EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE)/2014-7666– MR Final

OVERVIEW REPORT

OF A SERIES OF FVO MISSIONS

CARRIED OUT IN 23 COUNTRIES

FROM JANUARY 2013 TO NOVEMBER 2014

IN THE FRAMEWORK OF

THE VOLUNTARY JOINT ASSESSMENT PROCESS

FOR NOTIFIED BODIES DESIGNATED

UNDER THE MEDICAL DEVICES DIRECTIVES

EXECUTIVE SUMMARY

This overview report describes the outcome of a series of 25 Food and Veterinary Office (FVO) missions carried out in 23 countries between January 2013 and November 2014 which were undertaken in the framework of the voluntary 'joint plan for immediate actions' concerning the performance and designation of Notified Bodies in the medical devices sector. In each of the individual missions the joint assessment teams comprised FVO auditors and national experts drawn from national Designating Authorities.

The objective of this series of missions was to assist national Designating Authorities in the conduct of their surveillance, designation and re-designation assessments of Notified Bodies and to identify and document, where appropriate, opportunities for improvement in the Designating Authorities' performance of such assessments. Given the voluntary nature of this exercise and the absence of any legal basis to publish the reports of these missions, this overview report neither identifies Designating Authorities nor Notified Bodies. It summarises the experience gained during these voluntary joint assessments and collates examples of good practice by Designating Authorities as well as opportunities for improvement in their performance of surveillance assessments.

On the basis of the experience gained during these joint assessments, the Commission, and the national expert assessors involved (33 assessors from 20 countries), consider that the process has been beneficial – not just for each of the national Designating Authorities as a support for their assessments, but also to the national expert assessors from other Designating Authorities who, through this process, have been able to exchange views and opinions with their peers. In the missions carried out to date there have been no substantial areas of disagreement between the joint assessment teams and the Designating Authorities. Overall, it is considered that the assessments have provided an accurate picture of the performance of the Notified Bodies regardless of whether opportunities for improvement in the Designating Authorities' performance were identified. Such opportunities concerned elements such as the planning, scope and depth of surveillance activities. In two cases the standard of the Designating Authority's assessment and over-reliance on accreditation required the initiation of follow-up activities by the Commission services. In one of these cases, effective corrective actions were eventually taken leading to a significant improvement in the situation. In the other case, the required follow-up activities are still to be implemented.

It was also the case that a number of good practices in Designating Authorities' performance were identified during the joint assessments and, it was considered that, if these were to be adopted by Designating Authorities, they could enhance the effectiveness of surveillance assessments and strengthen confidence in the current regulatory system. With regard to the performance of the Notified Bodies assessed, there was, in most cases, a satisfactory level of compliance with legal requirements and best practices. Nevertheless, the joint assessment process has identified weaknesses which were common to a number of Notified Bodies in the areas of organisational requirements and implementation of quality management systems. More importantly, a number of Notified Bodies could not provide sufficient evidence that some of the staff employed for conformity assessment activities were appropriately qualified and experienced for the task. Other recurring issues concerned the thoroughness of some Notified Bodies' review of manufacturers' clinical evaluations, the sampling of technical files for Class IIa and Class IIb devices, the depth to which these files were assessed and, more marginally, the overall documentation and traceability of the certification process.

In all cases, the Notified Bodies in question were requested to put in place necessary measures to rectify the shortcomings identified. In several, the seriousness of the findings led to the Designating Authorities requiring urgent corrective actions from the Notified Bodies with restrictions and sanctions being imposed (including de-designation) and further surveillance assessments being conducted by the national Designating Authority, sometimes with the assistance of a Commission-led joint assessment team.

Overall, the joint assessment process has proven itself to be a useful instrument to gain a global view on the performance of both Designating Authorities and Notified Bodies in the medical devices sector. It has also helped to raise performance standards across the sector, and the experience gained has facilitated the implementation of the mandatory joint assessments pursuant to Commission Implementing Regulation (EU) No 920/2013 which became applicable in October 2013.

TABLE OF CONTENTS

ABBREVIATIONS & DEFINITIONS USED IN THIS REPORT

AIMDD	Active Implantable Medical Device Directive 90/385/EEC
CMC	Central Management Committee for Medical Devices
CV	Curriculum Vitae
DA	Designating Authority
DG(SANTE)	Directorate-General for Health and Food Safety
EC	European Community
EEA	European Economic Area
EFTA	European Free Trade Association
EN	European Standard
EU	European Union
EUDAMED	European Databank on Medical Devices
FVO	Food and Veterinary Office
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
IVDD	In Vitro Diagnostic Medical Device Directive, 98/79/EC
MDD	Medical Devices Directive, 93/42/EEC
MDEG	Medical Devices Expert Group
MEDDEV	Commission Guidelines relating to medical devices Directives - the MEDDEV aim at promoting a common approach by Member States, manufacturers and Notified Bodies and are carefully drafted through a process of consultation with various interested parties
NANDO	New Approach Notified and Designated Organisations Information System
NB	Notified Body
NBOG	Notified Body Operations Group
NCAR	National Competent Authority (vigilance) Report
QMS	Quality Management System

1. INTRODUCTION AND BACKGROUND TO THE 'JOINT ASSESSMENTS'

On 9th February 2012 the European Commissioner for Health and Consumers wrote to all Member States concerning the performance and designation of Notified Bodies [1] (NBs) in the medical devices sector (the 'joint plan for immediate actions' hereafter referred to as the joint plan).

One of the objectives of the joint plan is to ensure that only well-functioning, properly resourced and appropriately staffed NBs are authorised to conduct conformity assessment in the field of medical devices. The joint plan also requires that NBs make full use of their existing powers.

A specific action foreseen in the joint plan is the organisation of 'joint assessments' involving both the authorities responsible for designation of NBs - Designating Authorities - (DAs), national experts (from other DAs) and Commission experts, of NBs responsible for 'Class III' (high risk) medical devices[2]. In 2012, a coordination sub-group of the Notified Body Operations Group (NBOG)[3] was established at the request of the European competent authorities' Central Management Committee on medical devices (CMC)[4] to coordinate with the European Commission on the organisation of the voluntary joint assessments. All European countries having NBs (EEA-countries, Switzerland and Turkey) committed to cooperate in the process and a number of joint assessments carried out under the joint plan were scheduled in 2013 and 2014.

The list of NBs located in the European Economic Area (EEA) countries and in those third countries with which the EU has Mutual Recognition Agreements or Customs agreements providing for NBs is published on the New Approach Notified and Designated Organisations Information System (NANDO) here: http://ec.europa.eu/enterprise/newapproach/nando/

Between January 2013 and November 2014, 25 joint assessments were carried out in 23 countries. The vast majority of these joint assessments were surveillance assessments. The mandatory involvement of joint assessment teams in such assessments is not provided for in Commission Implementing Regulation (EU) No

---

1 Notified Bodies are defined in Article 16 (1) of Council Directive 93/42/EEC.

2 The classification of medical devices into Class I, IIa, IIb and III is described in Article 9 and Annex IX to Council Directive 93/42/EEC. Conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers. For Class IIa devices, the intervention of an NB should be compulsory at the production stage, including the review of the technical documentation as described for at least one representative sample for each device sub-category. For Class IIb and Class III devices, inspection by a NB is required with regard to their design and manufacture. Class III devices require explicit prior authorisation of conformity before being placed on the market.

