(Re-)designation of notified bodies: Process for joint assessments

1 Scope

1.1 This guide is intended to provide guidance to designating authorities (DAs) and joint assessment teams (JATs) when conducting (re-)designation and scope extension assessments of notified bodies (NBs) under Commission Implementing Regulation (EU) No 920/2013 (hereafter referred to as the Regulation). As the majority of those assessments will be for re-designations the timelines defined below refer primarily to those.

1.2 Whilst the Regulation does not apply to Directive 98/79/EC (IVDD), it could be the case that an NB wishes to combine its (re-)designation under both Council Directive 90/385/EEC on active implantable medical devices (AIMDD) and Council Directive 93/42/EEC on medical devices (MDD) with the IVDD. In such a case the joint assessment process deals solely with the MDD / AIMDD. Nevertheless, as the prerequisites for designation under both of those Directives have a bearing on an NB's capability to perform conformity assessments according to the IVDD, DAs shall consider the outcome of the joint assessment on the MDD / AIMDD when deciding on an NB's fitness to operate under the IVDD.

2 Pre-assessment activities

2.1 **NB's application**: When applying for (re-)designation, or for an extension of its scope of designation, the (applicant) NB shall use the application form NBOG F 2014-1 set out in Annex II and submit supporting documentation as requested.

For an existing NB, these data shall be provided ideally **around 18 months** prior to the expiry of the NB's (national) designation and **around 6 months** in advance of the anticipated on-site assessment. There shall be sufficient time within this overall 18-month period for the assessment of the application, execution of the on-site assessment and subsequent verification activities by the DA which would allow all of the nonconformities in NB performance to be rectified prior to the above expiry date. The flowchart in the annex to this document illustrates the process and the estimated length of time needed for each step.

Note: If 18 months is insufficiently long to carry out all of the above tasks, the NB's designation will, pending completion of the exercise, expire or the NB will be de-designated and placed in the suspended / withdrawn part of the New Approach Notified and Designated Organisations Information System (NANDO).

For an *applicant* NB, the time limits are less important but those conformity assessment bodies should be aware that a similar time period may be required before a recommendation on designation can be made. In the event that an *existing* NB applies for an extension to its scope of designation, the overall time period may be much shorter.

2.2 **Review of NB's application for completeness**. An initial review shall be carried out by the DA to verify the completeness and expected content of the documents according to NBOG F 2014-1. This review should take no more than one month after receipt. In the event that documentation is missing or incomplete, the DA shall request and receive these

data from the NB. If not forthcoming, the process should terminate at this point because it is not possible to proceed.

2.3 **Dates for on-site assessment**. If the application is sufficiently complete to allow the on-site assessment to proceed, the DA shall forward the application and the relevant documentation to the Commission's Directorate-General for Health and Food Safety, Directorate F (hereafter referred to as SANTE F). Following consultation with both the NB and SANTE F, the DA shall agree on the probable dates for the on-site assessment. This should normally be done between one and two months after receipt of the NB's application. The on-site assessment shall ideally be scheduled around 6 months after the submission of the application to the DA (and around 12 months before the expiry date of the NB's designation, if applicable). This is to give both the DA and the JAT sufficient time to assess the application in detail.

If the DA's process for re-designation requires an observed audit of a manufacturer as part of the on-site assessment a JAT must be involved in that component of the assessment.

2.4 **Composition of the JAT**. SANTE F will, from the pool of national expert assessors made available from all of the DAs, select two national expert assessors who are available and are best suited on the basis of their experience and language capabilities to effectively participate in the on-site assessment of the NB in question. This selection process shall be completed at the very latest 3 months before the scheduled date of the on-site assessment.

2.5 **Announcement letter regarding the on-site assessment**. After the dates of the on-site assessment have been discussed and agreed informally between the DA and SANTE F, the latter will write to the DA, formally launching the on-site joint assessment process. This letter will usually be sent out around three months prior to the on-site assessment. It will identify the SANTE F personnel (including the JAT coordinator) who will be involved in the joint assessment and the national expert assessors. The letter will describe the process for conducting the on-site assessment and will include, as an appendix, a specimen assessment plan for the on-site assessment.

