



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

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Medical Devices

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Preface

The document herein was produced by the Asian Harmonization Working Party (AHWP), a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

There are no restrictions on the reproduction, distribution, translation or use of this document. However, incorporation of this document, in part or in whole, into any other document does not convey or represent an endorsement of any kind by the AHWP.

This document has been developed by AHWP using the GHTF Final Document GHTF/SG1/N68:2012 of GHTF Study Group 1. This GHTF document is now available on the IMDRF website.

The appendix in this guidance has been consolidated by WG1a, as a recommendation to the readers on how to identify applicable EP and use related standards to conduct the safety and performance evaluation for IVD medical devices.

1. Introduction

The primary way in which the AHWP achieves its goals is through the production of a series of guidance documents that together describe a regulatory framework for IVD medical devices. The purpose of such guidance is to harmonize the documentation and procedures that are used to assess whether an IVD medical device conforms to the regulations that apply in each jurisdiction. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This document has been developed to encourage and support convergence of regulatory systems in the AHWP member economies. It is intended for use by Regulatory Authorities (RAs), 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 IVD medical devices in the interest of public health. It seeks to strike a balance between the responsibilities of RAs to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the industry.

This guidance document describes fundamental design and manufacturing requirements, referred to as 'Essential Principles of Safety and Performance' that, when met, indicate a medical device is safe and performs to its specification.

Where other guidance documents within the series are referenced within this text, their titles are italicised for clarity.

Work Group 1a of the AHWP has prepared this guidance document. Comments or questions should be directed to the Chair of AHWP Work Group 1a whose contact details may be found on the AHWP web page¹.

2. Rationale, Purpose and Scope

2.1 Rationale

The worldwide adoption of fundamental design and manufacturing requirements for IVD medical devices that, when met, provide assurance the device is safe and performs to its specification, offers significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities. Eliminating or reducing differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

2.2 Purpose

To identify and describe six general essential principles of safety and performance and to identify and describe additional essential principles of safety and performance which need to be considered during the design and manufacturing process.

Note: during the design process, the manufacturer² selects which of the listed design and manufacturing principles apply to the particular medical device and documents the reasons for excluding others.

¹ www.ahwp.org

² For the definition of manufacturer see GHTF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer*. AHWP will develop guidance later on.

2.3 Scope

This document applies to all products that fall within the definition of an IVD medical device.

3. References

GHTF final documents³

GHTF/SG1/N78:2012 *Principles of Conformity Assessment for Medical Devices.*

GHTF/SG1/N70:2011 *Label and Instructions for Use for Medical Devices.*

GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices.*

GHTF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer.*

GHTF/SG1/N046:2008 *Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices*

GHTF/SG5/N6:2012 *Clinical Evidence for IVD Medical Devices - Key Definitions and Concepts*

GHTF/SG5/N7:2012 *Clinical Evidence for IVD Medical Devices - Scientific Validity Determination and Performance Evaluation.*

GHTF/SG5/N8:2012 *Clinical Performance Studies for In Vitro Diagnostic Medical Devices*

International standards

ISO 14971:2007 *Medical Devices – Application of Risk Management to Medical Devices.*

4. Definitions

Analytical performance: the ability of an IVD medical device to detect or measure a particular analyte.

Clinical evidence for an IVD medical device: all the information that supports the scientific validity and performance for its use as intended by the manufacturer.

Clinical performance of an IVD medical device: the ability of an IVD medical device to yield results that are correlated with a particular clinical condition/physiological state in accordance with target population and intended user.

Harm: physical injury or damage to the health of people or damage to property or the environment

Hazard: potential source of harm.

³ The listed documents are subject to periodic review and may be superseded by later documents. GHTF documents are now maintained by IMDRF and the reader is encouraged to refer to the IMDRF website www.imdrf.org to confirm whether the referenced documents remain current. AHWP will develop AHWP guidance documents at a later moment.

Intended use / purpose: the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer

In Vitro Diagnostic (IVD) medical device: suggest to include the definition of an IVD medical device here in the absence of an AHWP definition document.

IVD medical device for self-testing: any IVD medical device intended by the manufacturer for use by lay persons.

Lay person: individual that does not have formal training in a relevant field or discipline.

Manufacturer: refer to GHTF/SG1/N055:2009 Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer.

Medical device: suggest to include the definition of a medical device here in the absence of an AHWP definition document.

Performance evaluation for an IVD medical device: assessment and analysis of data to establish or verify the performance of an IVD medical device.

Regulatory Authority (RA): 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.

Risk: combination of the probability of occurrence of harm and the severity of that harm.

Specimen: the discrete portion of a body fluid or tissue or other sample associated with the body taken for examination, study, or analysis of one or more quantity or characteristic to determine the character of the whole.

5. Safety and Performance of Medical Devices – General Principles

A manufacturer of an IVD medical device is expected to design and manufacture a product that is safe and performs as intended. This guidance document describes fundamental design and manufacturing requirements, referred to as ‘Essential Principles of Safety and Performance’, to ensure this outcome.