3 NBOG was established by the Member States and the European 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 twice yearly meeting of the competent authorities and to the Medical Devices Experts Group (MDEG), a group of Member States, industry and other stakeholder representatives in the area of medical devices. The MDEG is the umbrella group for other working groups in the field and coordinates and oversees their activities.

4 The CMC was comprised of representatives of the competent authorities of the EU Member States, EFTA/EEA countries (Iceland, Lichtenstein and Norway) and Switzerland. Turkey had an observer status. The CMC has subsequently been integrated in the CAMD (Competent Authorities Medical Devices) network.

920/2013 which entered into force on 15 October 2013 and, as such, the joint surveillance assessments were carried out on a purely voluntary basis with the consent of both the DA and NB. In the few cases where the assessments conducted were re-designation and/or scope extension assessments, these were carried out before the afore-mentioned Implementing Regulation entered into force, at a time when no compulsory involvement of a joint assessment team was required.

There is no legal basis allowing for the publication of the individual reports of these voluntary joint assessments. Each individual report was distributed to the relevant DA, the members of the individual joint assessment teams, the relevant Commission services and the coordination sub-group (see section 1).

In this overview report, the objective of which is to collate and summarise both examples of good practice and opportunities for improvement in DA performance, the individual DAs are anonymised and no mention is made of the NBs assessed. This report has been presented to the Medical Devices Expert Group (MDEG) and will be circulated within NBOG with a view to raising awareness among all DAs and encouraging better performance from both DAs and NBs. This report is the second overview report produced on the voluntary joint assessments, following on from an interim report which covered the first 10 such assessments.

2. LEGAL FRAMEWORK

As already stated there is no legal basis providing for the participation of the Commission services and national expert(s) in surveillance assessments of NBs by DAs. All of these voluntary joint assessments were carried out with the consent of both the DA and the NB. In accordance with Article 339 of the Treaty on the Functioning of the European Union, the NBs are neither identified in any of the individual reports (nor in this overview report) and any commercially sensitive material evaluated during the course of the individual missions has been treated as confidential.

The standards against which the performance of each DA has been judged comprise the criteria which NBs are required to satisfy in order to be designated by the DA. The criteria are laid down in the relevant EU legislation on medical devices[5], namely:

- Council Directive 90/385/EEC (Active Implantable Medical Devices Directive - AIMDD);
- Council Directive 93/42/EEC (Medical Devices Directive –MDD);
- Council Directive 98/79/EC (*In Vitro* Diagnostic Medical Devices Directive - IVDD)

Further to the entry into force of Commission Implementing Regulation (EU) No 920/2013 on 15 October 2013, the voluntary joint assessments carried out subsequent to that date took account of the relevant provisions of that legislation and, in addition, the common guidelines relating to the medical devices Directives (Guidance MEDDEVs) which, although not legally binding, aim at promoting a common approach by the Member States, medical device manufacturers and NBs.

[5] Articles 11 (2) of the AIMDD, 16 (2) of the MDD and 15 (2) of IVDD specify that Member States shall apply the criteria set out, respectively, in Annexes 8, XI and IX to the said Directives for the designation of notified bodies. In addition, Article 15.3 of the IVDD requires Member States to apply continual surveillance of NBs to ensure on-going compliance with the criteria set out in Annex IX to said Directive.

The guidance on designation and monitoring of NBs within the framework of the EU Directives on medical devices is covered by MEDDEV 2.10-2 Rev 1.

Other documents referred to, and which DAs have no legal obligation to follow but nevertheless are useful interpretative guidelines for, inter alia, the designation criteria, include the DA Handbook adopted by NBOG[6]. The Handbook is designed to be a best practice guide and a practical aid for DAs on the execution of their responsibilities for the designation, monitoring and control of NBs. NBOG has also published a number of Best Practice Guides for both DAs and NBs. These are available here: http://www.nbog.eu/2.html and were endorsed by the CMC (CMC Decision No 2).

Commission Recommendation 2013/473/EU contains guidance for NBs on the conduct of audits and assessments of medical device manufacturers.

It is also worth noting that ISO/IEC 17021:2011 contain some guidance which corresponds to the requirements of the medical devices Directives. This is the reason why some countries have decided to rely on the accreditation of NBs to this standard for presumption of conformity with some of the designation criteria. As detailed in section 4.3.3, following this rationale has been problematic, in particular in the area of resource criteria for NBs. In addition, ISO/IEC 17021:2011 guidance do not encompass product-related assessments such as, for example, EC-type examinations or design dossier examinations.

A list of the legal instruments referred to in this overview report is provided in Annex 1 and refers, where applicable, to the last amended version. Annex 2 lists the specific legal basis and/or guidance documents relevant to designation criteria for NBs.

3. ORGANISATION OF THE INDIVIDUAL MISSIONS AND THE REPORTING PROCESS

In general, each mission comprised a pre-meeting with the DA during which the objectives of the mission were confirmed and additional information required for the satisfactory completion of the mission was discussed. This was followed by an assessment on the premises of the NB where the joint assessment team observed and contributed, in almost all cases, to a surveillance assessment [7] carried out on the NB by the DA.

Each mission report:

- listed the national legislation and/or country-specific guidance documents concerning medical devices;
- listed the documentation provided to the joint assessment team (from both the DA and the NB) prior to the assessment;
- described the DA and its strategy for carrying out surveillance assessments of its NBs,
- described the NB (its scope of designation);
- summarised the outcome of the previous surveillance assessment and described the scope of the current assessment;

[6] See footnote nr. 3.

[7] Surveillance assessments are one of the four types of assessment of NBs which can be carried out by a DA. See Section 4, Point 2(5) of the NBOG DA Handbook – available here: http://www.nbog.eu/2.html - and MEDDEV Guidance Document MEDDEV 2.10-2 Rev 1.

- made findings and conclusions on the DA's assessment of the NB's continued compliance with the designation criteria listed in the relevant Annexes to the medical devices Directives, and, after its entry into force, Annex I to Regulation (EU) No 920/2013;
- recorded any diverging opinions between the joint assessment team and the DA on the performance of the NB and;
- listed a number of non-binding 'opportunities for improvement' for each DA to consider and address if it so wished.

Each DA was sent a draft report on which it was invited to correct any factual inaccuracies and provide further comments or clarifications (including possible actions in relation to the opportunities for improvement). The DA responses were taken into account for the production of each final report.

4. STRUCTURE OF THIS OVERVIEW REPORT

The objective of this overview report is to collate and summarise both examples of good practice and opportunities for improvement in the activities of DAs and to outline the main issues identified in NBs' performance. The structure of the individual reports has been followed and in each of the following sections (section 4.1 to 4.3) there is a description of the situations observed together with the main opportunities for improvement and best practices identified. Section 5 summarises the actions taken by DAs in response to the content of the individual reports and the opportunities for improvement contained therein.

4.1. DA monitoring and surveillance of NBs

4.1.1. Frequency of DA (surveillance) assessments

Whilst there are no requirements in the medical devices Directives concerning the frequency of assessments that a DA should perform on an NB, this has been defined in Article 5 of Regulation (EU) No 920/2013. Guidance is also given in the NBOG DA Handbook (page 73) which is based on the guidelines given in MEDDEV 2.10-2 (Section III 3. A.).

In 15 of the 25 voluntary joint assessments, it was noted that DAs were conducting surveillance assessments and observed audits with frequencies and durations following the guidelines of MEDDEV 2.10-2 and the NBOG DA Handbook.

