GHTF Study Group 1 Guidance: *Essential Principles of Safety and Performance of Medical Devices*

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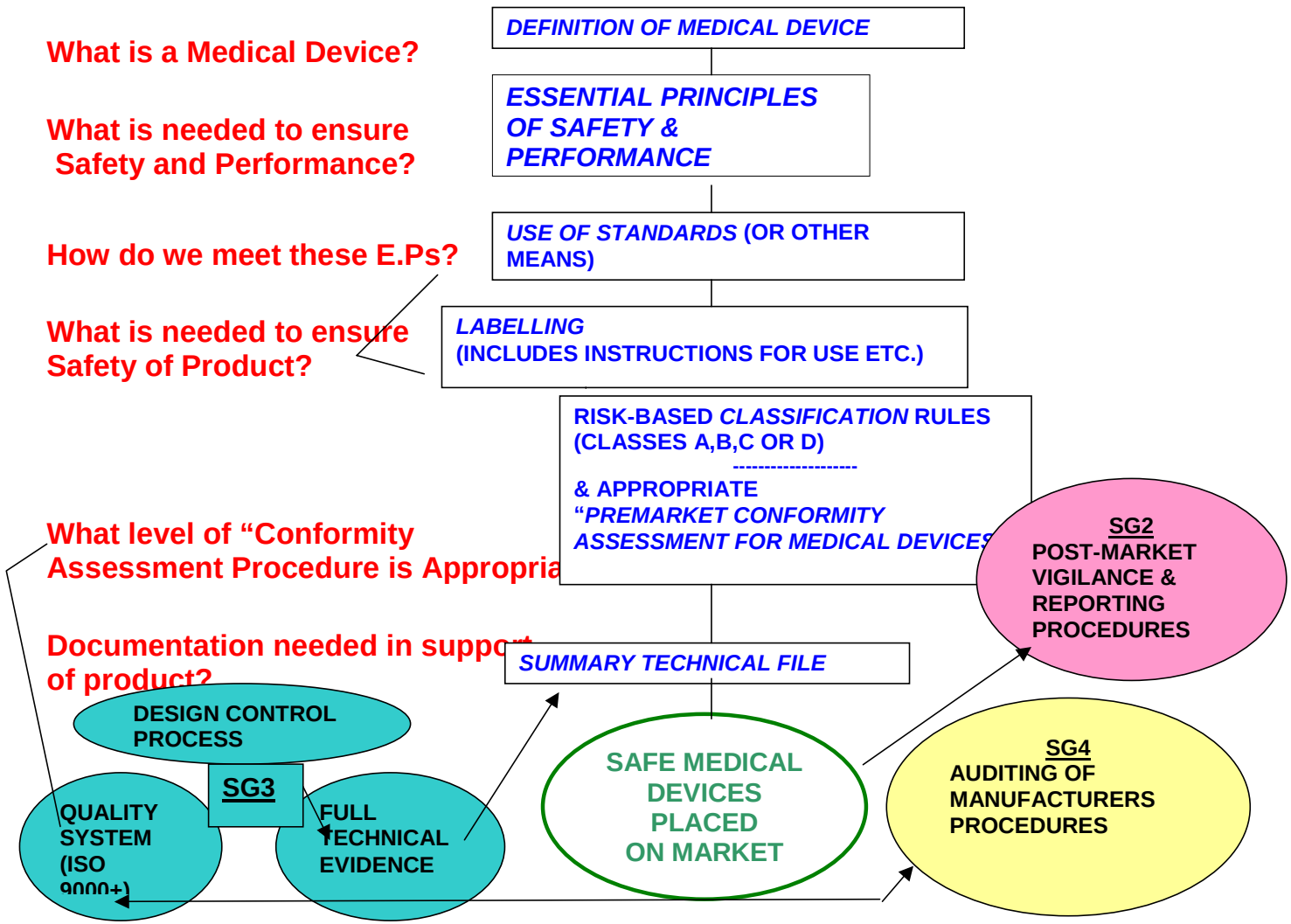
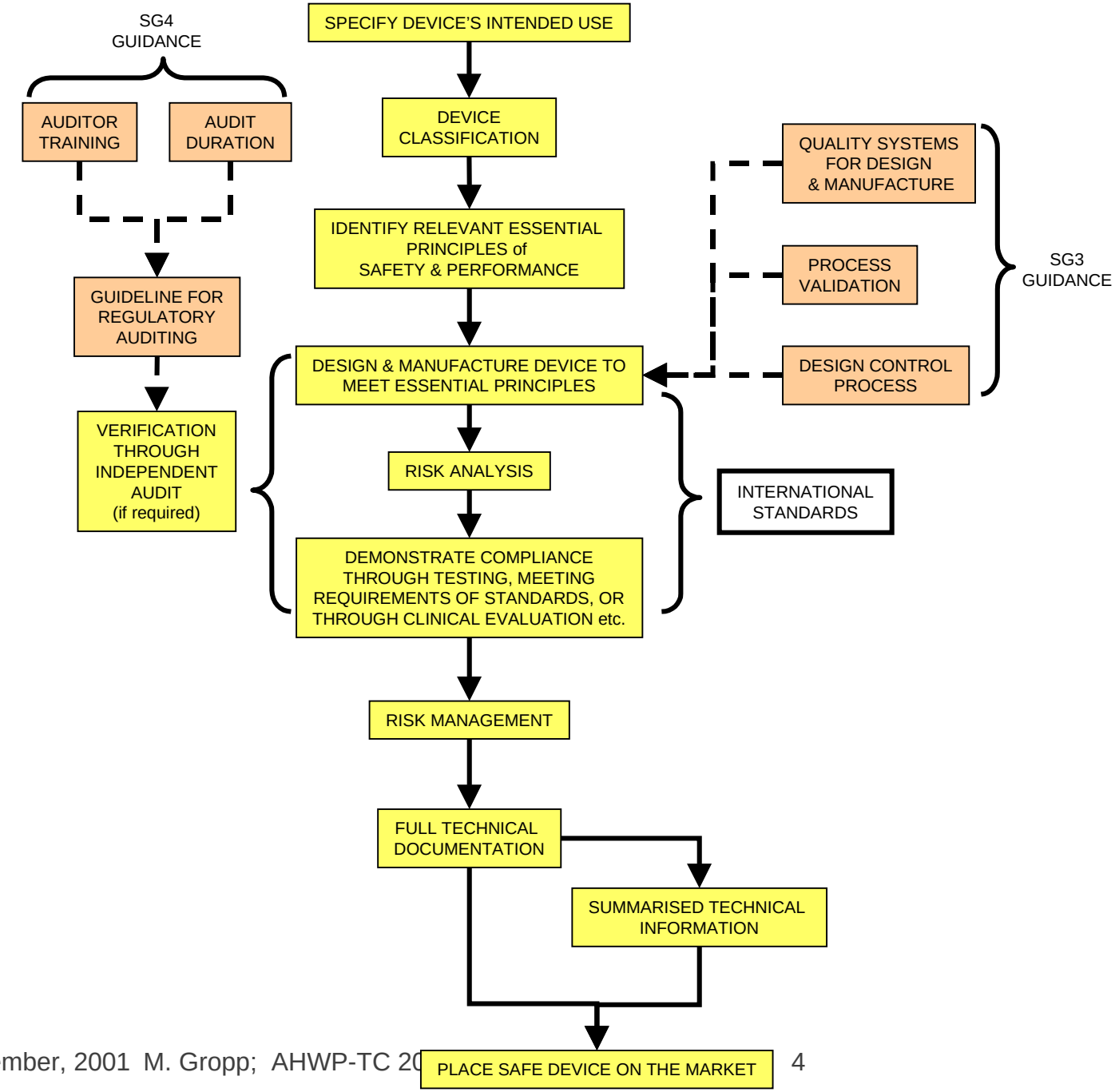
Essential Principles of Safety and Performance

