The **E**uropean **A**ssociation **M**edical devices
Notified **B**odies

Presentation of the changes and impact of the upcoming Medical Device regulations

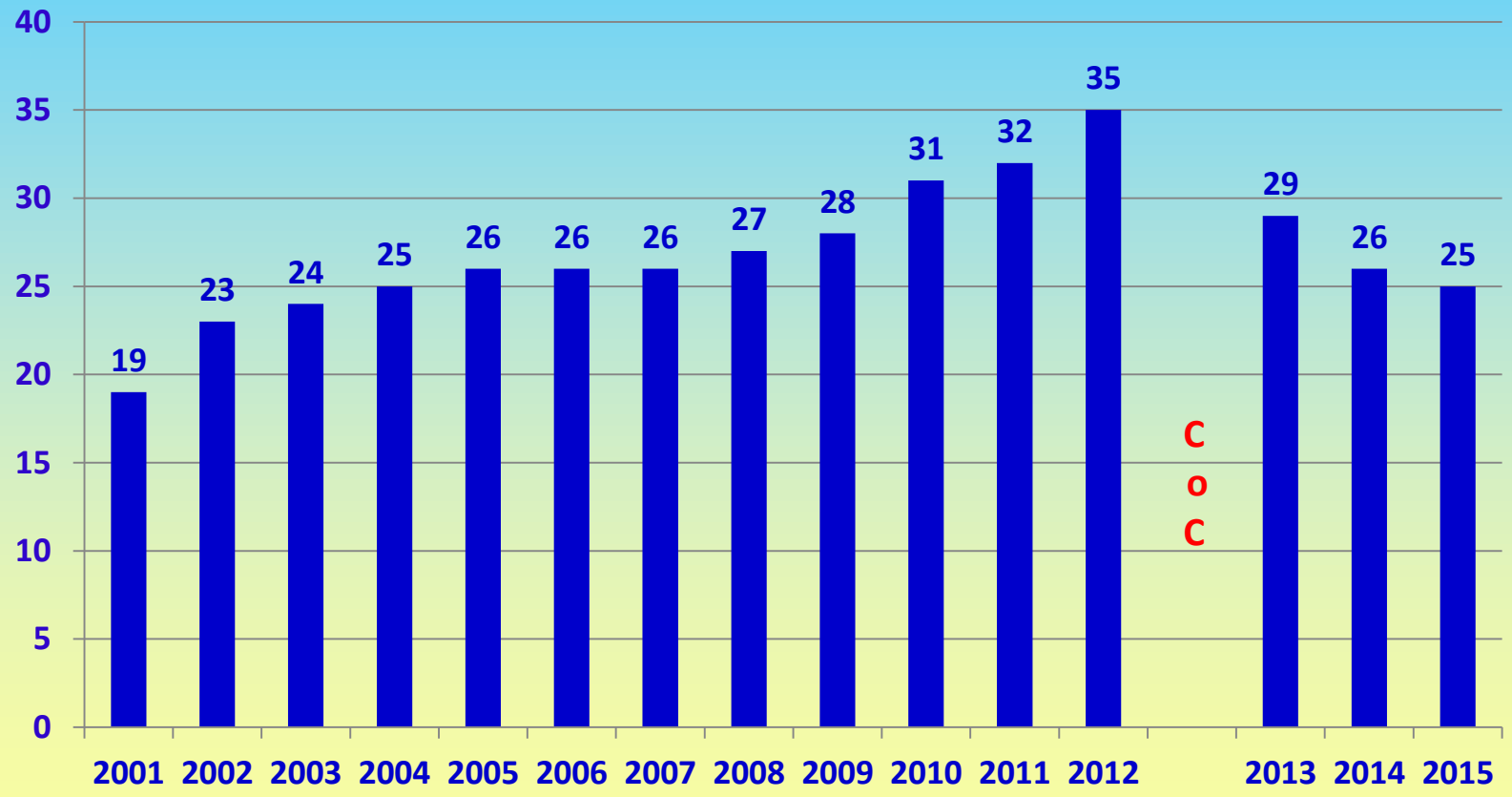
Françoise Schlemmer, Team-NB Director
Euromcontact, December 9th, 2015

TEAM-NB

- **Aims:**
  - Communication with
    - European Commission
    - Competent Authorities
    - Industry
  - Promote technical and ethical standards
  - Participate in improving the legal framework
  - Contribute to harmonization
  - Represent Notified Bodies

TEAM-NB

Members



Context of TEAM-NB

Commission

CEN
CENELEC

EMA

NB-MED ★

MDEG ★

NBRG ★

NBOG

COEN

Experts Groups
EUDAMED,
IVD,
Vigilance

M
R
A
- Switzerland
- Canada
- Australia
- New Zealand
- USA
- Japan, …

CPME

CMC

TEAM NB

EUROMContact,
EUCOMED, MedTech,
FIDES, EDMA, EUROM
UEAPME, Eur Assoc of Auth
Repr

