

# **Code of Conduct for Notified Bodies**

**under Directives**

**90/385/EEC, 93/42/EEC and 98/79/EC**

**"Improving implementation of the European CE  
certification of medical devices through harmonization of  
quality and competence of Notified Bodies"**

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## General Statement

The work of Notified Bodies (“NBs”) in the Conformity Assessment and Certification of Medical Devices is a key corner stone of the EU legislative system to safeguard public health. This role creates a strong interest in public opinion as well as among other stakeholders, such as European and national authorities.

Established in the early 1990’s to replace the nationally existing systems in the Member States, the legal framework follows the principles of the New Approach Directives to ensure the safety of Medical Devices on the European market and to contribute to public health. The system has proven to meet its objectives in this regard but needs improvements in its implementation. Since its adoption several changes took effect such as the increased number of Member States and with that the number of Notified Bodies almost doubled since the beginning. Also new and more complex technologies have been introduced.

Many items which bear an improvement potential are already addressed in Directive 2007/47/EC and the undersigning Notified Bodies believe that this Code of Conduct (“CoC”) (which sets out defined rules on qualification of work and personnel, the conduct of our work and guidelines on how to harmonize that work) will support this improvement of the current system, strengthen it and will make obsolete the need for more drastic change to the legislative system.

The undersigning Notified Bodies believe that with our experience over the last two decades with the system, current weaknesses in the harmonization of work of Notified Bodies will be reduced significantly once Notified Bodies follow this CoC.

Although adoption of this CoC is voluntary to Notified Bodies at this time, it gives a clear signal that signatory Notified Bodies declare to be fully aware of their responsibility to ensure that certification of Medical Devices complies with the Directives. Any party with recognized Notified Body status is entitled to sign up to the CoC. The procedure to enable Notified Bodies to sign up will be transparent, fair and non-discriminatory.

The signatory Notified Bodies aim to ensure a harmonized quality of work amongst the participating Notified Bodies, to gain trust in this work in public perception as well as from political and policy stakeholders, to contribute to ensure the trustworthiness of the system amongst international partners of the European Union and to support the reputation of the participating Notified Bodies.

By signing this CoC, the participating Notified Body commits to a high quality of work by education and training of staff involved, and depth and diligence of the work carried out.

The signatory Notified Bodies recognize that the strength of the medical device sector over the previous decades has been largely due to the very high level of innovation in technology and the short product life cycles. This has greatly advanced possibilities for diagnosis and treatment, quality of life for many patient populations and has enhanced the patient safety. The current EU legislative system is well suited to support this dynamic innovation level while safeguarding patient safety. Notified Bodies are well suited and motivated to adapt rapidly to the ever changing technological needs, hiring sufficient competent staff and help make new technologies quickly available to patients through efficient and robust approval processes.

By signing this **Code of conduct for Notified Bodies under Directives 90/385/EEC, 93/42/EC and 98/79/EC**, version 3.4, the participating Notified Body ensures its executives will lead by example and will actively live out and communicate the principles set forth in this Code of Conduct and all staff shall be responsible for ensuring their business conduct complies with it. We will not tolerate any violation and will apply appropriate measures to ensure the application of this Code of Conduct.

Date:

.....

**NOTIFIED**

**BODY:**.....

**NB number:**

.....

Signature:

.....

Name:

.....

Title:

.....

## General principles of conduct

This Code of Conduct is characterized by loyalty and integrity to patient safety, the requirements of our accreditation and designation as well as the support of our customers, which is reflected in the following core principles:

- We operate in compliance with recognized directives and standards, and observe all relevant local and international laws and regulations wherever we conduct business.
- We are accountable for our actions to the Competent Authorities and stand by them. Staff are continuously informed and trained to raise their awareness on how to address upcoming issues.
- We are committed to continuous improvement.
- We maintain integrity and build confidence. Management of the participating Notified Bodies encourages an open atmosphere among their staff and subcontractors to report any potential violations to this Code. Any Conflicts of Interests will be prevented, or in exceptional cases tightly controlled, following assessment of potential conflicts of interest. Data-protection will be in place to protect confidential data. We will ensure that nobody in any role within the Notified Body reviews and reflects on their own work.
- We are compliant to the applicable requirements of the EU medical device directives and the accreditation standards for notified and certification bodies EN 45011, EN ISO 17021 and EN ISO 17025 and may only deviate where the European Directives and associated guidance documents or national designation rules dictate otherwise.
- We provide our services independently and professionally in compliance with the relevant directives and in line with the methods, standards, and processes applicable for Notified Bodies and set by accreditors and designating authorities.
- We commit to an active participation of our organization in the NB-MED meetings and related working groups and committees to work on continuing harmonization between Notified Bodies, maintaining state-of-the-art knowledge of and contributing to ongoing regulatory developments and strengthening implementation of the legal framework for medical devices in the European Union.

There are a number of elements that were addressed in earlier drafts of this CoC but were taken out in this version. This is mainly due to ensure the CoC is issued to a broader public in a timely manner. We realize therefore it is not covering all aspects of the work of Notified Bodies. It is our intention to add to this CoC in later stages following engagement with and feedback from various stakeholders. Topics that still need to be addressed include but may not be limited to:

- Defining requirements for review of devices incorporating material from animal / human origin under MDD or AIMD
- Covering the Conformity Assessments defined in MDD Annex III, AIMD Annex 3 or IVDD Annex V (Type Examination) as well as MDD Annex IV, AIMD Annex 4 or IVDD Annex VI(EC Verification),
- Differences between Notified Bodies in review of clinical evaluations according to MEDDEV 2.7.1

## **Implementation and monitoring of the Code of Conduct**

### **Commitment**

The Quality Management System and business practise of the Signatories with respect to their medical device Notified Body activities shall be in compliance with this CoC. The Code is a set of rules to which all Signatories and their employees have pledged their commitment. It is signed by an authorized representative within the participating Notified Body.

By signing this CoC, the participating Notified Bodies commit to adoption and publication of detailed and transparent enforcement measures for this CoC based on the principles and options defined in this chapter.

### **Enforcement**

This CoC will be implemented by the signatory Notified Body within 12 months from the moment of signing the CoC, without conditions.

The CoC does not require retrospective implementation for all existing contracts. It shall apply for all new contracts, applications and re-certifications within twelve (12) months following signature.

Within the first 12 months after signature, a peer assessment will take place. If the conclusion of the assessment is positive (the NB complies with the requirements of the CoC), the management board grants full membership.

The first assessment for the Signatories to version 3.0 (valid per 1-1-2013) of this CoC takes place within 12 months after this enforcement program has been accepted formally as part of the CoC.

This CoC can only fulfill its purpose effectively if it is enforced strongly among all Signatories and adequate remedies are taken in case of structural non-compliance. All Signatories are committed to find ways of implementation and enforcement that are effective, transparent and will lead to structural harmonization and securing of the quality level of Notified Bodies.

## Peer Assessment

A Management Board will be established on behalf of all Signatories to ensure that enforcement takes place. The following principles will be applied:

- a. The management board of the CoC will be incorporated into TEAM-NB.
- b. The management board for the CoC consists of 3 elected representatives from the participating NB's, who signed the CoC.
- c. Any employee of a participating NB can volunteer to be part of the management board.
- d. The management board starts with 3 members. After 2 years, a new chairman is elected. After 3 years, a second initial member steps down and is replaced by a newly elected member. After 4 years, the last initial member is replaced by a newly elected member. From that moment on, the term for each member is 3 years, after which the position comes up for re-election again. When a person resigns during their period, a replacement will be elected for the remainder of the running period.
- e. Upon stepping down, a member may be re-elected.

The duties of the management board are:

- a. to manage of the peer assessment program;
- b. to ensure final decisions on assessment conclusions are taken;
- c. to store documents and data;
- d. to publish the conclusions of the assessments;
- e. to ensure decisions are implemented and followed through;
- f. to manage keeping the CoC up to date to members needs to harmonise implementation, new developments in the legislative system and the expectations of stakeholders;
- g. to manage the appeal process;
- h. to maintain a website; and
- i. to ensure appropriate and timely external communication.

