１２．８．２　機器は、危険が及ぶ恐れのある不正確な供給量を防止及び／又は警告する手段を備えるべきである。；機器は、エネルギー源及び／又は物質の供給源から危険なレベルのエネルギーが偶発的に放出するのを可能な限り防止できるように適切な手段を講ずるべきである。

１２．８．３　制御・表示機能については、その意味が機器上に明示されるべきである。機器が、視覚によるシステムで、その操作に必要な指示をしたり、操作又は調整のパラメータを示す場合、それらの情報は、使用者及び、適切な場合には、患者に理解できるようにすべきである。

製造業者により提供される情報

１３．１　各々の機器は、製造業者を識別し、予想される使用者の訓練又は知識の程度に応じて、当該機器を安全に使用し、かつ意図した性能を確保するうえで必要となる情報を伴うべきである。この情報は、ラベル上の詳細及び取扱説明書内のデータから構成され、容易に理解されるべきである。

（注：　ラベリング要求事項に関する詳細情報は、別のドキュメントの主題である。）

臨床評価

１４．１　この基本要件への適合性が臨床評価データに基づく場合、そのデータは各々の国で適用される関連要求事項に従って確立されるべきである。

ヒトを被験者とする臨床評価は、１９６４年、フィンランド、ヘルシンキの第１８回世界医学総会で採択されたヘルシンキ宣言、並びに１９８９年、香港の第４１回世界医学総会で改訂された修正条項に従って実施されるべきである。人体の保護に関するすべての方策は、ヘルシンキ宣言の精神に則って実行することが義務づけられている。これは、最初の研究の必要性及び正当づけの考察から研究結果の公表まで、臨床研究におけるすべての段階を含む。これに加えて、研究プロトコールの事前審査又はインフォームドコンセントについては、特別に法的要求事項を定めている国があるかもしれない。

（注：　将来、臨床評価について特別なガイダンスが作成されるかもしれない。）

98/12 SG1ロンドン会議での検討結果
改訂済ドキュメント

GHTF.SG1.N020R3
8 DECEMBER 1998

GLOBAL HARMONIZATION TASK FORCE

STUDY GROUP 1

FINAL WORKING DRAFT

Essential Principles of Safety and Performance of Medical Devices

This Essential Principles of Safety and Performance of Medical Devices 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 (CABs) 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. The regulatory requirements of some countries may not, at present, reflect the contents of this document.

FOREWORD

"Essential Principles of Safety and Performance of Medical Devices on a Global Basis"

Study Group 1 recognizes that to further the processes of global harmonization of regulatory requirements, it is necessary to have common guidelines to indicate the Essential Principles of safety and performance of medical devices in the interests of public health.

Existing regulations and draft regulations of participating members of the Task Force have already included, in many cases, such statements of principles and it has been the conclusion of the Study Group that, although presented in different ways, the features of such principles are common to all such regulations.

For these reasons, Study Group 1 proposes that the following set of principles should be considered in the development or amendment of regulatory systems.

Additionally, the Study Group, having established these Essential Principles, recommends that regulatory agencies consider accepting technical documentation prepared in accordance with these Essential Principles in order to support market entrance of medical devices.

NOTE: (1) There may be further safety and performance principles for devices incorporating substances derived from tissues of human or animal origin and in vitro diagnostic devices. This may suggest the need for additional review of this Essential Principles document by the Study Group in the future.
(2) It is understood that the operation of a quality 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 not addressed within this document.
(3) Information on labelling requirements are the subject of a separate document.

GLOBAL HARMONIZATION TASK FORCE
STUDY GROUP 1

ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

GENERAL REQUIREMENTS

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

2. The solutions adopted by the 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.

3. 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.

4. The characteristics and performances referred to in Clauses 1, 2 and 3 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.

5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

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

REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

Chemical, physical and biological properties

7.1 The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section I 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 and body fluids, 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.

7.2 The devices should be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to 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.

