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EU Regulation Recap: Notified Bodies, Chapter IV

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How can you be sure that your notified body is operating fairly and to a high standard? How long can your products remain on the market if your notified body's operations are suspended or simply cease? Chapter IV of the forthcoming Medical Device and IVD Regulations details requirements for notified bodies as well as the process for their designation and monitoring.

It has often been said that there is insufficient detail within the current EU medical device directives on the rules governing notified bodies (NBs). But that is not likely to be the case once the new Medical Device and IVD Regulations take effect. The new rules, expected to be adopted by early next year, contain detailed and thorough sections on these entities that play such a central role to the EU regulatory process.

The regulations flesh out provisions on notified bodies over some 21 pages each, with further detailed information contained in an appendix (Annex VI, "Requirements To Be Met By Notified Bodies"), featured in both the MDR and the IVDR, and spreading over 32 pages.

Notified bodies have arguably been the most contentious element of the EU's medtech regulatory system. The organizations have come in for a lot of criticism. Some of it has been merited when standards among some EU notified bodies fell short, particularly before specific measures were recently introduced to tighten rules around notified bodies and their designation. Meanwhile, some of the criticism, from the pharmaceutical sector and US officials in particular, has been based on a lack of understanding of the EU system.

Either way, concerns with notified bodies have led to a series of recent actions to improve the operation of the entities, culminating in the September 2013 *recommendation on the audits and assessments performed by notified bodies in the field of medical devices* and the European Commission's *implementing regulation, on the designation and supervision of medical device notified bodies (EU 920/2013)*.

Both these documents were published in the wake of the *PIP breast implant scandal* to tighten up all levels of oversight and anticipated to a significant degree the requirements under the forthcoming system. Nevertheless, the current regulations – which will likely be adopted in early 2017 and begin to take effect six months later – go further.

These forthcoming requirements are dealt with in chapter IV of the two regulations, articles 28 through 40a of the Medical Device Regulation and articles 26 through 38a of the IVD Regulation, and in Annex VI of the regulations. Annex VI is not outlined in detail here, but it generally addresses for notified bodies: organizational and general requirements; quality management requirements; resource requirements; and process requirements.

The wording of Chapter IV of the two Regulations is virtually identical. It details the role of all the players, including the European Commission, the Medical Device Coordination Group, which is being set up by the regulations, to support the commission in governance issues, the notified bodies and the manufacturers and their representatives. The following table highlights the most significant changes and observations and explains references.

Bolded article numbers reference the MDR, and unbolded article numbers reference the IVDR.

Article	Topic	Significant changes	Additional observations
28,26	National authorities responsible for notified bodies for medical devices	The national authority must have a sufficient number of competent personnel permanently available for its tasks (Article 28/26, 6).	The national authority responsible for NBs, will continue to participate in notified body peer-review activities (Article 28/26, 8).
		Within the national authority responsible for NBs, the decision relating to designation or notification must be taken by personnel different to those who carried out any assessments of those NBs (Article 28/26, 3).	Member states will have to make publicly available general information relating to their assessment, designating, notification and monitoring of NBs, and changes (Article 28/26, 7).
29,27	Requirements relating to notified bodies	NBs must have permanently available sufficient staff, including personnel with relevant clinical expertise, and where possible employed by the NB itself.	NBs must submit upon request documentation, including manufacturer's documentation, to the authority responsible for notified bodies (Article 29/27, 1a).
		Personnel responsible for establishing qualification criteria and authorizing	Commission may adopt