As part of the complaint, appeal and assessment programme in the peer review process a decisions process is established based on these principles:

- a. The assessment to be performed by assessors with suitable knowledge appropriate to the scope of the designation of the Notified Body.
- b. The assessment report is to be reviewed and approved by 1 independent assessor.
- c. Rules for the independency of the assessors are established and published.
- d. Confidentiality is maintained by assessors, management board as well as independent assessors. Confidentiality Statements by all stakeholders should cover all individual assessments.
- e. The approved report is sent at this stage only to the Notified Body that has been assessed. If there are no non-compliances with the CoC in the report, then the report goes to the Management Board at the same time.
- f. If the conclusion of the assessment team leads to non-compliances with elements of the CoC, the NB shall submit a corrective action plan within 1 month to the assessment team.
- g. The assessment team reviews the corrective action plan within 1 month after receipt. If they accept the corrective action plan, the report is finalized and sent to the independent assessor for review and approval. If they do not accept the corrective

action plan, the assessment team shall write a recommendation and submits that for review and approval to the independent assessor.

- h. The independent assessor approved assessment report is send to the management board for review and approval and the conclusion is published internally between members.
- i. Further rules will be established for the suspension and/or cancellation of the membership with TEAM-NB.

Principles for the storage and publication of data:

- a. Only the final conclusions of the assessment team will be made internally available for the members only.
- b. When a membership is suspended or cancelled due to unsolved non-compliances with the CoC, the member will be delisted without official/public announcement.
- c. All data are kept by the secretariat of the management board.
- d. A website is maintained where a list of members is published as well as the CoC and any development activity that has been undertaken.

Principles of an appeal process:

- a. Each Notified Body has the right to appeal against the result of the assessment.
- b. Each Notified Body has the right to appeal against the decision of the management board.
- c. Once an appeal has been brought forward, an independent Appeal Board will be established.
- d. The Appeal Board will consist of a representative of three Notified Bodies.
- e. Such Notified Bodies must be member of TEAM-NB, but are not represented in the management board nor participated in the assessment or peer review thereof.
- f. The Appeal Board will evaluate the appeal and communicate the result of the evaluation to all,
  - a. the Notified Body who did appeal
  - b. the members of the assessment team and peer review
  - c. the members of the management board

Maintenance of the programme:

- a. An annual meeting is held for all members of TEAM-NB.
- b. The objectives of this meeting, but is not limited to:
  - a. to assess the proper implementation of the programme;
  - b. to initiate further development of the programme;
  - c. to assess the functioning of the pool of assessors;
  - d. to discuss external communication to increase trust in NB's; and
  - e. to elect new members to the Management Board as needed.

The exact nature of enforcement measures and the management thereof will be established through additional annexes to this CoC.

The principles of the enforcement, as described in this text, are based on a peer assessment conducted by the signatories. In order to further enhance the CoC, changes to these principles may occur such as:

- implementation through adoption of this text in formal guidance documents issued by Competent Authorities (e.g. NBOG) or the European Commission;
- implementation through adoption of this text in EU legislation with respect to Notified Bodies; and
- implementation through another voluntary association of Notified Bodies yet to be developed.

By signing this CoC, the participating Notified Bodies commit to adoption and publication of detailed and transparent enforcement measures for this CoC based on the principles and options defined in this chapter, within three months of signing the CoC.

## **Qualification and Assignment of Notified Body Assessment Personnel**

Throughout this document, “MD directives” includes the AIMD 90/385/EEC, MDD 93/42/EC and IVD directive 98/79/CE unless otherwise specified.

A model for qualification of Notified Body assessment personnel is described in this chapter. This relates to key assessment personnel involved in Conformity Assessments as defined in the Directives. We realize that in addition specific experts may be invited as part of an assessment team, but their qualification is based on specific technical or clinical expertise and is not included in this base set of qualification requirements. Also qualifications of staff involved in the independent final certification decision are not included here - this is however included in section “Rules for Certification Decisions”.

Where a Notified Body adopts this harmonized model of qualification into its Quality Management System, the Notified Body is assumed to be compliant with this Code. Where a Notified Body has implemented a different qualification model, it must ensure that this model at least guarantees an equal or higher level of quality of its assessment staff.

This section of the CoC is based on the following key requirements in the MD Directives requirements from Annexes related to quality systems, and Annexes related to the Criteria to be met for the designation of notified bodies:

- The notified body and its staff must carry out the assessment and verification operations with ..... the requisite competence in the field of medical devices ...
- In particular, it must have the necessary staff ..... to perform properly the technical ..... tasks entailed in assessment and verification. This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, .....
- The notified body must have ..... satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections, .....
- The assessment team must include at least one member with past experience of assessments of the technology concerned.

We identify the following qualifications that have a role in the Conformity Assessments, where for each part of the assessments the Notified Body will assign the best fit **NBOG**:

Qualified role	Qualified for	Scope of qualification
QMS auditor <sup>3</sup>	Directive <sup>1</sup> + EN ISO 13485	For multipurpose audits this may be coupled to IAF code technology based or equivalent
Product assessor	Directive <sup>1</sup> + review of Technical Files (and/or Product related Technology Auditing)	Product subcategories as defined in NBOG document 2009-3 (e.g. MD 0201)
Product Specialist	Directive + examination of design dossier	Product subcategories as defined in NBOG document 2009-3 (e.g. MD 0201) and NBOG specifics codes (e.g. MDS 7001), 2

1 Qualified to the relevant Directive, associated Directives if applicable and the relevant regulatory guidance documents (e.g. MEDDEV documents).

2 A Product Specialist can be qualified for a generic device group as defined within GMDN and/or also for a specific technical or clinical specialism such as biocompatibility, EtO sterilization or animal tissue, based on his scientific background and competence.

3 Means an appropriately qualified medical devices QMS auditor

The Notified Body shall define special qualification requirements for auditing of specific technologies e.g.

- for sterile devices – knowledge of design & monitoring of controlled manufacturing environments, packaging of sterile devices, aseptic production, validation and process control of sterilisation processes.
- for software – knowledge of the principles of development life cycle , risk management, validation and verification according to the state of the art for software development.

Notified Body staff can be qualified to 1 or more of these roles simultaneously.

In order to be qualified and maintain qualification on an annual basis for the roles defined in this Code, the minimum requirements apply as identified further in this chapter.

Personnel involved in one or more of these roles, as well as those taking certification decisions, shall have enough knowledge, understanding of and experience with the English language. They shall be able to understand the guidance documents related to the medical devices directives. They shall be able to understand the relevant standards (when not available in the national language). In all cases this personnel should be able to correctly interpret mentioned English documentation in their discussions with manufacturers/clients and other stakeholders.

Where possible the personnel requirements described in this document should be used for the selection of NB staff, if the NB believes that they have a candidate of equivalent experience who does not meet the exact criteria described in this document, then they should justify why their qualification/ experience is equivalent. A list of all deviations from the qualifications described in the CoC will be reviewed as part of the peer review assessment. It is expected that such deviations would only be applied to a maximum of 10% of qualified staff.

Note: this should not be interpreted as up to 10% of staff may be used for activities for which they cannot be appropriately justified, all assessment staff must have a documented decision by the NB detailing the scope of activities for which they have been approved.

The aspects to be covered in a conformity assessment and the roles to be assigned are structured in below table.

Aspect to be covered	Audit on-site	Technical file	Design dossier
<b>Assessment of quality management system</b>	QMS Auditor	n/a	n/a
<b>assessment of product related technology aspects during audit e.g. sterilisation</b>	QMS auditor or Product Assessor <sup>(2)</sup>	n/a	n/a
<b>Assessment of product (Technical File or Design Dossier)</b>	n/a	Product Assessor	Product Specialist <sup>(4)</sup>
<b>Assessment of regulations</b>	QMS Auditor or Product Assessor <sup>(1)</sup>	Product Assessor	Product Specialist <sup>(4)</sup>

<sup>(1)</sup>:Whoever is trained and qualified to the requirements of the Directives, depending on how the Notified Body has organized it.

<sup>(2)</sup>:With technical expertise and qualification in sterile aspects.