The duration of the on-site assessment will depend on the language in which the on-site assessment is to be conducted and the purpose of the assessment. For example, a standalone scope extension should take proportionally less time than a full (re-) designation, though this depends on the number of new scope expressions being added and the time since the last full (re-)designation assessment took place. Depending on language requirements, a full (re-) designation should normally take a minimum of 4 days on-site with up to 5 days if interpretation is required. It is essential that the on-site assessment lasts long enough so that both the DA and the JAT can sufficiently assess if the NB does fulfil the requirements throughout its applied scope of designation.

2.6 **Arrangement of interpretation**. If the language in which the on-site assessment is to be conducted is not English, SANTE F shall arrange for interpretation to be provided at its expense. Up to four interpreters may be required for each on-site assessment.

2.7 **Transmission of the application and supporting documentation to the JAT**. The language in which the application is made will usually be that of the Member State / EFTA / EEA country in question but information made available in English facilitates the conduct of the joint assessment. It is usually the case that NBs with international clients will already have many procedures written in English. If not, it is in the interests of the NB to translate at least key documents into English in order to facilitate the conduct of the assessment.

In addition to the full application, important documents needed by SANTE F – preferably in English – include the procedures listed under points 19, 31, 32, 33 and 41 in NBOG F 2014-1, the DA's previous assessment / observed audit report and the list of EC-certificates (if applicable) issued by the NB.

Transmission of data from the DA will normally be by email. If the files are too large, or if the NB does not wish to have its documents transmitted by email (for security reasons), the DA can physically send the data (e.g. on an encrypted CD, DVD or memory stick) via recorded post. The JAT coordinator would expect to receive these data around 3 months prior to the on-site assessment to allow for sufficient time for the JAT assessment of the application.

2.8 **Dissemination of information to JAT members**. The JAT coordinator shall upload the data into a specific CIRCABC[1] workspace (SANTE F Joint Assessments) to disseminate the information referred to in 2.7 to the national experts. To facilitate this, the other JAT members shall be granted access to this workspace via their CIRCABC profiles.

Note: At the end of the assessment process the SANTE F shall delete information uploaded into this temporary repository.

In the event that a substantial part of the application and supporting documentation is not submitted in English, the JAT coordinator shall arrange for machine translation of appropriate documents. To this end, there may be a need for the JAT coordinator to request the resubmission of certain documentation from the DA in a format suitable for machine translation[2].

2.9 **Detailed assessment of the application**. Both the DA and the JAT must carry out a detailed assessment of the application against the requirements of the MDD and / or the AIMDD together with the Annexes to the Regulation. The outcome of this exercise should be documented on a NBOG agreed form.

The DA will invariably be in a position to complete its review in a shorter time frame than the JAT (due to language issues). In any case, the DA should send its assessment of the application to the JAT coordinator no later than one month prior to the date of the on-site assessment. The JAT review of the application should also be complete no later than one month prior to the date of the on-site assessment and submitted to DA.

The JAT coordinator is responsible for ensuring that the detailed assessment of the application is conducted in good time and that the national experts are actively involved in and contribute to this process. He / she may delegate specific parts of the assessment of the application to individuals in the JAT.

2.10 **Coordination with the DA**. The JAT coordinator is responsible for establishing and maintaining contact with the lead assessor from the DA. The JAT coordinator shall arrange for at least one teleconference to be held between the DA team and all of the members of the JAT in which the results of the off-site assessment of the application (by both the JAT and DA) are discussed, open questions on the application are addressed, decisions on the role of each of the team members during the on-site assessment will be taken and the DA's proposed assessment plan agreed and fine-tuned if necessary. This teleconference should be held shortly after the off-site assessment is completed, at the latest four weeks before the on-site assessment.

2.11 **Negative opinion of the application**. In the unlikely event that either the DA or the JAT considers that the application is insufficient to warrant progressing to the on-site assess-

[1] Communication and Information Resource Centre for Administrations, Businesses and Citizens
[2] For example, scanned pdf documents or protected pdf documents are unsuitable for machine translation

ment stage, the on-site assessment shall be postponed or cancelled latest three weeks prior to the assessment. It is the responsibility of the DA to inform the NB that this is the case.

Postponement is possible if the shortcomings in the application can be rectified, though in such a case the NB should be warned that, due to the postponement, it may not be possible to complete the entire joint assessment process in time to allow for a re-designation to take place before the expiry date of its designation. The NB would be asked to submit a revised application once the issues which precluded acceptance of the original application have been addressed. When this occurs, the process would continue where it has been interrupted.

Cancellation should be considered if there is no likelihood that the NB will meet the requirements for designation (thus rendering the on-site assessment superfluous).