		other personnel to perform specific conformity assessment activities, and with overall responsibility for final review and decision-making on certification, must be employed by the NB itself, and not be external experts or subcontractors (Article 29/27, 1).	implementing acts to ensure uniform application of NB requirements, as detailed in Annex VI, and resolve issues of divergent interpretation and practical application (Article 29/27, 2).
30, 28	Subsidiaries and subcontracting	NBs using a subcontractor or subsidiary, it must verify they meet Annex VI, take full responsibility, and inform the national authority (Article 30/28, 1 and 2). They must keep available for the national authority documents concerning the subsidiary/subcontractor qualifications, and of their work, (Article 30/28, 4). They must make publicly available a list of their subsidiaries (Article 30/28, 2a).	Companies that apply to NBs for conformity assessment must be informed where a subcontractor or subsidiary is being used (Article 30/28, 3).
31, 29	Application by a conformity assessment body for designation	NB submits application for designation to authority in country where it is based, and specifies the conformity assessment activities and type of devices it wants to be designated for. It must supply documentation showing compliance with Annex VI (Article 31/29, 1 and 2).	Once designated, the notified body must update its documentation when relevant changes occur so the authority can monitor and verify compliance with Annex VI. Requirements of Article 31/29 may be detailed in future implementing acts (Article 32/30, 7).
32, 30	Assessment of the application	Its requirements may be spelt out in more detail in future implementing acts, (Article 32/30, 7). As part of the application process, the commission, along with the MDCG, will assign a joint assessment team of	This is a lengthy article, spelling out the process and the many timelines involved in the assessment of the NB application to the national authority. As part of the assessment

		three appropriately experienced experts, one from the Commission, and two from two different member states other than the one in which the NB is based. The commission is responsible for coordinating the activities of the joint assessment team (Article 32/30, 3). This team will review documentation and conduct an on-site assessment of the applicant NB as well as of any subsidiary or subcontractor, whether inside or outside the EU. The on-site assessment of the NB will be led by that NB's national authority (Article 32/30, 4).	procedure, the applicant NB will be given a timeframe to submit to the national authority a corrective and preventive action (CAPA) plan to address non-compliances found on-site. This will be forwarded to the joint assessment team (Article 32/30, 4a-b). The final stages of designation involve the national authority drawing up a final assessment report, including confirmation that the CAPAs have been addressed, any diverging opinions with the joint assessment team, and a recommendation for the scope of designation (Article 32/30, 4a-b). This report and a draft designation are sent to the commission, MDCG and joint assessment team. They liaise (Article 32/30, 6) and then the MDCG issues a recommendation which the applicant NB's national authority considers in its decision on the NB designation
32a, 30a	Nomination of experts for joint assessment of applications for notification	Commission is responsible for nominating experts involved in the joint assessments of NB applicants (Article 32a/30a, 1).	Commission must keep a list of experts with their competence and expertise. This will be made available to the competent authorities through electronic system on NBs and on certificates, as part of the Eudamed database (Article 32a/30a, 2).

32b, 30b	Language requirements	NB's member state decides what language(s) need(s) to be used in the designation application documentation and for the assessment of the application, ideally in a "commonly understood language in the medical field".	Commission will be responsible for translations where necessary for the joint assessment team.
33, 31	Designation and notification procedure	Member states must notify the commission and other member states of the NBs they are designating through Eudamed, stating NBs' conformity assessment activities and type of devices it can assess, plus any conditions (Article 33/31, 1, 4 and 4a). The notification must contain the final reports from the national authority and joint assessment teams, and the MDCG recommendation. The commission must draw up a list of codes and corresponding device types to describe the scope of designation by implementing acts issued within six months of the regulation entering into force – that is, most likely by early in the second half of 2017. This list may be updated in the light of experience (Article 33/31, 4a). The procedure is not always straightforward, and there is a procedure to allow the different parties to raise objections: * where the member state does not follow the MDCG recommendation, it must provide reasons (Article 33/31, 5);	This article is about the communication of information related to designation and issues surrounding objections to notifications. The procedure for managing the objections is as follows: * where another member state or the European Commission raises objections (In writing), the MDCG becomes involved and gives an opinion within 40 days (Article 33/31, 8); * if the MDCG thinks the objection is valid, the member state has a further 40 days to reply and address the objections and set out the reasons for still designating, or now not designating, the NB (Article 33/31, 8 and 8a); *where the MDCG considers the notification can go ahead, or the member state – having given its reasons - decides to notify the applicant anyway, the commission has 14 days to publish the notification, and