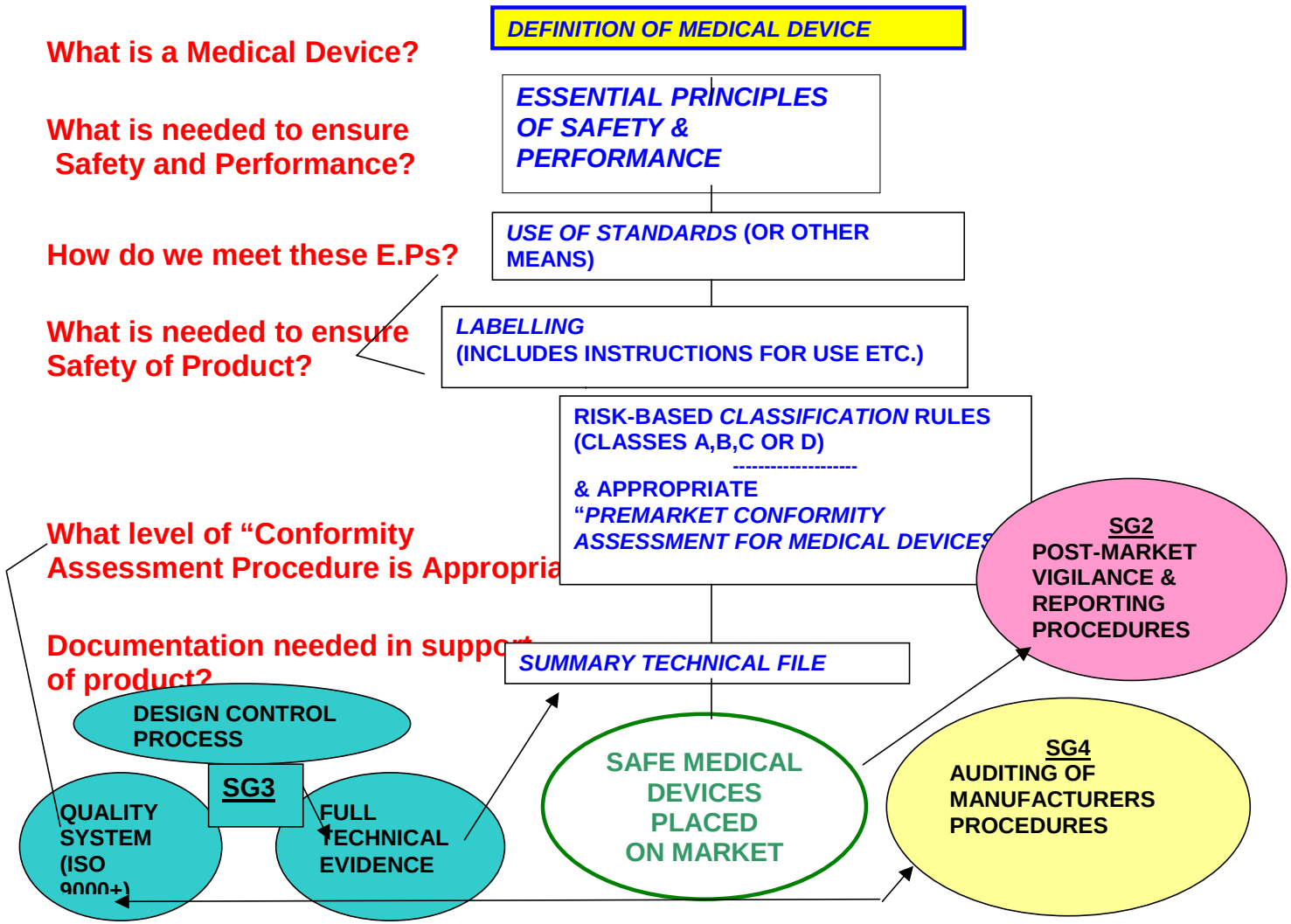
- **Presentation overview:**
  - **Overview of work programme of SG-1**
  - **Definition of “medical device”**
  - **Essential Principles of Safety and Performance**