<sup>(3)</sup>: Can be done on-site as well

<sup>(4)</sup>: A NB may choose to assign technical file reviews to a Product Specialist

The main tasks of a Conformity Assessment are:

#	Assessment task	Required role(s)	Remark(s)
I	On-site audit of the manufacturer's quality management system and that of subcontractors where applicable, to the requirements of the Directive(s).	QMS auditor + Product assessor (for product related technology auditing)	<ul style="list-style-type: none"> <li>• An AIMD-QMS/MDD-QMS/IVDD-QMS audit must take place once a year as a minimum.</li> <li>• At a frequency of minimally every 2 years, a Product assessor needs to take part of the assessment</li> <li>• For auditors stay within the technologies you are qualified for; get others in the team where needed or in selected cases work with dedicated briefing on the technology specifics.</li> </ul>
II	Assessment of technical documentation of MDD	Product assessor	<ul style="list-style-type: none"> <li>• Technical files need to be reviewed on a sampling basis, either on-site as part of the audit or off-site as a desk review.</li> <li>• Further reference is made to NBOG 2009-4 guidance and further in this CoC</li> <li>• Reviewer will have discretion to request assistance on specific elements of the review.</li> </ul>
III	Examination of the design dossier	Product Specialist	<ul style="list-style-type: none"> <li>• Product Specialists with qualifications for the relevant product category as defined in the NBOG code (throughout the documentation) shall take part in the design dossier reviews.</li> <li>• For initial design dossiers all relevant NBOG codes, all NBOG specifics codes will need to be present in the review team; for changes and renewals only those related to the areas that have been modified.</li> <li>• Clinical specialist must be added to the review team to ensure sufficient competence in the review.</li> </ul>

In case of devices provided in a *sterile* state, the Notified Body shall ensure in its planning of the Conformity Assessment cycle, that the following roles are part of the assessment team:

- In each audit team for all audits (initial, surveillance, renewal), at least one QMS Auditor shall have basic understanding of and experience in sterile device manufacturing aspects, especially when sterilization is done in house or at a non-certified external company.
- In the case of initial audits and subsequently once every 3 years, or in case of significant changes to the sterilisation process a Product Assessor with special qualification for sterile device manufacturing aspects shall be part of the audit team, focusing on the specific

processes in relation to sterile device manufacture.

1. AIMD-, MDD-IVDD-QMS auditor

Entry requirements	“Qualifications are based on the Technical areas as defined in the IAF MD9, Annex A” (e.g. a technology based QMS qualification would be for IAF/EAC code 14, plastic and rubber products) or equivalent
	Standard requirements for a MDD-QMS auditor as defined in relevant IAF guidance documents and ISO standards
Training	BSc degree in the relevant technology or equivalent, for one or several technologies used in the medical device sector.
	4 Years working experience in the relevant production technology for which the auditor wishes to be qualified. A master’s degree or PhD in a relevant subject e.g. including device design, clinical/performance requirements may be used to substitute 1 or up to 3 years working experience, respectively.. The total substitution together cannot exceed 3 years. Regular auditing in the relevant production technology may count as work experience.
Qualification requirements	40 hours of class room training in ISO13485 or 40 Hours of class room training in the ISO 9001 standard, of which minimum 8 hours can be dedicated to EN ISO 13485. In case of already qualified ISO 9001 auditors, minimum 8 hours of ISO 13485 class room training separate. These requirements can be substituted by evidence of competence obtained otherwise.
	32 Hours of training in medical devices, the Medical Device Directive(s) – regulations, and auditing to the regulations or equivalent; plus sufficient additional time for additional directives depending on existing experience of the trainee.
	The Notified Body shall ensure that an auditor to be qualified obtains adequate training in the relevant procedures of the Notified Body’s quality management system and is taken through a training plan consisting of sufficient audits witnessed, under supervision and observed before doing a qualification audit. Evidence of relevant audits with another Notified Body may replace this.
Renewal of qualification	Demonstration of capability/competence of conducting an audit to the requirements of the Directive(s) and where applicable EN ISO 13485. As a minimum have 1 fully observed audit to the applicable Directive (and where applicable EN ISO 13485) successfully concluded. Two partially observed audits performed as Lead Auditor can replace the fully observed audit if all the chapters of the applicable Directive are observed during these two audits and the two audits are successfully concluded.
	Persons authorized to monitor training and approve, suspend or withdraw qualifications must have adequate seniority / experience in Conformity Assessments for medical devices as defined below for Notified Body staff that is involved in the certification decision process.
Renewal of qualification	On an annual basis conducting 10 on-site audit days to the Directive(s) (and where applicable EN ISO 13485) or show relevant equivalent work experience for equivalent length of time in the medical device industry. At all times a minimum of 5 days on site audit days per annum to the Directive (averaged over 3 years) must be performed to maintain qualification, in case the other part of the minimum 10 on-site audits is evidenced through equivalent work experience. If auditors assess multiple directives simultaneously (e.g. both MDD and IVDD) the required on-site audit days should include audits according to both disciplines. Verification of this requirement shall be done at minimum on a 3 year basis, where the requirement of having done 10on-site audits can be interpreted as the average value of 3 consecutive years.
	8 Hours of maintenance training on regulatory and ISO 13485 update of relevant guidance documents pertaining to the Directives, or equivalent.
	Take into account evidence of satisfactory continual auditor’s performance (report analysis, client feedback, etc) and significant negative feedback.
	If the requirements for renewal of qualification are not met, the qualification will be suspended. Then in the first upcoming audit, the auditor needs to be observed again during the full audit and successfully conclude the observation in order to have his qualification re-instated. Two partially observed audits performed as Lead Auditor can replace the fully observed audit if all the chapters of the applicable Directive are observed during these two audits and the two audits are successfully concluded.
	The NB shall have a procedure to review renewal of auditors qualification. The maintenance of the qualification shall be conditioned to a continuous assessment of auditors performances through for example the evaluation of audit report, feedback from customers, etc. This procedure should take into account the principles above. In the event of an assessor not meeting any of the requirements the NB shall identify and document an action plan in order to maintain qualification. In the event that qualification is suspended requalification should include observation during an appropriate audit.

## 2. Product assessor MDD and IVDD

Entry requirements	Qualifications are based on the product categorization as defined in NBOG guidance document 2009-03. E.g. a product category based qualification would be MD0202, Non-active orthopaedic implants for technical file review (i.e. second level NBOG Code) and MD0200 for product related technology auditing (i.e. first level NBOG Code). In parallel to that qualifications are set on specific “horizontal” technologies, relevant for certain product categories, such as sterilisation.
	BSc degree in the relevant product or medical area for one or several technologies used in the medical sector (educational requirement), or equivalent. The educational requirement shall remain a strong basis for product categories qualified for. E.g. it is highly unlikely that somebody with a degree in electronics can be qualified for MD 0204 Non-active soft tissue implants. Typically product assessors can obtain qualifications in either active medical device product categories or non-active medical device product categories, but not in both. This is directly related to their educational background. Typical educational backgrounds for qualification in active product categories are electro-technology, electronics, software, or (clinical) physics. Typical educational backgrounds for qualification in non-active product categories and IVD reagents, kits are chemistry, (medical) biology, biotechnology, (bio)-materials or pharmacy. IVDs with a meter or software will require appropriately qualified active or software experts. In parallel the Notified Body can maintain qualifications in “horizontal” production technology areas such as sterilisation. Also here a strong link to educational background should exist.
	For a maximum of 10% of the assessor base qualification may be demonstrated deviating from the educational requirement, based on detailed written justifications.
	4 Years working experience with practical experience in the medical sector (medical device or pharmaceutical industry, relevant test laboratory, notified body, medical institution or equivalent). A master’s degree can substitute 1 year of working experience and a PhD in a relevant medical area can substitute 3 years of working experience. The total substitution together cannot exceed 3 years.
Training	32 Hours of training together in medical devices, the Medical Device Directive(s) – regulations, and audit techniques to the regulations or equivalent (if not covered by training as QMS Auditor); plus sufficient additional time for additional directives depending on existing experience of the trainee. For IVDD this includes training in the verification of manufactured product and the manufacturer’s batch release process for Annex II List A IVDs.
	The Notified Body shall ensure that a Product Assessor to be qualified obtains adequate training in the relevant procedures of the Notified Body’s quality management system and is taken through a training plan consisting of sufficient Technical File reviews witnessed, under supervision and peer reviewed before doing a qualifying full independent review. Evidence of relevant Technical File reviews for another Notified Body may replace this. This training must ensure that the trainee learns how to perform an assessment of a Technical File.
	For each product category for which qualification is sought, the Product Assessor shall obtain auditing training on how to apply product related competence in an audit environment.
	For each product category for which qualification is sought, irrespective of whether this is the first or later categories to be qualified to, the Notified Body must show evidence of appropriate knowledge in the product category. This can be in the form of training to applicable product standards, training to the products, product technology and clinical indications of the product category, etc.
Qualification requirements	To initiate the qualification process, having completed successfully (approved by certification management) 3 technical file reviews preferentially within one product category (e.g. MD 1106 or at least MD 1100) for which qualification is sought. Reviews of design dossiers in the relevant product category can count toward this requirement as substitute. Already approved Technical Files can be used for qualification purposes.
	For qualification to any subsequent product category within the same Directive, provide evidence of adequate product training, knowledge and/or experience For qualification to any subsequent product category for another Directive, provide evidence of adequate product training, knowledge and/or experience
	Persons authorized to monitor training and approve, suspend or withdraw qualifications must have adequate seniority / experience in Technical File assessments as defined below for Notified Body staff that is involved in the certification decision process.
	Qualification under NBOG code MDS 7006 of Product Assessors authorized to review detailed aspects of sterile medical devices, shall be based on: 1) Specialized competence obtained either through special training programs or professional experience in the areas for which qualification is granted: each sterilization validation method, sterile packaging validation, bio burden and residual determination, controlled environments. The relevant international and/or European standards for these topics shall be part of the competence

