

GHTF meeting Singapore

Refurbished Medical Equipment

Peter Linders

Summary

- **Confusion**
- **Refurbishment is desirable**
- **Refurbished ME needs more attention**
- **Definitions: needed, but possible ?**
- **Conclusions**

PS: capital medical equipment

Confusion

In Europe, MD-Directives do it all

- **New ME and fully refurbished: same treatment**
- **Just comply with Directives**

**But, eh, what is
fully refurbished ?**

Confusion

In Europe, Notified Bodies develop guidance

- **MEDDEVs and NB-MED Recommendations**
- **NB-MED/2.1/Rec5 describes “Fully Refurbished”**

**Brave attempt,
but ... no definition**

Confusion

In NB-MED/2.1/Rec5, “Fully Refurbished”:

both

- **stripping / checking suitability / replacement / assembly / testing / identify as fully refurbished**
- **placed on the market under name, without changing intended use**

✓ *intent to fully refurbish*

✓ *assign a new useful life*

**Leaves lot of
“open space”**

Confusion

Situations:

New intended use

Full refurbishment

Refurbishment

Repair

Maintenance

No maintenance

Confusion

Some additional complications:

- **Upgrades (HW or SW)**
- **Original CE-mark still valid ?**
- **CE devices versus pre-CE devices**
- **3rd party involvement**
- **User modifications**

**Why full
refurbishment ?**

Confusion

Some additional complications (2):

- **Fully refurbished ME must comply with latest regulations, incl. harmonized safety standards**

May be expensive and unattractive: full redesign needed for compliance with new rules.

Examples: EMC (IEC 60601-1-2), CT (60601-2-44), mammography (60601-2-45)

Why then full refurbishment ?

Refurbishment is desirable

Why (full) refurbishment?

- **Extend useful life of capital equipment**
- **Economic motives**
- **Trade-ins**
- **Environmental motives**
- **Reuse of components/subsystems**

NB customer satisfaction !

**Why then full
refurbishment ?**

Refurbishment is desirable

Why full refurbishment?

- **Customer may wish compliance with new regs. but at lower price than new machine**

**Why then full
refurbishment ?**

Refurbished ME needs more attention

Why still full refurbishment? If no FR, then

- **Any modification possible (except for other intended use, but who's to check)**
- **No need to comply with latest standards**
- **Old-timers can live “forever”**
- **In line with MDD exemption for local adaptation**

What about safety and essential performance ?

Definitions, needed but possible?

Medical devices and ME are regulated

- **To comply with essential requirements/principles**
- **For entering the market**
- **...**
- **What happens afterwards is undefined**
- **Definitions are needed, but impossible**

So, what to do ?

Conclusions

- **Refurbishment of capital ME is desirable**
- **Keep ME in good condition**
- **Keep ME in “state of the art”**
- **Regulation is related to regulating of use**
- **Full refurbishment may be too expensive**
- **Definitions are needed, but impossible**