SCOPE OF GHTF-SG1 PREMARKET TECHNICAL REQUIREMENTS




SG4
GUIDANCE
AUDITOR
TRAINING
AUDIT
DURATION
GUIDELINE FOR
REGULATORY
AUDITING
VERIFICATION
THROUGH
INDEPENDENT
AUDIT
(if required)
SPECIFY DEVICE'S INTENDED USE
DEVICE
CLASSIFICATION
IDENTIFY RELEVANT ESSENTIAL
PRINCIPLES of
SAFETY & PERFORMANCE
DESIGN & MANUFACTURE DEVICE TO
MEET ESSENTIAL PRINCIPLES
RISK ANALYSIS
DEMONSTRATE COMPLIANCE
THROUGH TESTING, MEETING
REQUIREMENTS OF STANDARDS, OR
THROUGH CLINICAL EVALUATION etc.
RISK MANAGEMENT
FULL TECHNICAL
DOCUMENTATION
SUMMARISED TECHNICAL
INFORMATION
PLACE SAFE DEVICE ON THE MARKET
QUALITY SYSTEMS
FOR DESIGN
& MANUFACTURE
PROCESS
VALIDATION
DESIGN CONTROL
PROCESS
SG3
GUIDANCE
INTERNATIONAL
STANDARDS

