MDCG 2019-6 Rev3

Questions and answers:

Requirements relating to notified bodies

Revision 3 - October 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Revision table

MDCG 2019-6 revision 3 changes	
Question I.6	Revised
Question IV.4	Typos corrected

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.

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?

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

[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.

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. 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 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.6. May CAB provide pre-certification services?

Pre-certification services are not allowed before an application is lodged by the manufacturer (e.g. review of clinical data or assessment of the quality management system[3]) and therefore these services have to take place under the scope of the application.

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) of the MDR / 49(2) of the IVDR. Whenever these activities consist in providing solutions to

[3] Assessments in the framework of certifications based on regulatory standards such as ISO 13485 are allowed.

the manufacturer, they fall under the definition of consultancy and therefore the notified body impartiality policy and procedure(s) will need to cover that these pre-certification activities could be seen as consultancy. The CAB has to implement in their policy and/or procedures how it prevents that pre-certification activities carried out as part of the conformity assessment activities are falling into consultancy.

Services provided by the CAB that could fall under the definition of conformity assessment activities are not allowed outside of an application 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" TD assessments). Nevertheless, general training activities that are not client specific and that relate to regulation of devices or to related standards are allowed. Trainings by the CAB or a related body[4] are considered to be not client-specific if they are open to public, their contents and materials are not customized and they are not attended, also if supplied in remote way, by only participants of one manufacturer or of a manufacturer's relevant supplier or subcontractor. They may not take place at the manufacturer's premises, at the premises of a manufacturer's relevant supplier or subcontractor or in locations rented or organized by them.

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, 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

[4] See MDR / IVDR Annex VII section 1.2.7, i.e. including subsidiaries or subcontractors.

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.

Any involvement in processes (e.g. design, risk management, manufacturing processes) being related with the devices and quality management systems for economic operators covered by the application/designation needs to be seen as consultancy. Other activities not specifically linked with the product will be also regarded as consultancy (e.g. internal audits to manufacturers or client specific training).

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[5] .

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[6]). 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

5 As defined in section 6.2.2. of NBOG BPG 2017-2
6 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.

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[7] (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" 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 Article 36(1) MDR / Article 32(1) IVDR carries out the key functions within the notified body, and therefore the Regulations expressly require that this personnel is employed by the notified body. 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:

- direct employment contract between the notified body and the employee setting out the rights and obligations of the latter;
- control and supervision over the activities of the employee by the notified body
- direct reporting obligations of the employee towards the notified body; and
- a direct paid remuneration by the notified body to the employee for the work carried out, accompanied by the payment of any relevant taxes and social security contributions.

Any reference to "internal activities" shall be intended as activities being carried out by personnel employed by the Notified Body.

[7] 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.

N.B. Whenever needed and appropriate, any action from the Notified Bodies aimed at ensuring compliance with those requirements should be taken throughout the designation period as soon as possible and completed at the latest by the time of their first re-assessment.

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.

It should be noted that MDD/AIMDD/IVDD certificates will remain valid until their expiration date and at the latest on 27 May 2024 as long as conditions laid down in Article 120(3) of the MDR and 110 (3) of the IVDR are complied with.

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?[8]

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.

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.

8 See also Q&A IV.8

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[9] and other manufacturers. There are just "manufacturers" and therefore OBL manufacturers must comply with the legal requirements, as any other manufacturer[10].

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.

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

[9] 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).

[10] 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).

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) 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.

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 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?

According to the Regulations (Section 3.3 of Annex IX and Section 7 of Annex XI), surveillance audits have to be carried out at least every 12 months. This means that the audit planning defined in Section 4.5.2 and 4.10 of Annex VII will need to take into consideration that surveillance audits have to be scheduled on at least an annual basis with a maximum of 12 months after the previous surveillance audit was carried out The first surveillance audit should be scheduled taking as a reference the certification decision date.

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?

Conformity assessment activities to be carried out in case of renewal of certificates/re-certification are laid down in Article 56(2) of the MDR / Article 51(2) of the IVDR, where the Regulations establish that the notified body can extend the validity of the certificate for further periods based on a re-assessment in accordance with the applicable conformity assessment procedures (i.e. as described in annexes IX-XI). In addition, Section 4.11 of Annex VII states that the notified body must use the same methods and principles for the decision on re-certification as for the initial certification decision.

While for EU Technical documentation assessment certificates and EU type examination, Section 4.11 of Annex VII establishes a targeted conformity assessment

(i.e. focusing in certain elements of the technical documentation review), this is not the case for the quality management system certificates.

The notified body will ensure 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 its entirety at least once after issuing the certificate and before its expiry date. In addition, prior to the renewal of a QMS certificate, it is required that the notified body will assess the results of the surveillance audits carried out during the period of validity of the certificate in accordance with section 4.10 of Annex VII, also including any unannounced audits and all audits carried out at subcontractors and suppliers.

This review must include the manufacturer´s system for vigilance, post-market surveillance, PMCF and risk management as well as all open non-conformities Furthermore, results of the notified body´s evaluation of additional scientific and clinical data and clinical evaluations and post-market information as well as the outcome of latest technical documentation assessments on sampling basis and product tests have to be considered.

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” as regards the list of standard fees of a notified body under Article 50 MDR / Article 46 IVDR?

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.

Not only Article 111 MDR / Article 104 IVDR refer to different type of fees (i.e. fees levied by Member States), but also it uses different wording. It 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