The European Association Medical Devices - Notified Bodies

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PRESS RELEASE
Team-NB – New version of CoC
July 29th, 2014

TEAM-NB *The European Association for Medical Devices of Notified Bodies* is a non-profit association, whose members are active in the field of certification of medical devices. The association is proud of valuing and promoting high technical and ethical standards as defined in its Code of Conduct.

The **Code of Conduct** for Notified Bodies under Directives 90/385/EEC, 93/42/EEC and 98/79/EC was adopted as mandatory by Team-NB in 2012 with effect on January 1st 2013. The document's purpose is to improve the implementation of the European CE marking certification of medical devices through clarified organizational criteria, management of competences and assessment practices.

The final **version 3.2** of the Code of Conduct, updated with changes agreed at the April General Assembly meeting is now available.

A **draft version 4.0** is in elaboration with new important modifications.

This new version should be implemented immediately. You will find below a list of the changes in version 3.2 of CoC compared to version 3.1:

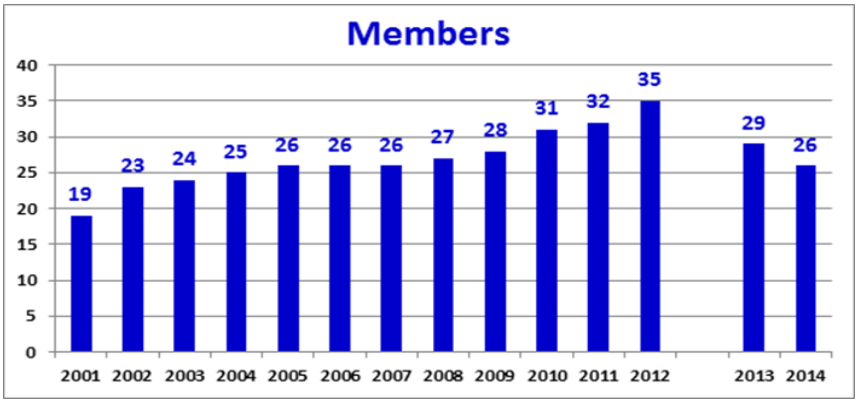
- Statement to be compliant to applicable requirements of EU medical devices Directive instead of to its core principles.
- As guidance on OBL is written by authorities at this moment, topic was removed from to-do list for further chapters on CoC
- Generic device group now referring to meaning in GMDN
- Product specialist section now referring to NBOG codes and use of external experts such as clinicians clarified
- Qualification allowed on series of partially observed audits
- Further detail on expansion and maintenance of qualification added
- State of art in dossier review more clearly linked to harmonized standards
- Section on unannounced visits geared to sampled products
- Adjustments to frequency of unannounced visits for high risk devices, addition of sampling for Is/Im and IVD selftest under unannounced visit scheme
- Mechanism to go back to normal frequency after resolution of 'often non-compliant' cases.
- Rewording of need to visit subcontractors of virtual manufacturers
- Sampling of technical file reviews clarified to only apply to IIa and IIb devices
- Use of additional experts such as clinicians in design dossier review further clarified
- Outsourcing of work as approved by national designating authority; affiliate legal entities are seen as external organizations
- Further details provided on assessment to CoC compliance

These are mainly minor changes to put the CoC in lines with European guidelines as well as wording which has been improved.

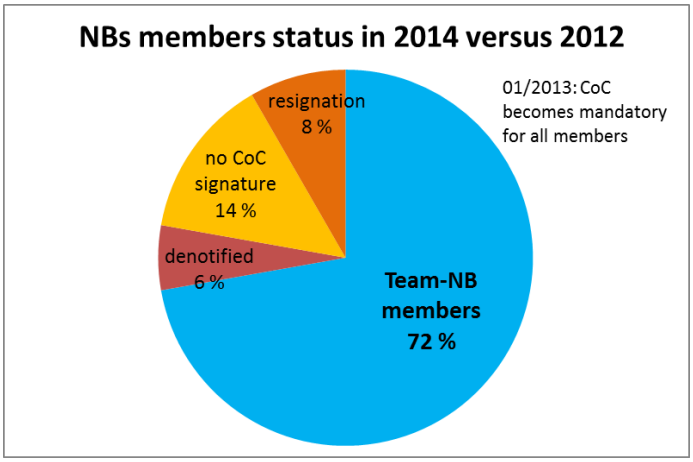
In the draft version 4.0, there are important points to discuss, such as:

- Define criteria to review technical knowledge and criteria for training and proofs
- Specific need to review of files under sampling regime
- Clarify the qualifications of auditors based on Technical areas
- Time needed for class Is devices in annex II
- Review minimum time spent on technical file reviews

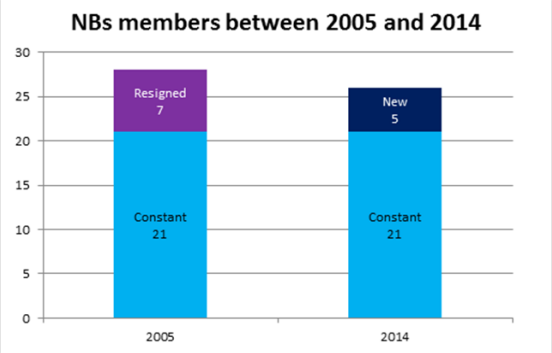
Moreover as a general information, from July, 1st, 2014, Team-NB has 26 members with the resignation of 3 members since the beginning of the year. One of them was following a fusion.



The diminution after 2012 is corresponding to the CoC becoming mandatory to all members.



With 80% of the members stable over the last 10 years



Team-NB provides information to all the sector stakeholders through its web site

www.team-nb.org

with documents such as recommendations, position papers or other useful information with news and events.