HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-16: Guidance on Essential Principles for Safety and Performance of Medical Devices

Revision 1

HSA
Health Sciences Authority

PREFACE

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1. INTRODUCTION

1.1. Purpose

This document provides an overview on meeting the essential principles of safety and performance of medical devices.

1.2. Background

For a medical device to be supplied in Singapore, it must be demonstrated that the Essential Principles of Safety and Performance for the medical device has been met.

The regulatory framework does not dictate how a product owner should prove that their medical device has met the essential principles, hence providing flexibility to the product owners and catering to technological advances and changes in the development of new medical devices.

1.3. Scope

This document is applicable to all medical devices that are to be supplied in Singapore.

1.4. Definitions

Nil.

2. ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

There are seven general requirements of safety and performance that apply to all medical devices products. There are a further eleven design and manufacturing requirements of safety and performance, some of which are relevant to each medical device.

The design and manufacturing requirements are grouped as:

- chemical, physical and biological properties,
- infection and microbial contamination,
- manufacturing and environmental properties,
- devices with a 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 product owner,
- performance evaluation including where appropriate, clinical evaluation.

NOTE The product owner selects which of the design and manufacturing requirements are relevant to a particular medical device, documenting the reasons for excluding the others.

3. ROLES OF STANDARDS IN MEETING ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE

3.1. What is a standard?

A standard is a document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

3.2. Types of standards

Basic standard (also known as horizontal standard): Standard indicating fundamental concepts, principles and requirements, with regard to general safety and performance aspects which are applicable to all kinds or a wide range of products and/or processes (e.g., standards concerning risk management, clinical investigation and the quality management system for the manufacture of medical devices).

Group standard (also known as semi-horizontal standard): Standard indicating aspects applicable to families of similar products and/or processes making reference as far as possible to basic standards (e.g., standards concerning sterile medical devices, electrically-powered medical devices, stability of IVD reagents).

Product standard (also known as vertical standard): Standard indicating necessary safety and performance aspects of specific products and/or processes, making reference, as far as possible, to basic standards and group standards (e.g., standards for infusion pumps, for anaesthetic machines or for blood glucose meters for self testing).

3.3. Source of standards

Standards are drawn up at international, regional and national level. There are 3 major international standardisation bodies:

- International Electrotechnical Commission (IEC) for electricity, electronics and related technologies;
- International Telecommunications Union (ITU) for telecommunications and radiocommunications;
- International Organisation for Standardisation (ISO) for nearly all other technical fields, service sectors, management systems and conformity assessment.

Examples of standard bodies at the regional levels are European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (CENELEC), European Telecommunications Standards Institute (ETSI), the African Regional Organisation for Standardisation (ARSO), Pan American Standards Commission (COPANT).

Examples of standards bodies at the national levels are Standards, Productivity and Innovation Board (SPRING Singapore), Association for the Advancement of Medical Instrumentation (AAMI), American Society for Testing and Materials (ASTM), American National Standards Institute (ANSI), British Standards Institution (BSI), German Institute for Standardisation (DIN), Japanese Industrial Standards Committee (JISC), etc.

3.4. Applicability of standards

Standards can serve different purposes. They can:

- provide reference criteria that a product, process or service must meet;
- provide information that enhances safety, reliability and performance of products, processes and services;
- assure consumers about reliability or other characteristics of goods or services provided in the marketplace;
- give consumers more choice by allowing one firm's products to be substituted for, or combined with, those of another.

The essential principles set out the requirements relating to the safety and performance characteristics of medical devices. Compliance with applicable medical device standards is not mandatory, but it is one way to establish compliance with essential principles.

International standards should be used whenever possible. It is important to note that medical devices that conform to a standard will be considered to have met safety, effectiveness and/or labelling requirements that are addressed by the standard. Further evidence in support of safety and effectiveness requirements not covered by extent of recognition of a standard will still be required.

3.5. Alternatives to standards

The use of standards is voluntary. Product owners have the option to select alternative solutions to demonstrate their medical device meets the relevant Essential Principles. Alternative means of demonstrating conformity with the Essential Principles may include, for example:

- industry agreed methods;
- internal product owner standard operating procedures developed by an individual product owner;
- other sources that describe the current state of technology and practice related to performance, material, design, methods, processes or practices.

