

GUIDANCE DOCUMENT

MEDICAL DEVICES REGULATORY SYSTEM

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Appendices

PART 1: PRE-MARKET ASSESSMENT

SECTION 1: INTRODUCTION

1.1 Principles and Main Features of A Regulatory Framework of Medical Device – Safety and Performance

1.1.1 The primary goal of the regulatory framework is to protect public health and safety. It should ensure that only safe devices are placed into the market and expedite valuable new technologies to medical community and patients.

1.1.2 Safety of a medical device is a risk management issue. It should be based upon proper identification, assessment, evaluation and control of risk. Procedures should be established to identify risk associated with the use of medical devices. In addition procedures should be introduced to control the product development, design, manufacture and inspection of finished products to assure the purchaser/user of the best possible devices to achieve the intended performance following use of appropriate management of risk.

1.1.3 The establishment of Governmental rules and procedures to be applied by all concerned parties is very crucial to ensure performance and safety during the entire life-cycle of medical device, ie from conception to distribution of final products into the market through its usage and disposal.

1.2 Global Harmonization

1.2.1 The protection of public health and safety in the use of medical devices should be based on principles accepted in the documents emanating from the Global Harmonization Task Force (GHTF) – to encourage the processes of free movement of devices between countries and regions having similar regulatory procedures.

1.2.2 The Global harmonization process is aimed at improving the acceptability of devices produced in any one part of the world for distribution and use in other parts of the world market without the need for significantly differing or alternative procedures.

1.2.3 The great benefit is that, if properly constructed, the resulting regulatory pre-market rules will allow easy movement of safe and performant devices both into and from Malaysia, and will reduce the need to carry out additional or duplicate procedures on both:

- i) devices brought into Malaysia from major parts of the Global Market; and
- ii) devices manufactured in Malaysia for distribution into major users of medical devices in the Global Market.

1.2.4 Many of the principles illustrated in the Guidance Documents emanating from the GHTF reflect similar procedures built into regulations

already adopted and implemented in Europe, Canada, Australia and being incorporated in Japanese evolving procedures. In the United States of America (USA) there is acceptance of many of these documents as representing the way forward.

1.2.5 For Malaysia it is thus important to take advantage of the immense amount of work and resulting GHTF documents, and to incorporate much of these into the Malaysian Regulatory Pre-Market Procedures.

1.3 Stakeholders and Processes in Pre-Market Phase

1.3.1 Figure 1 shows the interaction of various stakeholders and processes in pre-market phase of medical device

1.4 Services for Supervision of Regulatory Controls

1.4.1 As the regulator, the Ministry of Health Malaysia should be supervising the following services;

- i) Scientific and engineering services (including health technology assessment);
- ii) Information control – (Relevant listing/licensing/registration when required);
- iii) Conformity assessment either by Ministry of Health's in house body, or by using third party inspectorates (eg as European Notified Bodies) to perform auditing on the Manufacturers Quality Management Systems (QMS);
- iv) Accreditation (by in-house or third party body) of inspectorate processes;
- v) Post-market surveillance, and reporting processes including distribution of safety alert information;
- vi) Assessment and supervision of standards, including monitoring international standards and participation in development processes when appropriate (preferably at international level)

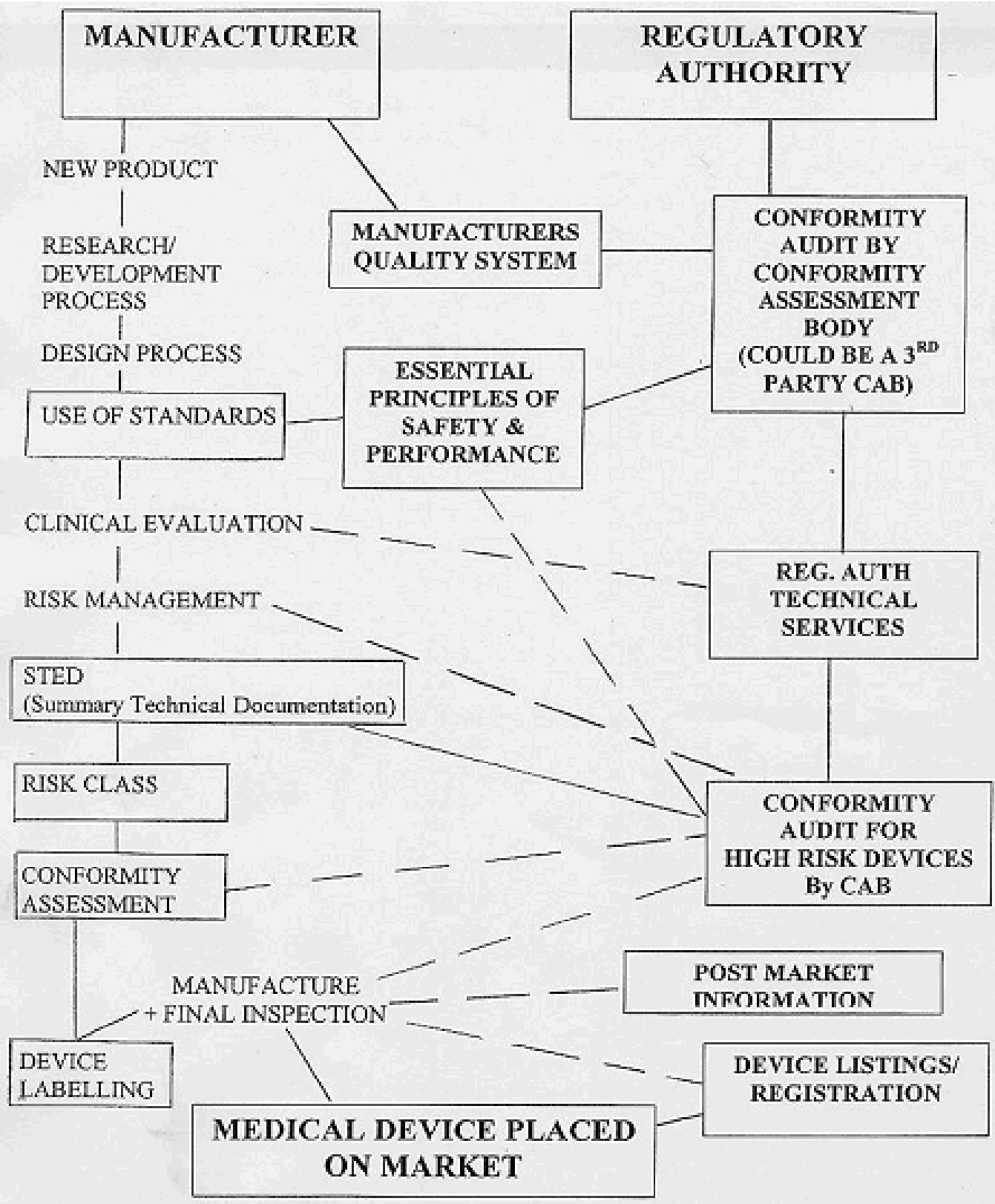


Figure 1: Interaction of various stakeholders and processes in pre-market phase of medical device

SECTION 2: DEFINITIONS AND TERMS

“Medical device” means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Note 1: The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, some *in vitro* diagnostic devices, including reagents and the like, may be covered by separate regulations.

Note 2: Products, which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- accessories for medical devices (see Note 3),
- disinfection substances,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.

Note 3: Accessories intended specifically by Manufacturers to be used together with a ‘parent’ medical device to enable that medical device to achieve its intended purpose, should be subject to the same GHTF procedures as apply to the medical device itself. For example, an accessory will be classified as though it is a medical device in its own right and this may result in the accessory having a different classification than the ‘parent’ device.

Note 4: Components to medical devices are generally controlled through the Manufacturer’s QMS and the conformity assessment procedures for the device. In some jurisdictions, components are included in the definition of a ‘medical device’.

“Accessory” means an article which, whilst not being itself a medical device or having a specific medical-device-intended purpose, is however intended by its Manufacturer to be used together with a ‘parent’ medical device to enable that medical device to achieve its intended purpose.

“Custom-made device” means any device made specifically in accordance with a duly qualified practitioners written prescription which gives specific design characteristics and is intended for the sole use of a particular patient.

“Manufacturer” of a medical device is the person/organization that places a medical device on the market under his/its own name and, thereby, is responsible for ensuring that the device is suitable for its intended purpose as indicated in the accompanying labeling.

The function of the Manufacturer includes one or more of the following activities:

- design;
- assignment of the intended purpose;
- production/fabrication;
- assembly;
- labeling;
- sterilization or other processing;
- packaging;
- modification or re-labeling or refurbishment of the medical devices

When any of these responsibilities are sub-contracted, the Manufacturer remains the responsible party

Note 1: “Under its own name” indicates the needs for the provision of information on the medical device sufficient to allow a beneficiary, user or Regulatory Authority to make contact with the Manufacturer, if such proves necessary

Note 2: “Placing on the market” is the initial action of making each finished medical device available on the market, either for payment or free of charge, with a view to its use for the purposes intended by the Manufacturer as indicated in the labeling

“Intended use” or “intended purpose” means the objective intent of the Manufacturer or other legal entity, or person, under whose name the device is placed on the market, in respect of the application and performance of the device, as indicated in the labeling and/or promotional material

“Active implantable medical device” means any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

“Active medical device” means any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated

by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices

“Active therapeutic medical device” means any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap

“Active device intended for diagnosis” means any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities

“Audit” means a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives **[Editorial: to be revised]**

“Authorized Representative” means any person explicitly designated by a Manufacturer, to represent it within a country or jurisdiction where it is not itself established, in respect of matters raised by the relevant Regulatory Authority, with regard to the Manufacturer’s obligations under the regulations that operate within that country or jurisdiction

“Central Circulatory System” – for the purpose of this document, ‘central circulatory system’ means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries and common iliac arteries

“Central Nervous System” – for the purpose of this document, ‘central nervous system’ means brain, meninges and spinal cord

“Conformity Assessment” means the systematic examination to determine the extent to which a medical device fulfils specified requirements

“Clinical evaluation” means the review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation

“Clinical evaluation” means a structured and systematic review of the evidence of the clinical safety and performance of the medical device

“Clinical investigation” means any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device

“Compliance status” means the outcome of the quality system assessment to determine conformance with regulatory requirements

“Conformity Assessment” means the systematic examination to determine the extent to which a medical device fulfils specified requirements

“Conformity Assessment Body (CAB)” means a body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A CAB is authorized to undertake

specified conformity assessment activities by a Regulatory Authority (RA) that will ensure performance of the CAB is monitored and, if necessary, withdraw designation.

“Device for self-testing/self administration” means any device intended by the Manufacturer to be able to be used by lay persons in a non-clinical environment

“Duration of use” means

- Transient: Normally intended for continuous use for less than 60 minutes
- Short term: Normally intended for continuous use for between 60 minutes and 30 days
- Long term: Normally intended for continuous use for more than 30 days

“Harm” means physical injury or damage to the health of people

“Hazard” means potential source of harm

“Immediate danger” means a situation where the patient is at risk of either losing life or an important physiological function if no immediate preventative measure is taken

“Instructions for use” means information provided by the Manufacturer to inform the device user of the products proper use and of any precautions to be taken

“Invasive devices” means a device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body

Body orifice means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy

Surgically invasive device means an invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation

Note: Devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices

“Implantable device” means any device, including those that are partially or wholly absorbed, which is intended;

- to be totally introduced into the human body; or,
 - to replace an epithelial surface or the surface of the eye,
- by surgical intervention which is intended to remain in place after the procedure
- Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device

“Label” means information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices

“Labeling” means written, printed or graphic matter;

- affixed to a medical device or any of its containers or wrappers, or,

- accompanying a medical device,
related to identification, technical description, and use of the medical device,
but excluding shipping documents

“Life supporting” or “life sustaining” means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life

“Performance evaluation” means the review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations

“Place on the market” means the first making available of a medical device with a view to its distribution and/or use, other than where the use is restricted to pre-market clinical investigation or performance evaluation of an *in vitro* diagnostic device

“Regulatory Authority (RA)” means a Government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements

“Re-useable surgical instrument” means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which are intended by the Manufacturer to be reused after appropriate procedures for cleaning and/or sterilization have been carried out

“Risk” means the combination of the probability of occurrence of harm and the severity of that harm

“Specimen” means the discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantity or characteristic to determine the character of the whole

“Summary Technical Documentation (STED)” means a summary of technical documentation held or submitted for conformity assessment purposes

“Technical File/Technical Documentation” means the source documentation from which the Summary Technical Documentation is extracted

“Validation” means conformation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

“Verification” means conformation, through the provision of objective evidence, that specified requirements have been fulfilled

SECTION 3: ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

3.1 Introduction

3.1.1 The objective of Medical Device Regulatory processes based on GHTF principles convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable. This is achieved by identifying and developing areas of international co-operation in order to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices.

3.1.2 The GHTF has identified, as a priority the need to harmonize essential safety and performance criteria for a medical device that allow the Manufacturer to demonstrate that its product is suitable for its intended use.

3.1.3 Eliminating differences between jurisdictions decreased the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

3.2 Scope

3.2.1 The purpose of this document is to describe generic product performance criteria, collectively referred to as 'essential principles' that may be used to assess the safety of a particular medical device. A Manufacturer is able to demonstrate its medical device is safe by reviewing these essential principles, selecting those that are relevant to a particular device, and ensuring through its design and manufacturing controls that the device meets them.

3.2.2 The document applies to all products that fall within the definition of a medical device, as defined in Section 2: Definition and Terms.

3.2.3 The operation of a quality management system, the use of standards, post-market vigilance, the pre-market review of a technical file, type testing and final product testing, are all important means, which may individually or jointly be utilized to achieve compliance with the Essential Principles. These matters are addressed in specific sections of the Pre-Market Assessment System guidance.

3.3 Essential Principles of Safety and Performance of Medical Devices (including *In Vitro* Diagnostic Devices)

(Source SG1/N041R6)

3.3.1 General requirements

- i) 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.

ii) The solutions 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 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.

iii) Devices should 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.

iv) The characteristics and performances referred to in **Clauses 5.1, 5.2 and 5.3** ?? 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.

v) 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 Manufacturer.

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

3.3.2 Design and manufacturing requirements

i) Chemical, physical and biological properties

– The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in **Clauses 5.1 to 5.6 ??** 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.

– The devices should be designed, manufactured and packed in such a way as to minimize 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.

– 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.

– 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 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.

– 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.

– 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.

ii) Infection and microbial contamination

– 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.

– 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.

– In some jurisdictions 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. National regulations may require that the Manufacturer and/or the RA 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.

– In some jurisdictions 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 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.

– Devices labeled 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 Manufacturer.

– 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 Manufacturer, until the protective packaging is damaged or opened.

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

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

– 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 sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the Manufacturer.

– 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.

iii) Manufacturing and environmental properties

– 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.

– 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.

– Devices should be designed and manufactured in such a way as to minimize 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.

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

iv) Devices with a diagnostic or measuring function

– 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 Manufacturer.

– 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.

– 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.

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

- Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device.
- v) Protection against radiation
 - 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.
 - Intended radiation: 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. 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.
 - Unintended radiation: 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.
 - Instructions for use: 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.
 - Ionizing radiation: Devices intended to emit ionizing 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.
 - Devices emitting ionizing 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 minimizing radiation exposure of the patient and user.
 - Devices emitting ionizing 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.

vi) Requirements for medical devices connected to or equipped with an energy source

– 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.

– 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.

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

– 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

– 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.

– 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.

– Protection against electrical risks: 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 Manufacturer.

vii) Protection against mechanical risks

– 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.

– 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.

- 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 minimize all possible risks.

- 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.

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

- 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.

- 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.

- 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.

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

- 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 Manufacturer should be easy for the user to understand and apply.

- 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.

- 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 Manufacturer.

x) Information supplied by the Manufacturer

– Users should 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 should be easily understood.

Note: Further information is provided in SG1/N009 Labeling for Medical Devices and in SG1/N043 Labeling for Medical Devices (including In Vitro Diagnostic Devices).

xi) Performance evaluation including, where appropriate, clinical evaluation

– All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in each jurisdiction.

– 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. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.

Note: Refer to SG1/N040 Pre-Market Conformity Assessment for Medical Devices for further information on the use of clinical evaluation to demonstrate compliance with these Essential Principles.

SECTION 4: RISK CLASSIFICATION PRINCIPLES FOR MEDICAL DEVICES

4.1 Background: Principles of Risk Classification

4.1.1 Regulatory controls are intended to safeguard the health and safety of patients, users and others by ensuring that Manufacturers of medical devices follow specified procedures during design, manufacture and marketing.

4.1.2 The level of controls will depend on the identified risks associated with devices, and the identification of a suitable way of generating a sustainable set of rules is an important feature of any regulatory control system.

4.1.3 In coming to conclusions, in the GHTF SG1 dealing with pre-market procedures, took into account the existing processes amongst its members.

4.1.4 In Europe a Risk Classification procedure was developed in the European Medical Device Directive 93/42/EEC – and took into account a number of factors which could be appropriate to influence the need for differing amounts of regulatory involvement. These factors included: -

- the duration of device contact with the body;
- the degree of, and site of, invasiveness into the body;
- whether the device delivers medicines or energy to the patient;
- whether the device is intended to have a biological effect on the body;
- intended action on the human body;
- whether the device comes into contact with injured skin;
- length of contact with the body;
- whether for diagnosis or treatment; and
- the ability to be re-used or not.

These, and many more detailed characteristics were used, and existing experience in other countries led to a decision to describe 4 Risk Classes.

4.1.5 In USA, the Food and Drug Administration (FDA) had established the need for different risk classes, and decisions as to which features should decide between three main risk classes were made by employing the services of a number of 'Panels of Experts' to reach appropriate conclusions.

4.1.6 The GHTF reviewed the resulting comparison of classification decisions in these regions and it was agreed that there was reason to establish a four-class Global system.

4.1.7 It became clear that although FDA had basically three classes, in fact the additional rules which allowed further differential due to particular characteristics meant that four classes were justified.

4.1.8 A pilot investigation was undertaken by all members of the GHTF. A selection of devices, representing a wide range of potential risks, were assessed by all, to establish how these devices would fit into a four class risk-based system, and to compare these results with the results obtained from application of existing rules (where they existed).

4.1.9 The results showed that the four risk classes, as identified by the new rules, produced a significantly consistent interpretation of the expectations of members as to which each device should be listed.

4.2 Classification of Medical Devices and Classification Rules

4.2.1 Regulatory controls are intended to safeguard the health and safety of patients, users and other persons by ensuring that Manufacturers of medical devices follow specified procedures during design, manufacture and marketing.

4.2.2 The risk presented by a particular device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design manufacture and use.

4.2.3 There is a need to classify medical devices based on their risk to patients, users and other persons; and there is benefit for Manufacturers and RA when there is a classification system.

4.2.4 Classification of an assemblage of medical devices that individually comply with all regulatory requirements depends on the Manufacturer's purpose in packaging and marketing such a combination of separate devices.

4.2.5 For the purpose of regulatory controls the level of risk associated with a medical device, the level of regulatory control should increase with increasing degree of risk, taking account of the benefits offered by use of the device. At the same time, the imposition of regulatory controls should not place an unnecessary burden on regulators or Manufacturers.

4.2.6 If a combination of devices as marketed results in a product that is intended by the Manufacturer to meet a purpose different from that of the individual medical devices that make it up, the combination is a new medical device in its own right and should be classified according to the new intended use.

4.2.7 If the combination is for the convenience of the user but does not change the intended use of the individual medical devices that make it up (e.g. a customized kit that provides all the devices necessary to carry out a particular surgical procedure) there is no need to classify the combination as a whole although the Manufacturer may do so if it wishes.

4.2.8 When one or more of the medical devices that is in the assemblage has yet to comply with all the relevant regulatory requirements, the combination should be classified as a whole according to its intended use.

4.2.9 When a medical device can be classified into more than one class, the class representing higher risk applies.

4.3 General Classification System for Medical Devices

4.3.1 Figure 1 indicates the four risk classes of devices. The examples given are for illustration only and the Manufacturer must apply the classification rules to each medical device according to its intended purpose.

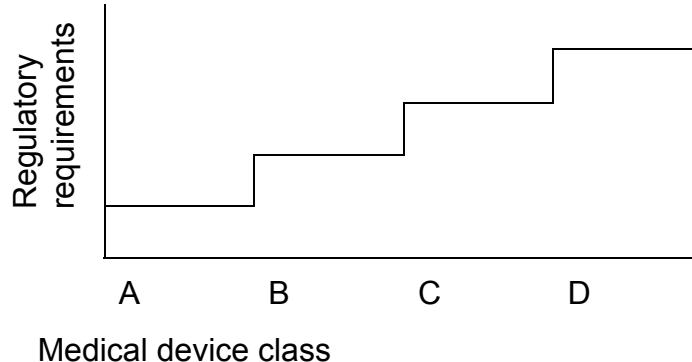
Figure 1: General classification system for medical devices

| Class | Risk level | Device examples |
|-------|--------------------|--|
| A | Low Risk | Surgical retractors/tongue depressors |
| B | Low-moderate Risk | Hypodermic needle/suction equipment |
| C | Moderate-high Risk | Lung ventilator/orthopedic implants |
| D | High Risk | Heart valves/implantable defibrillator |

4.3.2 Figure 2 shows a conceptual illustration of increasing levels of regulatory requirements as the device risk class increases. These regulatory controls may include, for example;

- operation of a quality system (recommended for all devices);
- documentation of clinical evidence to support the Manufacturer’s claims;
- technical data;
- product testing using in-house or independent resources;
- the need for and frequency of independent external audit of the Manufacturer’s quality system; and
- independent external review of the Manufacturer’s technical data.

Figure 2: Conceptual illustration of regulatory controls increasing with device risk class



The concept is expanded in Section 5: Principles of Conformity Assessment for Medical Devices.

4.4 Determination of Device Class Using Rules-Based System

4.4.1 The Manufacturer should:

i) Decide if the product concerned is a medical device, using the appropriate definition.

NOTE: Medical devices that are used for the *in vitro* examination of specimens derived from the human body are not covered by the classification rules within this document (see Scope).

ii) Determine the intended use of the medical device.

iii) Take into consideration all the rules that follow in order to establish the proper classification for the device, noting that where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated.

iv) Determine that the device is not subject to special national rules that apply within a particular jurisdiction.

4.4.2 Where special national rules are applied, resulting in a device class other than that suggested by the present rules, then a different conformity assessment procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in countries where these present rules have been adopted unless other, or additional, conformity assessment procedures are carried out.

4.5 Initial Classification Rules

4.5.1 The actual classification of each device depends on the precise claims made by the Manufacturer and on its intended use. While the provision of examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasized that the actual classification of a particular device must be considered individually, taking account of its design and intended use.

4.5.2 Where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated.

4.5.3 The classification rules for medical devices are shown in Table 1 and the decision trees illustrating how these rules may be used to classify specific devices are shown in Appendix 1.

4.6 Rationale for the Inclusion of the Additional Rules

4.6.1 There are a small number of products that fall within the scope of the definition of a medical device and which may need to be classified to take account of factors other than those covered by the risk-based rules (Rules 1 to 12). For the understanding of those countries that are not Founding Members of GHTF, it is felt important to offer guidance on the classification of such devices. Therefore, four Additional Rules are provided (Rules 13 to 16).

4.6.2 Matters that may need to be considered are:

Rule 13: Devices incorporating a medicinal product

- The regulations applying to medicinal products require different acceptance procedures to those for medical devices.
- The behavior of a medicinal product used in conjunction with a medical device may differ from that covered by its approved use as a medicine alone.
- The public perception of possible risks associated with such devices demands a high classification.

Rule 14: Devices incorporating animal or human tissues

- There is an absence of global regulatory controls for such devices.
- Classification needs to acknowledge the many different ethical and religious cultures throughout the world have an opinion on such devices.
- The public perception of possible risks associated with such devices, particularly after the problems caused by Bovine Spongiform Encephalopathies (BSE) and Creutzfeldt-Jacob disease (CJD), demands a high classification.

Rule 15: Disinfectants

- The particular concerns relating to those disinfectants that are used with contact lenses, due to sensitivity and vulnerability of the eye.

Rule 16: Contraceptive devices

- The risks associated with unwanted pregnancy if caused by mechanical failure of the device.
- The need to safeguard public health through the use of condoms to reduce the prevalence of sexually transmitted diseases.
- Public expectation that contraceptive devices are perfectly reliable and safe despite published data to the contrary.
- High political profile of these devices in assuring the protection of public health

Table 1: Classification rules for medical devices

| RULE | ILLUSTRATIVE EXAMPLES OF DEVICES THAT MAY CONFORM WITH A RULE |
|--|--|
| NON-INVASIVE DEVICES | |
| <p>1) All non-invasive devices are in Class A, unless Rule 2, 3 or 4 applies.</p> | <p>These devices either do not touch the patient or contact intact skin only.</p> <p>Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.</p> <p>NOTE: Non-invasive devices that are indirectly in contact with the body & can influence internal physiological processes by storing, channeling or treating blood, other body liquids or liquids which are returned or infused into the body or by generating energy that is delivered to the body are outside the scope of this rule.</p> |
| <p>2) All non-invasive devices intended for channeling or storing body, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,</p> | <p>Such devices are ‘indirectly invasive’ in that they channel or store liquids that will eventually be delivered into the body (see comment for Rule 1).</p> <p>Examples: administration sets for gravity infusion; syringes without needles.</p> |
| <p>unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;</p> | <p>Examples: syringes and administration sets for infusion pumps; anesthesia breathing circuits.</p> <p>NOTE: “Connection” to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and <i>vice versa</i>.</p> |
| <p>unless they are intended for use of storing or channeling blood or other body liquids or for storing organs, parts of organs or body tissues, in which case they are Class B.</p> | <p>Examples: tubes used for blood transfusion.</p> <p>NOTE: in some jurisdictions, blood bags have a special rule that places them within a higher risk class.</p> |
| <p>3) All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class C,</p> | <p>Such devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body (see comment for Rule 1). They are normally used in conjunction with an active device within the scope of either Rule 9 or 11.</p> <p>Examples: haemodialyzers; devices to remove white blood cells from whole blood.</p> <p>NOTE: for the purpose of this part of the rule, ‘modification’ does not include simple, mechanical filtration or centrifuging which are covered below.</p> |
| <p>unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in</p> | <p>Examples: devices to warm or cool blood; devices to remove carbon dioxide; particulate filters in an extracorporeal circulation system.</p> |

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| Class B. | |
| 4) All non-invasive devices which come into contact with injured skin: | Devices covered by this rule are extremely claimed sensitive. |
| - are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates; | Examples: simple wound dressings; cotton wool. |
| unless intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C. | Devices used to treat wounds where the subcutaneous tissue is at least partially exposed and the edges of the wound are not sufficiently close to be pulled together. The device manufacturer claims that they promote healing through physical methods other than providing a barrier are in Class C. Examples: dressings for chronic ulcerated wounds; dressings for severe burns. |
| - are in Class B in all other cases, including devices principally intended to manage the microenvironment of a wound. | Examples: non-medicated impregnated gauze dressings. |
| INVASIVE DEVICES | |
| 5) All invasive devices with respect to body orifices (other than those which are surgically invasive) and which: | Such devices are invasive in body orifices (refer to definition) and are not surgically invasive. Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynecology. Classification depends on the time of invasion and the sensitivity (or vulnerability) of the orifice to such invasion. |
| a) are not intended for connection to an active medical device or | |
| b) are intended for connection to a Class A medical device | |
| - are in Class A if they are intended for transient use; | Examples: dental impression materials; examination gloves; enema devices. |
| - are in Class B if they are intended for short-term use; | Examples: contact lenses, urinary catheters, and tracheal tubes. |
| unless they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A, | Examples: dentures intended to be removed by the patient; dressings for nose bleeds. |
| - are in Class C if they are intended for long-term use; | Example: urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning or maintenance is considered as part of the continuous use). |
| unless they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B. | Examples: orthodontic wire, fixed dental prosthesis. |
| All invasive devices with respect to body orifices (other than those which | Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental |

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| <p>are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.</p> | <p>aspirator tips. NOTE: independent of the time for which they are invasive.</p> |
| <p>6) All surgically invasive devices intended for transient use are in Class B,</p> | <p>A majority of such devices fall into three major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; surgical gloves; single-use aortic punch) and various types of catheter /sucker etc. NOTE: a surgical instrument (other than those in Class D) is in Class A if reusable and in Class B if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than A. NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</p> |
| <p>unless they are reusable surgical instruments, in which case they are in Class A;</p> | <p>Examples: Manually operated surgical drill bits and saws.</p> |
| <p>unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C;</p> | <p>Example: catheter incorporating/ containing sealed radioisotopes.</p> |
| <p>unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C;</p> | <p>NOTE: the ‘biological effect’ referred to is an intended one rather than unintentional. The term ‘absorption’ refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.</p> |
| <p>unless intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C.</p> | <p>Example: insulin pen for self-administration. NOTE: the term ‘administration of medicines’ implies storage and/or influencing the rate/volume of medicine delivered not just channeling. The term ‘potentially hazardous manner’ refers to the characteristics of the device and not the competence of the user.</p> |
| <p>unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.</p> | <p>Examples: angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.</p> |
| <p>7) All surgically invasive devices intended for short-term use are in Class B,</p> | <p>Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. Examples: clamps; infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilizers used in cardiac surgery. NOTE: includes devices that are used during cardiac surgery but do not monitor or correct a defect.</p> |

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| | NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13. |
| unless they are intended to administer medicines, in which case they are in Class C; | NOTE: the term ‘administration of medicines’ implies storage and/or influencing the rate/volume of medicine delivered not just channeling. |
| unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; | Example: surgical adhesive. |
| unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class C; | Example: brachytherapy device. |
| unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; | Example: absorbable suture; biological adhesive. NOTE: the ‘biological effect’ referred to is an intended one rather than unintentional. The term ‘absorption’ refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. |
| unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; | Example: neurological catheter. |
| unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D. | Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts. |
| 8) All implantable devices, and long-term surgically invasive devices, are in Class C, | Most of the devices covered by this rule are implants used in the orthopedic, dental, ophthalmic and cardiovascular fields. Example: maxilla-facial implants; prosthetic joint replacements; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating). NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13. |
| unless they are intended to be placed into the teeth, in which case they are in Class B; | Examples: bridges; crowns; dental filling materials. |
| unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; | Examples: prosthetic heart valves; spinal and vascular stents. |
| unless they are intended to be life supporting or life sustaining, in which case they are in Class D; | |

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| unless they are intended to be active implantable medical devices, in which case they are Class D; | Example: pacemakers, their electrodes and their leads; implantable defibrillators. |
| unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; | Example: implants claimed to be bioactive. NOTE: hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the Manufacturer. |
| unless they are intended to administer medicines, in which case they are in Class D; | Example: rechargeable non-active drug delivery system. |
| unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D. | NOTE: bone cement is not within the scope of the term 'chemical change in the body' since any change takes place in the short rather than long term. |
| unless they are breast implants, in which case they are in Class D. | |
| ACTIVE DEVICES | |
| 9) All active therapeutical devices intended to administer or exchange energy are in Class B, | Such devices are mostly electrically powered equipment used in surgery; devices for specialized treatment and some stimulators. Examples: muscle stimulators; TENS devices; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy. |
| unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C. | Examples: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. NOTE: the term 'potentially hazardous' refers to the type of technology involved and the intended application. |
| All active devices intended to control or monitor the performance of active therapeutical devices in Class C, or intended directly to influence the performance of such devices, are in Class C. | Examples: external feedback systems for active therapeutical devices. |
| 10) Active devices intended for diagnosis are in Class B: | Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology. |
| - if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or | Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators. |
| - if they are intended to image <i>in vivo</i> | Example: gamma/nuclear cameras. |

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| distribution of radiopharmaceuticals, or | |
| - if they are intended to allow direct diagnosis or monitoring of vital physiological processes, | Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs. |
| unless they are specifically intended for: | |
| a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or | Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. |
| b) diagnosing in clinical situations where the patient is in immediate danger, | Example: ultrasound equipment for use in interventional cardiac procedures. |
| in which case they are in Class C. | |
| Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C. | Example: diagnostic X-ray source; devices for the control, monitoring or influencing of the emission of ionizing radiation. |
| 11) All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class B, | Such devices are mostly drug delivery systems, or anesthesia equipment. Examples: feeding pumps; jet injectors. |
| unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application, in which case they are in Class C. | Examples: infusion pumps; anesthesia equipment; dialysis equipment; hyperbaric chambers. |
| 12) All other active devices are in Class A. | Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights. |
| ADDITIONAL RULES | |
| 13) All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D. | These devices cover combination devices that incorporate medicinal substances in a secondary role. Examples: antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound. |
| 14) All devices manufactured from or incorporating animal or human | NOTE: In some jurisdictions such products: - are considered to be outside the scope of the |

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| <p>cells/tissues/derivatives thereof, whether viable or non-viable, are Class D,</p> | <p>medical device definition; - may be subject to different controls. It is likely the regulations controlling these devices will be the subject of future harmonization efforts. Examples: porcine heart valves; catgut sutures.</p> |
| <p>unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class A.</p> | <p>Examples: leather components of orthopedic appliances.</p> |
| <p>15) All devices intended specifically to be used for disinfecting or sterilizing medical devices are in Class B,</p> | <p>Examples: disinfectants intended to be used with medical devices; washer disinfectors. NOTE: This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action e.g. washing machines.</p> |
| <p>unless they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses, in which case they are in Class C.</p> | <p>Examples: contact lens solutions. NOTE: In some jurisdictions solutions for use with contact lenses: - are considered to be outside the scope of the medical devices definition; - may be subject to different controls.</p> |
| <p>16) All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,</p> | <p>Examples: condoms; contraceptive diaphragms.</p> |
| <p>unless they are implantable or long-term invasive devices, in which case they are in Class D.</p> | <p>Example: intrauterine contraceptive device.</p> |

SECTION 5: PRINCIPLES OF CONFORMITY ASSESSMENT FOR MEDICAL DEVICES

5.1 Purpose of Conformity Assessment

5.1.1 The inter-relationship between device risk class and the appropriate conformity assessment procedure is the important factor when establishing a consistent pre-market acceptance procedure which will lead to Global acceptance for a particular medical device.

5.1.2 The purposes of conformity assessment are;

i) to describe the different procedures that may be used by a Manufacturer, alone or in combination, to demonstrate that a medical device conforms to the Essential Principles of Safety and Performance of Medical Devices.

ii) to describe which procedures should apply to each class of device such that regulatory demands increase with both the risk class of the medical device and the novelty of any innovation it incorporates

iii) to describe how a RA or CAB may confirm that such procedures are applied properly by the Manufacturer.

iv) to describe how a manufacture prepares a written Declaration of Conformity to attest that a medical device complies fully with all relevant obligations.

5.2 “Manufacturer’s Declaration of Conformity” with the “Essential Principles for Safety and Performance of Medical Devices”

5.2.1 One element of the Regulatory Model for Medical Devices is that the Manufacturer attests that it’s medical device complies fully with all applicable Essential Principles for Safety and Performance and prepares a written Declaration of Conformity. This should contain a declaration as follows: -

i) A statement that each device to which the conformity assessment procedures have been applied comply with applicable provisions in the Essential Principles, the Classification Rules, and appropriate conformity assessment procedures that have been applied.

ii) Information sufficient to identify the device in general (and where appropriate the lot/batch or serial numbers)

iii) The use of the device intended by the Manufacturer and any specific patient population for which it is intended

iv) The Risk Class of the device (after following guidance in Principles of Medical Device Classification)

v) The name and address of the Manufacturer or, where the Manufacturer outside the RA’s jurisdiction, the name and address of a Local Authorized Representative

- vi) The identity of any CAB involved if appropriate, and procedures applied
- vii) A list of recognized standards, if any, with which the device complies
- viii) The date from which the Declaration of Conformity is valid
- ix) Information to identify the person who has completed the Declaration of Conformity on behalf of the Manufacturer.

5.3 Available Conformity Assessment Procedures and Their Verification by the RA or CAB

5.3.1 The conformity assessment procedures that the RA may make available to the Manufacturer will be selected from those described below. They relate either to the design of the product, its manufacture, or both. As a general rule, a medical device is subject to conformity assessment during both design and manufacture. Some of the procedures described in this document are alternatives to others and it is neither intended nor desirable that every listed conformity assessment procedure should be applied to every medical device.

5.3.2 The conformity assessment procedures that appear in this Section describe the tasks of the Manufacturer and, where appropriate, the RA or CAB. Guidance on the selection of conformity assessment procedures that are appropriate for a particular medical device is also described in this document.

5.4 Quality Management System (QMS)

5.4.1 To meet customer requirements, and provide safe and effective medical devices, the Manufacturer implements and maintains a quality management system that incorporates both design control and manufacturing procedures and has a scope and depth appropriate to the risk class and the nature of the device. It is one part of the global regulatory model.

5.4.2 A system that complies with, or has been harmonized to, an internationally recognized standard on quality management systems for medical devices¹, will be presumed to meet this requirement. For Risk Class A (low risk) products, a simple good manufacturing practice (GMP) procedure is appropriate or other documented procedure to cover the production and inspection processes.

5.4.3 As part of its QMS, the Manufacturer should apply a risk management procedure to the device. Risk management continues throughout the life cycle of the product².

¹See ISO 13485:2003

²See ISO 14971:2000

5.4.4 Where the QMS is subject to audit by a RA or CAB, the Manufacturer will be required to inform the auditing organization of any significant change it has made to the system it is using. Alternative QMS are:

- i) a full QMS including design control; or
- ii) a production QMS excluding design control both based on ISO 13485 but with exclusions for ii).

5.4.5 The RA or CAB may determine whether the quality management system has been effectively implemented and maintained by

- i) for Class A devices, reviewing a self-declaration statement from the Manufacturer,
- ii) for all other classes of device, a regulatory audit of the Manufacturer's QMS³,
- iii) as permitted by the regulations that apply within the jurisdiction.

5.5 Design Output Verification Through Type-Examination

5.5.1 The regulations that apply within some jurisdictions may allow verification of the design output to be assessed by independent testing of a representative sample of the finished device, that is "the type", rather than through the design control procedures incorporated into the QMS referred to in Section 5.3. In this case, the Manufacturer subjects a representative sample of the finished product, to examination and testing by either a CAB or an accredited organization independent of the Manufacturer. After a successful test, the testing body issues a type-examination certificate that:

- i) identifies the Manufacturer,
- ii) confirms the product complies with the relevant provisions of the Essential Principles of Safety and Performance and any other conclusions of the type-examination,
- iii) describes the conditions of validity, and
- iv) provides the data needed for identification of the type approved.

5.5.2 The Manufacturer will also be required to inform the organization that issued the type-examination certificate of any significant changes made to type approved product.

5.5.3 Where the regulations allow verification of the design output to be assessed by independent type-examination, the Manufacturer will be required either:

- i) to implement and maintain a quality management system for the manufacturing phase that has a scope and depth appropriate to the risk class and the nature of the device⁴ or,

³ See SG4/N028 Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements.

- ii) verify the manufacturing process by testing every medical device before it is placed on the market to ensure each one complies with the relevant provisions of the Essential Principles of Safety and Performance (see Section 6.3).

5.5.4 The RA or CAB may determine whether the Manufacturer's design control procedures have been effectively implemented by reviewing the type-examination certificate and, if required, by examining the supporting documents.

5.6 Production Verification Through Testing Every Finished Device

5.6.1 The regulations that apply within some jurisdictions may allow verification of manufacturing procedures to be assessed by the independent testing of every finished device to ensure safety and performance requirements are achieved. In this case, the Manufacturer subjects each finished device, to testing by either a CAB or an accredited organization independent of the Manufacturer. After a successful test, the testing body issues a Verification Certificate confirming the individual manufactured device complies with the Essential Principles of Safety and Performance.

5.6.2 Where the regulations allow verification of the manufacturing process to be assessed by testing every medical device before it is placed on the market to ensure each one complies with the relevant provisions of the Essential Principles of Safety and Performance the Manufacturer will be required to verify the design output by independent testing of a representative sample of the finished device, that is "the type".

