applicable for ☒ MDR, and ☒ IVDR

2017-1

Designation and notification of conformity assessment bodies [1]

1 Introduction and scope

This document aims to provide guidance to the authorities responsible for notified bodies (hereafter, the designating authorities) and joint assessment teams (JATs) when conducting designation assessments of conformity assessments bodies (CABs) that apply for designation as a notified body in the field of medical devices and/or *in vitro* diagnostic medical devices.

Furthermore, this guide is intended to bring consistency and to align the working practices of the different designating authorities in the Member States [2], regarding the assessment, designation and notification [3] of CABs. These processes are established by Articles 38 to 42 of Regulation (EU) No 2017/745 [4] (hereafter, the medical devices Regulation – MDR) and Articles 34 to 38 of Regulation (EU) No 2017/746 [5] (hereafter, the *in vitro* diagnostic medical devices Regulation – IVDR).

In terms of scope, this guide focuses on the first designation of CABs under the MDR and/or the IVDR. Once sufficient experience from this process has been gathered, it may be updated accordingly.

2 Pre-assessment and off-site activities

2.1 CAB's application

When applying for designation, CABs need to use the application form(s) required by the designating authorities and submit the corresponding supporting documentation:

- form NBOG F 2017-1 for designation under the MDR, and/or
- form NBOG F 2017-2 for designation under the IVDR.

The content of the application will include a specification of the conformity assessment activities and types of devices to be covered by the designation, using the codes set out in Implementing Regulation (EU) 2017/XX [6] and specified in the corresponding NBOG form (NBOG F 2017-3 or NBOG F 2017-4).

---

1 The applicability of Best Practice Guides (BPGs) covering requirements set out in the new medical devices Regulations are contingent upon endorsement by the Medical Device Coordination Group (MDCG). In particular where its involvement is referred to in such BPGs, it must be emphasised that the MDCG should ultimately agree on the relevant steps and deadlines.

2 References made to 'Member States' in this guide, should be understood as referring to Member States, EEA and EFTA countries and other countries where a relevant agreement covering mutual recognition of designation of notified bodies exists.

3 At present, this document does not elaborate on the different steps covering notification of CABs. Once this part is developed, the BPG will be updated accordingly.

4 Regulation (EU) 2017/745 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, 5.5.2017, p. 1).

5 Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

6 Commission Implementing Regulation (EU) 2017/XX of 24 November 2017 (expected) on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in

CABs applying for designation should be aware of the time needed for the assessment of the application, execution of the on-site assessment and subsequent verification activities, designation and notification. On the basis of the experience gathered during the current joint assessment process, it is expected that CABs designated under the medical devices Directives [7] should apply for designation at least 18 months prior to the repeal of these Directives, as applicable [8], in order to ensure continuation of their activities under the new legal framework.

The flowchart in the annex to this guide illustrates the process and the estimated length of time for each of its steps.

2.2 Designating authority's check of CAB's application for completeness

An initial check is to be carried out by the designating authority to verify the completeness of the CAB's application. The designating authority should indicate in the same application form(s) used by the CAB (see section 2.1) if all documents have been submitted as required (by ticking the relevant boxes). If one or more documents have not been submitted but the application is considered to be complete by the designating authority, it should provide a brief explanation as to why. For this purpose, the designating authority should fill in the box provided in the last page of the relevant form(s).

The completeness check will be carried out within 30 days after receipt of the application [9]. In the event that information is missing, the designating authority will request this information to the CAB within these 30 days. It is recommended that designating authorities set a deadline for the submission of the missing information.

According to its own procedures, if after a number of rounds of correspondence with the CAB the requested information is not forthcoming or it is still incomplete, the designating authority may decide to reject the application and inform the CAB of the need to re-apply for designation.

2.3 Transmission of the application to the Commission

Once the completeness check has been finalised and the application has been considered complete, it will be sent by the designating authority to the European Commission's Directorate-General for Health and Food Safety, Directorate F (hereafter, SANTE/F) by email (sent to the functional mailbox SANTE-F-MEDICAL-DEVICES@ec.europa.eu [10]). In case the application is rejected, the designating authority should also inform SANTE/F.

All of the documents contained in the application need to be sent to SANTE/F in electronic format. This transmission will normally be carried out by email or via a file-transfer platform. If the CAB has used an encryption method to submit the documents to the designating authority (e.g. an encrypted CD, DVD or memory stick), the CAB could request that the designating authority uses the same form of transmission for security

the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council

7 Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices, and Directive 98/79/EC on *in vitro* diagnostic medical devices.

8 CABs should apply for designation under the MDR no later than 26 November 2018 and under the IVDR no later than 26 November 2020.

9 Articles 39 (1) of the MDR and 35 (1) of the IVDR.

10 All the email exchanges with SANTE/F referred to in this guide are to be made to and from the functional mailbox SANTE-F-MEDICAL-DEVICES@ec.europa.eu.

reasons. In these cases, the designating authority will physically send the data via registered post to SANTE/F [11].

