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Guidance on the renewal of designation and monitoring of notified bodies under Directives 90/385/EEC and 93/42/EEC to be performed in accordance with Commission Implementing Regulation (EU) 2020/666 amending Commission Implementing Regulation (EU) 920/2013

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1. Introduction

The COVID-19 pandemic has created extraordinary circumstances that demand substantial additional resources, as well as a continued availability of vitally important medical devices, that could not reasonably have been anticipated at the time of adoption of Medical Devices Regulation (EU) 2017/745 (hereafter referred to as 'MDR'). In order to allow Member States, health institutions and economic operators to prioritise the fight against the COVID-19 pandemic it was considered necessary to defer the application of certain MDR provisions by one year (i.e. until 25 May 2021)[1]. To ensure the continuous presence of a functioning regulatory framework for medical devices it was necessary to also defer by one year the date of repeal of the Medical Devices Directives 90/385/EEC and 93/42/EEC (hereafter referred to as 'the Directives').

The deferral of the date of repeal has a consequential impact on the designations of certain notified bodies under the Directives, including their ability to carry out their obligations and be operational until 25 May 2021. The current COVID-19 pandemic also affects the way in which designating authorities are able to perform the required appropriate surveillance and monitoring activities over notified bodies. To take account of these extraordinary circumstances, the Commission and the Member States, on 18 May 2020, adopted Commission Implementing Regulation (EU) 2020/666 amending Commission Implementing Regulation (EU) 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies (hereafter referred to as 'the Implementing Regulation')[2]. The amendment provides for a derogation from certain requirements on the renewal of designations of notified bodies and for alternative surveillance and monitoring activities that designating authorities should carry out.

In particular, in the interest of health and patient safety, and, to ensure consistency among the activities performed by designating authorities, this guidance document has been developed to outline common criteria for the renewal of designations of notified bodies under the Directives until 25 May 2021. In addition, this document intends to provide clarification on the appropriate activities performed by designating authorities over notified bodies in order to ensure an adequate level of surveillance in accordance with Article 5 paragraph 1, third subparagraph, of the Implementing Regulation.

[1] OJ L 130, 24.4.2020, p. 18–22.
[2] OJ L 156, 19.5.2020, p. 2–5

2. Scope

This guidance covers the following activities performed by designating authorities under exceptional circumstances, as referred to in Article 4(6) of the Implementing Regulation:

- renewal of designation under the Directives of notified bodies whose designation expires in the period from 26 May 2020 to 25 May 2021;
- surveillance activities to be performed by designating authorities in accordance with the Implementing Regulation under COVID-19 related restrictions, notably quarantine orders and travel restrictions.

This guidance does not apply to the procedure for the initial designation of a notified body under the Directives nor to the procedures for extensions of the scope of a notified body nor the lifting of limitations to the scope of a notified body[3].

3. Renewal of designation of a notified body until 25 May 2021

When deciding upon the renewal of the designation as a notified body in accordance with Article 4(6) of the Implementing Regulation, designating authorities should perform an appropriate assessment of the continuous competence of the notified body and its ability to accomplish the tasks for which it has been designated.

Designating authorities should base their decision to renew a designation on a review of documents, resources and activities, which lay ground for the verification of the criteria for designation as set out in the Directives and in Annex I to the Implementing Regulation.

This review should include in particular the following:

- assessment of relevant quality management system procedures, forms and records, in particular qualification criteria, procedures for selection and authorisation of persons involved in conformity assessment activities, procedures to ensure independence, objectivity and impartiality of the notified body's activities;
- assessment of an appropriate number of the notified body's reviews of the manufacturer's technical documentation, including clinical evaluations;
- assessment of an appropriate number of the notified body's personnel files;
- discussion of the results of the assessments of quality management documents and records with responsible personnel, including management responsible for the implementation and update of the quality management system as well as the notified body's assessors responsible for product review, including clinical evaluation, final review and decision-making processes;
- review of the outcome of the most recent on-site surveillance assessments and observed audits as well as of recent extraordinary assessment activities conducted by the designating authority

[3] See Article 11 of Directive 90/385/EEC and Article 16 of Directive 93/42/EEC.

When performing the above-mentioned review, the designating authority could also consider, if relevant, the outcome of the most recent joint assessment carried out in accordance with Article 3 of the Implementing Regulation as well as joint assessments recently carried out in accordance with the MDR.

In order to ensure a sufficient assessment the selection of the appropriate number of manufacturer's technical documentation reviews and personnel files to be reviewed should take into account the volume of the activities performed by the notified body, its scope of designation and any relevant vigilance data. The designating authority should be able to justify the number and type of files selected. The designating authority should ask the notified body to implement appropriate measures to correct any non-conformities found during the review

Normally, the renewal should include an on-site assessment. However, when exceptional circumstances prevent a designating authority from carrying out such an on-site assessment, alternative assessment measures should be used. Principles and arrangements of alternative measures described in Section 5 of this document concerning surveillance activities may apply.

The results of the assessment performed by the designating authority should be documented and the final decision on the renewal of a designation should be substantiated.

4. Notification and information to be provided to the Commission

In accordance with Article 4(6) of the Implementing Regulation, any decision by a Member State on the renewal of a designation as a notified body should be notified to the Commission and the other Member States through the New Approach Notified and Designated Organisations information system (NANDO) on or before the date of designation expiry. In line with the ordinary procedure, this should take place by means of submitting an update of the existing notification under the relevant Directive.

The Commission may request further information relating to a decision taken by a designating authority on the renewal of a designation. In particular, designating authorities should make available, upon request from the Commission, the reports describing the assessments performed in relation to the renewal of the designation and the relevant outcome as described in Section 3 of this guidance. This should clearly document the basis for the renewal decision detailing the elements reviewed by the designating authority to substantiate the decision, including the results of any surveillance and monitoring activities as described in Section 5 of this guidance. Relevant notified body's documentation should also be made available to the Commission on request.

5. Surveillance activities to be performed under exceptional circumstances

In the context of the current COVID-19 pandemic, the resulting travel and quarantine restrictions may significantly affect the ability of designating authorities to conduct their

mandatory surveillance and monitoring activities such as on-site assessments and observed audits of their notified bodies. Therefore, in accordance with Article 5(1) of the Implementing Regulation, in order to ensure an adequate level of surveillance, designating authorities should at least assess an appropriate number of notified body's reviews of the manufacturer's technical documentation, including clinical evaluations, and of personnel files, in addition to carrying out alternative surveillance measures. These alternative measures may include the following principles and arrangements:

- on-site surveillance assessments may be replaced by remote surveillance assessments using the most advanced available Information and Communication Technologies as deemed appropriate in accordance with Union legislation on information security and data protection;
- assessment of all relevant and required documents/records off-site.

In order to ensure a sufficient assessment, the selection of the appropriate number of notified body's reviews of the manufacturer's technical documentation, including clinical evaluations, and personnel files to be reviewed, should take into account the volume of the activities performed by the notified body, its scope of designation and any relevant vigilance data. The designating authority should be able to justify the number and type of files selected.