COMMENTARY ON RELEVANCE OF STANDARDS TO THE ESSENTIAL REQUIREMENTS

MEDICAL DEVICE DIRECTIVE

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The following commentary is intended to assist manufacturers, standards drafting bodies and regulators, to identify standards which may be adopted as harmonised standards, and hence used to demonstrate compliance with the Essential Requirements.

This document concentrates on the identification of the appropriate horizontal standards, and it is hoped that the number of vertical standards required would be minimal.

The Essential Requirements are not written in a fashion enabling simple and unambiguous identification of the relevant standards. The document therefore contains some remarks in this respect.

It is considered that the rigorous application of the EN 29000 series, supplemented by the EN 46000 series, of quality standards should ensure that a device satisfies all the Essential Requirements even in the absence of harmonised standards, by the use of the manufacturer's own standards addressing the ERs.

Manufacturers are recommended to examine their device with the aid of this document while completing the Device ER/Standards checklist.

Draft standards should be planned and monitored with the aid of the Work Item ER/Standards checklist using this commentary as a guide to planned and existing horizontal standards.

ERCOM4/3
27 October 1991

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

I. General Requirements

1. **The device must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, users and, where applicable, other persons. The risks associated with the devices must be reduced to an acceptable level compatible with a high level of protection of health and safety.**

Comment:

This is a general statement. Provided all the other applicable Essential Requirements are satisfied then this will also be satisfied.

The application of harmonised quality standards should ensure compliance.

Harmonised standard

EN 29001 + EN 46001

Action

Nil

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

I. General Requirements

2. The solutions adopted by the manufacturer for the design and construction of the devices must comply with safety principles, taking account of the generally acknowledged state of the art.

Comment:

This is a general statement. Provided all the other Essential Requirements are satisfied then this will also be satisfied.

The reference to state of the art is vague since it is not clear whether this refers to the date of design or construction.

Harmonised standard

Not applicable, although design control requirements of EN 29001 + EN 46001 should ensure compliance.

Action

Nil

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

I. General Requirements

3. **The devices must achieve the performance intended by the manufacturer, i.e. be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1(2) (a) as specified by the manufacturer.**

Comment:

This is a performance requirement. The manufacturer will need to have evidence that the device meets any claims made by him. The test procedure must reflect the manufacturer's specification.

When the manufacturer is operating a quality system to EN29001 + EN46001 or EN29002 + EN46002 this requirement is already covered.

Harmonised standard

EN 29000 +EN 46000 series

Action

Nil

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

I. General Requirements

4. The characteristics and performances referred to in sections 1 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device indicated by the manufacturer, when the device is subjected to stresses which can occur during normal conditions of use.

Comment:

The manufacturer should be able to demonstrate that he has considered the sort of stresses the device will experience during its expected lifetime, and that it will withstand them.

Harmonised safety standards e.g. EN 60601 series will normally address these requirements for medical electrical equipment.

The application of EN 29001 + EN 46001, design control, should include such considerations.

Harmonised standard

EN 29001 + EN 46001

EN 60601 series.

Action

CENELEC adoption of IEC 601 part 2s as ENs after checking.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

I. General Requirements

5. **The devices must be designed, manufactured and packed in such a way that the characteristics and performances during their intended use are not adversly affected in the storage and transport conditions (temperature, humidity, etc.) laid down by the manufacturer.**

Comment:

Design control by application of EN 29001 + EN46001 should cover this requirement.

Compliance with EN 60601 series covers this requirement for active medical devices.

Packaging of Medical Devices is also covered by 8.3 and 8.5.

Harmonised Standard:

EN 29001 + EN46001

EN 60601 series

Standard and Guidance on packaging of sterile medical devices.

Action

CEN to complete ENs on Guidance and General Requirements for Packaging Materials for sterile medical devices.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

I. General Requirements

6. Any undesirable side effects must constitute acceptable risks when weighed against the performances intended.

Comment:

If side effects or undesirable conditions are likely then these must be clearly indicated in the labelling or the accompanying documents, in order that the user can make a decision as to whether to use the device or not. Clinical evidence will need to be available to justify statements.