The language in which the application is made available will usually be that of the Member State. Nevertheless, it is usually the case that CABs with international clients or international personnel will already have many procedures and related documents in English. Therefore, in order to facilitate the assessment of the application by the JAT, the CAB should also include in the application copies of any documents that are already available in this language, in particular the quality manual, procedures related to qualification of personnel and procedures related to the process of conformity assessments. If these documents are not available in English, the CAB may provide copies of them translated into English in order to facilitate the organisation of the joint assessment.

Once the application is received, SANTE/F will acknowledge its receipt via email to the designating authority, informing the European Commission's Directorate-General Internal Market, Industry, Entrepreneurship and SMEs, Directorate D (hereafter referred to as GROW/D).

2.4 Review of the application by the designating authority

The designating authority will review the application(s) and supporting documentation according to its own procedures. There is no time limit established in the MDR and/or IVDR for this review, although the estimate is that this detailed assessment could take between 3 and 8 weeks upon finalisation of the completeness check.

The assessment will take into consideration the requirements under Annex VII to the MDR and/or IVDR and also any other applicable requirements of these Regulation(s). The guide NBOG BPG 2017-XX establishes the aspects to be reviewed in this step of the process in order to ensure consistency and adequacy of the review. The outcome of this exercise is to be documented, preferably in English, in the preliminary assessment report (form NBOG F 2017-5 or NBOG F 2017-6).

It must be emphasised that the receipt of this preliminary assessment report by the Commission will trigger the appointment of a JAT, and the subsequent scheduling of the corresponding on-site assessment (see section 2.6). Therefore, it is of the utmost importance that the designating authority makes sure that the outcome of the review is sufficiently satisfactory as to substantiate the conduct of an on-site assessment [12].

Where clarification is needed, the designating authority will request further information to be provided by the CAB within a predefined deadline.

According to its own procedures, if after a number of rounds of correspondence with the CAB the requested information is not forthcoming or is still unsatisfactory, the designating authority may reject the application and inform the CAB of the need to re-apply for designation. In such cases, the designating authority should inform SANTE/F by email.

2.5 Transmission of the preliminary assessment report

The designating authority needs to submit via email the preliminary assessment report to SANTE/F which will immediately transmit it to the Medical Devices Coordination Group

[11] Post needs to be sent to the following address:
European Commission,
Directorate-General for Health and Food Safety,
Directorate F: Health and food audits and analysis
Grange, Dunsany C15 DA39, Co Meath. Ireland

[12] For instance, the competence matrix of the CAB should show that it has the necessary qualified personnel to cover the scope of designation applied for, before the on-site assessment can be scheduled.

(MDCG) by means of uploading it into the MDCG CIRCABC [13] dedicated workspace [14]. SANTE/F will acknowledge receipt of the preliminary assessment report via email to the designating authority, informing GROW/D. In case the preliminary assessment report has not been submitted in English, SANTE/F will arrange for a machine translation [15] (or, time permitting, an official translation), which will be also transmitted to the MDCG.

Given that the receipt of the preliminary assessment report will result in the appointment of a JAT and the subsequent scheduling of the corresponding on-site joint assessment, the designating authority needs to inform SANTE/F about preferred dates for the on-site assessment and dates on which the on-site assessment cannot take place [16] (see section 2.6 regarding the scheduling of the on-site assessments).

2.6 Appointment of the JAT and scheduling of the on-site assessment

Whilst there is no time limit in the Regulations for scheduling the on-site assessment, following receipt of the preliminary assessment report, SANTE/F will liaise with the designating authority in order to seek preliminary agreement on a proposal of tentative dates for the on-site assessment.

The main criterion determining the order of the on-site joint assessments will be the precise time of receipt (day and hour) of the preliminary assessment report in the functional mailbox SANTE-F-MEDICAL-DEVICES@ec.europa.eu. Other criteria to be considered will be the availability of the CAB, the designating authority and/or suitable experts to be appointed as JAT members, as well as the content of the preliminary assessment report.

It is essential that the on-site assessment lasts long enough so that both the designating authority and the JAT can effectively assess whether the CAB fulfils the requirements throughout its applied-for scope of designation, and sufficient time is allowed for internal discussion of findings. Therefore, although this will depend on the size of the CAB and the applied-for scope of designation, on-site assessments will normally require 40 hours or, in the case where no interpretation is needed, 32 hours. The number of hours referenced should be understood as actual assessment time. In case there is a need to schedule further time to complete the on-site assessment (e.g. if observed audits or subsidiaries are included in the designation process), this should be communicated by the designating authority to SANTE/F in advance.

Within 10 days following receipt of the preliminary assessment report, SANTE/F will communicate a proposal for the composition of the JAT to the MDCG. SANTE/F will propose national experts who are best suited (on the basis of their field of competence and expertise in relation to the CAB's applied-for scope of designation and language capabilities) and are available to participate effectively in the on-site assessment. The JAT will generally include one expert from SANTE/F, who will act as JAT coordinator, and two national experts (from Member States other than the one of the applicant CAB) [17]. In specific circumstances, and on a case-by-case basis, a different number of experts could be proposed, for instance for training or calibration purposes or for a special need in the designation process.