5.6.3 The regulations are likely to restrict this conformity assessment procedure to long-established medical devices that are manufactured in low volumes.

5.6.4 The RA or CAB may determine whether the Manufacturer's production procedures have been effectively implemented by reviewing the Validation Certificate and, if required, by examining the supporting documents.

5.7 Technical Documentation

5.7.1 The regulations may designate technical documentation that the Manufacturer is required to establish, maintain and, in some cases, submit. A description of the topics likely to be covered is provided in Section 7.0 of the GHTF Guidance Document: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices. These topics include comparison with other marketed devices where this helps to establish conformity of the new device with the Essential Principles and compliance with relevant recognized standards. The information held is likely to increase with the risk class of the

⁴See ISO 13485:2003 clause 1.2

medical device, its complexity and the extent to which it incorporates new technology.

5.7.2 The RA or CAB, if authorized by the RA, may determine whether the required documentation has been established through a document review or during a regulatory audit of the Manufacturer's QMS. The nature of the regulatory audit is likely to be influenced by the risk class of the medical device, its complexity and the extent to which it incorporates new technology.

5.8 Submission of Pre-Market Technical Information to RA or CAB

5.8.1 In addition to the technical information that the Manufacturer may be required to establish, maintain and hold (Section 5.7), the regulations that apply within some jurisdictions may require the Manufacturer to submit technical information to a RA or CAB for review before the device is marketed. Submission is most likely to be required where the device falls within a moderate or high risk class, where it is complex, or where it incorporates novel technology.

5.8.2 Such regulations will describe the information required and may specify its format. It should permit such information to be summarized as described in the GHTF Guidance Document: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices.

5.8.3 The RA or CAB, if authorized by the RA, may determine whether the information provided to them meets the requirements of the regulations by reviewing the submitted material and, if required, by calling for other relevant information. The quantity of submitted material and the depth of the subsequent review is likely to be influenced by the risk class of the medical device, its complexity and the extent to which it incorporates new technology.

5.9 Clinical Evidence

5.9.1 The Essential Principles of Safety and Performance of Medical Devices are a key part of the global regulatory model recommended by the GHTF. Therefore, before the Manufacturer issues a Declaration of Conformity (Section 5.2), it must evaluate all relevant clinical evidence to establish safety and performance and any undesirable side effects. See Section 9: Evaluation of Clinical Data (Clinical Evidence)

5.9.2 The RA or CAB, if authorized by the RA, may determine whether the required information has been established and meets the requirements of the regulations during a regulatory audit of the Manufacturer's QMS (Section 5.4), by reviewing the material submitted to them (Section 5.7) or by other regulatory review. If required, it may call for other relevant information. The quantity of available/submitted material and the depth of the subsequent review are likely to be influenced by the risk class of the medical device, its complexity and the extent to which it incorporates new technology.

5.10 Additional Regulatory Controls

5.10.1 Registration and listing with the RA

i) As a condition of marketing approval when a medical device is imported into a country, the Manufacturer, its local distributor or its Authorized Representative may be required by the regulations that apply within a particular jurisdiction to register with the RA and provide data sufficient to identify all the medical devices that are to be used within that jurisdiction. This could include details of device labeling and instructions for use. The regulations may require that the local distributor's premises be inspected and its QMS audited.

ii) The RA may determine whether the information provided to them meets the requirements of the regulations by reviewing the submitted material and, if required, by calling for other relevant information. Registration of such premises and listing of the medical devices may follow.

5.10.2 Demonstration of the existence of post-market surveillance system

i) As a condition of marketing approval, the RA may require the Manufacturer or its Authorized Representative to have in place a systematic procedure to review experience gained from devices in the post-production phase, usually as part of its QMS, to implement appropriate means to apply any necessary corrective actions and report as required. Further details are provided through the GHTF Guidance Documents issued by Study Group 2, Study Group 3 and within standard ISO 13485.

ii) The RA or CAB, if authorized by the RA, may determine whether the required procedure has been established and meets the requirements of the regulations during a regulatory audit of the Manufacturer's QMS.

5.11 Harmonized Conformity Assessment System

5.11.1 Under the risk-based classification system recommended by the GHTF there are four classes of devices. Class A devices are the lowest risk devices, whereas Class D devices present the highest risk. Conformity assessment procedures to be applied by the Manufacturer will become more vigorous with increase in device class and risk.

5.11.2 This principle is illustrated in the guidance that follows. It identifies available conformity assessment elements and proposes a combination of those elements that may be applied to different classes of medical device to construct a harmonized conformity assessment system that may be adopted as part of a global regulatory model for medical devices. At this time, conformity assessment and regulatory requirements may vary between jurisdictions. Where the RA makes available alternative conformity

assessment procedures that offer equivalent levels of assurance, the Manufacturer may choose those it believes to be most suitable.

5.12 Elements of a Harmonized Conformity Assessment System

5.12.1 Basic element

- i) Manufacturer prepares, maintains and holds Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED).
 - identify applicable Essential Principles and the method/s used to demonstrate conformity with each (it is recommended the evidence of conformity be provided in tabular form with supporting documentation available for review as required);
 - provide information on the functional purpose of the device and its variants; its principles of operation; a specification; materials used; a description of any novel features; and a comparison with other devices where this is appropriate;
 - summarize design verification and validation documents, including: clinical evidence; certificates of conformity to recognized standards; and summaries of test reports;
 - summarize, reference or include device labels and labeling;
 - summarize, reference or include the results of the risk analysis;
 - summarize, reference or include documentation relating to the manufacturing process and quality management system.

5.12.2 QMS elements

- i) Manufacturer applies a full QMS.
- ii) Manufacturer applies a QMS that does not include design control elements.
- iii) Design verification through ‘type-testing’ by a CAB or other accredited organization independent of the Manufacturer.
- iv) Verification by a CAB or other accredited organization independent of the Manufacturer testing each individual device after its manufacture.
- v) For low risk Class A devices – documented procedures for GMP. Audit not normally necessary.

5.12.3 Vigilance element

- i) Manufacturer maintains a post-market surveillance system to review experience gained from devices in the post-production phase.

5.12.4 Control elements

i) The regulations require a regulatory audit of the Manufacturer's quality management system, post-market surveillance system, and Declaration of Conformity, by an RA or CAB. The nature of the audit is likely to be influenced by the risk class of the medical device, its complexity and the extent to which it incorporates new technology.

ii) The regulations require specified technical information to be submitted to the RA or CAB before the device is marketed. The quantity of submitted material and the depth of the subsequent review are likely to be influenced by the risk class of the medical device, its complexity and the extent to which it incorporates new technology (audit is not compulsory for Class A devices).

iii) The regulations require the Manufacturer or distributor to register with the RA before the device is marketed and lists the medical devices that will become available.

5.12.5 Attestation and responsibility element:

i) The Manufacturer prepares a Declaration of Conformity with all relevant requirements.

5.13 Summary of Combination of Elements According to Classification of Medical Device

5.13.1 Class A device

| Conformity assessment element (Clause 5.12) | Clauses applicable |
|---|---|
| Basic element | 5.12.1 – STED (limited detail, mainly outline) |
| QMS | 5.12.2 – Documented GMP, normally not audited |
| Vigilance | 5.12.3 as appropriate in relation to risk |
| Control elements | Normally not required except for assurance of sterility if relevant 5.12.4 – listing may be required |
| Attestation | 5.12.5 – Declaration of Conformity |

5.13.2 Class B device

| Conformity assessment element (Clause 5.12) | Clauses applicable |
|---|--|
| Basic element | 5.12.1 – STED (to be held by Manufacturer) |
| QMS | Either; 5.12.2 i) – full QMS; or |

| | |
|------------------|---|
| | 5.12.2 ii) + 5.12.2 iii) – production QMS; or 5.12.2 iii) + 5.12.2 iv) – product type test |
| Vigilance | 5.12.3 – documented procedures apply to all devices |
| Control elements | 5.12.4 i) – in relation to production QM elements 5.12.4 ii) if appropriate 5.12.4 iii) – listing may be required |
| Attestation | 5.12.5 – Declaration of Conformity |

5.13.3 Class C device

| Conformity assessment element (Clause 5.12) | Clauses applicable |
|---|---|
| Basic element | 5.12.1 – STED prepared and will be examined |
| QMS | 5.12.2 i) – optional; full QMS; or 5.12.2 ii) – to be audited; production QMS; plus either; 5.12.2 iii) – product type test; or 5.12.2 iv) – final test of each device |
| Vigilance | 5.12.3 – documented procedures; apply to all devices |
| Control elements | 5.12.4 i) – audited QMS 5.12.4 ii) – STED document 5.12.4 iii) – registration listing may be required |
| Attestation | 5.12.5 – Declaration of Conformity required for all devices |

5.13.4 Class D device

| Conformity assessment element (Clause 5.12) | Clauses applicable |
|---|---|
| Basic element | 5.12.1 – STED prepared and will be examined |
| QMS | 5.12.2 i) – full QMS |
| Vigilance | 5.12.3 – documented procedures; apply to all devices inspected |
| Control elements | 5.12.3 – submit QMS for audit + Declaration of Conformity + Post-Market |

| | |
|-------------|---|
| | <p>Surveillance System</p> <p>5.12.4 i) – STED audit with in-depth review of source material</p> <p>5.12.4 ii) – registration may be required</p> |
| Attestation | 5.12.5 – Declaration of Conformity required for all devices |

5.14 Needs for Occasional Departure from the Predicted Needs for Conformity Assessment Procedures as Related to Risk Class

5.14.1 The procedures indicated in this document are based upon the need for increasing levels of conformity assessment in proportion to the increasing risk classes identified by using the “Principles of Medical Device Classification”

5.14.2 Thus there are four indicated procedures based on an appropriate response to the controls necessary to cover each of the risk classes;

- i) Risk Class A – Low Risk Devices
- ii) Risk Class B – Medium to Low Risk Devices
- iii) Risk Class C – Medium to High Risk Devices
- iv) Risk Class D – High Risk Devices

5.14.3 In practice the associated conformity assessment procedures for each of these levels of risk provide a high level of safety. There are, however, a number of characteristics based upon special situations, experience, features, which suggest a need for adjusting the conformity procedures in proportion to a perceived need, to address such occasional indications. Such features include for example;

- i) The device incorporates “well established” technology
- ii) The device incorporates “innovative technology”
- iii) The RA or CAB is familiar with the Manufacturer and its products, and the device is an updated version of an earlier compliant device and contains little real change
- iv) A substantially equivalent device from another Manufacturer is at present on the market already
- v) Recognized internationally accepted standards are available to cover main aspects of the device, and have been used by the Manufacturer
- vi) The device is complex and perhaps multi-functional
- vii) The device generic type tends to be associated with an excessive number of adverse events including user errors
- viii) The device incorporates “innovative” or “potentially hazardous” materials

- ix) An existing compliant device is being used for a new clinical purpose.

5.14.4 The result of addressing these nine examples of particular features may mean that either;

- i) The particular risks associated with this feature would justify the need to document more information on particular aspects and to receive further CAB assessment than the risk class would suggest. There may be a need to ensure a much more rigorous control of production processes. There could be a need to insist on more clinical evidence to be provided. In assessing the amount of detail required in preparing the STED a more-than-usual level of information might be needed; or
- ii) The particular risks associated with risk class of this product are so well known, and of such a low level that it is reasonable to reduce the need for such an in-depth procedure (perhaps in terms of documentation need – or to treat the device as though it falls into a risk class one-below that originally indicated).

5.14.5 Those products falling into 5.14.4 i) above could include those with ‘features’ 5.14.3 ii), vi), vii), viii) and ix). Those products falling into 5.14.4 ii) above could include those with ‘features’ 5.14.3 i), iii), iv) and v).

5.14.6 It should be emphasized that there must be a fully justified case before changing in any way the relationship between risk class and conformity assessment procedure in this way which should be clearly indicated in the STED document. This situation should be used as an exception and only when clearly approved by the RA or CAB.

SECTION 6: ACCREDITATION AND REGISTRATION OF CONFORMITY ASSESSMENT BODY (CAB)

6.1 Introduction

The regulation of the Medical Devices is carried out by the regulatory authority called “Competent Authority (CA)”. Parts of the execution and surveillance of a regulation task of the regulatory authority may be delegated to reliable private bodies called Conformity Assessment Bodies (CABs). These CABs need to be accredited, notified and within surveillance of the regulatory authority.

6.2 Definitions

“Conformity Assessment Body (CAB)” means an auditing or testing organisation, independent from the CA, responsible for conducting audits of medical device manufacturers or performing tests of medical devices against the regulatory requirements.

“Designating Authority (DA)” means the authority responsible for identifying, designating, monitoring, suspending and withdrawing designation of the CAB conducting regulatory audits or performing tests.

“Competent Authority (CA)” means the National Authority with responsibility for implementing the relevant provisions contained in the specific regulation within its jurisdiction.

“Auditor” means the person employed by the CAB for the purpose of assessing a manufacturer’s conformity with the medical devices regulations, especially with its CAPs for QMS

“Essential Principles (EP)” means the requirements for medical devices that have been designed and manufactured in such a way that, when used under the conditions and for the purposes intended.

6.3 Reference Documents

- i) Malaysian Guidance Document for Regulatory Auditing of Quality Management System (QMS) and Auditing Process (Draft proposal)
- ii) Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General requirements. GHTF SG4(99)28.
- iii) Medical Devices Guidance Document MEDDEV 2.10-2 Rev 1 April 2001. Designation and Monitoring of Notified Bodies within the framework of EC Directives on Medical Devices. CEC, sector Medical Devices
- iv) European Directives – 93/42/EEC (MDD), 90/385/EEC (AIMDD), 98/79/EC (IVDD)
- v) IAF/IEC Guides 62, 65
- vi) EN 45000 series Standards

- vii) ISO 13485:2003 Quality Systems – Medical Devices – System requirements for regulatory purposes.
- viii) ISO/IEC 17025:1999: General requirements for the competence of testing and calibration laboratories
- ix) Designating Authorities Handbook. CEC, sector Medical Devices
- x) GHTF SG4-(00)3 – Training Requirements for Auditors
- xi) GHTF SG1/N041R6 – Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices)

6.4 Scope

6.4.1 The scope of this guidance document covers the criteria and registration of CABs registered in Malaysia. The assessment, accreditation, registration and monitoring of Conformity Assessment Bodies shall be performed by the Designation Authority in Malaysia.

6.4.2 Where, in this document, reference is made to “the Competent Authority responsible for designation”, this includes any appointed body, in particular accreditation body to which, in accordance with the national system, given tasks are assigned.

6.4.3 This document also covers the acceptance of CABs registered outside Malaysia who perform conformity assessment procedures to meet the requirements of the national regulation for the medical devices in question.

6.5 Criteria for CAB

This section refers to any auditing organisation independent from the CA, responsible for conducting audits of medical device manufacturers against the national regulatory requirements. In general, these criteria cover:

- i) Availability of personnel, equipment and test facilities (including sub contractors)
- ii) Independence and impartiality
- iii) Technical, scientific, and medical competence of CAB personnel both in relation to the conformity assessment procedures and to the medical devices in question
- iv) Professional confidentiality and integrity of the CAB and the staff it employs
- v) Civil liability insurance, unless covered by state under national law.

6.6 General Requirements

6.6.1 CABs should be legal persons under the same legislation as is the regulation itself (exception: acceptable foreign CABs, see chapter 9).

- i) Documentation clearly identifying its legal status;

- ii) Documentation which clearly shows both the authority and the responsibility of individuals and the reporting structure within the CAB
- iii) Documentation about its financial situation.

When a CAB is a legal entity, which is part of a larger organisation, the links and relationship between the CAB and the larger organisation shall be clearly documented.

6.6.2 CABs should provide the resources for conformity assessment of medical devices as specified in the regulation in a competent, transparent, neutral, independent and impartial manner.

6.6.3 CABs should be capable of taking full responsibility for all tasks required from a CAB in relation to the regulation and to the medical devices for which it is being designated.

6.6.4 CABs designated, shall, without delay, inform the Competent Authority responsible for designation of any change regarding availability of resources, including sub-contractors, and compliance with designation conditions which may have an impact on the maintenance of the designation and of the assignment of tasks.

6.6.5 CABs should be a sound organization, the necessary staff and an appropriate facility which allows them to perform their tasks with the highest degree of professional performance.

6.6.6 CABs may subcontract specific parts of their tasks as long as they keep the full responsibility for all tasks subcontracted. They must ensure that the subcontractor meets the provisions of the regulation in the same way as the CAB does. The CAB should keep at the disposal of the DA the relevant documents of assessing the subcontractor's qualifications and the work carried out by the subcontractor under the regulation.

6.6.7 CABs are required to check the manufacturer has followed his declared procedures and those required by the directive. The manufacturer through the Declaration of Conformity takes the ultimate responsibility for device safety and product liability. The CAB has a responsibility to monitor the manufacturer's system for producing the Declaration of Conformity for all classes of device except Class A (non sterile/non measuring).

6.6.8 CABs agree to the device classification with the manufacturer and whether the application is within the scope of the CAP. The manufacturer will be asked to submit a classification of his device or device category at the application stage for consideration by the CAB. The final responsibility for classification remains with the manufacturer.

6.6.9 CABs should refer to the Competent Authority instances where previously agreed clinical trial protocols have not been followed.

6.6.10 CABs should check the correct use of the approval of the medical device.

6.6.11 CABs should ensure the manufacturer informed them of any significant changes to its products, processes or QA systems since the last audit.

6.6.12 CABs should check the manufacturer's procedure for reviewing experience in the post-production phase.

6.7 Independence Requirements

6.7.1 CABs should be independent from the manufacturers of medical devices. This means that neither the management, nor the assessment and verification staff nor the administrative and other staff may be the designer, manufacturer, supplier, installer or user of the devices they are involved with, nor be the designer, implementer, operator or surveillant of the Quality Management System of a Medical Devices manufacturer or of a supplier to a manufacturer.

6.7.2 CABs should be free from all pressures and inducements, particularly financial, which might influence their judgement or the result of the inspections, especially from persons or groups of persons with an interest in the results of the verifications.

6.7.3 CABs should have civil liability insurance, unless liability is assumed by the state under domestic legislation.

6.7.4 CABs should observe strict professional confidentiality with regard to all information obtained in carrying out their tasks. This does not affect obligations of CABs with regard to legally required reporting and the dissemination of warnings, nor the obligation of the persons concerned to provide information under criminal law.

6.8 Tasks of the CAB

6.8.1 The tasks of the CABs are, according to the list of CAPs (see document "Regulation" 2.2.1) to perform, on application of a manufacturer:

- i) auditing, certification and surveillance of a Production Quality System
- ii) auditing, certification and surveillance of a Full Quality System
- iii) type testing of a Medical Device
- iv) technical file review of a Medical Device
- v) testing of every Medical Device manufactured
- vi) statistical testing of all Medical Devices manufactured
- vii) batch release for all Medical Devices manufactured

6.8.2 Auditing, certification and surveillance of a Quality System

This is the classical task of a QMS registrar. The difference in the task of a CAB to the task of a QMS registrar is that the QMS in this regulatory framework has a special purpose: it must assure that medical devices manufactured under the QMS comply with the product-related requirements of the regulation. Whereas a QMS registrar who in general is not involved in product technology at all.

6.8.3 Production Quality System

- i) To audit the quality systems to the requirements of declaration of conformity using the current ISO13485:2003 as a basis for the audit to meet the regulatory requirements.
- ii) For Class C and D devices, to check the validity of the Type Examination Certification and that production conforms to the type certificated. There is no responsibility to check the validity of the design solution, test reports, clinical data etc. This is the responsibility of the CAB that undertakes the Type Examination.
- iii) For Class B devices, to check procedures for controlling technical documentation and production conformity. Although there is no requirement to check all technical files for Class B devices, their content should be checked on a sample basis to gain confidence that the manufacturer is following the appropriate procedures and the Declarations are in the correct format. This should be checked on a sample basis for every product technology used by the manufacturer.

6.8.4 Full Quality System

- i) To audit the quality systems to the requirements using the current ISO13485:2003 standard as a basis for the audit to meet the regulatory requirements. There is no requirement in the assessment to be different depending on whether Class B or C devices are involved.
- ii) If sterilization or sterility are involved to include a technical evaluation by a suitably competent person.
- iii) To assess that the procedures for process control, inspection and testing are appropriate for that type of device and are in conformity with those indicated in the technical documentation.
- iv) To assess the procedures for controlling, monitoring and verifying the design of the device and its compliance with the requirements of the directive. To assess the capability of the manufacturer to use and interpret in the design process the "Essential Principles of Safety and Performance" (EP) and the relevant standards for all product technologies used by the manufacturer. This includes checking the procedures for producing the Declaration of Conformity, and checking the content of the Declarations themselves on a sample basis to gain confidence that they are in the correct format and properly specify the products to which they apply. There is no requirement to check technical files for every device, but some should be checked on a sample basis as part of the audit of the design process (including use of clinical data, risk analysis and other technical assessments) in order to gain confidence that the products meet the EP.

6.8.5 Type testing of a Medical Device

- i) If a CAB is accredited and notified for the CAP "type testing" it must either operate a test laboratory for the devices in question on its own or it must be able to perform type testing with the help of appropriate subcontractors. If subcontractors are used, the CAB

must have enough expertise to assess its subcontractors and to evaluate their test results.

- ii) The requirements of the CAB to perform type testing:
 - To verify that the device is in conformity with the technical documentation.
 - To agree with the manufacturer which standards or protocols are applicable and which tests are required to verify compliance with the EP.
 - To test or inspect to verify the solutions satisfy the EP:
 - using recognized standards where it is agreed that these apply;
 - or using other standards or protocols designed by the manufacturer where it is agreed that these verify compliance with the EP.
 - To verify conclusions drawn from clinical data, risk analysis and other technical assessments.
 - To issue, if relevant a Type-examination certificate with five-year validity.

6.8.6 When a manufacturer informs the CAB that a device previously granted a Type Examination Certificate has undergone a significant change, to reassess the device prior to the manufacturer placing the changed device on the market.

6.8.7 Technical file review of a Medical Device

- i) For Class D devices only, to undertake a Design Examination on the technical documentation of the medical device in question. The objective is to confirm that the product conforms to the relevant provisions of the Conformity Assessment Procedures by verifying the items listed below.
 - the conclusions of the risk analysis;
 - that the applicable EP have been addressed;
 - that relevant standards have been applied or that the solutions adopted, in the absence of standards, meet the EP;
 - the conclusions of the clinical data.
 - the CAB may require further tests or other data during this procedure.
- ii) For Class D devices only, the CAB must also approve changes which could affect the product's conformity with the EP or the conditions of use.

6.8.8 Testing of every Medical Device manufactured

Every product is examined individually and the appropriate tests defined in the relevant standard(s) or equivalent tests must be carried

out in order to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate (for class C and D products) or with the technical file (class B products) and with the requirements which apply to them

6.8.9 Statistical testing of all Medical Devices manufactured

- i) This CAP is only applicable for medical devices manufactured in homogeneous batches.
- ii) To verify that the type is in conformity with the technical file.
- iii) Prepare a plan to ensure sufficient and consistent application of tests and inspections.
- iv) To test each product or, where the batch size exceeds 50 and the manufacturer does not choose otherwise, random samples taken from a homogeneous batch according to the sampling plan described as below.
- v) Statistical control of products will be based on attributes, entailing a sampling system ensuring a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity percentage of between 3 and 7 %. The sampling method will be established by the harmonized standards taking account of the specific nature of the product categories in question.
- vi) If relevant, to prepare a testing and verification certificate specific to the product and limited to the batch or samples subjected to the verification process.
- vii) To take measures to prevent non-conforming samples or batches from being placed on the market.
- viii) For products supplied sterile, to ensure that the appropriate parts of production quality system have been applied.
- ix) As a non-statutory duty, the CAB may wish to examine the declaration of conformity, the technical file and the undertakings of the manufacturer.

6.8.10 Batch release for all Medical Devices manufactured (for some special IVD devices only)

- i) The manufacturer shall forward to the CAB without delay after the conclusion of the controls and tests the relevant reports on the tests carried out on the manufactured devices or each batch of devices. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities.
- ii) The manufacturer may place the devices on the market, unless the CAB communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

6.9 Requirements for Appointment of CAB Staff and Training

6.9.1 General

The skills and expertise CAB staff should have the following. It is therefore intended to supplement and expand upon when necessary. Experience has shown that ideally, CABs auditing personnel should have successfully completed a university or a technical college degree or equivalent qualification in relevant studies

6.9.2 Auditor qualifications, training and experience

In addition to basic auditing skills the competencies specifically required for auditing medical device manufacturers may be achieved through a variety of means including a combination of one or more of the training or experience elements listed below.

i) Qualification

Auditor qualification will be from one or more of the following fields:

- Biology or microbiology or biotechnology
- Chemistry or biochemistry;
- Computer or software technology;
- Electrical, mechanical or bioengineering;
- Human physiology;
- Medicine; Dentistry, Biomedical
- Pharmacy;
- Physics or biophysics.
- Other relevant fields

ii) Training

- Special programs may be established for training technically qualified staff in the following:
- Understanding the regulatory requirements and related laws/ordinances/statutes etc.
- Auditing of medical devices manufacturers' quality systems;
- Understanding the design and manufacturing processes and the technologies involved;
- Safety aspects relating to the intended use of medical devices.

iii) Experience

- Auditor experience is most likely to be in the following:
- Working in closely related industries and the workplace such as research and development, manufacturing;

- Working in the application of the device technology and its use in health care services and with patients;
- Testing the devices concerned for compliance with the relevant national or international standards;
- Conducting performance testing, evaluation studies or clinical trials of the devices.
 - Substantial relevant experience in e.g. the diagnostic, medical devices or pharmaceutical industries, the health care professions, medical laboratories, or test institutes,
 - Proven knowledge of medical devices regulations, other relevant regulations and relevant guidance documents.
 - Proven knowledge of quality management procedures, especially of relevant standards acquired through successful participation in relevant training courses and/or practical experience
 - Knowledge of the current status of applicable and relevant product-related standards upon when necessary and monographs in pharmacopoeias
 - Technical knowledge and experience of the design, manufacture, and quality control of medical devices and in vitro diagnostics
 - Risk assessment and management as applied to medical devices, including relevant standards
- In addition, and depending on the scope of designation being applied for in respect to device types and conformity assessment annexes, the applicant may need to show that the people it intends using as CAB auditors have additional specific expertise in other relevant areas, e.g.:
 - Sterile devices: where auditors will need to be able to assess technologies and methods used by manufacturers, e.g. for making sterile medical devices, the evaluation of sterility data, including environmental control, and the validation and routine control of sterilization processes
 - Assessment of medical devices against specific EP, where auditors will need to be able to, for example:
 - Evaluate the biological and medical functionality and performance of medical devices
 - Evaluate devices containing animal tissues
 - Evaluate devices containing human blood derivatives and have knowledge of the biological and medical functionality and performance,

including an up to date knowledge on relevant blood borne infectious agents and their epidemiology;

Evaluate bio-compatibility data and clinical data used by manufacturers to demonstrate compliance with the EP

Evaluate the electrical safety of medical devices

Evaluate software used in medical devices

- Knowledge of, and the ability to apply, relevant standards as applicable.

– In addition an applicant seeking designation under the IVD Requirements will need to demonstrate that it has suitably qualified/experienced staff in the following key areas:

- The evaluation of performance characteristics of IVDs
- The assessment of the complexity and variability of biological test systems
- The development and use of standard methods for the evaluation and assessment of IVDs and devices for self-diagnosis.
- Experience in the development and use of reference methods, reference materials and standards used in batch testing
- Experience/training in the batch testing of IVDs
- Knowledge of the complexity and variability of pathogens in so far as they affect the performance of those IVD's (HIV 1 and 2, HTLV-1 and II, hepatitis B, C and D)

– For applicants wishing to be designated for devices incorporating Animal Materials technical experts designated to assess systems to minimise the risk of infection should be able to demonstrate they have the following specialist skills and knowledge:

- experience and/or training in the application of the standard EN12442
- evidence of a structured program to keep up-to-date on relevant issues
- knowledge of the requirements and interpretation of the medical devices regulations including any guidance documents for this subject area.
- knowledge of risk analysis/management

– The type of experience and background is likely to be relevant to a technical expert's ability to assess measures to

reduce/eliminate risk are most likely to include some of the following:

- several years industrial experience in medical device technology using tissues or derivatives
- a sound knowledge of the fundamental principles behind the sourcing controls and validation of inactivation methods described in the standard EN12442
- knowledge of the biological materials available to the healthcare market
- assessment experience of medical devices containing animal origin
- participation in the development of relevant standards
- contribution to various committees on medical devices for these product types
- experience in presenting at National or International regulatory conferences on relevant issues

6.10 Assessment, Accreditation and Notification of CABs

CABs may seek accreditation and notification for all or for only a subset of the various CAPs which require involvement of a CAB. CABs may seek accreditation for all or for only a subset of Medical Devices types.

6.10.1 Application

The designation process normally begins with a formal application for designation from the potential CAB to its DA. There is no standard format in which this application must be made, but the DA should define what information has to be submitted. Whatever format of application is used, however, it should ideally contain the following information:

- i) Applied scope for designation
 - Details of which medical devices regulation and which Conformity Assessment Procedures the organization is applying to be designated under, and whether it is already designated under any other regulations (esp. medical devices regulations)
 - Range of products or technologies to be covered by designation
- ii) Organization – General information on organization and structure
 - Name, address and contact point

- Description of the legal status of the applicant, including links and relationship to parent and/or related organizations, if any
 - Details of the applicant's liability insurance
 - Organizational chart of the applicant
 - Job descriptions of the applicant's key personnel and auditors
 - Statements with respect to independence and impartiality. If another part of the applicant's organization provides consultancy services, details should be provided showing how these would be separated from the applicant's activity as a CAB
 - Name of "most responsible individual" or certification manager that would be responsible for the applicant's CAB activities should designation be granted
 - Details of how the CAB activities being applied for would fit into the applicant's current structure and be financed
 - A written undertaking that, if designated, the applicant will meet the requirements of the relevant national regulation.
- iii) Quality management (internal)
- The applicant's internal Quality Manual
 - Details of the applicant's document control procedures
 - The applicant's procedures for corrective and preventive actions including complaint handling
 - The applicant's procedures regarding internal audits and management review
- iv) Personnel (internal and external)
- Comprehensive details of existing expertise held within the applicant organization (e.g. authorization matrix). This should include the names of experts, their Curriculum Vitae (CVs) and details of the medical products or manufacturing processes for which they are experienced
 - Names and CVs of any sub-contractors the applicant proposes to use for specific technical expertise or as general quality systems assessors and details of products or processes to be covered
 - Procedure(s) for authorization and monitoring of assessment and verification staff
 - Overview of training programs provided by the applicant, or to be provided, to ensure personnel are familiar with medical devices regulation requirements, ISO 13485, etc.

- Procedures to ensure the avoidance of conflicts of interest and ensuring confidentiality
- v) Facilities (in-house and subcontractors)
 - If application covers product testing, details of relevant in-house facilities and any sub-contractors the applicant proposes to use, including any relevant accreditations held by either the applicant or the sub-contractor.
 - Terms of agreements with any sub-contractors the applicant proposes using.
- vi) Process – Conformity assessments
 - Copies of any documentation (e. g. General terms and conditions, marketing materials, application forms and contracts) the applicant would propose sending to potential new clients if designated
 - Procedures to assess clients' conformity with the appropriate Conformity Assessment Requirements and EP, including as applicable, those procedures specific to: Design Dossier reviews; the assessment of clinical and bio-compatibility data, devices containing animal tissues, sterile devices; and other specialized technologies; and the clinical pathology aspects of IVDs; etc.
 - Procedures how to take account of existing certifications and registrations, e. g. from other CABs, or medicines licensing authorities
 - Details of procedures to ensure conformity assessment certificates are only issued after a full assessment of all relevant information and that this assessment is subject to an independent check
 - Procedures aimed at ensuring the independence and impartiality of assessments and certification decisions
 - CA may wish to consider providing applicants with a detailed questionnaire and/or application form. At the least however it should provide detailed guidance to applicant organizations on the type and depth of information to be provided by them.

6.10.2 Assessment of the CAB

- i) The DA is responsible for checking the application and supporting data thoroughly to ensure the applicant meets the Criteria for the Operation of CABs.
- ii) It is essential that this is done thoroughly. To help DA in this vital task, there is a detailed checklist of the criteria available that needs to be satisfied. DA may find it useful to use a checklist as an aide as they review the application.

iii) The extent to which the applicant satisfies the designation criteria should be capable of being verified by a paperwork check of the documentation supplied with the application. But experience has shown that the DA should also consider visiting the applicant at its premises to assess the way in which its procedures are implemented and applied to any existing business.

iv) The DA's review of the documentary evidence may well identify various issues that it will want to discuss with the applicant or where it feels that further information is required. In practice it may be necessary for the DA to go back to the applicant for further information or clarification several times before a decision can be made. The review process is therefore iterative. It is important that any changes made to the applicant's systems during this review of its application should be updated.

v) The review of the application may also result in aspects of the applicant's own operating systems or procedures being updated and altered as potential problems or shortcomings are identified. Where changes are made it is important that these are documented by the applicant and sent to the DA, so that it has an up to date set of documents supporting the application for designation.

vi) Assessment of expertise of Applicant by scrutiny of CVs

– A key part of any application for designation will be the information provided on any auditing staff that the applicant proposes to use. The application should contain detailed CV's of these personnel (whether directly employed or not). It is essential that the DA carefully studies these CVs to re-assure itself that the applicant will have the necessary skills to perform the tasks for which it is seeking designation. Thus, for example, if an individual is to be used as an auditor he must have audit experience in the relevant area, unless the applicant undertakes to use him only in conjunction with a suitable qualified generalist auditor. Audit experience can be gained by working within a designated CAB in conjunction with a suitably qualified auditor.

– There is no standard format for the provision of CAB personnel's CVs and CA is free to request this information in any format that they choose or alternatively leave this to the applicant's discretion. To assist DA who wish to prescribe a format to be used by applicants is available.

– Nevertheless, whatever the format of the CVs submitted by the applicant to the DA for scrutiny they should cover the following:

– Education and qualification: this should be in a scientific or technical subject which can be readily related to the scope of the medical devices, processes or technology in which they will work

- Work experience: this should be relevant to current safety and performance aspects of the medical devices with which they will work
 - Training or professional development: this may be either in features related to relevant medical devices (their manufacture, safety or use) or to auditing against the regulatory requirements of the ISO 13485
 - Standards knowledge: this provides the link between academic and other knowledge and medical devices or technologies
 - Special processes: as defined in ISO 9001, these are processes whose effectiveness cannot be verified by subsequent testing so that they have to be properly validated and closely controlled. The most common example is sterilization which is sufficiently important to merit its own set of special rules.
- DA should use the CV's to help verify the suitability, expertise and capability of the personnel the applicant proposes using to cover the range of products or/and processes covered by the application.
- vii) Assessment of applicant's ability to cover the Conformity Assessment Procedures applied for
- CA must ensure that the applicant has systems to ensure that it can carry out all the responsibilities under the various conformity assessment procedures covered in the scope applied for, i.e.:
- Under the full quality assurance annexes, CABs must approve the manufacturer's quality system, including design control
 - Under the partial quality assurance annexes, CABs must approve the manufacturer's quality system as defined in the relevant Conformity Assessment requirements.
 - Where applicable carry out design dossier approvals.
 - Under the Type Examination requirements, CABs must specify in advance the tasks to be carried out (test protocol) and need adequate facilities (internal or subcontracted) to carry out inspections and tests to verify that products meet the EP
 - Under Verification requirements, CABs must specify in advance the tasks to be carried out (test protocol) and need adequate facilities (internal or subcontracted) to verify that each batch or unit meets the EP.

- For IVDs the CAB must verify each batch of manufacturer's product.
- The CABs should be able to check and thus ensure that manufacturers meet their responsibilities under the various Conformity Assessment Requirements of the medical devices regulation. The CA will need to check that this is the case for all applicant organizations. These procedures shall ensure that the applicant:
 - has appropriate personnel
 - can deal with manufacturing or design changes made by the device manufacturer
 - can identify devices with medicinal products and has procedures to consult with the relevant drug regulatory authority
 - has appropriate laboratory facilities (preferably accredited for the scope applied for) either themselves or sub-contracted
 - has procedures to carry out surveillance audits at suitable intervals
 - can implement any necessary statistical sampling regimes
- viii) Assessment of applicant's proposed use of sub-contractors
 - Depending on the scope of designation applied for, the applicant may propose obtaining the necessary specialist facilities or specialist staff skills or expertise needed (and briefly described above) by "buying in" those facilities from subcontractors. In such cases the CA must assure itself of the suitability of the subcontractor facilities or staff in exactly the same way as it assesses the suitability of the applicant. In addition, the CA will need to check that, where the applicant chooses to cover any aspects of its work by sub-contracting, it nevertheless has sufficient in-house expertise to judge the quality of the sub-contractor's work. It is the CAB and not any sub-contractor used that retains the ultimate responsibility for decisions on certification.
 - When assessing an application for designation from an organization that proposes using sub-contractors, the CA may find it helpful to keep the following factors firmly in mind:
 - A CAB may sub-contract any of its functions except:
 - initial contract review: this includes the assessment by the CAB as to whether the proposed job is within its scope and whether it has the necessary resources and expertise to carry it out properly

- final decision to issue a certificate of conformity: this includes an assessment of all the information derived from audits, tests or design dossier reviews; it must be carried out by appropriate personnel within the CAB who has sufficient knowledge and experience to come to a reasoned judgment of the information present and the authority to make that decision
- The applicant CAB should therefore have sufficient in-house expertise to:
 - enable it to decide whether to take on a particular contract
 - to assess the expertise of its sub-contractors, and to control their work
 - to assess and make judgments based on the work of its own employees and of its sub-contractors.
- The applicant CAB should ensure that its sub-contractors have the expertise necessary and are free from conflicts of interest. All sub-contractors must be covered by proper contracts with the CAB covering these requirements.

6.10.3 Designation Decision

- i) The DA should only agree to the designation of the applicant when it has clearly demonstrated that it has the structure, expertise and systems to fulfill all the relevant requirements set out.
- ii) To facilitate the decision making process, and provide an assessment trail following best practice, DA may find it useful for the person or persons who assess the application to prepare a report on their findings for the person or persons who will take the final decision on the application. This report should contain a recommendation to:
 - Agree to designate for the full scope requested
 - Agree to designate but for a more restricted scope from that requested
 - Refuse designation
- iii) Where the final decision is to agree to designate (either wholly or in part) experience has shown that the DA should clearly describe the designated scope it is agreeing to and thus avoid any possible future confusion or doubt as to which products or technologies are covered. In particular, the scope should not imply the inclusion of technologies for which the applicant has not demonstrated sufficient expertise. For example, a designated scope including “heart valves” is unclear as the expertise needed for metal heart valves is different from that needed for animal derived valves. Care also needs to be taken when describing medical devices, for example arterial stents should be distinguished from urinary stents.

iv) As part of the decision to designate the applicant, the DA may wish to impose conditions placing specific restrictions or obligations on the CAB. Such conditions should be designed to allow the DA to gain confidence in the new CAB's operational ability in specific areas where small doubts may still exist after the assessment of the application. Examples of conditions applied by DA in the past include, for example:

- informing the DA of any changes to the CABs staff or to the staff of its subcontractors
- getting prior approval from the DA before accepting any job, or jobs involving a particular Conformity Assessment Procedure or with a particular group of products or technologies
- information on conformity assessments planned to allow the DA to carry out observed audits or witness tests
- submission of test-plans for Type Testing or Verification to the DA prior to carrying out these assessments
- informing the CA of any certificates issued or refused to allow the DA to review files

v) The DA should discuss the proposed scope and any conditions with the applicant to ensure that they are clearly understood and agreed. Both the scope and any conditions imposed should be fully documented.

vi) Notification of the DA final decision on designation to the Competent Authority. However the DA should make it clear to the applicant that they cannot operate as a CAB until the required notification is made.

6.10.4 Notification

Once the decision is made to appoint the applicant the Competent Authority should convey its decision to the Regulatory Authority.