See also ER 13.3 and 13.6

Design control within EN 29001 should address this.

Harmonised Standard:

EN 29001

EN 60601 series for medical electrical devices.

ENs on Biological safety

Action

CEN TC206 to adopt standards for biological safety.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

II. Requirements regarding Design and Construction

7. Chemical and Physical properties

7.1 The device must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I. "General Requirements". Particular attention must be paid to:

- **the choice of materials used, particularly as regards toxicity and, where appropriate flammability;**
- **the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device;**

Comment:

Both these seem to relate to biocompatibility and biological safety.

The inclusion of flammability is probably intended to cover the safety of the patient in the event of the accidental ignition of a medical device worn by, or attached to the patient, and/or toxic gas emissions resulting from a fire.

Flammability is also addressed by 9.3.

Harmonised Standard:

ENs on biocompatibility and biological safety.

Flammability is addressed, although not fully, by EN60601 series for active medical devices.

Action

CEN TC 206 to complete ENs on biocompatibility and biological safety.

CENELEC to examine EN 60601 for adequacy regarding flammability.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

II. Requirements regarding Design and Construction

7. Chemical and Physical properties

7.2 **The devices must be so designed , manufactured and packed in such a way that they minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure.**

Comment:

Apart from Patients, this appears to deal with safety and health at work and would be concerned with devices containing potentially corrosive or poisonous chemical substances, or radioactive substances etc.

With respect to patients, the level of ethylene oxide and other processing residues are included.

Appropriate labelling will be required.

There are directives for safety and health at work.

Harmonised Standard:

EN29001 + EN 46001 and EN29002 + EN46002

EN 60601 series for medical electrical equipment.

This issue is also addressed in a number of non-active medical device standards and pharmacopeial monographs.

Action

CEN TC 206 to adopt standards to assess biologically acceptable levels of ethylene oxide and other chemical residues and reaction products.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

II. Requirements regarding Design and Construction

7. Chemical and Physical Properties

7.3 **The devices must be designed and manufactured in such a way that they can be used completely safely with the materials, substances and gases with which they enter into contact during normal use or routine treatment.**

Comment:

Evidence will need to be included in the documentation that foreseeable interactions have been investigated and proved satisfactory. If appropriate those materials which are compatible, and those which are not compatible, will need to be included in the labelling and/or the instructions for use. See also ER 13.1

Any cleaning or disinfection materials should be specified.

The effect of ingress of liquids and gases will need to be considered.

Could be addressed by Particular Standards for Safety when appropriate.

Harmonised Standard:

EN 29001

Some aspects are covered by EN 60601-1 for medical electrical equipment.

No general harmonised standard envisaged, although some Part IIs of EN 60601 may need to cover it.

Some standards e.g. hypodermic syringes, blood bags etc. include acceptability criteria.

Action

CENELEC to re-examine EN 60601 series.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

I.Requirements concerning Design and Construction

7. Chemical and Physical properties

7.4 Where a device incorporates, as an integral part, a substance which, if used seperately, may be considered to be a medicinal product, as defined in Article 1 of Directive 65/65/EEC, and whose action in combination with the device may result in its bioavailibility, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC, as last amended by Directive 89/341/EEC.

Comment:

Not often applicable to active medical devices, however might be applicable to some non-active devices e.g. catheters used for direct blood pressure measurement, implanted electrodes etc.

Harmonised Standard:

Directives quoted contain requirements which could be derogated with respect to a positive list of device/drug combinations which are acceptable without further testing..

Action

Biological safety tests are relevant. Either the Commission or CEN TC206 should define "bioavailable" in the context of these devices.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

I. Requirements concerning Design and Construction

7. Chemical and Physical properties

7.5 **The devices must be designed and manufactured in such a way as to minimize trhe health risks posed by substances leaking from the device during use.**

Comment:

"Leaking" presumably also means "leaching" or "released"

Mainly directed towards devices intended for long term implantation.

