MDCG 2019-6 Rev5

Questions and answers:

Requirements relating to notified bodies

Revision 5 - February 2025

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Revision table

MDCG 2019-6 revision 5 changes	
Questions I.5.1 and I.5.2	Added to replace I.5
Questions I.6.1, I.6.2 and I.6.3	Added to replace I.6
Question I.9.	Updated
Question IV.1.	Updated
Question IV.7.	Updated
Question IV.10.	Updated
Question IV.12.	Update
Question IV.13.	New Q&A added

Introduction

This document presents questions and answers on requirements relating to notified bodies under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR). The issues covered by this document have been identified in the context of joint assessments, and the document may be updated from time to time as new issues are identified.

I. ORGANISATIONAL AND GENERAL REQUIREMENTS

I.1. Are CABs obliged to follow guidance endorsed by the Medical Devices Coordination Group (MDCG)?

Guidance documents are by definition not compulsory. However, all guidance documents endorsed by the MDCG reflect the interpretation of the EU law jointly agreed by the authorities which are in charge of interpreting and applying the EU law. Hence notified bodies should be encouraged to apply these guidance documents (also taking into consideration Section 1.6.2 of Annex VII to the MDR/IVDR[1]). Furthermore, it is to be noticed that the European Court of Justice often refers to guidance documents when developing its rulings. Hence Notified Bodies have an interest, also in terms of liability risk, to follow that guidance.

[1] 1.6.2. The notified body shall take into consideration guidance and best practice documents.

I.2. What is the meaning of “legal personality” under Section 1.1.1 of Annex VII[2]?

The CAB needs to have legal personality, meaning that it has to exist as a legal entity. To that end, it must be registered as legal entity, also called "legal person". The wording of the MDR/IVDR does not exclude that only a part of a legal entity undertakes conformity assessment activities in the field of medical devices. In this case, where the CAB is part of a wider legal entity, the documentation provided should be clear as to where the CAB sits within that legal entity. In case the entire legal entity is the CAB, the documentation to be provided refers to the legal entity as such. It is always this legal entity as such which is designated (and not its organisational part).

I.3. What is the meaning of “organisation” as described in 1.1.2 of Annex VII?

The term of "organisation" as described in 1.1.2 refers to the whole organisation (e.g. corporate group) to which the CAB belongs including the CAB's legal entity. The concept of "organisation" should be based not only on ownership rights (e.g. shares), but also functional/hierarchical links, such as voting/management/other control rights. One typical example of organisation is a holding company owning different companies (i.e. separate legal entities), one of them being or containing the CAB.

I.4. Does the term “organisational structure” as per 1.1.5 refer only to hierarchical relationships?

If a notified body is part of a larger organisation, both hierarchical (i.e. mother and daughter companies of the CAB) and horizontal relationships (e.g. sister companies where there is a common mother company) between the notified body and other entities belonging to that organisation are covered by the term "organisational structure".

The organisational structure of the CAB will vary depending on the complexity of the legal entity and the organisation to which it belongs. For instance, in the case of holding companies, the CAB could provide a matricial organisational chart with dual reporting relationships (i.e. functional and managerial). In this case, hierarchical and reporting lines should be clear and should match the information provided in job descriptions for the activities related to the MDR/ IVDR certification.

I.5.

I.5.1. Is a 3-year competitor clause for consultants covered in the MDR / IVDR requirements?

The MDR/IVDR does no longer define the timelines for clearance of consultants that were defined in Section 1.3b of Annex I to the Implementing Regulation (EU) 920/2013, except in case that the person worked for the same company or the group (Section 1.2.4 of Annex VII). However, the requirements under the Implementing Regulation (EU) 920/2013 on the management of impartiality for consultants are

[2] Unless specified otherwise, a reference to Annex VII means a reference to both Annex VII of the MDR and Annex VII of the IVDR.

included in sections 1.2.2, and 1.2.3 (c), (d) and (e) of Annex VII. Therefore, it is expected that CABs will have similar measures in place under both regimes. It is essential that competitors, authorised representatives and suppliers are also included in the identification, analysis and resolution of potential conflicts of interests.

I.5.2. How long does personnel carrying out conformity assessment tasks need to be "banned" from a specific client when they were formerly employed by that specific client or a company belonging to the same group (holding) of the client?

The Regulations require personnel responsible for carrying out the conformity assessment tasks to have e.g., at least 2-years professional experience in the design, manufacture, testing or use of the device or technology. Therefore, notified bodies should usually hire staff who previously worked in those areas.

For this reason, in case personnel was previously involved in activities such as design, manufacture etc. listed in Annex VII Section 1.2.3, the requirement set out in Annex VII Section 1.2.4 establishing a 3-years-ban-period before conformity assessment tasks may be carried out for a former employer or the organisation to which it belongs should be applied as a general rule. However, according to Annex VII Section 1.2.3, conformity assessment tasks for devices in which notified body personnel was directly involved in their design or manufacture are not allowed. Additional guidance is provided in Q&A I.9.

I.6.

I.6.1. What is and what is not considered consultancy?