---

13 Communication and Information Resource Centre for Administrations, Businesses and Citizens.

14 All the exchanges with the MDCG referred to in this guide are to be made by email sent from the MCDG CIRCABC workspace, to which MDGC members as well as SANTE/F and GROW/D staff members will have access.

15 SANTE/F will arrange for machine translations using the Commission's machine translation software.

16 These dates could relate to prior commitments of the designating authority or could have been communicated previously by the CAB to the designating authority.

17 Articles 39(3) of the MDR and 35(1) of the IVDR. National experts will be selected from the pool made available according to Articles 40 of the MDR or 36 of the IVDR

SANTE/F will highlight, in its communications with the MDCG, those issues that could prevent the scheduling of the on-site assessment in accordance with the above-mentioned prioritisation criteria. Notably, these issues could concern an insufficient content of the preliminary assessment report, or a preliminary assessment report showing that the CAB's documentation is unsatisfactory.

Within 3 days after the communication of the proposed JAT composition, the MDCG will notify to SANTE/F of any need for clarification and/or objection to the composition of the JAT. In such cases, before the 14-days [18] period has elapsed, SANTE/F will communicate to the MDCG an amended proposal for a JAT and/or explanations, as appropriate. In the absence of objections, the appointment of the JAT will be considered confirmed.

When a CAB wishes to be designated under both the MDR and the IVDR Regulations, given that it is not possible to combine both joint assessments in a week (as different expertise of the JAT members will be required for each assessment), SANTE/F will schedule the assessments under each of the Regulations based on the availability of national experts. When the subsequent on-site assessment is scheduled, approximately within the following 12 months, it should be possible to reduce its duration, provided that the documentation submitted for the applications under both Regulations is essentially the same (i.e. as regards the organisational and general requirements, quality management system documentation, and general procedures related to resources and conformity assessment process).

Any circumstance that could have an impact on the conduct of the on-site assessment (e.g. modification on the number of days due to unexpected situations like flight delays or cancellations) or changes to the JAT composition (e.g. last minute cancellation by one of the experts due to sickness), will be communicated immediately to the designating authority concerned and the MDCG, alongside the corresponding risk mitigation measures taken or proposed by SANTE/F. Should a national expert who had been appointed as member of a JAT be no longer in a position to undertake his/her duties (for instance if this national expert has taken long term leave or has left the organisation), the designating authority which has nominated that expert should submit to SANTE/F the name of another national expert who could take over this JAT member's role and, ideally, tasks. Subsequently, and taking account of this nomination and the availability of other suitable experts, SANTE/F will notify an (amended) composition of the JAT team to the MDCG.

2.7 Announcement of the on-site assessment

After the JAT has been appointed and the dates of the on-site assessment have been agreed by the parties involved, SANTE/F will formally announce the on-site assessment to the designating authority, including its dates and the composition of the JAT. This formal letter will, ideally, be sent out at least 3 months prior to the on-site assessment and will include a specimen assessment plan for the on-site assessment. In parallel, SANTE/F will send formal invitation letters to the national experts participating in the JAT.

If the language in which the on-site assessment is to be conducted is not English or the relevant documentation to be reviewed is not available in English, SANTE/F will arrange for interpretation to be provided at the Commission's expense (up to four interpreters may be required for each on-site assessment). This information will be communicated to the designating authority.

[18] As referred to in Articles 39(3) of the MDR and 35(3) of the IVDR.

2.8 Dissemination of information to JAT members

SANTE/F will upload the information referred to in sections 2.3 and 2.5 into the SANTE F CIRCABC dedicated workspace in order to disseminate it among the JAT members, who will be granted access to this workspace via their CIRCABC profiles.

In the event that part of the application and supporting documentation is not submitted in English or in a language readily understandable by the JAT, SANTE/F will arrange for machine translation of the appropriate documents, which will be also uploaded into the SANTE F CIRCABC workspace. To this end, if the application and supporting documentation had been originally submitted in a format not suitable for machine translation [19], SANTE/F could request that the designating authority re-submits certain documentation in a suitable format.

2.9 Assessment of the application by the JAT

The JAT will review the CAB's application and supporting documents and will document this review using the preliminary assessment report template (NBOG F 2017-5 or NBOG F 2017-6). Within 90 days of the appointment of the JAT, the JAT coordinator will provide feedback of such a review to the designating authority concerned by email. During this period, the JAT could require clarifications on the application and supporting documents from the designating authority, if needed.

The JAT coordinator will be responsible for ensuring that the assessment of the application is conducted on time and that the national experts are actively involved in and contribute to this process. Therefore, specific parts of the assessment will be assigned to the national experts, taking into account their field of expertise.

2.10 Coordination between the designating authority and the JAT

The JAT coordinator will be responsible for establishing and maintaining contact with the designating authority. Once the off-site assessment by the JAT has been completed and, ideally, 5 weeks prior to the on-site assessment, the JAT coordinator will organise a teleconference (or any alternative arrangement, for example email exchanges) between the designating authority team and all of the JAT members, for the purpose of:

- discussing the results of the off-site assessments of the application carried out both by the designating authority and the JAT,
- addressing open questions on the application,
- taking decisions on the role of each member of the overall assessment team (i.e. the designating authority team and the JAT) during the on-site assessment, and
- seeking agreement on the designating authority's proposed assessment plan.