The medical device manufacturer’s design and manufacturing activities are under the control of its quality management system. Conformity of the IVD medical device to all the applicable Essential Principles will be demonstrated and assessed according to procedures designated by the Regulatory Authority and described in other AHWP guidance.

General Essential Principles

- A1 IVD 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, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and 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.
- A2 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 risks so that the residual risk 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 reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and
 - inform users of any residual risks.
- A3 IVD Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.
- A4 The characteristics and performances referred to in Clauses A1, A2 and A3 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.

- A5 IVD Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.
- A6 All known and foreseeable risks, and any undesirable effects, should be minimised and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.

6. Essential Principles applicable to IVD Medical Devices

Design and Manufacturing Essential Principles

The design and manufacturing principles listed in this Section of the document are additional to the general principles of safety and performance listed in Section 5.

C1 Chemical, physical and biological properties

- C1.1 The IVD medical devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section 6. Particular attention should be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of its intended purpose.
- C1.2 The IVD medical devices should be designed, manufactured and packaged 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 device.
- C1.3 The IVD medical 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 IVD medical device. Special attention should be given to substances which are carcinogenic, mutagenic or toxic to reproduction.
- C1.4 IVD medical 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 IVD medical device taking into account the device and the nature of the environment in which it is intended to be used.

C2 Infection and microbial contamination

- C2.1 The IVD medical 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 user, professional or lay, or, where applicable, other person .
The design should:

- allow easy and safe handling;

and, where necessary:

- reduce as far as reasonably practicable and appropriate any microbial leakage from the IVD medical device and/or microbial exposure during use; and
- prevent microbial contamination of the IVD medical device or specimen where applicable, by the user, professional or lay, or other person.

C2.2 IVD medical devices labelled either as sterile or as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.

C2.3 IVD medical devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.

C2.4 IVD medical devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

C2.5 Packaging systems for non-sterile IVD medical devices should maintain the integrity and cleanliness of the device.

C3 IVD medical devices incorporating materials of biological origin

C3.1 Where IVD medical devices include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety for user, professional or lay, or other person.

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. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals.

C3.2 Where IVD medical devices include human tissues, cells and substances, 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 for user, professional or lay, or other person.

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. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

C3.3 Where IVD medical devices include cells and substances of microbial origin, the processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for user, professional or lay, or other person.

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. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

C4 Environmental properties

C4.1 If the IVD medical device is intended for use in combination with other devices or equipment, the whole combination, including the connection system 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.

C4.2 IVD medical devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:

- C4.2.1 the risk of injury to user, professional or lay, or other person in connection with their physical and ergonomic features;
- C4.2.2 the risk of use error due to the ergonomic features, human factors and the environment in which the IVD medical device is intended to be used;
- C4.2.3 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 thereof;
- C4.2.4 the risks associated with the use of the IVD medical device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use;
- C4.2.5 the risk associated with the possible negative interaction between software and the environment within which it operates and interacts;
- C4.2.6 the risks of accidental penetration of substances into the IVD medical device;
- C4.2.7 the risk of incorrect identification of specimens/samples;
- C4.2.8 the risks of reasonably foreseeable interference with other devices such as carry over between IVD medical devices.

C4.3 IVD medical 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 IVD medical devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

C4.4 IVD medical devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.

C4.5 IVD medical devices should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

C5 Performance characteristics

C5.1 IVD medical devices should be designed and manufactured in such a way that the performance characteristics support the intended use, based on appropriate scientific and technical methods. In particular, where appropriate, the design should address sensitivity, specificity, accuracy which is trueness and precision (repeatability and reproducibility), control of known relevant interference and limits of detection.

These performance characteristics need to be maintained during the lifetime of the IVD medical device as indicated by the manufacturer.

C5.2 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 available reference measurement procedures and/or available reference materials of a higher order.

C5.3 Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device.

Note: While AHWP WG 1a generally supports convergence on the global use of internationally standardised measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognised measurement units.

C6 Protection against radiation

C6.1 IVD medical devices should be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other person to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as reasonably practicable and appropriate.

C6.2 When IVD medical devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should as far as reasonably practicable and appropriate be:

- designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and
- fitted with visual displays and/or audible warnings of such emissions.

C7 IVD medical devices that incorporate software and standalone IVD medical device software

C7.1 For IVD medical devices which incorporate software or for standalone software that are IVD medical devices in themselves, the software must be validated according to the

state of the art taking into account the principles of development lifecycle, risk management, verification and validation.

C8 IVD medical devices connected to, or equipped with, an energy source

- C8.1 IVD medical devices where the safety of the patient depends on an internal power supply in the IVD medical device, should be equipped with a means of determining the state of the power supply.
- C8.2 IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably 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.
- C8.3 IVD medical 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.
- C8.4 IVD medical devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the IVD medical device is installed and maintained as indicated by the manufacturer.

C9 Protection against mechanical and thermal risks

C9.1 IVD medical devices should be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

C9.2 Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated.

C9.3 IVD medical 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.