7.3 The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products

concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

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

7.5 The devices should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances that may leach from the device.

7.6 Devices should be 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.

Infection and microbial contamination

8.1 The devices and manufacturing processes should be 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.

8.2.1 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. 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.

8.2.2 In some jurisdictions products incorporating human tissues, cells and substances may be considered medical devices. In this case, 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 viral inactivation in the course of the manufacturing process.

8.3 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.

8.4 Devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.

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

8.6 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.

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

Construction and environmental properties

9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.

9.2 Devices should be designed and manufactured in such a way as to remove or minimise as far as is practicable:

- 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 environmental conditions,

such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,

- 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.

9.3 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 flammable substances or to substances which could cause combustion.

Devices with a measuring function

10.1 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.

10.2 The measurement, monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3 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

Protection against radiation

11.1 General

11.1.1 Devices should be 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.

11.2 Intended radiation

11.2.1 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.

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

11.3 Unintended radiation

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

11.4 Instructions for use

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

11.5 Ionizing radiation

11.5.1 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.

11.5.2 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.

11.5.3 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.

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

12.1 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.

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

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

12.4 Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health

12.5 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.

12.6 Protection against electrical risks

12.6.1 Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.

12.7 Protection against mechanical and thermal risks

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

12.7.2 Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified

performance.

12.7.3 Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

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

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

12.8 Protection against the risks posed to the patient by energy supplies or substances.

12.8.1 Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

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

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

Information supplied by the manufacturer

13.1 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: Detailed information on labelling requirements is the subject of a separate document)

Clinical Evaluation

14.1 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 evaluations on human subjects should be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in 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: Specific guidance on clinical evaluation may be developed in the future)

資料	I.2.1

GHTF.SG1.N012R6
9 December 1998

市販前において医療機器の要求事項への適合性をドキュメントするための

テクニカルファイル

第一巻

サマリーテクニカルファイル

和訳責任者：　日医機協グローバル整合部会　吉田　正人

はじめに

グローバルハーモナイゼーション・タスクフォース（ＧＨＴＦ）の目的は、医療機器の規制システムの進展に伴い、グローバルなレベルで集合性を推奨することである。それは、一方において最も適切と考えられる規制の手段により国民一般の健康を保護する参加メンバー国の権利を留保しながらも、貿易を促進することである。これを達成するには、医療機器の規制のために確立されたシステムにおける技術的、法規制的差異の進歩的な縮小を手助けするために、国際的な協力の領域を確認し、発展させることである。

ＧＨＴＦは、市販前の法的要求事項と手順の整合化の必要性を優先事項として確認した。これらの規制と手順の違いは、医療機器のタイムリーな国際市場へのアクセスの障壁をもたらす。その障壁は経済的なインパクトも与える。

「医療機器の市販前適合性評価のためのサマリーテクニカルファイル」と題するこのガイダンスドキュメントは、市販前の障壁を扱うものである。それは、規制を受ける企業、ＧＨＴＦ参加国の行政当局、これに加えて市販前法規制手順の整合化に興味をもつ他の国によって利用されることが意図されている。このガイダンスには次の情報が含まれる。

第一巻

サマリーテクニカルファイルは、適合性評価の目的のために医療機器から得られた技術情報のサマリーに対する共通フォーマットのガイダンスを提供する。このガイダンスの付属書には、情報となる参照や背景となる情報が提供されている。

重　要：　サマリーテクニカルファイルの中で得られる情報の性質は、医療機器のカテゴリー、関連する基本要件（エッセンシャルプリンシプル）、製品のリスククラスによっても異なることから、テクニカルファイルに含まれる情報の量と詳しさは、かなり変わるかもしれない。にもかかわらず、製造業者は、このドキュメントにリストされた技術的要求事項に含まれるすべての項目を精査し、問題を適切に処理すべきである。

第二巻

個々の国の特殊な補足的情報には、行政当局から提供されたサマリーテクニカルファイルの各セクションに関連する情報が含まれている。その国の特殊な情報は、第一巻で記載された共通フォーマットの情報に加えて扱われなくてはならない。