6.10.5 Amendment to Scope

The CAB, once designated, will sometimes wish to alter or extend its scope of designation. The process of submitting an application for this proposed change in scope to the DA for review follows an identical pattern to that for an initial designation. In such cases however the DA should already have a good knowledge of the basic organizational structure, facilities and expertise available to the CAB as well as detailed experience of the way it has performed in practice. In assessing the application for change therefore, the DA should require confirmation from the CAB that these aspects are unchanged and still meet the requirements. It can then concentrate on assessing the CABs capabilities for performing the additional tasks being applied for.

6.10.6 Limitation of scope, suspension and de-designation

- i) Where a CAB no longer meets the requirements for designation, or where its performance falls below the consistently high standards demanded, the CA must take action to correct the situation. In extreme cases this may require the DA to restrict its designated scope or to remove temporarily or permanently the CABs designation.
- ii) Illustrations of issues which may lead the DA to consider limiting the CAB's scope or withdrawing it completely are listed in Attachment 6. Where the DA is considering taking action that will restrict or remove the CABs designated scope it should ideally first hold an internal meeting to review all the relevant factors and information available to it about the performance of the CAB. Following this internal review of evidence the DA may then consider it sensible to meet with the CAB to see if there are any factors of which the DA is unaware and which could therefore influence its final decision.
- iii) Where nevertheless, the DA decides to de-designate (either in part or completely) it should inform the CAB giving its reasons. Depending upon the specific laws a period in which the CAB may appeal against the DA decision may also have to be provided.
- iv) Where the decision to remove or restrict designation is upheld, the DA should advise other CAs or DAs.

6.11 Acceptance of Recognized CABs

6.11.1 General

- i) The Malaysian Regulatory Authority may accept third party conformity assessment procedures performed by recognized CABs, where they are registered and accredited by their respective Competent Authorities having the capability of carrying out assessment of the medical devices.
- ii) The CABs shall have technical qualification with the appropriate accreditation or other official authorization and qualified personnel to conduct assessment of medical devices within the scope accredited that shall include scientific technical evaluations of high-risk medical devices and quality system assessments
- iii) The CABs shall fulfill the requirements of EN45000 series and ISO/IEC guides.

6.11.2 Determining the eligibility of a CAB prior to designation

- i) Designated CABs in the European Union or any other countries are equivalent to Notified Bodies associated with CE marking. Often they will be the same organizations, but they have been assessed for their competence to provide conformity assessment procedures to medical devices manufacturers.

ii) Any approved conformity assessment body or notified body may seek registration with the Malaysian Regulation Authority to be a recognized CAB.

iii) The Malaysia Regulatory Authority shall appoint reputable CABs or Notified Bodies with international experience and services located outside Malaysia to perform CAPs on manufacturers located in Malaysia, provided these CABs or Notified Bodies must demonstrate their technical competence based on:

- technological knowledge of the relevant products, processes or services;
- understanding of the technical standards and the general risk protection requirements for which designation is sought;
- the experience relevant to the applicable legislative, regulatory and administrative provisions;
- the physical capability to perform the relevant conformity assessment activity;
- an adequate management of the conformity assessment activities concerned; and
- any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed on a continuous basis.

6.11.3 Process for determining a CAB's technical competence

Usually the accreditation procedures will be applied, but in some cases other means procedures (also set out below) are allowed. The possible ways of demonstrating competence can be quite specific. For example, here CABs sub-contract testing it may be mandatory that the testing only be sub-contracted to testing laboratories accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing or be able to demonstrate competence under an equivalent accreditation scheme.

6.11.4 Accreditation

i) A presumption of technical competence sufficient to constitute accreditation arises when:

- The accreditation process is conducted in conformance with the relevant international documentation (EN 45000 series or ISO/IEC guides); and either
- The accreditation body participates in mutual recognition arrangements where they are subject to peer evaluation by individuals with recognised expertise in the field of the work being evaluated; or
- The accreditation body, operating under the aegis of the designating authority, takes part in comparison programs and

exchanges of technical experience in order to ensure continued confidence in its technical competence. Such programs may include joint assessments, special co-operation programs or peer evaluation.

- ii) When a conformity assessment body seeks designation to evaluate a particular product, process or service for compliance with essential requirements, the accreditation process is to incorporate elements that permit assessment of the CAB's capability. Capability is defined as having the technological knowledge and understanding of the generally stated risk protection requirements of the product, process or service or their use.

6.11.5 Other means

If appropriate accreditation is not available or special circumstances apply, the designating authorities can require the conformity assessment bodies to demonstrate their competence through other means such as:

- i) Participation in regional/international mutual recognition arrangements or certification systems;
- ii) Regular peer evaluations;
- iii) Proficiency testing; and
- iv) Comparisons between conformity assessment bodies.

SECTION 7: REGULATORY AUDITING OF QUALITY MANAGEMENT SYSTEMS (QMS) AND AUDITING PROCESS

7.1 Introduction

7.1.1 The purpose of this document is to be used as “Guidelines for Quality Management Systems and Auditing Procedures for regulatory auditing of quality systems of medical device manufacturers based on the process approach of standard of ISO 13485:2003. The audit strategy can be seen as guidance on how to audit the effectiveness of quality systems in a systematic and effective manner within a reasonable time. This includes the fulfilment of regulatory requirements of medical device manufacturers. The main aim of the guidance is to promote audit consistency – a necessity for harmonization and mutual recognition of audit results.

7.1.2 Benefits for the regulators include:

- i) Improved auditing, leading to improved quality systems and product quality
- ii) Achievement of greater consistency in regulatory audits both among auditors within a regulatory organization and between regulatory organizations
- iii) Promotion of greater collaboration between regulators in regard to regulatory audits
- iv) Increased confidence in audits performed by a regulatory organization and acceptance of those audits by other regulators
- v) Saving of resources

7.1.3 Benefits for the manufacturers of medical devices include:

- i) Improved auditing, leading to improved quality systems and product quality
- ii) Achievement of greater consistency in regulatory audits
- iii) Saving resources through easier preparation for regulatory audits
- iv) Reducing the number of times a single manufacturer undergoes audits by different regulatory bodies
- v) Increased confidence in and acceptability of audits by other regulators

7.1.4 Beneficiaries also include the users of medical devices and patients, who can have high degree of assurance that medical devices placed on the market will be safe and effective.

7.2 Scope

7.2.1 This document is intended to be used by regulatory auditing organizations and auditors as a guide for conducting medical device quality systems audits based on the process approach to the standard of ISO 13485:2003.

7.2.2 Additional regulatory requirements and guidance will need to be considered, depending on the regulatory authorities who will receive and use the audit report. This guidance document applies to initial audits and to surveillance audits.

7.3 Reference

ISO 13485:2003: Quality Systems – Medical Devices – Requirements for regulatory purposes

GHTF/SG4/N28R2: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements (1999)

GHTF/SG4/N30R6: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy (proposed document)

GHTF/SG1/N011R17: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

ISO 19011:2002: Guidelines for quality and/or environmental management systems auditing

ISO/TC 210/WG1 N62: ISO/TR 14969:200X Guidance on the Application of ISO 13485:2003

ISO/IEC Guide 62: 1996(E) General requirements for bodies operating assessment and certification/registration of quality systems.

International Electrotechnical Commission.

ISO 14971:2000 “Medical devices – application of risk management to medical devices”

7.4 Definitions

“**Audit**” means systematic independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. ISO 19011:2002

Note: For the purpose of these guidelines, “audit” means a regulatory audit.

“**Regulatory audit**” means the audit of a quality system is to demonstrate conformity with a quality system standard and the relevant regulatory requirements.

“**Audit criteria**” means set of policies, procedures or requirements. ISO 19011:2002

“Audit evidence” means records, statements of fact or other information, which are relevant to the audit criteria and verifiable. ISO 19011:2002

Note: Audit evidence may be qualitative and/or quantitative and is used to substantiate audit observations

“Technical files” means documentation required to assess conformity of the medical device with the regulations.

See attached document of GHTF/SG 1”STED, Summary Technical Documentation”, proposed document SG1/N011R17 of 2002.

“Medical device” is defined in the national and regional regulations listed in Appendix 4 and the GHTF document SG 4/N28 R2: “Guidelines for Regulatory Auditing of quality Systems of Medical Device Manufacturers – Part 1: General Requirements”.

“Process” means set of interrelated or interacting activities which transforms inputs into outputs

“Regulatory requirement” means any part of a law, ordinance, decree or other regulation, which applies to quality systems of medical device manufacturers.

Note: Guidelines, notes, draft documents, or the like should not be used as regulatory documents and are not to be construed as such unless formally promulgated.

7.5 General Remarks on Regulatory Auditing Strategy

Conducting the regulatory audit, the quality management system of a medical device manufacturer based on ISO 13485:2003: “Quality systems – Medical devices – System requirements for regulatory purposes” is checked with regard to conformity with the quality system requirements and compliance with the relevant regulatory requirements.

7.5.1 Objectives of a Regulatory Audit

i) Based on the definition of a regulatory audit the auditing organization determines during a regulatory audit the compliance of the auditee’s quality system with the relevant regulatory requirements. The audit checks how quality problems associated with a medical device or the quality system are recognized and settled.

ii) The audit should be planned and conducted in such a way that the following objectives are reached:

– The effectiveness of the manufacturer’s quality system – including the fulfilment of regulatory requirements - is measured and monitored in a systematic and effective manner within a reasonable time.

– The regulatory audit is process-oriented. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.

Therefore, the audit should preferably follow the workflow processes of the medical device manufacturer.

- The regulatory audit is risk-based with a focus on key processes of the quality system necessary to manufacture the medical devices. In other words the auditor should concentrate on factors that are most likely to affect patient safety.
- The audit is transparent to the auditee.
- The audit process and results are similar regardless of which auditing organization or individual auditors conduct the audit, with an ultimate goal for harmonization and mutual recognition of audit results.

7.5.2 Auditing Quality Management Systems and Subsystems

- i) Rather than focusing on the individual requirements of the standard, an audit should focus on the overall effectiveness of the quality management system. To break the audit into more manageable parts, key activities or subsystems have been identified. The guide for auditing process is shown in Appendix 4.
- ii) The subsystems and associated clauses of ISO 13485:2003 are:

| Subsystem | Clauses and secondary clauses (linkages) of ISO 13485:2003 |
|--------------------------------------|--|
| 1. Management | 4, 5, 6, 8 |
| 2. Design and development | 7 |
| 3. Technical files | 4, 7 |
| 4. Production Processes | 6, 7, 8 |
| 5. Corrective and preventive actions | 4, 5, 6, 7, 8 |
| 6. Purchasing controls | 7 |
| 7. Documentation and records | 2, 4 |
| 8. Customer requirements | 7, 8 |
| Appendix 5: Sterilization Process | 7, 8 |

Table 1: Subsystems and associated clauses (More detailed references to clauses and subclauses of ISO 13485:2003 are given in Chapter 6.0 Auditing Subsystems)

- iii) The key subsystems for addressing quality are the subsystems 1 to 5 identified in Table 1. These should receive the primary focus of the audit. It may be appropriate to treat the other subsystems as key

subsystems in some situations. Examples for the subsystem purchasing controls include:

- A “virtual” Manufacturer who contracts essential activities such as design and production
- A Manufacturer who contracts a sterilization process, or
- A Manufacturer of high risk medical devices who purchases significant components and subassemblies.

7.5.3 Auditing Approaches

i) There are different approaches to conducting a regulatory audit:

- The “top-down” approach for conducting a regulatory audit begins with an evaluation of the structure of the quality management system and its subsystems: management, design control, technical files, production processes, and corrective and preventive actions. Selected subsystems are reviewed to determine whether the manufacturer has addressed the basic requirements by defining and documenting appropriate procedures. It is important to check that a process approach is applied both in the quality system and in each subsystem, e.g. by using a PDCA cycle (see Chapter 5.4). With the “top-down” approach, the auditor will first confirm that the manufacturer has established appropriate procedures and policies. Then the auditor will review evidence including records to verify whether the manufacturer is implementing the procedures and policies effectively and the quality system is in conformity with regulatory requirements.

The advantage of this approach is a uniform approach for a systematic and transparent regulatory audit process – both for the regulatory sides and the manufacturer.

- The “bottom-up” approach for a regulatory audit can have as a starting point a quality problem; e.g., a medical device report of an adverse event or nonconforming product. Thus, the auditor starts at the bottom and works his way through the manufacturer’s quality system up to the management responsibility.

The advantage of this approach is a quick insight on the effectiveness of the selected subsystems and processes that have been affected by the specific quality problem and the cause(s) of the quality problem. The disadvantage of this approach is that it is very difficult for the auditor to determine how effectively the complete quality system works.

- A third alternative is a combination of these two approaches. The auditor starts by reviewing the top layer of the quality system (top-down); then audits some aspects of the implementation of the system (e.g., the production process)

and finally the auditor verifies that the relevant procedures are being used (bottom-up). The advantage of the combination approach is that it is often quicker to audit than using either the top-down or bottom-up approach. The combination approach also offers more flexibility in identifying the cause(s) of specific problems while assessing the effectiveness of the quality management system.

ii) Depending on the purpose and trigger of an audit, an appropriate approach should be selected. If there are no special events to be covered during the audit, the top-down approach is preferred. An initial audit will normally follow a top-down approach. Audits which include a potential significant safety issue will normally follow a bottom-up approach.

7.5.3 Process Based Auditing

Any effective quality management system (including the subsystems) works as a control process, which has the ability to detect deviations and nonconforming products and assures that the corrective and preventive action measures are effective. The regulatory auditor should check that all subsystems and processes of the quality management system are structured as self-regulating control processes. For example Deming's PDCA cycle demonstrates such a process with the following components:

i) Plan – Has the manufacturer established the objectives and processes to enable the quality system to deliver the results in accordance with the regulatory requirements?

ii) Do – Has the manufacturer implemented the quality system and the processes?

iii) Check – Has the manufacturer checked process monitoring and measurement results against the objectives and the regulatory requirements? Does the manufacturer evaluate the effectiveness of the quality system periodically through internal audits and management reviews?

iv) Act – Has the manufacturer implemented effective corrective and preventive actions? Confirm that the company is committed to providing high quality safe and effective medical devices, and that the company is conforming with applicable laws and regulations.

These are generic questions that can be asked throughout the audit.

7.5.4 Sampling

In general there are two ways of sampling records for review which are useful in regulatory audits – risk based and statistical. Where possible, auditors should select samples based on factors which are most likely to affect the safety of the patient. In this situation sampling tables are not necessary. The auditor may however decide to select a statistically valid sample. A sample can also be drawn using a combination of risk based and statistical sampling.

7.5.5 Audit Planning

i) Further to the requirements given in the chapter 11 of GHTF Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements (SG4/N28R2), some more consideration should be given to the following points:

- Information from the Manufacturer
- Estimation of audit duration, frequency and targeted on-site auditing time
- Further points to consider are given in chapter 6.
- Information required from the manufacturer

ii) In the planning phase, the following information should be requested from the manufacturer to estimate the audit duration and to prepare the audit plan for Regulatory Auditing of Quality Systems of Medical Device:

- manufacturer's name, address
- contact name, telephone, fax numbers and e-mail addresses
- total number of employees (all shifts) covered by the scope of the audit
- range and class of medical devices being manufactured
- types of devices sold and/or planned to be sold in the countries and/or regions for which the regulatory requirements will be assessed, including a complete list of authorizations (e.g. licenses) issued for those devices (where applicable)
- location and function of each site to be included in the audit
- a list of activities on each site
- the involvement of any special manufacturing processes, e.g. software, sterilization, etc.
- a list of the activities performed by subcontractors and their locations, including the type of control that is exercised over those outsourced operations
- any existing audit results from other auditing organizations e.g. from USA, Australia, Europe, Canada, Japan.
- do they install or service the medical devices produced
- changes since the last audit, if applicable.

iii) Audit frequency

The audit frequency is dependent on the factors mentioned in Appendix 3, the regulatory requirements and history of the Manufacturer.

iv) Audit duration

The audit duration has a significant effect on both regulatory agencies and industry. It is dependent on factors such as the audit scope and specific regulatory requirements to be assessed, as well on the range, class and complexity of devices, and the size and complexity of the manufacturer. If not specifically mentioned, the considerations in this section are applicable to initial, and surveillance-audits.

v) Relation between audit frequency and audit duration

Audit duration depends on the audit frequency. In the following an annual audit frequency is the baseline as reference in IAF Guidance on the Application of ISO/IEC Guide 62. For more or less frequent audits, audit duration should be adapted accordingly.

vi) Method of estimating audit duration

– When auditing organizations are planning regulatory audits, sufficient time should be allowed for the audit team to establish the conformity status of a medical device manufacturer's quality system with respect to the relevant regulatory requirements. Any additional time required to assess national or regional regulatory requirements must be justified.

– The table from the IAF Guidance on the Application of ISO/IEC Guide 62 may be used in order to establish a baseline initial audit duration for ISO 9000-series, measured in auditor-days. As this table is not intended for the special needs of medical device audits, additional time should be added for the requirements of ISO 13485:2003 and for regulatory requirements. This document also provides guidance for other types of activities, such as surveillance audits.

– The baseline includes time to prepare for the audit, preview the quality system documentation and write the report. It does not consider the time required for design dossier reviews, type examinations, pre-market approvals and other similar activities. The baseline for initial audits should be adjusted to take into account the other types of audits and the factors listed in Appendix 1 which may increase or decrease the estimated audit duration, but only if these factors are required by the applicable regulations.

– Targeted on-site auditing time
The targeted on-site time to complete the initial auditing of the subsystems should be based on the following dates given in Table 2:

| Subsystem | Targeted time | Remarks |
|-----------------------------------|---------------|-------------------------------------|
| Management | 5-10 % | |
| Design and development controls | 0-20% | Depends on regulatory requirements |
| Technical files | 5-20% | |
| Production processes | 20-30 % | |
| Corrective and preventive actions | 10-30 % | |
| Purchasing controls | 5-20% | More time for virtual manufacturers |
| Documentation and records | 5 % | |
| Customer requirements | 5 % | |

Table 2: Targeted on-site auditing time

– The targeted on-site audit time for each subsystem will vary depending on factors such as:

- the audit scope
- schedule changes
- the gathering of information from remote locations

7.5.6 Guidance for Logistics during an Audit

i) The following points should help the auditor in performing the audit in the most appropriate way:

- Does the manufacturer have changes (e.g. organization, quality system, facilities, processes, products) to present during the opening meeting?
- Limit the disturbance of the CEO and Executive Management to a minimum and be flexible in auditing Management Responsibility.
- Follow-up issues from last audit as soon as possible, to determine whether the manufacturer has effectively implemented corrective actions.
- Auditing the warehouse at the beginning of an audit allows for the selection of examples that can be followed up later on (e.g. nonconforming material, batch records, etc.)
- Auditing traceability at an early stage of the audit allows the traceability path to be followed either forward (e.g. simulated recall) or backwards, and gives the manufacturer sufficient time to access relevant information or to carry out the necessary actions.

- For surveillance audits focus either on design and administrative processes or on production and related activities.
- Internal audits, complaints, CAPA and management review should be covered at every audit.
- Auditing documentation and training at the end of an audit allows for better follow-up of the examples picked-up during the audit.
- The local situation may influence the sequence of audit and should be considered to avoid wasting time.
- Consideration to those points should be given, but the audit team is free to audit the subsystems in any sequence appropriate.

7.5.7 Linkages

i) Although most of the auditor's time will be spent on examining processes within the sub-systems, it is important to remember that links exist between the sub-systems and between different processes. Some of these links are less obvious than others, but should be checked during the audit.

Examples: Link between corrective and preventive actions and management and disseminating CAPA information to management for management review

ii) Design and development controls and purchasing controls: Design output used in evaluating potential suppliers of components and assemblies and communicating specified purchase requirement to that supplier.

iii) Within a process, the steps will normally be linked because the output from one step will be the input to the next. During a process based audit, these links may be picked up automatically by the auditor.

iv) There are also some obvious links between processes, e.g. the output from design will be an input to production. These links need to be checked during both parts of the audit (e.g. design and production) to verify that the link is working and the quality system is working as a coherent whole.

v) There are other links which may be less obvious, but which still need to be audited, e.g. if non-conforming product is seen in finished goods, did this problem originate in stores, production, final inspection or design?

vi) There also are links between sub-systems, e.g. if faulty components arrive on the production floor, was this caused by the supplier, receiving inspection, incorrect data to the supplier or by design?

- vii) In such instances, does the system require the manufacturer to always make a CAPA report?

7.6 Auditing subsystems

There is a specific goal in auditing each subsystem. The plan for auditing each subsystem should be process based (chapter 5.4) and should enable the goal to be reached. This should include verifying conformance with the requirements which affect each subsystem. For logistics see also chapter 5.7

Note 1: Numbers beneath each chapter refer to ISO 13485:2003

Note 2: Chapters marked with* are main subsystems and should receive a main focus of the audit, if this is a regulatory requirement. See also chapter 5.2.

7.6.1 Management

GOAL: The purpose of the management subsystem audit is to evaluate whether top management ensures that an adequate and effective quality system has been established and maintained.

Major Steps: The following major steps serve as a guide in the audit of the “Management“ subsystem:

- i) ISO 13485:2003: 4.1, 4.2 – Verify that a quality manual, management review and quality audit procedures, quality plan, and quality system procedures and instructions have been defined and documented.
- ii) ISO13485:2003: 5.3, 5.4 – Verify that a quality policy and objectives have been defined and documented and steps taken to achieve them.
- iii) ISO 13485:2003: 5.1, 5.5.1, 5.5.2, 6.1, 6.2 – Review the manufacturer’s established organizational structure to verify that it includes provisions for responsibilities, authorities (e.g. management representative), resources, competencies and training
- iv) ISO 13485:2003: 5.6 – Verify that management reviews, including a review of the suitability and effectiveness of the quality system, are being conducted.
- v) ISO 13485:2003: 8.2.2 – Verify that internal audits of the quality system are being conducted including verification of corrective and preventive actions.

In conclusion of the audit of the other subsystems a decision should be made as to whether top management has taken the appropriate actions to ensure a suitable and effective quality system is in place.

7.6.2 Design and Development

GOAL: The purpose of auditing the design and development subsystem is to determine whether the design process is controlled to

ensure that devices meet user needs, intended uses and specified requirements.

Major Steps: The following major steps serve as a guide in the audit of the “Design and Development” subsystem:

- i) ISO 13485:2003: 7.1 – Verify if products are subject to design and development procedures.
- ii) Select design project(s) according to the following criteria:
 - single product focus
 - risk based
 - based on complaints or known problems
 - most recent project
 - cover product range
- iii) ISO 13485:2003: 7.3.1 – Review the design plan for the selected project to understand the layout of the design and development activities, including assigned responsibilities and interfaces.
- iv) ISO 13485:2003: 7.3.1 – For the design project(s) selected, verify that design control procedures and risk management procedures have been established and applied.
- v) ISO 13485:2003: 7.2.1, 7.3.2 – Confirm that design inputs were established and address customer functional, performance and safety requirements, intended use, applicable statutory and regulatory requirements, and other requirements essential for design and development.
- vi) ISO 13485:2003: 7.3.3 – Review device specifications to confirm that design and development outputs meet design input requirements. Have the design outputs that are essential for the proper functioning of the device been identified?
- vii) ISO 13485:2003: 7.1, 7.3.5 – Confirm that risk analysis and risk control steps are completed and that the design and development outputs are compatible with the risk management data.
- viii) ISO 13485:2003: 7.3.6 – Determine that the intended use(s) have been identified. Confirm that design validation data show that the approved design meets the requirements for the specified application or intended use(s).
- ix) ISO 13485:2003: 7.3.6 – Confirm that clinical evaluations and/or evaluation of the medical device performance were performed if required by national or regional regulations. ISO 13485:2003: 7.3.1, 7.3.6. If the device includes software, confirm that the software was part of the validation.
- x) ISO 13485:2003: 7.1, 7.3.5, 7.3.7 – Confirm that design changes were controlled and verified or where appropriate validated

and that design changes have been addressed by the appropriate risk management steps.

xi) ISO 13485:2003: 7.3.1, 7.3.4 – Confirm that design reviews were conducted.

xii) ISO 13485:2003: 7.3.7 – Confirm that design changes have been reviewed for the effect on components and product previously made and delivered, and that records of review results are maintained.

xiii) ISO 13485:2003: 7.3.1 – Determine if the design was correctly transferred to production. Evaluate the “Design and Development” subsystem for adequacy based on findings.

7.6.3 Technical Files

GOAL: The purpose of auditing the technical files is to confirm that the manufacturer ensures that products will be safe and effective.

Major Steps: The following major steps serve as a guide in the audit of the “Technical Files” subsystem:

i) ISO 13485:2003: 4.2.1d – Verify if there are documents needed by the organization to ensure planning, operation and control of its processes. Select documents/documentation for product(s) according to the following criteria for selection:

- single product focus
- risk based
- based on complaints or known problems
- most recent project
- cover product range

ii) For the product(s) selected verify that documentation includes: ISO 13485:2003: 7.1, 7.2, 7.3.3

- a general description of the product including intended use(s) and any variants, accessories, or other devices used in combination with the selected product(s)
- design specifications, including the standards applied, results of risk analysis
- fulfilment of the principal requirements
- techniques used to verify the design and to validate the product(s)
- clinical data
- description of sterilization method and validation – if applicable
- instruction manual(s)
- labelling

- major subcontractors
- iii) Evaluate the “Technical Files” subsystem for adequacy based on findings.

7.6.4 Production Processes

Goal: The purpose of auditing the production process (including testing, infrastructure, facilities and equipment) is to confirm that manufactured products meet specifications.

Major Steps: The following major steps serve as a guide in the audit of the “Production Process” subsystem:

- i) ISO 13485:2003: 7.1 – Verify that the product realization processes are planned – including the controlled conditions.
- ii) ISO 13485:2003: 7.1 – Verify that the planning of product realization is consistent with the requirements of the other processes of the quality management system. Select one or more processes for review according to the following criteria:
 - CAPA indicators of process problems
 - risk based: use of the process for manufacturing higher risk products
 - degree of risk of the process to cause product failure
 - most recent project: the manufacturer’s lack of familiarity and experience with the process
 - use of the process in manufacturing multiple products
 - processes not covered during previous audits

Note: For auditing a sterilization process see Appendix 5

- iii) ISO 13485:2003: 7.5 – Verify that the processes are controlled and monitored and operating within specified limits.
- iv) ISO 13485:2003: 7.5 – Verify that the equipment used has been adjusted, calibrated and maintained.
- v) ISO 13458:2003: 7.5.2 – Verify that the processes have been validated if the result of the process cannot be verified.
- vi) ISO13485:2003: 4.1, 4.2 – Determine the linkages to other processes
- vii) ISO 13485:2003: 6.2.2 – Verify that personnel are appropriately qualified and trained to implement/maintain the processes
- viii) ISO 13485:2003: 6.3, 6.4 – Verify that the infrastructure and the work environment are adequate
- ix) ISO 13485:2003: 7.4.3 – Determine that the verification of purchased products is adequate
- x) ISO 13384:2003: 7.5.2.1 – If the process is software controlled verify that the software is validated

- xi) ISO 13485:2003: 7.6 – Verify that the control of the monitoring and measuring devices is adequate.
- xii) ISO 13485:2003: 7.6, 8.2.4 – Verify that the system for monitoring and measuring of products is adequate and that the monitoring and measuring devices used are adequately controlled
- xiii) ISO 13485:2003: 8.3 – Verify that the arrangement for control of non-conforming products is adequate. Evaluate the "Production Processes" subsystem for adequacy based on findings.

7.6.5 Corrective and Preventive Actions – CAPA

GOAL: The purpose of auditing the CAPA subsystem (including reporting / tracking) is to confirm that information is collected and analyzed to identify product and quality problems that these are investigated, and appropriate and effective corrective and preventive actions are taken.

Major Steps: The following major steps serve as a guide in the audit of the "Corrective and Preventive Actions - CAPA" subsystem:

- i) ISO 13485:2003: 4.1, 4.2, 8.5 – Verify that CAPA system procedure(s) which address the requirements of the quality system have been established and documented.
- ii) ISO 13485:2003: 8.4, 8.5 – Verify that the data received by the CAPA subsystem are complete, accurate and recorded in a timely fashion.
- iii) ISO 13485:2003: 8.1, 8.2.3, 8.4 – Determine if appropriate sources of product and quality problems have been identified, including sources which may show unfavourable trends. Confirm that data from these sources are analyzed, using valid statistical methods where appropriate, to identify existing product and quality problems that may require corrective action.
- iv) ISO 13485:2003: 8.5.2 – Determine if failure investigations are conducted to identify the causes of non-conformities, where possible.
- v) ISO 13485:2003: 8.3 – Verify that controls are in place to prevent distribution of non-conforming products.
- vi) ISO 13485:2003: 8.2.3, 8.5.2, 8.5.3 – Confirm that corrective and preventive actions were implemented, effective, documented and did not adversely affect finished devices.
- vii) ISO 13485: 2003: 5.6.3 – Determine if information regarding nonconforming product and quality problem and corrective and preventive actions has been supplied to management for management review.
- viii) ISO 13485: 2003: 8.5.1 – Verify that medical device reporting is done according to the applicable regulatory requirements.
- ix) ISO 13485: 2003: 7.2.3, 8.2.1 – Confirm that the manufacturer has made effective arrangements for handling complaints and investigation of advisory notices/recalls with provision for feed back

into the corrective and preventive action subsystem. Evaluate the "Corrective and Preventive Actions" subsystem for adequacy based on findings.

7.6.6 Purchasing Control

- This subsystem is a main subsystem for virtual manufacturers

GOAL: The purpose of auditing the purchasing control activities is to ensure that products, components, materials and services supplied by the subcontractor are in conformity. This is particularly important when finished products and/or sterilization services are purchased.

Major Steps: The following major steps serve as a guide in the audit of the Purchasing Control subsystem:

- i) ISO 13485:2003: 7.4.1 – Verify that procedures for conducting supplier evaluations have been established and are being implemented.
- ii) ISO 13485:2003: 7.4.1 – Confirm that the manufacturer evaluates suppliers for their ability to meet specified requirements.
- iii) ISO 13485:2003: 7.4.2 – Confirm that the manufacturer assures the adequacy of specifications for products and services that suppliers are to provide.
- iv) ISO 13485:2003: 7.4.1 – Confirm that records of supplier evaluations are maintained.
- v) ISO 13485:2003: 7.4.3 – Determine that the verification of purchased products is adequate. Evaluate the "Purchasing Controls" subsystem for adequacy based on findings.

7.6.7 Documentation and Records

GOAL: The purpose of auditing the records and documentation is to ensure that the relevant documents are controlled within the manufacturer and that the relevant records are available to the regulatory body.

Major Steps: The following major steps serve as a guide in the audit of the Documentation and Records Subsystem:

- i) ISO 13485: 2003: 4.2.3, 4.2.4 – Verify that procedures have been established for the identification, storage, protection, retrieval, retention time and disposition of documents and records.
- ii) ISO 13485:2003: 4.2.3 – Confirm that documents and changes are approved prior to use.
- iii) ISO 13485:2003: 4.2.3 – Confirm that current documents are available where they are used and that obsolete documents are no longer in use.
- iv) ISO 13485:2003: 4.2.1, 4.2.4 – Verify that required documents and records are being retained for the required length of time. Evaluate the "Documentation and Records" subsystem for adequacy based on findings.

7.6.8 Customer Requirements

GOAL: The purpose of auditing customer requirements is to ensure that customer requirements including regulatory requirements are met.

Major Steps: The following major steps serve as a guide in the audit of the Customer Requirements subsystem.

- i) ISO 13485:2003: 7.2.2 – Review product requirements to verify that they address the intended use as well as customer and regulatory requirements.
- ii) ISO 13485:2003: 7.2.2 – Confirm that incoming contracts and orders are reviewed to assure that any conflicting information is resolved and the manufacturer can fulfil the customer's requirements.
- iii) ISO 13485:2003: 7.2.3, 8.2.1 – Confirm that the manufacturer has made effective arrangements for handling communications with customers including documenting customer feedback to identify quality problems and provide input into the corrective and preventive action subsystem.
- iv) Evaluate the "Customer Requirements" subsystem for adequacy based on findings.

SECTION 8: SUMMARY TECHNICAL DOCUMENTATION FOR DEMONSTRATING CONFORMITY TO THE ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES (STED)

8.1 Introduction

8.1.1 The aim of STED is to provide a route for Global acceptance to encourage consistency in the preparation of documentation to demonstrate to a RA that the subject medical device to be placed on the market is in conformity with the Essential Principles.

8.1.2 A harmonized approach to the contents of STED is important to eliminate as far as possible the different expectations in different parts of the Global Market in terms of the content, level of detail, and treatment of the resulting information.

- i) STED should be produced by the Manufacturer for each device
- ii) The level of detail and depth of information will vary depending on the risk class of each device
- iii) STED is not the complete technical file
- iv) STED is intended to provide the information to support a device to be placed on the market – by providing the information expected in support of the conformity assessment procedures (Section 5) for the appropriate risk class of the device (Section 4)
- v) The STED information is expected to indicate relevant technical information which can be used to understand the features and intentions of the device
- vi) For lower risk devices there will usually not be a need to submit this information to a CAB, but only to have this information available. The information will be an indication of the important points.
- vii) For high-risk devices, STED would be the file which may be required to be submitted to a CAB. The amount of detail will be much higher than for low-risk devices and will need to include much to justify the development/design/production processes.

8.2 Intended Use of STED and Its Preparation

(Source SG1/N011R17)

8.2.1 The STED is intended for conformity assessment purposes. The Manufacturer creates the STED to demonstrate to a RA that the subject medical device is in conformity with the Essential Principles. The STED can be a real or virtual set of documents, at the discretion of the Manufacturer.

8.2.2 For all devices, the Manufacturer is required to conduct conformity assessment according to the Essential Principles before placing the device on the market. In certain cases (mostly determined by the risk class of the

device), the STED may need to be reviewed/approved by the RA or a CAB before the applicable device is placed on the market.

8.2.3 Study Group 1 of the GHF is proposing a set of rules to establish the “class” of a device⁵. It is also proposing harmonized guidance on the link between device classification and conformity assessment to the Essential Principles⁶.

Examples: In the European Community a Manufacturer determines the class of a generic type of device from a set of classification rules. Those in the highest risk class (ie Class III devices) require pre-market conformity assessment by a CAB. In the USA a regulation establishes the class for a generic type of device. Class I and II, non-exempt and Class III devices require pre-market conformity assessment by the RA.

8.2.4 The class of the device will affect the necessary format and content of the STED and also whether or not the STED needs to be submitted to a RA or CAB for review and approval or validation before placing the device on the market. The extent of that conformity assessment and the required resulting documentation vary according to device class, increasing with higher class.

8.2.5 The Manufacturer determines the type and detail of the total technical documentation they believe are needed to demonstrate conformity to the Essential Principles, and to any relevant country-specific requirements. The Manufacturer holds this documentation.

8.2.6 As Figure 1 illustrates, the Manufacturer derives the content of STED from the total technical documentation which it has already prepared and is holding to confirm and record that the medical device is in conformity with the Essential Principles. As an interim measure until full global harmonization of documentation requirements is achieved, the Manufacturer must also consider any country-specific requirements, such as product specific guidance, or legal forms, or legal statements. These country-specific requirements will have a bearing on the type and amount of total documentation that a Manufacturer should compile.

8.2.7 As Figure 1 further illustrates, the assessment of conformity to the Essential Principles by a RA may be required before a medical device is marketed (pre-market), or conformity may be audited after the medical device has been marketed (post-market).

8.2.8 Medical devices that typically have a high degree of risk are those that require pre-market conformity assessment in all jurisdictions. In such cases, documentation is frequently required to be provided to either a RA or CAB for review/approval⁷. It is intended that the STED be such documentation.

⁵ Refer to SG1/N015 *Medical Devices Classification* (a draft document awaiting public comment)

⁶ Document in work and not available for comment at the present time.

⁷ The documentation provided may be called a “dossier”, “application”, or “notification” depending on the Regulatory Authority or Conformity Assessment Body receiving it, and the regulatory class of the device.

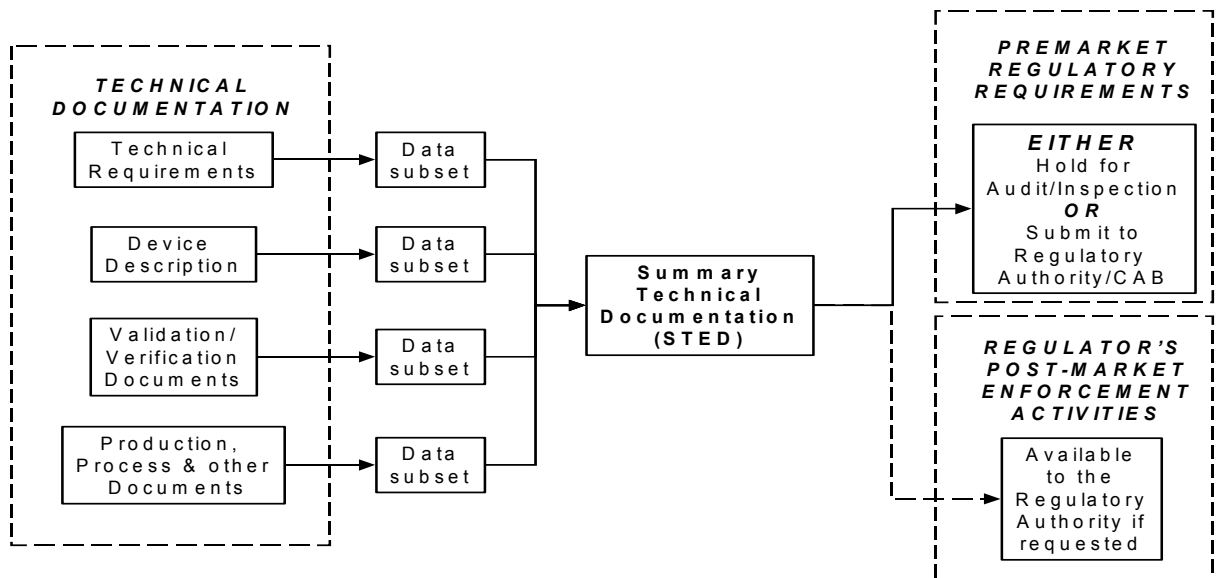


FIGURE 1: SOURCE AND APPLICATION OF THE STED

8.3 Format for STED

8.3.1 Basic format

For ease of use in a global situation, it is recommended that the STED be formatted as shown in the left-hand column of the table below. The right hand column indicates where expanded guidance on each recommended section can be found elsewhere in this document.

| Summary Technical Documentation | Location in this document of expanded guidance |
|--|--|
| Essential Principles and evidence of conformity | Section 6.4.1 |
| Device description | Section 6.4.2 |
| Summary documents of pre-clinical design verification and validation | Section 6.4.3 |
| Labeling | Section 6.4.4 |
| Risk analysis | Section 6.4.5 |
| Manufacturing information | Section 6.4.6 |

8.3.2 How to apply the basic format when a pre-market submission is not required

The respective sections of the STED may be in any of the forms shown below, at the discretion of the Manufacturer. In consideration

of the least burdensome means to demonstrate post-market conformity, the Manufacturer has the following options for the STED:

- i) Option 1: STED based on total documentation. When the total technical documentation is held in a central location and it is contained in a concise file or volume of a relatively few number of pages, then the Manufacturer may choose to designate this record as also the STED for post-market assessment purposes. Ideally, this file or volume should be in the harmonized format as described in Section 6.3.
- ii) Option 2: STED based on summary documentation. The Manufacturer may choose to create the STED as a summary of source documents and formatted as described in Section 6.3.
- iii) Option 3: Abbreviated STED. The Manufacturer may choose to use the Table of Conformity to the Essential Principles (Appendix 6) as the primary method to document conformity for post-market assessment purposes. When completed, this table will point to or reference the identity of the documents used to demonstrate conformity of each relevant Essential Principle. This method may be useful if the source documents consist of many pages and if they are held in more than one location.
- iv) Option 4: Combination STED. The Manufacturer may choose to create the STED containing a combination of the above options, ie
 - some complete source documents;
 - summaries of some source documents; and/or
 - references to source documents.

