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Change of Notified Body

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applicable for ☒ AIMD, ☒ MDD, and ☒ IVDD **2006-1**

Change of Notified Body

Introduction

This document aims to provide manufacturers, Notified Bodies and Competent Authorities with guidance on the procedures that need to be taken into account when there is a change in the manufacturer's Notified Body. Changes can be as a voluntary change by the manufacturer or an enforced change as a result of the Notified Body no longer being able or willing to provide a service. Such situations should normally be included in the contract between the Notified Body and manufacturer.

The document is intended:

- to set up good practices of a manufacturer transfer from one Notified Body (NB) to another;
- to clarify the actions that need to be undertaken by the relevant parties (e.g. manufacturers, previous Notified Bodies, new Notified Bodies and, if relevant, Competent Authorities);
- to clarify issues relating to labeling and Notified Body number.

Background

The manufacturer has to assure that medical devices are placed on the market only if

a) they meet the essential requirements according to the relevant Directive(s)

b) a required conformity assessment procedure has been followed.

The manufacturer confirms the fulfillment of both requirements by affixing the CE marking to the products and drawing up a Declaration of Conformity covering the specified product(s) according to the requirements of the relevant Directive(s). If the conformity assessment procedure requires the intervention of a Notified Body then the identification number of the NB involved is included with the CE marking of the relevant devices. This kind of marking may cause problems in the case where the NB which has carried out the conformity assessment procedure and whose identification number is affixed to the medical device is no longer available for the surveillance required by the Directive. This particularly applies to quality system assessment procedures.

Two cases have to be distinguished:

1. "Voluntary" change

   The manufacturer (applicant) parts with the NB although the NB is able to continue to provide its service, or the NB parts with the manufacturer although he continues to produce the devices the NB has certified (**dissolution of service agreement**).

2. "Enforced/Involuntary" (unintended) change

   The NB is no longer able or authorized to offer its service, either completely or partly (**breakdown of NB**).

According to the New Approach Guide the manufacturer is free to choose the Notified Body. However during the certification cycle cases may occur where a manufacturer chooses or has to transfer from a Notified Body to another one. There are no provisions in the relevant Directives nor is there detailed information on how to proceed in such cases.

Case 1 'Voluntary' change

In these cases, the contractual partners (manufacturer and NB) have to agree upon the date until which the medical devices will be placed on the market under the terms of the contract with this NB. The change of Notified Body should not be linked to a diverging interpretation on a specific conformity or regulation issue.

Once this date has been reached, the manufacturer is only allowed to place devices on the market after a new conformity assessment procedure has been carried out by a new NB. The new NB should take account of the available results of tests and audits of the former NB within the new conformity assessment procedure for which it is responsible. For QS Annexes if there is valid certification and all documentation indicates that an established quality system is in place and in operation then the new NB may issue certification without performing an audit. Similarly for design and type examinations if there is valid certification and all documentation is in order there may be no need for the 'new' NB to undertake a technical review until the next renewal. However if the documentation identifies ongoing existing concerns then these should be fully addressed prior to issue of any new certification. In these situations some form of 'transfer' audit may be justified. Similarly if a QS surveillance audit has not been undertaken within the routine timescales as laid down by the 'new' NB then they should undertake an audit as soon as possible.

Under Directives the manufacturer is not allowed to lodge a parallel application for a certain product with another NB (e.g. Annex II, 3.1 of the MDD). Therefore, the modalities of the change have to be defined clearly and unequivocally between the parties in a contract. It is essential to relieve the old NB from the obligation to confidentiality in order to allow a direct contact between old and new NB.

In particular, the following aspects should be covered:

- Date of invalidity of existing certificates, e.g.

  Concerning the production of the devices, the existing certificates No. … become void at … (at the latest with the day of issue of a certificate by the new NB).

  The certificates are valid for the devices, which have already been produced.

- Duties to inform, e.g.

  The manufacturer will inform the NB of the dates when the placing on the market of these devices has been completed.

