Central Management Committee Decision "Revised designation process for notified bodies"

PROTECTING PUBLIC HEALTH TOGETHER

CMC Decision

Introduction

The Central Management Committee (CMC) agreed to develop a revised process for designation and monitoring of notified bodies for medical devices in conjunction with the Notified Body Operations Groups (NBOG). This initiative, to be conducted in parallel with the development of new and more detailed designation criteria for notified bodies seeks to improve and standardise the performance of notified bodies for medical devices by improving and harmonising oversight and by setting standard minimum criteria to be applied.

These items have long been recognised as critically important to strengthen the regulatory system for medical devices and ensure that European notified bodies are performing to consistently high standards and having requirements and standards applied to them in a harmonised manner.

This proposal is made on the basis that the final responsibility for designation will remain with the relevant authority within the Member State in which the notified body is established. Thus, this initiative is not intended to reduce the rights or responsibilities of individual Member States in the designation of notified bodies based in their territory. When agreed between Member States this initiative may provide a possible process to be used for the purposes of conducting the joint assessments from 2013 as suggested by Commissioner Dalli's joint plan of immediate actions.

A proposal for a new designation process has to consider these developments and has to find specific solutions suitable for the medical devices sector. This will also require clearer and improved criteria and procedures for designation and monitoring of notified bodies and include an improved exchange of authority's reports for information with the Commission and other Member States.

It is not yet clear which policy options or legal framework will be included in the European Commission's proposal for the revision of the medical devices legislation. The process

proposed in this document therefore serves more to describe an action for Member States to take in advance of the revision, however its implementation may provide for useful information and lessons which may be taken into account for the definition of the future designation and oversight models provided for within the revision. The final stages of the process including oversight of the decision process by Member States and the Commission will require further discussion and elaboration, but this should not prevent agreement on the proposed process outlined.

Process Description & Elements

This process will be applied to new applications from certification bodies seeking to be designated as notified bodies for medical devices and to existing notified bodies for monitoring of their designation on a periodic basis (on a three to five yearly basis).

An applicant seeking to become a notified body (the 'applicant') for medical devices makes an application to the relevant designating authority (the 'authority') in the Member State in which they are based. Ultimately, the designation decision remains with the national authority.

It is proposed that in order to facilitate coordination of the new designation and monitoring process that potential applicants indicate intended dates for application to the authority and designation review activities are planned by the oversight committee in cooperation with the affected authorities. Following on from an application to an authority and an initial administrative check (i.e. to ensure all appropriate documentation is submitted and that designation à priori is not excluded), the authority should inform the oversight committee[1] (the 'committee') of receipt of the application. The committee should appoint assessors from a pool of European experts in notified body designation and monitoring to partner with the assessors from the national authority for review of the designation application.