	requirements. 2) Qualifications shall be defined and training records kept for each aspect of sterile manufacture separately (controlled environments, sterilization, aseptic processing, sterile packaging).
Renewal of qualification	Show evidence of having done 3 Technical File reviews, per year, independent of the number of product categories qualified for. Reviews of significant changes to the product range count for 50%. Up to 50% evidence may be shown through review of design dossiers. Verification of this requirement shall be done at minimum on a 3 year basis, where the requirement of having done 3 Technical Files can be interpreted as the average value of 3 consecutive years.
	Show ongoing competence in the product categories for which qualification is established.
	On annual basis show evidence that the Notified Body has provided to qualified persons update training / information with regard to latest status of Directives, harmonized standards and MEDDEV's, clinical evaluation/ performance evaluation/ CTS requirements and other relevant requirements, or equivalent.
	If the requirements for renewal of qualification are not met, the qualification will be suspended. Then the first upcoming Technical File review shall be done under supervision, and re-qualification confirmed by Certification Management based on the outcome of this review.
	The Notified Body shall have a procedure to review renewal of qualification on an annual basis based on above principles. In case the Product Assessor has auditor qualification, monitoring on-site (observed audit) at least once every 3 years shall occur.

### 3. Product Specialist

Entry requirements	Qualifications are based on the product categorization as defined in NBOG guidance document 2009-03. E.g. a product category based qualification would be MD0202, Non-active orthopaedic implants. In addition qualifications are based on technical or scientific specialisms such as sterilization, biocompatibility, animal tissue, software, functional safety, clinical evaluation, electrical safety, packaging, stability, in-vitro mechanical, chemical or physical verification testing and for IVD the specific technology such as NAT or ELISA.
	BSc degree or equivalent in the relevant product or medical area for which the Product Specialist wishes to be qualified (educational requirement), typically more specifically defined as for Product Assessors. The educational requirement shall remain a strong basis for product categories qualified for. E.g. it is highly unlikely that somebody with a degree in electronics can be qualified for MD 0204 Non-active soft tissue implants. Typically Product Specialists can obtain qualifications in either active medical device product categories or non-active medical device product categories, but not in both. This is directly related to their educational background. Typical educational backgrounds for qualification in active product categories are electro-technology, electronics, software, or (clinical) physics. Typical educational backgrounds for qualification in non-active product categories and IVD systems reagents are chemistry, (medical) biology, biotechnology, (bio)materials or pharmacy. IVDs with a meter or software will require appropriately qualified active or software experts.
	For a maximum of 10% of the assessor base qualification may be demonstrated deviating from the educational requirement, based on detailed written justifications.
	The qualification as Product Specialist for technical / scientific specialism should be based on a sound relevant scientific education combined with sufficient working experience in that particular topic.
	4 Years working experience with practical experience in the medical sector. Half of the working experience in R&D, production or quality control with medical devices or drugs in the medical device industry, a test laboratory, pharmaceutical industry, a hospital or a notified body or equivalent. A master's degree in a relevant area for medical devices can substitute 1 year of working experience and a PhD in a relevant area for medical devices can substitute 3 years of working experience. The total substitution together cannot exceed 3 years.
Training	4 Days of training in medical devices, the Medical Device Directive(s) – regulations, and assessment and certification principles or equivalent; plus sufficient additional time for additional directives depending on existing experience of the trainee.. This includes training in the verification of manufactured product
	The Notified Body shall ensure that a Product Specialist to be qualified obtains adequate training in the relevant procedures of the Notified Body's quality management system and is taken through a training plan consisting of sufficient Design Dossier reviews witnessed, under supervision and peer reviewed before doing a qualifying full independent review. Evidence of relevant Design Dossier reviews for

	<p>another Notified Body may replace this. This training must ensure that the trainee learns how to perform a Design Examination.</p> <p>For each product category for which qualification is sought, irrespective of whether this is the first or later categories to be qualified to, the Notified Body must show evidence of appropriate knowledge in the product category. This can be in the form of training to applicable product standards, training to the products, product technology and clinical indications of the product category, etc.</p>
Qualification requirements	<p>For the first product category in a given Directive for which qualification is sought, having completed successfully (approved by certification management) 4 design dossiers (at least 2 of them shall be initial applications or significant extensions of certification)</p> <p>For qualification to any subsequent product category within the same directive or technical / scientific specialism, provide evidence of adequate product knowledge and experience.</p> <p>Qualification for a technical/scientific specialism must be based on a sound combination of relevant scientific education and/or relevant working experience (e.g. design work in this specialism) in combination with relevant training. As guidance we give the following examples:</p> <ul style="list-style-type: none"> <li>• A biologist has been involved in biocompatibility testing in industry and has been trained to the biocompatibility standards series ISO 10993. This qualifies for Product Specialist for biocompatibility.</li> <li>• An electrical engineer has gained work experience in software verification and be trained to EN 62304 and qualified as software Product Specialist.</li> <li>• An electrical engineer that receives a 10-day training in sterilization standards does not qualify as Product Specialist for sterilization.</li> <li>• A biologist who has design experience in the IVD industry for specified reagents can be qualified as a product specialist</li> </ul>
	<p>Persons authorized to monitor training and approve, suspend or withdraw qualifications must have adequate seniority / experience in Design Examinations as defined below for Notified Body staff that is involved in the certification decision process.</p>
	<p>On an annual basis show evidence of having done 3 Design Dossier reviews, independent of the number of product categories qualified for. Reviews of significant changes to the approved design (not full design examinations) count for 50%. Verification of this requirement shall be done at minimum on a 3 year basis, where the requirement of having done 3 Design Dossiers can be interpreted as the average value of 3 consecutive years.</p>
	<p>On an ongoing basis, show evidence of state-of-art product knowledge / review experience in each product category for which qualification exists.</p>
Renewal of qualification	<p>On annual basis show evidence that the Notified Body has provided to qualified persons update training / information with regard to latest status of Directives, harmonized standards and MEDDEV's, clinical evaluation/ performance evaluation/ CTS requirements and other relevant requirements, or equivalent.</p>
	<p>If the requirements for renewal of qualification are not met, the qualification will be suspended. Then the first upcoming Design Dossier review shall be done under supervision, and re-qualification confirmed by Certification Management based on the outcome of this review.</p>
	<p>The Notified Body shall have a procedure to review renewal of qualification on an annual basis based on above principles.</p>

As an equivalent to a degree in the relevant product or medical area a lower level of tertiary qualification or a non-related degree supported by a minimum of 8 years' experience in the technological area or by a minimum of 5 years' experience in the technological area when combined with further independently examined technical training is accepted.

For design dossier reviews, specific technical or clinical expertise may need to be assigned to the review team (e.g. specialist on TSE / viral inactivation, orthopaedic surgeon as clinical expert). These experts are added to the review team and may not have any formal qualification, but are rather used based on their scientific expertise in a certain field. They never conduct a full review, but are only added for specific specialized aspects. The Notified Body must have a process to select, review and accept these experts to take part in design dossier reviews. It shall have a documented justification for the expertise of the expert. Records must be kept on selection, review, acceptance and justifications.

The Notified Body must have a system implemented that ensures effective and frequent updating of their qualified personnel with respect to developments towards state-of-the-art,

development in (harmonization of) standards, and developments in EU regulations (update on MEDDEV's, NB-MED documents, NBOG documents, GHTF documents). Evidence must be available to show qualified staff has been updated regularly on technical and regulatory developments.

### **Assignment of personnel**

#### **Auditor rotation**

No person can be the lead QMS auditor in a scheduled audit for more than 3 consecutive years.

## **Minimum time for Notified Body assessments**

This part of the CoC provides guidance for NBs to develop their own documented procedures for determining the amount of time required for the auditing of clients of different sizes and complexity over a broad spectrum of activities. It is intended that this will lead to consistency of audit duration between NBs, as well as between similar clients of the same NB.

NBs shall identify the audit duration for the stage 1 and stage 2 initial audit, surveillance audits, and re-certification audits for each applicant and certified client.