Design control by application of EN 29001 should include investigation of possibility of leaching.

Although addressing leaking "from" the device. Presumably this should also address leaking "into" the device e.g. air leaking into infusion apparatus

Harmonised Standard:

ENs on biocompatability and biological safety.

ENs for Anaesthetic and Respiratory equipment and connectors.

Action

Seek clarification of "leaking" in ER.

CEN TC 206 to complete EN on biocompatability and biological safety.

CEN TC 215 to complete ENs on Anaesthetic and Respiratory equipment.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

II. Requirements regarding Design and Construction

8. Infection and Microbial Contamination

8.1. The devices and their manufacturing processes must be designed to minimise the risk of infection to the patient. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

Comment:

Presumably this is referring to products supplied sterile, or at least internally sterile before use. Also in the context of single use devices, the design and presentation to ensure this i.e. ability to sterilise, maintain sterility and facilitate aseptic presentation.

The reference to ingress of contamination probably relates to single use packaging and the non-sterile handling of an internally sterile device.

The device should also be designed to facilitate cleaning, disinfection and drying after use, unless designed for single use only.

Standards addressing ease of cleaning do not exist.

Harmonised Standard:

EN 29001 + EN 46001 and standards relating to control and validation of sterilisation processes, sterility and packaging.

Instruction for cleaning and disinfection of active medical devices is covered by the EN 60601 series. However no specific requirements are included.

Action

EN 60601 part 2s should address requirements for ease of cleaning where appropriate.

CENELEC to re-examine EN 60601-1 and Part 2s.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

II. Requirements regarding Design and Construction

8. Infection and Microbial Contamination

8.2 **Where the device incorporates animal or human tissues, the risks of cross infection must be minimized by the use by selecting appropriate tissues and using appropriate inactivation, conservation and test procedures.**

Comment:

Manufacturers will need to demonstrate that these procedures have been followed.

Harmonised Standard:

Not known. Possible standard for inactivation of such tissues.

Action

CEN to advise regarding above standard.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

II. Requirements regarding Design and Construction

8. Infection and Microbial Contamination

8.3 Sterile devices must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.

Comment:

Hospitals often manufacture devices packed in re-usable sterilisation trays/boxes. Some devices are sold in "hard packs" i.e. for hospital sterilisation.

Harmonised Standard:

EN for packaging, requirements and guidance, of sterile devices.

Action

CEN TC 102 to complete EN for packaging, requirements and vertical standards and guidance, of sterile products.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

II. Requirements regarding Design and Construction

8. Infection and Microbial Contamination

8.4 Devices labelled sterile must have been sterilised by an appropriate, proven method.

Comment:

Reference to standards.

Harmonised Standard:

ENs on sterilisation and validation of sterilisation.

Action

CEN TC 204 to complete ENs for control and validation of sterilisation.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

II. Requirements regarding Design and Construction

8. Infection and Microbial Contamination

8.5 Packaging systems for non-sterile devices must keep the product without deterioration in the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination.

Comment:

This applies mainly to devices intended to be sterilised before use. The reference to microbial contamination should be to additional microbial contamination since the product was only "clean" when packaged.

Its applicability to non-sterile, ready-for-use products is unclear. A level of cleanliness is rarely specified although important as with food hygiene.

Harmonised Standard:

EN 29001 + EN46001 and EN 29002 + EN46002 have requirements concerning packaging and appropriate freedom from (control of) contamination.

Action

Seek clarification regarding application to non-sterile devices.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

II. Requirements regarding Design and Construction

8. Infection and Microbial Contamination

8.6 **The packaging and/or label of the device must differentiate between identical or similar products sold in both sterile and non-sterile packaging.**

Comment:

Devices supplied sterile and non-sterile should be so labelled if the same or similar products, even frtom some other source, are available in both conditions.

Harmonised Standard:

Standard for labelling of medical devices.

Standard for symbols.