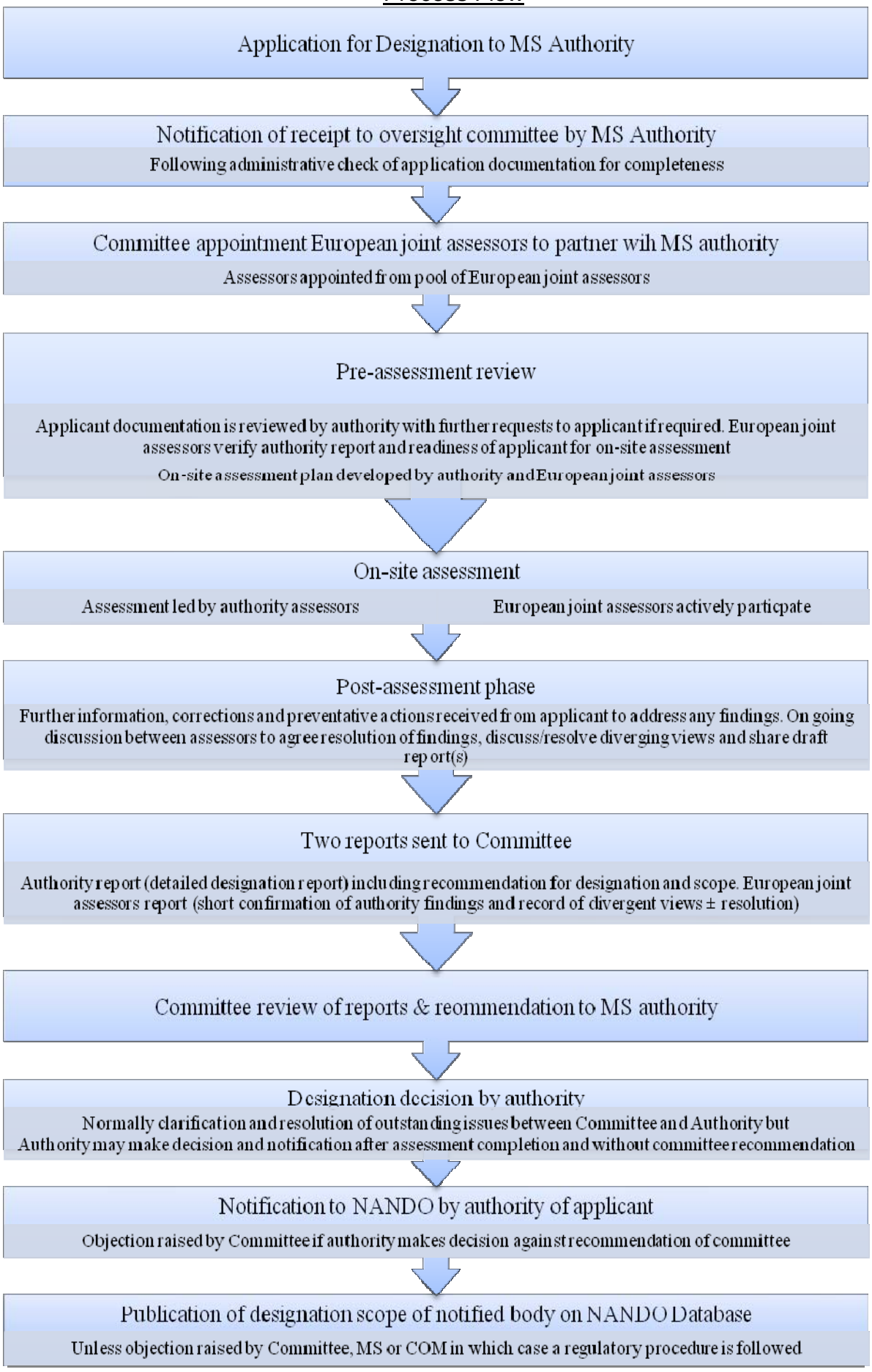
It is proposed that the authority assessors are in general accompanied by two 'external' colleagues to act as European joint assessors. Joint assessments should be conducted in a spirit of full cooperation and openness, seeking to reach agreement on differences in interpretation but nevertheless the joint assessors are necessary to provide an objective overall assessment. Any unresolved divergent views should be fully recorded for further discussion by the committee.

[1] The oversight committee is not identified in this document as it will be dependent on the European Commission's proposals to revise the medical devices legislation.

Every designating authority with responsibility for a notified body for medical devices shall officially nominate experts to the pool of European joint assessors. This nomination should be supported by evidence of the nominee’s expertise, experience in the designation and monitoring of Notified Bodies and language skills, e.g. using a standard nomination template document. The oversight committee shall identify specific qualification criteria for joint assessors and training schemes to be applied to the nominated assessors.

The European joint assessors should be nominated by the committee based on their expertise and experience in designation and monitoring of notified bodies and taking into account language skills, the scope of designation subject to the application and on any other relevant information. In addition, representatives from the European Commission may also be included into the team. The European joint assessor’s role is to assess the notified body application for designation and to make their independent recommendation to the committee based on the findings during the assessment. This role is not to assess the national authority responsible for the designation and does not replace the need for a formalised peer review programme for these authorities.

Process Flow



The designation application assessment or monitoring assessment is considered in three separate stages:

1. **Pre-assessment of designation application and supporting documentation**

   To support the application for, or confirmation of, designation as a notified body for medical devices documentation relating to the body's quality system, structure, qualification and training of personnel etc., is expected. This documentation would be sent by the applicant to the Member State authority and once it has passed an incoming administrative check it is to be distributed to the identified European joint assessors.

   This documentation[2] would then be reviewed by the authority and by the European joint assessors in parallel. The national assessors should prepare a report based on their review of the documentation. A standard notification template should be prepared for agreement with the joint assessors on the state of readiness for inspection of the application and/or on the need for further information to be submitted in advance of an audit. The assessors (national and European joint assessors) should have ongoing communications and/or meetings to discuss the application, documentation and the proposed assessment plan for the on-site assessment of the applicant body.