IMDRF International Medical Device Regulators Forum

I
M
D
R
F

Health
Professionals

Notified Bodies

Manufacturers

Authorised
Representatives

Notification

Accreditation

28 Competent
Authorities

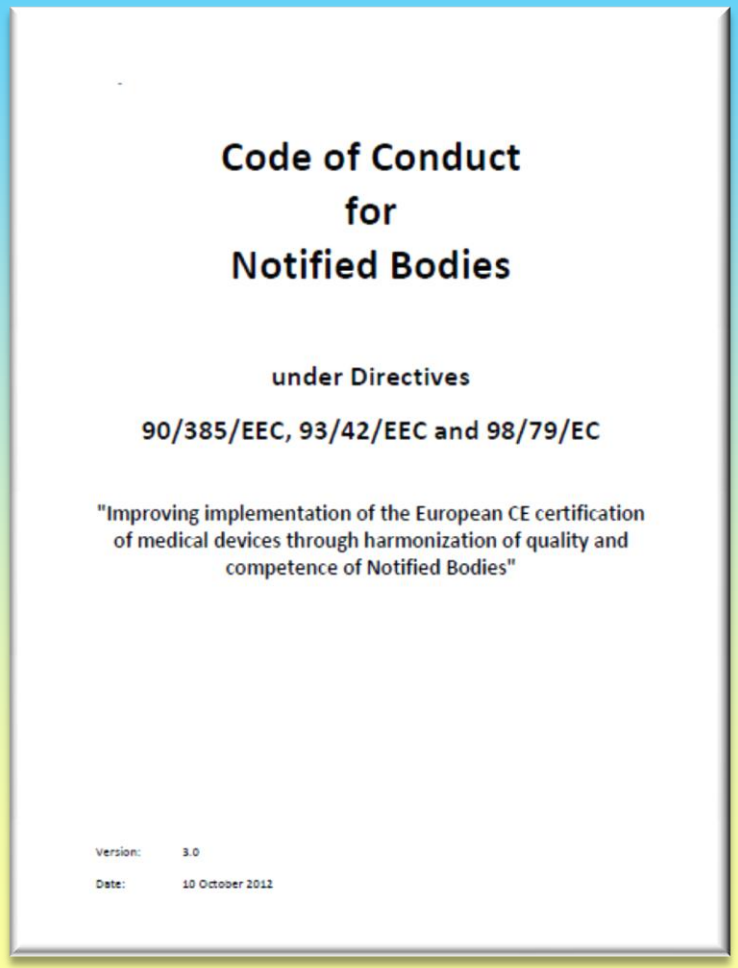
National Accreditation
Bodies

★ TEAM-NB representatives

Code of Conduct V 3.3

- Mandatory to sign for TEAM-NB members
- Available on website

  www.team-nb.org
- New version includes:
  - Peer assessment
  - Unannounced Visits
  - Details on Code of Conduct Compliance Audits by TEAM-NB auditors
- Version 3.4 in progress:
  - raising qualification levels



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: 3.0

Date: 10 October 2012

Code of Conduct : detailed content

- Implementation, enforcement and monitoring of the Code of Conduct
- Unannounced visits
- Qualification and Assignment of NB Assessment Personnel
- Minimum time for Notified Body assessments
- Sampling of class IIa and IIb technical files
- Design Dossier Reviews
- Rules for subcontracting
- Rules for Certification Decisions

Code of Conduct : peer review audits

- Code of Conduct audit
  - Cycle
    - 1st cycle : 3 years 2013-2015
    - 2nd cycle : 2 years 2016-2017
  - Audits
    - 1 audit of a NB member/cycle
    - 2 auditors in 1 day by audit
    - Standard : Code of Conduct
  - Pool of 5 auditors

    Mainly young retired experience people coming from :
    - Consultancy
    - Notified Bodies
    - Competent Authorities

Recommendation 2013/473/EU

- **Key Elements on Product assessment**
  - Essential safety and health requirements
  - All risks evaluated; Preclinical, Clinical, PMCF
- **Key Elements on quality system assessment**
  - Manufacturer's premises (incl. subcontractors or suppliers)
  - Critical processes
  - Obligations in case of outsourcing

Recommendation 2013/473/EU

- **Key elements on unannounced audits**
  - 1 day two auditors
  - All manufacturers
    - or critical subcontractors
    - or crucial suppliers
  - Sampling of a recent production
    - Technical documentation, forms
    - Sample 3 < 99
    - Testing on site or in a lab
  - 2 critical processes audited

Recommendation 2013/473/EU

- **Key elements on unannounced audits**
  - Frequency table of visits in a 3 year period

(only guidance, NB-Med Consensus Version 20140812)

- **Class I sterile, measuring function & Class II a / IVD self testing (under Annex IV)**

Suspicion (*)	None	Yes
NC rare	1	2
NC frequent	2	2

- **Class II b / List B IVD & Class III / AIMD / List A IVD**

Suspicion (*)	None	Yes
NC rare	1	2
NC frequent	2	3

(*) Suspicion: specific indicators to suspect nonconformities

UAVs Notified Bodies working group

UAVs working group topics

- Access to countries with difficult entry requirements
- Ensure UAVs are truly unannounced
- Costs for UAVs (travel)
- Impact for small companies
- Manufacturers under more than 1 directive (several UAVs?)
- UAVs for large companies (number of days?)
- UAVs at supplier / subcontractors premises?
- Selection of tests to be witness (not class III); to be done in accredited lab
- Feedback to NBOG on open issues / unclear requirements