8.3.3 How to apply the basic format when a pre-market submission is required

Where (for a particular higher risk class) the STED is provided to the RA for conformity assessment before placing the device on the market, it is recommended that the above sections be preceded by a cover page and an executive summary (Appendix 7).

8.4 Guidance on the Elements of the STED

8.4.1 Relevant Essential Principles and method used to demonstrate conformity

- i) General
 - The STED should identify the Essential Principles of Safety and Performance of Medical Devices that are applicable to the device.
 - The STED should identify the general method used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include compliance with

recognized or other standards⁸, state of the art or internal industry methods, comparisons to other similar marketed devices, etc.

– The STED should identify the specific documents related to the method used to demonstrate conformity to the Essential Principles. For example, when the Manufacturer uses international or other standards to demonstrate conformity with the Essential Principles, the STED should identify the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard. When the Manufacturer uses other means, such as internal standards, the STED should describe the means.

ii) Essential principles and evidence of conformity

– For ease of use in a global situation, it is recommended that the evidence of conformity be provided in tabular form with supporting documentation available for review as required. A sample checklist table is included in Appendix 6.

8.4.2 Device description

i) The STED should summarize or reference or contain (according to the option selected by the Manufacturer in Section 6.3.2) the following device description data, to the extent appropriate to the complexity and risk class of the device:

ii) General information

- the functional purpose of the device (intended use);
- the intended patient population(s) and medical condition(s) to be diagnosed and/or treated by the device (indications for use) and other considerations such as patient selection criteria;
- the reasonably foreseeable medical conditions for which the device is not to be used (contraindications);
- a general description of the device including its principles of operation, (capabilities, the inputs to the device and outputs);
- an explanation of any novel features;
- the accessories, and other devices or equipment which are intended to be used in combination with the device;
- the variants of the device to be marketed including, if the STED is to be provided for regulatory review, the parameters of the range of variants;
- a general description of each of the functional parts/components of the device with labeled pictorial

⁸ Refer to SG1/N012 on the Role of Standards in the Assessment of Medical Devices.

representations of the device (e.g. diagrams, photograph, drawing(s)), clearly indicating each part, including sufficient explanation to understand the drawings and diagrams;

- other information as needed to provide a description of the device, e.g., for an implant, a description of the anatomical location of the device in the body, attachment mechanisms for the device, including diagrams or illustrations of the implant in situ;
- comparisons to other devices to establish conformity to the Essential Principles. This could include, for example, information on previous designs of the same type of device or comparisons to other related devices.

NOTE: For simple, low risk devices, the above information will typically be contained in already existing sales brochures, instructions for use, etc.

iii) Materials

- a description of the materials of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles.

iv) Specifications

- the functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic devices, reliability and other factors;
- other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles.

v) Other descriptive information

- other important descriptive characteristics not detailed above, to the extent necessary to demonstrate conformity with the relevant Essential Principles (for example, the biocompatibility category for the finished device).

8.4.3 Summary of design verification and validation documents

i) General

- The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the Manufacturer in Section 6.3.2) design verification and design validation data to the extent appropriate to the complexity and risk class of the device:

- Such documentation should typically include:

- declarations/certificates of conformity to the “recognized” standards listed as applied by the Manufacturer⁹; and/or
- summaries or reports of tests and evaluations based on other standards, Manufacturer methods and tests, or alternative ways of demonstrating compliance¹⁰.

NOTE: RAs presently differ on what they expect in terms of a “summary”. As an interim measure until full global harmonization of documentation requirements is achieved, the Manufacturer should research available sources of information, e.g. country-specific information, to help determine the type of summary that is acceptable.

EXAMPLE: The completed Table of Conformity to the Essential Principles that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle. Section 6.4 of the STED would then include a Declaration of Conformity to the standard, or other certification permitted by the RA, and a summary of the test data, if the standard does not include performance requirements.

- The data summaries or tests reports and evaluations would typically cover, as appropriate to the complexity and risk class of the device:
 - a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the device with reference to the Essential Principles;
 - engineering tests;
 - laboratory tests;
 - biocompatibility tests;
 - animal tests;
 - simulated use;
 - software validation.

ii) Clinical evidence

The STED should indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met. Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar devices, or by clinical investigation. Clinical investigation is most likely to be needed

⁹ Refer to SG1/N012 *Role of Standards in the Assessment of Medical Devices*.

¹⁰ See Appendix **C4** for a **recommended** format **and content** of a test report.

for higher risk class devices, or for devices where there is little or no clinical experience¹¹.

8.4.4 Labeling

i) The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the Manufacturer in Section 6.3.2) the following labeling data to the extent appropriate to the complexity and risk class of the device, which is generally considered as “labeling”:

- labels on the device and its packaging;
- instructions for use;
- other literature or training materials;
- instructions for installation and maintenance¹²;
- any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform.

8.4.5 Risk analysis

The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the Manufacturer in Section 6.3.2) the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and is appropriate to the complexity and risk class of the device.

8.4.6 Manufacturer information

The STED should summarize or reference or contain (e.g. whether submitted or according to the option selected by the Manufacturer in Section 6.2) documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device.

¹¹ Refer to SG1/N036 *Global Approach to Pre-Market Conformity Assessment for Medical Devices (document in work and not available for public comment at the present time)*.

¹² Refer to SG1/N009 *Labelling for Medical Devices*

SECTION 9: ROLES OF STANDARDS IN THE ASSESSMENT OF MEDICAL DEVICES

9.1 Introduction

9.1.1 The processes for pre-market assessment of medical devices are based upon the central principal of a need to comply with a comprehensive list of Essential Principles. These Essential Principles deal with General Principles of a philosophical nature and a number of particular nature, relating to matters such as chemical, physical and biological properties, including choice of materials, safety characteristics, Infection and microbial contamination, cleanliness (sterility), manufacturing risks during manufacture, devices with measuring function, diagnostic accuracy and reliability, protection against radiation, exposure to energy sources, protection against electrical and mechanical risks and many others.

9.1.2 The Manufacturer has to show that all relevant general and particular Risks are suitably addressed before placing a device on the market. It will be necessary to describe and justify the routes taken to deal with matters of risk. This can be a very slow and difficult process. This is the reason for having available a set of standards to provide agreed routes for dealing with both General Principles and more device-related features.

9.1.3 It is recommended that the benefit of referring to standards when assessing the compliance of a device to relevant Essential Principles, and should encourage Manufacturers to similarly use appropriate internationally-recognized standards in reaching conclusions on device design etc.

9.1.4 It is recommended that Malaysia should support standards processes within the international standards organizations, and adopts such standards emanating from ISO and IEC (or European CEN, CENELEC) for its own use. It is not recommended to duplicate such standards activity and produce new national standards without reference to the above bodies.

9.1.5 The GHTF recognized the roles of standards as follows;

i) Basic safety standards (also known as horizontal standards): Standards indicating fundamental concepts, principles and requirements with regard to general safety aspects applicable to all kinds or a wide range of products and/or processes (e.g., standards concerning risk assessment and control of medical devices).

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

iii) Product safety standards (also known as vertical standards): Standards indicating necessary safety aspects of specific products and/or processes, making reference, as far as possible, to basic safety standards and group safety standards (e.g., standards for

infusion pumps, for anesthetic machines, for blood glucose meters for self testing or specifications detailing technical product requirements for certain IVD devices).

9.1.6 Recognized standards are standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

9.2 General Principles

9.2.1 International standards are a building block for harmonized regulatory processes to assure the safety, quality and performance of medical devices. To achieve this purpose, the following principles are recommended:

- i) RA and industry should encourage and support the development of international standards for medical devices to demonstrate compliance with the Essential Principles;
- ii) RA developing new medical device regulations should encourage the use of international standards;
- iii) RA should provide a mechanism for recognizing international standards to provide Manufacturers with a method of demonstrating compliance with the Essential Principles;
- iv) When an international standard is not applied or not applied in full, this is acceptable if an appropriate level of compliance with the Essential Principles can be demonstrated;
- v) While it may be preferable for harmonization purposes to use international standards, it may be appropriate for RA to accept the use of national/regional standards or industry standards as a means of demonstrating compliance;
- vi) Standards Bodies developing or revising standards for use with medical devices should consider the suitability of such standards for demonstrating compliance with the Essential Principles and to identify which of the Essential Principles they satisfy;
- vii) The use of standards should preferably reflect current, broadly applicable technology while not discouraging the use of new technologies;
- viii) Standards may represent the current state of art in a technological field. However, not all devices, or elements of device safety and/or performance may be addressed by recognized standards, especially for new types of devices and emerging technologies.

9.3 Recognized Standards

9.3.1 RA should have, or should develop, procedures for "recognition" of voluntary standards and for public notification of such recognition. The process of recognition may vary from country to country. An organization may be created/designated by a country or community to develop

recognized voluntary standards (e.g. CEN in Europe), or recognition may occur by publication of existing voluntary standards that a RA has found will meet specific pre-market requirements (e.g. USA).

9.3.2 Persons intending to market medical devices should obtain information from the relevant RA, CAB or other authorized third party, or through official publications, on any standards recognized by the RA.

9.3.3 The term “Recognized Standard” does not imply that such a standard is mandatory.

9.3.4 Compliance with recognized standards may be used (if the Manufacturer chooses) to demonstrate compliance with the relevant Essential Principles and/or specific pre-market requirements and/or other requirements of the RA.

9.4 Alternatives to Recognized Standards

9.4.1 The use of standards is voluntary, except in those particular cases where the RA has deemed certain standards mandatory. Manufacturers should be free to select alternative solutions to demonstrate their medical device meets the relevant Essential Principle. Manufacturers may use “non-recognized” standards, in whole or in part, or other methods. Alternative means of demonstrating compliance with the Essential Principles may include, for example:

- i) national and international standards that have not been given the status of a "recognized standard" by the RA;
- ii) industry standards;
- iii) internal Manufacturer standard operating procedures developed by an individual Manufacturer and not related to international standards;
- iv) current state of the art techniques related to performance, material, design, methods, processes or practices.

9.4.2 The acceptability of such other solutions should be demonstrated.

9.5 Technical Documentation

9.5.1 The Manufacturer should retain or be able to provide documentation to demonstrate that the device complies with the selected standard or alternative means of meeting the Essential Principles.

9.5.2 Documentation may include for example, the standard itself (or the alternative means used), how it was applied, deviations, test results and/or other outputs.

9.5.3 When a standard is not applied, or is not applied in full, the Manufacturer should retain, and submit where appropriate, data or information to demonstrate;

- i) that compliance with the Essential Principles has been achieved by other means, and if applicable,

- ii) that the parts of the standard that were not applied were not pertinent to the particular device in question.

9.5.4 A Declaration of Conformity to a recognized standard may be documented in the STED that demonstrates conformity to the Essential Principles, and submitted where appropriate, in lieu of the technical documentation. The format of the Declaration of Conformity may vary from country to country but it is desirable that a common format be developed.

9.6 General Information on the Use of Standards

9.6.1 General considerations

- i) The following considerations should be kept in mind when developing a regulatory program using voluntary standards:
 - Standards represent the opinion of experts from industry, regulators, users and other interested parties;
 - Standards are based on current scientific knowledge and experience;
 - Innovation may present unanticipated challenges to experience;
 - Rigid and mandatory application of standards may deter innovation;
 - Operation of a quality system, subject to assessment, has become widely acknowledged as a fundamental and effective tool for the protection of public health;
 - Quality systems include provisions that address both innovation and experience;
 - Such provisions include field experience, risk analysis and management, phased reviews, documentation and record keeping as well as the use of product and process standards.

9.6.2 Types of standards

- i) Standards are created and published by national or international standards organizations or by RAs. Examples of international standards bodies are IEC and ISO, of regional bodies are CEN and CENELEC, and of national bodies are Deutsches Institut fuer Normung, the British Standards Institute, the American National Standards Institute, ASTM, AAMI, the Japanese Industrial Standards Committee and European and National Pharmacopoeias. Appendix 8 shows some of the sources of standards for medical devices.
- ii) Standards are produced for different reasons and are used in some countries as regulatory requirements rather than being voluntary in application.

SECTION 10: LABELING FOR MEDICAL DEVICES

10.1 Introduction

10.1.1 Labeling is a term used to cover all written, printed, graphic matter presented by a Manufacturer concerning a medical device. This information for users, and others, may be attached to the device itself, on the device packaging, or as a packaging insert. Other parts of the labeling can be distributed together with the device, or made available by other means. The trend is often now to supply information, for example by electronic means, when appropriate for the purpose as an additional, or alternative way of transmitting certain information regarding the device.

10.1.2 When appropriate, labeling is used for eg

- i) Identification purposes related to a medical device – either on the device or its packaging
- ii) To provide instructions for use
- iii) To indicate assembly needs before use
- iv) To indicate technical details concerning device
- v) To indicate intended use
- vi) To indicate any regular maintenance needs
- vii) To indicate any regular maintenance needs
- viii) To indicate any necessary post-market servicing needs
- ix) Any particular limitations on the safe use
- x) Any de-commissioning or disposal information etc.

10.1.3 The provision of an agreed global format for labeling has significant safety implications. Harmonized Labeling is, in fact, an additional Essential Principle and probably is the most influential of all Essential Principles in protecting patient safety.

10.1.4 In dealing with post-market surveillance it is found that more adverse incidents are caused by incorrect, unclear or misleading labeling, than by any one other Essential Principle.

Note: In some regulatory schemes promotional documentation/materials may be considered “Labeling”. Such materials are not in the scope of this guidance.

10.2 Labeling Requirements

(Source SG1 N043R6)

10.2.1 General Principles

Labeling serves to communicate safety and performance related information to users of medical devices and/or patients as well as to identify individual devices. Such information may appear on the

device itself, on packaging (or as a packaging insert), or as instructions for use. Consistent worldwide labeling requirements would offer significant benefits to the Manufacturer, patient or consumer, and to RAs. To achieve this purpose, the following principles are recommended:

- i) As far as it is practical and appropriate, the information needed to identify and use the device safely should be provided on the device itself, and /or on the packaging for each unit, and / or on the packaging of multiple devices. If individual packaging of each unit is not practicable, the information should be set out in the leaflet, packaging insert or other media supplied with, or applicable to, one or multiple devices.
- ii) Where the Manufacturer supplies multiple devices to a single user and/or location, it may be sufficient and appropriate to provide with them only a single copy of the instructions for use. In these circumstances the device user should have access to further copies upon request.
- iii) The format, content and location of labeling should be appropriate to the particular device and its intended purpose.
- iv) Instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.
- v) Instructions may not be needed or may be abbreviated for devices of low or moderate risk if they can be used safely and as intended by the Manufacturer without any such instructions.
- vi) Labeling may be provided to the user in various media and by several means such as printed documents, through a display screen incorporated into the device, downloaded from the Manufacturer's Web Site using the Internet, magnetic or optical media. Whatever the media or the means, information should be targeted to the anticipated user population.
- vii) Country-specific requirements for labeling text, content, or the format of labels or labeling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.
- viii) Taking into consideration the type of user anticipated for the device, national language requirements should be kept to a minimum.
- ix) The use of internationally recognized (ie standardized) symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol is not obvious to the device user, eg for a lay-user or for a newly introduced symbol, an explanation should be provided.

10.2.2 RA and industry should encourage the development and use of international labeling guidelines for medical devices.

10.2.3 RA that are developing regulatory requirements to address device labeling, or modifying existing requirements, are encouraged to consider the adoption of these recommendations. This will help minimize the diversity of labeling requirements worldwide and facilitate the process of harmonization.

10.3 Contents of Labeling

10.3.1 General

The labeling should bear the following particulars. In general:

- i) The name or trade name and address of the Manufacturer and, if appropriate, a phone number and/or fax number and/or website address to obtain technical assistance. For imported devices, information may be required to contain in addition, the name and address of either the importer established within the importing country/region or of an authorized representative of the Manufacturer established within the importing country/region.
- ii) Sufficient details for the user to identify the device and, where these are not obvious, its intended purpose, user and patient population of the device; also, where relevant, the contents of any packaging.
- iii) An indication of either the batch code/lot number (eg on single-use disposable devices or reagents) or the serial number (eg on electrically-powered medical devices), where relevant, and to allow appropriate actions to trace and recall the devices and any detachable components,
- iv) An indication of the date until which the device may safely be used (ie put into service), expressed at least as the year and month (eg on single-use disposable devices or reagents) where this is relevant.
- v) For devices other than those covered by (d) above, and as appropriate to the type of device, an indication of the date of manufacture. This indication may be included in the batch code or serial number.
- vi) Any special storage and /or handling conditions at the appropriate packaging level.
- vii) Any warnings, precautions, limitations or contra-indications.
- viii) The performance intended by the Manufacturer and, where relevant, any undesirable side effects.
- ix) The information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature, and frequency of preventative and regular maintenance, replacement of consumable components, and calibration needed to ensure that the device operates properly and safely during its intended life.

- x) Details of any further treatment or handling needed before the device can be used (eg sterilization, final assembly, calibration, preparation of reagents and/or control materials, etc.).

10.3.2 Additional contents for labeling

Where applicable, the following should also be included in labeling;

- i) An indication that the device is sterile and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization.
- ii) An indication that the device has been specified by the Manufacturer for single-use only.
- iii) An indication that the device is for use by a single individual and has been manufactured according to a written prescription or pattern (ie it is custom-made).
- iv) An indication that the device is intended for pre-market clinical investigation or, for in vitro diagnostic medical devices, performance evaluation only.
- v) An indication that the device is intended only for presentation or demonstration purposes.
- vi) If the device is to be installed with or connected to other medical devices or equipment, or with dedicated software, in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.
- vii) If the device is implantable, information regarding any particular risks in connection with its implantation.
- viii) Information regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment or use (eg electromagnetic interference from other equipment).
- ix) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfections, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where a device is supplied with the intention that it is sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still comply with the Essential Principles of Safety and Performance of Medical Devices.
- x) If the device emits radiation for medical purposes, details of the nature, type and where appropriate, the intensity and distribution of this radiation.

10.3.3 Instructions for use

The instructions for use should also include, where appropriate, details allowing the medical staff to brief the patient on any

contra-indications, warnings and any precautions to be taken. These details should cover in particular:

- i) Precautions to be taken in the event of changes in the performance, or malfunction, of the device including a contact telephone number, if appropriate.
- ii) Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other devices, etc.
- iii) Adequate information regarding any medicinal product or products, which the device in question is, designed to administer, including any limitations in the choice of substances to be delivered.
- iv) Precautions to be taken against any special, unusual risks related to the disposal of the device.
- v) Any medicinal substances or biological material incorporated into the device as an integral part of the device.
- vi) Degree of accuracy claimed for devices with a measuring function.
- vii) Any requirement for special facilities, or special training, or particular qualifications of the device user.

10.3.4 Additional directions/instructions for use for in vitro diagnostic medical devices:

Additional directions/instructions for the proper use of *in vitro* diagnostic medical devices may include:

- i) Intended use/purpose (eg monitoring, screening or diagnostic) including an indication that it is for *in vitro* diagnostic use;
- ii) Test principle;
- iii) Specimen type, collection, handling and preparation;
- iv) Reagent description and any limitation (eg use with a dedicated instrument only);
- v) Assay procedure including calculations and interpretation of results;
- vi) Information on interfering substances that may affect the performance of the assay;
- vii) Analytical performance characteristics, such as sensitivity, specificity, accuracy (trueness and precision);
- viii) Diagnostic performance characteristics, such as sensitivity and specificity;
- ix) Reference intervals;
- x) The use of drawings and diagrams.

SECTION 11: EVALUATION OF CLINICAL DATA

11.1 Introduction

11.1.1 It is the primary purpose of this document to provide guidance to Manufacturers on reviewing and analyzing clinical data and to CAB'S when reviewing the Manufacturers evaluation of clinical data as part of the conformity assessment procedures. This document will also assist Manufacturers, by providing guidance on what is expected.

11.1.2 The Manufacturer must demonstrate that his intended purpose(s) and claim(s) made in relation to safety and performance are achieved.

11.1.3 Evaluation of clinical data relevant to the assessment of conformity with relevant Essential Principles.

11.2 Explanation of Terms

For the purpose of this document:

11.2.1 Clinical data is data which is relevant to the various aspects of the clinical safety and performance of the device. This must include data obtained from:

- i) published and/or unpublished data on market experience of the device in question; or a similar device for which equivalence to the device in question can be demonstrated; or
- ii) a prospective clinical investigation(s) of the device concerned; or
- iii) results from a clinical investigation(s) or other studies reported in the scientific literature of a similar device for which equivalence to the device in question can be demonstrated.

11.2.2 The Evaluation of clinical data is the process by which clinical data from all selected sources (literature, results of clinical investigations and other) is assessed, analyzed and deemed appropriate and adequate to establish conformity of the device with the pertinent essential requirements of the Directive as they relate to safety and performance, and to demonstrate that the device performs as intended by the Manufacturer. The outcome of this process is a report which includes a conclusion on the acceptability of risks and side effects when weighed against the intended benefits of the device.

11.3 Clinical Data to be Provided by the Manufacturer

11.3.1 The decision as to whether clinical data is necessary must be taken for every device on the basis of the type of data required to demonstrate compliance with the relevant Essential Principles, the claims being made for the device in question and the risk management assessment.

11.3.2 Clinical evaluation is based on the assessment of the risks and the benefits, associated with use of the device, through either:

- i) a compilation of relevant scientific literature, that is currently available as well as, where appropriate, a written report containing a critical evaluation of this compilation (the "literature route"); or
- ii) the results of all the clinical investigations relevant to the device in question (the "clinical investigation route"); or
- iii) a combination of (i) and (ii) above. Where the clinical evaluation is based on such a combination, it should include an overall assessment. This assessment should take account of market experience, if available. It is important that the Manufacturer relates the data to the specific device, having regard to the hazards identified.

11.3.3 The Manufacturer must demonstrate whether the available data is sufficient to establish conformity with the regulations, having regard to:

- i) the demonstration of equivalence of the device to which the data relates and the device(s) for which conformity is being assessed, and so the applicability of the findings to the device being assessed (see section 4.3.1 (i)d); and
- ii) the adequacy of the data in addressing the relevant aspects of regulation conformity.

11.4 Manufacturer's Statement on the Clinical Data

11.4.1 The Manufacturer should include in the technical documentation a simple statement on the clinical data used. The statement should make clear whether that clinical data was obtained from the published literature or the results of clinical investigations or a combination of both. Where data relates to other devices, the statement should indicate analogy with which device(s) and how equivalence was established. The full clinical data should be included within the technical documentation.

11.5 Identification of Aspects of Safety and Performance to be Addressed Through Clinical Data

11.5.1 A risk analysis is important in helping the Manufacturer identify known or reasonably foreseeable hazards associated with use of the device, and decide how best to estimate the risks associated with each hazard¹. From the results of the risk analysis, the Manufacturer lays out how each risk is addressed and decides on the acceptability of risks when weighed against the intended benefits.

11.5.2 The risk analysis includes technical and clinical aspects relating to the particular device concerned. It should distinguish between aspects associated with:

- i) the medical procedure for which the device is intended;
- ii) the technical solutions adopted;
- iii) aspects specific to the design and use of the particular device concerned;

11.5.3 This distinction should be used to identify the type and specificity of clinical data needed. Where the available data is not sufficient to address the identified clinical hazards relating to one or more of the above aspects, a clinical investigation(s) will be needed. The objectives of the clinical investigation(s) should focus on those aspects not sufficiently addressed by the available data. The Manufacturer should also set out the intended benefits of the device and relate those to the accepted benefits associated with the generally acknowledged “state of the art”

11.6 Requirements for Literature Route

Due regard needs to be paid to the extent to which the published data are relevant and applicable to the relevant characteristics of the device under assessment and the medical procedure for which the device is intended. A literature review should be performed by person(s) suitably qualified in the relevant field, knowledgeable in the “state of the art” and able to demonstrate objectivity. When the Manufacturer's clinical evaluation to be submitted to the CAB takes the form of a review of the relevant scientific literature, the following requirements should be fulfilled:

11.6.1 General

A protocol for the identification, selection, collation and review of relevant studies should be written and preferably be based on recognized practice for systematic review for literature.

11.6.2 Objective

The objective of the literature review should be clearly defined. The types of studies that are relevant to the objective of the literature review should be specified, taking into account the already well-established knowledge of the device.

11.6.3 Identification of data

Data should be taken from recognized scientific publications. Unpublished data should also be taken into account in order to avoid publication bias. The literature review should state:

- i) the sources of data and the extent of the searches of databases or other sources of information;
- ii) the rationale for the selection/relevance of the published literature;
- iii) the reasons for believing that all relevant references, both favorable and unfavorable, have been identified;
- iv) the criteria for exclusion of particular references together with a justification for this exclusion.
- v) Note: possible data sources for a systematic literature review are for example:
- vi) medical and paramedical databases
- vii) technical papers from relevant Standards Committees

- viii) foreign language literature
- ix) “grey literature” (theses, internal reports, non peer review journals, the internet, industry files)
- x) references listed in primary sources
- xi) other unpublished sources known to experts in the field (obtained by personal communication)
- xii) raw data from published trials (obtained from personal communication)

11.6.4 Relevance of data

i) A literature review should clearly establish the extent to which the literature relates to the specific characteristics and features of the device under consideration. If the published studies do not directly refer to the device in question, the following must apply.

ii) The Manufacturer must demonstrate equivalence in all the following essential characteristics with the device, which is the subject of the published reports. Equivalence means:

– Clinical:

- used for the same clinical condition or purpose;
- used at the same site in the body;
- used in similar population (including age, anatomy, physiology);
- have similar relevant critical performance according to expected clinical effect for specific intended use.

– Technical:

- used under similar conditions of use;
- have similar specifications and properties eg tensile strength, viscosity, surface characteristics
- be of similar design;
- use similar deployment methods (if relevant);
- have similar principles of operation

– Biological:

- use same materials in contact with the same human tissues or body fluids;

iii) To be equivalent, the devices should have similarity with regard to the clinical, technical and biological parameters with special attention to the performance, principles of operation and materials; or if there are differences identified, an assessment and demonstration of the significance these might have on safety and performance must be set out.

- iv) The Manufacturer must be able to demonstrate the adequacy of the data in addressing the aspects of conformity set out in the objective

11.6.5 Assessment of clinical data

- i) The literature review should make clear the significance that is attached to particular references based on a number of factors. These include:

- the relevance of the author’s background and expertise in relation to the particular device and/or medical procedure involved.
- whether the author’s conclusions are substantiated by the available data
- whether the literature reflects the current medical practice and the generally acknowledged “state of the art “ technologies.
- whether references are taken from recognized scientific publications and whether or not they have been reported in peer reviewed journals
- the extent to which the published literature is the outcome of a study/studies which have followed scientific principles in relation to design, for example, in having demonstrable and appropriate endpoints, inclusion and exclusion criteria, an appropriate and validated number of patients submitted, carried out for an appropriate duration, providing evidence and analysis of all adverse incidents, deaths, exclusions, withdrawals and subjects lost follow-up and identifying an appropriate statistical plan of analysis.

- ii) Ideally, evidence should be generated from a clinical trial (controlled if appropriate), properly designed cohort/case controlled study, well documented case histories or sequential reports conducted by appropriate experienced experts, whether in relation to the device itself or an equivalent device. If unpublished data is being included in the assessment, the literature review will need to weigh the significance that is attached to each report.

- iii) The evidence should not consist of:

- isolated case reports;
- random experience;
- reports lacking sufficient detail to permit scientific evaluation (including lack of accepted and validated statistical design if this is relevant to the design of the intended study);
- unsubstantiated opinions.

11.6.6 Critical evaluation of the literature

The literature review should contain a critical evaluation of the literature. This critical evaluation should:

- i) be written by a person suitably qualified in the relevant field, knowledgeable in the “state of the art” and able to demonstrate objectivity;
- ii) contain a short description of the medical device, its intended functions, description of the intended purpose and application of use;
- iii) contain an analysis of all the available data considered, both favorable and unfavorable;
- iv) establish the extent to which the literature relates to the specific characteristics and features of the device being assessed, taking due account of the extent of similarity between the device(s) covered by the literature and the device under assessment;
- v) demonstrate that those aspects of the use of the device, including performance, addressed in the clinical part of the risk analysis are met as claimed by the Manufacturer, and that the device fulfils its intended purpose as a medical device;
- vi) analyze the identified hazards, the associated risks and the appropriate safety measures of patients, medical staff and third parties involved in the study/studies, for example by reference to the Manufacturer’s risk analysis (see also ISO14155-2);
- vii) contain a risk analysis relevant to the device design, materials and procedures involved, taking into account any adverse events, results of post-market surveillance studies, modifications and recalls (if known) (see also ISO14155-2);
- viii) contain a description of the methods of weighting of different papers and the statistical methods of analysis employed taking into account the assessment methods, the type and duration of study and the heterogeneity of the population included within the study. Particular attention should be given in circumstances where there are repeated publications on the same group of patients by the same authors in order to avoid over weighting the experience;
- ix) include an analysis of the market experience of the same or similar devices, including the results of post-marketing studies, post-market surveillance and short- and long-term adverse events;
- x) contain a list of publications appropriately cross-referenced in the evaluation;
- xi) if the clinical data relates to an equivalent device, contain a statement that equivalence with all the relevant characteristics has been demonstrated;
- xii) include a conclusion with a justification, including an assessment of any probable benefit to health from the use of the device as intended by the Manufacturer, against probable risks of

injury or illness from such use taking account of the “state of the art”. If applicable, the findings should be compared with other studies covering the same field of application. These studies may involve other modalities, including alternative medical devices, medical therapy, surgery or other accepted health care methods provided they employ methods which are generally accepted as being common practice. The conclusions should make clear how the objectives of the literature review have been met and identify any gaps in the evidence necessary to cover all relevant aspects of safety and performance.

Note 1: Conclusions should be relevant in the field of use, indications, contra-indications and instructions for use intended by the Manufacturer

Note 2: The critical evaluation should be signed and dated by the author

11.6.7 Conclusions from analysis of literature review

As a result of a literature review, the CAB needs to be able to answer the following:

- i) that the Manufacturers’ conclusions are valid;
- ii) that the data, taken together with the available pre clinical data, is sufficient to demonstrate compliance with the essential principles covering safety and performance of the device in question under normal conditions of use; or
- iii) identify gaps in the demonstration of compliance with the relevant essential principles or in the demonstration of equivalence that need addressing through the means of a specifically designed clinical investigation(s); and
- iv) that the claims made in the device labeling are substantiated by the clinical data taken together with the pre-clinical data.

11.7 Requirements for Clinical Investigations Route

When data reviewed/Literature review is not assessed to be sufficient then it will be necessary to consider the need to carry out a clinical investigation. When the Manufacturer’s clinical evaluation to be submitted to the CAB takes the form of presentation and analysis of results from a specifically designed clinical investigation(s) involving the device in question, the following requirements should be fulfilled.

11.7.1 Identification of relevant documents

A clinical investigation plan should be submitted to the RA and to an Ethics Body for consideration.

11.7.2 Information to be checked

- i) The following must be checked in all cases. Particular attention should be paid to:
 - the number of patients entered

- the objectives of investigation(s) (in particular which Essential Principles are being addressed)
 - the duration of investigation(s) and patient follow up (short and long term)
 - the end points in terms of diagnostic tools and patient assessment
 - the inclusion and exclusion criteria;
- ii) Identification of any changes to CIP and rationale for any such changes (important to ensure RA was notified of changes, if this is relevant);

11.7.3 Final report

The contents of the final report should always be checked and should contain the following information

i) Summary

A structured abstract should be provided, presenting the essentials of the study, including:

- title of investigation(s);
- identification of the medical device(s), including names, models as relevant for complete identification;
- name of Sponsor;
- statement indicating whether the investigation(s) was performed in accordance with Standards;
- objectives;
- subjects;
- methodology;
- investigation(s) initiation and completion dates, including date of early termination, if applicable;
- results;
- conclusions;
- authors of report;
- date of report.

ii) Introduction

A brief statement placing the study in the context of the development of the medical device in question and an identification of guidelines followed in the development of the Protocol.

iii) Materials and methods

- device description;

- summary description of the device and its intended use, together with any modifications performed during the investigation;
- Clinical Investigation Plan summary.

iv) Results

This should contain summary information with a description of the analysis and results including:

- the investigation initiation date;
- investigation completion/suspension date;
- the disposition of patients/devices;
- the patient demographics;
- clinical investigation plan compliance;
- the analysis to include safety report, including a summary of all adverse events and adverse device events seen in the investigation, including a discussion of the severity, treatment required, resolution and assessment by the investigator of relation to treatment; performance or efficacy analysis; any sub group analysis for special population; a description of how missing data, including patients lost to follow up or withdrawn, were dealt with in the analysis.

v) Discussions and conclusions

These should contain:

- the performance and safety results of the study;
- the relationship of risks and benefits;
- clinical relevance and importance of the results, particularly in the light of other existing data and discussion of comparison with “state of the art”;
- any specific benefits or special precautions required for individual subjects or at risk groups;
- any implications for the conduct of future studies.

The final report should be signed off by the Sponsor, the co-coordinating clinical investigator (if appointed) and principal investigator at each center

11.7.4 Independent Analysis

An assessment and analysis carried out by an independent and unbiased expert in the field should always be considered, particularly if in-house expertise is not available.

11.8 The Roles of CAB

With regard to the evaluation of clinical data the CAB has different roles depending on the conformity assessment procedure followed. As part of quality system approval, the Notified Body assesses the Manufacturer's procedure for clinical data evaluation.

11.8.1 Decision-making

In reviewing the evaluation of clinical data submitted by the Manufacturer, the CAB decides whether or not the Manufacturer has adequately:

- i) described and verified the intended characteristics and performances related to clinical aspects;
- ii) performed a risk analysis and estimated the undesirable side effects;
- iii) concluded on the basis of documented justification that the risks are acceptable when weighed against the intended benefits.

11.8.2 CAB specific procedures and expertise

- i) RA should establish and implement internal policies and procedures for the assessment of clinical data in order to ensure that suitable resources, especially relevant knowledge and competence necessary for such evaluation, are available within the CAB and/or by contracting external experts.
- ii) Such expertise should be sufficient to identify and estimate the risks and benefits associated with the use of the medical devices. The evaluation team should be able to evaluate a risk analysis and the risk management strategy performed by the Manufacturer. The evaluation team should understand the device technology as well as the medical procedure [8].
- iii) Such an evaluation may require input from a qualified medical practitioner (for example physician, dentist, nurse), as appropriate for the particular device, who has clinical experience in the pathology of the condition being treated, the usual treatment, the therapeutic alternatives etc.
- iv) When examining the results of clinical investigations, the evaluation team should have knowledge in planning, conduct and interpretation of clinical investigations. All evaluators should be trained and qualified.
- v) Particular attention should be drawn to training of external experts with regard to the conformity assessment procedure. The RA should be responsible for reviewing the opinion of these experts, taking account of their level of knowledge of the provisions of the Directives.

SECTION 12: USE OF RISK MANAGEMENT – AN OVERVIEW

12.1 Introduction

12.1.1 The basis of all activities in assessing the suitability of medical devices for entry into the market is the establishment of a balance between;

- i) The needs for a particular device function
- ii) The solutions provided by a manufacturer in addressing the needs
- iii) The intended performance intended by the manufacturer in providing the solutions – as specified
- iv) The inherent risks as identified associated with use of the device-risk analysis
- v) Control measures taken to address identified risks
- vi) The residual risk after control measures have been taken
- vii) Identification of foreseeable hazards at all stages of the process
- viii) A comparison between the residual risk and the benefits obtained from using the device – the risk/benefit ratio
- ix) The need to inform users of residual risks by labeling or other instructions, or alarm mechanisms.

12.2 The Use of Risk Management

12.2.1 The whole process is one of Risk Management which is the mechanism which shall be applied at all times in meeting the Essential Principles of Safety and Performance of Medical Devices.

12.2.2 The application of Risk Management should follow the provisions of the appropriate International Standard – ISO 14971 – developed in ISO Technical Committee TC210 with full participation by IEC, and the European Standards Bodies CEN and CENELEC.

12.2.3 ISO 14971 is entitled “Application of Risk Management to Medical Devices” and supersedes the content of an earlier standard on – “Medical Devices – Risk Analysis” – developed originally in Europe and published as EN1441.

12.2.4 The intentions of EN1441 for Risk Analysis have been incorporated within the ISO 14971 standard.

12.2.5 Risk Management should be applied at all times in the development, design, production, inspection, distribution process and should be considered for aspects at all times in terms of correct use, maintenance of the device during its useful life, and including matters of safe disposal.

12.3 Possible Hazards and Contributing Factors Associated with Medical Devices

12.3.1 The following is the list of examples (non-exhaustive) of possible hazards and contributing factors associated with medical devices. The list is intended to provide an aide-memoire in identifying possible hazards under 3.3 of the risk analysis procedure (step 3 of figure 1).