		* where the notifying member state tells the other member states of any NB designation conditions, it must prove the NB will be monitored regularly and continue to meet requirements (Article 33/31, 6); and * another member state or the commission can raise written objections, within 28 days of notification relating to the NB or its monitoring by the national authority.	transparent details of discussions leading to that notification, in the NB section of the Eudamed database (Article 33/31,9); and *NBs must wait for the notification to become valid – the day after its publication in the database – before it performs its activities ((Article 33/31,10 and 11). There is no Article 33/31, 2 or 3.
34,32	Identification number and list of notified bodies	Commission to assign an identification number to each NB, even when the body is notified under several EU acts. NBs will keep current identification number assigned under medical device/IVD directives (Article 34, 32/1).	Commission to make list of notified bodies, and identification numbers and details of their scope of testing, accessible in the Eudamed section on notified bodies and on certificates (Article 34, 32/2).
35,33	Monitoring and assessment of notified bodies	Notified bodies must inform their national authorities of any significant changes that may impact their compliance of abilities within 15 days of the changes (Article 35/33, 0). In addition, the national authority must monitor its NBs, subsidiaries and subcontractors, and can call for documentation from NBs to verify compliance (Article 35/33, 1). Where the commission or a different member state requests information from a notified body relating to its conformity assessments, that NB's national authority must be informed too and ensure these requests are	As part of the on-site visit, the national authority must: * include witnessed audits of personnel from the NB, subsidiaries and subcontractors in the QS (Article 35/33, 3a); * consider data from market surveillance; vigilance and post-market surveillance as well as complaints against NBs (Article 35/33, 3 c); * record non-compliances and monitor CAPAs (Article 35/33, 3d);

		resolved or referred to the MDCG (Article 35/33, 2). The national authority must reassess its NBs each year, as well as their subsidiaries and subcontractors. If appropriate, this should include an on-side audit of all parties. This must be done in line with its annual assessment plan (Article 35/33, 3). The national authority will do a complete reassessment three years after original notification involving the joint assessment team, and then every fourth year. The timing of this reassessment could be altered by commission delegated acts (Article 35/33, 4 and 4a).	assess the NB assessments of manufacturers' technical and clinical documentation as in 35a (Article 35/33, 3cb) * The national authority may additionally conduct short-notice, unannounced or "for-cause" reviews (Article 35/33, 3ca). * It will then note NB non-compliances and monitor CAPAs (Article 35/33, 3ca). There is no Article 35/33, 3 b.
35a, 33a	Review of notified body assessment of technical documentation and clinical evaluation	As part of the national authorities' responsibilities, it must sample – during on- and off-site assessments – "an appropriate number" of NB assessments of manufacturers' technical documentation and clinical evaluations to verify the conclusions drawn by the NB (Article 35a/33a,1). These must be representative of the types and risk of devices certified by the NB, and focus, in particular, on high-risk devices (Article 35a/33a, 2). The assessments must be conducted using the special technical requirements for devices laid down in common specifications (CS) and also be conducted as part of reassessments and for-cause joint assessments (Article 37/35,2a) too (Article 35a/33a,	The MDCG may recommend that sampling involve a bigger or smaller proportion of clinical evaluations and technical documentation assessed by a NB (Article 35a/33a, 3 and 5). Such decisions would be based on the results of the sampling assessment by the national authority or joint assessment teams, as well as results from (Article 35a/33a, 6): * market surveillance, vigilance or post-market surveillance; or * continuous monitoring of technical progress; * the identification of concerns;

		3 and 5). Article 35a/33a, 4 is missing.	and * emerging issues on the safety and performance of devices, The commission may adopt implementing acts with respect to the methods of sampling and associated documents for, and coordination of, the technical and clinical assessments (Article 35a/33a, 7).
36, 34	Changes to designations and notifications	Changes to NB designation made by national authority must be notified to the commission and other member states. Where there is an extension of the scope, reassessment and designation procedures to be applied (Articles 32/30 and 33/31). The commission must publish the amended notification in Eudamed (Article 36/34, 1). Where a NB decides to cease activities, it must inform the national authority as soon as possible and a year before ceasing activities where it had planned to stop. In this case, certificates issued to manufacturers may remain valid for up to 9 months if another NB confirms it takes over responsibility, after which new certificates must be issued by the new NB (Article 36/34, 1a). If a national authority decides the NB needs to have its designation, suspended, restricted or withdrawn (partially or fully), that suspension	This is a key issue of concern to all players in the medtech space, as NB changes under consideration need to be monitored carefully by the authorities to ensure ongoing compliance, and unexpected withdrawal of a designation from a NB threatens ongoing manufacture and availability of products. One of the key issues is how long NB certificated issued to manufacturers remain valid where there are suspensions or restrictions. They will generally remain valid where a NB designation has been suspended or restricted (Article 36/34, 5a) as long as the national authority has either: * confirmed within a month there is no safety issue and outlined a timeline and actions to remedy

cannot exceed a year, renewable once. (Otherwise the NB, presumably, will be de-designated.)