This part of the document does not stipulate minimum/maximum times but provides a framework that shall be utilized within a NB's documented procedures to determine appropriate audit duration, taking into account the specifics of the client to be audited.

Time needed for technical file reviews shall be calculated separately. This time may be added to the onsite audit time or used for offsite reviews.

### **Application**

#### Audit Duration

Audit duration for all types of audits includes on site time at a client's premises and time spent off-site carrying out planning, document review, interacting with client personnel and report writing. The time spent for these off-site activities are calculated independently from the onsite audit duration time. At least 80% of the minimum audit time as specified in document IAF MD9:2015 shall be spent on-site. This applies to initial, surveillance and recertification audits. Where additional time is required for planning and/or report writing, this will not be accepted for justification to reduce on site audit duration for any audit. Each participating body has the liberty to define needed off-site time based on its own rules. This CoC only defines minimum criteria for on-site time.

#### Auditor Day

The various rules and tables present audit durations calculated in auditor days on the basis of 8 hours per day. National adjustments on the number of days may be needed to comply with local legislation for travel, lunch breaks and working hours, to achieve the same total number of hours of auditing. The number of auditor days allocated should not be reduced at the planning stages by programming longer hours per working day.

Extension of an auditor day up to 10 hours is allowed in duly substantiated cases based on difficult travel situations.

#### Effective Number of Personnel

The effective number of personnel at the manufacturer is used as a basis for calculation of audit duration following guidelines in IAF MD9:2015 guidance document. Dependent upon the hours worked, part time personnel numbers may be reduced and converted to the number of full time equivalent (FTE) personnel. Specific consideration may be given to those operations where the majority of employees are not located on site (e.g. sales and technical service personnel), working in multiple shift operation (24 hours a day / 7 days a week) or performing identical tasks.

### **Methodology for determining audit duration**

- The basis for calculation of required audit time is the table in Annex D of IAF MD9:2015. When performing a regulatory audit to ISO 13485 and potentially additional other schemes such as Medical Device Directives certification and Canadian Medical Device Regulations

certification, time needs to be added to cover all required clauses. Various other criteria may apply for adding or subtracting time which are defined in this CoC.

- Calculation of time for surveillance and recertification audit time shall follow the standard principles of IAF MD9:2015.
- All rules of IAF MD9:2015 apply unless specified differently in this CoC.
- It is appropriate to base audit duration on the effective number of personnel of the organization, the complexity of the processes within the organization, the nature and the characteristics of the medical devices included in the scope of the audit and the different technologies that are employed to manufacture and control the medical devices. The audit duration should then be adjusted based on any significant factors that uniquely apply to the organization to be audited. The NB should exercise discretion to ensure that any variation in audit duration does not lead to a compromise on the effectiveness of audits.
- Audit duration determinations as specified in this section shall not include the time of “auditors-in-training” or the technical file reviews.
- Audit time cannot be reduced by remote auditing techniques such as interactive web-based collaboration; web meetings, teleconferences and/or electronic verification of the client’s processes (see IAF MD4).
- The duration of any scheduled on site audit as part of the annual audit cycle cannot be less than 1 auditor/day (with the exception of small companies in an exclusive OBL situation).

The locations identified in the audit plan shall be physically visited at least annually.

#### CALCULATION

Using the tables below the appropriate factors shall be considered. If a factor is appropriate but no adjustment is used, the justification shall be recorded along with the calculation. The % adjustments for all the appropriate factors, both + and – shall be totalled and then applied to the initial IAF MD9 number of days based on employee numbers. To this number of days shall be added any adjustments where the adjustment is given in the table as days. If these adjustment calculations would result in a time less than 70% of the initial MD9 number of days than 70% of the initial IAF number of days shall be used as the minimum audit duration.

## Factors for adjustment of audit duration

Increase in audit duration:

<b>List of factors where an increase of the nominal time must be considered and must be applied if appropriate</b>	<b>Consequence on the nominal on site duration (at least...)</b>
Several medical devices directives included in the scope of the audit and/or Several conformity assessment routes for different devices and/or Significant number of certificates / types	+10%
Audit scope including class III, list A, DMIA devices	+10%
Number of NBOG categories included in the audit scope	+10% if more than 3 (and so on by group of 3)
Manufacturers using suppliers to supply processes or parts that are critical to the function of the medical device and/or the safety of the user or finished products .	+0,5 day
Manufacturers who install product on customer's premises. (time to assess actual installation)	+0,5 day
Poor regulatory compliance by the manufacturer (with evidence in previous audit reports)	+10- 30%
Complicated logistics involving more than one building or location where work is carried out. e.g., a separate design centre must be audited, particular manufacturing conditions	10%
Staff speaking in more than one language (requiring interpreter(s) or preventing individual auditors from working independently)	+10%
Very large site for the number of personnel included in the scope of the audit	+10%
System covers highly complex processes (eg software design and validation) or relatively high number of unique activities	+10%
Activities that require visiting temporary sites to confirm the activities of the permanent site(s) whose management system is subject to certification.	+0,5 day
In-house sterilization activities	+0,5 – 1 day /type of process

Decrease in audit duration:

<b>Factors justifying the potential reduction of the nominal time</b>	<b>Consequence on the nominal on site duration</b>
No design activity included in the scope of the audit	Maximum -15%
Audit scope including only low risk products (class IIa and less) or simple manufacturing processes	Maximum -15%
Maturity of management system (certified for more than two 3-years cycles + with evidence of performance of the QMS in previous audit reports)	Maximum -20%
Client preparedness for certification (e.g., the company is already certified by another certification body according to ISO 13485)	Maximum -15%

Client preparedness for certification (e.g., the company is already certified by another notified body according to medical devices directives and ISO 13485)	Maximum -15%
Combined audit of an integrated system of two or more compatible management systems	Maximum -15%
Prior knowledge of the client management system (e.g., already certified to another QM standard by the same NB)	Maximum -15%
Low complexity activities/ Processes involve a single generic activity	Maximum -15%
Identical activities performed on all shifts with appropriate evidence of equivalence performance on all shifts based on prior audits (internal audits and NB audits);	Maximum -15%
Where a significant proportion of staff carry out a similar simple function.	Maximum -15%
Where staff include a number of people who work “off location” e.g. sales persons, drivers, service personnel, etc. and where it is possible to substantially audit compliance of their activities with the system through review of records.	Maximum -15%
Outsourcing of most of the manufacturing processes (for all the medical devices included in the audit scope)	Maximum - 30%

Appropriate reduction should be made to the temporary unskilled personnel who may be employed in considerable numbers in some countries due to low level of technology and automation. Appropriate reduction of number of personnel also should be made where significant proportion of staff carry out a similar simple function for instance: transport, line work, assembly lines, etc.

All attributes of the client’s system, processes, and products/services should be considered and a fair adjustment made for those factors that could justify more or less auditor time for an effective audit. Additive factors may be off-set by subtractive factors.

In case of any change in the situation of the manufacturer’s situation having implications on the certification scope, the audit duration shall be recalculated. Where necessary, additional time, defined separately, is dedicated for each supplier to be audited.

### **Multi-site audit scheme**

Certification of Multiple Sites under one Quality Management System based on sampling as defined in IAF MD1:2007 guidance document (Multi-site auditing) is in principle not an option for Conformity Assessments. Rare exceptions must be substantiated.

# Unannounced Audits

## Basic principles

- Unannounced audits shall be set up and executed by notified bodies separately from and in addition to the regular audit cycle.
- All elements of unannounced audits shall be conducted by an appropriately qualified audit team
- The unannounced audits are product focused audits. All audited elements are geared towards the sampled device(s).

## Key definitions

NBOG 2010-1 defines supplier as an “organisation or person that provides a product, a service or information, and which is outside of the QMS of the manufacturer” and critical supplier as a critical supplier is a “supplier delivering materials, components, or services that may influence the safety and performance of the device” [taken from GHTF SG4 (PD1) N33 R13]. Although serving their purpose, they do not have the mind set of scoping the unannounced audit decisions. To that end the following definitions are introduced.

### Critical Subcontractors

Subcontractor performing operations that have a significant impact on the conformity with the requirements on safety and/or the essential performance of medical devices  
Subcontractor having responsibilities or performing essential activities for the conformity with the regulatory requirements.

Definition of **essential performance**: Performance of a clinical function, other than that related to basic safety, the loss or degradation of which beyond the limits specified by the manufacturer results in an unacceptable risk.