According to MDR/IVDR Annex VII, section 1.2.9, the independence and impartiality requirements do not preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer applying for conformity assessment activities. However, any activities consisting in providing advice to manufacturers, their authorised representatives, or suppliers regarding solutions on how to fulfil regulatory requirements, (e.g., advice as regards the design, construction, marketing or maintenance of devices or processes, i.e., on "how to comply") falls under the definition of consultancy and is prohibited according to Annex VII Section 1.2.3 (d) MDR/IVDR. This includes any involvement in activities (e.g. design, risk management, manufacturing processes) related with the devices or quality management systems for manufacturers, their suppliers or subcontractors, except third-party conformity assessment activities. Also, other activities not specifically linked with the devices will be regarded as consultancy (e.g. internal audits to manufacturers or client specific training).

However, general training activities that are not client-specific and that relate to regulation of devices or to related standards, are allowed. Trainings by the notified body, or a related body, are not considered client-specific if they are open to the public, content and materials are not customized, and attendance is not limited to one manufacturer or a manufacturer's suppliers/subcontractors. The above includes remote real-time training that is open to the public via online access. Training activities may not take place at the manufacturer's premises, at the premises of a

manufacturer's supplier or subcontractor, or in locations rented or organized by them. Notified bodies' attendance to conferences and other open events are also allowed, even if organised by a notified body's client. Similarly, dissemination of informative material, such as blog posts, guidance documents or informative presentations published by the notified body is allowed as long as the contents comply with the principles outlined before.

I.6.2. Why is a notified body only allowed to perform conformity assessment activities after an application has been lodged?

To be able to comply with the independence and impartiality requirements in Annex VII of the MDR/IVDR, notified bodies are not allowed to engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated. This is why pre-application[3] and post-application activities must be distinguished.

Before an application is lodged by the manufacturer, activities that are part of or could fall under the definition of conformity assessment activities like the review of clinical data or the (partial) assessment of the quality management system[4] are not allowed as they would be regarded as consultancy (e.g., gap analysis, check of MDR/IVDR readiness, use of mock-up files produced instead of "real" technical documentation assessments). A preliminary verification by the notified body that the product or which parts of a product are covered by the Regulations, the correct classification, whether it could qualify as an orphan device[5], and the correct identification of the MD/IVD codes[6] prior to issuing any quotation to the manufacturer are however legal requirements to be performed as pre-application activities.[7] These topics are expected to be discussed in the context of the structured dialogue before an application is lodged (see Q&A I.6.3) and will require exchange of the relevant information between the manufacturer and the notified body.

Every activity carried out once an application has been submitted will be considered part of the conformity assessment activities and therefore if the manufacturer withdraws its application after this process has started, the notified body has to inform the other notified bodies through EUDAMED according to Article 53(2) MDR / 49(2) IVDR.

The notified body has to reflect in its policy and/or implement in its procedures how it prevents that any of its activities become consultancy activities.

I.6.3. What is considered "structured dialogue"?

According to MDCG 2022-14, action item 15, notified bodies and manufacturers are encouraged to organise structured dialogues before and during the conformity

[3] See MDR/IVDR Annex VII, section 4.2.
[4] See e.g., MDR/IVDR Annex IX, section 2. However, voluntary third-party activities carried out e.g. in the framework of certifications based on regulatory standards, including ISO 13485, are allowed.
[5] See MDCG 2024-10 Clinical evaluation of orphan medical devices
[6] See Commission Implementing Regulation (EU) 2017/2185
[7] See MDR/IVDR Annex VII, section 4.2, d).

assessment process aimed at exchanges on regulatory procedures, i.e., exchanges of technical information and regulatory guidance[8] between the notified body and the manufacturer. In general, all structured dialogue should be focused on "what needs to be fulfilled" rather than "how to fulfill". Questions I.6.1 and I.6.2 further elaborate the context.

As part of the structured dialogue the notified body, taking into account Q&As I.6.1 and I.6.2, should provide to the manufacturer a comprehensive overview of the certification process, including pre-application and application processes. This would include but is not limited to information related to the contractual relationship, forms to be used, documentation that needs to be provided by the manufacturer and at which stages during the assessment procedure, possible options, special procedures, which languages are acceptable, timelines to be respected, fees charged for specific conformity assessment activities, and any other financial conditions.

Structured dialogues are expected to be performed before (i.e. pre-application) as well as during the conformity assessment process (i.e. post-application[9]). Costs related to structured dialogues should not entail extra fees but be integrated in fees related to pre-application and conformity assessment activities. Their aim is to enhance the efficiency and predictability of the conformity assessment process, without jeopardising independence, objectivity and impartiality requirements.

Manufacturer and notified body can discuss about the possibility to leverage evidence stemming from previous assessments (e.g., previously conducted under the MDR/IVDR, as relevant, or conducted with regard to requirements under the Directives or legislation under other jurisdictions) with a view to enhance the efficiency of the conformity assessment procedure under the Regulations (see Q&As IV.13).

Moreover, during a structured dialogue in the post-application phase, manufacturer and notified body may exchange views on the sufficiency of clinical data on which the clinical evaluation is based, including possible applicability of Article 61(10) of MDR, equivalence of the device under assessment with another device as well as the appropriateness of the post-market clinical follow-up plan. Such kind of structured dialogue in the early phase after submission of the application can significantly increase the predictability of the conformity assessment process without jeopardising the notified body's independence or impartiality.