Opportunities for improvement

In five cases assessments were following frequencies that were below those recommended by existing guidelines. In addition, in one case the frequency of assessments did not take account of the size and complexity of the NB; in another case assessments were of shorter duration than that recommended by MEDDEV 2.10-2 and the NBOG DA Handbook and, finally, in a third case the content of the assessment plan was not adapted to the duration of the assessment (i.e. too many topics to be covered in the time available).

Observed audits, which give DAs an opportunity to check the quality and thoroughness of individual NB auditors and their knowledge of the various Directives, national rules and standards were not conducted by five DAs and were carried out below the recommended frequencies by two DAs.

Best practice

Some DAs split into subgroups (in general two, one covering procedures and another one focusing on client files). When adequately coordinated, this resulted in a better use of assessment time, leading to more client files being reviewed.

4.1.2. Scope of DA (surveillance) assessments and the approach taken

- **Legislation and best practice guides**

National legislation giving implementation and enforcement powers to the DA was in place in all cases. In one country there was some uncertainty as regards the DA's ability to carry out designation duties under the existing national legal framework. This situation had been addressed through cooperation with the national accreditation body (as accreditation of NBs is a legal requirement under the applicable domestic legislation) and, according to the DA, a revision of the existing national legislation was on-going. In another two countries, it was not clear if national legislation enabled the DA to impose special measures on NBs (e.g. prohibition to acquire new clients or an obligation to review technical files).

MEDDEV 2.10-2, the NBOG best practice guides and other national guidance documents were taken into account by all of the DAs. In all cases, joint assessment teams noted that non-adherences of NBs to these guidelines were raised as nonconformities or at least as observations by the DAs.

Best practice

Four countries have made compulsory the use of part of best practice guides and national guidance documents by NBs either through national legislation or by including them in contractual arrangements between the NB and the DA (e.g. in the application for designation), hence facilitating their implementation.

- **Staff resources**

Qualifications and work experience of DA staff were largely relevant to their area of activity and, when necessary, completed and updated through training arrangements. In most cases, resources available to each DA were sufficient to enable them to perform their tasks effectively.

Opportunities for improvement

In one country limited staff resources available to the DA had resulted in limited preparation (e.g. no prior review of the NB's procedures concerning the areas under assessment) and a frequency of assessments which did not take into account the size and complexity of the NB. According to the DA, steps had been taken to increase the staffing level.

In another case, pending the training of its staff, the DA had hired technical experts from the industry for the purpose of using them in surveillance assessments. The joint assessment team noted that the DA had obtained only limited guarantees on the impartiality and independence of these experts, contrary to the recommendations of the NBOG DA Handbook.

In two countries, for certain types of medical devices (e.g. IVD) or specific technologies (e.g. software) included in the scope of designation of their NBs, the DA had no in-house expertise and did not make use of external competence, thus limiting the DA's ability to challenge the NBs' assessments in these areas.

In one country, the technical expertise available to the DA was far from being sufficient to cover the scopes of designation of the NBs. This had resulted in

assessments which were very superficial in nature.

Finally, in one country the DA had limited experience in terms of clinical evaluations and had received support from the competent authority.

Best practice

As regards best practices, in seven countries the respective DAs called upon clinicians and product specialists to support their assessments. This enabled them to perform detailed reviews of the assessments of technical files conducted by the NBs, in particular by assessing the documentation submitted by manufacturers and challenging the review of these data performed by the NBs. In all cases the use of such specialists proved very effective in identifying systemic deficiencies in the NBs' assessments.

In another three countries, the DAs made use of other countries DAs' experienced assessors to help them improve their assessment skills and methodology. This proved particularly helpful in cases where the DAs' assessors requiring assistance had limited overall experience or when the other DAs' assessors qualification and experience were complementary to those of the DA assessors requesting support.

- **Organisation of assessments**

Surveillance assessments in which the joint assessment team participated varied in scope and duration but usually included a follow-up of nonconformities raised during previous assessments, a review of client files and a review of several of the designation criteria laid down in the relevant Annexes to the medical devices Directives. In eight countries accreditation and surveillance assessments were combined. In one country, the national accreditation body had the overall responsibility for conducting the assessment, the DA participating with an observer status. In another two, the DA functions were performed by the national accreditation body. The plans for surveillance assessments and their implementation usually followed the guidance given in the NBOG DA Handbook. In the majority of cases DA teams usually comprised two assessors; in seven cases three assessors and one case four assessors participated. In three countries, the DA conducted the assessment with only one assessor, sometimes accompanied by an assessor of the national accreditation body.

Opportunities for improvement

In nine countries, the joint assessment teams noted that better preparation of assessments would have been possible and would have resulted in a better use of the assessment time, in particular if: (a) clear rules had been established for notification to the DA of changes in the organisation and procedures of the NB (one country); (b) the DA had enquired about changes in the NB's structure since the last assessment (three countries); (c) the DAs had obtained and reviewed the NBs' procedures pertaining to the activities under assessment (three countries), (d) a clear assessment plan had been established prior to the assessment (two countries) and (e) the DA had confirmed, prior to the on-site assessment, the availability of technical files at the NB premises (one country).

In five countries, while the designation of their respective NBs is not time-limited, there was no system in place to ensure that all of the designation criteria would be reviewed over a period of time during successive surveillance assessments, with the consequence that some of the criteria would not be assessed systematically. In one case, it was because the selection of criteria to be checked during surveillance assessments (performed jointly between the DA and the national accreditation

body), was mainly driven by the national accreditation body.

Best practice

When possible, the combination of accreditation and surveillance assessments, or close cooperation between accreditation bodies and the DAs, resulted in better knowledge of the nature and depth of the checks conducted by national accreditation bodies. In at least three countries, if this had occurred, it could possibly have prevented an over-reliance of the DAs on accreditation, in particular as compliance with ISO/IEC 17021:2011 does not ensure that all of the requirements of the medical devices Directives are met.

Several DAs had standard operating procedures for designation and surveillance of NBs. In two countries the DA had full on-line access to the NBs' Quality Management System (QMS). In some countries these procedures foresaw the review, prior to the assessment, of the NBs' QMS procedures relating to the areas evaluated as well as lists of documents and activities to be carried out by the DA. In particular, these activities included a review of the NB's website, an activity which proved very effective in preparing the assessments and identifying several shortcomings in the operations of NBs which were subject to the joint assessments (see section 4.3.1).

- **Assessment reports**

Reports drafted by DAs in surveillance assessments usually reflected the scope and depth of the checks performed.

Opportunities for improvement

In four cases the previous assessment reports contained limited evidence of the investigations conducted by the DAs, making it difficult for the joint assessment team to ascertain the scope and depth of those previous DA assessments.

- **Nonconformities**

Communication of nonconformities to the NBs was usually performed in a timely manner, taking into account the guidance in the NBOG DA Handbook.

Opportunities for improvement

Some DAs implemented practices which departed from those given in the various guidance documents available. In seven cases, no written list of nonconformities was left with the NB at the closing meeting of the assessment. In nine cases nonconformities were not categorised into major or minor and in three cases nonconformities were not clearly formulated or the standards and legal requirements breached were not mentioned by the DA.

Best practice

In three countries the DAs gave to the NBs a detailed account of the nonconformities and also linked nonconformities together in order to identify systemic issues which might have a negative impact on the performance of the NB.

- **Follow-up activities**

Follow-up of nonconformities and their closing out was performed in accordance with the recommendations of the NBOG DA Handbook in two thirds of the cases.