Action

CEN/CENELEC TC 257 to complete harmonisation of ENs for labelling and symbols.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

9. Construction and Environmental Properties

9.1 **If the device is intended for use in combination with other devices or equipment, the connection system must be safe and must not impair the specified performance of the devices. Any restrictions on use must be indicated on the label or in the instruction leaflet.**

Comment:

Applies also to Medical Systems.

Harmonised Standard:

For medical electrical equipment this is covered by EN 60601-1 and the relevant part 2.

For medical systems requirements will be covered by EN 60601 collateral standard "Safety requirements for medical electrical systems".

For other active medical devices a standard for connectors is required.

ISO standards for Luer fittings, anaesthetic connectors, catheter connectors are already in the process of adoption by CEN.

Action

CENELEC to ensure that all existing part 2s of IEC 601-1 are translated into ENs.

CEN to produce an EN for connectors.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

9. Construction and Environmental Properties

9.2 **Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:**

- **the risk of injury, in connection with their physical, including dimensional, features;**
- **risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration;**
- **the risks of interference with other devices normally required for the investigations or for the treatment given;**
- **risks possibly arising from lack of maintenance and calibration including:**
  - **ageing of the materials used;**
  - **loss of accuracy of any measuring or control mechanism.**

Comment:

The first and second dashs are, for medical electrical equipment, covered by the EN60601 series.

The third dash will be covered by the EN 60601 collateral standard on EMC.

The fourth dash confuses ageing with lack of maintenance which is addressed again in ER 13.6 e). This ER must be amended to either remove reference to lack of maintenance and calibration, or state that this is only applicable where maintenance and calibration are impossible i.e. an implanted device.

Harmonised Standards:

EN 60601-1 and the relevant part 2s.

EN 60601 collateral EMC standard.

Action

Request changes to fourth dash of ER.

CENELEC to convert IEC 601 part 2s into ENs.

CEN TC 102 to ensure that packaging requirements address need to withstand pressure changes inherent in sterilisation procedures and those associated with transport.

CEN to consider a horizontal standard addressing physical attributes which could be hazardous, e.g. sharp edges, resistance to spillage etc.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

9. Construction and Environmental Properties

9.3 Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and failsafe condition. Particular attention must be paid to devices which must be exposed to or used in association with flammable substance which could cause combustion.

Comment:

"Failsafe" is assumed to mean the failure of a single protective means, i.e. SINGLE FAULT CONDITION.

EN 60601-1 covers medical electrical equipment for use in flammable atmospheres, however it does not cover oxygen enriched atmospheres. Any special requirements should be covered by the relevant Part 2.

Harmonised Standard:

EN 60601 series.

A harmonised standard is required for Anti-static materials

Action

Request change "Failsafe" to Single Fault Condition" in ER

CENELEC to convert all IEC 601 part 2s into ENs after checking their suitability.

CEN or CENELEC to prepare EN/s for anti-static materials (e.g. ISO 2878, ISO/DIS 2882 and 2883)

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

10. Devices with a measuring function.

10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability as specified by the manufacturer, taking account of the intended purpose of the device

Comment:

This requirement is taken to require that the device performs according to the manufacturers specification, and that the choice of that specification of accuracy and stability will be justified in the technical documentation, or as required by the relevant EN 60601 part 2.

Harmonised Standard:

The relevant EN 60601 part 2.

Some non-active medical devices may need vertical standards specifying requirements for accuracy and stability.

Action

CENELEC to convert IEC 601-1 part 2s into ENs.

CEN to consider whether some non-active measuring devices need standards for accuracy and stability for safety reasons.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

10. Devices with a measuring function.

10.2 The units on the measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

Comment:

The choice of units is covered by EN 60601 series for medical electrical equipment.

"Units" is presumed to mean "markings". ER should be changed.

Consideration of the ergonomics of the display will need to be demonstrated in the design documentation.

Harmonised Standard:

EN 60601 series.

No standard is envisaged for the ergonomic aspects

Action

Request changes to the ER.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

10. Devices with a measuring function.

10.3 The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC, as last amended by Directive 89/617/EEC.

Comment:

Nil.