SCOPE OF GHTF-SG1 PREMARKET TECHNICAL REQUIREMENTS



Essential Principles of Safety and Performance

- **Harmonized definition of the term “medical device” (Draft)** (Working Draft SG1/N029R8; Aug. 2001)

  - **“`Medical device' means any instrument, apparatus/implement/machine, appliance, implant, reagent/calibrator, software, material or other similar or related article, whether used alone or in combination to be used for human beings for the specific purpose of:**

Essential Principles of Safety and Performance

- **Definition of "medical device" (Draft) (continued)**
  - **"- diagnosis, prevention, monitoring, treatment or alleviation/mitigation of disease,**
  - **- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,**
  - **- investigation, replacement, modification, or support of the anatomy/body structure or of a physiological process,**
  -

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- **Definition of "medical device" (Draft) (continued)**
  - **"- supporting and sustaining life,**
  - **- control of conception,**
  - **- disinfection of medical devices,**
  - **- providing information, by *in vitro* examination of specimens derived from the human body,**

Essential Principles of Safety and Performance

- **Definition of "medical device" (Draft) (continued)**
  - **"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."**

Essential Principles of Safety and Performance

- **Definition of "medical device" (Draft) (continued)**

  - **"NOTE: An accessory to a medical device is not considered to be a medical device but provided the accessory is intended specifically by its manufacturer to be used together with the 'parent' medical device to enable the medical device to achieve its intended purpose, then it is subject to the same regulations as apply to the medical device itself and to GHTF guidance documents."**

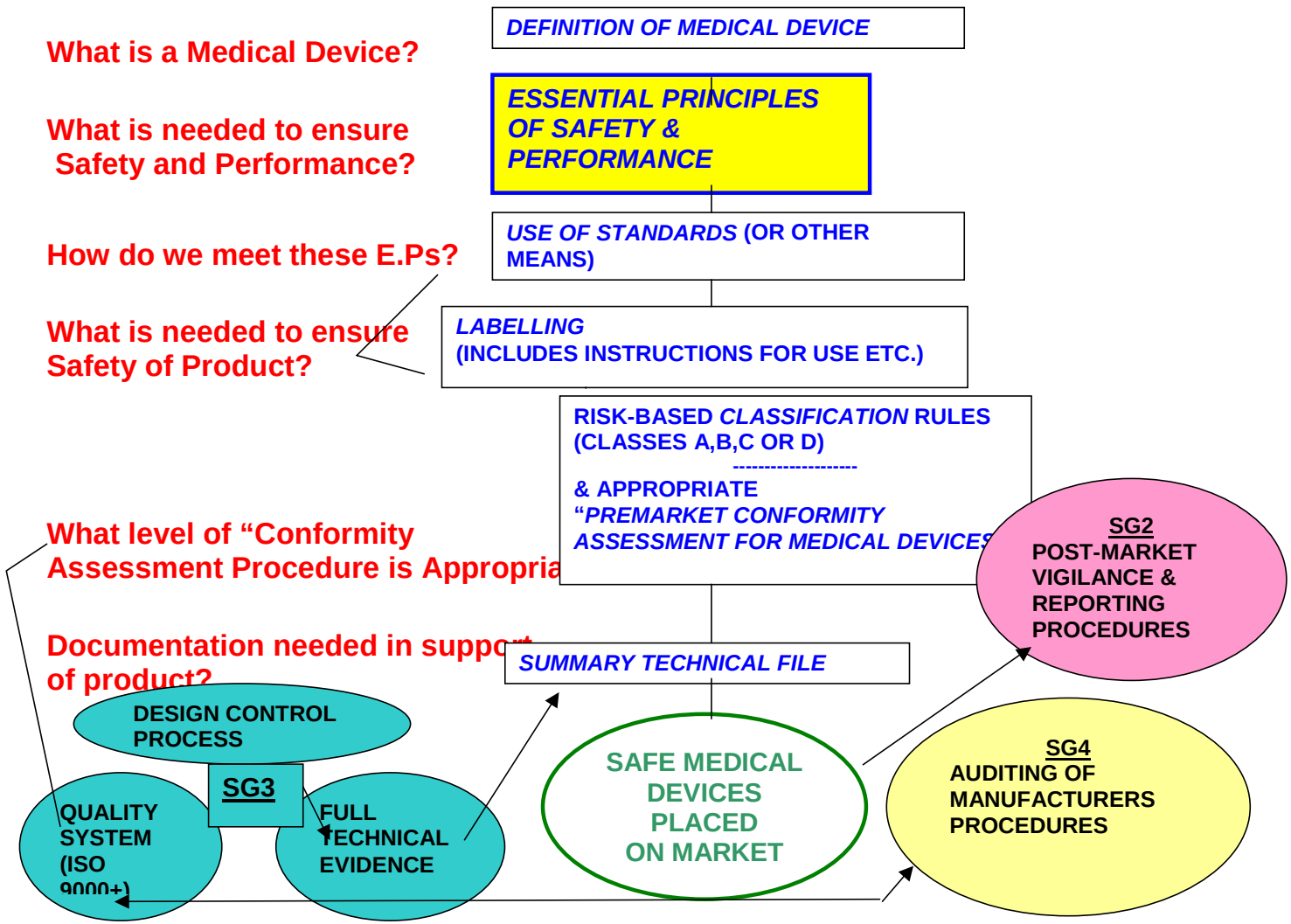
Essential Principles of Safety and Performance

