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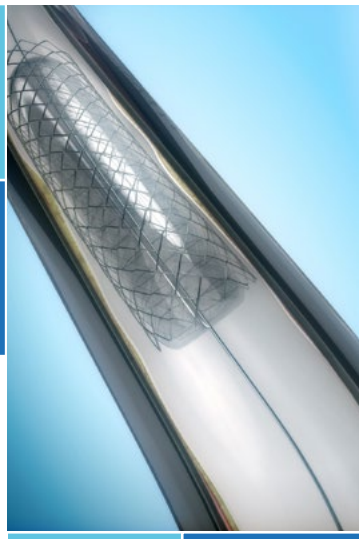

DG Health and Food Safety

OVERVIEW REPORT

Joint Assessments of Notified Bodies designated under the Medical Devices Directives

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2017-6255 - OR

OVERVIEW REPORT - JOINT ASSESSMENTS OF NOTIFIED BODIES DESIGNATED UNDER THE MEDICAL DEVICES DIRECTIVES

EXECUTIVE SUMMARY

This report provides an overview of the joint assessments of notified bodies designated under the medical devices Directive 93/42/EEC and the active implantable medical devices Directive 90/385/EEC which have been carried out from 10 December 2013 until 31 January 2017. The majority of the notified bodies are located in the Member States of the European Union (EU) with the remainder located in countries in the European Free Trade Association (EFTA) and in countries with which the European Commission has concluded Mutual Recognition Agreements (MRA). Such assessments have been mandatory since the entry into force of Commission Implementing Regulation (EU) No 920/2013 on 15 October 2013 (hereafter, the Regulation). They superseded the voluntary joint assessments of notified bodies which commenced in January 2013 and for which the Commission services have already published an overview report [6].

Joint assessment teams have comprised auditors from the Commission's Directorate-General for Health and Food Safety and national experts drawn from designating authorities in the EU Member States, EFTA countries and MRA partners.

The reports from these assessments (both the reports from the joint assessment teams and the reports from the designating authorities) are shared via the Commission's CIRCABC database with all of the (other) designating authorities prior to any decisions being taken on designation and subsequent notification of the respective notified bodies.

When the Regulation came into force, there were 78 notified bodies designated under one or more of the above Directives and notified in the New Approach Notified and Designated Organisations Information System (NANDO). Of these, 19 decided not to continue medical devices certification and were not subject to a joint assessment. Of the remaining notified bodies, 51 have been assessed to date with all of the previously designated notified bodies due to be completed in 2017. In addition there have been 6 new applicants. In all 59 joint assessments have been carried out with the majority (48) covering only the medical devices Directive; the remainder, both that and the active implantable medical devices Directive.

These joint assessments have identified a number of recurring and persistent problems in notified body performance and in their ability to meet the requirements for designation under the Directives. The majority of the problems have already been described in the previously published Commission overview report [6]. Issues of note include the independence and impartiality of notified body staff, insufficient evidence justifying the qualification of staff and their assignment to specific conformity assessment roles and a less than optimal performance of conformity assessments on medical devices.

Of the 59 joint assessments, the entire process has been completed in 41 cases (i.e. reports uploaded into CIRCABC). Of these 41, 35 were for existing notified bodies seeking re-designation and 6 were for new applicants. Renewals of designation were granted for 31 of the existing notified bodies and for 4 of the new applicants.

In all cases, (re-)designation has been contingent upon notified bodies putting in place and implementing corrective and preventive actions to address the nonconformities identified and the effectiveness of these actions being verified by the respective designating authorities. The latter has necessitated intensive dialogue with the notified bodies in question with one or more follow-up (surveillance) assessments carried out on-the-spot by the designating authority. The average time from completion of the on-site assessment to the finalisation of the designating authority report and the upload of the reports into CIRCABC is 9 months and in one case has been as long as 20 months. The time notified bodies have needed to satisfactorily address all of the nonconformities identified in the joint

assessments also explains why, of the 59 joint assessments carried out, the entire process has only been completed for 41 of these.

There are 56 notified bodies currently listed in NANDO. It is expected however, that this figure will fall to 53 by mid-2017, representing a 32% reduction in the number of notified bodies relative to the situation in October 2013 when 78 were listed. It is worth noting that several new applicants have been designated and the vast majority of previously designated notified bodies for which the joint assessment process has been completed (88.5%) have been successfully re-designated. However, in 40% of such cases, the final scope of designation was reduced compared to that applied for and in some instances the duration of designation granted to the notified bodies has been less than the 5 year maximum allowed. These data illustrate the increased level of scrutiny to which notified bodies have been subject.

The report concludes that joint assessments are a useful tool to help harmonise the interpretation of designation criteria and clarify expectations in notified body performance throughout the EU and beyond. Adoption of this assessment model has fostered cooperation between the Commission services and designating authorities and contributed to the smooth functioning of the medical device regulatory framework, helping ensure that only well-functioning, properly resourced and appropriately staffed notified bodies are authorised to conduct conformity assessment in the field of medical devices.

The Commission services expect that the recently published medical devices Regulation and its *in vitro* counterpart, the progress already made in improving the performance of notified bodies and strengthening the EU regulatory system will continue.

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*: all the figures and data take account of the situation as of 31 January 2017.

ABBREVIATIONS & DEFINITIONS USED IN THIS REPORT

CAPA	Corrective and preventive action
Designating authorities	Authorities responsible for designation of notified bodies
EEA	European Economic Area
EFTA	European Free Trade Association
EU	European Union
MRA	Mutual Recognition Agreement
NANDO	New Approach Notified and Designated Organisations Information System
NBOG	Notified Body Operations Group
QMS	Quality Management System
The active implantable medical devices Directive	Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices
The medical devices Directive	Council Directive 93/42/EEC concerning medical devices
The medical devices Directives	Council Directive 90/385/EEC and Council Directive 93/42/EEC (Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic devices is not included in the scope of the Regulation)
The Regulation	Commission Implementing Regulation (EU) No 920/2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices

1. INTRODUCTION

1.1. Legislative framework

The legislative framework for medical devices comprises Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices [1], Council Directive 93/42/EEC [2] concerning medical devices (hereafter and respectively, the active implantable medical devices Directive and the medical devices Directive, jointly referred to as the medical devices Directives), and Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices [3] (which is not included in the scope of joint assessments and therefore not covered by the present report).

