GHTF Study Group 1 Guidance: *Summary Technical Documentation*

Asia Harmonisation Working Party – Technical Committee Meeting and Workshop

Kuala Lumpur, Malaysia; 6-7 September 2001

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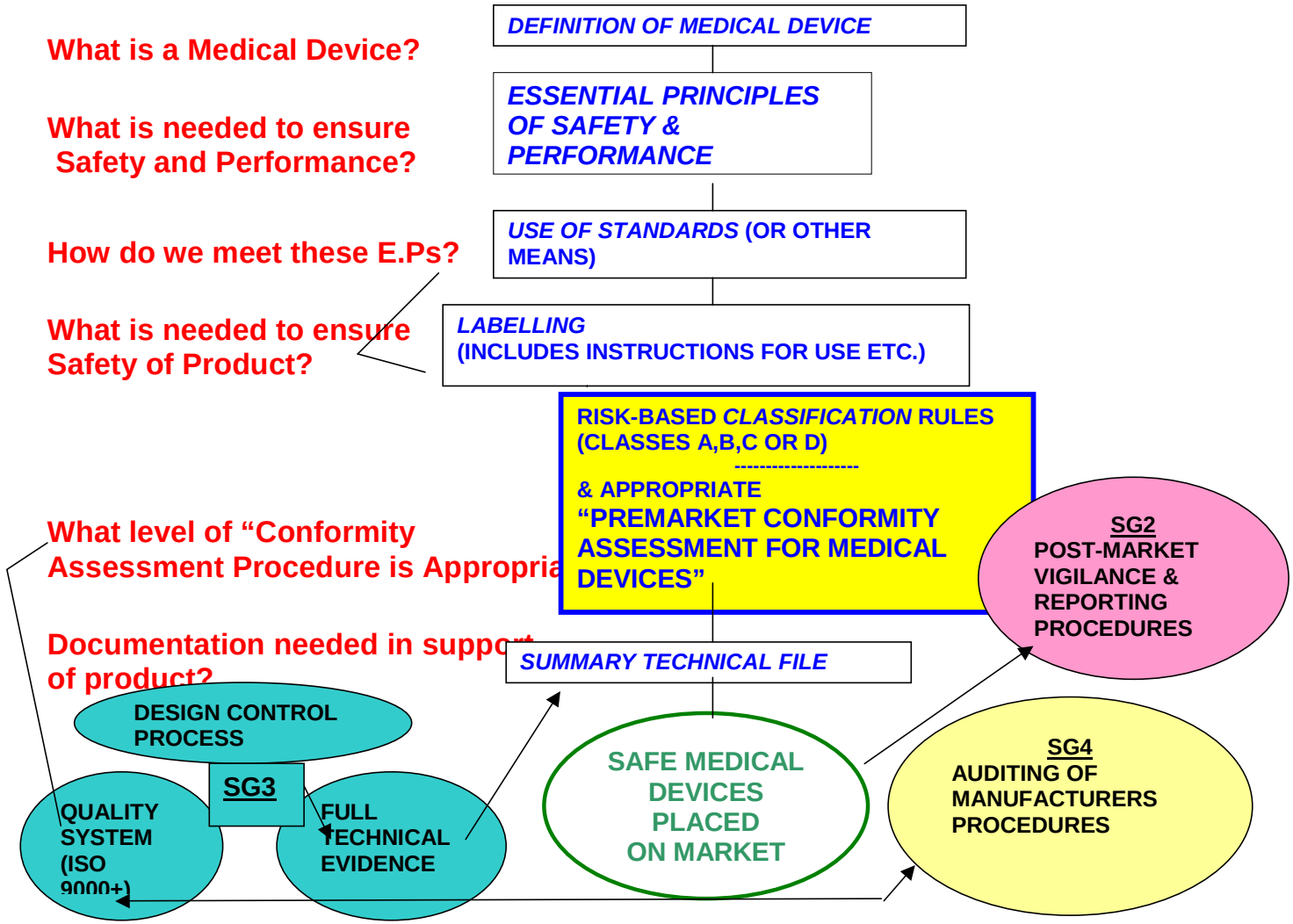
Summary Technical Documentation