Harmonised standards:

Some EN 60601 part 2s will specify requirements

Action:

Nil

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

11. Protection against Radiation

11.1 The devices must be designed and manufactured in such a way that the radiation emitted will not attain dangerous levels. Where emission of dangerous levels of radiation is necessary for a specific medical purpose considered to outweigh the risks inherent in the emissions, it must be possible for the user to control the emissions.

Comment:

Note that this covers all forms of radiation.

Active medical devices are covered by the EN 60601 series.

Harmonised Standard:

IEC collateral standard to IEC 601-1 for protection against ionizing radiation.

The relevant EN 60601 part 2.

Action

CENELEC to convert draft IEC Sec 131 into EN.

CENELEC to ensure that all devices intended to emit ionizing radiation are covered by an EN 60601 part 2.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

11. Protection against Radiation

11.2 Devices emitting ionizing radiation must be designed and manufactured in such a way as:
a) to ensure that the quantity and quality of radiation emitted can be adjusted and controlled.
b) to reduce exposure of the user at work and all unnecessary exposure.

Comment:

This requirement should be covered by EN 60601-1, the collateral standard on radiation protection and the relevant part 2s.

Harmonised Standard:

EN60601-1 and the relevant part 2.

EN60601 collateral standard on radiation protection.

Action

CENELEC to ensure that all devices intended to emit ionizing radiation are covered by IEC 601 part 2s converted into ENs.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

11. Protection against Radiation

11.3 The operating instructions for devices emitting radiation must give detailed information on the nature of the devices, means of protecting the patient and user and on ways of avoiding mishandling and the risks inherent in installation.

Comment:

Note that this requirement is addressed to all forms of radiation.

This requirement should be covered by IEC 601-1 and the relevant part 2s.

Harmonised Standard:

EN 60601 and the relevant part 2s.

Collateral standard to EN 60601-1 on protection against ionizing radiation.

Action

CENELEC to ensure that all devices intended to emit radiation are covered by EN 60601 part 2s.

CENELEC to expedite the adoption of an EN on protection against ionizing radiation.

CENELEC to consider preparation of a collateral standard on protection against non-ionizing radiation.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

11. Protection against Radiation

11.4 Devices emitting radiation must be designed and manufactured in such a way as to reduce unnecessary exposure of the patient and user as far as possible.

Comment:

This requirement should be covered by IEC 601-1 and the relevant part 2s.

Harmonised Standard:

EN 60601 and the relevant part 2s.

Collateral standard to EN 60601-1 on radiation protection.

Action

CENELEC to ensure that all devices intended to emit ionizing radiation are covered by EN 60601 part 2s.

CENELEC to expedite the adoption of an EN on radiation protection.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

11. Protection against Radiation

11.5 Instruments, apparatus or appliances emitting radiation must be fitted with visual displays and/or audible warnings of radiation emissions.

Comment:

This requirement should be covered by IEC 601-1 and the relevant part 2s.

Harmonised Standard:

EN 60601-1 and the relevant part 2.

EN on Medical Alarms and Signals

Action

CENELEC to ensure that all devices intended to emit ionizing radiation are covered by EN 60601 part 2s.

CEN TC 255 to complete EN on Medical Alarms and Signals.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.1 Devices dependent on software must be designed in such a way as to minimise the risks arising from errors in the programme.

Comment:

A collateral standard to IEC 601-1 is under preparation addressing this issue.

Harmonised Standard:

An EN 60601 collateral standard on safety of programmable systems.

EN 29001-3 Quality system for software.

Action

CENELEC to adopt the IEC 601-1 collateral standard as an EN.

CENELEC to examine EN 29001-3 for suitability for medical device manufacturers.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.2 Devices where the safety of the patient depends on an internal power supply must be equipped with a means of determining the state of the power supply.

Comment:

To be covered by the relevant EN 60601 part 2.

Harmonised Standard:

The relevant EN 60601 part 2.

Action

Nil.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.3 Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure.