Example:

- Subcontractor involved in the design or development of a medical device
- Subcontractor involved in the design or development of Software
- Subcontractor that performs critical manufacturing process or compliance check(s) for which any deviations from specifications will impact the safety and/or the claimed essential performance(s): cleaning, sterilization, primary packaging, ...
- Subcontractor in charge of post market data collection

### Crucial Suppliers

Suppliers of finished medical devices or critical component or sub-systems.  
Suppliers of critical raw materials used in the medical devices.

Examples:

- Suppliers of raw materials for implantable medical devices (e.g. : silicone for breast implants)
- Supplier of materials of animal origin, active substances
- Supplier of radioactive seeds to treat cancer

- Supplier of critical components/sub-systems such as : Suppliers of Printed Circuit Boards, X-Ray Tubes, digital detectors, piezoelectric components mounted on ultrasound probes, ultrasound probes, ECG Electrodes

### **Unannounced audit methodology**

- The unannounced audit shall be based on verifying conformity of a recently produced adequate sample (product, batch, lot) of an approved device type.
- The unannounced audit shall be a traceability audit based on the following principles:
  - Selection of one or more catalogue numbers (individual device types) attached to a declaration of conformity, linked to a valid CE certificate.
  - Selection of a random recent batch or lot from those catalogue numbers
  - Requesting for those batches or lots the relevant documentation covering the full process from incoming raw materials and components till final release (Batch or lot history records, manufacturing traveler, bills of materials, etc).
  - Audit the process backwards from final release to incoming materials and components and during this audit verify the following aspects.
    - That the raw materials and components are the same as those specified in the technical documentation of the approved device or device family.
    - That the equipment used in the manufacturing process is still the same compared to the specifications given in the technical documentation of the approved device or device family.
    - That incoming, in-process and final inspection steps are the same compared to the documentation based on which approval was given.
    - Compare testing results done (either physical, electrical, chemical, mechanical or other) on a sample or 100% basis during in-process or final inspection with equal testing done during design verification to ensure device specification are still the same as when the device was approved.
- Apart from auditing documentation, the Notified Body shall also where possible witness selected tests to verify test data fall within the specifications. Where appropriate, more testing coordinated by the Notified Body might be required.
- Take into account during the audit process the applicable controlled changes that the device has undergone within the scope of approval issued by the Notified Body.
- A report with findings should be delivered following the assessment.

In case the manufacturer has subcontracted one or more critical parts of manufacture either to own manufacturing locations or to suppliers and they are regarded significant for the safety and performance of the device under review, then the Notified Body needs to determine whether those sites need to be audited as part of the unannounced audit.

In case the Notified Body determines that it can assess traceability and equivalence between the manufactured lot or batch and the approved device without auditing those significant additional sites (manufacturing locations and/or subcontractors), then this shall be duly substantiated.

- Manufacturers must have appropriate contracts with their critical subcontractors and with crucial suppliers that allow an unannounced audit by their Notified Body.
- Subcontractors that have already undergone an unannounced audit in the last 12 months, may be eligible for waiving the need to undergo another unannounced audit. This is at the discretion of the Notified Body performing the unannounced audit.

### Frequency

- An unannounced audit must take place at least once per 3 year.
- To determine the frequency of unannounced audits, the following criteria need to be considered:
  - If the devices bear a high risk
  - Devices are often non-compliant
  - Specific reasons for suspicion of nonconformities of the devices or manufacturer

Minimum frequency in number of years for an unannounced audit	Classification			
	Is/ Im IVD self test (annex IV)	IIa	IIb IVD list B	III / AIMD IVD list A
Normal conditions	3 yr	3 yr	3 yr	2 yrs
If the devices bear a high risk	2 yr	2 yr	1 yr	1 yr
Devices that are often non-compliant	2 yr	2 yr	1 yr	1 yr
Specific reasons for suspicion	2 yr	2 yr	1 yr	1 yr

#### Devices that bear a high risk

Reasons for increased frequency as listed in the table above under this category could be:

- All to add examples
- —
- —

#### Devices that are often non-compliant

Reasons for increased unannounced audit frequency as listed in the table above under this category could be:

- Post-market feedback that the Notified Body receives, such as vigilance cases in an unusual high frequency.
- Very high complaint rates observed during the regular audit schedule, compared to industry norm on that type of product(s).
- Very high number of non-conforming products in manufacturing observed during the regular audit schedule.
- When the non-compliance is no more applicable thus the audit frequency is considered in normal conditions

#### Specific reasons for suspicion of nonconformities of the devices or manufacturer

Reasons for increased unannounced audit frequency as listed in the table above under this category could be:

- Any of the reasons listed above

- Other input received through Authorities or news media about possible malfunctioning devices or fraudulent manufacturers.

### **Where to audit**

- The whole supply chain should be taken into consideration when determining where to perform an unannounced audit: the legal manufacturer, manufacturing locations, critical subcontractors.
- The same principles apply as in a normal Conformity Assessment with respect to determining when a critical subcontractor should be part of the unannounced audit

### **Unannounced audit duration**

- A man day constitutes of 8 hours; the unannounced audit should be completed with a minimum of two people for one day, including as minimum a QMS auditor and ~~and~~ a person covering the most relevant NBOG code.
- For a legal manufacturer that has subcontracted all critical manufacturing and final inspections steps, and where only documentation is kept and management tasks take place, the minimum duration of the unannounced audit shall be 0.5 day (+ additional time for the subcontractor audit if necessary).
- In all other cases where there at least final inspection takes place at the legal manufacturer, the minimum duration of the unannounced audit shall be 1 day.
- The Notified Body shall define the suitable appropriate duration for the unannounced audits to additional sites (manufacturing locations and/or critical subcontractors), and shall document the rationale for determining the appropriate duration.

## **Sampling of class IIa and IIb medical device technical files**

In this section, the minimum requirement for the number of technical files/dossiers that must be assessed is described.

Technical file sampling may have different implications in relation to initial assessment of manufacturers, product line extension, changes through addition of new product categories or generic device group to a certificate, renewal of certification and transfer of certificates to other Notified Bodies.

The review of technical files shall be executed by product assessors with sufficient medical device product competence as specified under the section Qualification of NB personnel earlier in this CoC. Different experts may be involved depending on the complexity and risk of the devices in question. Therefore, Notified Bodies may not be able to perform the complete assessment on site.

Product Assessors conducting technical file reviews are qualified and assigned on the basis of subcategory level (e.g. MD 0202 – non-active orthopaedic implants) as specified in NBOG document 2009-3. They can either be internal staff or external resources.

### **New clients – Initial review and subsequent audits**

2007/47/EC has added requirements for the required number of technical files to be sampled in Class IIa (at least one representative sample for each device subcategory) and IIb (at least one representative sample for each generic device group). Under defined circumstances NBOG 2009-4 allows sampling of files: “this review can be achieved by taking a representative example of design documentation of one or more type(s) of devices from those being manufactured”. Yet over time the sampling should continue until all documentation ultimately might be reviewed: “As long as there is still a technical documentation not yet reviewed, at least one technical documentation should be sampled each year”.

Technical files in class I sterile and class I measurement may be subject to sampling per subcategory, similar to class IIa files, with review limited to aspects of manufacture concerned with securing and maintaining sterile conditions or metrological requirements.

In the case of sampling (IIa and IIb), in accordance with NBOG 2009-4 the remaining files reviewed during subsequent audits, where possible, samples chosen should reflect the period in which a specific file has not been reviewed by the Notified Body.

### **Product line additions**

Products added to the portfolio by a manufacturer, should be added to the sampling plan where appropriate. New Generic Device Groups and/or device subcategories shall require a review of the technical file before they can be added to a certificate. Products of already certified generic device groups and/or device subcategories representing already certified technologies do not require prior review and approval by a Notified Body. However it is recommended to prioritize the respective technical files during sampling.

### **Re-certification process - State of the art and Technical File Maintenance**

During the certification period the Notified Body should focus during its audits on the manufacturer’s processes and their effectiveness to maintain the technical files and ensure devices currently CE marked continue to be “state-of-the-art”.

### **Assumed clients – Initial review and subsequent audits**

If there is a valid certification based on a sampling plan that meets the requirements, then there is – in case of certificate transfer -no need for a technical review until the next audit, unless there are existing concerns. The need for review of additional technical files during the next audit will be based upon the NB assessment of the technical files already reviewed by the previous NB. Appropriate objective evidence, e.g. the sampling plan from the previous NB and/or the reports of technical files reviewed, should be made available. A Notified Body may choose to review a limited number of files for verification purposes during the transfer process.

### **Depth of assessment**

The aspects to be reviewed in a technical file shall be compliant with the elements specified in the NBOG 2009-4 guidance document. The time spent on the review of one technical file should be proportionate to the risk and complexity of the devices in question.