In the context of the structured dialogue, questions by the manufacturer should respect the notified body's independence, objectivity and impartiality requirements, i.e., they should not be open-ended and need to avoid expecting solutions on "how to comply" thus ensuring that no consultancy services are taking place (see also Q&A I.6.1). The responsibility to meet the regulatory requirements remains with the manufacturer.

The notified body should establish documented procedures ensuring that the main topics exchanged on within structured dialogues are documented[10].

[8] See MDR/IVDR Annex VII section 1.2.9.

[9] The post-application phase starts when the notified body has received the application, irrespective if it is complete or not.

[10] See Annex VII 4.2 and 4.6

The following table provides a list of possible topics of interest for a structured dialogue, and it is not intended to be exhaustive.

Possible topics of interest for a structured dialogue

Prior to the application ("pre-application")	**During the conformity assessment activities ("post-application")[11]**
<u>Administrative questions</u> • Timelines for conformity assessment until certification, including estimated timelines for possible special procedures, e.g. drug-device combinations, companion diagnostics or orphan devices • Clarification on the data / documentation to be provided with the application • If applicable, procedure related to the onboarding as a customer, including access to a possible portal, and relevant procedural guidance • Options of conformity assessment procedures and – for legacy devices – timing for submission of individual technical documentation, i.e. discussion about the manufacturer's "conformity assessment programme" • Information on all necessary conformity assessment activities – e.g., initial audit, (annual) surveillance audits, technical documentation assessments, assessment of changes / change notifications – and any special (process) audits or additional (sub-) assessments / reports for TD	• Clarification of missing data • If test reports were initially not accepted, next steps regarding the submission of new test data • Timelines for providing additional missing data • Early information / discussion on a planned significant / substantial change of a product (design) and the consequences for the certification process

[11] Topics listed in the pre-application column and not mentioned below can also be discussed during conformity assessment activities

assessment not explicitly mentioned in the Regulations; it should be specified if such activities are required or not and if they will be performed once or more often • Pricing and fees • Exchange of information about involved persons for different conformity assessment activities on both sites (notified body and manufacturer) including contact persons	
Regulatory guidance / requirements • Applicable standards and guidance documents • How to apply and reference standards or guidelines • Referring to the possibility of getting advice by EMA expert panels (Art. 106, Art. 61 (2) MDR, Art. 48 (6) IVDR) • Possibility of "modular approach" (e.g., review of specific parts of the technical documentation / clinical evaluation at different points in time, to allow (earlier) feedback on testing / evaluation strategies) • General requirements regarding and acceptance of (third party) test reports / certificates • Leveraging evidence from previous assessment (see Q&A IV.13)	• Leveraging evidence from previous assessment (see Q&A IV.13) • Appropriateness of equivalence claim (see Art. 61(4), second indent, MDR / Art. 48 (5) IVDR) • Sufficiency of quality / quantity of clinical data • Applicability of Article 61(10) MDR • Appropriateness of PMCF plan
Technical information • Qualification and Classification of a product (Annex VII 4.2 (d) MDR/IVDR) • Requirements for sampling of devices for technical documentation assessments • Best practice guidance for	• Clarification of non-conformities raised

technical documentation (TD), including preferred structure of TD	

I.7. Can the CAB accept applications prior to being notified?

No, applications under the MDR / IVDR cannot be accepted before the designation of the CAB became valid, i.e. the day after the notification is published in NANDO.

I.8. How are the conditions on remuneration to be assessed within the meaning of 1.2.5 of Annex VII?

The MDR/IVDR establishes that remuneration cannot depend on the results of the assessments. Both direct and indirect correlations between results of the assessments and remuneration are prohibited. Hence an individual examination is needed. Special care has to be applied with regard to bonuses. Bonuses on the basis of general objectives, even when not directly linked to the result of the individual conformity assessments, might still be problematic if they indirectly correlate to the average result of assessments. In the context of a joint-assessment, sampling of contracts or agreements covering remuneration (sheets) should take place. The sampling should cover different grades of influence, e.g. project handlers, final reviewers/decision makers, or head of the CAB / medical devices' certification.

I.9. Are declarations of absence of conflict of interests sufficient to ensure compliance with legal requirements for impartiality?

No, declarations are not sufficient in isolation to ensure compliance. CABs should define their own system to comply with the legal requirements for independence and impartiality (see Q&As I.5.1.- I.6.3), but a system based on analysis of risk and control measures should be generally in place. This system will usually include a comprehensive risk analysis of the CAB's activities, its staff (including top-level management) and the activities of its organisation or related bodies. Risks posed to impartiality from each individual should be assessed with regard to past employment, consultancy services and financial interests. For instance, shares in companies certified by the notified body or in competitors of these companies (investment funds can be seen differently) as well as relatives of the person under analysis. Also, the risks linked to subcontractors/suppliers (1.2.1) of the manufacturer need to be assessed.

Section 2.4 of Annex VII also requires, as part of this system, a “multi-level” statement. Firstly, a general one, listing any existing or prior association with clients or devices or processes under assessment. This general one needs to be renewed from time to time (e.g. annually). In addition, there is a need for a written statement and verification by the notified body within each conformity assessment project.

I.10. Does a CAB that is part of a larger organisation need individual liability insurance?