The above legislation is based on a framework whereby independent third party conformity assessment bodies are involved in the conformity assessment of medical devices, particularly those in the highest risk categories regarding patient safety. These third party conformity assessment bodies are referred to as notified bodies [4].

Notification is the act by which a Member State, or a country in the European Free Trade Association (EFTA) which is a member of the European Economic Area (EEA), or a country with which the Commission has concluded a Mutual Recognition Agreement (MRA), informs the Commission and the other countries concerned that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment tasks according to one or more of the so-called New Approach Directives [5].

Designation is the responsibility of the Member State, EFTA/EEA country or MRA partner where the notified body is located. Notified bodies are listed in the New Approach Notified and Designated Organisations (NANDO) Information System which is maintained by the Commission.

1.2. The need for joint assessments

Following the discovery of the fraudulent use of non-medical grade silicone in breast implants that were manufactured by the company “Poly Implant Prothèse", questions were raised at political level and in the media on the effectiveness of the medical devices regulatory framework and its operation in the European Union (EU). In February 2012, the Commission agreed with the Member States, EFTA/EEA countries and MRA partners a 'Joint Plan for Immediate Actions' (hereafter, joint plan) aimed at tightening controls on medical devices and at restoring public confidence in the regulatory system.

One of the four objectives of the joint plan was to ensure that only well-functioning, properly resourced and appropriately staffed notified bodies were authorised to conduct conformity assessment in the field of medical devices. The joint plan also required that notified bodies make full use of their existing powers.

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1 OJ L189, 20.7.1990, p. 17.
2 OJ L169, 12.7.1993, p. 1.
3 OJ L 331, 7.12.1998, p. 1.
4 Article 16 of the medical devices Directive, Article 11 of the active implantable medical devices Directive, and Article 1(c) of the Regulation..
5 Point 5.3 of the Commission Notice - The ‘Blue Guide’ on the implementation of EU products rules 2016 (OJ C 272, 26.7.2016, p. 1).

As a means to achieve this objective, the joint plan foresaw the organisation of 'voluntary joint assessments' of notified bodies involving the authorities responsible for designation of notified bodies (hereafter, designating authorities), national experts from other designating authorities and Commission experts. Such assessments were carried out in 23 countries from January 2013 to November 2014 and an overview report of this exercise has been published [6].

1.3. Strengthening legislation

The joint plan provided grounds for Commission Implementing Regulation (EU) No 920/2013 on the designation and the supervision of notified bodies under the medical devices Directives [7] (hereafter, the Regulation), which entered into force in October 2013. It aimed to enshrine the concept of joint assessments of notified bodies as a pre-requisite for (re-)designation of notified bodies, harmonise the interpretation of the criteria for designation of notified bodies and to ensure the consistent application of these criteria. *In vitro* diagnostic medical devices are not included in the scope of the Regulation as the *in vitro* Directive, unlike the medical devices Directive or the active implantable medical devices Directive, did not include a provision allowing for detailed measures necessary to ensure a consistent application of the criteria for designation to be adopted by the Member States in accordance with the regulatory procedure for so doing.

In addition to the Regulation, Commission Recommendation 2013/473/EU [8] describes how notified bodies should conduct, *inter alia,* (announced and unannounced) audits of medical device manufacturers and assessments of manufacturers' technical documentation.

Articles 3 and 4 of the Regulation lay down the modalities for conduct of joint assessments (described in more detail in section 2 of this report) and the sharing of information on the performance of notified bodies and their compliance with the designation criteria with designating authorities in Member States, EFTA/EEA countries and MRA partners. Practical arrangements and mechanisms for conducting the assessments have been further elaborated by the Commission services and designating authorities' representatives within the Notified Body Operations Group (NBOG) [9], and published as a Best Practice Guide document (NBOG BPG 2016-1) [10].

This overview report summarises the progress made, since the entry into force of the Regulation until 31 January 2017, in the conduct of joint assessments, provides data on the number of assessments performed, the contribution made by national experts and the outcome of the entire process (new designations, re-designations, changes in scope of designation etc.). Additionally, some of the recurring challenges faced by notified bodies in meeting the designation criteria are highlighted.

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6 Available at http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=74

7 OJ L 253, 25.9.2013, p. 8.

8 OJ L253, 25.9.2013, p. 27.

9 NBOG was established by the Member States and the Commission in July 2000. It is chaired by a representative of a Member State's competent and/or designating authority and is hosted by the Commission. It reports on its work to a biannual meeting of the competent authorities, and also to a group composed of representatives of Member States, industry and other stakeholder in the area of medical devices, the Medical Devices Experts Group, which is the umbrella for other working groups in the field and coordinates and oversees their activities. http://www.nbog.eu

10 http://www.doks.nbog.eu/Doks/NBOG_BPG_2016_1.pdf

2. JOINT ASSESSMENTS

2.1. Objectives

The objective of each joint assessment is to determine (a) whether the (applicant) notified body fulfils the criteria for designation set out in either Annex 8 to the active implantable medical devices Directive or Annex XI to the medical devices Directive and in Annex I to the Regulation and (b) to make a recommendation as to whether the notified body should be (re-) designated.

2.2. Process followed

The process is described in detail in the above mentioned guide NBOG BPG 2016-1 [10]. Briefly, each joint assessment comprises a preliminary off-site evaluation of the documentation submitted by the notified body (in line with Annex II to the Regulation) followed by an on-site assessment at the premises of the notified body. The on-site assessment is led by the national designating authority and the joint assessment team participates fully in the assessment. Whilst there is a possibility in the Regulation for the joint assessment process to include an observed audit of a manufacturer (i.e. the notified body is observed carrying out such an audit), no designating authority has yet availed of that possibility for the purposes of designation. Nevertheless, such observed audits are included in each designating authority's surveillance assessment cycle of notified bodies.

Joint assessments also take into account guidance documents which represent the state-of-the-art as regards conformity assessments of medical devices. These documents include the NBOG Best Practice Guides and other guidance documents for medical devices (guidance MEDDEVs) [11].

At the end of each joint assessment, a joint assessment team report is produced (see section 2.6.). Nonconformities identified in joint assessments are raised against legal requirements in the Regulation and the medical devices Directives. In the event that the practices of notified bodies were not in line with best practice (e.g. NBOG or MEDDEV documents), these would be recorded as observations in the joint assessment team report.