Comment:

To be covered by the relevant EN 60601 part 2.

Harmonised Standard:

The relevant EN 60601 part 2.

EN on Medical Alarms and Signals

Action

CEN TC 255 to complete EN on Medical Alarms and Signals.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.4 Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe degradation of the patient's state of health.

Comment:

To be covered by the relevant EN 60601 part 2.

Harmonised Standard:

The relevant EN 60601 part 2.

EN on Medical Alarms and Signals

Action

CEN TC 255 to complete EN on Medical Alarms and Signals.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.5 **Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the vicinity.**

Comment:

To be covered by completion of Clause 36 of EN 60601-1 by reference to collateral EMC standard and any changes required in the relevant part 2.

Harmonised Standard:

EN 60601-1, collateral EMC standard and any relevant part 2.

Action

CENELEC to convert IEC 601-1 collateral EMC standard into an EN.

CENELEC to ensure that Clause 36 of EN 60601-1 refers to the collateral standard for EMC.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.6 Protection against Electrical Risks

Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of electric shocks during normal use and in single fault condition, provided that the devices are installed correctly.

Comment:

Covered by EN 60601-1 and any relevant part 2.

Harmonised standards:

EN 60601 series

Action

CENELEC to adopt IEC 601 part 2s as ENs

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.7 Protection against Mechanical and Thermal Risks

12.7.1 The devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.

Comment:

"Resistance" is assumed to mean resistance to breakage e.g. "Strength"

Covered by EN 60601-1 and any relevant part 2s.

Harmonised Standard:

EN 60601-1 and the relevant part 2.

Action

CENELEC to adopt IEC 601 part 2s as ENs after checking.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.7.2 The devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

Comment:

Difficult to see the relevance of this requirement. IEC decided not to address vibration when preparing the second edition of IEC 601-1.

Vibration is unlikely to affect the patient, but could affect the operator or environment. Again difficult to set limits. A hand held vibro-massager passes almost as much vibration to the user as to the patient.

Harmonised Standard:

A part 2 of EN 60601 only if clause 26 is invoked.

Action

Propose deletion of this requirement.

CENELEC to consider whether Clause 26 of EN 60601-1 needs modification.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.7.3 **The devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.**

Comment:

Hazardous levels of noise are defined in ISO standards, however it is extremely unlikely that any medical devices would approach such levels.

Certain equipment will for medical reasons require limits for low noise e.g. baby incubators. If necessary these limits will be defined in the appropriate EN 60601 part 2.

Where alarms are fitted, the EN for Audible Alarms will specify minumum sound levels.

Harmonised Standard:

ISO standards for hazardous noise levels.

EN 60601 part 2 where relevant.

EN for Audible Alarms.

Action

CEN/CENELEC to complete EN on Medical Alarms and Signals.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.7.4 The terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimise all possible risks.

Comment:

Covered generally by EN 60601-1 and specifically by the relevant part 2s.

Harmonised Standard:

EN 60601-1 and any relevant part 2.

ENs for Anaesthetic and Respiratory gas systems.

EN for connectors.

Action

CEN to complete ENs for Anaesthetic and Respiratory gas systems.

CEN to consider whether a horizontal standard is needed for connectors.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.7.5 Accessible parts of devices and their surroundings must not attain potentially dangerous temperatures under normal use.

Comment:

Impossible to satisfy for some devices, e.g. Cautery, Radiant heat lamps, sterilisers etc. ER needs to be reworded to exclude devices intended to supply heat.

The hazards to the environment, unless specifically covered by EN 60601 should be covered by labelling and warnings.

Harmonised Standard:

EN 60601-1 and the relevant part 2 if any.

Action

Press for clarification of ER

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.8 Protection against the risks posed to the patient by energy supplies or substances

12.8.1 Devices for supplying the patient with energy or substances must be designed and manufactured in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and the user.

Comment:

Even if absolute accuracy was assumed this could not guarantee the safety of the patient and user.

Covered by EN 60601-1 and the relevant part 2s.

