)**
  - **Plus CB conforms to IAF MD 9 :2011 Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485)**

Document Development



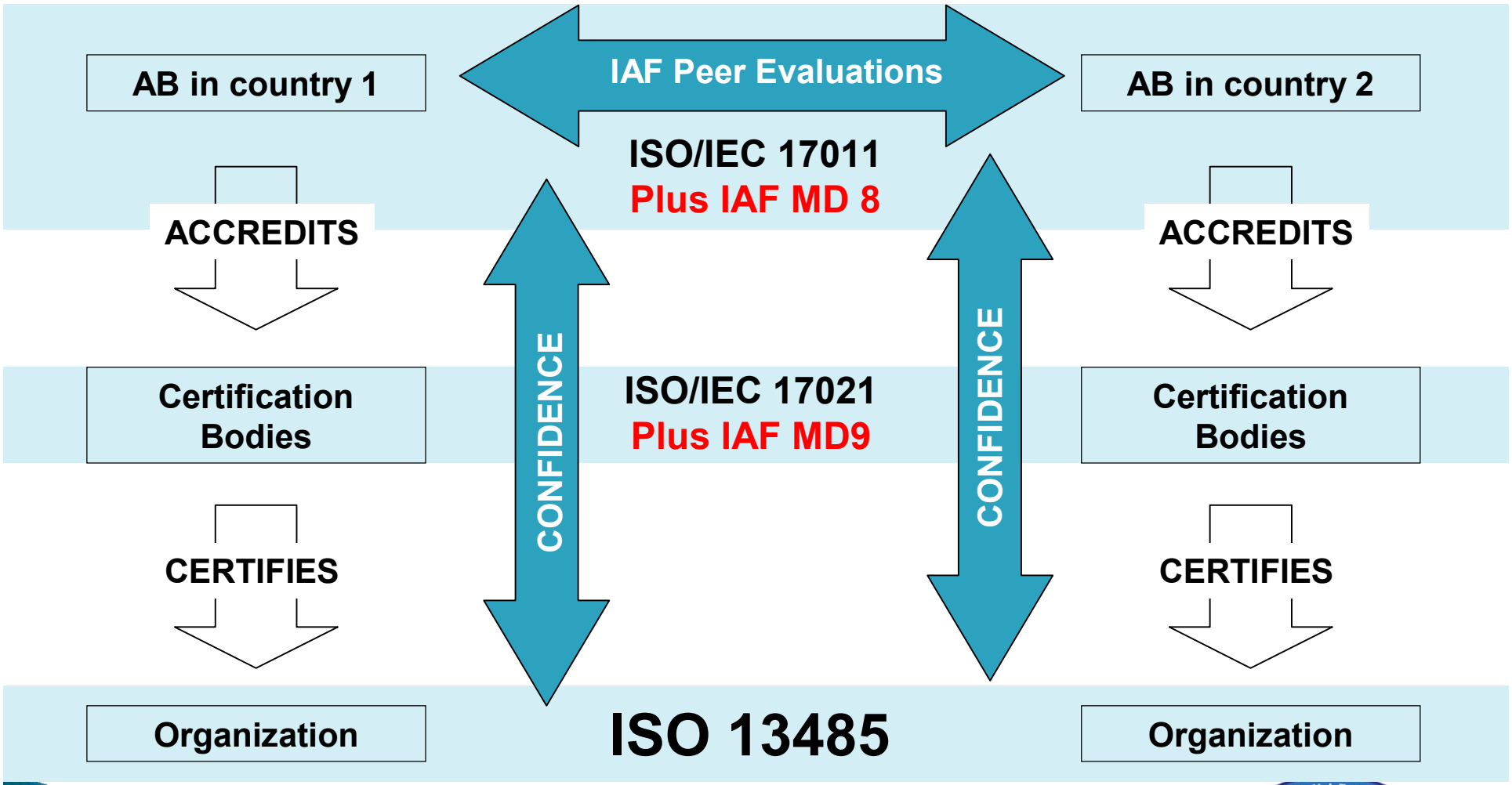
ISO 13485 Subordinate Group Composition

- Industry,
- CABs,
- ABs,
- Regulators,
- Global Harmonization Task Force.