第一巻

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サマリーテクニカルファイルの内容

A. 技術的要求事項

1. 規格と法規制に関する情報

サマリーテクニカルファイル（ＳＴＦ）は、設計、安全性又は性能の許容度及び合否判定基準を含めて技術的要求事項をドキュメントすべきである。設計のインプット及びアウトプットに適用される技術的要求事項を含めた設計管理に関する詳しい情報は、スタディグループ３からのガイダンスを参照すること。ＳＴＦは例えば次の事項をドキュメントすべきである。

技術規格

・規格の全標題、識別番号、規格の公表日、及び規格を作成した組織

・規格が適用されるテクニカルファイルのセクションにおいて、機器の設計と試験のために使用される製造業者の内部「規格」の完全なドキュメンテーション、又はその他の解決法

・製造業者により全部又は一部が適用され、行政当局により容認された「認知」規格の場合、行政当局により特定された内容及びフォーマットを用いた「認知」規格への適合性宣言

注： 医療機器の評価における規格の役割に関するガイダンスは、付属書Ｃを参照すること。

医療機器と組み合わせの医薬品又は生物製剤

・医療機器の一部として含まれる、又は機器と共に使用されるか、若しくはそれに接触するかもしれない医薬品の技術的要求事項（即ち、医薬品又は生物製剤を注入するための注射筒又はポンプ）

・組み合わせられた機器、医薬品又は生物製剤の意図された使用が、主として機器の要求事項及び基本要件に該当するためには、医療機器の法的な定義に適合しなくてはならない。（さもなければ、その製品には、医薬品又は生物製剤の要求事項が適用されるかもしれない。）

個々の国の特殊な法的要求事項及びガイダンス

・機器の設計及び試験の法的要求事項。市販前テクニカルファイルを行政当局又は適合性評価機関に提出する場合、機器を市販することが意図された国で適用される要求事項（その機器に関連する一般的かつ特別な法的要求事項をリストすること。）

・行政当局又は適合性評価機関によって提供され、テクニカルドキュメンテーションを作成する場合に利用される他のガイダンス又は指導

注：　このドキュメントの第二巻を参照すると、関連する個々の国の特殊な法的要求事項が提供されている。

2．　医療機器の安全性及び有効性の関連基本要件

ＳＴＦは次の事項をドキュメントすべきである。

・その機器に適用されるＧＨＴＦ医療機器の安全性及び有効性の関連基本要件

・各基本要件に関連するデータと情報の所在を明確にするために、サマリーテクニカルファイルのページの他所参照

注：　「医療機器の安全性及び有効性の基本要件」と題するドキュメントは、付属書Ｂを参照すること。

3．　設計特性の根拠と正当づけ

ＳＴＦは、次の要素を勘案して特定機器の設計特性の根拠と正当づけをドキュメントすべきである。

機能的要求事項

・機能的特色
・意図された適用
・意図された使用条件
・リスクと関連づけた患者への意図された利益

性能的要求事項

・原材料の生体適合性
・原材料の物理的、機械的、化学的性質
・原材料の強度
・機器の磨耗による影響
・滅菌を含めた製造プロセスによる原材料及び機器性能への影響
・構成原材料と他の原材料・物質との間の相互作用による機器及びその機能への影響
・相互に結合した部品とそれらの影響
・寸法と重量及びそれらの影響
・機器全体の生体適合性
・環境による機器への影響（例、温度、衝撃、振動、湿度、電磁両立性）
・電気的要求事項
・携帯の可能性
・身体の生理機能又は構造に影響するアウトプツト
・機器の留置、除去及び置換の可能性
・微生物及び微粒子の汚染による影響
・保管・輸送用包装の安定性
・操作の制限
・速度
・応答時間
・正確度
・感度
・信頼性
・特殊性

インターフェース要求事項

・ヒューマンファクター
・他のシステムとの両立性
・機器への電気的、物理的又は化学的インプット