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

3.6. Technical documentation

The product owner must retain or be able to provide documentation to demonstrate that the device conforms with the selected standard or alternative means of meeting the Essential Principles.

Documentation may include for example, the standard itself, how it was applied, deviations, test results, relevant pass/fail criteria when these are not specifically stated in the standard and/or other outputs.

When a standard is not applied, or is not applied in full, the product owner should retain, and submit where appropriate, data or information to demonstrate:

- that conformity with the Essential Principles has been achieved by other means, and/or
- that the parts of the standard that were not applied were not pertinent to the particular device in question.

A declaration of conformity to a recognised standard is to be included as part of product registration.

ANNEX 1:

Essential Principles of Safety and Performance of Medical Devices

General Requirements

1. Medical devices should 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 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.

2. The solutions adopted by the product owner 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 product owner should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The product owner should 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. Devices should achieve the performance intended by the product owner 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.

4. The characteristics and performances referred to in Clauses 1, 2 and 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 product owner, 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 product owner's instructions.

5. The devices should 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 (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the product owner.

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

7. Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles. A clinical evaluation should be conducted.

Design and Manufacturing Requirements

8. Chemical, physical and biological properties

8.1 The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 1 to 6 of the 'General Requirements'. Particular attention should 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 should reflect, where appropriate, matters such as hardness, wear and fatigue strength.

8.2 The devices should 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.

8.3 The devices should 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 should 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.

8.4 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies 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.

8.5 The devices should 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 device.

8.6 Devices should 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 into account the device and the nature of the environment in which it is intended to be used.

9. Infection and microbial contamination

9.1 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.

9.2 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.

9.3 Products incorporating non-viable tissues, cells and substances of animal origin falling within the definition of a medical device, should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. The product owner is required to retain 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 should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

9.4 For products incorporating cells, tissues and derivatives of microbial or recombinant origin falling within the definition of a medical device, the selection of sources/donors, the processing, preservation, testing and handling of cells, tissues and derivatives of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

9.5 For products incorporating non-viable human tissues, cells and substances falling within the definition of a medical device, 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 should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

9.6 Devices labelled as having a special microbiological state should 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 product owner.

9.7 Devices delivered in a sterile state should 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 product owner, until the protective packaging is damaged or opened.

9.8 Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilised by appropriate, validated methods.

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

9.10 Packaging systems for non-sterile devices should 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 should be suitable taking account of the method of sterilisation indicated by the product owner.

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

10. Manufacturing and environmental properties

10.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the

devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.

10.2 Devices should 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.

10.3 Devices should 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 should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

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

11. Devices with a diagnostic or measuring function

11.1 Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should 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 should be indicated by the product owner.

11.2 Diagnostic devices should 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 should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.

11.3 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 should be assured through a quality management system.

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

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

12. Protection against radiation

12.1 General

12.1.1 Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should 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.

12.2 Intended radiation

12.2.1 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 should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

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

12.3 Unintended radiation

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

12.4 Instructions for use

12.4.1 The operating instructions for devices emitting radiation should 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.

12.5 Ionising radiation

12.5.1 Devices intended to emit ionising radiation should 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.

12.5.2 Devices emitting ionising radiation intended for diagnostic radiology should 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.

12.5.3 Devices emitting ionising radiation, intended for therapeutic radiology should 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.

13. Requirements for medical devices connected to or equipped with an energy source

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

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

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

13.4 Devices intended to monitor one or more clinical parameters of a patient should 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.

13.5 Devices should 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.

13.6 Devices should 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.

13.7 Protection against electrical risks

13.7.1 Devices should 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 product owner.

14. Protection against mechanical risks

14.1 Devices should 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.

14.2 Devices should 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.

14.3 Devices should 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.

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

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

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

15.1 Devices for supplying the patient with energy or substances should be designed and constructed 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.

15.2 Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

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

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

16.1 Such devices should 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. The information and instructions provided by the product owner should be easy for the user to understand and apply.

16.2 Such devices should 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.

16.3 Such devices should, 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 product owner.

17. Information supplied by the product owner

17.1 Users should be provided with the information needed to identify the product owner, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.

18. Clinical Investigation

18.1 Clinical investigations on human subjects should 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.

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