IAF Mandatory Documents (MD)

MDs are required to assure that Accreditation Bodies and Conformity Assessment Bodies operate their programs in a consistent and equivalent manner.

Equivalence



Should & Shall

- The term “should” is used to indicate a recognised means of meeting the requirements of the standard. An AB can meet these in an equivalent way.

- The term “shall” is used to indicate those provisions which, reflecting the requirements of the relevant standard, are mandatory.

IAF MD 8 – Objective

Objective is to enable ABs to harmonize their application of ISO/IEC 17011 for accreditation of bodies providing audit and certification to ISO 13485

IAF MD 8 – Scope

The scope of the document includes:

- Provides normative criteria for assessing and accrediting CABs that provide audit and certification against ISO 13485
- Appropriate requirements document for the peer evaluation process for the IAF MLA.

IAF MD 8 – Normative References

- IAF/ILAC A5 Application of ISO/IEC 17011
- IAF GD3 – Guidance on Cross Frontier Accreditation

IAF MD 8 – Definitions

Regulatory Authority – A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical device products marketed within its jurisdiction comply with legal requirements.

IAF MD 9 – Definitions

National Regulatory Authority Regulatory Authority in the country where the AB is registered as a legal entity.

Defined but not used

IAF MD 8 – MD 4.3.2 Impartiality

Interested parties may include manufacturers or manufacturer associations, CABs, nongovernmental organizations (NGOs), Regulatory Authorities or other organizations and users.

IAF MD 8
MD 5.8.2 Management review

Feedback from interested parties of clause 5.8.2 d) shall include any feedback received from Regulatory Authorities.

IAF MD 8 – MD 6.2.1 Personnel involved in the accreditation process

Normative Annex 2 specifies the type of knowledge and skills that the accreditation body shall define for specific functions.

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IAF MD 8– MD 7.5.6 Preparation for the assessment

- For initial and reassessment witnessing shall include higher risk class of the technical areas covered under scope of accreditation

- Witnessing should consider CAB experience and recognized regulatory schemes

IAF MD 8 – MD 7.9.5 Decision-making and granting accreditation

- Accreditation certificate shall include scope of accreditation as per Annex 1

- Annex 1 states – The accreditation certificate shall use only Main Technical Areas and Technical Areas
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IAF MD 8 – MD 7.11.2 Reassessment and surveillance

- Surveillance on-site office assessments should be conducted at least once a year where higher risk medical devices are concerned.

- Surveillance shall include witnessing

IAF MD 8 – MD 7.14.3 Records of CABs

- Records shall include concerns, opinions and feedback from Regulatory Authority on the performance of the CAB pertaining to the scope of accreditation.

IAF MD 9 – Scope

The scope of the document includes:

- Provides normative criteria for CABs auditing and certifying organizations QMS to ISO 13485

IAF MD 9 – Normative References

- ISO/TR 14969 – Guidance on the application of ISO 13485
- ISO 14971 – Application of risk management to medical devices
- GHTF documents
- IAF MD5 Duration of QMS and EMS audits

IAF MD 9 – Definitions

- Regulatory Authority

IAF MD 9 – MD 4.4.1 Responsibility

- Guidance
- Organization responsible for legal compliance
- CAB responsible for verifying the organization has evaluated legal compliance and taken action where noncompliant including notification to Regulatory Authority when required

IAF MD 9 – MD 4.5.1 Openness

- It is expected that CBs establish agreements with their clients to release audit report information to regulators that recognize ISO 13485

IAF MD 9 – MD 5.2 Management of impartiality

CABs and its auditors shall not be:

- a) involved in the design, etc. of the medical device
- b) involved in the design, etc. of the QMS being audited
- c) an authorized representative of the client organization, nor parties engaged in these activities

IAF MD 9 – MD 5.2 Management of impartiality

The following are examples where impartiality is compromised:

- i. auditor having a financial interest in the client organization
- ii. auditor being employed currently by a manufacturer producing medical devices

IAF MD 9 – MD 5.2 Cont.

- iii. auditor being a member of staff from a research or medical institute or a consultant having a commercial contract or equivalent interest with the manufacturer or manufacturers of similar medical devices.