2.12 **Positive opinion of the application: Selection of client files for the on-site assessment**

In order to gain an understanding of the adequacy of the NB's conformity assessment process, it is necessary, not only to look at the NB's audit reports of manufacturers and records of its technical file reviews and design dossier examinations, but to have the opportunity to see the source data upon which such reports are based. Given that NBs may not keep copies of manufacturers' technical files at their premises, the NB would have to know in advance the client files which will be subject to review by the DA and JAT so that the documentation can be requested from the manufacturer and be present on-site for the duration of the on-site assessment.

Both the DA and the JAT shall agree on a list of such files (ideally including examples of devices certified according to all of the Annexes for which the NB is designated). Criteria for selection of files could include the Class, distribution of the geographical origin of the clients, complaints, vigilance reports and other information as well as specialist interest of the JAT and DA team members. If possible, recent files that have been assessed in accordance with the procedures and forms included in the application should be prioritised.

The selection of the client files is normally confirmed at the time of the teleconference between the DA and JAT (see 2.10). If the technical documentations are not kept at the NB's premises the DA shall submit this list to the NB between 3 and 4 weeks in advance of the on-site assessment to give sufficient time for the files to be called in.

3 On-site-assessment activities

3.1 **Scope of the on-site assessment**. The assessment will cover all of the designation criteria laid down in the relevant annexes to the MDD and / or AIMDD and as elaborated further in the Regulation. The assessment should follow the agreed assessment plan. Ordinarily the overall team (DA + JAT) will be subdivided into two or more sub-teams which between them will cover the four main subject areas detailed in Annex II to the Regulation. Usually, in parallel to the discussion on the main subject areas by one sub-team the other team(s) will focus on assessment of NB files.

3.2 **Roles during the on-site assessment**. The assessment is led by the DA lead assessor, who has the overall responsibility for the on-site assessment. The JAT will be embedded as part of the overall assessment team with distinct roles for each team member.

3.3 **Opening meeting**. This will be led by the DA lead assessor. He / she will outline the legal basis for the assessment. The JAT coordinator shall also describe the role of the JAT in the process and the NB shall be informed as to how the whole process will pro-

gress (regarding the reports, access thereto, confidentiality issues, follow-up post-assessment activities etc.).

3.4 **Conduct of the on-site assessment**. Throughout the assessment there shall be constant communication between the DA and JAT with time allocated for discussion of findings at intervals during and at the end of each day's activities. The DA may also decide to debrief the NB at regular intervals during the assessment (usually at the end of each day).

3.5 **Problems with completing the on-site assessment**. In exceptional cases it may prove impossible to assess the NB's compliance with all of the designation criteria in the time allocated for the joint assessment. In such cases, the JAT shall discuss the options available with the DA to ensure that all of the designation criteria are assessed with sufficient rigour. Such options could include continuing the on-site assessment at a mutually agreeable future date.

In the unlikely event that the DA disagrees with the JAT and considers that the assessment has covered all of the requisite areas in sufficient depth and thus does not agree with a request to extend the duration of the assessment, the JAT coordinator shall record this difference of opinion in the JAT report which will form the basis of a negative JAT opinion on (re-)designation.

3.6 **Nonconformities**. If found, shortcomings in the NB's procedures or performance should be raised as nonconformities against a legal requirement, for example an article or a clause in one of the Annexes to the MDD / AIMDD or the Regulation. Findings pertaining to individual client files would ordinarily be recorded as examples or supporting evidence for the nonconformities identified, or, when not applicable, as nonconformities. Nonconformities should be classified as major or minor as outlined in Section 4, Chapter 8.0 of the NBOG designating authorities' handbook.

3.7 **Observations**. Observations may be recorded where there is no legal requirement breached.

3.8 **Pre-closing meeting**. Before the closing meeting with the NB the DA and the JAT together shall compile, if applicable, a list of nonconformities and observations, with the appropriate supporting evidence. For the purpose of the reports that will be issued from both the DA and the JAT, agreement shall also be sought on where within the four main chapters of the report the nonconformities should be placed (general, QMS, resource or process). If DA and JAT have diverging views on individual nonconformities or the outcome of the assessment such differences of opinion between the DA and the JAT shall be clearly expressed and documented by the JAT.

3.9 **Special measures**. If the outcome of the assessment is sufficiently negative in the opinion of the JAT to warrant immediate action on the part of the DA, for example restricting the NB's activities, pending resolution of the nonconformities identified, there should be free and frank discussion between the JAT and the DA team on the options and possibilities available.

