The European Association Medical devices
Notified Bodies

Unannounced Audits

Status, Implication, Impact & Management

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MedPharmPlast Europe Conference

23 June 2015, 3 p.m – 3:25 p.m.
Clariant Innovation Centre Frankfurt

The Author

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The European Association for Medical Devices of Notified Bodies

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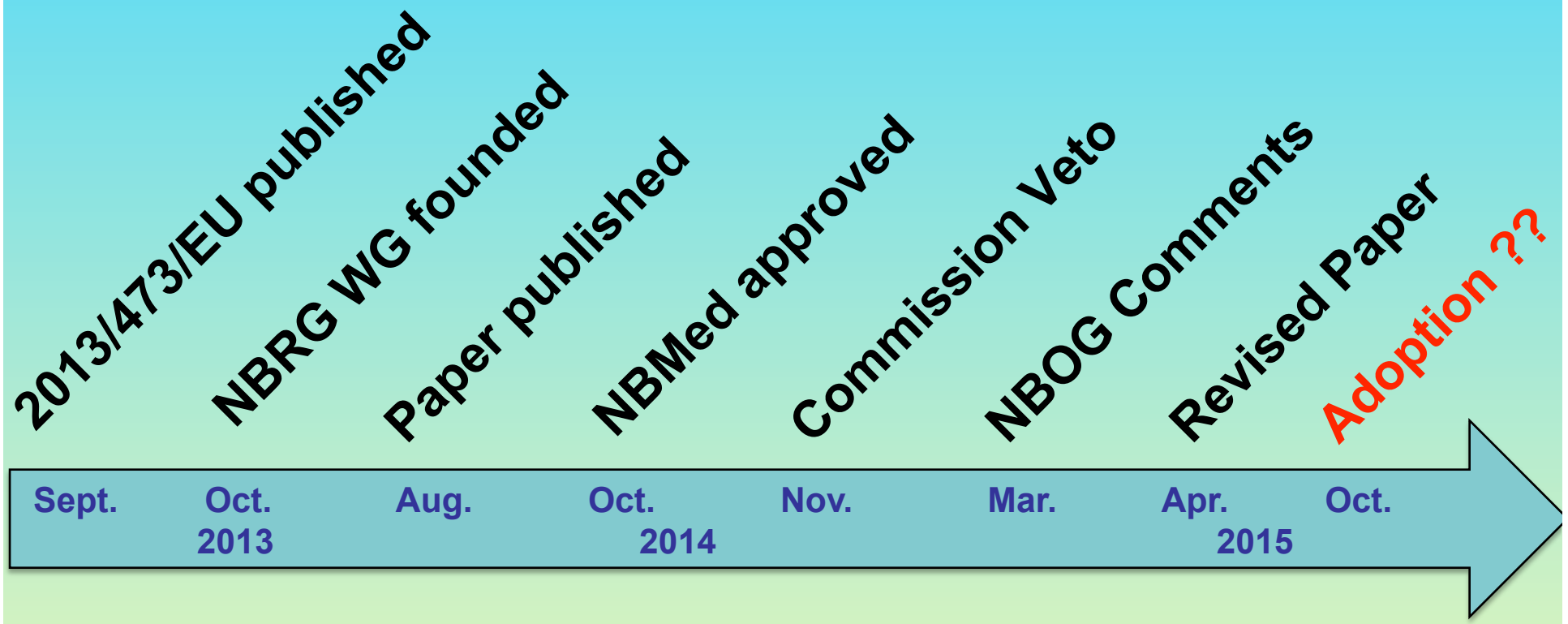
Status


2013/473/EU published
NBRG WG founded
Paper published
NBMed approved
Commission Veto
NBOG Comments
Revised Paper
Adoption ??
Sept.
Oct.
2013
Aug.
Oct.
2014
Nov.
Mar.
Apr.
2015
Oct.

Relevant Requirements

- Carry out UA's at least once every third year.
- Increase the frequency if
  - the devices bear a high risk,
  - the devices in question are frequently non-compliant,
  - there are reasons to suspect non-conformities.
- Unpredictable timing, minimum a day / two auditors.

Relevant Requirements

- Check a recently produced sample for conformity of the technical documentation vs. legal requirements
- Include verification of the manufacturer's traceability system and of all critical components and materials
- Encompass a file review and if necessary, a test of the device

Guidance Paper : Testing during UA's

Audit terms

Objectives : Product testing if no alternative to verify conformity

Tests with minimum ressources : use Manufacturer's Personnel / Test Equip. / Tests at subcon's

Parameters	What to be tested			Where to be tested*				How the test is to be done				
	Raw Mate-rial	Critical Compo-nents	Device	Manu-facturer's premises	offsite at critical subcon / crucial supplier	offsite at NB's Lab	offsite at 3rd Party accre-dited Lab	NB witnesses Manufac-turer,	critical subcon / crucial supplier conducting the test	offsite at NB's Lab	offsite at 3rd Party accre-dited Lab witnessed by manufactur er	offsite at 3rd Party accredited Lab witnessed by critical subcon / crucial supplier
Medical Devices / AIMD / IVD	case dependant			X	O	O	O	X	O	O	O	O

X = preferably: the preferred option for testing when needed

O = conditional : alternative options in the event that the preferred testing is not sufficient.

* = dependent on where technical equipment is available

Guidance Paper : Testing during UA's

Frequency

Objectives : Minimum No. !

No handicap for Producers of High Risk products with low level of Non-Conformities / without reasoned suspects

Risk group	Class I s, m		Class II a / IVD self testing (under Annex IV)		Class II b / List B IVD		Class III / AIMD / List A IVD	
Reasoned Suspicion	none	yes	none	yes	none	yes	none	yes
Frequency of NC: Rare	1	2	1	2	1	2	1	2
Frequency of NC: Frequent	2	2	2	2	2	3	2	3

Impact and Management of UA‘s

Impact :

- **Overall predominantly positive !!**
- **Resonable time frame to focus in depth on the value chain to complement regular audits**
- **Improvement of trustful collaboration and support level**
- **Identification of fraudulent activities questionable**

Impact and Management of UA‘s

Management :

- Challenging at all !!
- Ressource management / availability of Test Engineers
- Framework planning vs. immediate action
- Learning curve still ongoing

Lessons Learned from 1st UA's

- Lack of presence from key personnel (MD, RA / QA Officer, etc.)
- Due to small batches selected sample not always on hand in production or on stock
- High level of flexibility demanded from Auditors

…. don't ring the bell before 9 a.m. …!