The CAB is responsible for taking out liability insurance and therefore there must be evidence that the legal entity is covered by a liability insurance that fulfils the legal

requirements. The contract with the insurance company can be signed by other legal entity of a larger organisation (i.e. mother company) provided that the contract gives the CAB the individual right to be protected against liability claims. The notified body must be able to invoke that right directly towards the insurance company, and not only indirectly via the company which has signed the contract (this is important e.g. in case of insolvency of the signing company or in case of unwillingness or inability of the signing company to effectively invoke the insurance contract towards the insurance company). Furthermore, the signing legal entity must involve the notified body in any change of insurance conditions affecting the medical devices conformity assessment activities of the CAB so that the notified body has the possibility to react if it considers that the coverage is insufficient.

Any change on the liability insurance which may affect the compliance of the notified body with the requirements set out in Annex VII should be communicated by the body to the authority responsible for notified bodies in accordance with articles 44 (1) of the MDR / 40(1) of the IVDR.

II. QUALITY MANAGEMENT SYSTEM

III. RESOURCES REQUIREMENTS

III.1. Is a complete re-authorization of existing personnel necessary to document satisfaction of the new qualification criteria under section 3 of Annex VII?

Yes, all personnel that will be used to perform conformity assessment tasks under the MDR/IVDR shall be authorized under the new criteria. For the satisfaction of the work experience criteria, the CAB can accept previous experience in a notified body but it cannot automatically grandfather authorisations (i.e. transfer authorisations) granted by other notified body or by the same notified body under the Directives. However, the experience in a notified body needs to be extensive and traceable and always specific to the tasks to be carried out and the specific technology or product (specific codes) in order to satisfy the MDR/IVDR qualification criteria. In addition, comprehensive and objective evidence of such previous experience in a notified body in the relevant scope shall be part of the personnel files.

III.2. What is the meaning of “permanent availability of sufficient personnel” within Section 3.1.1 of Annex VII?

In respect to the availability of personnel, MDR / IVDR Annex VII Section 3.1.1 do not establish the number of auditors / reviewers per code to ensure permanent availability of sufficient personnel. As a very minimum, it is considered that notified body should have one person available and authorised per applied-for scope code and role as per Section 3.2 of Annex VII at the time of the joint assessment. Nevertheless, it is recommended that the notified body has two product reviewers/auditors authorised per code to ensure a sufficient capacity to allow fulfilment of other related requirements such as rotation of personnel. When this is

not the case, an observation may be raised at the joint assessment in order to flag that for certain codes the available resources are limited.

The notified body is expected to have 2 auditors / reviewers available and authorised per applied-for scope in order to fulfil the legal requirements under Section 3.1.1 of Annex VII at the moment of its re-assessment joint assessment.

III.3. What is the meaning of “possess or have access to all equipment and facilities” needed to perform its tasks within the meaning of Section 3.1.1 of Annex VII of the MDR?

This question refers to the requirements in relation to possessing or having access to sufficient equipment and facilities to properly perform the conformity assessment activities within the CAB's applied-for scope. It is expected that the CAB would have internal testing facilities or access to testing subcontractor(s) (e.g. by a framework agreement) for device tests in support of the codes for which it seeks designation under Annex X and Annex XI(B).

In order to be designated under Annex X and XI(B), the CAB's personnel needs to have the technical knowledge to identify and select all the tests needed; the CAB must have implemented detailed procedures ensuring the identification of the relevant tests; and have access to at least some of the tests to be performed within the scope of designation. In particular, for each MDA or MDN code for which the CAB applies under Annex X or XIB it should identify at least the basic tests to be performed and the corresponding testing facilities (internal or subcontracted). The CAB should be able to demonstrate how the facilities available are linked to the codes the CAB applies for.

Nevertheless, the CAB is not expected to have testing equipment and facilities (either in house or a framework agreement) covering all possible tests within a code under Annex X or XI(B) or as part of surveillance or unannounced audits as some of the tests are very specific or rarely used. For these purposes, the CAB should have procedures in place in order to find additional subcontractors whenever needed or to define under which circumstances the CAB will perform witness testing (i.e. when the test equipment needed is very specialised)

III.4. What is the meaning of "two years' professional experience" in cases where the experience has been gained within a CAB under section 3.2.5 of Annex VII?

According to MDR/IVDR Annex VII 3.2.5 product reviewers have to demonstrate two years’ professional experience in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed. Experience related to the scientific aspects to be assessed could include, but not be limited to, extensive experience in conformity assessment activities in a specific type of device or technology gained within a CAB[12] .

12 As defined in section 6.2.2. of NBOG BPG 2017-2

In such case, when professional experience – based on a relevant background education – is to be proven by activities only within a CAB, this experience should have been gained during at least two years. As a guideline if one individual has carried out at least five full technical documentation assessments of devices in the relevant code (or aspects to be assessed) or under the equivalent code under the Directives, during at least 2 years, this can be accepted as a valid work experience within the meaning of 3.2.5 of Annex VII. Nevertheless, based on the assessment of the educational background and specific work experience of the individual, the CAB has always to analyse if additional assessments must be performed (i.e. under supervision).