- **Presentation overview:**
  - **Reference document**
  - **Document overview**
  - **Pilot study of STED use**

SCOPE OF GHTF-SG1 PREMARKET TECHNICAL REQUIREMENTS



Summary Technical Documentation

- **Preface:**
  - **“The document is intended to provide non-binding guidance to Regulatory Authorities for use in the regulation of medical devices and has been subject to consultation throughout its development and endorsement by the current Chair. Endorsement by the Chair signifies acceptance by consensus amongst members of the GHTF Steering Committee, as a document to be promoted by all members of the GHTF. …..**

Summary Technical Documentation

- **Preface:**
  - **…. The primary way in which the Global Harmonization Task Force (GHTF) achieves its goals is through the production of harmonized guidance documents suitable for implementation or adoption by member Regulatory Authorities or by nations with developing regulatory programmes.”**

Summary Technical Documentation

- **Introduction:**
  - **"The GHTF has identified as a priority the need to harmonize the documentation of evidence of conformity to regulatory requirements.**
  - **Differences in documentation requirements necessitate additional work for the same device in different jurisdictions, increase costs and between countries pose barriers to the timely international access to medical devices. The barriers also have economic impact."**

Summary Technical Documentation

- **Document overview:**
  - **Guidance on summary technical documentation (STED)**
  - **For demonstrating device conformity with the *Essential Principles of Safety and Performance of Medical Devices***
  - **Describes format for harmonised STED**
  - **General recommendations on content**

Summary Technical Documentation

- **Document overview:**
  - **Guidance applies to all "medical devices" except *in vitro* diagnostic medical devices**
    - **IVDMD may be added in future**
  - **Document does not recommend any new or additional technical documents above those which should be created by the manufacturer to comply with existing requirements to demonstrate conformity**

Summary Technical Documentation

- **Document overview:**
  - **This STED is not a:**
    - **Device master record**
    - **Device history record**
    - **Quality system record**
    - **Design history file**
    - **Design dossier**
      - **Refer to GHTF SG-3 documents and national requirements**
  - **STED may contain, or refer to, elements of above**

Summary Technical Documentation

- **Document overview:**
  - **"…. based upon the goal of both regulators and manufacturers to strive for the least burdensome means to demonstrate conformity to the *Essential Principles* for all classes of medical devices."**
  - **As an interim measure until full global harmonization of documentation requirements is achieved, the precise content of the STED …. will need to be augmented by documentation required by country-specific regulations and regulatory guidance."**

Summary Technical Documentation

- **Document overview:**
  - **"…. The regulatory requirements of some countries may not, at present, reflect the contents of this document. Regulatory Authorities with existing systems are also encouraged to consider adopting this system. It is the goal of the GHTF that country-specific divergences will ultimately be reduced to a minimum."**

Summary Technical Documentation

- **Document overview - Definitions:**
  - **Clinical investigations: "any specific study in human subjects undertaken to verify the safety and performance of a specific medical device under normal conditions of use."**
  - **Conformity assessment: "the systematic examination to determine the extent to which a medical device fulfils specified requirements."**

Summary Technical Documentation

- **Document overview - Definitions:**
  - **Conformity Assessment Body (CAB): "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 that will ensure performance of the CAB is monitored and, if necessary, withdrawal of designation."**

Summary Technical Documentation

- **Document overview - Definitions:**
  - **Design Dossier: "documentation the manufacturer is required to submit to a Conformity Assessment Body to demonstrate conformity of:**
    - **Certain high risk medical devices with requirements specified in Annex II of the European Directive Concerning Medical Devices**
    - **Active implantable medical devices with requirements specified in Annex II of the European Directive Concerning Active Implantable Medical devices.**
  - **It is also a general term applied to device design records."**

Summary Technical Documentation

- **Document overview - Definitions:**
  - **Regulatory Authority: "a government agency or other entity, that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and to take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements."**

Summary Technical Documentation

- **Document overview - Definitions:**
  - **Summary Technical Documentation: "an abstract of the complete technical records. It is held for conformity assessment purposes."**
  - **Technical Documentation: "documentation required by the European Directives to assess conformity of the medical device with the regulations. Also, general terms describing premarket records."**

