

Essential Principles of Safety and Performance of Medical Devices

1.0 Rationale

Consistent identification, selection and application of safety and performance principles to a medical device offers significant benefits to the manufacturer, user, patient or consumer, and to regulatory authority since it allows its manufacturer to design, manufacture and to demonstrate the device is suitable for its intended use. Moreover, eliminating differences between jurisdiction decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

2.0 Purpose

To describe six general requirements of safety and performance that apply to all medical devices.

To provide a comprehensive list of design and manufacturing requirements of safety and performance, some of which are relevant to each medical device. These are grouped as :

- Chemical, physical and biological properties.
- Infection and microbial contamination.
- Manufacturing and environmental properties.
- Devices with diagnostic or measuring function.
- Protection against radiation.
- Requirements for medical devices connected to or equipped with an energy source.
- Protection against mechanical risks.
- Protection against the risks posed to the patient by supplied energy or substances.
- Protection against the risks posed to the patient for devices for self-testing or self-administration.
- Information supplied by the manufacturer.
- Performance evaluation including, where appropriate, clinical evaluation.

3.0 General Requirements

3.1 Medical devices shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

3.2 The solution adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer shall apply the following principles in the priority order listed:

- identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse,
- eliminate risks as far as reasonably practicable through inherently safe design and manufacture,
- reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms,
- inform users of any residual risks.

3.3 Devices shall achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.

3.4 The characteristic and performances referred to in Clauses 3.1, 3.2 and 3.3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

3.5 The devices shall be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (e.g. fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

3.6 The benefits must be determined to outweigh any undesirable side effects for the performances intended.

4.0 Design and Manufacturing Requirements

4.1 Chemical, physical and biological properties

4.1.1 The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 3.1 to 3.6 of the 'General Requirements'. Particular attention shall 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, body fluids, and specimens, taking account of the intended purpose of the device,
- the choice of materials used shall reflect, where appropriate, matters such as hardness, wear and fatigue strength.

4.1.2 The devices shall be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.

4.1.3 The devices shall be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

4.1.4 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.

4.1.5 The devices shall be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the devices.

4.1.6 Devices shall be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking account the device and the nature of the environment in which it is intended to be used.

4.2 Infection and microbial contamination

4.2.1 The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users, and, where applicable, other persons. The design should :

- allow easy handling, and where necessary,
- reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use,
- prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.

4.2.2 Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.

4.2.3 In some cases products incorporating tissues, cells and substances of non-human origin may be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Manufacturers may be required to maintain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

4.2.4 In some cases products incorporating human tissues, cells and substances may be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin shall be carried out so as to provide optimal safety. In particular, safety with regards to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

4.2.5 Devices labeled as having a special microbiological state shall be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

4.2.6 Devices delivered in a sterile state shall be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.

4.2.7 Devices labeled either as sterile or as having a special microbiological state shall be processed, manufactured and, if applicable, sterilised by appropriate, validated methods.

4.2.8 Devices intended to be sterilised shall be manufactured in appropriately controlled (e.g. environmental) conditions.

4.2.9 Packaging system for non-sterile devices shall keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

4.2.10 The packaging and/or label of the device shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.

4.3 Manufacturing and environmental properties

4.3.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instruction for use.

4.3.2 Devices shall be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate :

- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;
- risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration;
- the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use;
- the risks of accidental penetration of substances into the device;
- the risk of incorrect identification of specimens;
- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;
- risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

4.3.3 Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

4.3.4 Device must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

4.4 Devices with a diagnostic or measuring function

4.4.1 Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy shall be indicated by the manufacturer.

4.4.2 Diagnostic devices shall be designed and manufactured in such a way as to

provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design shall address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.

4.4.3 Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials shall be assured through a quality management system.

4.4.4 Any measurement, monitoring or display scale shall be designed in line with ergonomic principles, taking account of the intended purpose of the device.

4.4.5 Wherever possible values expressed numerically shall be in commonly accepted, standardised units, and understood by the users of the device.

4.5 Protection against radiation

4.5.1 General

4.5.1.1 Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users, and other persons to any emitted radiation shall be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

4.5.2 Intended radiation

4.5.2.1 Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

4.5.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they shall be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

4.5.3 Unintended radiation

4.5.3.1 Devices shall be designed and manufactured in such a way that exposure of patient, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.

4.5.4 Instruction for use

4.5.4.1 The operating instructions for devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

4.5.5 Ionising radiation

4.5.5.1 Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

4.5.5.2 Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.

4.5.5.3 Devices emitting ionising radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.

4.6 Requirements for medical devices connected to or equipped with energy source

4.6.1 Devices incorporating electronic programmable systems, including software, shall be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of single fault condition in the system, appropriate means shall be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.

4.6.2 Devices where the safety of the patients depends on an internal power supply shall be equipped with a means of determining the state of the power supply.

4.6.3 Devices where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.

4.6.4 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 deterioration of the patient's state of health.

4.6.5 Devices shall be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual

environment.

4.6.6 Devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

4.6.7 Protection against electrical risks

4.6.7.1 Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the manufacturer.

4.7 Protection against mechanical risks

4.7.1 Devices shall be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

4.7.2 Devices shall be designed and manufactured in such a way as to reduce to the lowest practicable 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.

4.7.3 Devices shall be designed and manufactured in such a way as to reduce to the lowest practicable 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.

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

4.7.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal use.

4.8 Protection against the risks posed to the patient by supplied energy or substances

4.8.1 Device for supplying the patient with energy or substances shall be designed and manufactured in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

4.8.2 Devices shall be fitted with the means of preventing and/or indicating any

inadequacies in the delivered amount which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

4.8.3 The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operations or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.

4.9 Protection against the risks posed to the patient for devices for self-testing or self-administration

4.9.1 Such devices shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment shall be easy for the user to understand and apply.

4.9.2 Such devices shall be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.

4.9.3 Such devices shall, where reasonably possible, include a procedure by which the user can verify that, at the time of use, that the product will perform as intended by the manufacturer.

4.10 Information supplied by the manufacturer

4.10.1 Users shall be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information shall be easily understood.

4.11 Performance evaluation including, where appropriate, clinical evaluation

4.11.1 All data generated in support of performance shall be obtained in accordance with the relevant requirements applicable under current regulations.

4.11.2 Clinical investigations on human subjects shall be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results (including pre-study protocol review or informed consent).