Following the above-discussion, the designating authority will draft the final assessment plan and forward it to the CAB and the JAT coordinator.

Every effort should be made by the CAB to ensure that there are no changes in the application supporting documents once the designating authority has finalised its preliminary assessment. However, if changes are made to the supporting documents, the CAB needs to send the amended versions to the designating authority highlighting any difference with the documentation submitted in the initial application. The designating authority will inform the JAT about these changes during the above-mentioned teleconference and an agreement should be reached about which are the amended documents that should be sent to the JAT coordinator prior to the on-site assessment.

[19] For example, scanned pdf documents or protected pdf documents are unsuitable for machine translation.

3 On-site-assessment activities

3.1 Scope and organisation of the on-site assessment

The on-site assessment will be led by the designating authority team. The JAT will be included in the overall assessment team and will actively participate in the assessment, asking for any clarification or further documentation to be provided by the CAB at any time.

The on-site assessment will cover all of the designation requirements laid down in Annex VII to the MDR or the IVDR and also any other applicable requirements of these Regulations.

The on-site assessment will follow the agreed assessment plan. The pre-defined starting and finishing times indicated in this assessment plan should be respected in all cases, unless duly justified. In order to avoid lengthy sessions in the CAB's premises, where possible, evening coordination meetings between the designating authority team and the JAT should take place in another location.

3.2 Opening meeting

Prior to the opening meeting of the on-site assessment, the designating authority team and the JAT will hold a coordination meeting, aimed at clarifying any outstanding issues, confirming the role of each member of the overall assessment team, and sorting out practicalities for the conduct of the on-site assessment.

The opening meeting of the on-site assessment will be led by the designating authority team. An outline of the following aspects will be covered:

- legal basis for the assessment,
- introduction of the members of the designating authority team and the JAT,
- brief description of the designation process, and
- confidentiality rules.

After the above aspects have been covered, the CAB will be given the floor to make a brief presentation of its organisation, and to introduce the personnel who will participate in the on-site assessment. The CAB could also seek clarifications on any of the above-mentioned aspects. The JAT could take the floor at any time of the opening meeting to provide clarifications or further information about the above-mentioned issues.

3.3 Conduct of the on-site joint assessment

The designating authority team and the JAT will split into two (or more) sub-teams in order to cover the assessment of the four main subject areas detailed in Annex VII to the Regulations, namely organisational and general requirements, quality management requirements, resource requirements and process requirements. Usually, one sub-team will focus on the said four main subject areas, whereas other sub-team(s) will focus on the assessment of personnel files (and mock-up files, if applicable) provided by the CAB.

Where possible, the JAT member(s) within the sub-team(s) focussing on the assessment of personnel (and mock-up files, if applicable) will be allowed to work individually to ensure an efficient use of time. This approach will be allowed on condition that the designating authority is informed of progress on a daily basis, that the outcome of these assessments is documented, and that the CAB has sufficient personnel to clarify the questions from each member of the overall assessment team.

Constant communication between the designating authority team and the JAT needs to be ensured throughout the on-site assessment, with time allocated for coordination meetings

at the beginning of, during and/or at the end of each day's activities, in order to discuss the findings. The designating authority team may also decide to debrief the CAB at regular intervals during the assessment (usually at the end of each day).

The conduct of the on-site assessment could reveal the existence of different interpretations of the legal requirements by the designating authority team and the JAT. In such cases, the discussion on these discrepancies will not be held in the presence of the CAB personnel. Instead, the matter will be put on hold and discussed in a coordination meeting between the designating authority team and the JAT, with a view to reach consensus. If consensus cannot be reached, the discrepancies will be documented as diverging opinions [20] (see section 4.1).

3.4 List of non-compliances

In case any shortcomings are found in the CAB's documentation or performance, these will be raised as non-compliances against legal requirements (for example, an article or a clause of the MDR or the IVDR). Findings pertaining to specific documents or individual files would be recorded as examples or supporting evidence for the non-compliances identified. Non-compliances should be classified as major or minor, depending of their importance and influence on the results of conformity assessments or the safety and performance of medical devices. When there is no legal requirement breached, findings should be classified as observations.

On a daily basis, the JAT coordinator will collate the non-compliances gathered by all of the JAT members, and provide them in writing to the designating authority team, with a view to discuss these non-compliances during coordination meetings. The designating authority team may take this list as a basis for its final list of non-compliances or may draft its list according to the designating authority's own procedures.

Before the closing meeting with the CAB, the JAT coordinator will provide the designating authority team with a written *preliminary JAT assessment* (consisting of the JAT preliminary list non-compliances and preliminary diverging opinions). The designating authority team will also provide its written list on non-compliances to the JAT. Subsequently, there will be a coordination meeting between the designating authority team and the JAT, with a view to reaching consensus on the list of non-compliances and resolving any diverging opinions.