New regulations positions

State of play just after start of Trilogue

Commission	Parliament	Council
• UDI	• UDI: single system; to be updated with PMCF data	• UDI on label, packaging, DoC; included in implant card, stored by health institutes; on NB certificates IIb implants and III
• High risk: Summary on safety and performance data	• Safety and full clinical performance report + layman's summary	• Detailed requirements on summary
• EUDAMED: Public access	• EUDAMED: public access to vigilance and market surveillance data	
• Manufacturer/AR, importers registered		

New regulations positions

Legal Manufacturer

- Full control of the distributor
  - ✓ Regular audits
  - ✓ Incoming inspection process
- Control against MDR/IVDR

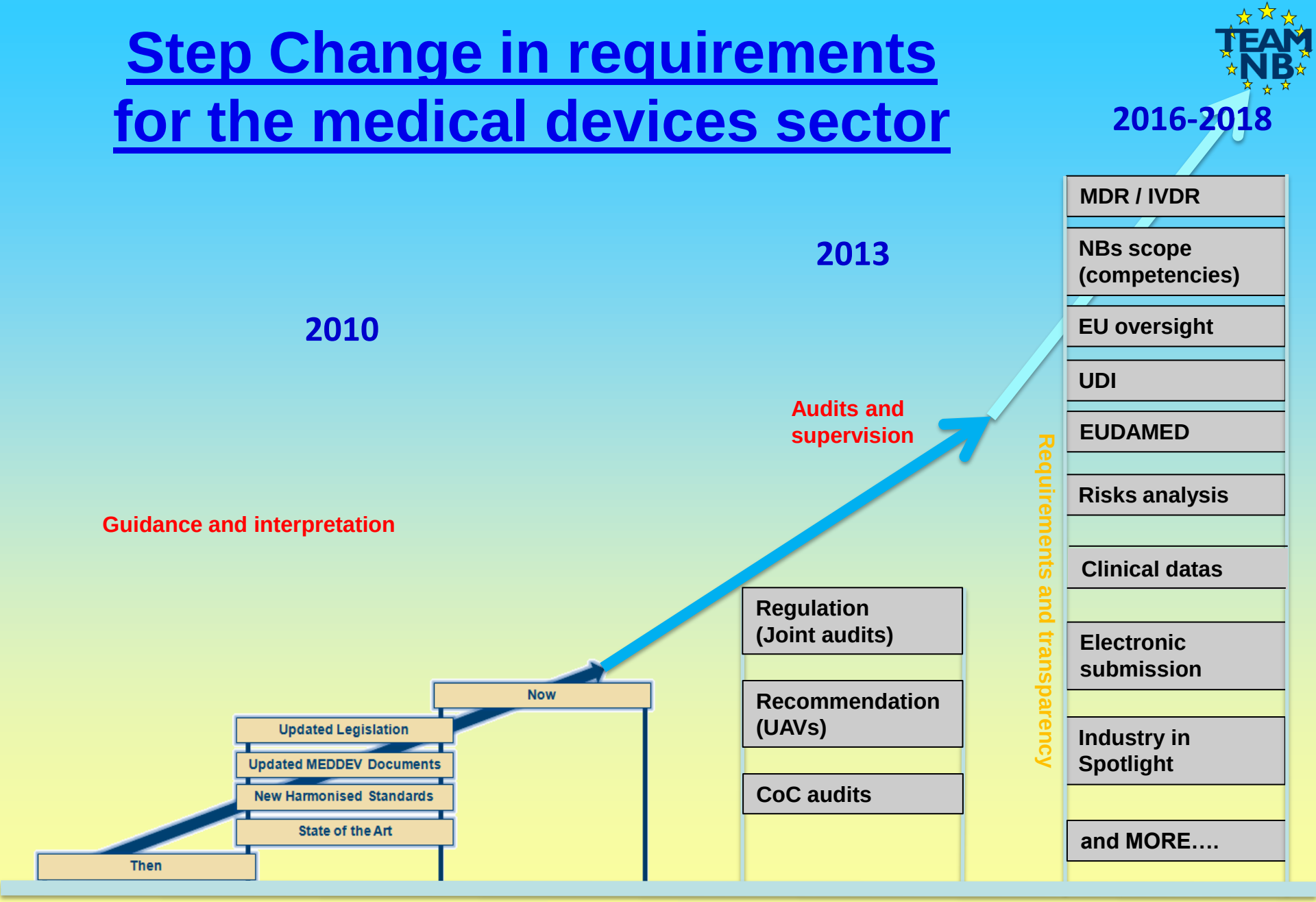
Distributor

- Control against MDR/IVDR of the Manufacturer

  - Article 12: General obligations of distributors

  - ✓ CE marking
  - ✓ Instruction For Use
  - ✓ UDI
  - ✓ etc…

Step Change in requirements for the medical devices sector



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www.team-nb.org

Members


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...making excellence a habit.
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