- i) Energy hazards
 - electricity
 - heat
 - mechanical force
 - ionizing radiation
 - non-ionizing radiation
 - electromagnetic fields
 - moving parts
 - suspended masses
 - patient support device failure
 - pressure (vessel rupture)
 - acoustic pressure
 - vibration
 - magnetic fields (e.g. MRI)

12.3.2 Biological hazards

- bio-burden
- bio-contamination
- bio-incompatibility
- incorrect output (substance/energy)
- incorrect formulation (chemical composition)
- toxicity
- cross-infection
- pyrogenicity
- inability to maintain hygienic safety
- degradation

12.3.3 Environmental hazards

- electromagnetic interference
- inadequate supply of power or coolant
- restriction of cooling

- incompatibility with other devices
- likelihood of operation outside prescribed environmental conditions
- accidental mechanical damage
- contamination due to waste products and/or device disposal

12.3.4 Hazards related to the use of the device

- inadequate labeling
- inadequate operating instructions
- inadequate specification of accessories
- inadequate specification of pre-use checks
- over-complicated operating instructions
- unavailable or separated operating instructions
- use by unskilled/untrained personnel
- reasonably foreseeable misuse
- insufficient warning of side effects
- inadequate warning of hazards likely with re-use of single use devices
- incorrect measurement and other metrological aspects
- incorrect diagnosis
- erroneous data transfer
- mispresentation of results
- incompatibility with consumables/accessories/other devices

12.3.5 Hazards arising from functional failure, maintenance and ageing

- inadequacy of performance characteristics for the intended use
- lack of, or inadequate specification for maintenance including inadequate specification of post maintenance functional checks
- inadequate maintenance
- lack of adequate determination of end of device life
- loss of mechanical integrity
- inadequate packaging (contamination and/or deterioration of the device)
- improper re-use

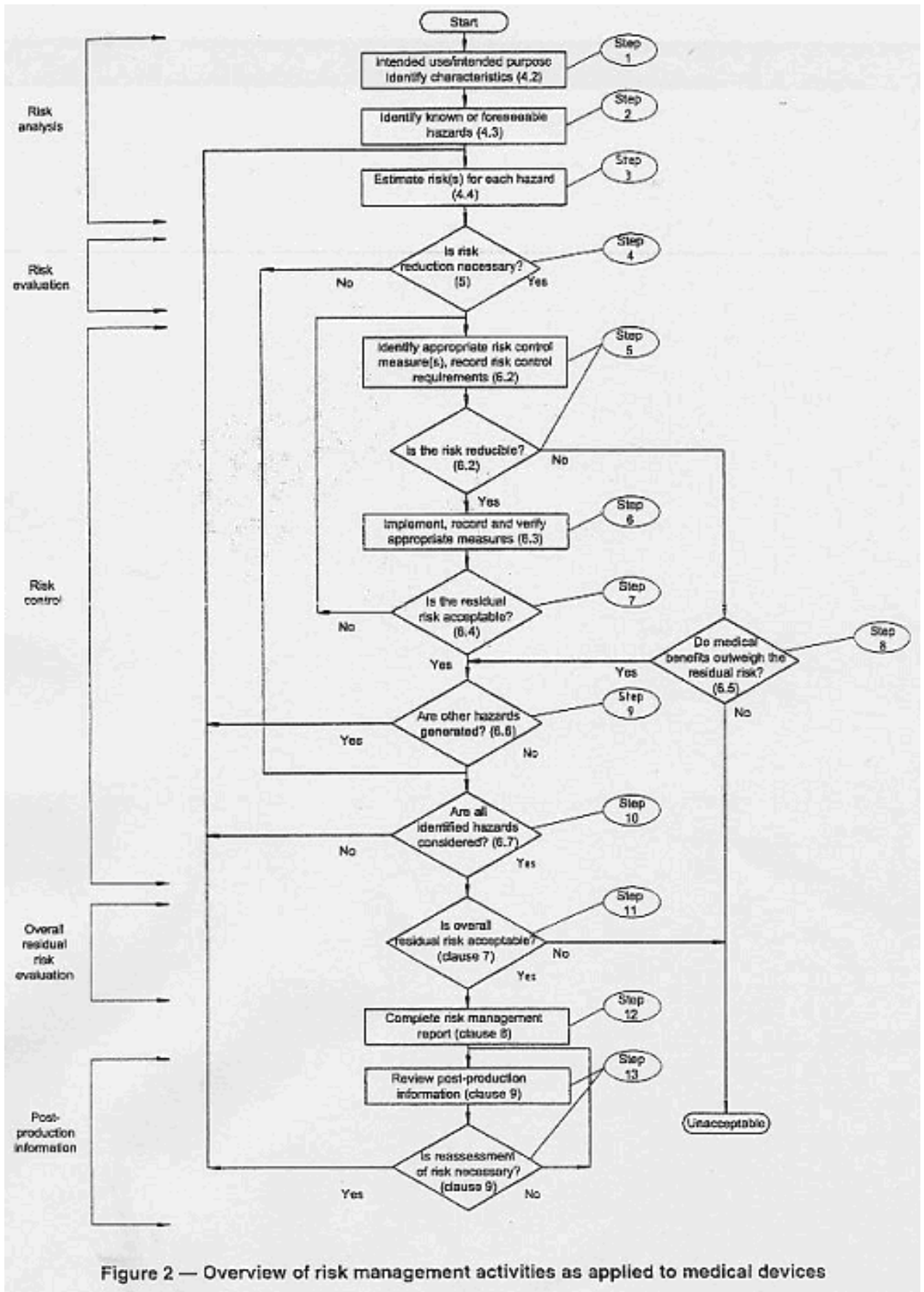


Figure 2 — Overview of risk management activities as applied to medical devices

SECTION 13: REGULATORY NEEDS FOR IDENTIFYING LISTING OF MEDICAL DEVICES AND NEED FOR GLOBAL MEDICAL DEVICES NOMENCLATURE (GMDN)

13.1 Introduction

13.1.1 Registration of Manufacturer

- i) The RA may require that Manufacturers in Malaysia shall inform the RA of their registered place of business in Malaysia and a general description of the devices concerned for this purpose the Manufacturer shall identify the generic description of the devices by using the Global Medical Device Nomenclature (GMDN) Code as appropriate for the devices concerned.
- ii) The level of detail for this registration increases with increasing risk-classification. For Class A products the identification can be at a collective-term or template term level.
- iii) For Classes B, C and D, more details should be used (generic preferred term code) and for high-risk Class D devices, mainly the generic code should be used plus more specific individual device type (unique product identifier).

13.1.2 Manufacturer's Authorized Representative

For imported products, a Manufacturer's Authorized Representative shall be identified and designated by the manufacturer. In this case the obligation to register the product with the RA shall fall to this Authorized Representative.

13.1.3 Regulatory Authority Listings

The RA will require the information to be included in a Register of Medical Devices, to be aware of the generic devices present on the Malaysian market at all times, and who is the primary body responsible for such products. This is important to address any serious public health issues involving particular devices, and which may, for instance, result in a product recall or other corrective action.

13.1.4 GHTF Information Exchange on Incidents Involving Medical Devices

The Malaysian RA may request to become a member of the Post-Market Report Exchange as introduced by GHTF Study Group 2.

13.2 Global Medical Device Nomenclature (GMDN)

13.2.1 Background

i) The development of Medical Devices Directives revealed a need for common generic descriptors for medical devices to be available for a number of purposes and in particular for identification of devices involved in adverse incident reports, and for the exchange of specific information between member states, as foreseen in the Directives. The need for such a nomenclature was also recognized in the FDA, in Canada and other countries.

13.2.2 Action – The Standard

i) In 1993 the Commission mandated work within CEN to produce a standard indicating the structure of a nomenclature system. The mandate indicated that such structure and a subsequent nomenclature should meet the needs of the global market. For this reason ISO was invited to participate in the work so that international considerations were addressed.

ii) The resulting standard was adopted as EN/ISO 15225: "Nomenclature - Specification for a nomenclature system for medical devices for the purposes of regulatory data exchange". BSI acted as secretariat of the TC257 SC1 Committee.

13.2.3 Action – The Project Team

i) The European Commission provided the finance for the establishment and development of the Nomenclature using the system identified in the published standard.

ii) A Project Team was managed by Project Council led by MDA and a team of 70 device experts from 16 different countries worked within 12 identified categories of medical devices to develop the base nomenclature. In this process appropriate terms were used, if available, from one of the existing nomenclatures. These were: -

- The ECRI - UMDNS nomenclature
- The Norwegian - NKKN nomenclature
- The FDA - nomenclature
- The EDMA - nomenclature for IVD's
- The Japanese - JFMDA nomenclature
- The ISO nomenclature on 'Aids for the Disabled'

iii) The resulting Global nomenclature is the only comprehensive system for medical devices. This work was published in November 2001 and comprises approximately 15,000 terms. There are approximately 7,000 main (preferred) terms, approximately 7,000 synonyms and nearly 1,000 template (or main title) terms.

- iv) The nomenclature is published in Europe as CEN report - CR 14230 (which is identical to ISO Technical Specification ISO/TS 20225).

13.2.4 The resulting nomenclature

- i) The GMDN is intended for purposes as follows: -
 - To give a Common Generic Descriptor for every general term describing characteristics of a medical device. This is to be used for identifying similar devices to those identified as being involved in an adverse incident report.
 - To identify, using the generic term, a device having been the subject of a specific design or other certificate.
 - As a basis for E-commerce - providing a generic basis for purchasing individual types of manufactured devices, by establishing a heading for comparison of products from different manufacturers.
 - For the exchange of data between regulatory bodies.

13.2.5 Those intending to use the nomenclature

- i) Japan has already translated the GMDN into Japanese for use as indicated above.
- ii) Australia has written the use of GMDN into the draft legislation.
- iii) The FDA has assessed GMDN and they have provided written confirmation, of their intention to use GMDN for regulatory purposes.
- iv) Canada has indicated their intention to use the GMDN.
- v) The GMDN was designed to meet the European requirements for regulatory purposes and the Medical Device Expert Group has accepted GMDN for this purpose.
- vi) The GHTF has supported the GMDN as the intended nomenclature, and has indicated the use of GMDN in the processes of global vigilance exchange - now in the pilot phase.
- vii) New candidate countries in Europe are asking to use GMDN.
- viii) The World Health Organization has investigated the use of GMDN and it is hoped that confirmation of this will soon be received.

13.2.6 Maintenance and distribution process

- i) The Copyright of the GMDN is held by CEN and the application of this and organization of the ongoing maintenance

process has been delegated to a Maintenance Agency Policy Group (MAPG).

- ii) This Group comprises nominated representatives from: -
 - The European Commission
 - FDA
 - Ministry of Health and Welfare Japan
 - GHTF
 - Up to 5 individuals selected from within CEN members
 - Up to 5 individuals selected from within ISO members

13.2.7 Maintenance Agency Policy Group (MAPG) – following the structure agreed by CEN-BT

- i) Delegated to arrange the updating and maintenance of the GMDN
- ii) Arranges for a Secretariat to distribute the GMDN
- iii) Prepares License Agreements for those asking for the use of the nomenclature
- iv) Endorses appropriate bodies that wish to translate the nomenclature into individual languages. The MAPG will take advice from appropriate regulatory bodies in selecting the preferred body to be the recognized translating body for each language.
- v) The MAPG sets appropriate fees for those bodies wishing to use the GMDN under license for commercial purposes.
- vi) The MAPG will invite sponsorship from regulatory bodies to support the ongoing maintenance process. Such sponsorship is of a voluntary nature.
- vii) The fees received will be used to enable the costs of the secretariat and expenses for experts to support the maintenance process.

13.2.8 Future work

- i) The Commission has a mandate for CEN to carry out further work in preparing a list of headings known as "Sub-Categories" for specific use when there is a need of general collective terms: -
- ii) To illustrate the scope of certificates issued by Notified Bodies when assessing which groups, families, types of medical devices are covered within a manufacturers quality system.
- iii) To be used to identify the range of skills and general technological abilities for which a Notified Body has been

approved and is so appointed by the relevant Competent Authority.

iv) For the exchange of information between Competent Authorities when general information on individual manufacturers capabilities is noted for inclusion in the European Database for Medical Devices (EUDAMED).

v) These sub categories are additional to the terms included in the GMDN nomenclature and are for specific purposes to simplify the data exchange purposes and certification purposes as listed above.

vi) It is anticipated that these "Sub Categories" will be similarly valuable in applying regulatory procedures within the Global market, as being addressed within the GHTF.

13.2.9 Distribution and maintenance of GMDN

i) The original base GMDN as published in CEN report CR 14230 (identical to ISO Technical Specification – ISO/TS 20225) was distributed by CEN and ISO) members who may have translated this report into their national language. This "read-only" version has now been superseded by the first official enhanced and updated version which is distributed under license by the MAPG.

ii) The MAPG provides, through an Expert Group, a continuous service for editing, correcting, updating and enlargement of GMDN as found necessary.

iii) The MAPG establishes and runs a distribution process of the continuously updated GMDN in its English language version as the reference nomenclature for licensed users, and retains all distribution rights for this English language version. This data-file may be loaded into any suitable database for ease of use.

iv) Whilst recognizing, by license, the intention of certain bodies to translate the nomenclature into other languages, the MAPG does not control distribution of those other language versions, except that it insists on the use only of the original GMDN codes for each term and that additions or changes to terms must only be established with the consent of the MAPG as appropriate for such change to be incorporated in the base nomenclature.

v) It is anticipated that at regular intervals the Standards Bodies CEN and ISO will decide to update the original CEN report or ISO technical specification to include the current updated version of the GMDN. The standards bodies may then decide to make this revised version available to its members.

Note: - The GMDN now has some 17,000 terms, and there is a constant process of review and addition as requests are processed to provide new generic terms as identified by manufacturers and regulatory bodies.

PART 2: POST-MARKET SURVEILLANCE SYSTEM

SECTION 14: FRAMEWORK FOR POST-MARKET SURVEILLANCE SYSTEM

14.1 Definitions

The Global Harmonization Task Force (GHTF) has not yet a consensus on many terms such as incident versus event; surveillance versus vigilance. Here we shall follow the general, non-legal, meaning of terms used in the World Health Organization Document: “Medical Device Regulations: Global Overview and Guiding Principles”. Some important terms used in this document have meanings described below:

“Incident” and “event” are generally used synonymously except in determining “reportable event” where an “event” is defined in Appendix 15, or in GHTF/SG2 N21R8.

National Competent Authority (NCA) and Regulatory Authority (RA) are used synonymously.

Post-market surveillance is used as a broad term that covers any and all monitoring activities including the vigilance system for medical devices in use. In Europe, vigilance concerns the responsibility of the manufacturer to inform the competent authority of incidents, according to National/European legislation.

“Vendor” is synonymous with “Authorized Representative” in the European system. Here, a Vendor could be the manufacturer, importer or distributor.

The writer anticipates that the Medical Device Technical Committee and the Legal Adviser of the Ministry of Health Malaysia will decide on a set of definitions for all final Guidance Notes to follow.

14.2 Introduction

14.2.1 After pre-market approval, the safety and performance of medical device depends on;

- i) Preservation of the integrity of device that includes storage, handling, transportation, delivery, installation and pre-commissioning verification test before acceptance into actual operation;
- ii) Continued monitoring to ensure safety and performance, to detect, investigate unexpected incidents for possible adverse events, and to resolve and share with other users any useful, preventive or corrective information resulting from an adverse event. (Of course, it is vitally dependent upon training of users on safe and effective use);

- iii) Maintenance including repair and calibrations that are necessary to preserve its specified performance

14.2.2 These essential requirements form the basis for the development of the Proposed Framework for the Post-market Surveillance System in Malaysia (see Appendix 9). Paragraphs 14.2.1 i) and 14.2.1 iii) above rely greatly on the Vendor/Manufacturer while paragraph 14.2.1 ii) relies more directly on the User. For optimum results, however, close cooperation between the two is essential.

14.2.3 Recommendations from all current final documents of the GHTF Study Group 2 (GHTF/SG2) (listed in Appendix 10) have been incorporated in this Document. As well, similar documents of the established systems of Australia, Canada, the United Kingdom (UK) and the United States of America (USA) have been referenced.

14.2.4 Section 15 derives from the Quality Management System requirements that in fact cover all post-market activities. Sections 16, 17 and 18 specify procedure and documentation requirements in order to support adverse event investigation, reporting and recall. Sections 19, 20 and 21 reflect an integration of recommendations from the current final GHTF/SG2 documents.

14.2.5 Section 22 is the writer's proposal for user post-market surveillance requirements. It is important to recognize the vital roles of the users in post-market activities. Many established regulatory system do not have mandatory requirement for adverse event reporting by users. Whether this is advisable or not depends of the local culture, legal and healthcare practices. Voluntary device problem reporting by users works very well in the UK and some European countries but so far not so well in North America.

14.2.6 This Document is proposed to the Government of Malaysia for consideration and consultation with the stakeholders. Modifications and amendments of these proposals to suit the Malaysian situation are expected.

SECTION 15: VENDOR QUALITY SYSTEM REQUIREMENTS

15.1 Introduction

15.1.1 After pre-market approval, the safety and performance of medical device depends on;

- i) Preservation of the integrity of device that includes storage, handling, transportation, delivery, installation and pre-commissioning verification test before acceptance into actual operation;
- ii) Continued monitoring to ensure safety and performance, to detect, investigate unexpected incidents for possible adverse events, and to report and resolve such events for the prevention of repeated occurrence;
- iii) Maintenance including (repair and calibrations) that are necessary to preserve its specified performance

15.1.2 This Section proposes the responsibilities and duties of Vendors of medical devices in Malaysia. All of the responsibilities and duties proposed can be derived from the Quality Management System requirements for the manufacturers. The following proposed responsibilities and duties are for all Vendors/Manufacturers of medical devices including the low risk (Class I) medical devices that are exempt from a Quality Management System for manufacturers.

15.1.3 The ISO 13485:2003 standard is the international standard for the Quality Management Systems developed for the regulatory requirements for medical device manufacturing. All major medical device producing countries now have quality management system requirements for medical device manufacturers virtually identical to those specified by the ISO13485:2003. In countries that import most of their medical devices, the Authorized Representative for the original Manufacturer will be made responsible for the local regulatory requirements. In this Section, we shall use the term “Vendor” as the responsible person. Appendix 11 provides the extracts of some requirements from the ISO13485:2003 relevant to post-production activities required of Manufacturers of medical devices.

15.2 Requirements for Vendors

15.2.1 Storage, handling, transportation and delivery

- i) The Vendor shall store, handle, transport and deliver medical device they supply according to the original manufacturer’s procedures or documented work instructions for preserving the conformity of product during storage, handling and transportation and delivery including instructions for the control of product with a limited shelf life or requiring special storage conditions.

- ii) Documents of the original manufacturer's storage, handling, transportation and delivery instructions shall be kept by the Vendor and made available to the customer when requested.

15.2.2 Installation

- i) The Vendor shall install medical devices in accordance with the original manufacturer's requirements and acceptance criteria for installing and verifying the installation of the medical device.
- ii) Documents of the original manufacturer's installation procedures, verification and acceptance criteria shall be kept by the Vendor and made available to the customer when requested.

15.2.3 Maintenance and services arrangements

- i) The Vendor should receive appropriate training from the original manufacturer for maintenance and services for medical devices supplied by the Vendor.
- ii) For high-risk medical devices, the Vendor must receive appropriate training from the original manufacturer for maintenance and services activities.
- iii) The Vendor may designate their maintenance and services duties to a third party provided the National Competent Authority (NCA) approves that third party
- iv) The Vendor shall keep documents of the original manufacturer's specified procedures, work instructions and reference materials and reference measurement procedures, as necessary, for performing servicing activities.
- v) The Vendor shall ensure the supply of replacement parts and offer (or arrange competent third parties) to offer preventive and corrective maintenance including calibration and other services, if applicable, to the users when requested.

15.2.4 Monitoring, reporting, corrective and preventive actions

The set of quality management system requirements under Section 8 of the ISO13485 (Appendix 11) translate into the following Vendor post-market requirements and activities:

- i) Distribution records and implant registration
See Section 16
- ii) Post-market surveillance studies
 - In post-market surveillance studies, specific and structured data collections are required of the manufacturer in one of two situations:
 - as a condition of product approval; or
 - to re-affirm product safety when post-market adverse event reports suggest that pre-market

safety claims are inconsistent with actual use and result in unacceptable risk.

– Japanese authorities and the US Food and Drug Administration (US FDA) actively make use of surveillance data collection to augment the findings of pre-market trials.

– When the Vendor markets in Malaysia a medical device that is subject to domestic regulatory requirements of the producing country to perform post-market surveillance studies, the Vendor must inform the NCA in Malaysia before marketing such a device. The Vendor must have a study plan in place and provide periodic reports to the original manufacturer and the Malaysian NCA. Additionally, the NCA of Malaysia may require Vendors to perform post-market surveillance studies on designated medical devices.

- iii) Reporting of adverse events – See Section 19
- iv) Complaint handling records – See Section 17
- v) Recall procedures – See Section 18
- vi) Trending of events and criteria for determining a “significant increase” in the trend

In Section 19, adverse events that are exempt from individual case reporting, and identified use errors are subject to trending. A significant increase in the rate (trend) of these events could indicate potential problems lurking. Thus, irrespective of whether such events are individually reportable, periodically reportable or currently exempt from reporting as agreed with the NCA, a significant increase in the trend (see criteria in Appendix 12) should be reported to the NCA.

It should be understood that there are circumstances when a Vendor/manufacturer should take action immediately without waiting for a trend to occur. It may be based on the severity of the event, or by perceived risks associated with the adverse event(s) regardless of the number or trend of events.

- vii) Adverse Event trending procedure
 - Based on the diversity of the medical devices in the market it is not meaningful to define a single trending procedure valid for all devices. Depending on the type of device (e.g. IVD, implant, diagnostic and therapeutic device, surgical and dental instrument, hearing aid, compression, etc.), the devices risk classification, the number of products delivered, single or multiple use of devices, devices with traceability requirements, unavailable information on device disposals and other

parameters a Vendor/manufacturer must adopt a trending procedure which is applicable and adequate for his operations and devices. Basic methods for performing trending can be found in the literature (e.g. for statistical quality control) and will not be repeated in this document.

– While for many Vendors/Manufacturers the use of simple graphs and charts will be sufficient, the implementation of more sophisticated methods will be advisable for others. It is important that valid statistical methods are used for trend evaluation. It is the responsibility of the Vendor to select and apply a trending scheme that is most appropriate to their products. The NCA may request the Vendor/manufacturer to demonstrate that the applied method is appropriate for the particular case.

viii) The difference between complaint trending and adverse event trending

– Complaint trending (see Section 17) as an established quality system requirement provides the basis on which Vendors/manufacturers are asked to accumulate and analyze their data. Since complaints come from the data source from which reportable adverse incidents are identified, trending of adverse events uses essentially the same methods as trending of complaints.

– However, the decision making process and following activities are different in that:

- Trending of complaints may lead to the discovery of a complaint trend (and the appropriate corrective and preventive actions) but not necessarily to a report to the NCA.
- Trending of adverse events and use errors (see Section 4, GHTF/SG2/N31R8:2003) may lead to a report to the NCA

ix) Determining “Significant Increase in Statistical Trending”

– In the medical device area, it is hard to find a definition in the literature on what constitutes a significant increase in the rate of adverse events. Appendix 12 provides some guidance to Vendors/Manufacturers on how a creditable baseline for trending can be established and provides information to NCAs that might facilitate decisions regarding reporting exemptions for devices with well-established baselines.

SECTION 16: VENDOR DISTRIBUTION RECORD AND IMPLANT REGISTRATION

16.1 Introduction

16.1.1 The purpose of the Distribution Record and Implant Registration is for the tracking of a medical device sold so that the owner or the patient can be located. Whenever it is necessary, problems notification or other useful information can be sent quickly to the clients owning the devices. During a recall of a device, accurate distribution information is essential in order to locate the device owner or the user.

16.1.2 No specific method of tracking is prescribed for general medical devices, but the Vendor must have written standard operating procedures for a method of tracking that will enable efficient location of the devices in case of needs. In the case of an implanted device, implant registration cards intended for direct tracking of the patient are specified.

16.2 Distribution Records

16.2.1 General requirements

- i) The Vendor of a medical device shall maintain a distribution record in respect of each device sold in Malaysia. The distribution record shall contain sufficient information to permit;
 - contact with the user/owner of the device for information transfer
 - rapid and complete withdrawal of the medical device from the market in case a recall is needed (see Section 5).

16.2.2 Implantable high-risk devices

- i) The Medical Device Technical Committee will designate devices for this requirement.
- ii) The distribution record maintained by a Vendor of a high-risk implant device shall also contain a record of the information received on the implant registration cards (see Paragraph 3.3 below) forwarded to the Vendor from a healthcare facility or the patient. The Vendor of an implant shall update the information in accordance with information update received from the healthcare facility or the patient.

16.2.3 Proposed minimum data set

Repeat the following data set for each device sold

- i) Device information
 - Device brand name

- Model number
 - Catalogue number
 - Device identifiers e.g., serial number, batch number, software version number, etc.
 - Device intended purpose
 - Device risk class
 - Nomenclature system
 - Nomenclature code
 - Name of Manufacturer
 - Name of Manufacturer’s contact person
 - Manufacturer address
 - Manufacturer phone
 - Manufacturer fax
 - Manufacturer e-mail address
- ii) Device approval information
- Name and address of Regulatory/National Competent Authority who approved device
 - Name and address of Conformity Assessment Body
 - Device approval certificate identification
 - Name and address of Quality Management System assessment body
 - Quality Management System certification identification
- iii) Distribution record of this device

| | Client Name | Address | Email | Phone | Fax | Number of units | Remarks |
|---|-------------|---------|-------|-------|-----|-----------------|---------|
| 1 | | | | | | | |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |
| 5 | | | | | | | |
| 6 | | | | | | | |

16.2.4 Retention of records

- i) The Vendor shall retain the distribution record maintained in respect of a medical device for the longer of;
 - the projected useful life of the device, and
 - two years after the date the device is shipped.

16.3 Implant Registration

16.3.1 Vendor responsibility

- i) The Vendor of an implant shall provide, with the implant, two implant registration cards that contain
 - the name and address of the Vendor and the Manufacturer;
 - the name and address of any person designated by the Vendor or the Manufacturer for the collection of implant registration information;
 - a notice advising the patient that the purpose of the cards is to enable the Vendor or the Manufacturer to notify the patient of new information concerning the safety, effectiveness or performance of the implant, and any required corrective action; and
 - a statement advising the patient to notify the Vendor and the Manufacturer of any change of address.
- ii) An implant registration card shall be designed for the recording of the following information:
 - the name of the device, its control number and its identifier, including the identifier of any
 - medical device that is part of a system, test kit, medical device group, medical device family or
 - medical device group family;
 - the name and address of the healthcare professional who carried out the implant procedure;
 - the date on which the device was implanted; the name and address of the healthcare facility at which the implant procedure took place; and the patient's name and address or the identification number used by the healthcare facility to identify the patient.
- iii) The two implant registration cards shall be printed in the official languages of Malaysia; however, the Vendor may choose to provide one card for each official language in Malaysia. It will be the Vendor's responsibility to translate any information in the Malaysian languages for any foreign manufacturers.

16.3.2 User responsibility

- i) A member of the staff of the healthcare facility where an implant procedure takes place shall, as soon as possible after the completion of the procedure, enter the information on each implant registration card, give one card to the implant patient and forward one card to the Implant Registry designated by the Ministry of Health Malaysia.
- ii) The healthcare facility including healthcare professionals, the Vendor or the Manufacturer shall not disclose the patient's name or address, or any information that might identify the patient, unless the disclosure is required by law. (Group 3 of the Medical Device Technical Committee has recommended that this clause be deleted, but Group 2 did not make this recommendation. The final decision rests with the Regulator).

SECTION 17: VENDOR COMPLAINT HANDLING PROCEDURES

17.1 Introduction

17.1.1 Because of the large variety and its physical nature, medical devices are regulated with risk management approach. No amount of rigor in any pre-marketing review process can predict all possible device failures or incidents arising from device misuse. It is through actual use that unforeseen problems related to safety and performance can occur. The safety and performance of medical devices in use depends critically on continuous monitoring or its performance to investigate any unexpected incidents.

17.1.2 An incident with a medical device is an unusual (or unexpected) event associated with the use of a medical device. Not all incidents lead to adverse events, but all incidents should be investigated to identify potential product or use problems that can lead to an adverse event. Any identified problems must then be systematically resolved to eliminate the potentials for an adverse even.

17.1.3 Complaints by users or the public about a medical device could be a symptom of potential problems and Vendors of medical devices are require to have in place a written procedure on how to handle complaints from clients and a strategy on how to follow up on such complaints. This Section describes the requirements for Vendor Complaint Handling Procedures.

17.1.4 The Medical Device Technical Committee Meeting (Langkawi 2004) has recommended that the requirements of documented Complaint Handling Procedures be extended to in-house manufacturers (eg healthcare facilities that construct medical devices).

17.2 Maintenance of Records

17.2.1 Vendors of a medical device shall maintain records of the following:

- i) reported problems relating to the performance characteristics or safety of the device, including any consumer complaints, received after the device was first sold in Malaysia;
- ii) all actions and timely investigation of the problems reported, and when necessary, effective and timely recall of the device;
- iii) the records on problems and complaints related to a medical device must include the following information;
- iv) the name, registration number, model/catalogue number or bar code, the control, serial or lot number and any other means of identification of the device;
- v) the names and addresses of the Vendor; and

- vi) records regarding the problem investigation, as describe in Paragraph 4.3 below.

17.2.2 All actions taken by the Vendor in response to the problems must be kept on record. These actions include any communications with the reporter/complainant, the evaluation of the problem/complaint, and any steps taken to correct the problem or prevent the recurrence of the problem. Such steps might include increased post-market surveillance of the device; corrective and preventive action respecting the design and production of the device when a recall is not warranted (provision of information to users of the device, reconditioning, disposal, or corrective action on any unit of the device still in use); or product recall.

17.2.3 Attention should also be given to identifying the development of patterns or trends in problems with medical devices (see Sections 2, 6 and GHTF/SG2 N-36R7). The report of an isolated incident would assume much greater significance if other similar occurrences were reported.

17.3 Written Problem Investigation Procedure

17.3.1 Vendors of a medical device should have in place a written procedure for problem investigation that outlines the steps to be taken once a problem/incident report is received. The procedure should identify the personnel involved, and describe their functions and responsibilities. It is strongly recommended that the user be involved in a joint investigation (see Section 9). In addition, the procedure should explain how to maintain records of the complaints or problem reports, and how to assess these records. The procedure should also specify a reasonable time frame for completion of the investigation.

17.3.2 The procedure should provide a description of the problem/incident and an assessment as to

- i) whether there is a health hazard associated with the device;
- ii) whether the device fails to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety;
- iii) whether the device fails to meet any Malaysian regulatory requirement;
- iv) whether “root cause analysis” has been conducted to identify and resolve triggering factors from other components of the healthcare system.
- v) what preventative/corrective action is appropriate on the basis of the above information; and
- vi) whether a decision not to take action is justified, as in the case of an unfounded or invalid complaint.

17.3.3 Description of the incident/problem – The report should include a detailed description of the incident or problem and the circumstances that led to the discovery of the defectiveness or possible defectiveness of the device, as well as the date that the problem was first noticed.

17.3.4 Health hazard assessment – To assess the health hazard, the Vendor must gather, correlate and evaluate all known information on the nature and extent of the reputed health risk. The factors considered may include but are not limited to the following;

- i) death, disease or injury that has already occurred from use of the product;
- ii) hazard to various segments of the population, such as children, surgical patients and the elderly, who are more likely to be exposed to the product;
- iii) degree of seriousness of the health hazard to individuals exposed to the product;
- iv) benefits from use of the device that may offset the risk of exposure, such as in the treatment of a life-threatening condition;
- v) probability of hazard occurring during exposure to product;
- vi) consequences (immediate or long-range) of occurrence of the hazard;
- vii) user qualifications (professional, trained user versus untrained, inexperienced user)
- viii) user awareness or anticipation of the hazard (a problem that most users would anticipate, such as backflow of body fluids or electromagnetic interference, or an occurrence that most users would not expect);
- ix) distribution of the product; and
- x) public perception of the problem/incident.

17.3.5 The NCA will consider all pertinent information provided to assess the health hazard of a device and to assign a priority to the problem/incident according to the following scheme. This scheme has three levels of priority for medical devices incidents:

- i) Priority I: A situation in which there is a reasonable probability that the use of, or exposure to, a device has led to the death or serious deterioration of the state of health of a patient, user or other person, or a reasonable belief that recurring exposure could lead to the death or serious deterioration of the state of health of a patient, user or other person.
- ii) Priority II: A situation in which the use of, or exposure to, a device may cause temporary deterioration of the state of

health of a patient, user or other person, or where the probability of serious deterioration of health is remote.

iii) Priority III: A situation in which the use of, or exposure to, a device is not likely to cause any deterioration of the state of health, of a patient, user or other person.

These Priority Levels will be used to determine the level of effectiveness checks during a recall situation (see Section 5)

17.3.6 Compliance with the requirements of the Malaysian regulations – Failure with a device to comply with Malaysian regulatory requirements should be documented, and the consequences of any deficiency identified should be assessed in terms of associated health risks.

17.3.7 Reportable adverse events – When an incident/problem meets the criteria of a reportable adverse event described in Section 6, mandatory reporting of the problem to the NCA is required.

17.3.8 Corrective/Preventative Action – The problem investigation procedure determines the appropriate preventative/corrective action in a given situation. A decision tree could be developed to ascertain what action would best resolve the identified problem and any other deficiency that may have been unveiled by the problem investigation. The options for preventative/corrective actions are:

- i) increased post-market surveillance of the device;
- ii) corrective and preventive action respecting the design and manufacture of the device when a recall is not warranted; and
- iii) recall of the device (see Section 18).

Vendor/Manufacturers should promptly respond to all user complaints. Otherwise, the Regulatory Authority will intervene.

SECTION 18: VENDOR RECALL PROCEDURES

18.1 Definition of a Recall

"Recall" with respect to a medical device means any action taken by the Vendor/Manufacturer to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness after becoming aware that the device;

- i) is or may be hazardous to health;
- ii) fails or may fail to conform with any claims made by the Vendor relating to the effectiveness, benefits, performance characteristics or safety of the device; or
- iii) does not comply with the regulations.

Note: Recall requirements apply to medical devices that are provided as free samples.

18.2 Criteria for Initiating A Recall

The initiation of a recall may be triggered by the following conditions:

- i) A problem investigation (Sections 15, 17 and 22) may determine that a recall is necessary to protect the public health and well-being.
- ii) Any information that indicates an unacceptable increase in risk posed by a medical device. This information may arise from any aspect of post-market surveillance, such as field experience of device use, device service or maintenance, the results of internal device testing, report from users, review of device design, production or component specifications etc.
- iii) The NCA will inform the relevant medical device Vendor of any adverse incidents reported directly to them by users and which may give rise to the need for a device recall. The NCA will provide the Vendor with available information in order to help enable them to conduct a full investigation.
- iv) On occasions, the NCA may advise the Vendor to recall affected medical devices due to a risk of serious injury or death to patients, users or others, which has been brought to the NCA's attention through adverse event reports or other means.
- v) Where the NCA has sufficient concern over the possibility that affected devices may remain available for future use, the NCA may mandate the removal for safety reasons of the medical device from the Malaysian market.
- vi) A recall is normally carried out by the Vendor and may include the physical retrieval of the device from users, as well as any form of retrofit or correction made at user institutions, including labeling or instructional changes and user advisories.

vii) During recalls, the primary role of the NCA is to monitor the effectiveness of the Vendor recall actions and to provide scientific, technical and operational advice when needed. If a recalling Vendor's performance is deemed to be inadequate, the NCA should be prepared to take appropriate action to remove the product from sale or use. The NCA may deem it necessary to initiate enforcement actions either during or following the completion of the recall.

18.3 Written Recall Procedure

18.3.1 The Vendor of a medical device must have in place a written recall procedure that details the steps to be taken in case a problem investigation concludes that a recall is necessary. The recall procedure should identify all internal and external personnel involved, along with their functions and responsibilities, and sets out the channels and means of communications for executing the recall.

18.3.2 The procedure also should specify the level of priority and assigns a time frame for completion of the recall (in general within 30 days as recommended by the Medical Device Technical Committee, Langkawi 2004). The written recall procedure should include the development of the recall strategy.

Note: If the Vendor's procedure and execution are ineffective, the Regulatory Authority will take action.

18.4 Recall Strategy

18.4.1 The recall strategy is a detailed plan for implementing a Vendor's recall procedure in a specific case. The strategy is based on the particular circumstances of the situation, including the following factors:

- i) the hazard or risk the product represents;
- ii) the target population;
- iii) the ability of users to identify the product;
- iv) the description of the product's defect;
- v) the number of the affected devices in the marketplace;
- vi) the anticipated shelf life of the product; and
- vii) the continued availability of alternative products that have the same intended healthcare function.

18.4.2 Based on these factors, the recall strategy will address the following elements:

- i) Depth of the recall;
- ii) Recall communications;
- iii) Effectiveness checks; and

iv) Stock control.

18.4.3 Depth of the recall – The users of the affected device should be identified in order to determine the depth of the recall. Users may be hospitals, clinics and members of the medical profession or a subgroup of the medical profession, such as orthopedic surgeons and anesthetists, and members of the Malaysian public when the device is for home use, as in the case of insulin syringes or pregnancy tests.

18.4.4 Recall communications –

i) The recalling Vendor is responsible for promptly notifying each of its consignees (anyone who received or purchased the affected device) about the recall.

ii) The format, content and extent of communication should be commensurate with the hazard of the product being recalled and the strategy developed for the recall. Recall communications should be brief and to the point and should not contain irrelevant qualifications, promotional material, or any element that may detract from the message. In general, recall communications should include the following:

- Description of the product: name, size, lot number(s), serial number or any other relevant descriptive information should be specified to enable immediate and accurate identification of the product that is subject to recall.

- Hazard associated with the product: the reason for the recall should be concisely explained. It should be made clear that further distribution or use of the product should cease immediately. The consequences of using the product in its affected state should be stated.

- Instructions for recall of the product: specific steps should be given for the return, disposal or correction of the affected product.

- Instructions for notification of users: the recall communication must emphasize the consignees' awareness of their responsibility to notifying any clients that received the affected product. Consignees should immediately carry out the instructions set forth by the recalling Vendor and extend the recall to its own consignees (e.g. other retailers).

- Methods of response to recall communications: provision must be made for product users and retailers to respond to the recalling Vendor quickly and with all necessary information. This could include provision for the recipient to place a collect call or to return a pre-addressed card to the recalling Vendor. Follow-up contact should be made with those who fail to respond to the initial recall communication.

- For implantable devices it is often clinically unjustifiable to explant the device. Corrective action taking the form of special patient follow-up must be given.
 - When in-vitro diagnostic devices (IVDD) are subject to recall because of false results, the consequences of the subsequent incorrect diagnostic must be examined, and where warranted, users should be instructed to ensure that all affected patients are informed and retested.
- iii) Recall communications can be accomplished by several means, including telephone, facsimile and special delivery letters. Envelopes and letters should be conspicuously marked, for instance, by displaying the statement "MEDICAL DEVICE RECALL" in bold, red type. Fax cover sheets and letters should be marked in bold type as well. Priorities I and II recalls should be labeled "URGENT." Telephone calls or personal visits should be documented and confirmed with written communication.
- iv) Public notification is usually reserved for hazards classed as Priority I, and occasionally Priority II, or situations where other means of controlling the hazard appear inadequate. The notice could be disseminated through the general news media, either national or local as appropriate, or targeted to specific segments of the population through the use of specialized news media, such as the community press.
- v) Where the recall strategy requires public notice, the NCA will encourage a Vendor to issue a news release or other appropriate means of notifying users. In some situations, the NCA may issue a release in cooperation with the Vendor rather than duplicating the Vendor's communications. Where the communication by the Vendor is inappropriate, inadequate or untimely, the NCA will take action to inform the Malaysia public.

18.4.5 Effectiveness checks

- i) Effectiveness checks are performed by the recalling Vendor to verify that consignees have received notification about the recall and have taken appropriate action. The recalling Vendor may conduct effectiveness checks through personal visits, telephone calls, facsimiles, letters or a combination of various means. Vendors should maintain records of their effectiveness checks for review by the NCA.
- ii) The NCA may carry out its own effectiveness checks as part of its monitoring of the recalling Vendor's performance. This will be a separate exercise and should not be considered as a part of or a supplement to the recalling Vendor's responsibilities for adequate effectiveness checks.

iii) The recall strategy should specify the method that will be used and the level of effectiveness check that will be conducted. The levels are as follows:

- Level A 100% of the total number of consignees to be contacted;
- Level B between 10 and 100% of the total number of consignees to be contacted (percentage determined on a case-by-case basis);
- Level C between 0 and 10% of the total number of consignees to be contacted (percentage determined on a case-by-case basis).

iv) The level of effectiveness checks is determined by the Priority assigned to the problem. The following table serves as a general guide. For Priority II and III, the percentage should be determined on a case-by-case basis.

| Priority | Effectiveness check | Verification of recall notice received by consignees |
|----------|---------------------|--|
| I | Level A | 100% |
| II | Level B | 10 -100% |
| III | Level C | 0 -10% |

- Priority I: A situation in which there is a reasonable probability that the use of, or exposure to, a device has lead to the death or serious deterioration of the state of health of a patient, user or other person, or a reasonable belief that recurring exposure could lead to the death or serious deterioration of the state of health of a patient, user or other person.
- Priority II: A situation in which the use of, or exposure to, a device may cause temporary deterioration of the state of health of a patient, user or other person, or where the probability of serious deterioration of health is remote.
- Priority III: A situation in which the use of, or exposure to, a device is not likely to cause any deterioration of the state of health, of a patient, user or other person.

18.4.6 Stock control

The recalling Vendor is responsible for ensuring that the product returned to it is properly identified and isolated until a decision has been made to dispose of it, return it to the Vendor or correct it. The recalled product must not be put back on the market unless it meets regulatory requirements.

18.5 Notices to the NCA

18.5.1 Each recall requires at least two pieces of correspondence. The initial notice must be provided before or upon initiating a recall and must contain all the information listed under Paragraph 5.5.2. The completion notice, which will contain the results of the recall and the action taken to prevent a recurrence, must be issued as soon as possible after the completion of the recall.