Opportunities for improvement

In nine cases there were weaknesses in the procedures in place for follow-up activities: in four the follow-up conducted by DAs was not well documented, was subject to significant delays or was not particularly effective; in two the deadlines agreed between the NBs and the DAs for resolving the nonconformities identified were not enforced; in one the DA surveillance assessment report (of the previous assessment) neither included details of the corrective actions proposed by the NB nor any information on their assessment by the DA; in one the DA did not verify the effectiveness of the corrective actions put in place by the NB; and finally, in one the DA's methodology for following up on the previous nonconformities did not ensure that all of these nonconformities were systematically reviewed.

Best practice

Three DAs requested the NBs to provide root cause analyses for the nonconformities identified during the assessments and one DA also requested the NB to provide measures for the verification of effectiveness of the corrective actions proposed. This helped in the assessment of the appropriateness of the corrective actions proposed by the NBs and offered the DAs a convenient means of verifying the implementation of these actions.

4.2. Scope of designation of the NB being assessed

The NBs subject to joint assessments varied in size and scope of operations. All were carrying out assessments of devices falling under the MDD, additionally twelve had clients for devices covered by the IVDD and six for clients falling under the AIMD. Three of these NBs had more than 1,000 valid certificates, eight had between 200 and 1,000 certificates and thirteen had less than 200 certificates.

In all cases but five the scope expressions used by the DA (as seen in NANDO or on the designation decision) were in line with the recommendations of NBOG 2009-3. In three cases the MDD annexes and the scope expressions present in NANDO did not reflect all of the medical device codes and annexes for which the NB conducted conformity assessments.

Opportunities for improvement

In six countries only, the data contained in EUDAMED largely reflected (although with some minor discrepancies) the certificate data provided by the NB to the DA. In all of the other cases, there were significant discrepancies between these two sets of data: in four cases these were explained by incorrect, incomplete or in some cases a total absence of information uploaded into EUDAMED; in six cases differences stemmed from either delays in uploading the information or technical issues (e.g. incorrect format or incompatibility of national systems with EUDAMED) and in another four cases the reasons were not known and had to be investigated by the DAs. In one case, uploading information into EUDAMED had not been envisaged by the DA; in another, the NB did not always consistently provide the DA with information on certificates issued and, finally, in another case the DA explained that the incomplete information contained in EUDAMED was due to, what it felt were, unclear rules for uploading manufacturers' information into this databank.

In one country it appeared that the competent authority did not upload information on suspended or withdrawn certificates onto the EUDAMED system and did not circulate an email correspondence in such instances. This has significant implications in cases where certificates are being withdrawn or suspended for safety

reasons as there would be no way to take the necessary market actions throughout the Union, unless the manufacturer proactively informs the relevant competent authority and recalls the products concerned[8].

4.3. Designation criteria for NBs

The designation criteria to be met by NBs are, for the sake of clarity, grouped into the following four separate sections (4.3.1. to 4.3.4.) rather than in the order in which they appear in the relevant annexes to the medical devices Directives.

4.3.1. Organisational and general requirements

In this section the following elements are included: organisation of the NB, its **legal status** and **liability** (professional indemnity insurance); in relation to **staff**, **subcontractors** and **external experts** employed by the NB, the provisions concerning **confidentiality**, **independence** and **impartiality** [9] (objectivity).

In all cases but one the assessments conducted by the DAs were surveillance assessments and therefore did not aim at covering all applicable requirements. Nevertheless, all of the assessments did include verification of compliance with at least some of the organisational and general requirements.

A review of **organisational charts** of NBs was conducted in 18 assessments. These charts were largely found to be satisfactory, although some issues were identified in three countries as regards their accuracy and completeness. The **legal status** of the NB was checked in 15 assessments and no (adverse) issues were noted in this respect. The **financial situation** of NBs was only assessed in eight countries although this is one of the elements which can potentially affect the independence and impartiality of NBs and, for such reason, is included in the items recommended to be checked by the NBOG DA Handbook.

Provisions pertaining to **independence** were reviewed in 22 assessments. In 15 assessments, deficiencies were identified in the rules implemented by NBs. While such provisions were always in place (usually catering for the absence of links with the manufacturers), they were not always implemented as designed (one case), were inconsistently drafted or applied in the NBs' documents (three cases), did not cover subcontractors or trade partners of the NBs (two cases) or did not take into account all of the recommendations of MEDDEV 2.10-2 and, when applicable, the requirements of Regulation (EU) No 920/2013, in particular those concerning consultancy provided to competitors, suppliers or authorised representatives (twelve countries).

In four cases, the NBs did not have a pro-active approach to ensure identification of potential **conflict of interest** or had limited procedures available in that respect (e.g. limited risk analysis for identification of potential conflicts of interest). In another two cases some of the NBs' external staff used in conformity assessment tasks was employed by manufacturers of medical devices. Such a situation could prove problematic in terms of independence and impartiality as, even though the manufacturers subject to assessments were informed beforehand of the composition

[8] At the time this report was drafted, the DA concerned had taken action to ensure such information was circulated.

[9] In ISO/IEC 17021:2011 impartiality is defined as the actual and perceived presence of objectivity. Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the certification body.

of the NB team and could object to the presence of such experts, this did not provide guarantees as to the impartiality of these experts. In one case, the NB had devised a system to mitigate such risk by avoiding that such experts were involved in the assessments of competitors; in another case it was not envisaged.

In one country, the fact that the same person was head of the DA, CA and NB cast some doubts as regards the actual independence of the NB from the DA and the CA. The DA committed to provide additional information about the mechanisms possibly ensuring that such independence existed as required by Section 1.5 of Annex I to Regulation (EU) No 920/2013.

As regards the **impartiality** of staff, the obligation to ensure that remuneration of personnel does not depend on the number of audits and verifications carried out, was only checked in 12 assessments. Although in some cases, the DAs noted that such rules were provided for by the NBs' procedures, apart from a few countries the DAs didn't assess whether such rules were effectively implemented.

Rules concerning **confidentiality** were verified in 15 assessments with no adverse findings.

Checks on **liability insurance** were included in 19 of the assessments. In most cases, the DA verified whether the insurance was present, valid and covered all geographic areas of activities of the NBs. While in most cases the policies in place were found to be adequate, in two countries, the amounts covered by the policies followed the minimum set in national legislation but appeared to be very low in comparison to similar sized NBs located in other countries. The NBs in question could not prove whether or not such amounts were sufficient in view of the nature and level of their activities. In another two countries the liability insurance did not cover all of the countries in which the NB carried out its activities. Some DAs consider that an evaluation of whether the maximum amount covered by liability policies is sufficient in light of the number/types of certificates and clients of the NBs is very difficult. In one country a practical solution had been found by the DA whereby its NBs are encouraged to set out in their contracts with manufacturers the financial limits of their liability.

Opportunities for improvement

In nine countries the DAs paid limited attention to the recommendations of MEDDEV 2.10-2 or, when applicable, verified the requirements of Regulation (EU) No 920/2013 on independence. This particularly concerned the rules applicable to providing consultancy to competitors, suppliers or authorised representatives of the manufacturers under assessment. Amongst the elements rarely checked by DAs during these assessments, were the marketing documentation and websites of NBs as well as the implementation of rules concerning absence of links between staff remuneration and the number and outcome of audits or verifications they had performed.