3.10 **Closing meeting**. The DA shall inform the NB about all the nonconformities detected. The list of nonconformities shall be given to the NB in writing, in advance of a formal report being issued by the DA. Whilst not obligatory it would be useful if the DA also allows the JAT coordinator to comment on the assessment and reiterate the reporting procedures (from the JAT perspective). If at the time of the closing meeting the DA team has the authority to impose special measures on the NB and decides to do so, the NB shall be informed of this.

3.11 **Expected NB response**. The DA shall ask the NB to respond to any nonconformity with a corrective and preventive action plan (CAPA) containing a thorough root cause analysis. The urgency for receiving such a CAPA plan depends on the seriousness of the noncon-

formities. If any nonconformity represents a serious health risk, the NB has to take immediate action. For all other nonconformities, the CAPA plan shall be produced within a timeframe defined by the DA, e.g. within a maximum of 2 weeks for any major issues raised and within 4 weeks for the minor nonconformities raised. If necessary, further on-site follow-up assessments might be conducted by the DA.

4 Post-assessment activities

4.1 **JAT report – timing and content**. The time limit for production of the JAT report (45 days after completion of the on-site assessment) is prescribed in the Regulation. If applicable, this report will include the list of nonconformities and observations raised and will include a recommendation with regard to the (re-)designation. The JAT report will also include, as appendices, the NB's applied-for scope of designation (on form NBOG F 2012-1 or NBOG F 2012-2 for the AIMDD and MDD respectively).

The JAT coordinator is responsible for writing this report and he / she will rely on input from all of the JAT members. The report will not contain information such as the names of the notified body's staff and clients and their trademarks. Within 45 days of completion of the on-site assessment, a *draft* version of the report will be sent to the DA for its comments on the factual content, or other elements, of the report. These comments should be returned to the JAT coordinator within 25 working days of its receipt. The JAT coordinator will address the comments, modify the report accordingly and send the *final* JAT report to the DA along with a table indicating how individual comments have been taken into account for the production of the final report. This final JAT report will eventually be uploaded into the Joint Assessments workspace in CIRCABC for perusal by all of the EU / EFTA / EEA DAs. The JAT report will be in English.

When sending this final JAT report back to the DA, the JAT coordinator will also include a proforma for completion by the DA (in English) which will be uploaded into the CIRCABC database alongside both the final DA report and the final JAT report.

4.2 **DA Report – timing**. There is no time limit for the production of the DA report. Depending on the number and nature of the nonconformities identified, the time the NB will need to implement corrections and CAPAs and the time needed by the DA to verify the effectiveness of those corrections and CAPAs (which may well involve further on-site assessments and off-site reviews of documentation), the final DA report may take many months to produce.

4.3 Post-assessment verification. Ordinarily this aspect is handled solely by the DA. As a courtesy the DA lead assessor should periodically liaise with the JAT coordinator in respect of the NB's CAPA plan, the progress being made by the NB in implementation of its corrective and preventive actions and the judgement of this by the DA.

The DA may seek to avail of advice and assistance from the JAT members when assessing the adequacy of the NB's actions or for discrete activities such as assessment of competence of NB personnel for NBOG scope expressions and specific conformity assessment roles. If time and resources permit, SANTE F may arrange for JAT assistance to be provided, though such assistance cannot always be guaranteed for practical reasons.

4.4 **DA Report – content**. Normally, the DA report will contain the same nonconformities as identified in the JAT report. The DA report will usually be written in the language of the DA. Additionally, it should contain as a minimum:

- for each of the nonconformities identified, at least a summary on how corrections and CAPAs proposed by the NB have been assessed (as satisfactory or not) by the DA.

The DA may decide to finalise its report only after receipt and assessment of all evidence of the NB's actions;

- a clear recommendation on the proposed scope of designation of the NB (if applicable). The proposed *final* scope should be detailed in either NBOG F 2012-1 and / or NBOG F 2012-2.

Note: Based on the outcome of the assessment, this scope may well differ from the applied-for scope submitted with the NB's application and appended to the JAT report.

4.5 **Submission of the final DA report to the Commission**. SANTE F has agreed to handle the process of uploading both the final JAT and final DA reports including attachments and the proforma into the Joint Assessments workspace on CIRCABC on behalf of the DA whereupon both reports will be available for perusal by all of the EU / EFTA / EEA DAs.