18.5.2 Initial Notice

Before undertaking the recall, the Vendor is required to provide the NCA with an initial notice of the recall containing the following information:

- i) the name, registration number, model/catalogue number or bar code, the control, serial or lot number and any other means of identification of each device being recalled.
- ii) the name and address of the importing Vendor (in different to the Vendor).
- iii) the reason for the recall, the nature of the defectiveness or possible defectiveness, the consequences of using the affected device, and the date on and circumstances under which the defectiveness or possible defectiveness was discovered. If all information on the problem is not immediately available, a preliminary report should be submitted, followed by a more detailed description when additional information has been collected.
- iv) an evaluation of the risk associated with the affected device, which should have been completed as part of the problem investigation procedure. If the risk evaluation is not available immediately, a preliminary evaluation should be submitted and then completed when more information is available.
- v) determination of the priority of the problem/incident. Based on the information contributed by the Vendor and other sources, the NCA will also assign a priority (I, II or III) to the incident. The NCA's decision regarding priority will take precedence over that of the Vendor.
- vi) the number of affected units of the device that were manufactured in Malaysia, imported into Malaysia and sold in Malaysia, and the dates of manufacture and importation.
- vii) the period during which the affected device was distributed in Malaysia by the Vendor.
- viii) the name and address of each client that purchased the device targeted for recall and the number of units sold to each.
- ix) a copy and a list of recipients of any communication issued with respect to the recall. If the problem resulting in the recall was the object of a communication from the Vendor to its

client prior to the recall, a copy of that communication should be provided as well.

x) the proposed strategy for conducting the recall, including the beginning date, information as to how and when the Department will be informed of progress, and the proposed date for completion.

xi) the measures that the Vendor intends to take to prevent the problem from happening again, such as examination of and possible changes to the design, the validation of a sterility procedure, or the addition of a step in the quality control process. If a detailed plan is not immediately available, the initial recall notice should indicate where the Vendor would focus its efforts to resolve the problem.

xii) the name, title and telephone and fax numbers of a designated representative the Vendor to contact for any information concerning the recall. This representative should be easy to reach and up to date with all developments regarding the recall. For high priority recalls, the Vendor's representative should be accessible outside working hours.

18.5.3 Completion Notice

i) After the completion of a recall, the Vendor is required to submit a written report to the NCA as soon as possible. The report should provide the following information:

- the dates of initiation and completion of the recall, tabulate the replies from consignees, specify the number and the method of effectiveness checks conducted, and designate a final evaluation of risk if different from the initial evaluation.

- the results of the recall, including how many units were recovered, how many units were not recovered (due to destruction, implantation or voluntary detention for reconditioning), and how many units from each consignee were corrected (modified, repaired or retrofitted).

- the results of its corrective actions to resolve or prevent recurrences of the problem by such measures as changing the product design, introducing a new sterility procedure or adding a step to the quality control process.

ii) The recall will be closed only when the NCA and the recalling Vendor are in agreement that the product subject to recall has been removed or that proper disposition or correction has been made.

18.6 Key Activities During a Recall

18.6.1 The written recall procedure and strategy will provide systematic guidance for efficient activities for any emergency recall situation. Three first questions before initiating a recall are:

- How extensive is the device distributed?
- What should the user do with the device?
- What should be the level and means of communication?

18.6.2 If early warning is advisable, use phone, email, and fax before written recall is sent. It is important to maintain close communications with the user and the Regulatory Authority.

18.6.3 Key activities during a recall are illustrated in the flow chart of Appendix 13.

18.7 Medical Device Alert/Recall Policy and Procedures

18.7.1 User facilities should establish Medical Device Alert/Recall Policy and Procedures commensurate with the organization nature and structure. Essential features of the policy and procedures include the following:

- i) Designate a person as a manager/ coordinator of Medical Device Alerts or Recall Notices
- ii) Direct all Medical Device Alerts and Recall Notices within the healthcare facility to this person for distribution to all relevant professionals and work units of the health facility for action.
- iii) The distribution list shall be specified on the alert or recall document.
- iv) The flow of this distribution should be clearly specified, preferably by a flow-chart
- v) All actions must have feedback to the manager/ coordinator upon completion of task by the message recipient.
- vi) The manager/coordinator is responsible for overseeing that recall are completed as soon as possible and in no case more than 3 days after receiving a recall notice.
- vii) All Medical Device Alerts and Recalls must be retained chronologically in a master file.

SECTION 19: VENDOR ADVERSE EVENT REPORTING

19.1 Introduction

19.1.1 Because of the large variety and its physical nature, medical devices are regulated with risk management approach, and post-market surveillance is critical in ensuring its continued safety after devices are put into services.

19.1.2 The objective of the adverse event reporting and subsequent evaluations is to improve protection of the health and safety of patients, users and others by disseminating information which may reduce the likelihood of, or prevent repetition of adverse events, or alleviate consequences of such repetition. A decision flow-chart for adverse event reporting is shown in Appendix 14.

19.1.3 The act of reporting an event to a NCA is not to be construed as an admission of manufacturer, user, or patient liability for the event and its consequences. Submission of an adverse event report does not, in itself, represent a conclusion by the manufacturer that the content of this report is complete or confirmed, that the device(s) listed failed in any manner. It is also not a conclusion that the device caused or contributed to the adverse event. It is recommended that reports carry a disclaimer to this effect.

19.1.4 It is possible that the manufacturer will not have enough information to decide definitely on the reportability of an event. In such a case, the manufacturer should make reasonable efforts to obtain additional information to decide upon reportability. Where appropriate, the manufacturer should consult with the medical practitioner or the health-care professional involved, and do his utmost to retrieve the concerned device.

19.1.5 As a general principle, there should be a pre-disposition to report rather than not to report in case of doubt on the reportability of an event.

19.2 Criteria for Reportable Events

19.2.1 Any event, which meets all of three basic criteria listed below, is considered an adverse event reportable to the NCA:

- i) An event (see definition in Appendix 15 and examples in Appendix 16) has occurred OR a potential adverse event is recognized through information available – The manufacturer becomes aware of information regarding an event (as defined below) has occurred OR may occur with its device.
- ii) The manufacturer's device is a contributing factor (OR potential contributing factor) to the event – In assessing the link between the device and the event, the manufacturer should take into account:

- The opinion, based on available information, from a healthcare professional;
- Information concerning previous, similar events;
- Other information held by the manufacturer.

This judgment may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device was associated with the event.

iii) The event led to one of the following outcomes:

- Death of a patient, user or other person.
- Serious injury of a patient, user or other person.

Serious injury (or serious deterioration in state of health) is either:

- life threatening illness or injury.
- permanent impairment of a body function or permanent damage to a body structure.
- a condition necessitating medical or surgical intervention to prevent permanent
- impairment of a body function or permanent damage to a body structure.

The interpretation of the term "serious" is not easy, and should be made in consultation with a medical practitioner when appropriate. The term "permanent" means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage. Medical intervention is not in itself a serious injury. It is the reason that motivated the medical intervention that should be used to assess the reportability of an event.

- No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs (also known as "near incidents"; "near adverse event")

The non-occurrence of a serious result might have been due to circumstances or to the timely intervention of healthcare personnel. The event is considered "adverse" if in the case of recurrence, it could lead to death or serious injury. This applies also if the examination of the device or a deficiency in the information supplied with the device, or any information associated with the device, indicates some factor that could lead to an event involving death or serious injury.

19.2.2 In addition to the above, report any significant increase in the trending of;

- i) use errors; and
- ii) data that have potentials to cause an adverse event.

Please refer to Section 2: Vendor Quality Management System Requirements.

19.3 Criteria for Exemption to Report

Reporting is not required if one of the exemption criteria listed in Appendix 17 applies, except:

- i) there is a change in trend or pattern of an issue associated with the device that can potentially lead to a reportable adverse event;
- ii) when a manufacturer initiates corrective action to prevent death, serious injury or public health concern.

19.4 Timeframe for Submitting Adverse Event Reports

19.4.1 The report should be made as soon as possible. The times given below are the maximum elapsed times for determining the relevant facts and making an initial report.

19.4.2 If the event is a reportable “near adverse event” (see Paragraph 6.2.1 iii) above) or the event did not result in death or serious injury, the Vendor must submit a manufacturer's report of the adverse event no later than 30 calendar days from the date of becoming aware of the event.

19.4.3 If the event resulted in a serious injury or a death, the Vendor must submit a manufacturer's report of the adverse event no later than 10 calendar days from the date of becoming aware of the event.

19.4.4 If after becoming aware of a potentially reportable adverse event there is uncertainty about whether the event is reportable, the Vendor must submit a report within the timeframe required for that type of event.

19.5 Data Requirements for Adverse Event Reporting

A Universal Data Set (as in Appendix 18) has been adopted by the GHTF SG2 for Adverse Event Reporting by the Vendor. The set consists of the following sections;

- i) Administrative information
- ii) Clinical information
- iii) Healthcare facility information
- iv) Device information

- v) Result of Manufacturer's investigation
- vi) Patient information
- vii) Other reporting information
- viii) Comments
- ix) Manufacturer disclaimer

SECTION 20: NATIONAL COMPETENT AUTHORITY (NCA) NATIONAL DISSEMINATION OF INFORMATION

20.1 Introduction

20.1.1 The objective of the adverse event reporting and subsequent evaluations is to improve protection of the health and safety of patients, users and others by disseminating information which may reduce the likelihood of, or prevent repetition of adverse events, or alleviate consequences of such repetition.

20.1.2 However, the information resulting from adverse event reports must be handled in a manner assuring that those concerned will not oppose to reporting. This can only be achieved if the resulting information is of some benefit, *and* does not damage the reputation of the manufacturer or healthcare facilities, or cause embarrassment to healthcare workers.

20.2 Guiding Principle for National Dissemination of Information

20.2.1 Principle: Information should be brought to the attention of those who specifically needs it, and preferably nobody else. In fact, do not make more noise than what is strictly necessary.

20.2.2 A good national reporting culture can only be achieved through *confidence between all parties concerned*. The question will always remain; what happens to data handed into the system? Can everybody along the line be trusted? Will the information be properly treated? As important as confidential and discrete handling and treatment of data, will be the way conclusions are drawn. What information is to be released and used, and how will this be done.

Note: patient identification should not be disclosed in this reporting system.

20.3 Considerations Before Releasing Information Nationally

20.3.1 The following factors must be considered:

- i) What actions as a result of the adverse event are to be taken? e.g. recall, alert or both? Others?
 - if further use of the device could be dangerous, the device should be recalled from the market
 - if there is an existing risk, guidance on use should be given while awaiting further investigations, e.g. the patient should consult a medical doctor for follow up or investigation ; the device should be checked/ adjusted/ altered/ modified in order to avoid risk
- ii) How extensive is the device distributed and used?

- is the device for professional use?
 - is it carried by the patient?
 - is it an implant?
 - is it extensively used in the homes?
- iii) Can the persons, natural or legal, who should have the information be *traced and located* and given information individually? e.g. implants with individual registration
- iv) If the information needs to be disseminated via the public media in order to reach the relevant users, what media should be used?
- v) Is the information collected, or received, of *relevance and benefit* to the public at large?
- do the public, as such, need this information?
 - do the public have «a right» to know?
 - will releasing the information benefit public health?
 - will it be sufficient with generic information?
 - could releasing the information scare, or harm, the public?

20.3.2 It is essential to consult with the vendor/manufacturer and the user on all these aspects. If the decision is to disseminate the information to the public the authority has an obligation to reach all concerned. The release can either be handled in a generic manner or specific model. Generic information should be preferred if this is adequate. Type specific information should only be given *to the public* if strictly necessary as this can do harm to companies, as well as others involved, far beyond the case in question. Dissemination of information must be handled professionally and be dealt with on a case-by-case approach.

20.3.3 Information to the public about adverse events will easily lower the healthcare profession's and the healthcare system's reputation. It will easily cause anxiety and could thus do more harm than good. On the other hand, for the public it is also assuring to see that such matters are dealt with properly.

20.4 Recommended Procedure for National Dissemination of Information

20.4.1 Make sure the manufacturer or his authorized representative is *informed in advance* about the case(s), the conclusions and the intended actions. Agreement on what information to disseminate should preferably be obtained.

20.4.2 Whenever possible, *the manufacturer or his representative should do the information work*, in accordance with the instructions given by, as well as *supervised by, the authorities*.

20.4.3 When choosing ways of informing, the following *steps of priority* should be preferred;

- i) by giving specific information to the customers, when this assuredly can be conveyed to the users, professionals or non-professionals.
- ii) by contacting or writing directly to only the facilities that use the device. *Example: all hospitals for a device which could not be used elsewhere.*
- iii) by sending out hazard notes to all relevant facilities.
- iv) by announcing the information in the media directed specifically towards professionals, where there is a great possibility of reaching all concerned.
- v) by announcing in national papers, radio or television, taking note of the following:
 - making sure of describing the case in a precise and understandable way so that those concerned can identify themselves, and all others will know they are not to worry.
 - give adequate information about the problems and possible risks involved.
 - include proper follow-up means for those concerned. Inform about whom to contact with what information at hand, as well as about legal and economic matters. Make sure the capacity will be adequate - personnel and telephone lines - to handle the contacting public.
 - consider possible support or further follow-up, including general or specific information to the public.

20.4.4 Appendix 19 shows the decision flow-chart for national dissemination of information

SECTION 21: NATIONAL COMPETENT AUTHORITY REPORT (NCAR) INTERNATIONAL INFORMATION EXCHANGE

21.1 Introduction

21.1.1 This Section provides guidance to NCA in determining when to exchange information with other NCAs. It provides suggested criteria that can be used to make this decision. Countries participating in the exchange of GHTF National Competent Authority Reports (NCAR) are encouraged to use this guidance and follow the procedure outlined. A decision flow chart is given in Appendix 20.

21.1.2 The NCAR exchange format and instructions for completion of the report is given in Appendix 21. Requirements for participating in the GHTF NCAR exchange program are given in Appendix 22.

21.2 Criteria for Decisions on NCA Exchange

21.2.1 The decision flow chart in Appendix 20 should be used to determine the route for information exchange between NCAs. At this time, no information is being exchanged under the “Passive Exchange”. “Passive Exchange” is a concept for a future database available to exchange participants to view at their discretion, whereas the e-mail is an active exchange and the current means for exchanging high-risk issues.

i) If the investigation is complete, and a decision has been made by the NCA or manufacturer that action is required, then the NCA should consult the following ten criteria to determine the degree of public health threat or concern related to the issue. The public health threat or concern should be categorized as either High and sent to the immediate attention of the other NCAs, or Low and added to the passive exchange database.

- Seriousness
- Unexpectedness of the incident/event
- Population vulnerable (pediatric/elderly)
- Preventability (can useful recommendations be made?)
- Public concern/outrage (eg: lead aprons containing radioactive material)
- Benefit/risk: State of the art? Alternatives?
- Lack of scientific data (especially long term effects)
- Repeated device problems that re-surface (eg: heating pads, O.R. fires)
- Class I recall or equivalent

- Written notifications by the NCA to the public (hospitals, physicians, etc.)
 - NCAs should involve the manufacturer in the investigation of incidents and resolution of issues or actions and consult with the manufacturer before sending out notices to other NCAs. ‘Seriousness’ should be linked with many of the other criteria. For example, an unexpected but non-serious event is unlikely to be exchanged.
- ii) If the investigation is not complete but a decision has been made to take action or action is likely, the public health threat or concern must be assessed and if high, a report should be sent. If such reports are exchanged, questions to the manufacturer should be directed to the lead NCA whenever possible.
- iii) If the Investigation is complete and no action is required, then the report should not be exchanged.

21.3 Procedures for NCA Exchange

21.3.1 The Competent Authority Reporting Form GHTF/SG2/N9R11: 2003 (Appendix 21) should be used. Comments may be added to the report to maintain its confidentiality or to prevent public disclosure. For example, “Still under investigation, do not disclose through access to information”, or “Do not release to public”. Also, send electronically any background information such as a “Dear Doctor” letter or company letter.

21.3.2 Send forms to mdv@hc-sc.gc.ca. (Canada). A note indicating receipt of the form will be returned to the sender.

21.3.3 In order to minimize the risk of confusion, Canada, on behalf of GHTF, will review the form for completeness, the correct sequential references and track the reports. Content is not edited. The form will then be forwarded by e-mail to countries participating in the exchange (see note).

21.3.4 In rare circumstances, such as when there are time critical issues of significant public health threat or concern, NCA’s may send reports directly to countries participating in the exchange. In such circumstances, the issuing NCA should ensure that the form is completed fully and contains the correct sequential reference, preferably by contacting MDV Canada.

21.3.5 The lead NCA is the originator of the report unless the report says otherwise. The manufacturer must be notified of the intention to exchange information internationally.

21.3.6 Countries can contact the source country of the report for more information if they wish. This should be the first point of contact for incidents “still under investigation”.

SECTION 22: USER POST-MARKET SURVEILLANCE REQUIREMENTS AND INCIDENT INVESTIGATION

22.1 Introduction

22.1.1 Because of the large variety and its physical nature, medical devices are regulated with risk management approach. No amount of rigor in the pre-marketing review process can predict all possible device failure or incidents arising from actual use in the real live environments. Many factors can cause adverse events associated with the use of medical devices. Post-market surveillance/vigilance on medical devices IN USE is vital in ensuring their continued safety and performance.

22.1.2 The work of GHTF so far focuses on regulatory requirements for adverse event reporting from manufacturers while leaving reporting from users or healthcare providers to the discretion of the NCA. This Section will present the case that the USER should be made a primary participant in post-market surveillance/ vigilance activities and propose corresponding requirements for users and healthcare providers.

22.2 User as Key Participant in Post-Market Activities

22.2.1 From a practical point of view, user involvement is vital for the following reasons:

- i) for incidents associated device in use, the user would normally be the first person to know of the occurrence;
- ii) the healthcare environment is a complex system in which medical devices is one of the many components (e.g. the device, the operator, the patient, the facility and the environment) within that system. These components have interactions. An incident or adverse event associated with a medical device could be triggered by other components of this complex system. The user (operator, healthcare workers) is normally key to revealing systematic component matters.
- iii) investigating and identifying the medical device, as the DIRECT CAUSE of an incident alone does not provide optimum preventive measures. The same problem could appear at another time in the same or different location. A more effective approach to resolve an incident associated with a medical device used in the healthcare environment is to systematically identify the ROOT CAUSE of the incident and to implement corrective/preventive measures to all potential triggering factors in the system.

22.3 User Requirements

22.3.1 Device inventory and location records

In order to implement instructions from medical device alerts or to withdraw the device upon a recall notice, the healthcare facility must maintain a master inventory of all devices owned by the facility together with information on where these devices are located. If a device is shared among different locations, this must be described. Appendix 21 proposes a data set for the records that is coherent with the Vendor distribution record.

22.3.2 Training on the use of medical devices

Any user of a medical device (including home use medical devices for the public) must receive training on proper use of the device before actual use. The kind and levels of training will be determined by the original manufacturer in collaboration with the professional associations and facilities in accordance with the nature and risk class of the device. If deemed necessary, a user shall perform calibration or other adjustments before each use of the device.

22.3.3 Post-market surveillance studies

- i) In post-market surveillance studies, specific and structured data collections are required of the manufacturer in one of two situations:
 - as a condition of product approval, or
 - to re-affirm product safety when post-market adverse event reports suggest that pre-market safety claims are inconsistent with actual use and result in unacceptable risk.
- ii) Japanese authority and the US FDA actively make use of surveillance data collection to augment the findings of pre-market trials.
- iii) When a medical device has regulatory requirements for post-market surveillance studies by the Malaysian or other Regulatory Authorities, the user must collaborate with the Vendor according to the prescribed study plan and provide periodic reports to the Vendor or/and original manufacturer and the Malaysian NCA.

22.3.4 Implanted device registration

- i) A healthcare professional who inserts an implant in a patient is required to:
 - ensure that the implant is delivered with two registration cards
 - as soon as possible after the completion of the procedure, enter the information on each implant registration card; give one card to the implant patient and

forward one card to the Implant Registry designated by the Ministry of Health Malaysia.

ii) the healthcare professional, the healthcare facility, the Vendor and the manufacturer shall not disclose the patient's name or address, or any information that might identify the patient, unless the disclosure is required by law or with the consent of the patient. (Group 3 of the Medical Device Technical Committee has recommended that this clause be deleted, but Group 2 did not make this recommendation. The final decision rests with the Regulator)

22.3.5 Reporting of adverse events

i) Any user (including home user) and facility must report adverse events to the Malaysia NCA and the Vendor/manufacturer. Reportable adverse events are defined in Section 6.

ii) The Medicines and Healthcare Product Regulatory Agency (MHRA) of the UK has developed comprehensive reporting systems and forms including internet on-line options at <http://devices.mhra.gov.uk/mda/mdawebsitev2.nsf/webvwSectionsMDA/Reporting+adverse+incidents?Open>. Their system could be considered for adoption by Malaysia.

22.3.6 Maintenance of medical devices

Any user and facility must ensure that in-house personnel and facilities, outsourced third party, or a combination of in-house and outsourced services are adequate for the maintenance of medical devices. A home use medical device user must follow the manufacturer's instruction for use, maintenance and periodic calibration.

22.3.7 Medical device safety regional coordinator/liaison officer

The MHRA of the UK has established an excellent post-market surveillance program whereby each health service region nominates a liaison officer to deal with medical device safety matters. This officer facilitates the two-way communications between the regulatory agency and the user facilities. Critical information from MHRA is transmitted effectively to the frontline healthcare workers. Malaysia could consider the establishment of such a position to provide linkages from medical device users to the regulator. The position of the Liaison Officer depends on the size of the facility and the relevant workload. It does not have to be a dedicated post.

22.3.8 Medical device alert and recall management procedures

Professional users and facilities must have in place a systematic plan to handle Medical Device Alerts sent out or posted by the Vendor/Manufacturer of the NCA. The recommended features for Medical Device Alert/Recall Policy and Procedures are as described in Section 18.7.

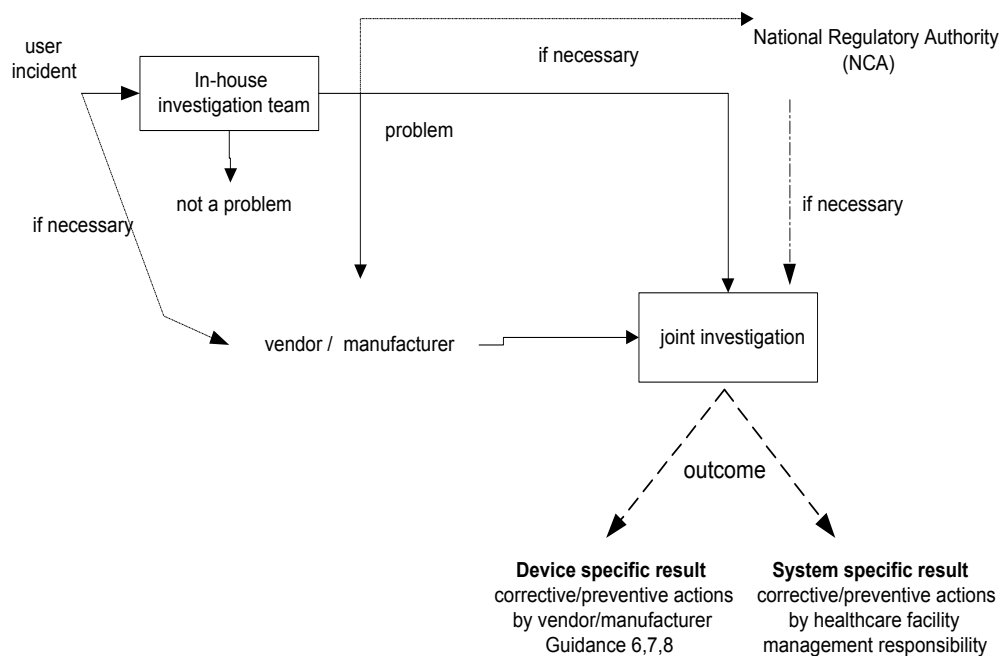
22.3.9 Medical device incident investigation procedure

i) Professional users and facilities should have in place a systematic procedure to investigate incidents associated with a medical device that occurred with the services they provide. The following description will provide the background information to establish this procedure.

ii) The need for incident investigation

– An incident with a medical device is an unusual (or unexpected) event associated with the use of a medical device. Not all incidents lead to problems or adverse events, but all incidents should be investigated, preferably as soon as possible by a competent in-house team, to identify device or other system problems that can lead to potential events resulting in impairment or injury to the patient or other persons.

– In case it is a potential problem with the device, the Vendor/manufacture should be immediately contacted to investigate and to make a decision on possible preventive and corrective actions must then be established and implemented to prevent the problem from recurring. The following process chart illustrates these recommendations.



– Advantages of in-house incident investigation capability include:

- Quick response to minimize hazards

- If the incident turns out to be not a problem or a problem not connected with the device, then the Vendor need not be called in
 - As the number of medical devices in healthcare increases, the need for in-house capability in problem solving increases especially for identifying systemic root cause to ensure safety of medical devices. This need is consistent with the current movement in Patient Safety Programs in user facilities
 - The output from the investigation would have two outcomes, ie device specific (“direct cause”) or system specific (“root cause”) that involves components other than the devices.
- iii) Major factors for “root cause” analysis of medical device incidents.
- Devices can contribute to adverse outcomes by their complex design or labeling, unique features and functions, and failure to meet manufacturing specifications.
 - Users can contribute to adverse outcomes by failure to follow labeled instructions or indications for use, lack of training, misapplication of the product, and failure to provide routine maintenance on the product. With the ever-increasing variety and sophistication in medical devices, use problems could result from insufficient considerations in human factor or ergonomic aspects in the design of the device. User feedback will help the manufacturer to improve the design of the device.
 - Patients can contribute to an incident in several ways. An active patient can interfere with the operation of a device. A passive patient may be more or less susceptible to an injurious element of a device’s function simply by virtue of age, weight, height, or physical condition. A patient may also contribute to adverse outcomes by not following healthcare guidelines appropriate to the product, failure to get regular medical and surgical monitoring and assessments, and failure to report product incidents.
 - The healthcare facility can contribute to the performance of a medical device by the adequacy of supports such as utilities. The location of receptacles, air, gases or water supply. Line cords that run along the floor may result in people tripping or damaging the cords or the devices. Lack of facility maintenance can result in intermittent receptacle contacts and leaky gas supply.

- Even the environment can contribute to adverse outcomes; low lighting at night, less available healthcare workers after regular work hours, no after-hours vendor support to resolve product questions. Electromagnetic Interference, ambient temperature, extraneous heat sources and humidity can certainly affect device performance.
 - All of these system factors are important to consider in determining why an adverse event occurs and how it might be prevented in the future. The investigation procedures should specify how each of these system components is investigated. An investigation report should record the results of investigation on all the five system factors described above.
 - In the investigation process, care should be taken not to blame people or induce shame feelings. Problem resolution focused on identifying the root cause in the system and prevention remain the ultimate goals and are fundamental in assuring safety for all.
- iv) The In-House Medical Device Incident Investigation Team
- An official in-house medical device incident investigation team should be established in facilities that use a significant quantity of medical devices. Smaller facilities may share such services. If possible, this team should be integrated with the Patient Safety Council Program.
 - The multi-disciplinary team should be consist of an experienced device operator of the device under investigation, a physician or a nurse who is familiar with the clinical procedure, and a technical professional who is knowledgeable on device technology (biomedical engineers/technicians, radiology technicians, laboratory technicians). Staff members who are directly involve with the incident should preferably not be a member of the investigation team, but they must be interviewed by the investigation team for the incident and background information.

22.3.10 Safe and appropriate disposal of medical devices

Medical device users and facilities must dispose unwanted medical devices in accordance with government or manufacturer's instructions. Personal and environmental safeties are mandatory considerations.

References

- 1) World Health Organization, "Medical Device Regulations: Global Overview and Guiding Principles". 2003

- 2) Shepherd MA, “A System Approach to Hospital Medical Device Safety”. Association for the Advancement of Medical Device Instrumentation. 1983

SECTION 23: DISPOSAL OF MEDICAL DEVICES

23.1 Introduction

23.1.1 The objective of this guidance note is to preserve, protect and improve the quality of the environment, protect human health and utilize natural resources prudently and rationally. That policy is based on the precautionary principle and principles that prevention action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

23.1.2 Medical devices meant for disposal could be hazardous due to their material content or contaminated with micro-organisms and thus can present a risk to those handling them prior to disposal, to those involved in the disposal process, the general public and the environment. Putting safe systems into place to manage disposal of medical devices will contribute significantly to preserve, protect and improve the quality of the environment and protect human health.

23.1.3 Achievement of sustainable development calls for significant changes in current patterns of development, production, consumption and behaviour and requires reduction of wasteful consumption of natural resources and the prevention of pollution. In this regards, waste medical device is one of the target areas to be regulated, in view of the application of the principles of prevention, recovery and safe disposal of waste.

23.1.4 Strategy for waste management states that, where the generation of waste cannot be avoided, it should be reused or recovered for its material or energy.

23.1.5 Strategy for waste management states the need for promoting waste recovery with a view to reducing the quantity of waste for disposal and saving natural resources, in particular by reuse, recycling, composting and recovering energy from waste and the choice of option in any particular case must have regard to environmental and economic effect. Reuse and material recovery should be considered preferable where and in so far as they are the best environmental options.

23.1.6 The government acting individually may not achieve improved management and disposal of medical devices effectively. Manufactures of such medical devices, users such as health-care establishments and private households, (disposal) contractors and the general community as a whole need to be committed towards the objective.

23.1.7 Information to users about the requirement not to dispose medical devices as unsorted municipal waste and about the collection system and their role in the management of environment and health is indispensable for the overall success.

23.1.8 Manufacturers should be encouraged to show purchasers, on a voluntary basis at the time of sale, the costs of collecting, treating and

disposing in an environmentally sound way while ensuring that the costs mentioned do not exceed the actual costs incurred.

23.1.9 Information on component and material identification to be provided by manufacturers is important to facilitate the management, and in particular the treatment and disposal of medical devices.

23.1.10 Disposal of medical devices by approved contractors is the precondition to ensure proper collection, transport, specific treatment and is necessary to achieve the chosen level of protection of human health and the environment. Consumers have to actively contribute to the success of such collection and should be encouraged to return medical devices meant for disposal. For this purpose, convenient facilities should be set up for the return of medical devices meant for disposal, such as public collection points, where even private households should be able to return their waste at least free of charge. This will also minimize disposal of medical devices as unsorted municipal waste and ensure safe disposal of such waste.

23.1.11 Specific treatment of medical devices meant for disposal is indispensable in order to avoid the dispersion of pollutants into the waste stream. Such treatment is the most effective means of ensuring compliance with the chosen level of protection of the environment. Any establishment or undertaking carrying out treatment operations should comply with minimum standards to prevent negative environmental impacts associated with the treatment of medical devices. Best available treatment, recovery and recycling techniques should be used provided that they ensure human health and high environmental protection.

23.1.12 Approved contractors shall set up systems to provide for the treatment of medical devices meant for disposal using best available treatment, recovery and recycling techniques. The systems may be set up individually and/or collectively. The treatment shall, as a minimum, include selective treatment based on material characteristics.

23.2 Aim

To describe the actions required for safe handling of medical devices meant for disposal and to outline the regulatory requirements and guidance that govern the entire processes of decontamination, transportation, dismantling, segregation, storage and disposal.

Note: This guidance note is intended to compliment the current 'Guidelines on the handling and management of clinical wastes in Malaysia, Department of Environment, 2002'. It is recommended that both documents be referred concurrently.

23.3 Objectives

23.3.1 To comply with the prevailing regulatory requirements while disposing medical devices.

23.3.2 To ensure that the medical devices being disposed do not pose a threat to the general public and the environment.

23.3.3 To protect personnel involved during the disposal process from any infection risks from medical devices.

23.3.4 To ensure segregation of medical devices and their components based on material characteristics.

23.3.5 To ensure that the segregated materials are properly stored and disposed without effecting the environment or human health.

23.4 Prevailing Regulations

23.4.1 Environmental Quality Act 1974 (Act 127) and the following subsidiary regulations made under it.

23.4.2 Environmental Quality (Scheduled Waste) Regulations 1989.

23.4.3 Environmental Quality (Clean Air) Regulations 1978.

23.4.4 Environmental Quality (Sewage and Industrial Effluents) Regulations 1979.

23.4.5 Control of Infectious Diseases Act, 1989

Waste contaminated with pathogens of diseases is covered by this Act.

23.4.6 Occupational Safety and Health Regulations, 1994

i) This Act establishes the employer's responsibility for the health, safety and welfare of employees and visitors to their premises. It also includes employers making a systematic assessment of all the risks to the health and safety of their employees and others, arising from work activities.

ii) There may be civil liability, with payments for damages, for any injuries caused to the persons involved in the disposal process by inadequately decontaminated items that cause infection.

23.4.7 Atomic Energy Licensing Act, 1984

The disposal of radioactive waste must comply with the Atomic Energy Licensing Act, 1984.

23.4.8 Factories and Machinery Act and Regulations, 1967

An act to provide for the control of factories with respect to matters relating to the safety, health and welfare of persons therein, the registration and inspection of machinery and for matters connected therewith.

23.4.9 Use and Standards of Exposure of Chemicals Hazardous to Health Regulations, 2000

These regulations relate to chemical risks, including risks arising from the use of disinfectants. These regulations require a risk assessment to be carried out of all potentially hazardous substances.

23.5 Definitions

24.5.1 Approved contractor means a third party that is involved in the process of collection and transportation of medical device intended for disposal. A third party that is involved in the process of dismantling medical device, segregation of materials, storage and final disposal (for one or more of these activities).

Categories of health-care waste: As per World Health Organization (WHO), Safe Management of Wastes from Health-Care Activities, 1999, refer Appendix 23 for details.

Cleaning means a process that physically removes all organic and inorganic material from objects and surfaces.

Collection means medical device which are decontaminated, stored and readily available for collection by approved contractors.

Critical item means objects that enter sterile tissue or the vascular system. They carry a high risk of infection if they become contaminated with any micro-organism. Examples include, but are not limited to: surgical instruments, cardiac and urinary catheters, vascular devices and implants.

Decontamination means a process which removes or destroys contamination (defined as soiling or pollution with harmful, potentially infectious or other unwanted matter) and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response.

Device category: As per Global Medical Device Nomenclature (GMDN) user guide: version 2002, refer Appendix 24 for details.

Disinfection is the process that eliminates many or all pathogenic micro-organisms (with the exception of bacterial spores).

Dismantling means a complete process of disassembly or stripping of the medical device.

Disposal means final disposal process of the segregated materials as per regulations and/or the recommended methods.

Establishment means any public or private organization, private households, healthcare establishment, educational or research institution and manufacturing unit.

Healthcare establishment means government and private hospitals, polyclinics, health centres, medical and health related research institutions, diagnostic and research laboratories, blood transfusion services, private practitioners and dental surgeries.

Local council means various bodies of the State authority, for example Majlis Daerah or Majlis Perbandaran.

Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software or other similar or related article, intended by manufacturer to be used, alone or in combination for human beings for one or more specific purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment or alleviation of or compensation for an injury,
- investigation, replacement, modification or support of the anatomy or of a physiological process,
- supporting of sustaining life
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Non-critical item means item that come into contact with intact skin but not mucous membranes. Examples include, but are not limited to: bedpans, blood pressure cuffs, bed rails, bedside tables, portable pumps, toys.

Premises means a dedicated, designed and well-equipped facility intended for dismantling, segregation, storage and final disposal of medical device while considering safety and strategic location for the activities of dismantling processes to be carried out.

Risk means possibility that a harmful event arising from exposure to a chemical, physical or biological agent may occur.

Risk assessment means a systematic approach to assess the risk levels and determine the recommended decontamination procedure(s) to be undertaken.

Segregation means the process of separating dismantled items according to the material characteristics and placed in appropriate containers.

Semi-critical item means item that come into contact with mucous membranes or non-intact skin. Examples include, but are not limited to: GI endoscopes, laryngoscope blades, diaphragm fitting rings, some respiratory and anaesthesia device, TEE probes and vaginal ultrasound probes.

Sterilization is the complete elimination or destruction of all forms of microbial life.

Storage means specifically designed and suitably equipped location for effective storage of segregated materials for disposal.

Transportation means the activity of transporting a medical device, which is intended for disposal, to the dismantling site by means of dedicated vehicle.

23.6 Responsibilities

23.6.1 A management structure may be adopted to suit the particular local circumstances in each establishment.

23.6.2 All managerial responsibilities outlined for any head of establishment must include the responsibilities outlined for disposal, as applicable.

23.6.3 The head of establishment shall formulate a written plan for his establishment on the disposal of medical device as applicable. Within this plan, the duties and responsibilities of all members of staff, involved in the processes for disposal shall be clearly defined. Clear lines of accountability shall be indicated in the management structure.

23.6.4 The head of establishment may also designate personnel to establish the procedures, supervise and coordinate the disposal of medical device. The procedures for disposal would include and not be limited to the use of recommended products, risk assessment, areas for decontamination, segregation, storage, transport, holding area allocation, documentation, controls, assessment and monitoring of the relevant procedures.

23.6.5 Where applicable, a recommended local protocol for disposal activities should be established. As below, is an example for an established health-care facility which should consider technical inputs from the following:

- i) device manufacturers.
- ii) infection control team.
- iii) waste disposal officer.
- iv) matron and hospital supervisor.
- v) clinical nurse specialist.
- vi) technical personnel.
- vii) risk manager.
- viii) health and safety officer.

23.6.6 A user of the medical device which requires removal would contact the relevant personnel such as the engineer or the safety and health officer who will make arrangements for decontamination and disposal of the medical device.

23.6.7 Removal of the medical device to a dedicated decontamination area will be undertaken by trained technical personnel, under the guidance of the personnel in charge.

23.6.8 All necessary documentation involved in the removal of the device shall be undertaken by the relevant user or department using the device, as required. This documentation would be in addition to the procedures for notification of condemnation of device.

23.6.9 The head of establishment may delegate any of the personnel under his appointment to supervise and coordinate this activity of

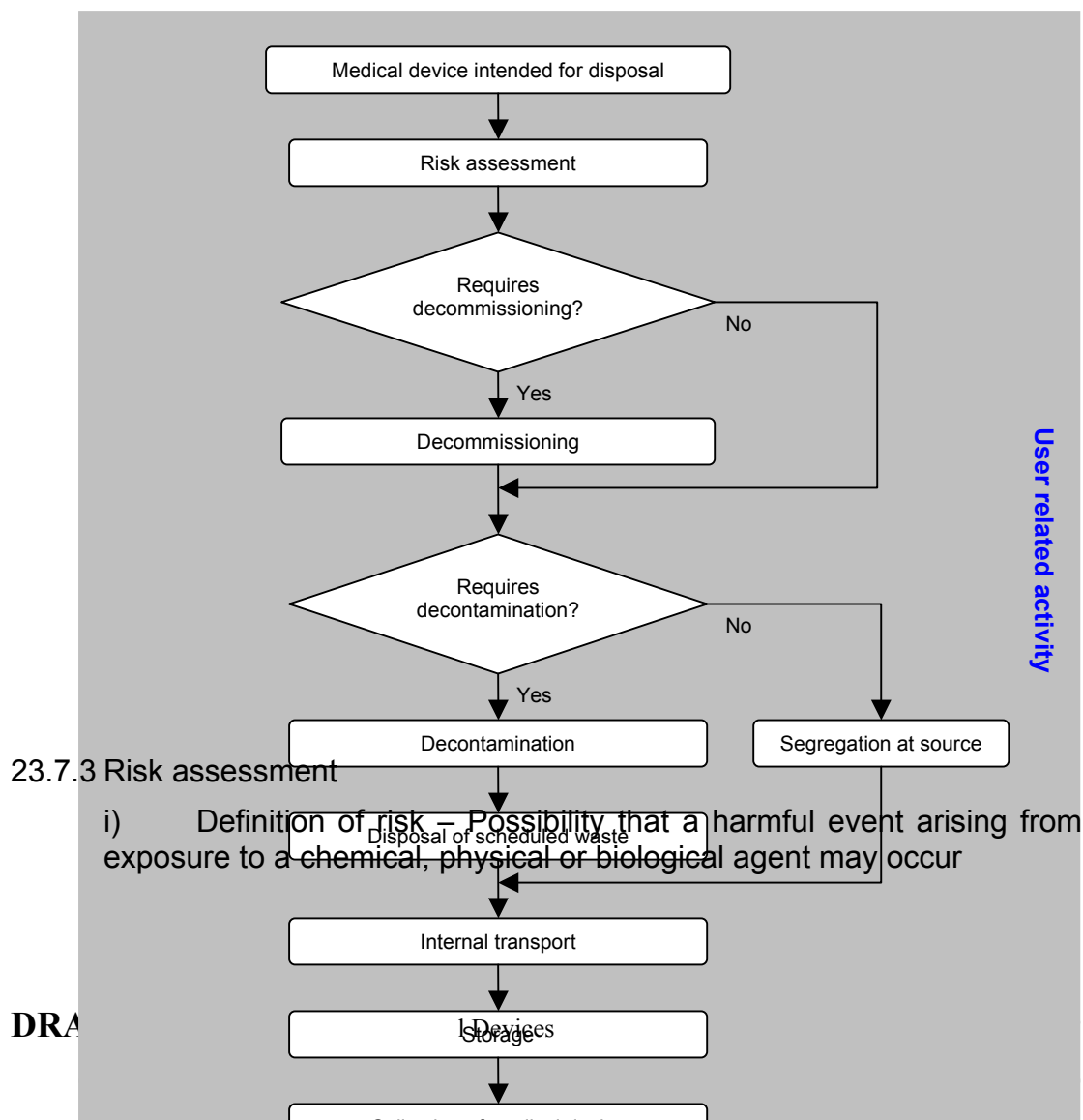
decontamination where applicable. However, such appointment shall not relieve him of his overall responsibilities.