2. **On-site assessment of applicant**

   The on-site assessment of the applicant body should be conducted as a joint rather than a parallel assessment. The European joint assessors form a specific part of the on-site assessment team which would be led by the national authority. As part of the on-site assessment team the European joint assessors should be sufficiently involved in each element of the review (e.g. asking additional questions) so that they can make an informed opinion on the applicant body. The European joint assessors may also review individual elements of the applicant independently but only with full visibility to the authority. The European joint assessors should not be conducting discussions or interviews with the applicant body's personnel in isolation and without the involvement of the authority. The European joint assessors should not raise issues or topics that fall outside of the scope of the agreed assessment plan. Deviations from the agreed plan should be with the agreement of and ideally led by the authority assessors.

   When the European joint assessors have findings arising from their assessment which they judge are non-conformities these need to be discussed in full with the authority and as required with the applicant body. The European joint assessors should detail these findings in their assessment trail/notes. These findings should be considered by the

[2] For language requirements please see section “specific issues”

authority when preparing for the closing meeting and writing the non-conformity report. Where there is a divergence in opinion on the status or significance of particular findings these should be discussed between the authority and European joint assessors to try to reach a resolution. The discussions should be appropriately informed by available guidance, standards, agreed best practices, existing precedence etc. If sufficient information is not available to resolve the diverging opinion the issue should be referred to the relevant committee[3], such as the Notified Body Operations Group (NBOG), for discussion and ideally advice in advance of final notification (this does not affect the rights of the national authority to make a notification as outlined below). This does not prevent the authority assessors asking for specific input into the non-conformity report from the European joint assessors. If a non-conformity identified by the European joint assessors is not taken into account by the authority assessors this will be documented in the European joint assessors report.

The assessment process envisaged in this proposal is intended to be joint and collaborative. The majority of issues identified by the authority and European joint assessors will be resolved through discussion between the assessors during the on-site assessment. Nevertheless while the assessment activity is conducted in tandem as part of the same assessment team it is expected that the European joint assessors will provide an independent opinion on the designation application to verify the findings of the authority and especially to record any divergent opinions.

3. Post-assessment communication & reporting

Following on from the review of documentation and the on-site assessment it is likely that there will be outstanding issues or questions which the applicant will be required to resolve prior to a final decision.

The authority should send its draft report to the European joint assessment team. The European joint assessment team's report will be a short confirmation of the findings in the authority's draft report and will include a section to record any divergent views between the assessors which should be described in detail. The draft report will be shared with the authority prior to finalisation of its report. This will allow an opportunity for further discussion if desired and further opportunity for resolution of outstanding issues. Divergent opinions may be referred to the relevant committee for further discussion and advice, prior to final decision on notification. This does not affect the right

[3] This will be determined by future coordination structures

of the national authority regarding notification. A process would have to be in place to ensure that advice would be provided in a timely manner.

Where the authority report is amended as a result of further discussion in this phase the resolved divergent opinions shall be noted in the European joint assessors report along with their resolution.
It could be envisaged that summaries of the designation and monitoring activities are made publicly available, detailing the activities conducted and the agreed outcomes. Care would be necessary to ensure that while these summaries are provided for transparency but that they obsereve appropriate levels of protection for confidentiality with respect to specific findings/diverging opinions.

The committee will be provided with two standardised reports, one from the authority and one independent report from the European joint assessors, which will comprise of a short report outlining the national authorities findings, resolution of those findings, diverging opinions and their resolution (when applicable) and a recommendation from the national authority and a clear opinion on this recommendation from the joint assessors. Differences in opinion between the authority and the European joint assessors on the designation of a notified body shall be evident to the committee and require resolution through this oversight mechanism. This may involve specific discussion on these differences at the committee. During that time the authority shall be advised by the committee not to make the notification until the outstanding issues have been resolved. The committee will make a final recommendation to the authority within 1 month. After receiving the Committee’s recommendation it is the authority's sovereign right to decide to make the notification based on their existing report not taking into account the committee’s recommendation. The recommendation of the Committee will be made publically available, in the spirit of transparency but with appropriate levels of confidentiality on specific issues.

The notification is made to the existing NANDO system. If the committee’s recommendation is not followed it may be decided to use the instrument of formal objection within 2 months.
Specific timeframes for the specific phases of this exercise need to be defined. While sufficient time should be allowed for report review it is necessary to ensure that the post-assessment and decision phase of the process is not too long.

Date: 23rd of May 2012