  The manufacturer commits himself to submit a copy of the certificate(s) of the new NB to the former NB.

  The manufacturer has to take care of any necessary notifications of change to the authorities.

  Relevant information should be provided on request to the new Notified Body by the Manufacturer and previous Notified Body (e.g. Technical information, Notified Body reports including non conformities, corrective actions etc.).

- Duties to label, e.g.

  The manufacturer will need to liaise closely with the new NB and the previous NB to agree to the extent that any old labeling (containing the old NB's number) can be used.[1] This applies as well to the use of the identification number in brochures and promotional materials.

- Responsibilities, e.g.

  With the date of issue of the certificate the new NB assumes full responsibility for all their conformity assessment tasks including those resulting from the change (e.g. contract, conditions of certification procedure).

  The timely surveillance of the quality system belongs to the tasks of the new NB.

- Property rights, e.g.

  The documents submitted and generated for the execution of the conformity assessment procedure remain the property of the previous NB.

- Regulations of costs, e.g.

  Costs incurring to the former NB due to requests after the expiration of the contract have to be borne by the manufacturer.

The change in the labeling has to be fixed to a specific production or batch number and has to be documented.

In certain circumstances the 'old' NB may not be co-operative and/or relations are poor between them and the manufacturer wishing to change. In such cases the 'new' NB will need to review all available documentation and decide on whether an audit is undertaken.

Case 2 "Enforced" change

The notification expires if a NB ceases its activities due to withdrawal of designation by the Designating Authority (partly or completely) or voluntarily abandons its designation (partly or completely). The same applies to liquidation. In these latter cases the NB is obliged to notify the Designating Authority immediately. As a consequence of the expiration as well as the withdrawal or the cancellation of the designation the NB is no longer able to fulfill its obligations for the surveillance of existing certificates. As described in chapter 6.2.2 of the "Blue Guide" [1] "the withdrawal of a notification does not affect certificates issued by the Notified Body until such time as demonstration can be made that the certificates should be withdrawn". However if de-designation by the DA was as a result of inadequate audits by the NB then the Competent Authority should review the impact on the NB certifications and take any necessary action to ensure the safety of the devices being placed on the market

The Competent Authority also has to take appropriate steps to ensure that another NB is taking over the tasks and – depending on the nature of the de-designation – to ensure that appropriate transfer measures are taken as well as time limits kept. The previous NB should[2] provide all relevant information and materials to the manufacturer's new NB to ensure a smooth transfer of the responsibilities for the conformity assessment.

In the above mentioned cases CAs may allow the manufacturer to place devices on the market for a certain time with the identification number of the previous NB although this NB does not offer its service any longer or is no longer existent.

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[1] The transition period should not exceed 6 months. In justified cases this period may be prolonged.

[2] There might be stricter obligations due to national laws

If the NB foresees its breakdown it is obliged to inform its clients early enough and to manage current contracts properly according to the guidance as described under case 1. In this case a new certificate should not be issued solely on the basis of the previous NB's documentation but a separate review of the manufacturer's documentation and/or a site visit by the new NB may be necessary.

If the breakdown of the NB is not foreseeable the procedure should be as follows: The NB immediately informs the holder of certificates being subject to surveillance by this NB. The Designating Authority informs the Competent Authorities for the manufacturers concerned. The manufacturers are obliged to contract with a new NB taking the tasks. The manufacturer and the new NB have to come to an agreement from which product, serial or batch number the new NB is responsible for the proper implementation of the conformity assessment procedure and until which product, serial or batch number the identification number of the former NB may be affixed. The CE marking along with the identification number of the previous NB should be notified to the manufacturers' Competent Authority.

The process of changing NBs must ensure that all NB tasks for the conformity assessment are properly performed according to the requirements of the Directives and that there is an unambiguous traceability to the responsible NB for every medical device placed on the market.

Sources [1] Guide to the Implementation of Directives Based on the New Approach and the Global Approach, European Commission 1999

Keywords Change, conformity assessment, de-designation, expiration, Notified Body, withdrawal

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