Medical devices may be categorized into three complexity levels, to aid in determining the time needed to complete the technical file review

#### High

Devices that are complex in level of technology and different technologies and materials used (e.g. MRI equipment with complex functionalities, technologies and software, minimal invasive peripheral stent delivery system)

#### Medium

Devices of medium complexity and risk in terms of materials and technology and typically not novel (e.g., orthopaedic screw, blood pressure measuring equipment)

#### Low

Well established products of low complexity (e.g. hypodermic needle, urinary catheter)

Given the objectives of the review, the evaluation time of the technical documentation of a medical device of high complexity, including the verification of the consistency with the implemented manufacturing processes, should be between 6 to 8 hours.

## **Design Dossier Reviews**

The scope of this section includes reviews according to MDD class III under Annex II.4 or AIMD Annex 2.4 or IVDD Annex II List A Annex IV.4. When performing design examinations, the Notified Body should follow a documented procedure for review, using appropriate expertise to all technical and regulatory aspects covered by the review, allowing sufficient time for the reviewers to come to justified conclusions on the compliance of the design to all essential requirements of the appropriate directive.

Design dossiers shall be assigned for review to a Product Specialist qualified for the product category specific technical and/or clinical specialism that the design belongs too, as defined in the chapter “Qualification requirements for NB personnel”. Additional experts without a formal qualification (e.g. an interventional cardiologist as clinical specialist for the review of a drug eluting stent design dossier) may be added to the review team for specific and limited advice to ensure sufficient competence in the review. The product specialist has to document the required competences and the choice for the expert used.

A procedure must be implemented to assign and qualify external experts on a project basis. When using external resources for review of part of the design dossier, particular attention should be given to expertise level and impartiality of these experts.

The assessor should take account of EU Commission, NBOG, NB-MED, GHTF/IMDRF and other guidance documents as appropriate, recognizing them to represent the state of art regulatory interpretation of the medical device directives. Particular account should be taken of NBOG guidance document 2009-1 on “Guidance on Design Dossier Examination and Report Content”.

The dossier is reviewed in detail by the review team to establish that the essential requirements and aspects of the device performance have been adequately addressed, referencing suitable (harmonised) standards, specifications, verifications, tests and/or other evidence of compliance. Strong focus should be on clinical data, performance data, risk management and a selection of other essential requirements.

Suitable evidence of performance of similar predecessor devices may be taken into consideration, noting substantial equivalence to a competitor’s product is not considered suitable evidence, as European regulations require manufacturers to demonstrate for individual devices to conform to all essential requirements.

The table below supports the expectations on the expertise that should be involved in these reviews. It is intended as guidance to further support the requirements set forth in this CoC and should not be seen as specific requirements.

Aspect	Reviewer
General aspects (risk management file, labelling, ER checklist, design specifications, etc), in-vitro test reports, validations and related data	Product Specialist qualified for the product category that the design belongs too
Sterilization validation	Product Specialist qualified for sterile aspects
Biocompatibility data	A Product Specialist qualified in one of these aspects or an external expert in one of these fields. The Product Specialist may also have one of these particular expertise areas.
Medical device utilizing animal tissue, human blood derivatives, medicinal substances	
Software validation (e.g. AIMD)	
Clinical evaluation report (MDD/AIMD)	Either the Product Specialist with sufficient specific experience with this product group to assess clinical aspects or an external expert in this field. This also depends on the clinical complexity. If the Product Specialist (typically somebody with an engineering background) covers this aspect, his sufficient clinical experience should be duly substantiated.
Performance Evaluation (IVDD)	Either the Product Specialist with sufficient specific experience with the analyte/ technology/ including CTS if appropriate or an external expert in this field.

The review is finalized by an independent certification reviewer or certification board.

All changes effecting the design examination must be reported by the manufacturer to the Notified Body. An examination of the changes is carried out using an abbreviated review, focussing on the changes. The Product Specialist shall verify that the manufacturer has identified those essential requirements that have been affected, and ensure that the manufacturer has reviewed the risk analysis.

A full design examination for any medical device needs in principle a minimum of 5 man days in order to cover all aspects per the NBOG guidance documents with a sufficient level of detail and competence. Deviations should be duly substantiated. Design changes which effect only part of the essential requirements most likely only take a percentage of the time needed for a full design examination.

A full design examination for any IVD device needs in principle a minimum of 3 man days in order to cover all aspects per the NBOG guidance documents. Annex II list A of the IVD Directive includes calibrators and controls which require a design dossier review but are less complex than kits in addition IVD require in depth review of the analytical performance rather than review of supporting clinical papers which will take less time to review.

### **Verification of Manufactured Products for the IVD Directive**

The verification of manufactured product should be conducted according to the modalities defined in the Notified Body recommendation NB-MED/2.5.4/Rec2 according to predefined and documented release criteria. All batches should be released by the notified body regardless of physical testing has been conducted.

## **Rules for subcontracting**

Notified bodies are at all times responsible for the granting, maintaining, renewing, extending, reducing, suspending or withdrawing of EC certificates. In order to fulfil this responsibility, they are responsible for the execution of the whole certification process (including all the technical aspects of the commercial proposals), as outlined in section 6.5 of the Blue Guide 2014. It is not possible to delegate any of these tasks to external organisations!

If necessary, notified bodies may outsource or subcontract some stages of the assessment process through contracts or agreements. Procedures with criteria for selection of experts and assessors shall be in place for any outsourced part of the assessment.

The requirements for any subcontracted tasks are at the same level as what is expected for personnel who works within the Notified Bodies organizations. Policies pertaining to outsourced work should include details on:

- Competence and experience;
- Confidentiality;
- Conflict of interests;
- Control of the subcontracted/outsourced services.

Recognising that separate notification (accreditation or designation) for subcontractors is not necessary, external personnel and external laboratories working on behalf of a Notified Body must comply with the requirements of the annex XI of 93/42/EEC, Annex IX of 98/79/EC or Annex 8 of 90/385/EC, MEDDEV 2.10-2, EN ISO 17025, EN ISO 15189 and EN ISO 17021. This is also applicable for employees of affiliated companies. The outsourced work must be carried out following procedures approved by the designating authority monitoring that notified body.

Subcontracted parties are not allowed to subcontract parts of the contract to other subcontractors.

Records of the qualification of external personnel and external laboratories must be kept by the Notified Body, as well as evidence on regular monitoring on this established competence and the correct fulfillment of the outsourced work. A register of all subcontracting activities should be kept.

The qualification of personnel involved in the Conformity Assessment cannot be outsourced. Decisions on qualification, suspension, withdrawal and renewal of qualifications must be taken by senior staff of the Notified Body meeting the same requirements as staff taking certification decisions. For qualification requirements of staff that take such qualification decisions, please see the chapter on qualifications.

## Rules for Certification Decisions

Outsourcing of certification decisions to an external organization is not allowed. Affiliated legal entities within a corporate company should also be seen as external organizations.

Notified Body staff involved in certification decisions shall not have been involved in the Conformity Assessment on which a certification decision needs to be taken.

The Notified Body should demonstrate having own staff with sufficient technical competence to supervise and approve the outsourced work and to take certification decisions. Sufficient technical competence of own staff must be related to the scope designation of the Notified Body based on NBOG product categorization.

Notified Body staff that is involved in the certification decision process shall be a person or a group of persons meeting the following criteria:

- Adequate technical and/or clinical experience under the medical device directives (93/42/EEC, 98/79/EC and/or 90/385/EEC) during at least 5 years within the medical device industry or relevant service organizations (e.g. CRO's, NB's).
- Adequate seniority / experience in Conformity Assessments under the Medical Device Directive, IVD Directive and/or Active Implantable Medical Device Directive during at least 3 years within a Notified Body.
- Independence from the sales process and from the responsibility for the acquisition of new clients and from the contract review/contract acceptance decision of the certification work under review, as far as possible under national law. For QM related conformity assessment procedures (e.g. MDD, Annex II excluding (4)):
  - Having clear competence as QMS auditor and as Product Assessor in a Notified Body, authorized as Product Assessor for one or more of the Product Subcategories (e.g. MD Code 0203 as identified in NBOG guidance document 2009-3 for the related EC directive)
  - Qualification for personnel who takes certification decisions should be set at a level of the EC directive, for general medical devices (MDD), qualification should be limited to non-active or active medical devices
  - Rules for specific qualifications needed (e.g. MDS Code 7001) should be defined.
- For product related conformity assessment procedures (e.g. MDD, Annex II.4):
  - Having worked as Product Specialist in a Notified Body, authorized for one or more of the Product Subcategories (e.g. MD Code 0203) as identified in NBOG guidance document 2009-3 for the related EC directive
  - Qualification for personnel who takes certification decisions should be set at a level of Product Group (e.g. MD Code 1100) as a minimum. A general qualification like "Active medical devices" is not adequate.
  - In cases where the certification decision maker is qualified under another Product Category (e.g. MD Code 0300) than the Product Group in which the device falls (e.g. MD Code 0200), he is required to obtain input for his decision from an internal staff member who holds Product Specialist qualification for the same Product Category as where the device belongs to and who has not been involved in the assessment.
  - Rules for specific qualifications needed (e.g. MDD 7001) should be defined within the management system of the Notified Body.