Summary Technical Documentation

- **Document overview - Definitions:**
  - **“Other terms used in this Summary Technical Document Guidance are derived from *ISO 8402 – Vocabulary*.”**

Summary Technical Documentation

- **Document overview – Intended use of STED:**
  - **"…. The STED is intended for conformity assessment purposes.**
  - **The manufacturer creates the STED to demonstrate to a Regulatory Authority that the subject medical device is in conformity with the Essential Principles. ….**

Summary Technical Documentation

- **Document overview – Intended use of STED:**
  - **"…. The STED can be ….**
    - **a tangible set of documents all centrally located, or**
    - **a "virtual" set of documents, i.e., an STED with a summary document centrally located but with sections at various locations within the company, at the discretion of the manufacturer.**

Summary Technical Documentation

- **Document overview – Intended use of STED:**
  - **"…. 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 Regulatory Authority or a Conformity Assessment Body before the applicable device is placed on the market."**

Summary Technical Documentation

- **Document overview – Intended use of STED:**
  - **"…. 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 Regulatory Authority or Conformity Assessment Body 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."**

Summary Technical Documentation

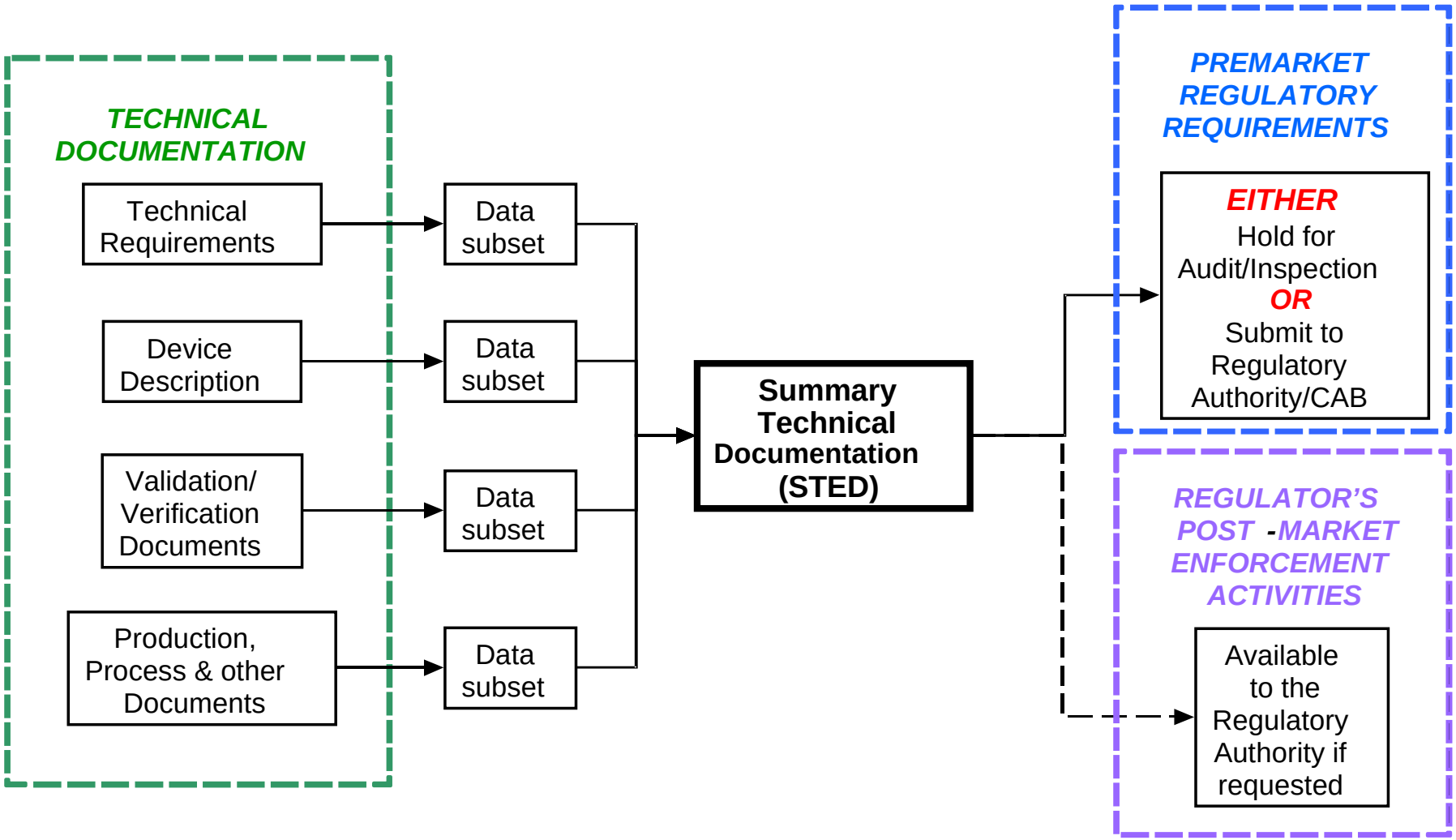


FIGURE 1: SOURCE AND APPLICATION OF THE STED

Summary Technical Documentation

Appendix A2

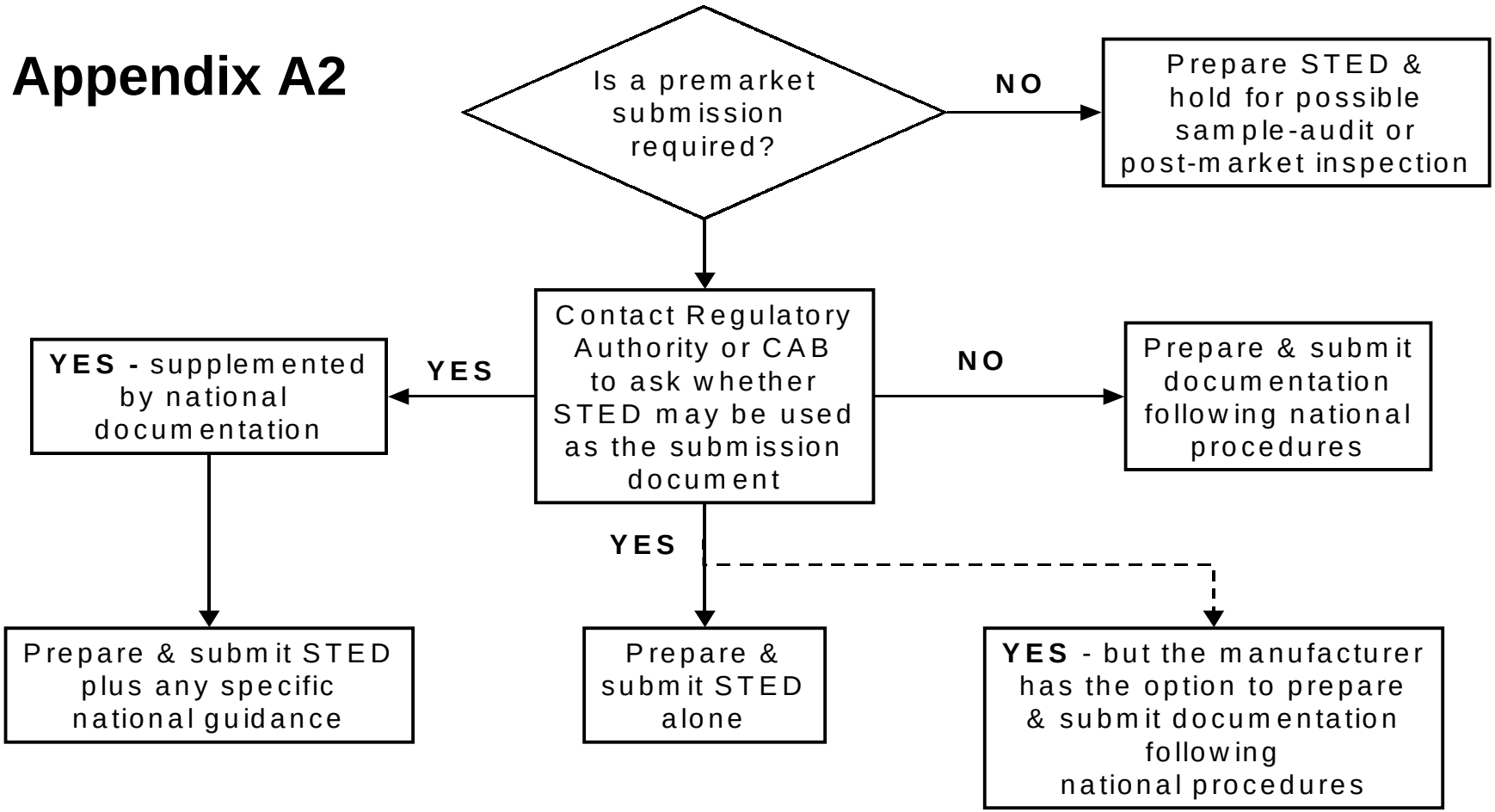


FIGURE 2: DECISION MAKING PROCESS

Summary Technical Documentation

- **Document overview – Intended use of STED:**
  - **STED contains:**
    - ***Essential Principles* and evidence of conformity**
    - **Device description**
    - **Summary documents of pre-clinical design verification and validation**
    - **Labelling**
    - **Risk analysis**
    - **Manufacturing information**

Summary Technical Documentation