C9.4 IVD medical 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.

C9.5 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to handle should be designed and constructed in such a way as to minimize all possible risks.

C9.6 IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the device are intended to be connected or reconnected before or during use.

C9.7 Accessible parts of the IVD medical 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.

C10 Protection against the risks posed by IVD medical devices for self-testing

C10.1 IVD medical devices for self-testing 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 lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.

C10.2 IVD medical devices for self-testing should be designed and manufactured in such a way as to reduce as far as reasonably practicable the risk of error by the lay person in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.

C10.3 IVD medical devices for self-testing should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.

C11 Label and Instructions for Use

C11.1 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 understood⁴.

⁴ Further information is provided in GHTF/SG1/N70:2011 *Label and Instructions for Use for Medical Devices*. AHWP will publish a *Label and Instructions for Use* guidance for IVD medical devices at a later moment.

C12 Clinical evidence including scientific validity, analytical performance and, where appropriate, clinical performance

C12.1 For an IVD medical device clinical evidence should be compiled based on AHWP guidance to be developed (use of GHTF guidance documents for IVD medical devices is recommended in the absence of the AHWP guidance). The clinical evidence should provide the scientific validity, a review of the analytical performance data and, where appropriate, clinical performance data in the form of any:

- literature;
- performance study reports; and
- experience gained by routine diagnostic testing.

to establish that the IVD medical device achieves its intended performance during normal conditions of use.

C12.2 Clinical performance studies using specimens from human subjects should be carried out in accordance with the spirit of the Declaration of Helsinki. This includes every step in the clinical performance study 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 informed consent.

9 Appendix (should be moved out and create a separate document)

Example--Essential Principles and related standards that apply to IVD medical devices

Essential Principles	Applicable to IVD Medical Devices ?	Related Standards
C1 Chemical, physical and biological properties	C12.2 Applicable : Reagents containing microbial agents, carcinogens, toxic substances, tissues/cells derived from human or animal sources, etc.	not for IVDs
C2 Infection and microbial contamination	Applicable : <ul style="list-style-type: none"> • Substances or microbial agents identification / concentration per unit • Sterility of vacutainers • Clinical lab practices 	EN 13641:2002; other applicable standards
C3 Medical devices incorporating materials of biological origin	Applicable : Product containing tissues/cells derived from human or animal sources, etc.	Applicable standards
C4 Manufacturing and environmental properties	Applicable : <ul style="list-style-type: none"> • Compatibility between reagent and instruments, orientation, connections, etc. • Handling, processing and disposal of hazardous materials • Clinical laboratory practices 	these standards are for medical devices not for IVD medical devices
C5 Performance Characteristics	Applicable : <ul style="list-style-type: none"> • Analytical and clinical performance characteristics • Use scenario (professional, OTC, etc.) 	*CLSI standards on performance characteristics; EN13612:2002; other product specific standards
C6 Protection against radiation	Applicable : <ul style="list-style-type: none"> • Proper handling, processing, labeling of RIA kits • Use scenario (professional, OTC, etc.) 	; IEC 61010-2-101:2002 60601 is for medical devices not for IVD
C7 IVD medical devices that incorporate software and standalone IVD medical device software	Applicable : <ul style="list-style-type: none"> • Instruments containing software or stand-alone software • Validation according to 	; *CLSI standards on performance characteristics; EN 13612:2002; other product specific standards

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	analytical and clinical performance characteristics of specific assays	
C8 IVD medical devices connected to, or equipped with, an energy source	Applicable : Instruments	; IEC 61010-2-101:2002
C9 Protection against mechanical and thermal risks	Applicable : Instruments	IEC 61010-2-101:2002
C10 Protection against the risks posed by IVD medical devices for self-testing	Applicable : <ul style="list-style-type: none"> • Self-testing devices which indicate parameters by means of visual system • Proper labeling including instruction for use and use of symbols 	EN ISO18113-4:2009; EN ISO 18113-5:2009; EN 13532:2002
C11 Label and Instructions for Use	Applicable : Proper labeling including instruction for use and use of symbols	EN ISO18113-1~5:2009; EN 980:2008 ISO 15223-1
C12 Performance evaluation including analytical performance and, where appropriate, clinical performance	Applicable : <ul style="list-style-type: none"> • Analytical and clinical performance characteristics • Use scenario (professional, OTC, etc.) 	*CLSI standards on performance characteristics; EN 13612:2002; EN 13640:2002; other product specific standards

* CLSI standards on performance characteristics

Performance Characteristics	Recognized Standards
Accuracy (trueness and precision)	CLSI EP5-A, CLSI EP12-A, CLSI EP15-A
Analytical sensitivity	CLSI EP12-A
Analytical specificity	CLSI EP7-A2
Linearity and measuring range	CLSI EP-6A
Limit of detection, limit of quantification of the method	CLSI EP-17A
Assay cut-off	CLSI GP10-A
Laboratory error, total analytical error	CLSI EP18-A, CLSI EP21-A
Stability	EN13640:2002
Interference	CLSI EP7-A2