In addition, in situations where the objective evidence for the experience gained during technical file reviews is insufficient (e.g. if the staff was authorised for the code in a different CAB without detailed supporting evidence), as a guideline, the technical documentation assessments on the code (or aspects to be assessed) to which the individual wishes to be authorised have to be carried out under close supervision of an experienced product reviewer (e.g. mirror review[13]). At least five of these assessments should be related to a full assessment. In addition to technical documentation assessments or product tests, product-related audit activities can be considered as work experience as long as they are not used solely and they are adequately documented and assessed by the authorising personnel of [or within] the CAB.

In all of the cases above, the CAB has to analyse individual training needs (e.g. on relevant standards) especially when the work experience was gained a few years ago in the past or when the individual has experience related to a very similar technology. Before authorisation, the authorising personnel needs to ensure that all the qualification criteria under 3.2.5 of Annex VII are fulfilled and their satisfaction fully documented (including an adequate justification in the exceptional cases where the criteria cannot be fully demonstrated as established in 3.3.1 of Annex VII) and that the knowledge is state-of-the-art.

For codes (MDR/IVDR) comprising a broad range of devices, the CAB has to ensure that the individual has carried out technical documentation assessments in different devices covered by the code or the authorisation to the code is to be granted with appropriate limitations.

III.5. Does the CAB need to define qualification criteria for monitoring and maintenance of competences in accordance with Section 3.5 of Annex VII?

Yes. The CAB's personnel competence needs to be maintained and therefore reviewed at regular intervals. For this purpose, the authorising personnel[14] (as per 3.2.3 of Annex VII) needs to define qualification criteria for monitoring and maintenance of competence of its entire staff (internal and external, as well as subcontractors), involved in conformity assessment activities. Such "re-qualification"

13 Mirror review is to be understood as a review carried out simultaneously by two product reviewers of the notified body, one being on training and the other one being an experienced product reviewer on that code. Once the review is finalised from the two reviewers, the most experienced will assess and document the quality of the review carried out by the person in training.

14 Short term used in NBOG BPG 2017-2 to refer to "personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities" according to Section 3.2.3 of Annex VII.

or "maintenance" criteria will be used as a basis for re-authorisation of personnel to codes and roles.

In respect of monitoring of competence, such criteria should be defined for personnel involved in conformity assessment activities, at least for personnel with relevant clinical expertise, product reviewers, site auditors and final reviewer / decision-maker, and authorising personnel.

III.6. What is the meaning of the term “employed” in MDR Article 36(1) / IVDR Article 32(1)?

The personnel referred to in the third subparagraph of Article 36(1) MDR / Article 32(1) IVDR, read in conjunction with Sections 3.2.3 and 3.2.7 of Annex VII MDR / IVDR, perform key functions within the notified body. In particular, section 3.2.3 refers to personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities and Section 3.2.7 refers to personnel with overall responsibility for final reviews and decision-making on certifications. Therefore, both Regulations expressly require that these personnel are employed by the notified body itself and not external experts or subcontractors/subcontracted. This requirement is estimated to be complied with when the contractual relationship between the notified body and the individual meets at the minimum the following criteria:

- employment contract between the notified body and the employee setting out the rights and obligations of both parties in accordance with the applicable employment and labour legislation[15] ;
- control and supervision over the activities of the employee by the notified body; and
- direct reporting obligations of the employee towards the notified body.

Contracts between the notified body and another legal entity providing for an assignment of staff employed by that other legal entity to the notified body (often called ‘secondary contracts’) should not be considered as fulfilling the requirement of ‘employed by the notified body itself’.

Moreover, Section 4.1 of Annex VII to MDR / IVDR lists the following processes to be fulfilled as part of the internal activities of notified bodies and that are not to be subcontracted:

- application review and contract (Section 4.3);
- allocation of resources (Section 4.4);
- final review (Section 4.7);
- decisions and certifications (Section 4.8).

[15] The law applicable to individual employment contracts is determined in accordance with Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I), in particular its Articles 3 and 8.

Any reference to “internal activities” shall be intended as activities being carried out by personnel employed by the notified body.

III.7. What is the meaning of “permanent availability of personnel with relevant clinical expertise” in accordance with sections 3.2.4 and 3.1.1 of Annex VII?

With regard to “personnel with relevant clinical expertise”, in order to fulfil the tasks covered in Section 3.2.4 of Annex VII it is expected that the CAB has at least one "internal clinician" who, where possible, has to be employed by the CAB. This does not preclude the possibility to subcontract such a role, provided that the notified body produces a justification as to why it is not possible to employ the person(s). In any case, when the CAB does not have the possibility of employing that person(s), it should at least ensure that she/he is fully integrated throughout the conformity assessment and the decision-making process, which means that the person is involved in the CABs assessment and decision-making process in the same way as an employed staff. However, it should be noted that when the internal clinician is a subcontractor even if this person will support the final review and decision making process as indicated in 3.2.4 (e.g. in case an external clinical expert has been involved making a recommendation to the final reviewer or decision maker) they cannot be authorised as final reviewer or decision maker as these personnel should be employed by the notified body itself as required in Art. 36 of the MDR and Art. 32 of the IVDR.

Accordingly, all “internal clinicians” are integrated, whereas some internal clinicians are not employed. Given that the term "internal clinician" is widely spread, and it has been used to defined personnel carrying out tasks established in Section 3.2.4 of Annex VII it is assumed that when the term "internal clinician" is used, it could refer either to an employee of the CAB or not.