- A maximum of 10% the Notified Body staff involved in certification decisions can be qualified deviating from the educational requirement, based on a written justification.

To ensure that the Notified Body has sufficient internal competence among its own staff to take certification decision and not rely solely on external expertise for certain product categories, the following requirement applies also. This competence shall be related to the scope of designation of the Notified Body for the product group title as defined in NBOG document 2009-3 (e.g. MD Code 0200 Non-active implants).

- For each product category (e.g. MD Code 1100) for which the Notified Body is designated, there shall be in-house product expertise by having at least one qualified Product Assessor or Product Specialist in that product category.

## ANNEX A - REFERENCES

The intent of this CoC is to provide requirements for Notified Bodies and their subsidiaries that adhere to this Code, in addition and while adhering to existing requirements and guidance. Some of these existing requirements and guidance documents are referenced below:

1. Active Implantable Medical Devices Directive 90/385/EEC, Annex 8 (Minimum criteria to be met when designating inspection bodies to be notified)
2. Medical Device Directive 93/42/EEC, Annex XI (Criteria to be met for the designation of Notified Bodies)
3. In Vitro Medical Device IVD Directive (IVDD) 98/79/EC, Annex IX Criteria for the Designation of Notified Bodies
4. MEDDEV 2.10-2 Rev 1 (April 2001), Designation and monitoring of Notified Bodies within the framework of EC Directives on Medical Devices
5. IAF MD 5:2013, IAF Mandatory document for duration of QMS and EMS audits
6. IAF MD 9:2015, IAF Mandatory Document for the Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485)
7. Designating Authorities Handbook
8. ISO/IEC 17021:2015, Conformity Assessment – Requirements for bodies providing audit and certification of management systems
9. NBOG guidance 2009-3, Guideline for designating authorities to define the notification scope of a Notified Body conducting medical devices assessments
10. NBOG guidance 2009-1, Guidance on design-dossier examination and report content
11. NBOG guidance 2009-4, Guidance on Notified Body's tasks of technical documentation assessment on a representative basis
12. NBOG CL 2010-1 Checklist for audit of Notified Body's review of Clinical Data/Clinical Evaluation
13. Common Technical Specifications (CTS): Commission Decisions 2009/886/EC and 2011/869/EC
14. NB-MED/2.5.4/Rec2 Verification of Manufactured Products for the IVD Directive
15. COMMISSION RECOMMENDATION No 2013/473/EU of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices (text with EEA relevance)
16. COMMISSION IMPLEMENTING REGULATION (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (Text with EEA relevance)
17. NBOG guidance 2010-1, Guidance for Notified Bodies auditing suppliers to medical device manufacturers
18. ISO/IEC 17025: 2005, General requirements for the competence of testing and calibration laboratories
19. ISO/IEC 17065:2012, Conformity assessment -- Requirements for bodies certifying products, processes and services

In addition, there are many applicable guidance documents and standards that apply to the work of Notified Bodies in practise. These are issued by the European Commission (MEDDEV documents), IAF, NBOG, GHTF, IMDRF, NB-MED, etc. All these documents are deemed to be applicable for the Notified Bodies who undersign this CoC.

## **ANNEX B–Assessment to CoC Compliance**

### **Management board of TEAM-NB**

- Members of the management board will sign a confidentiality statement. These will be available on the members part of the TEAM-NB website.
- The management board will coordinate scheduling of assessments, and schedule will be regularly updated.

### **Assessment**

- The assessments will be done by a minimum of two assessors, one of which will be assigned lead-auditor for the specific assessment.
- Assessors will be recruited by the management board. They should not be employed by or have a contract with the TEAM-NB member they will audit.
- Assessors may be senior staff from Competent Authorities, Notified Bodies, manufacturers that have resigned from such work; in all cases a qualification file demonstrating suitable knowledge appropriate to the scope of the designation of the Notified Body will be maintained by the management board.
- The NB to be audited shall be given the names and qualifications of the proposed assessors. The NB may object “for cause” (reasons to be stated) to the appointment of the assessors.
- An assessment plan shall be clearly defined and made known to the NB at least one week prior to the audit.
- Before each assessment, the assessors will sign a combined declaration of independence & confidentiality statement.
- The assessment will be reported on in a fixed template. It will be reviewed by an independent assessor. When in agreement to the content, all three auditors sign the report and the approved report is sent at this stage only to the Notified Body that has been assessed. Lead-auditor will notify the management board that the report has been issued, identifying status of compliance.
- If the assessment team concludes there are non-compliances with elements of the CoC, the Notified Body shall submit a corrective action plan within 1 month, directly to the assessment lead-auditor, notifying also the management board that corrective actions have been submitted.
- The lead-auditor, where needed assisted by other members of the assessment team, reviews the corrective action plan within 1 month after receipt. If they accept the corrective action plan, the report is finalized and sent to the independent assessor for review and approval. If they do not accept the corrective action plan, the assessment team shall write a recommendation and submits that for review and approval to the independent assessor. Again at this stage the management board is informed of the steps that are finalised.
- In both above scenarios, the independent assessor approved assessment report is send to the management board for review and approval and the conclusion is published internally between members.

## **Payment**

- The Notified Body that will be assessed will pay a fixed day rate for the auditors that will be defined by TEAM-NB plenary session, and will cover the (second/coach class) travel and accommodation expenses from the assessors.

## **Suspension and/or cancellation of membership of TEAM-NB**

- When the audit team concludes there is no effective closure of non-conformities, the management board will decide on the suspension of the member.
- In the letter of suspension, clarification should be given on what steps need to be taken, including timelines and communication methods, in order for the suspension to be lifted. Clear identification should be included on the elements that will result in final cancellation of membership of TEAM-NB based on consistent non-compliance to elements of the Code of Conduct.
- Suspension and cancellation letters will be posted on the members only part of the TEAM-NB website.
- In the event of suspension of a member Notified Body, it will remain on the Notified Body listing with the 'suspended' status, until the suspension is resolved or the membership of the Notified Body is cancelled.
- Upon cancellation of membership, the name of the Notified Body will be removed from the membership list displayed on the website.

## **Appeal process:**

- Each Notified Body has the right to appeal against the result of the assessment as well as against the decision of the management board. Such appeal should be made available in written format to the lead-auditor as well as to the management board.
- Once an appeal has been brought forward, an independent Appeal Board will be established, consisting of a representative of three Notified Bodies member of TEAM-NB that are not liaised with the Notified Body filing the appeal, nor should these members be represented in the management board. The Notified Bodies in the appeal board will be appointed by the managing director of TEAM-NB, at his/her sole discretion.
- The Appeal Board will evaluate the appeal and communicate the result of the evaluation to all,
  - the Notified Body who did appeal
  - the members of the assessment team and peer review
  - the members of the management board.
- The conclusion of the appeal process will be provided on the member's only section of the TEAM-NB website.

## **Maintenance of the programme:**

- An annual meeting is held for all members of TEAM-NB specific to the Code of Conduct assessment scheme. Such meeting maybe combined with a plenary meeting of TEAM-NB.
- The objectives of this meeting, but is not limited to:
  - to assess the proper implementation of the programme;
  - to initiate further development of the programme;
  - to assess the functioning of the pool of assessors;
  - to discuss external communication to increase trust in NB's; and
  - to elect new members to the Management Board as needed.

### **Communication and Transparency**

- On behalf of the management board, the task to store the documents and data from the assessments of TEAM-NB members under this CoC will be enacted by the managing Director, acting as secretariat of the management board.
- Conclusions of assessments as well as conclusions of any appeal process will be published on the member's portion of TEAM-NB website in a standard format listing the conclusion of the assessment signed by the management board.
- A qualitative / semi-quantitative report will be published and regularly updates on the open portion of the website. Announcements on selected achieved progress in compliance confirmation and enforcement will be published in the news section to update all stakeholders on progress made.