Joint assessment team reports, by their nature, reflect the situation seen on-the-spot during the on-site assessment and, in line with Article 3 of the Regulation, contain only a summary of the identified nonconformities. Positive aspects in notified body performance are not recorded in the joint assessment team report, whereas these may be captured in the designating authority's report.

Furthermore, designating authority reports reflect not only the situation seen during the on-site assessment but also the outcome of follow-up visits and further assessments. The designating authority carries out such follow-up visits and further assessments to verify the effective implementation of corrective and preventive actions (CAPAs) put in place by the notified body to address the nonconformities identified.

The Commission official leading each of the joint assessment teams is kept appraised of developments by the designating authorities. If necessary, the designating authority and joint assessment team may reconvene to consider and discuss the appropriateness of the notified body's CAPA plan. Ultimately though, it

[11] Available at: http://ec.europa.eu/growth/sectors/medical-devices/guidance_en

is the designating authority which takes the final decision as regards designation of a notified body.

In accordance with Article 3(4) of the Regulation, both the joint assessment team report and the designating authority report are shared with all of the designating authorities via a secure workspace on the Commission's CIRCABC database [12]. These documents form the basis for decisions on the designation of notified bodies.

2.3. Make-up of joint assessment teams

As the Commission service leading the joint assessment process, the Directorate-General for Health and Food Safety (the Health and Food Audits and Analysis Directorate), with the cooperation of the relevant regulatory authorities in the Member States, EFTA and EEA countries and MRA partners, compiled and maintained a list of national experts nominated by those countries in line with Article 3(3) of the Regulation.

In liaison with the designating authorities, the Commission services established the timetable for both the preparatory and on-site components of the joint assessments and, issued an open invitation to the pool of nominated national experts to participate. In the case of notified bodies already designated under the medical device Directives, national experts were requested to consult the European database on medical devices (EUDAMED [13]) and peruse the range of certificates issued by the notified bodies under these Directives in order to decide whether their expertise would be appropriate for the notified bodies in question.

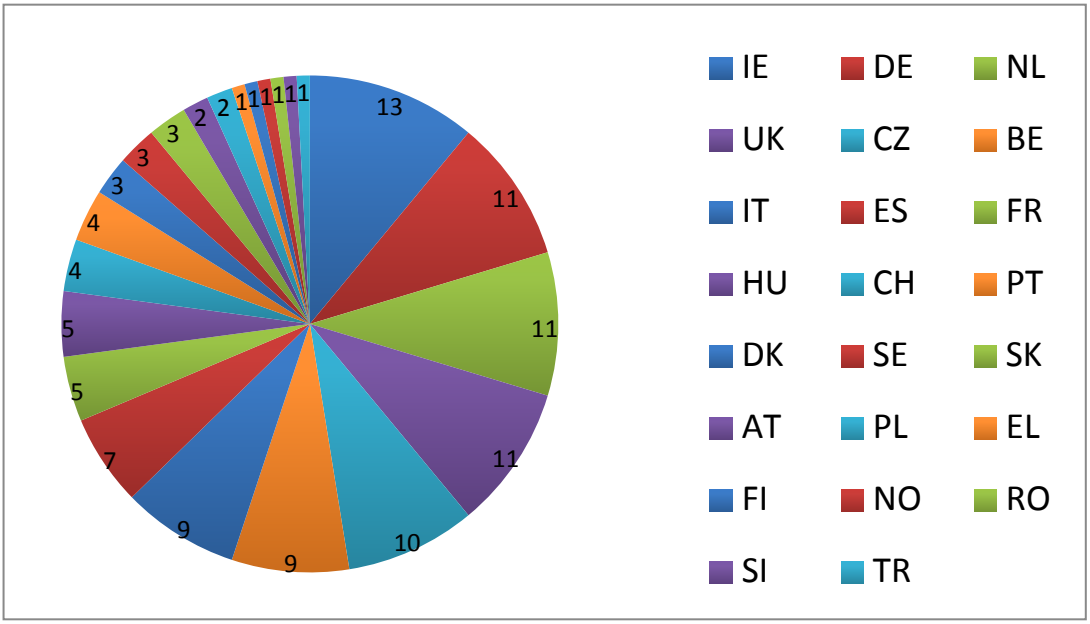
For applicant notified bodies (i.e. those which have not been previously designated under the medical devices Directives), experts were invited to examine the scope of designation applied for and decide accordingly as to whether they were suitable for the task. Experts were also asked to consider language issues and, where possible, experts with knowledge of the language of the notified body were used as this facilitated more rapid assessment of documentation on-site. In the majority of joint assessments however, interpreters provided by the Commission services were employed with either simultaneous or consecutive translation provided.

Figure 1 provides details on the usage and nationalities of national experts involved in the joint assessments.

[12] Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC) http://ec.europa.eu/idabc/en/document/7400/5644.html

[13] Available at: http://ec.europa.eu/growth/sectors/medical-devices/market-surveillance_en

Fig 1: Number of national experts provided per country



Overall, 62 experts from 23 countries participated on 118 occasions in the 59 joint assessments with 10 Member States providing experts who participated on 5 or more occasions. It is also notable that 2 Member States which no longer have notified bodies on their national territory also have provided experts. The largest number of joint assessments in which an individual expert participated was seven with three experts having participated in five joint assessments each.

Each joint assessment team comprised two Commission officials, one of which acted as the team leader responsible for, *inter alia*, organisation of the assessment and production of the joint assessment team report), and two national experts from designating authorities in countries other than the country in which the notified body was established.

The practice of providing two Commission officials, in line with the approach taken during the voluntary joint assessments [6], has facilitated the assessments to be carried out as efficiently as possible. In practically all joint assessments, the combined designating authority and joint assessment team have been able to split into at least two sub-teams for the duration of the assessment, thus covering all of the designation criteria in greater depth than would have otherwise been possible in the time allocated.

2.4. Language of assessments

In advance of each of the joint assessments, the Commission services liaised with the national designating authority regarding the language to be used for the on-site assessment. The joint assessment teams operate in English and the reports are drafted in English. Prior to the on-site assessments, designating authorities were asked to provide (or, request the notified body to provide) in English certain key documents associated with the notified body's application. For other documents, the Commission services arranged for machine translation and distribution to the selected national experts, where necessary.

For the 59 joint assessments performed, 20 were carried out in English (in 8 countries) with no interpretation required. Interpreters were used in the remaining 39 joint assessments (12 different languages) with a total of 140 interpreters being

used. For several of the assessments carried out in two Member States, whilst interpreters were present and were used for the translation of supporting documentation into English, the assessments were conducted in English for the most part without any interpretation.

