



The European Association Medical Devices - Notified Bodies

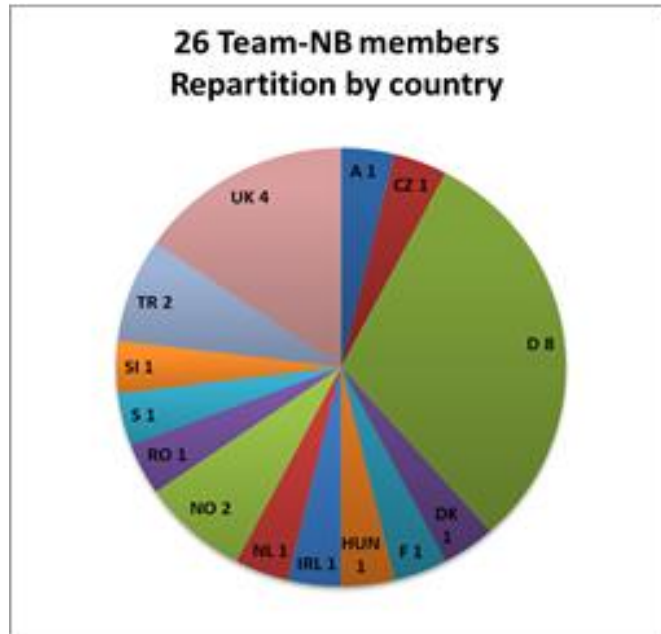
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Editor : Francoise SCHLEMMER (FSC)	Date : October 20 <sup>th</sup> , 2014
<b>PRESS RELEASE</b> Team-NB – Code of Conduct October 20 <sup>th</sup> , 2014	

During the October 14<sup>th</sup> General Assembly of Team-NB association, the main topic was the Code of Conduct with 2 different aspects:

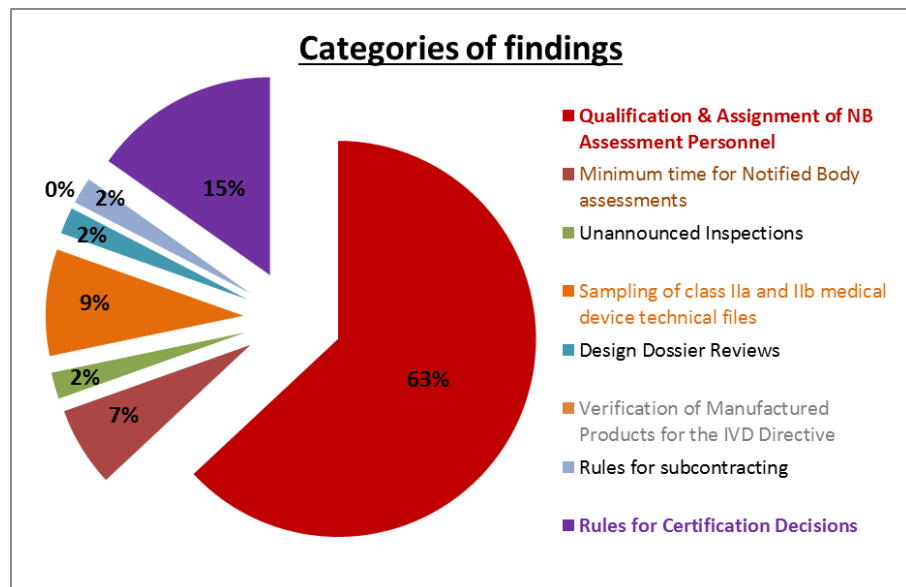
On one hand, a point was made on the enforcement of the Code of Conduct through a pool of experienced auditors coming from NBs, Industry and Competent Authority.



Until today, nearly 2/3 of the 1st cycle took place. Full cycle is expected to be completed late 2015.

So far, the audited notified bodies were not dissatisfied on the experience from those audits. Of course there is room for further harmonization in the audit team. To this end a training day has been planned in November with the pool of auditors and the members of the CoC board.

During these audits, the auditors pool has pointed different categories of findings



On the other hand a discussion took place regarding the approbation of a new version of the Code of Conduct. Many comments were received showing the interest of the members in this important document. Taking that into consideration, it was decided to split the work.

In a first step the reasonably straightforward comments were approved during the General assembly meeting and will be published in a revised **Code of Conduct version 3.3**.

## **Code of Conduct for Notified Bodies**

**under Directives  
90/385/EEC, 93/42/EEC and 98/79/EC**

**"Improving implementation of the European CE  
certification of medical devices through harmonization of  
quality and competence of Notified Bodies"**

Version:3.3

It has been agreed to a 6 months transition period for the implementation of the new version. Secondly, a working group was set up with the aim to come up with a further draft to be presented at the April General Assembly meeting for adoption. The working group will meet in January in Cologne with representatives of 8 members' volunteers. Main focus will be further detailing on qualification towards technical and process skills, and on unannounced visit details.