Best practice

Examination of the NBs' websites as part of the DA's preparatory work proved an excellent tool. In one country the joint assessment team was able to identify potential consultancy services and training activities at manufacturers' premises (which could potentially drift into consultancy) which the national DA was unaware of. In another country, through the review of the NB website, the DA identified statements which appeared to give the NB a role in product development.

4.3.2. Quality management system (QMS) requirements

In this section the following elements are included: **internal audits**, **management review** and handling of **complaints** and **appeals**.

In 22 countries the assessments included a review of some elements of the NBs' QMS. In all cases where QMS elements were reviewed, the DA took account of the guidance of ISO/IEC 17021:2011 and in some cases of ISO/IEC 17065:2012 or EN 45011. In three cases both the DAs and the joint assessment teams identified nonconformities which had been overlooked by recent assessments conducted by the national accreditation bodies in the framework of the ISO/IEC 17021:2011 accreditation. These concerned annual schedules for internal audits which were not respected (one country), insufficient interfacing between the QMS of a NB and its mother company (one country) and several important systemic issues in the QMS and procedures of a NB (one country).

All NBs had devised QMS covering conformity assessment tasks and all were accredited to ISO/IEC 17021. The main issue identified in the operation of these QMS concerned the implementation of internal audits, in particular the follow-up of nonconformities identified. In several cases, a root cause analysis had not been conducted or was not recorded (four countries) and corrective actions were delayed in their implementation, not followed-up, not taken or were superficial (seven countries). Other issues identified in the area of internal audits concerned: the limited effectiveness of these internal audits (which had overlooked most of the nonconformities identified during the joint assessments – two cases); too much focus on the voluntary certification process and insufficient attention paid to the CE certification process (one case) and internal auditors reviewing part of their work in relation to conformity assessment activities (one case). In one case, there was no formal internal audit report drafted after the audit had been carried out.

On the contrary, when reviewed, the procedures in place, and their implementation, for dealing with complaints and appeals or management review were in most cases deemed satisfactory. In three cases only were management reviews found to be missing some relevant inputs such as, for instance, the outcome of DA assessments.

Concerning QMS in general, the joint assessment teams noted that in two cases the procedures for conducting conformity assessment tasks were not available in the languages spoken by the external experts used by the NBs. This finding questioned these experts' ability to be aware of the rules to be followed when conducting their tasks. In one case not all of the updates of QMS procedures had been communicated to external staff, in one case there was no system in place to make staff aware of possible changes in procedures and in another case, the NB could not demonstrate that it had informed all staff about all relevant changes on a regular basis. Finally, in another case, there were inconsistencies between procedures and guidance notes and some of the procedures were not adhered to.

Best practice

Some DAs asked for advance copies of the QMS procedures to be reviewed during the assessments in order to be aware of their content. In one case the DA had drafted an internal report outlining the elements to be checked on the spot.

In two cases the DAs had decided to review internal audits at the end of the assessment in order not to be influenced by the findings of these audits.

In six cases the DAs reviewed the NBs' corrective and preventive actions database as part of the verification of actions taken following internal audits. This enabled them to assess the way in which nonconformities were handled in general and not

only in relation to those identified in internal audits. This exercise proved effective as, in several cases, it could be confirmed that there had been delays in taking actions or in keeping the database up to date.

Finally, some DAs reviewed reports from the national accreditation bodies, an interesting exercise given the overlaps which exist between the provisions of Regulation (EU) No 920/2013 and the guidance provided by MEDDEV 2.10-2, and ISO/IEC 17021 in the area of QMS.

4.3.3. Resource requirements

In this section the following elements are included: the NB's **facilities**, **equipment** and **staff** – both internal and external - (knowledge, experience, technical competence and training) used for conformity assessment activities.

Only five of the NBs subject to the joint assessments had testing laboratories in operation. When no testing facilities were located on the NBs premises, the DAs usually did not include **facilities and equipment** in the assessment plan but, on some occasions, focused on the storage and archiving of files or on computer system security. In the five cases where testing was taking place at the NBs, in one case a calibration certificate was reviewed by the DA and in another case a tour of the laboratory was performed in order to check the presence of adequate equipment.

In all cases but one the DAs sampled curriculum vitae (CV) of staff involved in conformity assessment tasks in order to ascertain whether or not there was objective evidence supporting the allocation of these staff to specific tasks or categories of medical devices. When present, except in one case, competence matrices were examined by the DAs. Training arrangements were checked by the DAs in all cases but one. In many cases DAs paid special attention to the NBs' arrangements for dealing with staff who could not attend training sessions.

Opportunities for improvement

A minority of DAs reviewed the arrangements in place for assessing, on an on-going basis, the competence of staff, in particular the organisation of field assessments although, in at least two cases where the DA checked them, delays were noted in the implementation of such assessments.

In one country the DA assumed competence requirements were met through accreditation. This meant that when accreditation covered the harmonised standards listed as technical specifications for each of the scope expressions, the NBs were deemed to avail of sufficient competence. However, in one NB, while the list of harmonised standards in place at the NB was considered satisfactory by the accreditation body, the joint assessment team noted that several basic harmonised standards were not listed and that core competences expected of the NB, such as biocompatibility or risk assessment, were subcontracted while it should normally be available in-house. In another NB, both the DA and the joint assessment team, identified gaps in the competence and experience of the staff allocated to the review of manufacturers' clinical evaluations (the lack of required expertise was confirmed through the file examination in which such staff had been involved). In another country, where the DA mainly relied on accreditation standards, there was no check on whether, overall, the NB availed of the required level of expertise, while this was doubtful given the number and expertise of NB staff compared to its scope of designation. In all three above-mentioned cases, the over-reliance on accreditation had resulted in questionable staff qualifications being overlooked by the DA.

Two DAs did not verify, on an on-going basis, that NBs availed of the required level

of expertise to conduct their tasks. This was either because CVs of staff were not scrutinised (one country) or when they were, there was no verification that the types of devices or activities to which the staff were allocated was consistent with the competence and experience described in their CVs (one country).

In five cases, the DAs did not pay enough attention to the existence and adequacy of the competence criteria devised by the NBs.

Best practice

Some DAs systematically checked the CVs of staff involved in the client files reviewed and focused on new staff members or on staff involved in NBs' new scopes of activities (for instance, following a request for a scope extension).

All NBs kept CVs of staff, which, in most cases followed the format proposed by MEDDEV 2.10-2 and the NBOG DA Handbook. However, in four cases CVs were incomplete or were not up-to-date (e.g. field of operation not filled in, training and audit records not up-to-date or CVs not signed). Clear written criteria for allocation of some categories of staff members to conformity assessment tasks were missing in at least 12 NBs and in 10 cases there was not enough evidence (e.g. qualification, training or work experience) to support the designation of some NB staff as product specialists for specific categories of medical devices. Details of the main issues identified were: absence of or unclear formal criteria for allocation of staff (seven cases) or allocation of technical experts to their functions (two cases); unclear criteria for selection of clinical experts to be involved in reviews of clinical data (three cases) or very "light" experience criteria for specialists involved in design dossier examinations (one case).

In the area of assessment of manufacturers' clinical evaluations, the main issues identified fell into two types: (a) in five assessments the NBs could not demonstrate that (their) reviewers of manufacturers' clinical evaluations possessed sufficient expertise for this task (and this was confirmed through file examinations by the DAs and the joint assessment teams). In two of these cases the NB could avail of a pool of external clinicians but they had not been used yet; (b) in two cases, the NB did not avail of sufficient internal clinical expertise to review the work carried out by external clinicians and in another case, the NB had not established clear rules as to when to use clinicians.

