Role of Standards in the Assessment of Medical Devices

GHTF/SG1/N012:2000

(and updates due in 2008 version)

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Role of Standards in the Assessment of Medical Devices

Which Standards?

Answer:

International Consensus Standards

- Basic (horizontal)
- Group (semi-horizontal)
- Product (vertical)

International standards represent global opinions of experts from all interested parties, including industry, regulators, users and others

- Which Standards?
- What is their Role?
- Recognised Standards
- 2008 Updates
- Revision to Standards
- Change to Status
- Use during Transition
- Using Superseded Versions
- Alternatives to Standards

Role of Standards in the Assessment of Medical Devices

What is their Role?

Answer:

- International consensus standards are a tool for harmonization to assure the quality safety and performance of medical devices as set out in the Essential Principles
- International consensus standards can set out the technical specifications that an authority can 'Recognise' as meeting one or more Essential Principles
- Manufacturers who meet 'Recognised Standards' can benefit from a 'Presumption of Conformity' to the applicable Essential Principles

Role of Standards in the Assessment of Medical Devices

Recognised Standards

In order for a manufacturer to know which standards to be used, it should be 'Recognised'

Authorities should provide for:

- Recognition Mechanism
- Identify the Standards (version and date)
- Periodic Review
- Official Publication of Lists
- Voluntary (exceeds standard, particular product characteristics or innovation)

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2008 Updates

- Extend Scope to include *in vitro* diagnostic medical devices
- Provide guidance on use of recognised standards that have been revised or replaced

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Role of Standards in the Assessment of Medical Devices

Revision to Standards

Why are standards revised?

- Standard no longer deemed to meet the Essential Principle
- Essential Principles change
- Technological progress necessitates an update to the standard

So revision is a normal activity

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Change of Status

So revision is a normal activity, but revision has an effect on status

So does post-market experience of device safety

- An authority may cease to recognise a standard due to safety concerns identified trough post-market activities or through user experience (and request a revision or alternative solution)
- And in all cases the authority will have to submit the new revision to the recognition mechanism, with the replacement of the old revision

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Change of Status

Depending on the reason for ceasing recognition of a standard the authority should:

- set a date of removal of presumption of conformity
- which could be immediate for safety concerns
- for reasons other than safety, this date should allow manufacturers a sufficient 'Transition Period' to adapt

Role of Standards in the Assessment of Medical Devices

Use during Transition

The world doesn't stop for standards.
What do I do with the devices I have in the design pipeline and on my factory floor?

Which standard do I use, the old or the new?

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Role of Standards in the Assessment of Medical Devices

Use during Transition

Answer:

During the Transition Period – Both

After the Transition Period – Only the new

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Role of Standards in the Assessment of Medical Devices

Use during Transition

Answer:

During the Transition Period – Both

After the Transition Period – Only the new

If you want to maintain the benefit of presumption of conformity

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Using Superseded Versions

You can use superseded versions but you do not benefit from the presumption of conformity

You still have to meet the Essential Principles and you should justify your decision through a documented risk assessment and take any risk mitigation action as appropriate

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Role of Standards in the Assessment of Medical Devices

Using Superseded Versions

What about devices I've already produced and that are out there in the market?

Devices already in the supply chain or with the user prior the transition period (i.e. designed and manufactured to the superseded version) are not affected by the recognition of the new standard and can continue to be supplied and used...

...unless there are safety implications in which case the manufacturer should implement a risk mitigation strategy and take appropriate action to address these safety concerns

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Alternatives to Standards

Standards are voluntary – alternatives are allowed

Manufacturers may use “non-recognised” standards, in whole or in part, or other methods.

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Alternatives to Standards

Alternative means of demonstrating conformity with the Essential Principles may include:

- national and international standards that have not been given the status of a "recognised standard" by the Regulatory Authority;
- industry agreed methods;
- internal manufacturer standard operating procedures developed by an individual manufacturer;
- other sources that describe the current state of technology and practice related to performance, material, design, methods, processes or practices.

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Alternatives to Standards

The acceptability of such other solutions should be justified and may be subject to review by the RA/CAB, as appropriate.

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Thank You For Listening

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