2.5. Chronology of joint assessments

The breakdown of joint assessments carried out since the entry into force of the Regulation is as follows: of the 59 assessments, 1 was done in 2013, 12 in 2014, 24 in 2015, 21 in 2016 and one to date in 2017. The Commission services forecast that a further 13 joint assessments will be performed in 2017 of which 3 will be for new applicants, 3 will be repeat assessments of notified bodies which already went through a joint assessment process but where the duration of designation granted was less than the maximum 5 years, and the remaining 7 will be for notified bodies which have not yet been subject to a joint assessment.

In a special case 2 joint assessments were carried out on the same notified body (in 2015 and 2016) due to the restricted (1 year) duration of designation granted to the notified body following the first assessment in 2015. In another case an applicant notified body has been subject to two separate joint assessments, having not fulfilled the criteria for designation following the initial assessment.

Concerning the joint assessments which will need to be carried out in 2017 pursuant to the Regulation, most of the notified bodies in question were nationally designated in mid-2013. Given the time needed for notified bodies to address nonconformities and for designating authorities to verify the effectiveness of notified bodies' CAPAs, the assessments under the Regulation are needed in order for these bodies to be re-designated within 5 years from their previous designation.

2.6. Timescales for reporting

According to Article 3(2) of the Regulation, joint assessment team reports shall be produced within 45 days of the completion of the on-site component of the joint assessment. There are no deadlines for the corresponding national designating authority reports.

The draft joint assessment team report is aimed to be produced within a 45 day deadline and submitted to the respective designating authority for its comments, for which it has 25 days [14]. Following receipt of those comments, the joint assessment team report should then be finalised within 10 days – in accordance with applicable reporting procedures in the Health and Food Audits and Analysis Directorate - taking into account the comments received and being amended if necessary. Additionally, for each designating authority comment received, a detailed table is produced indicating how the comment has been taken on board (or not) in the production of the final joint assessment team report and the rationale for so doing. It is this final joint assessment team report which is eventually uploaded into CIRCABC alongside the final designating authority report.

The 59 joint assessments have generated 58 draft reports – the 59th was pending at the time of production of this overview report. The average number of days from

[14] NBOG BPG 2016-1, point 4.1.

completion of the on-site assessment to production and submission of a draft report was 49 days (median 47), with a range from 7 to 118 days.

Delays in production of draft reports have been mainly due to the time taken to seek clarifications from national experts on the nonconformities and/or the supporting evidence for those nonconformities. Other factors have been the involvement of Commission officials on multiple joint assessments within relatively short time periods, and internal review and discussion of the reports for consistency and coherence.

Out of the 58 drafts which have been sent to the designating authorities for comments, 57 final reports have been produced at the time of writing this overview report; one is pending. The average number of days between the sending of the draft reports to the designating authorities and the production of the corresponding final joint assessment team reports was 72 days (median 68), with a range from 13 to 183 days. The average number was as expected given that designating authorities have 25 days in which to submit comments, but, exceptionally, some designating authorities took considerably longer to provide comments on the draft report. In the longest (and most unusual) case, the nature and detail of the designating authority's comments necessitated the joint assessment team leader to consult extensively over several months with the national experts, and for those experts to revisit their hand written notes of the assessment in order to generate the evidence needed to either rebut or accept the comments from the designating authority.

No deadlines are specified in the Regulation with regard to the production of the final report from the designating authorities, and the time taken to produce this report is dependent on the situation encountered during the joint assessment, the time needed by the notified body to rectify problems identified and the time needed by the designating authority to verify that those actions have been implemented and are effective.

Of the 59 joint assessments, 41 final designating authority reports have been uploaded into CIRCABC. The average period from the end of the on-site assessment to the upload has been 271 days (9 months; median 266 days), with a range from 95 to 602 days. These data underline the importance of planning and executing the joint assessments between 12 and 18 months in advance of the expiry of designation. Experience has shown that notified bodies' CAPAs which are related to personnel issues (i.e. recruitment and qualification of suitable staff) can take many months to complete and thus such timescales are needed for notified bodies to meet all of the requirements for re-designation. Such timescales are foreseen in NBOG BPG 2016-1 [10].

3. OUTCOMES FROM JOINT ASSESSMENTS

3.1. Designations

The 59 joint assessments have been performed on 57 conformity assessment bodies, 51 of which have been previously designated and notified under the medical devices Directives and 6 of which have been new applicants. Of the 51 previously designated notified bodies, 52 assessments were performed – one notified body being assessed twice as the initial duration of re-designation granted after the first assessment was restricted to 1 year. For the 6 new applicants there have been 7 joint assessments; one which failed its first joint assessment subsequently re-applied and was re-assessed.

A total of 41 final designating authority reports have been uploaded into CIRCABC, 35 of which concerned notified bodies seeking re-designation under the medical devices Directives and the remaining 6 being applicant notified bodies.

This has resulted in 31 renewals of designation and 4 applicant notified bodies have been newly designated. There have been six notified bodies which did not satisfy the criteria for designation (four existing notified bodies and two new applicants).

It should be noted that of the 59 joint assessments, for which final joint assessment team reports have been completed (57), there are 16 for which no final designating authority report has yet been produced. In such cases the designating authorities are still in the process of verifying the implementation of the CAPAs by the notified bodies.