23.7 Work flow process for the disposal of medical devices

23.7.1 The entire process would include:

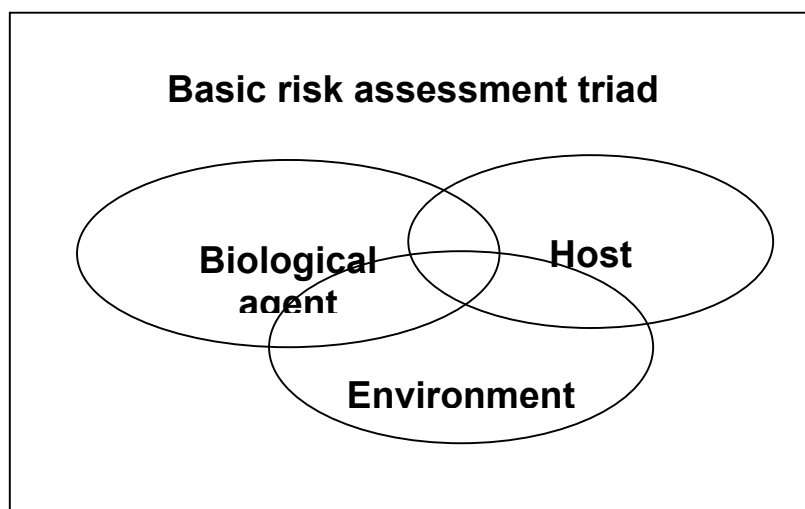
- i) risk assessment;
- ii) decommissioning (where applicable).
- iii) decontamination;
- iv) disposal of scheduled waste (where applicable);
- v) internal transportation;
- vi) storage;
- vii) collection of medical device;
- viii) transportation;
- ix) dismantling of medical device;
- x) segregation of dismantled parts;
- xi) storage of segregated material;
- xii) final disposal.

23.7.2 Workflow chart



ii) Risk assessment – A risk assessment of the medical device is to determine the levels of contamination of that particular medical device to be disposed for which levels of risk should be considered prior to undertaking any decontamination.

iii) Risk assessment triad – There are three basic components in the biological risk assessment triad: biological agent, host and environment. To differing degrees, characteristics of these factors can repeatedly demonstrate cause-effect, be experimentally reproduced and be quantitatively or qualitatively measured or described. This provides the general guideline for the basis of factors to include in the risk assessment process. (Forney, 1986-American biological safety association)



iv) Output of risk assessment – The output from risk assessment is used in decisions about control of risks. Imposing controls will reduce the exposure to levels where the risk is insignificant or acceptable. Careful assessment and communication of risk is one of the underpinnings of a successful decontamination program. This assessment can be conducted in consultation with relevant personnel and technicians performing the work. Some of the objectives taken into consideration would include methods of transmission, levels of risk and types of infection.

v) Levels of pre-determined risks – The level of decontamination therefore would depend on the risk of the item transmitting micro-organisms. Any medical device can be categorized into the three levels of pre-determined risks:

- Critical items;
- Semi-critical items;
- Non-critical items.

vi) Definition of critical items – Objects that enter sterile tissue or the vascular system. They carry a high risk of infection if they become contaminated with any micro-organism. Examples include, but are not limited to: surgical instruments, cardiac and urinary catheters, vascular devices and implants.

vii) Definition of semi-critical items – Items that come into contact with mucous membranes or non-intact skin. Examples include, but are not limited to: GI endoscopes, laryngoscope blades, diaphragm fitting rings, some respiratory and anaesthesia device, TEE probes and vaginal ultrasound probes.

viii) Definition of non-critical items – Items that come in contact with intact skin but not mucous membranes. Examples include, but are not limited to: bedpans, blood pressure cuffs, bed rails, bedside tables, portable pumps, toys.

ix) Undetermined risk – In the event, due to lack of information, it is not possible to determine the risk category of any medical device meant for disposal, it is recommended to treat the medical device as High Risk and perform decontamination accordingly.

Note: Unused medical device being disposed need not be decontaminated.

Table on risk assessment levels of pre-determined risks and recommended decontamination:

| Risk category | Application of device | Recommended decontamination |
|---------------|---|--|
| High | Critical items Penetrates skin or mucous membrane In contact with broken skin or mucous membrane Enters sterile body areas e.g. instruments used for surgical/operative procedures. | Cleaning followed by high level disinfection (HLD) and/ or sterilization |
| Medium | Semi-critical items In contact with intact mucous membrane Contaminated with blood/body fluids e.g. thermometers, auroscope ear-pieces. | Cleaning followed by intermediate disinfectant (ILD) |
| Low | Non critical items In contact with intact skin Not in direct contact with patient e.g. furniture, mattresses | Cleaning followed by low level disinfectant (LLD) |

(Adapted from Medical Device Agency first published 1993, reprinted 1996 and Second Edition July 2002)

23.7.4 Decontamination

i) Definition of decontamination – A process which removes or destroys contamination (defined as soiling or pollution with harmful, potentially infectious or other unwanted matter) and

thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Three processes are cleaning, disinfection and sterilization.

Note: Single use medical device need not be decontaminated prior to disposal. However, segregation and disposal should comply with regulatory requirements

ii) Definition of cleaning – Cleaning is a process that physically removes all organic and inorganic material from objects and surfaces.

– Process of cleaning (Adapted from MDA Second Edition July 2002). Cleaning is basic first step for all decontamination. It is a process which physically removes contaminants e.g. Dust, dirt, grease and body fluids, using general purpose detergent (washing up liquid) and hot water. This is the first step and should be undertaken prior to any disassembly of parts.

- Cleaning is important for two reasons:
 - As a method for decontaminating for low risk items.
 - As an essential pre-requisite to any disinfectant or sterilization process. Organic matter must first be removed in order for heat or chemicals to be able to penetrate and therefore disinfect or sterilize effectively.
- Detergent is essential for breaking down grease and dirt. It therefore improves the ability of water to remove soiling. Approximately 80% of micro-organisms will be removed by thorough cleaning. There are two methods of manual cleaning – immersion and non-immersion. (Refer Appendix 25 for examples on manual cleaning and immersion methods).

Note: Cleaning is an essential pre-requisite to ensure effective disinfection and sterilization. All active medical devices for disposal should be decontaminated without exception. This is a compulsory process

iii) Definition of disinfection – Disinfection is the process that eliminates many or all pathogenic micro-organisms (with the exception of bacterial spores).

Note: Disinfection and sterilization policy and practice by Ministry of Health Malaysia (1994) should be referred to before performing any disinfection and sterilization on medical devices.

iv) Process of disinfection – This process is intended to kill or remove pathogenic micro-organisms with the exception of bacterial spores. This can be achieved by a number of means dependants upon the nature of the medical device being decontaminated.

– Three levels of disinfectants to be considered for use in the decontamination process would be:

- Low level disinfectant (LLD);
- Intermediate level disinfectant (ILD);
- High level disinfectant (HLD).
- Note: The process of disinfection may be skipped if it has been determined that the medical device needs to be sterilized.

v) Definition of sterilization – Sterilization is the destruction and removal of all micro-organisms and spores. Sterilization of medical device to be disposed, should be done only on recommendation by the relevant personnel.

vi) Use of products for decontamination – Products used should be as recommended by Ministry of Health, Disinfection and Sterilization Policy & Practice 1994. Inappropriate use of cleaning agents and disinfectants can be ineffective, expensive and potentially harmful to the user (Refer examples in Appendix 26).

vii) Dedicated facility for decontamination – Wherever possible, the decontamination process should take place in a dedicated area, away from general public, specially allocated for the purpose. Such an area will have specific design requirements (e.g. floor/wall finishes/sanitary ware).

viii) In the absence of a dedicated facility for decontamination, it is recommended the cleaning and disinfection of the medical device be carried out in an area, away from general public.

Note: Transport of medical device outside the establishment without decontamination is not recommended.

Note: Decommissioning of medical device is carried out where applicable such as for active medical device. The active medical device is made safe and unusable prior to decontamination.

23.7.5 Process for decommissioning active medical device

i) The purpose of decommissioning is to make medical device safe prior to disposal. Any active medical device deemed not re-usable due to wear, damage, and breakdown or having become obsolete, must be decommissioned and decontaminated prior to disposal. Any active medical device containing radioactive contamination should be decommissioned

as per the procedures laid down in the Atomic Energy Licensing Act, 1984.

ii) For decommissioning any active medical device, some documentation of the procedure is required and would include:

- notification for decommissioning.
- inventory of active medical device.
- reporting to the relevant regulatory body/management.
- scheduling of decontamination/decommissioning.
- removal of medical device to a decontamination area;
- record keeping.

iii) The vendor/manufacturer should be contacted for advice on decommissioning active medical devices and advice in areas where the personnel are unsure of methods for decommissioning.

iv) The recommended steps involved in the cycle of decommissioning would include:

- ensuring electrical component/connection is cut off to discharge electricity;
- dismantle mechanical components of medical device;
- dismantle electrical components of medical device;
- dismantle electronic components of medical device.

23.7.6 Disposal of scheduled waste

i) Any radioactive source to be removed from the medical device should be disposed in accordance Atomic Energy Licensing Act, 1984.

ii) Any scheduled waste found during the course of decommissioning should be treated and disposed in accordance with Environmental Quality Act requirements.

iii) All decommissioned medical device should be decontaminated and transported to the storage area.

iv) Spill or accidental discharge – During the course of decommissioning, any spillage should be reported as soon as possible to the personnel responsible, who should investigate, preferably before the medical device is disposed of, in order to identify and decontaminate in accordance with Environmental Quality Act requirements.

23.7.7 Internal Transportation (refer Guidelines on the handling and management of clinical wastes in Malaysia - DoE)

- i) Internal transport of contaminated medical device
 - Contaminated medical device meant for temporary storage should be transported by the facility personnel to a dedicated holding facility using dedicated wheeled containers, trolleys or carts. They should be thoroughly cleaned and disinfected immediately after such transportation (Refer to Appendix 27 for example).
 - Any secondary transportation vehicles can be used, but must undergo the cleaning and disinfection procedure after delivery is made to the holding area on a weekly basis or when visibly soiled.
- ii) Internal transport of decontaminated medical device
 - Decontaminated and appropriately labelled medical device may be transported by facility personnel to a suitable storage facility using clean wheeled containers, trolleys, carts or secondary transportation vehicles.
 - Such means of transportation need not undergo cleaning and disinfection as items being transported is decontaminated and hence considered safe.

23.7.8 Storage

- i) Storage of contaminated device
 - Contaminated medical device must always be identified, labelled and stored separately. If storage of contaminated medical device is found necessary due to space constraints or other factors, the same may be stored in a dedicated holding facility. The items must be identified and clearly marked as 'contaminated'.
 - Contaminated medical device should be held in a dedicated holding area prior to decommissioning and decontamination.
 - The storage of both contaminated and decontaminated medical device should preferably be kept at opposite ends of the workflow.
- ii) Storage of decontaminated medical device
 - Decommissioned and decontaminated medical devices should be labelled and stored separately.
 - Such medical devices should be stored in a location free from the risk of re-contamination.
 - It is highly recommended that approved contractors collect the decontaminated medical device

within its stability period so as to avoid repeated decontamination.

23.7.9 Collection of medical device

Collection is done by approved contractors, specifically engaged for this activity.

23.7.10 Transportation

i) The external and internal transportation means used to transport the medical device intended for disposal, should comply with the designs and construction requirements as per Environmental Quality Act 1974 (Act 127) and the following subsidiary regulations.

ii) Guidelines on the handling and management of clinical wastes in Malaysia - DoE, is one such document which stipulates the requirements for transportation of clinical wastes and related wastes.

23.7.11 Dismantling of medical devices

i) Approved contractors may perform second level of decontamination process to the medical device intended for disposal if necessary, before dismantling.

ii) The medical device for disposal should be dismantled (if necessary) by a competent person(s) using suitable tools and methods.

iii) Any item that is suspected to be hazardous should comply with Guidelines on the handling and management of clinical wastes in Malaysia - DoE.

23.7.12 Segregation of dismantled parts

i) Segregation is the separation of dismantled medical device in the defined material categories as in the following Table.

Table: Material identification

| No | Categorization | | Related material | Disposal reference guidelines |
|----|----------------|-----------|---|---|
| 1 | Metal | Toxic | Cadmium, mercury, chromium | Environmental Quality Act (N151) |
| | | Non-toxic | Zinc, manganese, plumbum, tungsten, nickel, lithium | Environmental Quality Act (N202: ash, dust may contain one or several metals) |

| | | | | |
|---|--|-----------|--|---|
| 2 | Non-metal Minerals | Toxic | Sulphate, arsenics | Environmental Quality Act (N271: used material contaminated with cyanide, arsenic compound) |
| | | Non-toxic | Fluoride compounds, sodium, cobalt, phosphate | Environmental Quality Act (S141: containing fluoride) |
| 3 | Plastics and resin | | | Environmental Quality Act (N141: Photographic waste, S251: contaminated with organic solvent, S111: uncured resin residues from electronics appliances) |
| 4 | Polymers | | | Environmental Quality Act (N281, N282) |
| 5 | Isocyanides compound | | foams | Environmental Quality Act (S091) |
| 6 | Rubber | | | Environmental Quality Act (S121: rubber containing heavy metals, S122: containing organics solvent) |
| 7 | Asbestos | | Asbestos products or fibres, and component which contain asbestos | Environmental Quality Act (S162, S163) |
| 8 | Solvent, Oxidizing Agents and Reagent (organics & inorganic) | | Aromatic and non-aromatic solvents, containing or without containing compounds of organic halogen or sulphur, including toluene, xylone, turpentine, and kerosene; acetone, ketones, alcohols, cleansing-benzene and dimethyl formamide. | Environmental Quality Act (N221: Oxidizing agent) |

| No | Categorization | Related material | Disposal guidelines reference |
|----|---|--|---|
| | | Halogenated solvents | Environmental Quality Act (N061) |
| 9 | Oil | Oil products and mineral oils. Any petroleum-based or synthetic oil that has been used. | Environmental Quality Act (N011, N013, N015) |
| 10 | Lacquer, varnish | | Environmental Quality Act (N183) |
| 11 | Polychlorinated biphenyls (PCB) and polychlorinated tri-phenyls (PCT) | Electrical parts, container. | Environmental Quality Act (N022) |
| 12 | Tar | | Environmental Quality Act (S021) |
| 13 | Mercury waste | | Environmental Quality Act (S211, S212, S213) |
| 14 | Batteries | Containing lead, mercury, nickel, lithium | Environmental Quality Act (S271) |
| 15 | Pathogenic and clinical wastes and quarantined materials | | Environmental Quality Act (N261) |
| 16 | Containers and bags containing hazardous residues | Containers or bags contaminated with arsenic, chromium or lead compound or salts | Environmental Quality Act (N271) |
| 17 | Glass and Glass Product | | As per general waste in Environmental Quality Act |
| 18 | Wood, Paper and cardboard | | |
| 19 | Textiles | | |
| 20 | Ceramics, porcelain | | |
| No | Categorization | Related material | Disposal guidelines reference |
| 21 | Gases | | As per disposal of pressurized containers in Environmental Quality Act |
| 22 | CFC | CFC, HFC, HC and etc | Environmental Quality Act (Prohibition of the use of Chlorofluoro-carbons and |

| | | | |
|----|------------------------------|--|--|
| | | | Other Gases as Propellants and Blowing Agents) Order 1993, Section 30, 1974 |
| 23 | Leather | | Environmental Quality Act (N281, N282) |
| 24 | Printed circuit board | | As per Directive of the European Parliament and of the Council on Waste Electrical and Electronic Equipment (WEEE: 27 Jan, 2003) |
| 25 | Liquid crystal display (LCD) | | |
| 26 | Cathode ray tube (CRT) | | |
| 27 | Electrical cables | | |
| 28 | Radioactive substance | Components containing radioactive substances | As per Atomic Energy Licensing Act 1984 |
| 29 | Not otherwise specified | | Environmental Quality Act (N281, N282) |

ii) Dismantled parts of medical device intended for disposal should be identified in accordance with the defined material categories as in to Environmental Quality Act 1974 (Act 127) for scheduled waste and segregated accordingly.

iii) Approved contractors may also refer to the list of wastes in Official journal of the European Communities (Decision 2000/532/EC as regards the list of wastes) for supplementary information.

iv) Dismantled parts should be segregated, into a labelled or marked container and should comply with the requirements of Environmental Quality Act 1974 (Act 127).

23.7.13 Storage of segregated material

Based on the material being stored, storage should comply and meet the requirements as per Environmental Quality Act 1974 (Act 127).

23.7.14 Final disposal

i) Approved contractors responsible for the transportation of segregated material from one location to another location (if applicable) or transfer the waste to other approved contractors should have a safe system of work operation (for example, as outlined in ISO 14001:1996, Environmental management systems – specification with guidance for use).

ii) The segregated material which is meant for special disposal, shall be reduced to the maximum extent practical, using practicable means as stipulated in the Environmental Quality Act 1974 and European Union Directive (EU/Directive74/442/EEG/Article3).

- iii) Segregated material which are categorised as general waste may be disposed in an arrangement and cooperation with the Local Council or approved contractors.

23.8 Premises

23.8.1 Special design and construction precaution can minimize risk. The premise shall be specially designed, constructed and equipped with appropriate facility and comply with the requirement as per Environmental Quality Act 1974 (Act 127) and the following subsidiary regulations made under it, Factories and Machinery Act and Regulations 1967, and Control of Infectious Diseases Act 1988.

23.8.2 It is recommended that the approved contractor is accredited for ISO 14001 (Environmental management systems – specification with guidance for use) and ISO 18001 (Occupational Health and Safety Management Systems).

23.9 Emergency response

An emergency response system should be established as per Occupational Safety and Health Regulations 1994, Factories and Machinery Act and Regulations 1967, ISO 18001 and ISO 14001.

23.10 Training, awareness and competency

23.10.1 Personnel involved in the disposal of medical devices should be competent with relevant experience in the various methods to be adopted. Proper education and training must also be offered to all workers to ensure an understanding of the risks posed by medical devices, thus creating awareness.

23.10.2 The designated personnel appointed to undertake disposal procedures may be also be responsible for training other staff. He/she shall ensure that staff at all levels are aware of the necessity and of their responsibilities and obligations. A record of such training must be maintained. The contents of the training program shall be periodically reviewed and shall be updated accordingly.

23.11 Personal protective equipment

23.11.1 The objective of personal protective equipment is to protect employees from risk or injury by creating a barrier against the hazards.

23.11.2 Workers may be exposed to biological hazards and from the risk of contacting hepatitis, HIV/AIDS and tuberculosis.

23.11.3 Prevention of infectious diseases is not reliant on personal protective equipment alone, but has to be considered where there is a need to increase the level of protection.

23.11.4 Refer to Factories and Machinery Act and Regulations 1967 and regulations, Act 139 (Part VI, section 24) for selection criteria.

23.11.5 Some examples would include but not be limited to: masks, shields, protective eyewear, gloves, protective barrier creams, footwear, clothing, aprons etc.

23.12 Documentation

23.12.1 Proper documentation and record of medical devices intended for disposal is important in order to comply with the Environment Quality (Scheduled Waste) Regulations 1989 which requires an inventory to be kept and a consignment note system to be established for the transport of the decontaminated medical device being transported to the off site facility by the approved contractor.

23.12.2 An inventory provides an accurate and up to date record of the quantities of medical devices being disposed. The consignment note also captures other essential details of the device being transported by the approved contractor to the off-site disposal facility.

23.13 Record keeping

These records should be retained by the respective parties for a period of 3 years.

23.14 References

Environmental Quality Act 1971 (Act 127) and subsidiary regulations.

Occupational Safety and Health Regulations, 1994 (Act 514).

Factories and Machinery Act and Regulations 1967.

Control of Infectious Diseases Act, 1989.

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US Environmental Protection Agency / Guide for Industrial Waste Management, June

ISO 13485:2003, Medical devices – quality management systems – requirements for regulatory purposes.

ISO 14001:1996, Environmental management systems – specification with guidance for use.

ISO 18001:1999, Occupational health and safety management systems – specification.

SECTION 24: EFFECTIVE OPERATION AND GOOD MAINTENANCE MANAGEMENT OF MEDICAL DEVICES

24.1 The Objective and Use of the Guidance Note

24.1.1 It is important that the objectives and potential uses of the guidance note are clearly understood, i.e., a continued increase in safe and effective application of current technologies to patient care. This guidance note must be understood within the framework of the Medical Devices Act of Malaysia.

24.1.2 This Guidance Note provides guidelines for operation and maintenance management of medical devices or system. This Guidance Note does not address device performance per se, but rather procedures and practices that will help ensure that a device is operated, maintained and managed as recommended by the manufacturer to ensure that its performance will be maintained throughout its lifetime.

24.1.3 This Guidance Note applies to any medical device used as part of the routine care of patients, including health care organizations as a whole, divisions and departments within the health care organizations, and outside vendors such as medical device manufacturers, shared service providers, independent service organizations or individuals involved in medical device usage.

24.1.4 The Guidance Note reflects the collective effort of professionals involve in health care including representatives from manufacturers, service providers and independent organization. As such, the consensus recommendations embodied in the Guidance Note are intended to respond to the needs of medical device operation and maintenance and, ultimately, to help ensure patient safety. A Guidance Note is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. The Guidance Note is an important reference in responsible decision-making, but it should never replace responsible decision-making.

24.1.5 The Guidance Note is necessarily a static document applied to a dynamic technology. Therefore, this document must be carefully reviewed and understood as to the reasons why it was initially developed and the specific rationale for each of its provisions. This review will reveal the document remains relevant to specific operational and maintenance needs.

24.1.6 Particular care should be taken in applying a product standard to existing devices, and in applying a Guidance Note to current procedures and practices. While observed or potential risks with existing device typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing device. No single source of

information will serve to identify a particular product as “unsafe”. A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a Guidance Note should be analyzed in the context of the specific needs and resources in the effective operation and maintenance of medical devices.

24.1.7 In summary, a standard or Guidance Note is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

24.2 Abstract

This Guidance Note specifies minimum criteria for the effective operation and good maintenance management of medical device. The Guidance Note addresses the complete lifecycle of medical devices from procurement planning, installation, operation, maintenance, and disposal.

Keywords: maintenance, operation and safety of medical devices

24.3 Introduction

24.3.1 Medical device is an essential part of health care. Effective operation and maintenance management of device maintenance is vital to ensure safety of medical device and used as intended by the manufacturers and designers.

24.3.2 The Guidance Note is developed by specialists in the field of medical device operation and maintenance. This Guidance Note defines the minimal requirements for an effective operation and maintenance management of medical device. It is hoped that this Guidance Note will help provide a clear understanding of the minimal expectations for an effective device maintenance management program.

24.4 Scope and Aim of Guidance Note

24.4.1 Scope

- i) This Guidance Note applies to any medical device used as part of the routine care of patients, including health care organizations as a whole, divisions and departments within the health care organizations, and outside vendors such as medical device manufacturers, shared service providers, independent service organizations or individuals involved in medical device usage.
- ii) Only active medical devices as defined by GHTF will be dealt with in this guidance note, specifically corresponding to

devices in Class B, C and D. These devices are associated with higher risk compared to the others. In addition, these active devices will be further categorized in the following manner.

- DC sourced devices – these are devices using DC supply from batteries or other equivalent sources.
- AC sourced devices – these are devices using AC supply from 240 volts 50 Hz power supply.
- Other energy sourced devices – these are devices powered by non-electrical means e.g. pneumatic drill.
- Major and Complex devices – these are devices requiring the installation of Mechanical & Electrical facilities, 3 phase supply and also Civil & Structural work.

iii) This Guidance Note provides guidelines for operation and maintenance management of medical devices or system. Procedures and practices that will help ensure that a device is operated, maintained and managed as recommended by the manufacturer shall be presented in this document. Detailed standards for safety and performance shall be cross-referenced where relevant and necessary.

24.4.2 Aim

i) The overall aim of the Guidance Note is to promote safety and effective use of medical device. The Guidance Note aims is to ensure that whenever a medical device is used, it is:

- safe and effective
- suitable for its intended use as defined by the manufacturer
- maintained in a safe and reliable condition throughout its lifespan
- complying to available standards

ii) Medical device safety is effectively a risk management issue that requires shared responsibility among all the stakeholders.

24.5 Definitions

Definitions are provided for the terms used in this document and will follow closely those in GHTF/WHO as far as possible.

Active Medical Device means any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy (definition by GHTF)

Acceptance date means the date on which a piece of device is placed into service for its intended use.

Acceptance testing means interaction with medical device designed to determine whether or not newly received device is in good operating condition, prior to being placed into service for its intended use.

Competent authority means the relevant government agency that is empowered to regulate and enforce rules and laws in a particular domain.

Competent person means a person who is qualified and trained, and has the relevant experience to perform the task or job he/she claims to be competent in. The competent person is authorized by relevant competent authority in his/her area of competency.

End-user means a patient or client who uses the medical device themselves.

Health care organization means an organization which either uses devices or loans them to end-users and provides medical, dental, psychiatric, nursing, obstetrical, or surgical care e.g. government hospital, private hospital or clinics.

Inspection means interaction with medical device designed to detect unsuspected device problems, or to perform preventive maintenance.

NOTE – In general, an inspection is initiated on a scheduled basis and not in response to a reported failure.

Maintenance means interaction with medical device designed to identify and correct suspected device problems, or to perform activities designed to prevent the future occurrence of problems (preventive maintenance).

NOTE – Maintenance may be initiated on either an unscheduled basis (usually repairs) or on a scheduled basis (usually preventive maintenance)

Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by manufacturer to be used, alone or in combination, for human beings for one or more specific purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment or alleviation of or compensation for injury
- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices
- Providing information for medical purposes by means of in vitro examination of specimens derived from human body and which does

not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

- Critical care such as ventilators, defibrillators, baby incubators.
- Care in the home. For example urine drainage systems, domiciliary oxygen therapy systems, pressure care device.
- Emergency services. For example stretchers, trolleys, resuscitators.

Normal use means the use of device in a manner consistent with the operating instructions provided by the manufacturer of the device.

Planned preventive maintenance means servicing operations carried out at fixed intervals by technical staff.

Professional user means the trained and qualified person who operates a device for the benefit of patient or client.

Routine maintenance means inspection and device-care operation carried out by end-users and professional users.

Service agent means individual, generally an employee, providing inspection and/or other maintenance services on medical device on behalf of a service provider.

Supplier means the manufacturer or their agent.

Service provider means the group with the responsibility to provide inspection and/or other maintenance services on a specific piece of medical device.

NOTE – A service provider may be a department with the health care organization, device manufacturer, an independent service organization operated by a third party, a shared service, or other similar organizations.

Training means interaction with medical device designed to provide education to a device user or a service agent about the proper operation or maintenance of the device.

User means professional user and/or end-user

24.6 Maintenance Management Based On Device Life Cycle

24.6.1 Medical Device Lifecycle

i) In general, medical device product life cycle in relation to maintenance management is as shown in Figure 1. This lifecycle consists the following main stages.

- Purchase Planning
- Installation
- Operation
- Maintenance

- Device Calibration
 - Disposal
- ii) Although the life cycle is a continuous flow from planning till disposal the application of it to particular device may omit certain stages that are not necessary.

24.6.2 Purchase Planning Stage

i) All new devices to be purchased or planned for purchasing shall be evaluated against criteria listed in Table 1. As much as possible, input from clinical personnel, technical personnel, and other relevant parties should be sought in the decision making process. Suppliers who are ISO 9001 compliant may be recommended. The evaluation shall be documented and made readily available at later stages should the need arise.

| Factor | Notes |
|----------------------------------|--|
| Life Span of Device | Devices with longer life span are usually constructed more rigidly and are more expensive. |
| Placement of Device | The location where the device is to be used would put a constrain on the device specification. For example, devices placed in a more open environment should be able to withstand harsher conditions as opposed to devices put in an air-conditioned room. |
| Guarantee / Warranty | The terms and conditions are not always the same for every supplier, and the cost may reflect this differences. |
| Service Support | Availability of hot line and quick response time are usually very important factors but it can cost more. Are spares readily available? What is the history of service support and competency of personnel? What about end of service support? |
| Maintenance Requirements | Intervals between inspection, frequency and complexity of checks and calibration requirements. Maintenance requirements in terms of personnel, tools and methodology. |
| Safety and Reliability | Evaluation of device performance and safety characteristics. Experiences of other users are important source of information. |
| Fitness for intended purpose | The device must meet fully the user specifications, other extra features must be viewed from the user's perspective since these can be either a bonus or a problem. |
| Training | The nature and requirements of user and technical training may differ from one manufacturer to another. Will there be advance training program? |
| Manuals and Device Documentation | The completeness of manuals and documentation is an important factor. There should be user manuals as well as service/repair manuals which come complete with circuit diagrams, trouble-shooting and repair procedures, parts |

| | |
|--|---|
| | lists, and special tools list. The language in the manuals and documentation should be one that is easily understood by users and technical personnel. |
|--|---|

Table1. Medical Device Selection Criteria

24.6.3 Installation Stage

- i) Certain devices, especially those in the major and complex category, may require site preparation work that should comply with all relevant statutory requirements such as uniform building by-laws, Environmental Quality Act 1974 and regulations and/or Atomic Energy Licensing Act 1994 and regulations. This work shall be supervised by competent person or persons.
- ii) When the site and associated work such as shielding, gas piping, electrical wiring and switchgear, piling and concrete work, has been duly approved by relevant authority, the device should be properly installed, tested and commissioned under the supervision of competent person. All testing and commissioning results shall be documented for safekeeping, verification, auditing or any other purposes.

PURCHASE-INSTALLATION-OPERATION-MAINTENANCE OF MEDICAL DEVICES

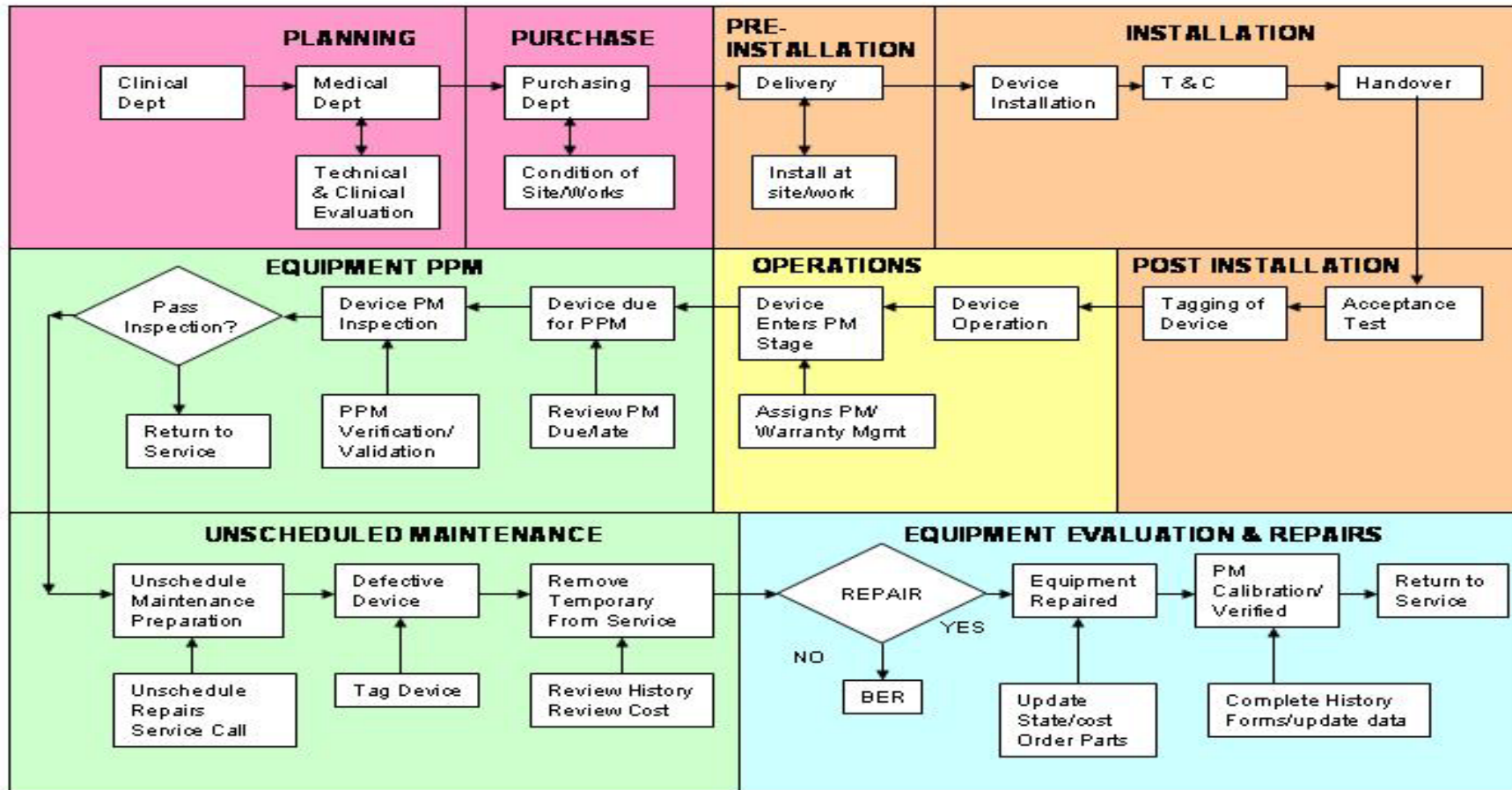


Figure 1 Medical Device Life Cycle

iii) Acceptance testing shall be done to meet the following requirement:

- It has been delivered complete and is in good condition without visible defects.
- It is in full working order and performs within the specification as specified by the manufacturer.
- It passes all relevant standard safety and performance test such as electrical safety and gas safety.
- Compliance to operating environment in accordance with manufacturer's specification.
- Accessories function properly with the device as intended by the manufacturer.
- User instruction manuals, maintenance and repair manuals, circuit diagrams, and other relevant manuals are complete and in the language as defined in the purchasing documents. (as required by the competent authority).

iv) The acceptance test shall be performed or supervised by competent person. The party performing or supervising the acceptance test shall be responsible and accountable for it. The result of acceptance test shall be documented for safekeeping, verification, auditing or any other purposes. This can be kept in the device logbook or asset records or device inventory list which shall be established and maintained. The device logbook or asset records or device inventory list shall contain at least the following information.

- Initial configuration
- Supplier
- Dates of initial delivery, handover & first use
- Inventory number
- Changes to the initial configuration
- Category of medical device
- Product identification
- Service support contact

v) Acceptance test is applicable to all categories of devices.

vi) Once the device has been successfully tested, appropriate tagging or marks shall be attached to the device in such a way that it is noticeable yet does not interfere in the operation of the device. The tag or mark shall follow closely to the GHTF.SG1.N09R3 recommendations and must consist of one or more of the following:

- Date of purchase
- Supplier
- Unique ID according to GMDN

- Validity dates – calibration and scheduled maintenance

24.6.4 Operation Stage

- i) Appropriate training in the operation and handling of the device shall be provided to users.
- ii) Users should perform operational checks daily to ensure that the device is operating as intended by the manufacturer. Users are also expected to perform the necessary shut down procedure if relevant. Devices found to be not operating in the intended manner it shall be appropriately marked, segregated and prevent from use, and corrective action taken.
- iii) The tag or mark must be checked to ensure that the validity dates have not lapsed, failing which the device must be appropriately marked, segregated and prevent from use and corrective action taken.
- iv) Devices that broke down during operation shall be appropriately marked, segregated and corrective action taken. Causes of failure shall be identified and documented.
- v) Users are responsible for routine maintenance and up keep of the medical devices. Routine maintenance includes regular cleaning, preparation for use and checking of device.

24.6.5 Maintenance and Repair Stage

- i) All planned preventive maintenance and repair, whether performed by in-house unit or third party service provider or manufacturer's servicing facilities, shall follow manufacturer's guidelines or procedures. Any proposed changes shall be approved by the manufacturer or it can be demonstrated that performance and safety is not affected by a competent body or competent authority.
- ii) Devices due for planned preventive maintenance or repair shall be appropriately marked and should be isolated in a predetermined area. If necessary the device must be cleaned and decontaminated following appropriate standard before releasing it for planned preventive maintenance or repair whatever relevant.
- iii) Planned preventive maintenance and repair shall only be undertaken or supervised by trained and competent person. Planned preventive maintenance and repair activities shall make references to manufacturer's documents, manuals and diagrams including any latest revision.
- iv) Planned preventive maintenance and repair activities shall utilize adequate and appropriate tools and any special tools as prescribed by the manufacturer.
- v) Planned preventive maintenance and repair activities shall use genuine spare parts approved by the manufacturer or equivalent or similar or better part that does not compromise safety and performance criteria of the device. The use of cannibalized spare

parts shall not be permitted. Spare parts inventory list shall be updated correspondingly.

vi) The competent person shall verify that devices that pass planned preventive maintenance checks have met performance and safety criteria according to standards and manufacturers' specifications. These devices shall be appropriately tagged or marked as described in section 4.3 before releasing it for clinical use. Conversely, devices that fail planned preventive maintenance checks shall be marked for corrective action.

vii) Devices that have been repaired must, if relevant, be recalibrated, and undergo appropriate performance and safety testing and verified by competent person before releasing it for clinical use. The device must be appropriately tagged or marked as described in section 4.3.

viii) All planned preventive maintenance and repair works on the devices shall be appropriately documented in the device logbook or asset records or device inventory list or appropriate records for safekeeping, verification, auditing or any other purposes.

ix) Devices that are deemed beyond economic repair by the competent person shall be appropriately marked for disposal.

24.6.6 Device Calibration

i) Calibration of devices, whether performed by in-house unit or third party service provider or manufacturer facilities, shall be performed by competent person in accordance with appropriate procedures using appropriate tools and equipment.

ii) Test equipment, simulators or analyzers for device calibration must be calibrated to traceable standards recognized and approved by competent authority. Devices that have been calibrated shall be appropriately tagged or marked as described in section 4.3, and calibration certificate issued by competent person or competent body. Records in the device logbook or asset records or device inventory list shall be updated correspondingly. The validity date on the devices must be clearly indicated.

24.6.7 Disposal Stage

i) The device is deemed no longer serviceable and must be disposed when any of the following criteria applies:

- Worn out beyond repair
- Damage beyond economic repair
- Unreliable (check service history)
- Clinical or technically obsolete
- Spare part no longer available
- More cost-effective or clinically effective devices have become available.

- Statutory requirement revision which may render a device obsolete
- ii) Devices that are meant for disposal shall be appropriately prepared to comply with relevant statutory requirement, for example Environmental quality act 1974 and Atomic Energy Licensing Act 1994.
- iii) Records in the device logbook or asset records or device inventory list shall be updated correspondingly.

