The European Association
Medical Devices - Notified Bodies

Code of Conduct for Notified Bodies

under Directives 90/385/EEC, 93/42/EEC, 98/79/EC EU 2017/745 and EU 2017/746

"Improving implementation of the European CE certification of medical devices through the harmonization of Notified Bodies"

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General Statement

The work of Notified Bodies ("**NBs**") in the Conformity Assessment and Certification of Medical Devices continues to be 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.

Directives established in the early 1990's to replace the nationally existing systems in the Member States, followed 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 needed improvements in its implementation due to the increased number of Member States, increased number of Notified Bodies and more complex technologies being introduced.

Many items were improved with Amending Directive 2007/47/EC, Recommendation 2013/473/EU and Implementing Regulation EU 920/2013 and the original Notified Bodies Code of Conduct (**"CoC"**). The CoC set out defined rules on qualification of work and personnel, the conduct of our work and guidelines on how to harmonize that work.

Regulations that entered into force in 2017 (MDR EU 2017/745 and IVDR EU 2017/746) have an Annex dedicated to the Requirements to be met by Notified Bodies. The words adopted took many of the original concepts from the CoC. It is therefore time to update the CoC to improve the implementation across Notified Bodies designated under the Directives and Regulations.

The update to the CoC in 2019 removed aspects that were already covered by MDR/IVDR or ISO 17021-1:2015. There will be further updates to re-harmonise after the Joint Assessments to the new regulations are complete.

Adoption of this CoC continues to be voluntary to Notified Bodies, and continues to give 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 and Regulations. 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 EU regulations are very new with improved requirements. They are suited to support dynamic innovation while safeguarding patient safety. Notified Bodies need to be 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, 98/79/EC and Regulations EU 2017/745, EU 2017/746**, version 4.0, 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 regulations, directives and standards, and observe all relevant local and international laws 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. 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 regulations, 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 legislation and associated guidance documents or national designation rules dictate otherwise.
- We provide our services independently and professionally in compliance with the relevant regulations or 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 / NBCG meetings and related MDCG 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 MDR, MDD or AIMD
- Covering the Conformity Assessments defined in MDR & IVDR Annex X, MDD Annex III, AIMD Annex 3 or IVDD Annex V (Type Examination) as well as MDR & IVDR Annex XI Part B, 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 practice 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 24 months after signature or adoption to version 4.0. and designation against the new regulations, 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 confirms full membership.

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 one 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 one month to the assessment team.

g. The assessment team reviews the corrective action plan within one 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 to the management board and members.
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. NBO) 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 and “MD regulations” includes EU 2017/745 and EU 2017/746 unless otherwise specified.

The qualification codes for Notified Body assessment personnel are described in Implementing Regulation EU 2017/2185. These codes are replicated on the MDR and IVDR application for designation forms NBOG F2017-3 and NBOG F2017-4.

Personnel within the Notified Body complete NBOG F2017-7 (MDR) or NBOG F2017-8 (IVDR) or an equivalent to document competence.

Qualification and requalification criteria for Site Auditors, Product Reviewers, Project Leaders, Internal Clinicians, Clinical Specialists, Final Reviewers, Decision Makers, Authorising Personnel is provided in NBOG 2017-2

Where a Notified Body adopts the codes described in EU 2017/2185 documented on NBOG F2017-7 (MDR) or -8 (IVDR) 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.

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 MD9:2017 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 MD9:2017 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 MD9:2017. 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 MD9:2017.
- All rules of IAF MD9:2017 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).

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 + an – 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:

List of factors where an increase of the nominal time must be considered and must be applied if appropriate	**Consequence on the nominal on site duration (at least…)**
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:

Factors justifying the potential reduction of the nominal time	**Consequence on the nominal on site duration**
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).
- When a manufacturer have products under more than one piece of EU legislation, the plan should ensure that all have been considered.

Key definitions

By following NBOG 2010-1 supplier is defined 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 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, critical suppliers do not have the mind set of scoping the unannounced audit decisions.

The term supplier may refer to a "contractor" or "subcontractor"; the terms are regarded as synonymous.

Examples:

- 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
- 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 5 years per MDR/IVDR Annex VII 4.5.1 and 4.10 in addition to Annex IX 3.4
- The frequency of unannounced audits can increase dependent upon:
    - If the devices bear a high risk
    - Devices are often non-compliant
- An unannounced audit may take place for specific reasons e.g. suspicion of nonconformities of the devices or manufacturer

Devices that are often non-compliant

Reasons for increased unannounced audit frequency as listed 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 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

Sampling requirements are described NBO DRAFT Guidance Guidance on sampling of Class IIa / Class IIb and Class B / C devices for the assessment of the technical documentation.

This guidance references the need for class IIB (MDR) and class C (IVDR) to use the European nomenclature CND.

Depth of assessment

The depth of assessment is per MDR/IVDR Annex IX Chapter II and Annex II and III.

Verification of Manufactured Products for the IVD Directive

The verification of manufactured product should be conducted according to EU 2017/746 Annex IX 5.

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 5.2.5 of the Blue Guide 2016. These roles are also defined in MDR & IVDR Annex VII 3.4.1 as written "The following activities may not be subcontracted by notified bodies:

- review of the qualifications and monitoring of the performance of external experts;
- auditing and certification activities where the subcontracting in question is to auditing or certification organisations;
- allocation of work to external experts for specific conformity assessment activities; and
- final review and decision making functions."

and 4.1. the following requirements shall be fulfilled as part of the internal activities and shall not be subcontracted. See

4.3. Application review and contract
4.4. Allocation of resources
4.7. Final review
4.8. Decisions and Certifications

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 VII EU 2017/745, Annex VII EU 2017/746, 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.

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 have requirements described in NBOG 2017-2.

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 5:2019 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems
6. IAF MD 9:2017, IAF Mandatory Document for the Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)
7. Designating Authorities Handbook
8. ISO/IEC 17021-1:2015, Conformity Assessment – Requirements for bodies providing audit and certification of management systems - part 1: requirements
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 2013on 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. COMMISSION RECOMMENDATION of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices
19. 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
23. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
24. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
25. COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the

designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council

26. NBOG 2017-2 Guidance on the Information Required for Conformity assessment bodies' Personnel Involved in Conformity Assessment Activities
27. NBOG F2017-3 Applied-for scope of designation and notification of a Conformity Assessment Body – Regulation (EU) 2017/745 (MDR)
28. NBOG F2017-4 Applied-for scope of designation and notification of a Conformity Assessment Body – Regulation (EU) 2017/746 (IVDR)
29. NBOG F2017-7 Review of qualification for the authorisation of personnel (MDR)
30. NBOG F2017-8 Review of qualification for the authorisation of personnel (IVDR)
31. EN ISO/IEC 17065:2012 Conformity assessment. Requirements for bodies certifying products, processes and services
32. EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

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, MDCG, IAF, NBOG, 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.
- The NB to be audited shall confirm audit date within 1 month.
- 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. When in agreement to the content, all 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 member 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. If they do not accept the corrective action plan, the assessment team shall write a recommendation. Again at this stage the management board is informed of the steps that are finalised.
- In both above scenarios, the approved assessment report is send to the management board for review and approval and the conclusion is available internally between members on request.

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 within 6 months of the audit, the management board will decide on the suspension of the member within 1 month after the audit team decision.
- 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.