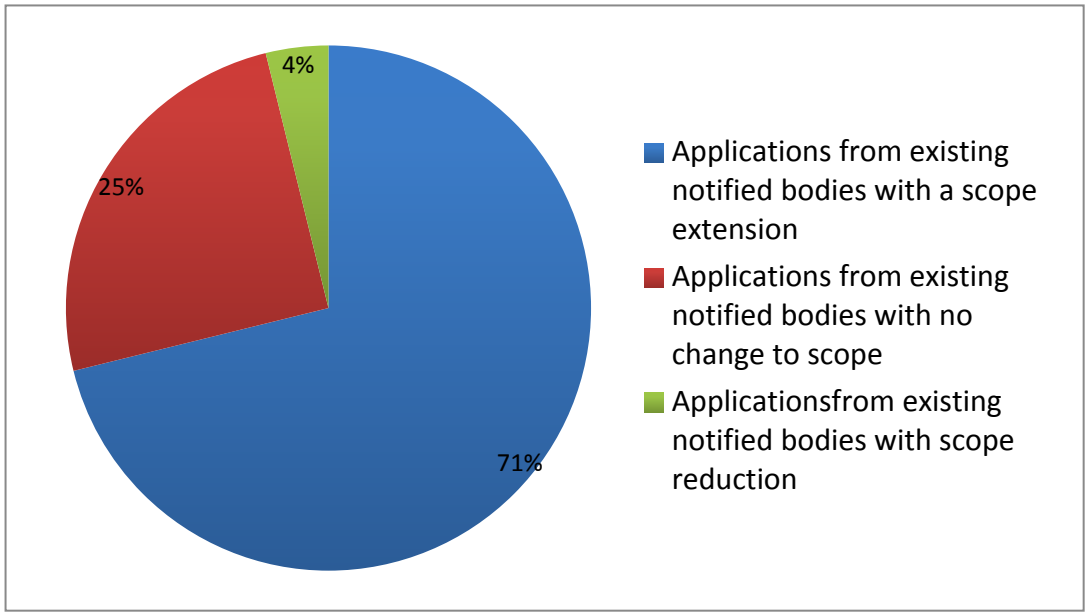
3.2. Changes in scope of designation

As described in Article 3 (1) of the Regulation, together with its application for (re-) designation (or initial designation, if it is a new applicant) for which the application form laid down in Annex II to the Regulation should be used, each notified body should provide the designating authority with the scope of designation it is applying for (list of NBOG scope expressions/NANDO codes and certification routes). Specific NBOG forms have been designed for this purpose, which indicate the types of devices and the conformity assessment routes to be followed. These are, for instance, NBOG F-2012-1 (for the medical devices Directive) and NBOG F-2012-2 (for the active implantable medical devices Directive).

Of the 59 joint assessments, 52 concerned already designated notified bodies (51 notified bodies in all as one of these was assessed twice) for (re-)designation under the medical devices Directive (7 joint assessments were carried out on 6 new applicants) and 11 applications covered both medical devices Directives.

As regards the 52 applications for re-designation under the medical devices Directive from already existing notified bodies, a scope extension had been requested in the majority (37) of the joint assessments; 13 notified bodies applied for no new NBOG scope expressions and 2 notified bodies applied for a scope reduction. The data are summarised in Figure 2.

Fig 2: Applied-for scope of designation under the medical devices Directive for existing notified bodies

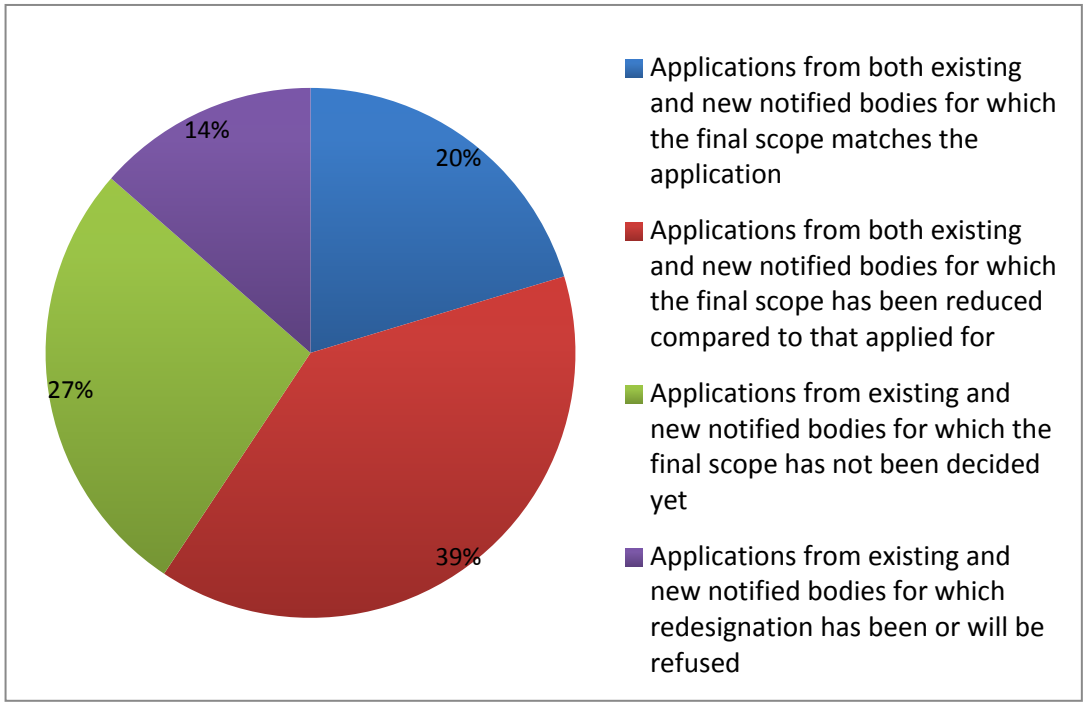


As regards the eventual scope of designation granted under the medical devices Directive compared to that requested by either existing notified bodies or new applicants, this was reduced in 23 of the 59 assessments and in 12 cases matched the applied-for scope. In 17 cases a decision has not yet been taken (there is either no final designating authority report (14) or no final joint assessment team report produced).

In 8 cases, designation has either been refused already (6) or will be refused (2 notified bodies have indicated their intention to withdraw from certification or will be de-designated).

The data on the changes in scope of designation under the medical devices Directive are summarised in Figure 3.

Fig 3: Eventual scope of designation under the medical devices Directive compared to that applied-for – existing and new notified bodies