Following this coordination meeting, the lists of non-compliances may be amended if necessary. Ideally, the designating authority and the JAT lists of non-compliances should have identical content. Therefore, it is recommended that grading of findings is clearly agreed on-site by the designating authority and the JAT. Any outstanding diverging views with respect to the outcome of the assessment (e.g. on individual non-compliances, legal interpretations and/or the overall outcome of the assessment) will be documented in the *JAT assessment* as diverging opinions (see section 4.1).

3.5 Closing meeting

The closing meeting will be led by the designating authority who will have the responsibility to provide the CAB and the JAT with its list of non-compliances resulting from the assessment. In addition, the designating authority team will summarise the *JAT assessment.* However, should the designating authority team agree, the JAT coordinator will summarise the *JAT assessment* and/or comment on the outcome of the assessment

[20] Different view between the designating authority and the JAT which might include but not be limited to i) additional non-compliances, including non-compliances that are listed by the designating authority as observations, ii) different wording only in case that it could influence the relevance or the grading of the non-compliances, and/or iii) actual and potential diverging interpretations of the legislation that should be further explored.

(see section 4.1). In particular, remaining diverging opinions should be brought to the attention of the CAB by the designating authority or, should the designating authority agree, by the JAT.

Any changes introduced by the designating authority to its list of non-compliances should be sent in writing within 5 working days after the on-site assessment to the JAT coordinator and, if needed, discussed with the JAT prior to its submission to the CAB.

3.6 CAPA plan: deadline for submission and content

At the end of the onsite assessment, the designating authority will require the CAB to provide a CAPA plan within a specific deadline. In order to set this deadline, the designating authority should take into account the seriousness and complexity of the non-compliances identified, (e.g. root cause analyses of system related non-compliances could identify a number of causes that would require a wide range of actions to be implemented in different areas).

Ideally, the CAB will provide the designating authority with a complete CAPA plan within 20 working days after the on-site assessment.

The designating authority needs to inform the CAB about the minimum information that needs to be included in the CAPA plan in relation to each non-compliance identified in the final list of non-compliances, namely as follows:

- The root cause(s) of non-compliances, taking into account that often more than one cause will be the root of the deficiency.
- Corrections and CAPAs for each of the root causes identified. The deadline for its implementation should be specified.
- The actions planned to verify the effectiveness of each CAPA and the timeframe for its review (e.g. internal audit, witness audits to monitor competence, etc.).

3.7 Problems in completing the on-site assessment

In exceptional cases, it may not be possible to assess the CAB's compliance against all of the designation criteria in the time allocated to the on-site assessment. In such cases, the designating authority and the JAT will discuss the options available to ensure that all of the designation criteria are assessed with sufficient depth. Such options could include continuing the on-site assessment at a mutually agreeable future date.

If the designating authority disagrees with the JAT and considers that the assessment has covered all of the requisite areas in sufficient depth and thus does not agree to extend the duration of the assessment, this disagreement will be recorded in the *JAT assessment* (see section 4.1).

4 Post-assessment activities

4.1 JAT remaining diverging opinions

The JAT coordinator, in agreement with the rest of the JAT team, will issue the *JAT remaining diverging opinions* resulting from the on-site assessment and formally submit it to the designating authority within 30 days of completion of the on-site assessment.

The *JAT remaining diverging opinions* will be produced taking into account the *JAT assessment* and the designating authority's list of non-compliances received at the closing meeting (see section 3.5). In addition, the *JAT remaining diverging opinions* should document any disagreement of the JAT in relation to the presentation of the list of non-compliances and/or the summary of the *JAT assessment* made by the designating authority team at the closing meeting.

Within 25 working days of receipt of the *JAT remaining diverging opinions*, the designating authority may comment thereon, in particular it could provide clarifications and/or confirm its views.

If necessary, the JAT coordinator will update the remaining diverging opinions taking into account the above-mentioned comments. The *JAT updated remaining diverging opinions* will be submitted to the designating authority within 15 working days following receipt of the comments or lack thereof.

4.2 Assessment of the CAPA plan by the designating authority

Upon receipt of the CAPA plan from the CAB (see section 3.6), the designating authority will confirm it by means of assessing whether each non-compliance [21] identified during the assessment has been appropriately addressed. In order to carry out this task, the designating authority should verify that:

- all non-compliances raised in the on-site assessment are included in the CAPA plan,
- the root cause(s) of all non-compliances has/have been appropriately assessed,
- corrections have been identified and implemented, where appropriate,
- CAPAs have been identified for each of the root causes, as well as the deadline for their implementation, and
- actions to verify the effectiveness of each CAPA have been identified, as well as the timeframe for its review.

For each non-compliance, the designating authority should classify the actions proposed (and deadlines for their implementation) as follows:

- **Satisfactory:** When root cause analysis has been properly conducted, CAPAs and deadlines for their implementation have been considered adequate, and processes proposed for verifying the effectiveness of such actions have been satisfactorily defined.
- **Unsatisfactory:** Whenever the information provided by the CAB is not sufficiently clear or relevant information is missing, or it is deemed to be inadequate or insufficient to address the non-compliances and/or prevent their recurrence. The designating authority should explain the rationale for this classification, which elements need to be further clarified and/or which information has to be provided by the CAB, including applicable deadlines.