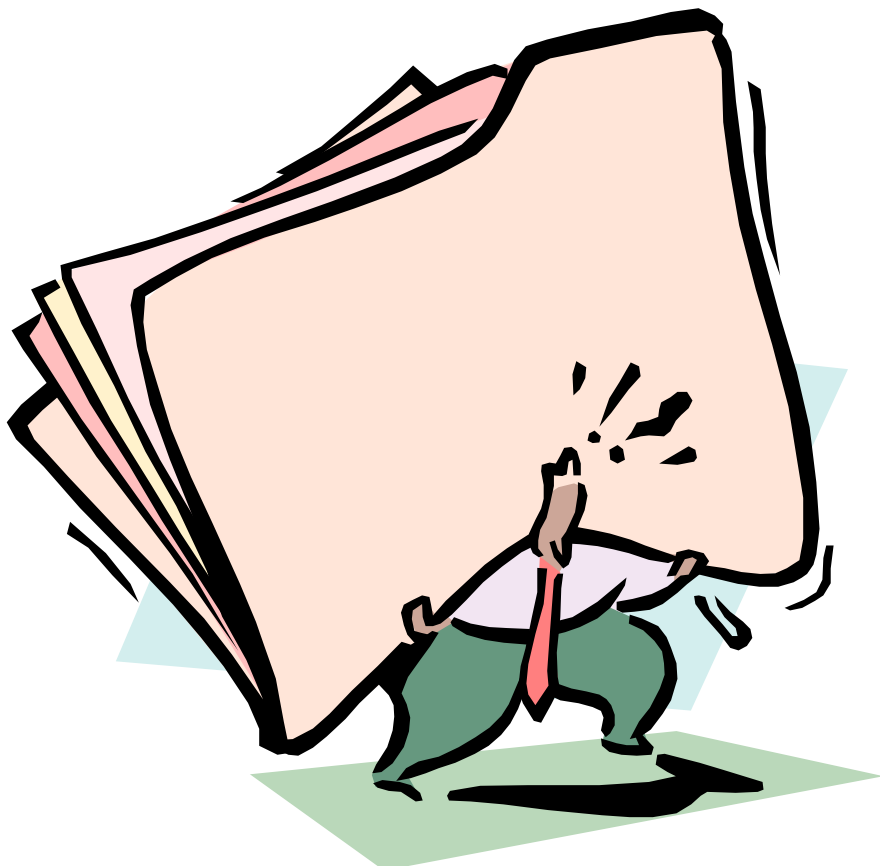
- **Document overview – Intended use of STED:**
  - **Basic format when premarket submission is not required**
    - **Option 1: total documentation, held in central location**
    - **Option 2: based on summary documentation**
    - **Option 3: abbreviated STED (refers to documents held in other locations)**
    - **Option 4: combination STED**

Summary Technical Documentation

- **Document overview – Intended use of STED:**
  - **Basic format when premarket submission is required**
    - **Required information**
    - **Cover page**
    - **Executive summary**

Summary Technical Documentation

- **Document overview – Elements of STED:**



Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **"…. 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 standards[1], state of the art or internal industry methods, comparisons to other similar marketed devices, etc.**

[1] Refer to SG1/N012 on the *Role of Standards in the Assessment of Medical Devices*.