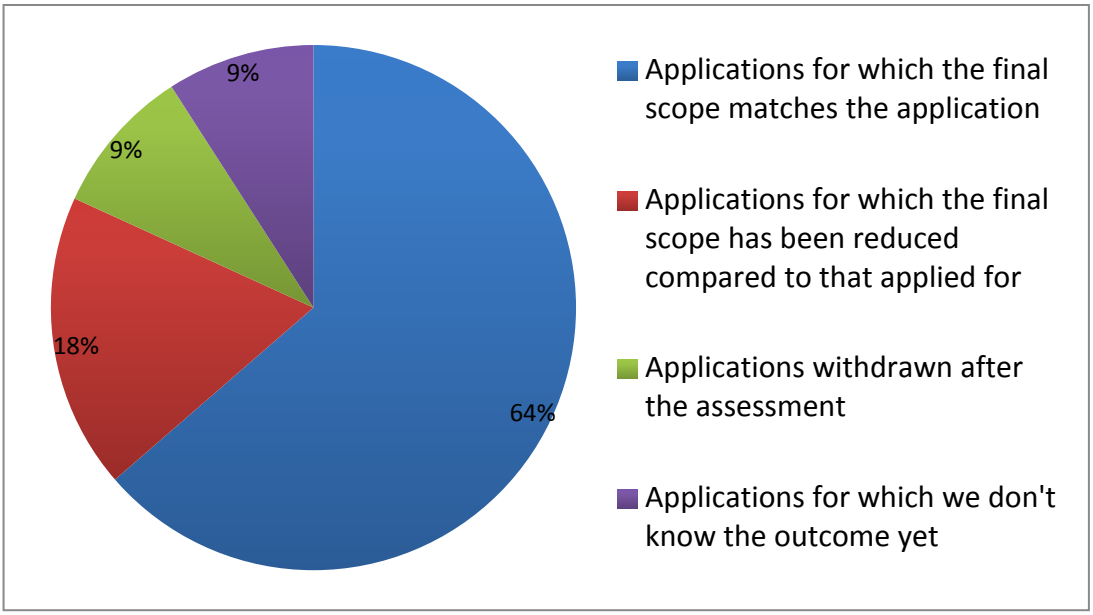


As regards the active implantable medical devices Directive, 11 joint assessments were carried out in which this Directive was also included – no applications were for designation solely under this Directive and none of the new applicant notified bodies applied for designation under this Directive.

It is also notable that there were joint assessments carried out on four existing notified bodies which, whilst designated under the active implantable medical devices Directive, requested to be de-designated for this Directive; consequently these joint assessments only covered the medical devices Directive.

Of the 11 joint assessments dealing with the active implantable medical devices Directive, 4 notified bodies requested a scope extension. One subsequently withdrew its application after the joint assessment, requesting to be de-designated for this Directive. The data on the changes in scope of designation under the active implantable medical devices Directive are summarised in Figure 4.

Fig 4: Existing notified bodies: eventual scope of active implantable medical devices Directive designation compared to that applied for



3.3. Changes to notified body status in NANDO

At the start of the voluntary joint assessment process in January 2013 there were 81 notified bodies listed in NANDO under the medical devices Directives. By the time of the entry into force of the Regulation in October 2013, this figure had dropped to 78 either due to notified bodies being de-designated in the intervening period by their respective designating authorities or deciding not to continue their activities under the medical devices Directives.

Since the entry into force of the Regulation, 19 of these 78 notified bodies have either decided on their own not to seek re-designation under the medical devices Directives, or a decision had already been taken by the designating authority not to proceed with a joint assessment. In addition, a further six designations were either withdrawn (or are in the process of being withdrawn) following an unsatisfactory joint assessment.

Overall, out of the 78 notified bodies (in October 2013), 25 of these will no longer be operating under the medical devices Directives by mid-2017, which is a 32% reduction. However, one should not gain the impression that the joint assessment process has solely led to a rash of de-designations of existing notified bodies. Of the six new applicant notified bodies jointly assessed (one of which has been done twice), four have already been successfully designated. At the time of writing this report there are a further three new applicants which will undergo a joint assessment in 2017.

4. ISSUES IDENTIFIED WITH NOTIFIED BODY PERFORMANCE: COMPLIANCE WITH DESIGNATION CRITERIA

Each of the joint assessment team reports examines the compliance of the (applicant) notified body with designation criteria which are grouped under four main headings: Organisational and general requirements; Quality Management System; Resources; and (the conformity assessment) Process.

The following are common problems identified under each of those four headings.

4.1. Organisational and general requirements

These encompass the **organisation** of the notified body, its **legal status** and **liability** (professional indemnity insurance) in relation to staff, subcontractors and external experts employed by the notified body and the provisions concerning **confidentiality**, **independence** and **impartiality** (**objectivity**).

Common issues identified included:

1. Insufficient management of independence and impartiality. (See section 1.1, 1.2, 1.3, 1.4 and 1.6 of Annex I to the Regulation). In particular:
   a. Lack of independence of the notified body from economic operators having an interest in the product.
   b. Having or offering a range of services which could compromise (or be perceived as compromising) the notified body's ability to act independently. For example, consultancy services or other activities which could be construed as consultancy (i.e. pre-assessment activities).
   c. Lack of an effective system to identify, investigate and resolve potential conflicts of interest which might arise. This was a very commonly found issue with notified bodies either not ensuring that external staff in particular updated their declarations of independence and impartiality (as such staff would often tend to also work as consultants) or, not checking the veracity of such claims when made.
   d. Inappropriate management of risks to impartiality for notified body personnel (internal and external/part-time) staff who have been involved in consultancy activities within the last three years (especially as regards the competitor's clause in point 1(3)(b) of the Annex to the Regulation) or (if external staff) are performing other duties at the same time for manufacturers (e.g. working on the design of medical devices for a manufacturer, conducting clinical investigations, etc.)
2. Lack of contractual agreements and insufficient monitoring of the notified body's subsidiaries and trade partners where these exist (see section 3.7 of Annex I to the Regulation), in particular with regard to the services they provide on its behalf.
3. Key conformity assessment tasks not being kept internal by the notified body (see section 2.1 of Annex I to the Regulation). For example the review of the qualification and the monitoring of the performance of external experts, those experts' assignment to specific conformity assessment activities and/or the final review and decision-making functions were in some cases performed by a subsidiary or by a subcontractor of the notified body or by its external staff.
4. Liability insurance not covering the entire range of activities carried out by the notified body (see section 4.1 of Annex I to the Regulation). In some cases the liability insurance either did not cover all conformity assessment activities for which the body was notified or the full geographic scope of its activities (i.e. did not extend to countries where either manufacturers or their critical suppliers were located).
5. Insufficient management of confidential information (see section 5 of Annex I to the Regulation). In some cases notified bodies' procedures did not properly

address how information coming into their possession for the performance of conformity assessment activities would be kept confidential, how data would be secured and destroyed.

4.2. Quality management system (QMS) requirements

The QMS covers the **control of documents**, **corrective and preventive actions**, **internal audits**, **management review** and handling of **complaints** and **appeals**.