If there are CAPAs that have been classified as unsatisfactory, the designating authority will ask the CAB for a revised CAPA plan, which should address the above-mentioned issues.

Where no CAPA plan or clarifications or modifications thereof have been received by a specified deadline, a new deadline could be established for the submission of this information. If after a number of rounds of correspondence with the CAB the requested clarifications are still missing or are unsatisfactory, the designating authority may decide according to its own procedures to reject the application. In such cases, the designating authority should inform SANTE/F.

Ideally within 20 working days of having received and assessed the CAPA plan (including its revision, where applicable), the designating authority will confirm the CAPA plan and

[21] Where there is a diverging opinion related to the grading of non-compliances, for instance if the designating authority has not included in its list a non-compliance raised by the JAT, it is expected that this situation will be brought to the attention of the CAB as a diverging opinion in the closing meeting and that the CAB will include such a non-compliance in its CAPA plan.

draft its *opinion on the CAPA plan*. This opinion will indicate, for each non-compliance, whether the proposed actions and deadlines for their implementation are considered satisfactory or unsatisfactory. This may be documented in the CAPA form NBOG F-YY.

The confirmed CAPA plan and the designating authority's opinion thereon will be forwarded by the designating authority to SANTE/F.

If the CAPA plan is not deemed to be satisfactory in a given period of time, the designating authority may consider the possibility of not proceeding with the assessment, i.e. rejecting the application.

4.3 JAT review of the CAPA plan

After receiving the CAPA plan and the designating authority opinion thereon, the JAT coordinator will arrange for their machine translation (if needed) and will subsequently submit the documents to the national experts in a language that could be readily understood by the team.

Ideally within 10 working days, the JAT coordinator will forward a preliminary review of the CAPA plan and designating authority's opinion to the national experts for their comments. All comments will be collated in a consolidated version and a conference call will be organised to allow for further discussion whenever deemed necessary. The designating authority will be invited to attend this call conference.

Following the above step, and ideally within 20 working days, the JAT should provide the designating authority with the *JAT CAPA review*, which will include its review of the CAPA plan and of the designating's opinion thereon. The JAT will indicate whether clarifications are needed and/or whether any of the actions are not deemed as acceptable, and therefore a modified CAPA plan should be submitted. A rational should be provided in any of these cases.

4.4 Feedback to the CAB on the assessment of CAPA plan

Following the receipt of the *JAT CAPA review*, the designating authority should finalise its assessment of the CAPA plan and provide the CAB with feedback. In case the CAB is requested to amend the CAPA plan, the designating authority should establish a deadline for these amendments.

Where clarifications and/or modifications of the CAPA plan have been requested by the JAT, the designating authority should update its assessment and will repeat the procedure referred in 4.2 until it is satisfied with the content of the CAPA plan. The designating authority will keep SANTE/F informed about the subsequent progress in the implementation, verification and assessment and of the CAPA plan (see section 5.1).

5 Decision on designation

5.1 Final review of the implementation of the CAPA plan to address the non-compliances prior to designation decision

The designating authority will need to verify the progress on the implementation of all CAPAs before taking a decision on designation, namely whether non-compliances have been closed or they need to be followed-up, where applicable:

- Closed. If the designating authority has verified the implementation of the relevant CAPAs and the verification of effectiveness of such actions have been finalised through documented evidence(s) and/or on-site follow-up assessment(s).

- To be followed-up [22]. The follow-up date should be specified by the designating authority for actions that are to be implemented according to a satisfactory schedule and/or for actions that had been already implemented but for which the verification of effectiveness is still to take place.

In assessing the implementation of the CAPA plan and the fulfilment of conditions for designation, the designating authority should consider the following:

- Minor non-compliances: the implementation of the proposed actions and their effectiveness may be verified by the designating authority following designation.
- Major non-compliance (or multiple minor non-conformities on similar issues): the implementation of the proposed actions needs to be verified by the designating authority prior to the issuing of the final assessment report [23]; the effectiveness of these actions may be verified by the designating authority following designation [24].

5.2 Designating authority's final assessment report

There is no time limit for the production of the designating authority's final assessment report. This is because: i) the number of non-compliances identified will influence the time that the CAB will need to put in place corrections and CAPAs, and ii) depending on the nature of non-compliances identified, the CAB will need to implement CAPAs before the designating authority produces its final assessment report (at least for major non-compliances).

The designating authority's final assessment report needs to contain, as a minimum, the following elements:

- the result of the assessment, including the list of non-compliances;
- confirmation that the corrections and CAPAs have been appropriately implemented and verified, where required:
  - ✓ for each of the non-compliances identified, the assessment of the corrections and CAPAs proposed by the CAB,
  - ✓ where applicable, information on the designating authority's verification that the corrections and CAPAs have been implemented by the CAB,
  - ✓ where required, information on the designating authority's assessment on the effectiveness of the CAPAs already implemented by the CAB,
- where applicable, any remaining diverging opinions with the JAT, and,
- where applicable, a recommendation on the CABs proposed scope of designation as set out in the corresponding NBOG form, including any conditions and sufficiently detailed information in case the recommended scope of designation differs to the CAB's applied-for scope of designation.