Competence matrices had been developed by 21 of the NBs but in nine the matrices were incomplete as, for instance, they did not include all staff involved in conformity assessments (e.g. external experts or some of the auditors), did not distinguish between different types of tasks (e.g. auditor, product specialist or decision-maker), were not backed up by clear criteria for qualification of staff, did not cover the entire scope of designation or were not updated on the basis of a set frequency.

Training arrangements were usually in place and, in most cases, were adequate. However, in nine cases, weaknesses were identified in training arrangements. They mainly concerned: absence of regular training for some internal or external staff (two cases with, for instance, no evidence of training for more than six years), training for internal and external staff too generic or not covering applicable EU legal requirements (four cases), staff who could not attend internal training sessions were not informed about their outcome or had not received relevant training material or there was no procedure in place to deal with such absences (three cases), lack of evidence for half of the staff involved in conformity assessment tasks that

they were trained on EU legal requirements or relevant harmonised standards (one case).

Finally, in one case, the NB had no system in place to monitor that staff remained competent after their initial allocation to specific functions or categories of medical devices.

4.3.4. Process requirements

In this section the following elements are included: **certification** activities, **case file reviews**, **surveillance** activities and reports by the NB and the NB's role in **vigilance**.

- **Case files**

All of the assessments but one (which was a follow-up assessment) included a review of client files by the DAs. The number of files reviewed varied, depending on the duration of the assessments, the number of assessors and the fact that some DA teams split into subgroups. In six cases, the DAs only reviewed two files while in eight cases more than seven files were examined. Overall, an average of six files was checked per assessment, including both Class III and other classes of medical devices. Communication to the NBs of the files to be selected was mostly done during the assessment but in some cases, in order to ensure that files would be readily available, the DAs communicated them to the NB shortly before the assessment. All of the DAs had criteria for the selection of files and they usually took account of the type of devices, the conformity assessment routes, the geographic distribution of clients and vigilance or market surveillance information. In the vast majority of cases the DAs focused mainly on the client files pertaining to those certificates issued since the last surveillance assessment.

When reviewing the files, the DAs assessed compliance with the NBs' own procedures and, with two exceptions, verified some of the content of the files submitted by manufacturers. In one country, manufacturers' documents (technical files) were not reviewed as the DA had not requested in advance that such documents be prepared by the NB (which did not keep such files on its premises but returned them to manufacturers or had originally assessed them off-site). In two countries there was limited evidence that the DA had looked into the manufacturers' documents, in another case, the ability of the DA to challenge the NB's review of such documents was very limited, in particular in the area of clinical evaluation[10]. Sampling of technical files (Class IIa and Class IIb medical devices) on a representative basis was verified by 20 of the DAs.

Opportunities for improvement
While the selection of files was generally pertinent, in 10 cases the way these files were sampled and their number could be improved or did not enable the DAs to adequately cover the entire scope of designation. In five cases, the depth of the review conducted by the DA was insufficient as it did not cover, or covered very superficially, manufacturers' documents.

Best practice
Several DAs had established clear criteria for the selection of client files and in

[10] The situation has improved since this was observed, in particular through collaboration between the DA and the CA, the latter providing clinical expertise during assessments of NBs.

these cases the number of files selected was a representative sample of the work of the NBs.

Some DAs perform off-site activities in relation to file examinations. These can consist of a pre-review of files, specifically on the certification process, to ascertain that, for instance, the NB staff members allocated to the files are competent and that the NB criteria for allocation of staff have been met or, more generally, that the NB has implemented its procedures as designed. In other cases, these off-site activities can be a full review of both the certification process and technical evaluation conducted by the NB, including a review of some of the documents supplied by manufacturers, in order to assess the quality of the NB review.

- **Certification activities**

The most frequently identified nonconformities in the operation of NBs concerned the review of clinical evaluations submitted by manufacturers. In 16 assessments NBs had not noted that the clinical data and reports obtained from manufacturers were not in line with the guidance provided in following MEDDEV 2.7.1. In particular, the NB reviewers had not identified that such data did not contain all of the required supporting documentation (one case), did not provide enough substantiation of equivalence claims with devices already present on the market (four cases) or were insufficient in content (five cases), did not cover all devices for which certification was sought (two cases), were not based on up-to-date information (one case) or did not challenge the absence of a post-market clinical follow-up or did not assess it (three cases).

In another seven cases regardless of the quality of the data supplied by manufacturers, based on the documents made available by the NBs, it was noted that the quality of the reviews of the clinical evaluations that had been carried by out NBs was poor or was poorly documented and were not in line with the guidance provided in MEDDEV 2.7.1. For instance, in one case the review of clinical evaluation reports consisted of a single box that was ticked by the NB reviewer, making it impossible to understand the nature and depth of the assessment carried out. In another case, there was no procedure for conducting reviews of clinical evaluations.

The second most frequent nonconformity regarding NBs' conduct of conformity assessments pertained to the sampling of technical files on a representative basis for Class IIa and Class IIb medical devices. In two cases NBs were behind schedule in terms of technical file reviews and in nine cases, planning (one case), criteria (two cases), detailed procedures for the selection of such files were not in place (four cases), were not always adequately implemented (one case) and, finally, in one case checklists and reports from the NB were insufficiently detailed.

The third most frequent nonconformity was that some NBs had issued certificates for Class IIa or Class IIb devices on the basis of technical files which were incomplete and this had been overlooked by the said NBs. This was noted in seven assessments and concerned: incomplete stability tests (two cases), incorrect declaration of conformity (one case), inadequate risk assessment (one case), missing instructions for use (one case), incomplete biocompatibility tests (one case), lack of validation of sterilisation and no sampling of technical files (one case) and missing information on raw material specifications (one case). Additionally, in two cases technical files contained documents drafted in a language that the NB assessment team did not understand and therefore could not assess.

The fourth most frequent nonconformity related to limited traceability of the certification process which was noted in six assessments. It consisted in either

missing or incomplete documents (two countries) or limited evidence of the elements reviewed by the NBs (four countries). In one of this case, there was a total absence of reports on technical file reviews or design dossier examinations, which, together with an absence of guidance documents and checklists, seriously questioned the depth of the assessments conducted by the NB.

Opportunities for improvement

In three NBs major nonconformities were identified in relation to staff competence and the certification decisions made. The joint assessment team recommended that in such cases, given the significance of the nonconformities, the DAs should consider the impact that these could have on the scope of designation and the validity of existing certificates. Following these recommendations, in one case, the NB in question was eventually de-designated and in another case, a review of all certificates issued was requested by the DA (see section 5 of this report).

Best practice

In 13 assessments the DAs conducted a 'vertical' review of the entire certification process (from application for certification until the issue of the certificate, the subsequent surveillance audits and the close-out of the nonconformities identified during these audits). This was usually done on at least one of the files selected for review and it proved effective in getting an insight into the certification process and identifying nonconformities.

4.3.4.1. Surveillance activities and reports by the NB

Contents of the NBs' audit reports were checked by the DAs in all 25 assessments but the overall implementation of NBs' surveillance activities, in particular with a view to assessing if they were conducted on a regular basis as per the NBs' procedures, was only assessed in 12 cases. Conduct of unannounced audits of manufacturers by NBs or testing was discussed in all of the assessments and DAs had reminded NBs of this action which is one of those foreseen in the joint action plan. In two cases the DAs had not envisaged to strictly enforce this action before a Recommendation was issued by the Commission and in one case, no deadlines had been imposed by the DA to carry out such audits.