In such cases, the authority must tell the commission and other member states immediately (Article 36/34, 2). It must tell manufacturers concerned at the latest within 10 days (Article 36/34, 2a). And all files must still be kept available (Article 36/34, 2).

There is a list given of all steps that national authorities must take where there is a change to designation (Article 36/34, 4).

the suspension or restriction; or

* confirmed that the NB will not issue any certificates relevant to the suspension, and a) either has the capability of remaining responsible for existing certificates during the period of suspension or, b) where the authority determines the NB is incapable of supporting existing certificates issued, the manufacturer proves within three months that another NB is temporarily monitoring and remaining responsible for those certificates.

They will remain valid for nine months where a NB cases activity and (Article 36/34, 5a):

* the authority of the member state in which the manufacturer or the authorized representative is based has confirmed there is no safety issue with the devices in question; and

* another NB has confirmed it will assume immediate responsibility for these products and has completed assessment within 12 months from the previous NB designation withdrawal.

Under the nine-month cases, the member-state authority may

			extend the validity of the certificates for further periods of three months, up to a maximum of an additional 12 months. The usual requirements concerning notifications to other authorities and Eudamed apply.
37, 35	Challenge to the competence of notified bodies	The commission, with the MDCG, will investigate all cases brought to its attention concerning NBs, their subsidiaries or subcontractors, ensuring the national authority is informed and given the opportunity to investigate (Article 37/35, 1). In such cases, these two bodies may initiate a joint assessment, including on-site review (Article 33/30, 3 and 4). If severity warrants it, they may ask the national authority to have two of the commission-nominated experts (Article 32a) participate in a planned on-site assessment (Article 37/35, 2a).	The commission will instruct the member state to take corrective measures including suspension, restriction or withdrawal of the designation, if necessary, and can – by implementing act – do this itself if necessary (Article 37/35, 3).
38, 36	Peer review and exchange of experience between national authorities responsible for notified bodies	Commission to provide for organization of experience exchange and coordination of administrative practice between national authorities responsible for NBs (Article 38/36,1). National authorities to take part in a peer review every third year. Normally, reviews will be conducted during on-site joint assessments, but may take place as part of the national authority's annual monitoring activities (Article 38/36, 2). Commission to compile public annual	Elements to be addressed in commission-initiated exchange include (Article 38/36,1a-g): * development of best practice documents relating to the activities of the national authorities; * development of guidance documents for NBs; * training and qualification of joint assessment team experts;

		summary of peer review activities, as well as to help organization of peer review (Article 38/36, 3 and 3a). Commission may issue implementing acts related to methods and associated documents for peer review, training and qualification mechanisms (Article 38/36, 4).	* monitoring of trends relating to changes to NB designations and notifications, and trends in certificate withdrawals and transfers between NBs; and * methods of communication to the public on NB monitoring and surveillance activities (Article 38/36, 1).
39,37	Coordination of notified bodies	All bodies notified under the regulation will participate in a commission-initiated notified body coordination group, which must meet at least annually.	Notified bodies designated under the IVD Regulation are to work under the same coordination group as medical devices.
40a, 38a	List of standard fees	Notified bodies will make lists of standard fees publicly available.	

[Editors' note: *This is the fifth article in an ongoing series delving into the MDR and IVDR chapter-by-chapter. The first article focused on the scope and definitionsof the two regulations. The second article and third article explored the MDR and IVDR regulations, respectively, on the topics of making devices available and putting them into service, the obligations of economic operators, reprocessing, CE-marking and free movement. The fourth article examined traceability and Unique Device Identification requirements. Next up is a look at Chapter V of the regulations focusing on classification and conformity assessments.*]

From the editors of Clinica