In every single joint assessment issues with the structure and operation of QMS were identified. Common issues included:

1. Quality Management Systems which were either insufficiently structured to assure the consistent application of conformity assessment processes or were not being sufficiently implemented (see section 3.4 of Annex I to the Regulation).
    a. Quality manuals which did not cover medical devices Directives conformity assessment activities (only focussing on ISO certification) or include all of the notified body's personnel and their responsibilities.
    b. Key procedures and processes described in Annex II to the Regulation (sections 19-25 and 41) not being covered within the notified body's QMS.
    c. Procedures which were not sufficiently elaborated or implemented to ensure proper document and record control.
    d. Management reviews not covering medical devices Directives conformity assessment activities or failing to have any impact on the maintenance and improvement of the QMS.
    e. Ineffective internal audits and implementation of corrective and preventive actions which were incomplete or ineffective.
    f. Failure to properly cover complaints and appeals.

4.3. Resource requirements

These include the notified body's **facilities**, **equipment** and **personnel** – both internal and external and focus on these individuals' **knowledge, experience**, **technical competence** and initial and ongoing **training,** the **qualification criteria** used to determine **competence** and their **assignment** to specific conformity assessment roles and to technical areas.

Shortcomings in this area were probably the most frequently found in all joint assessments. Examples included:

1. Insufficient or inappropriate expertise within the notified body to cover its application for scope of designation (see section 3.1(a), 3.2 and 3.5 of Annex I to the Regulation). Many notified bodies did not avail of the necessary technical, scientific or clinical expertise to properly execute conformity assessment procedures. This was usually the case for certain types of devices or technical areas for which the notified body was either already designated or had applied to be designated.
2. Inadequate qualification criteria for personnel (see section 3.6 of Annex I to the Regulation). Some notified bodies had not established appropriate competence criteria for all of the roles in conformity assessment, such as decision makers. Furthermore, in some cases the criteria for authorisation of personnel as product

assessors and product specialists were insufficient to guarantee that appropriately qualified and experienced personnel were used.

3. Deficiencies in the systems used for selecting, authorising and/or assigning personnel to conformity assessment tasks (see section 3.6 of Annex I to the Regulation). In particular:
    a. Procedures for the selection of personnel not taking proper consideration of the level of experience and knowledge which would be needed for the performance of certain conformity assessment tasks and the consequent inappropriate assignment of individuals to specific conformity assessment tasks/client files.
    b. The system for the authorisation of personnel not properly taking account of the notified body's own pre-established qualification criteria.
    c. Difficulties in demonstrating the rationale used for assignment of individuals usually accompanied by a lack of evidence underpinning the authorisation of particular staff to scope expressions or horizontal technical areas.
4. Notified bodies not availing of sufficient internal competence to supervise conformity assessments when external staff are used (see section 3.8 of Annex I to the Regulation). In particular some notified bodies did not have internal staff to cover *all* of the areas for which it applied to be designated and thus had no one *internal* to its organisation, who could direct conformity assessments, verify the appropriateness and validity of (external) expert opinions and make the decision on certification when subcontractors or external experts were used. Linked to this issue was the finding that the required assessment and monitoring of performance of external staff (see sections 2.1 and 2.3 of Annex I to the Regulation) was also not appropriately carried out.
5. Notified bodies not providing their personnel with adequate initial and ongoing training (see section 3.6 of Annex I to the Regulation), not properly assessing individual and collective training needs and not verifying the effectiveness of the training activities.

4.4. Process requirements

These include the notified bodies' medical devices Directives **certification** activities, their **assessment of manufacturers' technical documentation**, their **surveillance** activities and reports and their role in **vigilance**.

In particular, joint assessment team reports focussed on the implementation of the conformity assessment process, evaluating notified bodies' performance in assessing actual manufacturers' files (for obvious reasons, this could not be done in the case of applicant notified bodies). Issues identified included:

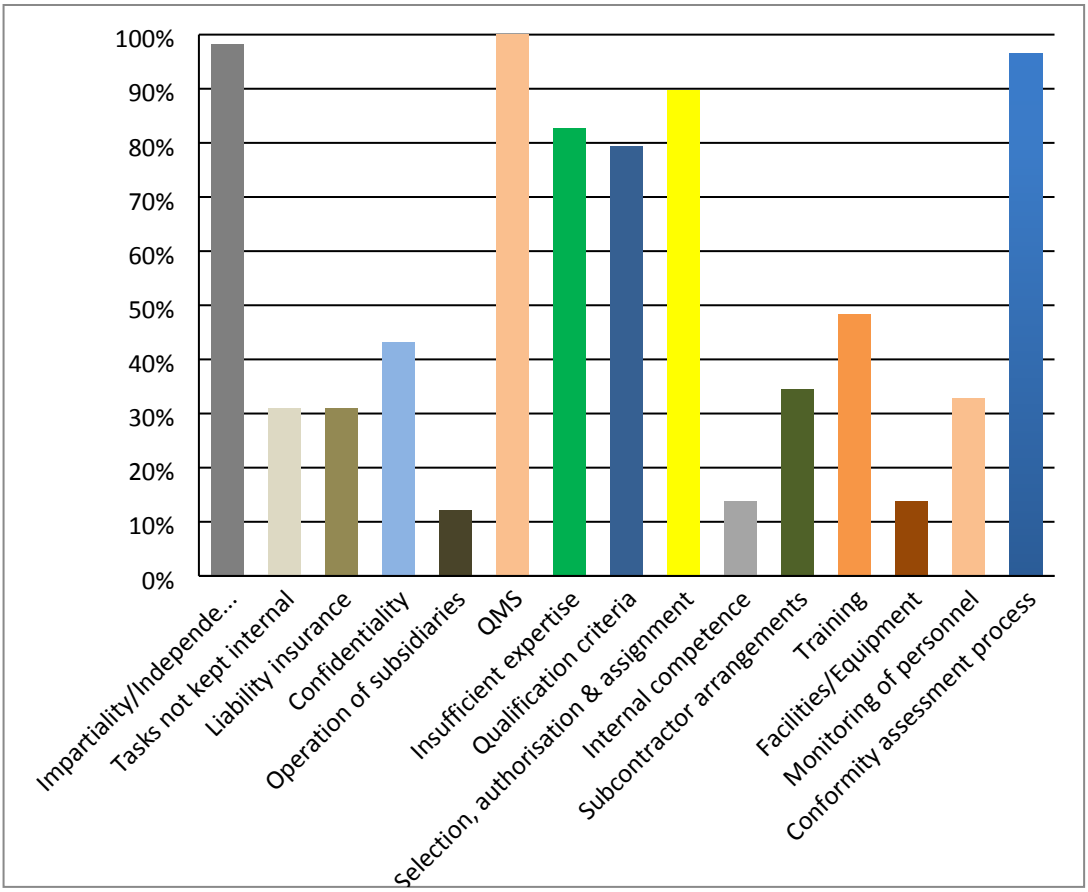
1. Overall, it was frequently seen that conformity assessments had not been implemented appropriately (see section 3.1(b), 3.5(d) and 3.5(e) of Annex I to the Regulation). In some cases the process was inadequately described, and this had, in part, resulted in notified bodies overlooking nonconformities in the manufacturers' technical documentation which were identified during the joint assessment, thus questioning the appropriateness of the certification decision and necessitating the bodies in question to take appropriate remedial action (such as re-examination of the files in question and similar files).