All of the NBs had foreseen to conduct annual audits of manufacturers and, when checked by DAs, the frequency of audits was found to be complied with, except in one case. The content of the reports of these audits was usually found to be in line with the recommendations provided in MEDDEV 2.10-2 (in terms of content and presence of a discernible audit trail) except in three cases where the report lacked references to the documents checked by the NB or were not sufficiently detailed to permit the DA to verify the extent of the assessment. Concerning the depth audits were conducted, in two cases, on the basis of the audit reports examined, it was identified that one NB overlooked nonconformities with EU legislation and another one very rarely identified any nonconformities, including during its initial certification audits. In the latter case, this seriously questioned the quality and depth of the assessments conducted by the said NB.

Unannounced audits had been performed by 6 NBs and in 16 cases the provisions for conducting such audits had been included in contracts with manufacturers or in the NBs' general terms and conditions or in certificates. In three cases the joint assessment team noted that general terms and conditions or contracts did not allow

the conduct of unannounced audits as there was an obligation on the NBs to inform the clients prior to any audits. This had been overlooked by the DAs (see previous paragraph).

Opportunities for improvement

Three DAs overlooked that general terms and conditions or contracts prevented NBs from conducting unannounced audits of manufacturers. This is a possibility foreseen by the MDD and should be included in the contractual arrangements with manufacturers.

4.3.4.2. Vigilance activities by the NB

The review and processing of vigilance information by NBs was checked in 17 of the 25 assessments. In most cases, the DAs reviewed all of the relevant elements, including (as requested by the joint action plan) that contractual arrangements between NBs and manufacturers included the obligation for the manufacturers to provide NBs with vigilance information.

Best practice

In 6 cases the DAs had selected vigilance reports they had received to check whether or not the NBs were aware of such reports. In one case, this helped the DA in identifying that the NB had not been informed by a manufacturer, contrary to what was required by the contractual arrangements. In another case, this enabled the DA to identify that the NB had no system in place to detect that several incidents reported by different sources could concern the same device.

Opportunities for improvement

In one case, the DA did not receive information from the competent authority or from any other sources about market surveillance or specific compliance issues. This did not enable the DA to follow-up on such cases and see whether or not they had been correctly dealt with by the NB.

All but three NBs had devised procedures for dealing with vigilance information received from manufacturers. In all cases but three the NBs had included the communication of vigilance information in their contracts, general terms and conditions or applications. The most commonly identified nonconformities concerned the NBs' procedures for dealing with vigilance, both as regards their design and their implementation. In four cases, the design of these procedures could be improved: in two NBs they were found not to be specific enough as regards actions to be taken and in another two cases they did not consider the potential impact on certificates, in particular because the NB had no system in place to detect that several incidents reported by different sources could concern the same device. In two cases, the implementation of the NB procedure was deficient: in one case there were delays and inconsistencies in the processing of incidents by the NB and in another case, it was noted that during audits, the NB did not verify the assessment of claims by manufacturers and whether or not these had been correctly categorised as incidents.

5. ACTIONS TAKEN BY THE DAS IN RESPONSE TO THE OPPORTUNITIES FOR IMPROVEMENTS.

The joint assessment teams identified a total number of 132 opportunities for improvement for DAs. Although there was no obligation for them to do so, most DAs (except five) submitted action plans addressing the opportunities for improvement. For one country, the action plan was still outstanding at the time of preparation of this overview report. The DAs agreed with 119 of these opportunities for improvement and expressed some reservations or disagreement for 10 of them.

In seven cases, the seriousness of the DAs' findings required urgent corrective actions to be implemented by the NBs. These included requesting the NBs: (a) not to accept new clients until the systemic problems identified were resolved, (b) to review internally, under the DA supervision, all certificates issued; (c) to review internally, by an additional duly qualified staff member, 50% of the certification decisions, (d) to stop issuing certificates and to review all procedures and client files to identify potential nonconformities (this NB was eventually de-designated), (e) to close-out all outstanding nonconformities carried over from previous assessments or to face legal sanctions and, finally, (f) in one case, the DA confirmed the restriction on the NB preventing it issuing new certificates (a restriction which had been put in place in a surveillance assessment which took place prior to the joint assessment).

It was not foreseen that the FVO would follow-up on the actions taken by DAs. Nevertheless, in several cases, given the seriousness of the findings of the joint assessment team, the Commission services undertook to verify that effective and appropriate actions would be taken by the DAs towards the NBs in question and this included the conduct of follow-up joint assessments as well as the participation in further surveillance assessments.

6. OVERALL CONCLUSIONS ON DA AND NB PERFORMANCE OBSERVED DURING THE SURVEILLANCE ASSESSMENTS

On the basis of the experience gained during these 25 joint assessments, the Commission, and the national expert assessors involved (33 assessors from 20 countries), consider that the process has been beneficial – not just for each of the national DAs as a support to their assessments, but also to the national expert assessors from other DAs who, through this process, have been able to exchange views and opinions with their peers.

In the missions carried there were no substantial areas of disagreement between the joint assessment teams and the DAs. Overall, it is considered that each of the assessments has provided an accurate picture of the performance of NBs regardless of whether opportunities for improvement in the DAs' performance were identified (except in two cases where the assessments were too superficial or too short). Such opportunities concerned elements such as the planning, scope and depth of surveillance activities. In two cases however, the standard of the DA's assessment and over-reliance on accreditation required follow-up activities to be initiated by the Commission services. In one of these cases, effective corrective actions were eventually taken, leading to a significant improvement in the situation. In the other case, the required follow-up activities are still to be implemented.

It was also the case that a number of good practices in DA performance were identified during the joint assessments and, if these were to be adopted by DAs, they could enhance the effectiveness of surveillance assessments and strengthen confidence in the current regulatory system.

With regard to the performance of the NBs assessed, there was, in most cases, a satisfactory level of compliance with legal requirements and best practices. Nevertheless, the joint assessment process has identified weaknesses which were common to a number of NBs in the areas of organisational requirements and quality management systems. More importantly, a number of NBs could not provide sufficient evidence that some of the staff employed for conformity assessment activities were appropriately qualified and experienced for the task. Other recurring issues concerned the thoroughness of the NBs' review of manufacturers' clinical evaluations, the sampling of technical files for Class IIa and Class IIb devices, the depth to which these files were assessed and, more marginally, the overall documentation and traceability of the certification process.

In all cases, the NBs in question were requested to put in place necessary measures to rectify the shortcomings identified. In several cases, the seriousness of the findings led to the DAs requiring urgent corrective actions from the NBs with restrictions and sanctions being imposed (including de-designation) and further surveillance assessments being conducted by the national DA, sometimes with the assistance of a Commission-led joint assessment team.

Overall, the joint assessment process has proven itself to be a useful instrument to gain a global view on the performance of both Designating Authorities and Notified Bodies in the medical devices sector. It has also helped to raise performance standards across the sector, and the experience gained has facilitated the implementation of the mandatory joint assessments pursuant to Commission Implementing Regulation (EU) No 920/2013 which became applicable in October 2013.