24.7 Training

24.7.1 Technical Personnel Training

- i) Maintenance management of medical devices shall be carried out by technical personnel who are qualified, competent and appropriately trained. The personnel shall have undergone at least the following training programs:
 - Preventive Maintenance and Device Repair training.
 - Theoretical and Hands-on training
 - Training on use of device as intended by the manufacturer including aspect on safety.
 - Duration of training – at least 36 hours for medium risk devices and 72 hours for high risk devices; can be in the form of seminar, courses, factory schools, or mentoring.
- ii) The personnel shall be certified to handle appropriate class or category of devices by competent body based on qualification, experience and training. Manufacturer's training on the device or appropriate level of experience shall be a necessary criterion to handle maintenance of that device.

24.7.2 User Training

- i) Effective operation of medical devices can only be achieved when users are properly trained to operate and handle the device as intended by the manufacturer. To this effect, whenever a new medical device is handed over to users after acceptance testing, appropriate training shall be provided to them by the supplier. The person providing the training must be competent and certified by the manufacturer to do so.
- ii) When the device is already in operation, users who are new to the device are required to attend user training program before they are allowed to handle the device. This shall also apply to newer models of particular device since the newer models may have new features or properties not present in the older one. Training shall be provided by competent person or persons certified by the manufacturer to do so or person approved by competent body.

24.7.3 Space

- i) In order to ensure good maintenance management of medical devices there shall be sufficient space for the following:
 - planned preventive maintenance and repair work area
 - device awaiting planned preventive maintenance and repair
 - tools and spare parts storage
- ii) These spaces must be clearly marked and identifiable. The space must be a safe working environment in accordance with OSHA 1994 and its regulations.
- iii) In order to ensure effective operation of medical devices, operating conditions and work area must be sufficient and appropriate as specified by the manufacturer. This shall include conditions such as temperature, humidity, and lighting as specified by the manufacturer.

24.8 Communication

24.8.1 When documentation for particular medical device has been updated or revised by the manufacturer, this information shall be communicated to users and other relevant parties.

24.8.2 Whenever a medical device is transferred from one organization/user to another, the manuals, instructions, diagrams and relevant documentation as provided by the manufacturer shall accompany the device.

24.8.3 Any changes to planned preventive maintenance program from manufacturer's recommendation for a particular device shall be communicated to the manufacturer and approval sought. In cases where this is not possible, for critical devices, the approval of the competent body or competent authority shall be sought.

24.8.4 Whenever a user of a medical device has any information regarding the operation or maintenance of the device that is deemed to be of importance to other users shall communicate this information to the competent authority.

PART 3: USER PERSPECTIVE

SECTION 25: PRE-MARKET GUIDANCE – DESIGN PHASE

25.1 Definition of Medical Device

For the purposes of this document, medical device is defined as follows:

any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

25.2 Objective

The objective of the guidance document is to ensure that there are minimum use-related hazards, ensure that medical devices can be used safely throughout the life cycle of the device, and that devices used are effective.

25.3 Scope

While it is recognized that the degree of risk varies with the type and class of device, these guidance notes will apply to all devices. However, the onus is on the manufacturer to decide the need and applicability of these guidance notes. The scope of this document includes the user perspective throughout the life-cycle of the medical device and includes pre-market, placement on market, and post market phases.

25.4 Design Phase

25.4.1 Safety of medical devices

- i) All medical devices especially those that are used on or come into contact with the human body, and especially those inserted or implanted into the body should be safe. Hazards related to devices should be addressed during development of the device. In addition, safety should be assured through testing prior to actual use of the

device. In the design phase, the manufacturer needs to have in place a mechanism for the identification of the hazards associated with a medical device, estimating these risks and subsequently evaluating in relation to benefits. These work processes should conform to the requirements of international quality systems. Rare or unusual use of devices may result in hazards with serious consequences, and this may be a serious threat to the safe and effective use of a medical device. Users are often not prepared for infrequent, unexpected use scenarios because they may not be dealt with adequately in device design. In addition, infrequent but dangerous use scenarios are often difficult to identify. Hence, there is a need for the careful application of the analytic and empirical approaches early in and throughout the design process.

ii) It is essential that manufacturers ensure conformance to the essential requirements even while in the design phase of the device. Errors as a result of faulty design can lead to injuries to patients and even deaths. Currently the user is faced with a wide of medical devices for application in every aspect of health care. The user is influenced by the operating characteristics of the medical device. User interfaces that are confusing, misleading or illogical can cause errors by even among well-trained users. Users of medical devices vary greatly in their physical and mental abilities. This is more so among the community who are becoming an increasingly important proportion of the users of medical devices. Apart from this, the environment where medical devices are used is also important. These include accident and emergency areas, operating theatres, critical care facilities, wards, clinics, clinical laboratories, x-ray departments, emergency vehicles, and homes. Poor lighting, heat, humidity and moisture, noise, electro-magnetic interference, glare-producing surfaces, and dirt can affect the performance of a medical device. In addition, poorly written instructions for use can also affect use. Human factors like stress and fatigue can also influence the performance of a medical device. A medical device can be used safely and effectively only if the manufacturer takes into account during the design of the device the interaction between the user capabilities, device, operating environment, stress levels, and design.

25.4.2 Ensuring Safety and Effectiveness

User preference should not be the only criterion in the design of a medical device. This is due to the fact that users have a tendency to opt for devices that fulfils their needs, are simple to operate, and have a sophisticated appearance. Manufacturers and users emphasize these device characteristics and pay less attention to safety and effectiveness. Even if features of design to ensure safety and effectiveness could decrease user preference in some instances, they need to be given priority. Examples of these are safety-related user interface design features such as shields over critical controls, mechanical or software-based interlocks, or verification requirements that could slow down the use of a device or affect its aesthetics.

25.4.3 Environments of Use of Medical Devices

The environments in which medical devices are used can vary widely and can have major impacts on device use and use-related hazards. The amount of thinking and concentration a person exerts while using a device is called mental workload. The mental workload imposed on users by the environment in which they use devices can exceed their abilities to use devices properly. Mental workload is often used synonymously with mental “stress”. There can be a physical component to workload associated with medical device use referred to as physical workload, which also adds to the stress experienced by the user. Under high stress levels, the user is distracted and will have less time to make decisions, consider multiple device outputs, follow complex operating logic, or physically manipulate device components. Devices that can be used safely under conditions of low workload could be difficult or dangerous to use under conditions of high stress. Use environments can also limit the effectiveness of visual and auditory displays like lighted indicators, auditory alarms and other signals, if they are not designed appropriately. Consequently, if the users are unable to understand critically important information, errors are likely to occur. For devices used in noisy environments, the user might not be able to notice alarms if they are not sufficiently loud or distinctive. When multiple alarms occur for different devices or on the same device, the user could fail to notice them or to make important distinctions among them. Similarly, motion and vibration can affect the degree to which people are able to perform fine physical manipulations such as typing on the keyboard portion of a medical device. Motion and vibration can also affect the ability of users to read displayed information.

25.4.4 User Factors

Users may not have the same ability to use a device. A device that is easy for one person or a certain group of users to use safely and effectively may present problems for another person or group of people. To ensure that devices are used safely and effectively, it is important to understand the abilities and limitations of the intended users. For any device, the abilities and limitations of the user population may be relatively uniform, or some components of the population may have significantly different abilities. For example, young and old users may have different abilities and limitations as will home users compared to healthcare personnel. Fatigue, stress, medication, or other temporary mental or physical conditions can temporarily affect ability levels of device users. Some of the important characteristics of the user population include knowledge about operation of the device and the associated medical condition, previous experience with similar devices expectations about how a device will operate, general health and mental state when using the device e.g. stressed, relaxed, affected by medication or disease, sensory capabilities of vision, hearing, and touch, physical size and strength, coordination, cognitive ability and memory, motivation, and ability to adapt to adverse circumstances. For example, older users

might have difficulty remembering specific sequences for operation, using their hands to do tasks that require fine manipulation, or sensing device outputs such as auditory alarm sounds or information displayed visually. On the other hand, highly trained and motivated users are often much more capable of operating complex devices than typical users. They are also more likely to adapt better to unexpected or variable circumstances. The design of a device can often be made to compensate for limitations in user ability. User experience and expectations are important considerations. Users will expect devices and device components to operate in ways that are consistent with their experience with other similar devices or device interface components.

25.4.5 User Interfaces

The device user interface and responses of the device to user actions is another important area. The user interface includes all the components of a device with which users interact while using the device. This includes preparing it for use like calibration and set-up, performing maintenance like repairing and cleaning, hardware features that control device operation such as switches, buttons, and knobs as well as device features that provide information to the user such as indicator lights, displays, auditory, and visual alarms. The user interface also includes the logic that directs how the system responds to user actions including the feedback that is provided to the user. A well-designed user interface will facilitate correct actions and will prevent or minimise actions that could result in hazards. An important aspect of the user interface is the extent to which the logic of information display and control actions is consistent with users' abilities, expectations, and likely behaviour. Where user interfaces are computer-based, interface characteristics include the way data is organized and presented, control and monitoring screens, screen components, prompts, navigation logic, alerting mechanisms, data entry requirements, help functions, keyboards, mice, and pointers. The size and configuration of the device are important parts of the user interface, particularly for hand-held devices. Device labeling, packaging, training materials, operating instructions, and other reference materials are also considered part of the user interface. An important concept pertaining to user interface use-safety is error tolerance, which refers to the quality of a user interface that prevents or mitigates dangerous or disastrous consequences when an error occurs. Some kinds of error can be anticipated and are essentially unavoidable – such as inadvertently pressing an adjacent key on a keypad, or bumping the keypad inadvertently while doing other tasks. Device design should be able to increase the likelihood that the design is tolerant of errors that are likely to be made by users. The logic of device operation can also determine its degree of error tolerance. In other cases, devices can be designed to do tasks that users do not do well, such as timing certain steps in home-testing procedures, remembering set-up parameters, or test dates, or performing calculations. For complex procedures, devices can prompt

users to perform the appropriate action at critical points in the procedure.

25.4.6 Consideration of User's Abilities and Characteristics

i) A person's basic physical and mental capabilities include sight, hearing, strength, manual dexterity and flexibility. Design factors can interact with some of these capabilities to influence human performance. Some of these include the legibility and the ability to discriminate displayed signs and symbols, audibility and distinctiveness of alarms, the strength required to operate parts of a device, and the requirements for accessing the operating mechanisms or switches.

ii) A person's perceptual and cognitive abilities must also be taken into account in design. Understanding human limitations is crucial for safe design of equipment. On the other hand, perceptual characteristics are important in the design, placement and arrangement of displays, controls and alarms. In computer technology for example, a designer can adopt easy-to-use retrieval systems, using established written and symbolic techniques for screen and menu design. Similarly conventionally accepted representations in the community like the use of colours like red for danger or stop, green for go, as well as the standards and conventions in healthcare can be incorporated into design of medical devices. Designs that are consistent with accepted norms and ingrained habits would facilitate optimal performance. On the other hand, designs that conflict with such habits can lead to errors.

iii) Apart from this, an understanding of work processes and operating characteristics in diagnosis, treatment and monitoring is also important in design. For example, status of acutely ill patients is monitored based on information about heart rate, blood pressure, respiration, oxygen levels, and other physiological parameters. Consequently, patient monitors should present such information in a manner that conforms to such models.

iv) Home-use of medical devices has become increasingly important. For example, home monitoring of blood sugar is commonly being carried out, as is monitoring of blood pressure. In the use of medical devices, various factors like illness and age play major role. Due to the reduction in abilities like vision, hearing, strength, manual dexterity, and memory, users face difficulties in managing devices. This is compounded by other factors like inadequate facilities, insufficient assistance, and inexperience. All these present special difficulties in the design of medical devices. For example some people would prefer devices with manual functions while other prefers fully automated ones. Again, some patients may be unfamiliar with computer-controlled devices and may hesitate to use them. Other patients may be concerned about the potential effects of medication when using medical equipment. Hence given all these and the lack of medical training, there may be many problems associated with home user's operation of highly complex devices. This may be compounded

by the fact that devices meant for health facility use may end up in home use. In addition, there could be other problems that could occur at home like by power blackouts, insufficient electrical sockets necessitating the use of single outlets for multiple uses and electromagnetic interference.

25.4.7 Implications for Design

It may be difficult to overcome all the possible problems, incorporate all features, taking into account all human limitations, environmental factors, and stress, the cumulative and interactive effects of user errors. However, manufacturers would need to design the interface with the user in mind so that the device is least prone to user error, accommodates a wide range of users working under varying conditions and requiring minimal user training.

i) Devices with displays

– Important considerations for displays, including visual alarm indicators, and device labeling include ambient light levels, viewing angles, and the presence of other devices in the use environment. If the device will be used in low light conditions, display scales or device status indicators might not be clear to the user. Some scales will be read inaccurately when viewed from an angle due to parallax or because part of the display is blocked. Other display information can be lost under brightly lit conditions due to insufficient contrast. When certain types of equipment are used in close proximity with other devices, it could be difficult for users to associate visual displays and auditory signals with the corresponding equipment. With too much distraction, important information could be missed.

– Some of the suggested approaches to design are to ensure that the design conforms to user expectations as far as possible. This would be in keeping with the user's previous experience with medical devices and the conventions described above. In devices with displays, layout and design of controls significantly affect the user's ability to perform functions safely and efficiently as well as easily extract relevant information when operating a device, especially in emergency situations. Thus, displays should be clear with well-organized and uncluttered control switches for ease of identification without taxing the user's memory load. The control knobs switches and keys should correspond to the conventions of the user population and existing medical device standards. Universally accepted colours, shapes, sizes and codes should be used for these to facilitate their rapid identification. They should be placed sufficiently apart for ease of manipulation and also so that there is minimal likelihood of accidental activation. The controls should also provide tactile feedback. The auditory signals need to be set at an intensity and pitch that would enable them to be heard easily by device users, taking into

account as well the effects of ambient noise. Visual signals are of sufficient brightness that users can perceive them easily no matter what the ambient illumination is, with appropriate brightness and color contrast. Labels and displays have the appropriate size, color contrast, and display depth so that they are easily read from various distances and angles. Standard abbreviations, symbols, text, and acronyms should be used and these should be consistent in all instructions and manuals as well.

ii) Software

These same principles should apply in the provision of software in microprocessor-controlled functions. Microprocessing enables functions to be carried out rapidly, allows ready access to data, manipulation, computation and storage of this data. However, problems may be encountered if the software design is carried out without a thorough understanding of the user capabilities. As with other areas, manufacturers should utilise standard guidelines, carry out extensive analysis, and conduct preliminary testing with users during development of the software. For this to be effective there needs to be intimate knowledge of the user population. There should also be close coordination between hardware and software design. Thus, again manufacturers should not contradict expectations of the users, but instead use their previous experience with computerised equipment, and use conventions for language and symbols. As with displays, standard abbreviations, symbols and formats should be used that are consistent and unambiguous. The software should provide users information about the current status of the device. Whenever users make entries, there should be immediate and clear feedback provided. Procedures should be in easy-to-remember steps with prompts, pull-down menus and pop-up windows to cue the user regarding important steps. When errors have been made, there should be provision of easy corrective action as well as clear and simple guides for troubleshooting. Users should not be overloaded or confused with inadequate, unformatted, or densely packed information. Instead, accepted symbols, icons, colors, and abbreviations should be used to convey this information that can quickly be understood. Where a simple hardware solution is available, preference should be given to this over the use of software.

iii) Components and accessories

With respect to device components and accessories, too, potential hazards need to be identified, with the use of appropriate design and coding techniques to prevent problems with installation. For example, there could be confusion between similar components and accessories resulting in improper connections. There should be appropriate designs for

cables, tubing, connectors, leuers, and other hardware to facilitate easy installation and connection, so that it would extremely difficult or even impossible to install these incorrectly. To further facilitate this, colour codes or other suitable markings can be used to assist in this regards. In addition, where there is a possibility that connections may be compromised by motion, casual contact, or even due to wear and tear of the components, positive locking mechanisms can be instituted. Where there is possibility that body leads that can be inadvertently introduced into outlets, power cords, extension cords, or other common connectors, exposed contacts should be avoided. There should also be numbering of components and accessories to enable defective ones to allow appropriate replacement. There should be clear user instructions with conspicuous warnings as further safeguards.

iv) Alarms

Alarms and related components serve to alert device users about potential problems either with the patient or about status of the device. However, in some situations similar alarms going off in one or more devices make proper identification difficult, and this may distract staff. Hence, alarms have to be designed to make them distinguishable not only from one another, but also from alarms on other devices used in the same setting. There is a need to consider whether priority status should be given to critical alarms. The output from a particular auditory or visual display can be masked by ambient noise as well as numerous visual displays. So visual and auditory alerts and critical alarms have to be included ensuring that there is sufficient brightness contrast and colour contrast for legibility under a variety of lighting conditions, using standard colour codes where necessary. Alarms have also to be designed to activate as soon as there is a critical problem, and they should also point to the source of the problem. Since extremely loud alarms can mask other alarms, these have to be designed to meet or even exceed normal hearing and visual limits of the typical user. Alarms may be considered a nuisance or part of the background, and so may be mechanically switched off without rectifying the problem. Consequently, alarms may have to be designed so that when they are silenced, they remain silent temporarily. Visual indicators to indicate status and a mechanism for querying the reason for the alarm may be useful. Apart from this, there may be alarm failures and false alarms due to electro-magnetic interference, static electricity, or over-sensitivity and this too has to be included in the design requirements for the device. Hence, there is a need to consider the wide spectrum of operating environments in the design of alarms.

v) Physical characteristics

Design of medical devices should also take into consideration physical factors like dimensions. Thus, workstations and seats associated with medical devices should fit the user population with respect to body dimensions. This way seating arrangements would be comfortable and controls would be within reach. These aspects are especially important for devices like anesthesia workstations, prosthetics, and rehabilitative devices. Measurements are also applicable to many home-use devices, such as wheelchairs, in which portability, compatibility with structures, and compactness is important. Thus, it can be seen that knowledge of the clinical or home use environments is extremely important. The biomechanical characteristics of devices that require dexterity, strength or involve repetitive movements like surgical instruments, dental and control knobs. Some of these require not only dexterity or strength but the ability to precisely manipulate instruments in limited spaces like instruments used in laparoscopic surgery. Apart from this, aspects like visibility, reach, and compatibility with other devices need also to be considered.

25.4.8 Implications of new designs and features

With advances in technology, manufacturers may design devices with unique, distinctive features. However, healthcare personnel who have been used to specific types or models may then face a problem so that they have to undergo re-training. However, there could be more serious implications for example, if there two models having very similar user interface configurations but requiring conflicting operator actions. In this case, habits established with one device can interfere with user performance on the other, resulting in higher chances of user errors. For example, if the ON/OFF or CUTTING/COAGULATION switch positions were reversed on two very similar devices, a user transferring from one to the other would automatically follow the switch operation habits learned with the first device. Thus manufacturers would need to evaluate very critically the impact of user interface changes on user performance.

25.4.9 Maintenance

Another important area in design of medical devices that manufacturers should consider is maintenance. It is suggested that design should allow for simple maintenance, since poor maintenance can affect the safety and reliability of a device. Apart from this, devices that are difficult to maintain usually have a longer down time so that they may not be available for use for long periods of time. Some of the factors in design that can affect maintenance are inadequate self-diagnostic capability, inadequate design for easy cleaning, confusing component arrangements, materials that are not durable and degrade the user interface, poor component labeling, coding, or numbering, and parts that are hard to locate visually or by touch.

25.4.10 Packaging

The packaging of a medical device can affect its operation. Users can neglect to detect and remove packaging materials enclosed in the device so that it can impair functioning of the device. Good design should actually facilitate removal and storage of devices or accessories. In some cases, package design can reduce the likelihood of error like for example in catheters and compatible guide wires, needles and syringes, some infusion pumps and dedicated administration sets, and various contact lens accessories.

25.4.11 Consideration of human factors

In the design of medical devices, attention has also been paid to human factors. This can be achieved by studies on users or by computerized testing of prototypes. Manufacturers need to have early consultation with users to assess needs and develop requirements. Input from users is also critical for analysis of different aspects as well as for testing throughout the phase of development of the device. Some of the factors that manufacturers need to consider in designing a medical device are the similarity of a device to an existing one, complexity of the device, criticality of errors, experience with other devices, pre-existing data, and human factors expertise.

25.4.12 Approaches to user involvement in design

Many potential hazards involving unsafe or ineffective device use can be identified through careful inspection and analysis of existing information pertaining to the use of similar devices. Some involve unusual or unexpected ways of interacting with a device, or involve use in unusual circumstances. However, use scenarios of this type are difficult to identify by the use of analytic approaches only. Hence, it is important to obtain information from the intended user population and test devices under actual or simulated use conditions. When a manufacturer is planning to develop a device to automate a previously manual task, one approach would be for healthcare personnel to analyse the performance of the task in a clinical setting. Another would be to carry out clinical testing of existing models on the market to identify strengths and weaknesses of the existing designs. This would include a study of modifications made by users to compensate for design deficiencies. Where there are plans to modify an existing design, potential clinical impacts of change as well as the problems encountered with the current design would need to be studied. It is suggested that this analysis be carried out in a systematic fashion with input from users. Information collected during these efforts can help reduce errors, time, and costs in future projects involving similar products.

25.4.13 Preliminary studies

In determining the strengths and weaknesses of the design of a device it is important to obtain direct input from doctors, nurses, other healthcare personnel as well as home-users. This information can be obtained through surveys, interviews, focus-group discussions and the like.

Direct contact with users should be initiated in the earliest stages of product design. One of the most effective methods of study is by observation. In a hospital, the accident and emergency areas, operating theatres, critical-care areas like intensive care units, special care nurseries, coronary care units, and high dependency units are useful areas for observational studies of related devices. These include the observation during operations and the inspection of devices after the operation, especially of devices that have been in prolonged, continuous use. Information on installation, cleaning, maintenance, and the effects of environmental conditions can be obtained. For example, in the operating environment, substances such as dirt, water, saline solutions, other cleansing solutions like alcohol, bactericidal and disinfecting solutions like glutaraldehyde, blood and other body fluids, may have an effect on the proper functioning of a device, as well as its use. It should be pointed out that observing different users under varying work conditions is would ensure the generalisability of the observations. Apart from this interviews of healthcare personnel can be carried out. This allows obtaining information on problems, opinions about specific devices, as well as user preferences and ideas about improving the design. Interviews also can be conducted quickly and carried out together with observations. It will be seen that healthcare personnel and home users' views and perceptions may differ greatly from those of the manufacturer or designer. The most effective approach would be to take doctors, nurses and home users through the various steps in operation of the device, obtain critical information with respect to device failure or similar incidents, compare the strengths and weaknesses of different models, and where indicated recommend changes in a device, as well as evaluate new concepts in design.

Information on existing devices, features of good design and working conditions can provide input on how healthcare personnel use devices, the problems that are encountered, indicate how operating conditions affect use of the device, provide ideas for new designs and user reactions to new design concepts. In addition, information that is necessary to establishing performance test protocols and performance criteria could be obtained. It has been suggested that early studies stimulate creative thinking and minimise the likelihood of major mistakes during the design process.

25.4.14 Analysis of various aspects of devices

A thorough analysis carried out frequently will greatly contribute to the design process. This input can be combined with other data like user profiles to help in arriving at alternative user-interface designs, indicate design flaws in, and provide the focus for subsequent human-factors tests. Carrying out an analysis of functions, tasks, and hazards of a medical device will contribute to good device design by providing useful information about the requirements of users, the goals of usage, factors that impede performance or are likely to induce errors, possible hazards and other devices in the users environment. The number of functions or the degree of automation

can pose problems to the user, depending upon the user population and working environment. The current trend in devices is towards making them multi-functional to accommodate a wider range of users and increase the flexibility of applications of the device including home use. However, such increased capability can have a bearing on the use of the device. The capabilities of the respective users must be weighed against the benefits of having various features and functions in the device. It must be born in mind that some functional issues are influenced by various factors like medical practice and tasks, operating conditions, and the preferences of individual healthcare personnel.

An analysis of the potential hazards associated with the user should also be carried out. Hazard analysis can consider information on possible hazards obtained from complaint files during previous studies, as well as from tests, user studies, and task analyses. From this analysis the potential causes can also be identified so that conclusions about consequences can be made and appropriate remedial measures be incorporated into new designs. One advantage of hazard analysis is that it can identify low-frequency errors not discovered in prototype tests involving users.

Other analysis include focusing on areas like estimating expenditures of energy for physical tasks, performance measures and other performance requirements on users.

25.4.15 Testing on users

It is important to obtain performance data from actual users. If personnel carrying out a test cannot use a device under test conditions safely and effectively, consequently healthcare personnel will have problems with it under actual conditions of use. The development of user requirements and thorough testing ensures that medical device ultimately addresses the needs of healthcare professionals and patients. Devices have to be tested for ease of use as well as accuracy of use by users. This will consequently ensure that all users can safely and effectively operate, install, and maintain devices. By testing a prototype, the concepts of design can be tested, refined, and subsequently re-tested throughout the development process. Prototypes can be used to select alternative designs as well as uncover problems in design. Finally, the full testing of a model that incorporates all the user-interface characteristics of a fully functioning device has to be carried out. Testing can be carried out in laboratories, before testing in real-life facilities or field-testing. While initial testing can be carried out with a few clinical users, subsequent testing may require larger numbers. Using new healthcare personnel would facilitate discovery of user-related problems in design although the pre-existing habits of experienced individuals may also be an important concern. Some of the performance measures that can be used in the sample scenario include set-up times, number of errors, type of errors, changes in error rates, failures to detect and

discriminate alarms, task completion time, and any observations that indicate performance obstacles.

25.5 Incorporating User Considerations into Risk Management

25.5.1 Introduction

i) Risk management can be described as the systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk. It can help to identify, understand, anticipate, and prevent failures giving rise to hazards when people use medical devices.

ii) It is necessary for the manufacturer to consider the intended purpose or application of the medical device, its indications for use, or what the device is intended to be used for in relation to the safety of the medical devices.

iii) The manufacturer should also consider the possible or foreseeable misuse of the device under normal conditions of use. Apart from this there is also a need to anticipate hazards arising from use of the device under improper conditions.

iv) In addition, the areas or aspects that have an influence on the safety of the device have also to be borne in mind. An estimate of the severity of the consequences has to be made. The limitations of the device are to be included as well.

v) There is also a need to consider who the users would be – whether it would be healthcare practitioners like doctors, nurses in health facilities like hospitals or clinics or users at home like patients or carers.

vi) Once the potential hazards are identified, efforts should be made in the design phase to control, reduce or minimize these hazards.

vii) Where safety cannot be controlled by design alone, the manufacturer has to consider the need for protective measures in the medical device itself, special training needs of the user, or safety warnings or safety information.

25.5.2 Identification of user-related hazards

i) A hazard refers to a potential cause of harm or danger. Hazards could be related to the mode of medical treatment itself, from use of a medical device, or as a result of side effects or failures of the device.

ii) Hazards can be detected through risk analysis. Information can also be obtained for a study of incident reports and incident failures on similar or related devices from users or manufacturers. Some of the more common hazards are pathological hazards like infections, tissue reactions like allergy and bio-incompatibility; radiation hazards like burns, genetic effects and tissue reactions from both ionizing and

non-ionizing radiation; mechanical hazards like, pain or energy produced from motion or pressure; electrical hazards like leakage of current, electromagnetic interference; chemical hazards like poisonous chemicals, environmental hazards like extreme temperatures

iii) The above hazards may be inherent in the device arising from failure of the device or failure of one or more of the components of the device. Apart from these hazards, there may also be hazards that could arise from improper usage of devices. User-related hazards could arise from using devices in situations or for indications not recommended by the manufacturer or the use of the device requires special skills beyond the ability of the average untrained user. For diagnostic devices this may result in failure to identify a disease or condition, for monitoring devices certain essential parameters may not be monitored or monitored incorrectly possibly giving rise to grave consequences while for therapeutic devices dangerous or ineffective treatment again resulting in morbidity for patients.

iv) One example of unanticipated use of a device resulting in a serious incident that occurred as a result of faulty design is a cot bed that allowed a semi-conscious patient's head to be forced in between the railings resulting in death of the patient. Another is an anaesthetic machine where controls for halothane and oxygen were similar in appearance and situated close together so that halothane was inadvertently switched on when emergency oxygen was needed. Similarly, the foot controls of a diathermy machine could be placed so close together that the cutting mode could be inadvertently switched on when coagulation is required and vice versa resulting in drastic consequences.

v) Just as the classification of devices is based on severity of risk, the severity of the consequences as a result of failure or malfunction of devices should be given careful attention. It is important to consider the likelihood of risk of every device, without making prior assumptions that the risk may be low. It may be pertinent to note that unexpected events can result in much more serious consequences since the user would not be in apposition to take defensive action or institute immediate remedial measures.

vi) The following are some of the ways in which analysis of risk could be carried out in the design phase of a medical device:

- analysis of risks of similar types of devices or devices with similar functions
- evaluating risks based on possible user-related hazard situations
- analysis of literature and other information on the device
- early user testing

vii) Having identified risks there is a need to devise mechanisms to overcome possible hazards identified.

SECTION 26: PLACEMENT ON MARKET – GUIDANCE ON LABELLING FOR MEDICAL DEVICES, INSTRUCTIONS FOR USE, ADVERTISING, USER REPORTING OF MEDICAL DEVICE INCIDENTS

26.1 Guidance on Labeling for Medical Devices

26.1.1 General principles

The purpose of labelling is to provide information on safety and performance to users of medical devices and/or to patients. This information may be provided separately as information for use, or it may be on the device itself, or it could be on the packaging, or even as a packaging insert. Labelling would provide significant benefits to the manufacturer, patient or consumer, and to Regulatory Authorities.

26.1.2 Location of labelling

It is suggested that appropriate user information to ensure safety should be provided on the packaging either of each unit, or on the packaging of multiple devices, or on the device itself. Where it is not practical for individual packaging of each unit, the information should be provided in the leaflet, packaging insert or other means supplied with one or multiple devices. The location of labelling should be appropriate to the particular device and its intended purpose

26.1.3 Format of labelling

The format and content of labelling depends on the specific device as well as the purpose it is intended for. The trend is for uniform international labeling in the text, content, and the format of labels. The use of national language should be kept to a minimum taking into consideration the type of user anticipated for the device. It is also suggested that internationally recognised symbols be used so that device safety is not compromised by a lack of understanding by the patient or user. If the meaning of the symbol is not obvious to the device user, the symbol should be accompanied by words describing it.

26.1.4 Content of labelling

The labelling should generally have the following:

i) General labelling

Name or trade name and address of the manufacturer; for imported devices, name and address of either the importer established within the importing country or of an authorized representative of the manufacturer established within the importing country, the label should be put on the outer packaging, or instructions for use.

- intended purpose, user and patient population of the device where these are not obvious
- details of device to enable user to identify it

- batch code/lot number or the serial number, date of manufacture (where relevant)
 - date until which the device may safely be used (where relevant)
 - special storage and /or handling conditions on the external packaging.
 - warnings and /or precautions.
 - performance intended by the manufacturer
 - any undesirable side-effects.
 - information to verify whether the device is properly installed, can operate correctly and safely
 - information on nature and frequency of preventative and regular maintenance, replacement of consumable components, and calibration needed to ensure optimal and safe operation of the device
 - further treatment or handling needed before the device can be used (e.g. sterilization, calibration etc.).
- ii) Specific labelling
- sterile devices - the word 'STERILE' should be stated
 - sterility indicators and precautions and instructions if the sterile packaging is damaged
 - devices to be sterilized before use- instructions for cleaning and sterilization
 - single-use only (where indicated).
 - reusable devices - information on cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization, and any restriction on the number of reuses.
 - investigational devices - devices intended for clinical and /or performance investigations prior to placement on market, labeled 'exclusively for clinical investigations'
 - intended for presentation or demonstration purposes only.
 - where device is to be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose - sufficient details to identify the correct devices or equipment to use to obtain a safe combination.
 - implantable device - information regarding any particular risks in connection with its implantation.

- information on risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations or treatments
- radiation emitting devices -details of the nature, type, intensity and distribution of this radiation.
- for custom-made devices - use by a single individual

26.2 Guidance for Instructions for Use

Every device needs to be accompanied by information needed to use it safely, taking into account the knowledge of the potential users and their training. The instructions for use or operating instructions give important information on the proper use of the medical device. If the intended purpose of the device is not obvious to the user, the manufacturer should clearly state it on the label and in the instructions for use. Where there are detachable components these must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices as well as the detachable components.

26.2.1 Location of instructions for use

It is suggested that the information needed to use the device safely be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. Only if this is not practicable should the information be set out in the leaflet supplied with one or more devices. However, for low or moderate risk devices instructions may not be needed or may be abbreviated if they can be used safely and as intended without any such instructions. The instructions for use should include, where appropriate, details allowing medical staff to brief the patient on any contra-indications, warnings and any precautions to be taken

26.2.2 Media for instructions for use

Instructions on use of the device as well as related information can be provided to the user in various media targeted to the anticipated user population. This can also be done by several means such as printed documents, through a display screen incorporated into the device, or by using other media. The instructions for use should be written so that the intended user readily understands them. Where appropriate, this information should take the form of symbols or identified colours, which should as far as possible conform to international norms or standards. In areas for which no such standards exist, the symbols and colours must be described in the documentation supplied with the device

26.2.3 Content of instructions for use

Where appropriate, the instructions for use must contain the following particulars:

- i) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of

the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times

ii) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination

iii) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);

26.2.3.iii.1.1 Precautionary labelling

iv) The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should include the following:

v) precautions to be taken if there are changes in the performance of the device

vi) precautions with respect to exposure to environmental conditions like magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

vii) where drugs are incorporated into the device as an integral part this should be indicated in the label

viii) adequate information regarding the drug(s) which a device is designed to administer, including any limitations in the choice of substances to be delivered;

ix) precautions to be taken against any special, unusual risks related to the disposal of the device

x) for devices with a measuring function the degree of accuracy claimed by the manufacturer

xi) requirements for special facilities, or special training, or particular qualifications of the device user.

26.3 Guidance for Advertising

26.3.1 An advertisement can be defined as any statement, pictorial representation or design, that is intended to promote the use or supply of medical device either directly or indirectly. This includes product labels, pamphlets, and instructions for use, promotional samples, promotional seminars, demonstrations and displays. Advertising is considered as part of the information provided with medical devices required by the regulations.

26.3.2 Advertisements for devices should contain correct and balanced statements only and claims, which has already been verified by the sponsor. They should not give rise to unwarranted or unrealistic expectations of effectiveness of a device. Besides this, they should not induce consumers to self-diagnose or inappropriately treat potentially serious diseases. In addition, advertisements should not mislead directly or by implication or

through emphasis, comparisons, contrasts or omissions. They should also not abuse the trust or exploit the lack of knowledge of consumers or contain language that could bring about fear or distress. Further, advertisements should not contain any matter which may suggest to people that they are suffering from a serious disease, or that harmful consequences may result from the devices not being used. Apart from this, they should not encourage inappropriate or excessive consumption or contain any claim, statement or implication that it is miraculous, or that it is a certain, guaranteed or sure cure. A device should not be claimed to be totally safe or that its use cannot cause harm or that its use does not produce any side effects or that it is effective in all cases of a condition.

26.3.3 Complaints on advertising

Complaints about medical devices that appear in all media like labels, leaflets, flyers, promotional brochures, information on the Internet, newspapers, magazines, billboards, outdoor posters, cinema films, radio, and television will all be considered. If the complaint is found to be valid, the advertiser may be requested to withdraw the advertisement or publish corrective advertising. If the advertiser fails to comply with this request, the matter will be referred for further action.

26.4 Guidance on User Reporting of Medical Device Incidents

26.4.1 To ensure post-market vigilance and for monitoring the safety and effectiveness of medical devices all device related incidents need to be investigated to determine the cause of such incidents. This is especially true if there is serious morbidity or mortality associated with the use of the device. Thus, user and user facilities are required to report deaths and serious injuries when there is a reasonable suggestion that a medical device has or may have caused or contributed to the adverse event. They are also required to establish and maintain adverse event files. Medical device incident report should be reported to the notified body and to the Competent Authority. A user facility is not required to evaluate or investigate the event by obtaining or evaluating information that is not reasonably known to it.

26.4.2 The adverse event report should include the following information:

- i) name and address of the device manufacturer;
- ii) device brand name and generic name
- iii) device model, catalog, serial, and lot number
- iv) a brief description of the adverse event or product reports of death and serious injury which are problem
- v) information such as professional, scientific, or medical facts and observations or opinions that a device has caused or may have caused or contributed to a reportable event. This includes information found in documents in the possession of the user facility and any information that becomes available as a result of reasonable follow-up within the facility.

SECTION 27: POST MARKET – GUIDANCE ON TRAINING AND USER REQUIREMENTS

27.1 Introduction

27.1.1 Adequate and appropriate user training is an integral part of use of devices. This may also include specific user requirements. Inadequate or lack of user training may result in decreased efficiency of operation of the device, wrong treatment /intervention or diagnosis leading to detrimental effects on the health of the patient, the user or other persons as well as to damage or deterioration of the medical device. This is especially true of complex and/or high-risk class medical devices, where a training program for users is indispensable. Correct user and application training and continued support are conditions for optimal and safe use of the device.

27.1.2 It may be useful for purposes of identifying training needs to categorise devices into one of two classes as follows:

27.1.3 High tech mechanical or electrical devices, usually expensive associated with relatively high purchase costs, ongoing maintenance or servicing requirements with associated costs and significant training implications to ensure safe use. Examples of these are pumps, blood sugar monitoring devices, cardiac monitors, ECT machines, hoists and the like.

27.1.4 Low-tech, usually disposable, items with relatively low purchase costs, little or no maintenance or servicing requirements and relatively low training implications to ensure safe use. Examples of these include devices like incontinence pads, mattresses, wound dressings, and gloves.

27.2 Type of Training

All device users should be trained in the safe operation of medical devices, both new and existing. The manufacturers as well as health care facilities and providers need to ensure that there are adequate arrangements for such training at various levels. This includes the familiarisation (novice/acquaintance) training, advanced user training, application training and continuous refresher courses. It must also be ensured that the user has the correct adaptation and background for receiving the training. Personnel involved either directly and indirectly in the provision of health care provision have the right to decline to use or operate any medical device that they have not been adequately trained to use. This is to ensure that all medical devices are used in a safe and effective manner. The manufacturer is responsible for providing training – this can be carried out either in-house by an application specialist or other appropriate parties identified or qualified by the manufacturer like a healthcare facility or a qualified clinical engineering function.

27.3 Documentation and Certification of Training

27.3.1 Documentation of training is another important aspect. There should be a training plan specific to the device specifying the type of staff to be

trained, the level of training, and the training schedule and frequency including re-training, updating, upgrading of skills and refresher courses. There should also be a training log based upon device and user dynamics included application training, if applicable.

27.3.2 In healthcare facilities, the adequacy of the training and the knowledge and practice of the device user should be assessed by a clinically competent person before the user is allowed to operate the device or provide service. The results of the training and assessment should be documented in the device user's training record using the format as in Appendix 29. This documentation must be regularly reviewed for new devices as well as for new personnel.

27.3.3 Some of the criteria to be used to assess adequacy of training are as follows:

- i) Medical device risk assessment
- ii) Able to show patients or other users how to use the device (where relevant)
- iii) Awareness of differences between various brands and models (where applicable) and effects on safety and function
- iv) Disassembly/assembly of the device (including accessories) for cleaning
- v) Be able to set the controls appropriately and recognise malfunctions and subsequently take corrective action

27.4 Medical Devices Requiring Specialist Training

It has been generally recognized that some devices clearly require specialised intensive training to enable them to be used in a safe and effective manner. In addition some of these devices will, in addition, require basic professional training to enable a clear understanding of the pathophysiology of the specific diseases to enable devices to be used safely and optimally. Apart from this, specific devices will require a basic knowledge of anatomy or physiology to enable an understanding of the proper functioning of the device. These are especially true of high-risk devices. Examples of such devices would include devices with therapeutic functions like electroconvulsive therapy (ECT) machines and associated anaesthetic devices, diagnostic devices like blood glucose measuring devices, devices with a monitoring function like blood oxygen saturation monitors (O₂ saturation monitors), as well as rehabilitative devices like lasers and Transcutaneous Electrical Nerve Stimulation (TENS). For such devices, the capability of the user would need to be certified by an accredited/authorised credentialling authority