IV. PROCESS REQUIREMENTS

IV.1. Do devices certified under the Directives need to be subject to a full conformity assessment under the new Regulations if the manufacturer applies for certification under the MDR / IVDR?

The conformity assessment activities described under Article 52 / Article 48 apply to any certificate issued under the new regulations. As no exceptions were established under the regulations for the migration or transfer of MDD/AIMDD/IVDD certificates to the MDR / IVDR the general provisions should apply. Therefore, all devices to be certified under the MDR / IVDR should be subject to an initial certification according to the applicable annex. The notified body should ensure that all requirements under the MDR / IVDR are fulfilled. It may not restrict its procedures to gap audits or gap file reviews. However, when possible, the notified body should make use of leveraging evidence (see Q&A IV.13).

It should be noted that MDD/AIMDD/IVDD certificates shall be considered to be valid as long as conditions laid down in Article 120(3) of the MDR and 110 (3) of the IVDR are complied with[16].

IV.2. What should be the criteria for auditing suppliers and subcontractors?

The MDR/IVDR established that the audit of the manufacturer premises must include an audit on the premises of subcontractors and/or suppliers if appropriate. Therefore, the notified body should have criteria for auditing these actors on the basis of their criticality. At the very least, the criteria defined in Section 4.5.2(b) of Annex VII should be applied (i.e. the control over the supplier/subcontractor and its influence on the conformity of the device is essential whereas the sole existence of a certificate against ISO 13485 is not sufficient).

IV.3. What is the meaning of "examinations and tests" to be included in a certificate in accordance with Section 10 of Annex XII of the MDR / IVDR?[17]

Certificates do not need to include reference to relevant common specifications or harmonised standards as long as such information on all examinations and tests performed is traceable and available from e.g. report(s) which are mentioned in the certificate.

IV.4. What are the applicable requirements for voluntary certificate transfer under MDR Article 58 / IVDR Article 53?

While MDR Article 58(1) / IVDR Article 53(1) sets out the requirements for a transfer agreement, it does not specify the conformity assessment activities to be performed by the incoming NB.

The incoming NB may decide not to carry out full conformity assessment activities according to Article 52 MDR / Article 48 IVDR, as long as it does have sufficient information in respect to the conformity activities performed by the outgoing NB.

For quality management system certificates, the incoming NB needs to perform appropriate on-site audit(s) and assessments to ensure that the manufacturer in question applies the approved QMS and the post-market surveillance plan prior to the issue of any certificate. In respect to the assessment of technical documentations on a sampling basis, the incoming NB shall review the previous assessment results together with a sample of a technical documentation and draw up or amend a sampling plan.

[16] For further details please see Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices as well as Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860 of 13 June 2024.

17 See also Q&A IV.8

For product certificates (Annex IX Chapter II/Annex X), new certificates without a comprehensive (initial) review may be issued as long as the documentation received does not identify ongoing existing or other concerns.

The incoming NB assumes full responsibility for the new certificates issued following the transfer.

IV.5. What are the applicable requirements for OBL manufacturers?

The MDR / IVDR does not distinguish between OBL[18] and other manufacturers. There are just "manufacturers" and therefore OBL manufacturers must comply with the legal requirements, as any other manufacturer[19].

IV.6. What is the role of the internal or integrated clinician in the notified body´s assessment and decision-making process?

The internal or otherwise integrated clinician is responsible to identify when specialist input is required for the assessment of the clinical evaluation as defined in Section 3.2.4 of Annex VII of the MDR and IVDR. This decision will be made by the internal or integrated clinician on a case-by-case basis, based on the products covered by the applications lodged by the manufacturer and the clinical expertise available. The internal clinician or integrated clinician will be responsible for this process in all cases where the conformity of the device to the requirements of annex I is achieved also by clinical data. In cases where demonstration of conformity to requirements of Annex I based on clinical data is not deemed appropriate (in accordance with Article 61(10)) the internal or integrated clinician will also examine the justification provided in order to assess its adequacy. The internal or otherwise integrated clinicians will decide if the review of clinical evaluation is to be carried out by themselves, to be delegated to other qualified staff or if it necessitates the input of external clinical experts. This process is also defined in Section 4.3 of Annex IX of the MDR and Section 5.4 of NBOG's best practice guide 2017-2 as endorsed by the MDCG.

Section 3.2.4 of Annex VII defines that there must be a clinician who is either internal (= employee) or otherwise integrated into the CAB's assessment and decision-making process. To be regarded as integrated, a clinician (who is not an employee) must have access to all the information, required to perform its activities, circulating in the CAB and must be involved in the internal processes in the same way as an employee, the only difference to an employee being that there is no employment contract, but a service contract and therefore this person should not be considered final reviewer or decision-maker as per 3.2.7 of Annex VII.

In addition to this, the internal or otherwise integrated clinician will clinically judge the opinion provided by any external expert (including verification of comparability and consistency of the assessments of clinical evaluations conducted by clinical experts) and will be responsible to make a recommendation to the decision maker on the adequacy of the clinical evaluation.

[18] OBL" (own brand label manufacturer) is a term used in the field that describes manufacturer that are supplied with the finished medical device by their supplier, who often is called "OEM" (original equipment manufacturer). Neither of both are defined in the MDR (or ever were defined in the Directives).