ANNEX 1 : LEGAL REFERENCES:

Medical Devices Directives
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. Official Journal, L 189, 20/07/1990 pp. 17 - 36
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Official Journal, L 169, 12/07/1993 pp. 1 - 43
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Official Journal, L 331, 07/12/1998 pp. 1 – 37
Other relevant legislation
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. Official Journal L 253, 25/09/2013 pp. 8 – 19
Commission Recommendation 2013/473/EU of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices. Official Journal L 253, 25/09/2013 pp. 27 - 35

ANNEX 2 : SPECIFIC LEGAL BASIS AND/OR GUIDANCE DOCUMENTS RELEVANT TO DESIGNATION CRITERIA FOR NOTIFIED BODIES UNDER THE VOLUNTARY PHASE BEFORE THE ENTRY INTO FORCE OF COMMISSION IMPLEMENTING REGULATION (EU) NO 920/2013.

General requirements for designation
Legal Basis (as per EU Directives):
Articles 11 (2) of the AIMDD, 16 (2) of the MDD and 15 (2) of IVDD specify that Member States shall apply the criteria set out, respectively, in Annexes 8, XI and IX to the said Directives for the designation of NBs.
Guidance and interpretation documents:
Point 1 of Chapter II of MEDDEV 2.10-2 Rev.1 and section 3 of the NBOG DA Handbook provide guidance on 'general requirements' concerning NBs. These include some elements such as resources, legal status and organisational structures which are not specifically mentioned in the Directives. Other elements such as competence, independence, impartiality and subcontracting are specifically mentioned in the Directives in the relevant annexes of the AIMDD, MDD and IVDD.

Specific requirements for designation
Independence
Legal Basis (as per EU Directives):
Point 1 of Annex 8 to the AIMDD, Annex XI to the MDD and Annex IX to the IVDD respectively, specifies that the NB and its staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorised representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities.
Guidance and interpretation documents:
Point 2 of Chapter II of MEDDEV 2.10-2 Rev.1 and section 3 of the NBOG DA Handbook provide guidance on the implementation of the above requirements. Independence is also dealt with in section 7.3 of ISO 17021:2011.

Integrity and impartiality
Legal Basis (as per EU Directives):
Point 2 of Annex 8 to the AIMDD, Annex XI to the MDD and Annex IX to the IVDD respectively, specifies that the NB and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications.
Point 5 of Annex 8 to the AIMDD, Annex XI to the MDD and Annex IX to the IVDD respectively, specifies that the impartiality of the NB must be guaranteed and that remuneration of the NB must neither depend on the number of inspections carried out, nor on the results.
Guidance and interpretation documents:
Point 3 of Chapter II of MEDDEV 2.10-2 Rev.1 provides guidance on impartiality and, additionally, section 3 of the NBOG DA Handbook provides guidance on both integrity and impartiality.
In the note to section 4.7 of ISO 17021:2011 the demonstration of integrity and credibility to all users of certification is recommended to rely on the certification body having an appropriate balance between the principles of openness and confidentiality, including responsiveness to complaints.

Subcontracting
Legal Basis (as per EU Directives):
Point 2 of Annex 8 to the AIMDD, Annex XI to the MDD and Annex IX to the IVDD respectively, specifies that should the NB wish to subcontract specific tasks, it must first ensure that the subcontractor meets the provisions of the (relevant) Directive and, in particular, of this Annex. Furthermore the NB shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor under the aforementioned Directives.
Guidance and interpretation documents:
Point 8 of Chapter II of MEDDEV 2.10-2 Rev.1 and section 3 of the NBOG DA Handbook provide guidance on this criterion. Section 7.5.1. of ISO 17021:2011 lays down the conditions to be observed for subcontracting (outsourcing) and the Standard also draws a distinction between individual external experts

contracted to carry out specific tasks (section 7.3) and organisations contracted to do so (section 7.5.1). There is no such distinction in the Directives.

Liability

Legal Basis (as per EU Directives):

Point 6 of Annex 8 to the AIMDD, Annex XI to the MDD and Annex IX to the IVDD respectively, specifies that the NB must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.

Guidance and interpretation documents:

Point 7 of Chapter II of MEDDEV 2.10-2 Rev.1 and section 3 of the NBOG DA Handbook provide guidance on the implementation of the above requirements.

Confidentiality

Legal Basis (as per EU Directives):

Point 7 of Annex 8 to the AIMDD, Annex XI to the MDD and Annex IX to the IVDD respectively, specifies that the staff of the NB are bound to observe professional secrecy with regard to all information gained in the course of their duties (with the exception of their dealings with competent authorities of the State in which their activities are carried out).

Guidance and interpretation documents:

Point 6 of Chapter II of MEDDEV 2.10-2 Rev.1 and section 3 of the NBOG DA Handbook provide guidance on this criterion.

Aspects pertaining to confidentiality are laid down in section 8.5. of ISO 17021:2011. Sections 7.3 and 7.5.1 of this standard contains guidance on confidentiality as they apply to individual external experts and organisations subcontracted to carry out specific tasks by the conformity assessment body (NB).

Facilities, equipment and staff (experience, technical competence and training) used for conformity assessment activities

Legal Basis (as per EU Directives):

Point 3 of Annex 8 to the AIMDD, Annex XI to the MDD and Annex IX to the IVDD respectively, specifies that the NB must be able to carry out all the tasks assigned to such bodies by the relevant Annexes of the aforementioned Directives and for which it has been notified, whether these tasks are carried out by the NB itself or on its behalf. The NB must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. It must have access to the equipment necessary for the verifications required. In both the MDD and IVDD explicit mention is made of the fact that the above requirement presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the (biological – IVDD) and medical (IVDD and MDD) functionality and performance of devices for which it has been notified, having regard to the requirements of the relevant Directives and, in particular, those set out in Annex I to both Directives.

To that end Point 4 of Annex 8 to the AIMDD, Annex XI to the MDD and Annex IX to the IVDD respectively, requires NBs to have (a) sound vocational training covering all of the assessment and verification operations for which it has been designated, (b) satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections and (c) the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

Guidance and interpretation documents:

Appendix A, point A2 (3) of MEDDEV 2.10-2 Rev.1 and section 3 of the NBOG DA Handbook provide guidance on facilities and equipment.

Point 4 of Chapter II of MEDDEV 2.10-2 Rev.1 and sections 2.7 to 2.11 and 4.6 to 4.9 of the NBOG DA Handbook provide guidance on the (technical) competence, knowledge, experience and training of staff.

The review of technical documentation (technical files) is described under several 'Quality System' headings in Appendix A to the MEDDEV 2.10-2 Rev.1. (This guidance note does not cover IVDD devices). It is also described on pages 51, 54 of the NBOG DA Handbook.

Guidance for examination of design dossiers by NBs can be found in Appendix A to the MEDDEV 2.10-2 Rev.1.

Guidance on surveillance activities for NBs is described in Appendix A to the MEDDEV 2.10-2 Rev.1. The frequency of NB audits of manufacturers' QMS, and NB technical file reviews is not laid down in EU legislation.

Role of the NB in the vigilance system

Legal Basis (as per EU Directives):

None

Guidance and interpretation documents:

Section 7 of MEDDEV 2.12-1 rev 8 provides guidance on the role that NBs should play in the vigilance system. NBOG best practice guide 2009-2 adds additional details to this. It is also worth mentioning that

two actions envisaged in the joint plan concern communicating vigilance reports to NBs and granting them access to vigilance reports contained in the European Databank on Medical Devices (EUDAMED).