Note: The format of DA reports is not prescribed. However it is helpful if they are additionally submitted in machine readable formats (as opposed to scanned pdfs) as this facilitates machine translation (if necessary).

4.6 **Translation**. In respect of those DA reports which are not written in English, as a courtesy to other DAs, SANTE F may arrange for a machine (or, time permitting, an official) translation and also upload this into the Joint Assessments CIRCABC workspace.

Note: The time limits for DAs to raise questions or comments on the report(s) are not affected by the upload of the translated report which is for informative purposes only.

5 Post-upload activities

5.1 Following the upload of both the final DA report and the final JAT report into CIRCABC, there is a one month period during which both the other DAs and the Commission services can address questions or raise concerns and request further information from the DA in question. In this regard the JAT is in a unique position to assess the DA's final report and determine whether the evidence provided justifies the DA decision on designation of the NB and the scope thereof. To that end, the JAT coordinator shall arrange for the members of the JAT to review the requisite documents. In the event that there are concerns or questions, the JAT coordinator shall submit these to the DA in writing.

5.2 Questions or requests from either SANTE F (or other Commission services such as the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs) or the other DAs do not need to be uploaded into CIRCABC. In the event that such questions or concerns are raised, the DA is invited to inform the SANTE F of the questions raised (from which other DA) and the answers it proposes. Such answers are to be provided to the questioning DA (and, for courtesy copied to SANTE F) within four weeks of receipt of the question.

5.3 During this one month period the other DAs may also request an exchange of views on the NB's application, organised by the Commission – the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.

5.4 Following the DA's response to questions or concerns raised (which will have been addressed to the questioning DA and copied to SANTE F), each of the other DAs or SANTE F and other Commission services have a further month in which they may individually or jointly address recommendations to the DA. The DA is obliged to take account of such recommendations when it finally takes the decision on the (re-) designation of the NB. If the recommendations are contrary to the DA's intentions as regards designation, and it decides not to follow the recommendations, the DA has two weeks in which to provide the questioning DA(s) its rationale for its (re-)designating decision. As a courtesy this response should also be copied to SANTE F.

5.5 When no questions and comments described above do arise, one month after the upload of both the reports into CIRCABC, the DA can then formally (re-)designate the NB and notify it's designation via the NANDO system.

6 References

References
90/385/EEC[3]
93/42/EEC[4]
98/79/EC[5]
Commission Regulation (EU) No 920/2013[6]

Sources
[1] NBOG F 2012-1 Notification form – Directive 93/32/EEC
[2] NBOG F 2012-2 Notification form – Directive 90/385/EEC
[3] NBOG F 2014-1 Application form to be submitted when applying for designation as a notified body
[4] NBOG designating authorities' handbook

Keywords
CIRCABC, designating authority, designation, joint assessment, notification, notified body, NANDO, (re-)designation, reporting, SANTE F

Date of issue
June 2016

[3] Directive 90/385/EEC on Active Implantable Medical Devices, O.J. L 189, 20.7.1990, p. 17, as amended
[4] Directive 93/42/EEC on Medical Devices, O.J. L 169, 12.7.1993, p. 1, as amended
[5] Directive 98/79/EC on *in vitro* diagnostic Medical Devices, O.J. L 331, 7.12.1998, p. 1, as amended
[6] 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, O.J. L 253, 25.9.2013, p. 8

Annex: Flowchart of activities and times

Timetable	Activity	Example timetable
18 months in advance of expiry of designation (if applicable) and around 6 months in advance of the anticipated on-site assessment	Application sent to DA from the NB	5 January 2016
Within 1 month of receipt of the application	Completeness check of application by DA (iterative process – may require repeated contacts with NB to seek further documentation)	5 Feb 2016
Within 2 months of the DA's receipt of the NB application (and any further documents requested)	Agreement between DA and SANTE F on dates for on-site assessment	27 Feb 2016
Around 3 months *before* the anticipated on-site assessment	SANTE F arranges interpretation if required and selects the JAT members	27 Feb 2016
Within 2 months of the DA's receipt of the NB application and around 3 months *before* the anticipated on-site assessment	SANTE F announcement letter for on-site assessment, requesting submission of full application and supporting documents including specimen assessment plan	27 Feb 2016
Around 3 months *before* the anticipated on-site assessment	Submission of full application and supporting documents by DA to SANTE F /JAT	Submission by 29 March 2016
JAT assessment of the application between 3 months and 1 month *before* the anticipated on-site assessment (i.e. the assessment will take up to 12 weeks)	Assessment of full application and supporting documents by DA and SANTE F /JAT	Assessment complete by 29 May 2016
One month *before* the anticipated on-site assessment	Teleconference between SANTE F / JAT and DA to discuss the DA and JAT assessments of the application, agree the assessment plan for the on-site assessment and select technical files for review	1 – 5 June 2016
Three weeks *before* the anticipated on-site assessment	DA to request the NB to call in technical files from manufacturers to ensure that these are available on-site in time for the on-site assessment	8 June 2016