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **STED should identify the specific documents related to the method used to demonstrate conformity to the *Essential Principles*.**
    - **when the manufacturer uses international or other standards, 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.**

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **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.**
    - **See Appendix B**

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **Device Description**
    - **The STED should summarize or reference or contain the following device description data, to the extent appropriate to the complexity and risk class of the device:**
      - **Functional purpose of the device (intended use)**
      - **Intended patient population(s) and medical conditions(s) to be diagnoses and/or treated (indications for use)**
      - **Reasonably foreseeable medical conditions for which device not to be used (contraindications)**

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **Device Description (continued)**
    - **General description of device, including principles of operation**
    - **Explanation of any novel features**
    - **Accessories, and other devices intended to be used in combination**
    - **Variants of device, e.g., size range**
    - **General description of each of functional parts/components**
    - **Other descriptive information, e.g., anatomical location, attachment mechanisms**
    - **Comparisons to other devices**

Summary Technical Documentation

- Document overview – Elements of STED:
  - Device Description
    - Materials:
      - Description of materials and their physical properties (to extent necessary to demonstrate conformity)
    - Specifications
      - Functional characteristics and technical performance specifications
      - Other, e.g., chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage, transport, packaging

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **Summary of design verification and validation:**
    - **STED should summarise, refer to, or contain design verification and design validation data**
      - **Linked to complexity and risk class of device**
      - **Typically includes:**
        - **Declarations or certificates of conformity to "recognised" standards applied**
        - **Summaries or reports of tests and evaluations**

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **Data summaries or test reports and evaluations typically include:**
    - **Listing and conclusions of published reports that concern safety and performance**
    - **Engineering tests**
    - **Laboratory tests**
    - **Biocompatability tests**
    - **Animal tests**
    - **Simulated use**
    - **Software validation**

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **Clinical evidence**
    - **"…. 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.**

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **Clinical evidence**
    - **Clinical investigation is most likely to be needed for higher risk class devices, or for devices where there is little or no clinical experience”**

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **Labelling: Include or refer to:**
    - **labels on the device and its packaging;**
    - **instructions for use;**
    - **other literature or training materials;**
    - **instructions for installation and maintenance[1];**
    - **Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform.**

[1] Refer to SG1/N009 *Labelling for Medical Devices*

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **Risk analysis: Include or refer to:**
    - **Results of the risk analysis**
    - **Risk analysis should be based upon international or other recognised standards, and be appropriate to the complexity and risk class of the device.**

Summary Technical Documentation

- **Document overview – Elements of STED:**
  - **Manufacturer information**
    - **documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device**

Summary Technical Documentation

Example: Essential Principles Conformity Checklist

Essential Principle	Applicable to device?	Method of Conformity [1]	Identity of Specific Documents
1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes		
2. 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: • 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.	Yes		

Summary Technical Documentation

- **STED pilot study**
  - **Intended to assess adequacy, completeness, utility, and practicality of proposed harmonised STED**
  - **First pilot study (1999-2000)**
    - **Devices already in market in Founder Member countries/regions**
    - **Selected devices of all classes**
    - **Volunteer manufacturers**
    - **Manufacturers prepared sample STEDs**

Summary Technical Documentation

- **STED pilot study**
  - **First pilot study (1999-2000)(continued)**
    - **Reviewers in each country/region assessed adequacy of documentation**
    - **No judgment on premarket approval**
    - **Revised draft STED**

Summary Technical Documentation

- **STED pilot study**
  - **Second pilot study (2001)**
    - **US FDA published notice of proposed pilot study in *Federal Register* 25 July 2001**
      - **Only certain devices, in certain divisions, eligible**
      - **If documentation adequate, would lead to premarket approval or clearance**
      - **Waiting for public comments (24 Sept. 2001)**
    - **Australia TGA has announced its intention to participate in pilot study**
    - **Others?**

Summary Technical Documentation