- Two year rule can reduce threat to impartiality

IAF MD 9 – MD 6.2.3 Committee for safeguarding impartiality

- Committee for safeguarding impartiality shall have access to individual(s) with experience and knowledge of medical devices in order to get expert opinions

IAF MD 8 – MD 7.1.1 Management and personnel competence

- Personnel shall meet the knowledge and skills listed in Annex B
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IAF MD 9 – MD 7.2.1 Auditor

- Each auditor shall have demonstrated competency as defined in Annex C.

- The CAB shall identify authorizations of its auditors/technical experts using the Technical Areas in Tables in Annex A.

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IAF MD 9 – MD 7.2.4 Auditor Experience

Auditor shall have gained experience in the entire process of auditing medical devices' quality management system, including:

- review of documentation and risk management of medical devices,
- audit implementation and
- audit reporting.

IAF MD 9 – MD 7.2.4 Auditor Experience

This experience shall have been gained by participation as a trainee (under supervision) in:

- a minimum of four audits for a total of at least 20 days in an accredited QMS program,
- 50% of which shall be against ISO 13485 preferably in an accredited program, and the rest in an accredited QMS program;

IAF MD 9 – MD 7.2.4 Auditor Experience

- In addition to criteria a), audit team leaders shall fulfil the following:

- b) have experienced an audit team leader role under the supervision of a qualified team leader at least three ISO 13485 audits.

Auditor summary

- MD7.1.1 refers to Annex B for skills and knowledge
- MD7.2.1 refers to Annex C for education and work experience
- MD7.2.4 refers to Auditor experience

IAF MD 9 – MD 7.2.9 Personnel making the certification decision

- Group or individual making the certification decision shall fulfill the competencies in Annex B

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IAF MD 9 – MD 8.1.3 Publicly accessible information

- Where required by law CAB shall provide information about certifications granted, suspended and withdrawn to the relevant Regulatory Authority

IAF MD 9 – MD 8.2.1 Certification documents

- The CAB shall precisely document the scope of certification (Annex A)

- Not exclude any part of the processes, products or services that have an influence on safety and quality of products unless allowed by Regulatory Authority

IAF MD 9 – MD 9.1.3.2 General requirements

- Audit teams shall have competency in the Technical Area (Annex A)
- Technical Area is the link between Annexes A and B
- Annex B auditor and expert not the team
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IAF MD 9 – MD 9.1.4.1 Determining audit duration

- IAF MD 5 applies except for EMS
- Annex D table D.1 replaces table QMS 1
- Audit duration does not consider time required for design dossier reviews, type examinations, pre-market approval audits

IAF MD 9 – MD 9.1.9.6 Identifying and recording audit findings

- Provides a number of examples of nonconformities most of which are not specific to medical devices

- d) products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling

- e) the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements

IAF MD 9 – MD 9.2.3 Initial certification audit

- No need to repeat audits if organization has been audited against regulatory requirements that go beyond ISO 13485

- CAB has to demonstrate the requirements of IAF MD 9 have been complied with

IAF MD 9 – MD 9.3.2.1 Surveillance audit

- In addition to ISO/IEC 17021 Cl. 9.3.2.1, surveillance shall include a review of actions taken for notification of adverse events, advisory notes and recalls

IAF MD 9 – MD 9.5.2 Short-notice audits

Short notice audits may be required when:

a) external factors apply such as:

i) available post-market surveillance data known to the CAB on the subject devices indicate a possible significant deficiency in the QMS

ii) significant safety related information becoming known to the CAB

IAF MD 9 – MD 9.5.2 Short-notice audits

b) significant changes occur which have been submitted as required by the regulations or become known to the CAB, and which could affect the decision on the client's state of compliance with the regulatory requirements

IAF MD 9 – Annex A

The CAB shall use the Technical Areas described in the tables of this Annex

- a) to help define the scope of certification,
- b) to identify if any technical qualification, including competence in sterilization processes of its auditors is necessary for that particular technical area and
- c) to select a suitably qualified audit team.

When using technical areas other than specified in the tables, the technical areas shall be detailed.