Usually 4 to 5 days on site	On-site assessment in accordance with assessment plan agreed between the DA and the JAT	29 June – 3 July 2016
Within 45 days of completion of the on-site assessment	Production of JAT draft report and submission to DA for comments	17 August 2016
Within 25 days of receipt of the draft JAT report	Receipt of comments from DA; production of final JAT report and submission to DA	11 Sept 2016
Can take **several months** following completion of the on-site assessment	DA verification of NB's CAPA plan, further on-site assessments (if necessary) and subsequent production of final DA report and summary (in English)	7 March 2017 (8 months following completion of on-site assessment)
On receipt of the DA final report	Upload of final DA and final JAT reports into CIRCABC by SANTE F	11 March 2017
On receipt of the DA final report	SANTE F to arrange for JAT members to review uploaded DA report	Up to 11 April 2017
Within one month of the upload of DA and JAT final reports	Comment period for Commission services and other DAs	Up to 11 April 2017

If there are **no comments** / **questions** submitted to the DA from either other DAs or the JAT or the Commission services

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	DA (re-)designates the NB and sends notification to NANDO	12 April 2017 **(END OF PROCESS)**

If there **<u>are</u> comments** / **questions** submitted to the DA from either other DAs or the JAT or the Commission services

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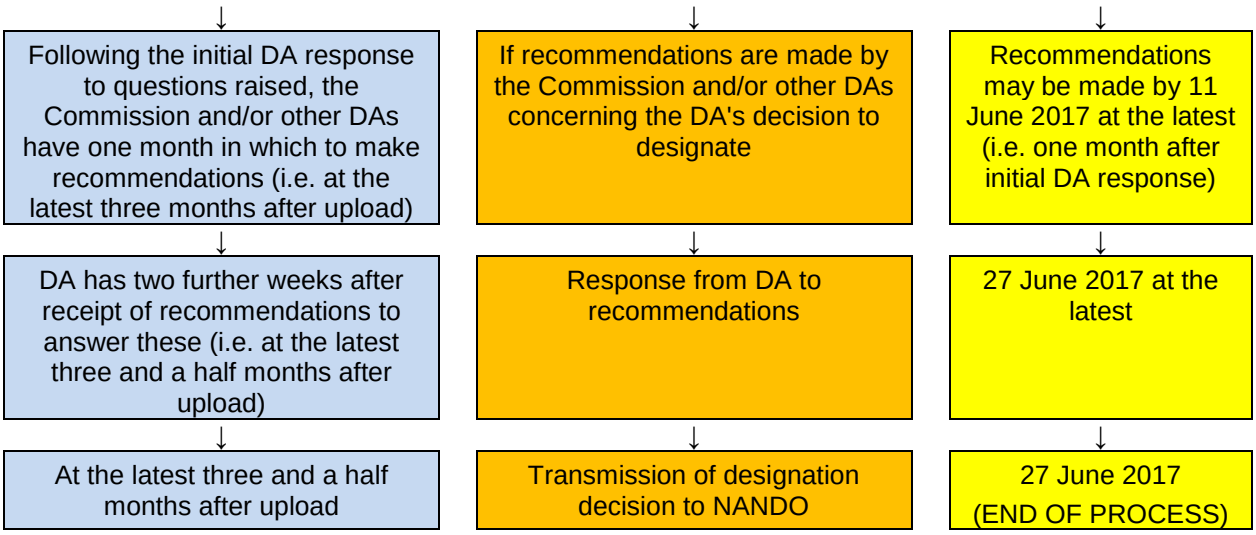
DA has one month in which to respond to questions. Questions may be sent, at the latest, one month after upload	Response from DA	For question sent on 11 April, DA response will be 11 May 2017



Total time from submission of application to (re-)designation – 18 months.