The language in which the designating authority's final assessment report will usually be that of the Member State concerned. Nevertheless, the designating authority will fill in the corresponding *Key Information document* in English, in order to allow the JAT and the

22 Contingent to the nature of the non-compliances, subsequent verification by the designating authority can take place after designation. This verification should take place during surveillance assessment or at an earlier stage through on-site follow up assessment or off-site assessment of documented evidence(s) provided by the CAB.

23 As defined in Articles 39(7) of the MDR and 35(7) of the IVDR.

24 For instance, for non-compliances concerning availability of sufficient qualified personnel, the corrective action (e.g. hiring of new qualified staff) will have to be implemented by the CAB and verified by the designating authority before designation. However, the CAB could verify the effectiveness of this type of CAPAs later on (e.g. by an internal audit with assessment of technical documentation), and this effectiveness be subsequently verified by the designating authority during the next surveillance audit.

MDCG to understand the outcome of the assessment and the post-assessment activities. Should the recommended scope of designation differ to the CAB's applied-for scope of designation, this should be explained also in this *Key information document*.

5.3 Submission of the final assessment report to the Commission

The designating authority needs to submit its final assessment report together with the *Key Information document* and, where applicable, the CAB's draft designation to SANTE/F, which will immediately transmit it to the MDCG, the JAT and GROW/D. SANTE/F will acknowledge receipt of these documents via email to the designating authority.

In respect of those designating authority's final assessment reports and, if applicable, CAB's draft designations which are not written in English, SANTE/F will arrange for a machine (or, time permitting, an official) translation, which will be also transmitted to the MDCG, the JAT and GROW/D.

5.4 JAT final opinion

Within 21 days following receipt of the designating authority final assessment report and *Key Information document* and, if applicable, the CAB's draft designation, SANTE/F will submit the *JAT final opinion* to the MDCG. The *JAT final opinion* will also be submitted to the designating authority.

The *JAT final opinion* will include, as applicable:

- a summary of the JAT assessments: the off-site review of the application (see section 2.9) and the on-site assessment (see section 3.5),
- a summary of the JAT assessment of the CAPA plan and the designating authority's opinion thereon, including, if applicable, the JAT views on progress made in the implementation, verification and assessment of the CAPA plan (see section 4.2),
- the *updated remaining diverging opinions* (see section 4.1), and considerations as to whether these could have an impact on the MDCG's recommendation on designation (see section 5.5),
- the JAT opinion on the designating authority's recommended scope of designation and, if applicable the CAB's draft designation (see section 5.2).

For the purpose of reaching agreement on the *JAT final opinion*, the JAT coordinator will discuss the above-mentioned elements between all of the JAT members by means of organising a teleconference or any alternative arrangement, for instance email exchanges.

5.5 MDCG's recommendation on the draft designation

Within 42 days of receipt of the *JAT final opinion*, the MDGC will issue a recommendation on the CAB's draft designation proposed by the designating authority.

For this purpose, the MDGC's chair will coordinate the preparation of a proposal for a recommendation on the draft designation, which will be shared with the members of the MDCG as soon as possible, for their comments.

The MDCG's chair should arrange for a teleconference (or any alternative arrangement, for instance email exchanges) with all MDCG members within 30 days of receipt of the *JAT final opinion*. During this teleconference, MDCG members should seek consensus about the recommendation on the draft designation. Where consensus cannot be reached, the MCDG will issue the recommendation in accordance with its Rules of Procedure.

The MDGC will arrange for the submission of the recommendation on the draft designation to the designating authority, informing SANTE/F.

5.6 Designating authority's final decision on designation

The MDCG's recommendation will be duly taken into consideration by the designating authority for its decision on the designation of the CAB.

6 Notification

To be developed.

7 References

References: Regulation (EU) 2017/745 Chapter IV

Regulation (EU) 2017/746 Chapter IV

Sources:

[1] NBOG F 2017-1 rev. 2 Application form to be submitted when applying for designation as a notified body under the medical devices Regulation (MDR)

[2] NBOG F 2017-2 rev. 2 Application form to be submitted when applying for designation as a notified body under the *in vitro* diagnostic devices Regulation (IVDR)

[3] NBOG F 2017-3 Applied-for scope of designation and notification of a Conformity Assessment Body form – Regulation (EU) 2017/745

[4] NBOG F 2017-4 Applied-for scope of designation and notification of a Conformity Assessment Body form – Regulation (EU) 2017/746