2. Some devices had been certified even though they were clearly not in compliance with the essential requirements for safety and performance described in Annex I to the medical devices Directive (e.g. medical devices put on the market without sufficient clinical evidence, insufficient proof of sterility, without appropriate risk control measures or with inadequate instructions for use). Some notified bodies had either failed to identify problems in manufacturers' technical documentation, or, if they had identified such problems, did not adequately challenge the manufacturers, or, disregarded these issues which had been (correctly) flagged by their personnel.
3. In some cases products had been certified even though they had not been adequately qualified as medical devices or were incorrectly classified according to the medical devices Directive classification rules.
4. In some cases the conformity assessments did not follow the provisions of the relevant Annexes to the medical devices Directives laying down the requirements for conformity assessments under the different conformity assessment routes. For example, the tasks to be performed by the notified bodies according to the different annexes were not always defined in their respective procedures. In some cases there was inadequate assessment of technical documentation, no established criteria for sampling technical documentation (for Class IIa and IIb devices) or misinterpretation of the NBOG/MEDDEV guidance, inadequate audit criteria (particularly for surveillance audits) and difficulty in clearly establishing from the reports of audits on manufacturers, what had and had not been looked at and in what depth.
5. As regards the issue of own brand label devices, in a small number of notified bodies the certification of these devices was inappropriate as the own brand label manufacturers (virtual manufacturers) were treated differently from original equipment manufacturers in that the virtual manufacturer was not required to have access to the full technical documentation for the products and the notified bodies had not therefore conducted a "full" conformity assessment process.

4.5. Pattern of nonconformities observed

Of the 59 joint assessments the proportion of those reports thereof containing nonconformities in each of the areas (subdivided into 15 different categories) described in section 4.1 to 4.4 above is illustrated in Figure 5.

Fig 5: Proportion of joint assessment team reports containing nonconformities (15 categories)



Of the 15 categories, the maximum number of categories in which 1 or more nonconformities were reported was 12, and the minimum was 3 with a median of 8. There was no relationship between the number of existing notified bodies de-designated and the number of categories in which nonconformities were found (ranged from 6 to 10). Both of the applicant notified bodies which were not designated had nonconformities in 9 of the 15 categories.

There was also little relationship between the number of categories in which nonconformities were found and the eventual scope of designation. Notified bodies which ended up with the same scope of designation as applied-for had nonconformities in 5 to 12 categories (mean 8.6), in comparison to a range of 6 to 12 categories (mean 8.4) for those which ended up with a reduced scope of designation.

This lack of correlation is not surprising since many if not all of the nonconformities identified in the 15 categories would have been closed by the time that the designating authority made a final recommendation on (re-)designation, several months after completion of the on-site assessment by the joint assessment team.

5. SUMMARY AND CONCLUSIONS

Joint assessments have now been carried out on notified bodies for 4 years, initially on a voluntary basis, where the main focus was the performance of the designating authorities and, since the first joint assessment in December 2013, on a mandatory basis pursuant to the Regulation.

The 59 mandatory joint assessments have revealed shortcomings in the (already existing and applicant) notified bodies' ability to meet the criteria for designation under the medical devices Directives with many of the nonconformities identified having been previously identified during the voluntary joint assessments and recorded in the Commission's overview report of those missions [6].

At the time of writing, the (re-)designation process has been completed for 41 joint assessments, 35 of which have concerned notified bodies seeking re-designation and the remainder being new applicant notified bodies. The re-designation rate for the existing notified bodies and new applicants are 88.5% and 67% respectively.

Designating authorities are acting diligently in ensuring that notified bodies are meeting those criteria before decisions on re-designation are taken with a median time for re-designation being around 10 months. In all cases, (re-)designation has been contingent upon notified bodies putting in place and implementing corrective and preventive actions to address the nonconformities identified and the respective designating authorities verifying the effectiveness of these actions. This has necessitated intensive dialogue with, and follow-up assessments of, the notified bodies in question.

It is also notable that the scope of designation and subsequent notification has also been reduced in over two thirds of the cases and in some instances, the duration of designation granted to the notified bodies has been less than the 5 year maximum allowed. This illustrates the stringent approach to designation being taken by both designating authorities and joint assessment teams. It is also worth mentioning that in the one case where a notified body was subject to two successive mandatory joint assessments (in 2015 and 2016), a marked improvement in its performance was seen, demonstrating the benefit of increased scrutiny.

The report concludes that joint assessments are a useful tool to help harmonise the interpretation of designation criteria and clarify expectations in notified body performance throughout the EU and beyond. Adoption of this assessment model has fostered cooperation between the Commission services and designating authorities and contributed to the smooth functioning of the medical device regulatory framework, helping ensure that that only well-functioning, properly resourced and appropriately staffed notified bodies are authorised to conduct conformity assessment in the field of medical devices.

The Commission services expect that with the advent of the new medical devices Regulation [15], and its *in vitro* counterpart [16], the progress already made in improving the performance of notified bodies and strengthening the EU regulatory system will continue.

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[15] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. OJ L 117, 05.05.2017, p.1.

[16] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. OJ L 117, 05.05.2017, p.176.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 90/385/EEC	OJ L 189, 20.7.1990, p. 17–36	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
Dir. 93/42/EEC	OJ L 169, 12.7.1993, p. 1–43	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
Dir. 98/79/EC	OJ L 331, 7.12.1998, p. 1–37	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
Reg. 920/2013	OJ L 253, 25.9.2013, p. 8-19	Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices
Rec. 2013/473/EU	OJ L 253, 25.9.2013, p. 27-35	2013/473/EU: Commission Recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices

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