[19] Including but not limited to having: full and permanent access to the technical documentation; (ability for) post-market surveillance including post market clinical follow-up; sufficient technical competence; and control of the quality system (control of the design, manufacture and/or final verification and testing of the devices).

IV.7. What is the meaning of allocation of resources under Section 4.4 of Annex VII?

Allocation of resources is to be understood as the allocation of appropriately authorised and qualified personnel and means (including equipment and facilities) for a given project (application), as stated in second paragraph of Section 4.4 of Annex VII "appropriate resources including personnel". Section 4.4 of Annex VII describes the assignment of tasks within a project to “individuals”, starting with the individual responsible for ensuring that the assessment of that application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources including personnel are utilised for each of the tasks of the assessment (often referred to as project leader[20]) and following with the identification of individual personnel that will carry out each task of a given project.

The assessment of the resources needed for each application is a key function that has to be fulfilled as part of the internal activities of the CAB as indicated in Section 4.1 of Annex VII and any changes on such allocation should be documented.

The notified body may assign the tasks of allocating resources, documenting of any change on such allocation and/or ensuring that the assessment of that application is conducted in accordance with the relevant procedures to different functions (individuals). In this case, the notified body needs to specify and document clearly the roles and responsibilities. For every project, the notified body needs to identify clearly which individual is taking care of a specified task. Any of the tasks specified in Section 4.4. need to be fulfilled as internal activity.

IV.8. How can a CAB ensure that information on "examinations and tests" in accordance with Section 10 of Annex XII of the MDR / IVDR is available to all interested parties (as referred to in Section IV.3 of this document)?

According to Annex XII information on tests and examinations performed as part of the conformity assessment activities need to be included on the certificates issued by notified bodies. This information might be of interest for competent authorities and third parties.

If the certificates do not include explicitly references to relevant common specifications, harmonised standards or other standards or referential but include a reference to the relevant report(s), the CAB should ensure that competent authorities and interested parties can have access this information on request. For example, the certificate may include a sentence like "information on examinations and tests as per Annex XII, section 10 is available on request" and possibly provide a contact (e.g. e-mail).

IV.9. Which changes need prior approval by the CAB?

The Regulations - in Annex VII and in the specific conformity assessment annexes (i.e. Annex IX, X and XI) -establish the need for the manufacturer to notify certain

[20] The term “project leader” is not mentioned in the regulations, but frequently used.

planned changes. Section 4.9 of Annex VII contains general requirements for notified bodies in respect to changes.

For manufacturers, the specific conformity assessment annexes (i.e. Annex IX, X and XI) detail such requirements e.g. asking for plans for “any” changes (e.g. MDR Annex IX, 5.2 f), 5.3.1 d) or Annex X 5.2), for changes could affect the safety and performance of the device or the conditions prescribed for use of the device (e.g. MDR Annex IX 4.10) or for “substantial” changes only (e.g. MDR / IVDR Annex IX 2.4). With regard to the latter, the CAB needs to make clear in its communication to the manufacturer (e.g. in the terms and conditions) what it considers as “substantial changes” to the quality management system, or the device-range covered.

In order to fully comply with all the relevant requirements, the CAB must have documented procedures defining how different changes need to be notified and assessed prior to their implementation and how the assessment will be documented. In particular, the CAB will define in its procedures when the approval of such changes will take the form of a supplement of the previously issued certificate.

IV.10. What is the frequency of surveillance audits according to the Regulations?

Surveillance audits according to the Regulations can take place only after a MDR or IVDR certificate has been issued. According to the Regulations, surveillance audits have to be carried out on at least annual basis (Section 4.10 of Annex VII MDR/IVDR), further specified in Section 3.3 of Annex IX MDR/IVDR and Section 7 of Annex XI MDR/Section 4 of Annex XI IVDR as at least every 12 months. The first surveillance audit should be scheduled 12 months after the certification decision date. This is the so called “due date” (e.g. December) which defines the target dates for all upcoming regular surveillance audits (e.g. each December).

In order to take in consideration, the necessity for contingent scheduling adjustments, surveillance audits can be conducted within a limited window of +/- three months from the due date without particular concern. However, if the surveillance audits are conducted outside this time window (earlier or later) this should be exceptional and must be justified and documented in consideration of the possible impact on the certificate's validity. A cumulation of deviations over the years, e.g. changing the due date is not allowed.

IV.11. What is the meaning of the last sentence in Section 4.5.1 of Annex VII with regard to the need for notified bodies to take into consideration standards and guidance even if the manufacturer does not claim compliance?

CABs need to consider all the available guidance, common specifications and harmonised standards to carry out its assessments. This means, that CABs will have to consider this documentation when developing its own procedures and processes (including checklists and report templates) and when assessing the manufacturers QMS (e.g. by taking into consideration EN ISO 13485) and technical documentation.

For instance, in order to assess if the solutions adopted by the manufacturer are state of the art and in line with expectations, the CAB need to use the available

guidance documents and standards. It should be noted that non-conformities will not be raised against standards or guidance but need to be phrased against legal requirements. For instance, Annex I Chapter I Section 1 of the Regulation which states that “devices shall be safe and effective […] taking into account the generally acknowledged state of the art” can be used when the technical documentation does not follow standards or guidance.