- **Definition of "medical device" (Draft) (continued)**
  - **"NOTE: The definition of an *in vitro* diagnostic device includes, for example, reagents, calibrators, control materials and related instruments/apparatus. In some jurisdictions, reagents and the like may be covered by separate regulations."**

Essential Principles of Safety and Performance

- **Definition of "medical device" (Draft) (continued)**
  - **"NOTE: Products, which are 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,**
    - **spare parts for medical devices,**
  - **devices incorporating animal and human tissues which may meet the requirements of the above definition but be subject to different controls."**

SCOPE OF GHTF-SG1 PREMARKET TECHNICAL REQUIREMENTS



Essential Principles of Safety and Performance

- **Document overview:**
  - **Final document (GHTF.SG1.N020R5)**
  - **Adopted June 30, 1999**
  - **Accessible via GHTF website**
    - **http://www.ghtf.org**

Essential Principles of Safety and Performance

- **Document overview:**
  - **General requirements**
  - **Requirements regarding design and construction**
    - **Chemical, physical and biological properties**
    - **Infection and microbial contamination**
    - **Construction and environmental properties**
    - **Devices with a measuring function**
    - **Protection against radiation**
    - **Requirements for medical devices connected to or equipped with an energy source**

Essential Principles of Safety and Performance

- **Document overview:**
  - **Information supplied by the manufacturer**
  - **Clinical evaluation**

Essential Principles of Safety and Performance

- **Document overview:**

  - **"This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices regulators, Conformity Assessment Bodies and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. The document will be of value to countries developing or amending regulations. ……"**

Essential Principles of Safety and Performance

- **Document overview:**
  - **"Common guidelines to indicate the Essential Principles of safety and performance of medical devices in the interests of public health"**
  - **"…. understood that the operation of a quality system, the use of standards, postmarket 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 not addressed within this document."**

Essential Principles of Safety and Performance

- **Document overview:**
  - **Under the harmonised scheme, compliance with Essential Principles is required for all devices**
  - **Not all Essential Principles apply to all devices**
    - **Intended use**
    - **Mode of action**
    - **Interaction with human body**
  - **Manufacturer must consider all Essential Principles**
    - **Document rationale for those not applied**
    - **Choice of means for demonstrating compliance**

Essential Principles of Safety and Performance

- **Document overview – General Requirements:**

- **"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, ….."**

Essential Principles of Safety and Performance

- **Document overview – General Requirements:**

- **"…. 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."**

Essential Principles of Safety and Performance

- **Document overview – General Requirements:**
- **“The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art.”**
- **“In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: …….”**

Essential Principles of Safety and Performance

- **Document overview – General Requirements:**
  - **"…. identify hazards and the associated risks arising from the intended use and foreseeable misuse,**
  - **·eliminate or reduce risks as far as possible (inherently safe design and construction),**
  - **·where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,**
  - **inform users of the residual risks due to any shortcomings of the protection measures adopted.**