[5] NBOG F 2017-5 Preliminary assessment report form – Regulation (EU) 2017/745

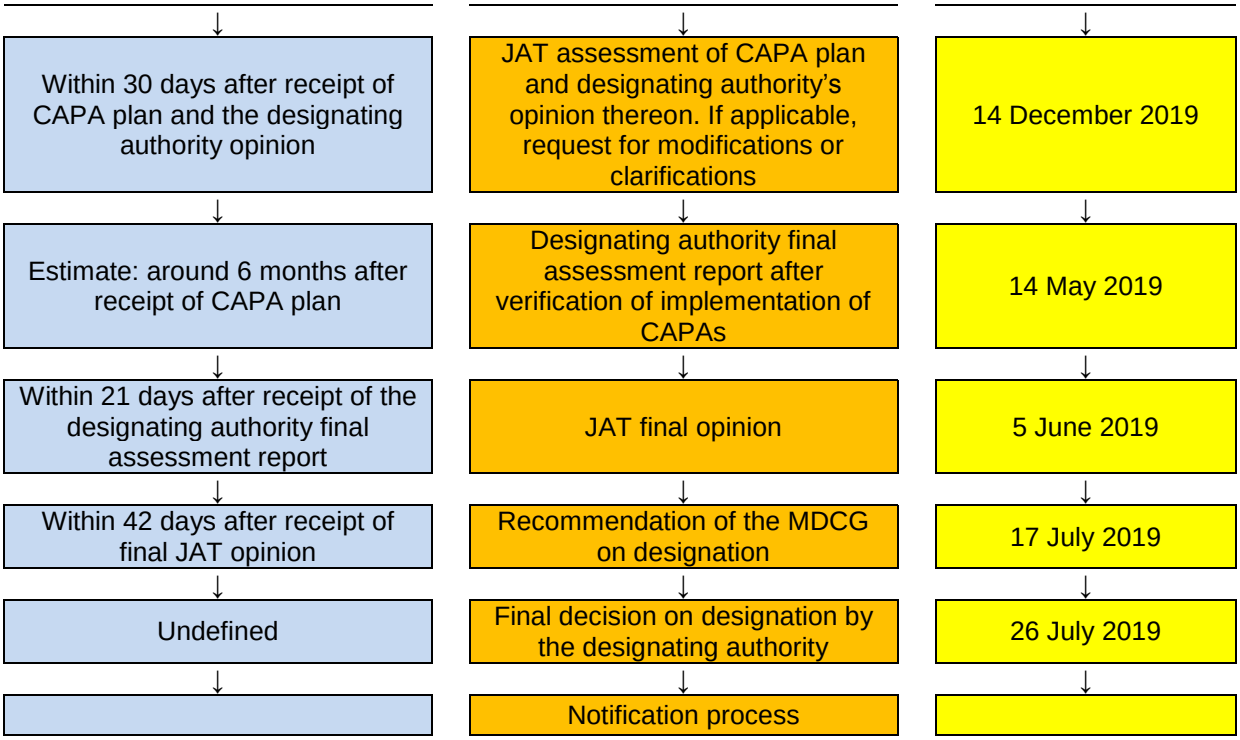
[6] NBOG F 2017-6 Preliminary assessment report form – Regulation (EU) 2017/746

Keywords: CIRCABC, conformity assessment body, designating authority, designation, JAT, joint assessment, MDCG, notification, reporting, SANTE/F

Date of issue: November 2017

Annex 1: Flowchart of activities and times

Tentative time-line	Activity	Tentative calendar for existing notified bodies (see section 2.1)
18 months in advance of repeal of relevant Directive	Application sent to the designating authority from the CAB	27 November 2017
Within 30 days of receipt of the application	Completeness check of application by the designating authority	27 December 2017
Immediately after application is considered complete	Transmission of application to SANTE/F	27 December 2017
Estimate: within 2 months after application is considered complete	Assessment of CAB's application by the designating authority and issuing of preliminary assessment report	27 February 2018
Within 14 days after receipt of preliminary assessment report	Appointment of the JAT and scheduling of the on-site assessment	13 March 2018
Within 90 days after appointment of the JAT	Formal announcement of and arrangement of practicalities for the on-site assessment Dissemination of information to JAT members Assessment of CAB application by the JAT	13 June 2018
At least 5 weeks *before* the anticipated on-site assessment	Coordination teleconference between the JAT and the designating authority	20 July 2018
On-site assessment	In accordance with the agreed assessment plan	10 September 2018
Last day of the on-site assessment	Designating authority list of non-compliances and summary of the JAT assessment to be presented at the closing meeting	14 September 2018
Timeframe defined by the designating authority	CAB's submission of the CAPA plan	September/October 2018
Within 30 days after the on-site assessment	JAT remaining diverging opinions to be sent to the designating authority	14 October 2018
Estimate: within 2 months after the on-site assessment	Designating authority's confirmation and assessment of CAB's CAPA plan. To be forwarded to the JAT	14 November 2018


Within 30 days after receipt of CAPA plan and the designating authority opinion
JAT assessment of CAPA plan and designating authority's opinion thereon. If applicable, request for modifications or clarifications
14 December 2019
Estimate: around 6 months after receipt of CAPA plan
Designating authority final assessment report after verification of implementation of CAPAs
14 May 2019
Within 21 days after receipt of the designating authority final assessment report
JAT final opinion
5 June 2019
Within 42 days after receipt of final JAT opinion
Recommendation of the MDCG on designation
17 July 2019
Undefined
Final decision on designation by the designating authority
26 July 2019
Notification process