IV.12. What are the applicable requirements for re-certification?

Based on an application by the manufacturer and according to Article 56(2) of the MDR / Article 51(2) of the IVDR and Section 4.11 of Annex VII of the Regulations, notified bodies can extend the validity of QMS certificates (EU quality management system or EU quality assurance certificates) as well as product certificates (EU technical documentation assessment or EU type-examination certificates) for further periods of maximum five years (re-certification).

Re-certifications are not repetitions of initial certifications.

Notified bodies should have documented procedures and appropriate forms for re-certifications of

- **product certificates** requiring the manufacturer to submit a summary of changes and scientific findings as outlined in Section 4.11 of Annex VII, to perform a targeted assessment of this information and to pay particular attention to clinical data from post-market surveillance and PMCF activities undertaken since the previous certification or re-certification, including appropriate updates to manufacturers' clinical evaluation reports.

- **QMS certificates** ensuring that all relevant Regulation requirements for conducting audits (i.e. those covered in Section 4.5.2 of Annex VII, and Sections 2.2 and 2.3 of Annex IX) are assessed in their entirety at least once after issuing the certificate and before their expiry date. They should foresee the notified body to review the results of all surveillance activities carried out, announced or unannounced, in accordance with Section 4.10 of Annex VII during the certification cycle, especially on-site audits of the manufacturer, its subcontractors / suppliers, and product tests carried out, as well as the outcome of technical documentation assessments on sampling basis to verify whether the approved quality management system still conforms to the relevant provisions of the Regulation. In addition, they should contain an obligatory check whether the audit programme and the sampling plan drawn up according to Section 4.5.2 (a) of Annex VII are still up to date or need to be adjusted.

In both cases, the procedures should foresee that the notified body, before renewing a certificate, ensures:

- that all nonconformities identified are either closed or followed up by an adequate and accepted Corrective Actions and Preventive Actions (CAPA) plan with appropriate timelines,

- if the scope of the certificate needs to be adjusted, especially restricted,
- when the certification was subject to specific conditions or limitations to verify whether those are still valid or obsolete or need to be changed,
- or if new conditions need to be imposed.

According to Annex VII Section 4.11, for the decision on re-certification the notified body shall use the same methods and principles as for the initial certification decision, meaning a final review and decision shall be made in accordance with Sections 4.7 and 4.8 of Annex VII.

IV.13. What is considered “leveraging evidence”?

According to MDCG 2022-14, action item 2, notified bodies should avoid unnecessary duplication of work when performing their conformity assessment activities. In this respect, a differentiation between evidence provided by the manufacturer and assessment of such evidence already performed by notified bodies needs to be made.

As part of the structured dialogue (see Q&A I.6.3), for (a) specific device(s), manufacturers and notified bodies should discuss and agree in the pre-application phase if / which evidence provided with previous applications by the manufacturer can be referred to. In principle, this is possible as long as the evidence provided still meets the “state of the art”.

To facilitate such an approach, manufacturers should clearly indicate which parts of a technical documentation have changed compared to previous ones.

Notified bodies should make (partial) use of the assessments previously performed on such evidence. This is generally recommended as long as

- the applicable assessment requirements (including harmonised standards and common specifications used to prove compliance with the requirements) didn’t change,
- the assessments were performed by personnel demonstrably meeting the qualification requirements of the Regulations,
- the applicable reporting requirements in Section 4.6 of Annex VII of the Regulations are met and traceability is ensured.

In these cases, the report should identify what part of the technical documentation assessment has been performed by leveraging evidence from previous assessments and ensure traceability.

V. OTHER REQUIREMENTS

V.1. Are activities described under articles 16 and 17 of the Medical Devices Regulation (MDR) and Article 16 of the In-vitro Medical Devices Regulation (IVDR) will be covered during joint assessments?

Conformity assessment bodies (CABs) can issue certificates following the process described in articles 16 and 17 of the MDR and Article 16 of the IVDR but these are not considered conformity assessment activities covered by Chapter IV and Annex VII of the Regulations and therefore will not be part of joint assessments.

V.2. What is the meaning of “publicly available” in regard to information provided by notified bodies?

Whenever the Regulations require certain information to be made “publicly available”, that implies that a member of the public can access this information at any point in time, without the need for additional steps. In view of the public functions carried out by notified bodies, this requirement supports transparency of their activities.

Article 37 (3) MDR / Art. 33 (3) IVDR as well as Annex VII sections 1.2.5 and 4.2 MDR/IVDR make reference to the term “publicly available” in regard to certain information the notified body needs to provide. Article 50 MDR / Article 46 IVDR refer to a list of standard fees notified bodies have to make “publicly available”. It is worth noting that Article 111 MDR / Article 104 IVDR refer to different type of fees (i.e. fees levied by Member States) and use different wording. They cannot therefore be used to support the interpretation of Article 50 MDR / Article 46 IVDR. Moreover, public availability of fees levied by Member States will usually result from the official publication of national laws setting out such fees (therefore, there will be no need to request information on such fees).

To assist notified bodies defining their list of standard fees for publication in accordance with MDR Article 50 and IVDR Article 46, MDCG has issued the document MDCG 2023-2 “List of standard fees”.