Essential Principles of Safety and Performance

- **Document overview –General Requirements:**
  - **"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."**

Essential Principles of Safety and Performance

- **Document overview – General Requirements:**
  - **"The characteristics and performances …. should not be adversely affected to such a degree that the clinical conditions and safety of the patients 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.**

Essential Principles of Safety and Performance

- **Document overview – General Requirements:**
  - **“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 during transport and storage taking account of the instructions and information provided by the manufacturer.”**

Essential Principles of Safety and Performance

- **Document overview – General Requirements:**
  - **The benefits must be determined to outweigh any undesirable side• effects for the performances intended.**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"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 and body fluids, taking into account the intended purpose of the device,**
    - **The choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength"**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"….. designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. designed and manufactured in such a way as to reduce to a minimum the risks posed by substances that may leach from the device. "**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. designed and manufactured in such a way as to reduce, as much as possible, 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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and, where applicable, other persons. The design should allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use"**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"Tissues of non-human origin as far as considered a medical device, 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 Competent/Regulatory Authority should retain information on the geographical origin of the animals. ……"**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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 viral inactivation in the course of the manufacturing process."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"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 storage and transport conditions laid down, until the protective packaging is damaged or opened."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"Devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.**
  - **Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**

  - **“The packaging and/or label of the device should distinguish between identical or similar products sold in both sterile and non• sterile condition.”**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"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 should be indicated on the label or in the instructions for use."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **…. designed and manufactured in such a way as to remove or minimise as far as is practicable:**
    - **Risk of injury, in connection with physical features …**
    - **Risks connected with reasonably foreseeable environmental conditions**
      - **Magnetic fields**
      - **External electrical influences**
      - **Electrostatic discharge**
      - **Pressure**
      - **Temperature**
      - **Variations in pressure and acceleration**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **…. designed and manufactured in such a way as to remove or minimise as far as is practicable:**
    - **Risk of reciprocal interference with other devices …**
    - **Risks arising where maintenance or calibration are not possible (as in implants), from ageing of materials or loss or accuracy of any measuring or control mechanism**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**

  - **"…. 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 flammable substances or to substances which could cause combustion."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**

  - **"Devices with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy should be indicated by the manufacturer."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"The measurement, monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device."**
  - **The measurements made by devices with a measuring function should be expressed in legal units as required by the legislation governing such expression of each jurisdiction in which the device is to be sold"**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. designed and manufactured in such a way that exposure of patients, users and other persons to radiation should be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**

  - **"Where devices are designed to emit hazardous levels of 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 and tolerance of relevant variable parameters."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **“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.**
  - **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 possible.”**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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.**
  - **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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. Devices incorporating electronic programmable systems 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 possible consequent risks."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **“…. 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.”**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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 minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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 correctly.**
  - **"….. 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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimise all possible risks.**
  - **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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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. ….**
  - **…. 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."**

Essential Principles of Safety and Performance

- **Document overview – Design and construction:**
  - **"…. 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."**

Essential Principles of Safety and Performance

- **Document overview – Information supplied by the manufacturer:**
  - **"…. Each device should be accompanied by the information needed to identify the manufacturer, to use it safely and to ensure the intended performance, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use, and should be easily understood."**
    - **Note: Separate SG-1 draft guidance document**

Essential Principles of Safety and Performance

- **Document overview – Clinical evaluation:**
  - **"Where conformity with these Essential Principles should be based on clinical evaluation data, such data should be established in accordance with the relevant requirements applicable in each jurisdiction.**
  - **Clinical investigations on human subjects should be carried out in accordance with the Helsinki Declaration ……"**

Essential Principles of Safety and Performance

- **Summary:**
  - **Essential Principles form foundation of harmonised approach to medical device regulation**
  - **Comprehensive in scope**
  - **Cover safety and performance**
  - **Define design requirements**
  - **Do not define methods of demonstrating and documenting compliance**
    - **Often covered by international standards**

Essential Principles of Safety and Performance

- **Summary:**
  - **Flexible to accommodate advances in the state of the art and new medical devices**
  - **Recognise risks and benefits associated with medical devices**
  - **Are founded on risk management principles**
  - **Essential Principles are intimately linked to the manufacturer's quality system for design and manufacture**

Essential Principles of Safety and Performance

- **Summary:**
  - **Well-established in regulatory systems in other regions**
  - **Provide basis for free trade in medical technology**