Harmonised Standard:

EN 60601-1 and any relevant part 2.

Action

Propose change of words to ".....minimise the risk to patient and user."

CENELEC to adopt IEC 601 part 2s as ENs after checking.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.8.2 Devices must be fitted with an interlock and/or alarm system to prevent and/or indicate any inadequacies in the flow rate which could pose a danger.

Comment:

Covered generally by EN 60601-1 and specifically by any relevant part 2.

Harmonised Standard:

EN 60601 and any relevant part 2.

Action

Nil.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

12. Requirements for Devices connected to or equipped with an energy source

12.9 The function of the controls and visual displays must be clearly specified on the devices.

Comment:

Covered generally by EN 60601-1 and specifically by any relevant part 2.

Harmonised Standard:

EN 60601-1 and any relevant part 2.

Action

Nil.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

13. Information supplied by the Manufacturer.

13.1 **Each device shall be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential user.**
This information comprises the details on the label and the data in the instruction leaflet.
As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.
An instruction leaflet must be included in the packaging for every device.
By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions.

Comment:

The English needs improving, e.g. "by way of exception" in the last paragraph could be replaced by "normally". However there would appear not to be a requirement for reference to standards in view of the specific requirements.

"Instruction leaflet" should be replaced by "Instructions for use" to align with IEC definitions.

Harmonised Standard:

The sectorial standards covering information to be supplied by the manufacturer, coming from TC 205, TC 140 and harmonised by TC 257 will complement these requirements.

Action

Propose editorial changes as above.

CEN TC 205,140 and 257 to complete their work.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

13. Information supplied by the Manufacturer.

13.2 Where appropriate this information should take the form of symbols. Any symbols and identification colours used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.

Comment:

This requirement is already within EN 60601-1.

Harmonised Standard:

The requirement is specific within itself and is identical with that contained in EN 60601-1.

IEC 417, 445, 529, 878, ISO 7000

Action

CENELEC should ensure that IEC 417, 445, 529, 878 are made available as ENs.

CEN to convert ISO 7000 into EN.

CEN TC 257 to complete EN on Terminology, Labelling and Symbols.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

13. Information supplied by the Manufacturer.

13.3 The label must bear the following particulars:

a) the name or trade name and address of the manufacturer;
b) the details strictly necessary for the user to identify the device and the contents of the packaging;
c) where appropriate the word "STERILE";
d) where appropriate, the batch code, preceded by the word "batch" or the serial number.
e) where appropriate an indication of the time limit for completely safe use, expressed as the year and month;
f) where appropriate, an indication that the device is dosposable;
g) if the device is custom-made, the words "custom made device";
h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations";
i) any special storage and/or handling conditions;
j) any special operating instructions;
k) any warnings and/or precautions to take;

Comment:

These requirements are specific and complete in themselves. No reference to standards is necessary.

A check must be made to ensure that these do not contradict marking requirements in EN 60601-1.

Harmonised Standard:

EN 60601 series

EN on Terminology, Labelling and Symbols.

Action

CENELEC to press Commission to transfer "address of manufacturer" from 13.3a) to 13.6.

CENELEC to check that there is no conflict with the harmonised version of EN 60601.

CEN TC 257 to complete harmonisation of ENs on Terminology, Labelling and Symbols.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

13. Information supplied by the Manufacturer.

13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instruction leaflet.

Comment:

The requirement is clear and does not conflict with IEC 601-1.

Harmonised Standard:

Nil.

Action

Nil.

MEDICAL DEVICE DIRECTIVE

Harmonised Standards to be used to demonstrate compliance with the Essential Requirements

13. Information supplied by the Manufacturer.

13.5 wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

Comment:

It may be difficult, if not impossible, to mark some single-use devices other than on the packaging.

Presumably it is intended that all detachable parts should bear an identifying number.

Harmonised Standard:

EN 60601 series for active medical devices.

CEN TC 257 standard for labelling.

Action

CEN/CENELEC to determine scope of TC 257's activities.