

Comparison between KFDA and CE for system requirements



April 2011



Quality System of KFDA

Criteria for Evaluation for Compliance with the Manufacturing and Quality Management Standards for Medical devices and the Evaluation Sheet (Related to Paragraph 1 of Article 4)

[Attached Table 1]

1. Purpose

The purpose of these criteria is to specify requirements for the quality management system applicable as the Medical device manufacturer offers design, development, production, installation, and service of the Medical device.

2. Scope

If a requirement for 7. Product Realization is not applicable due to characteristics of the medical device, the manufacturer may exclude it in the quality management system. However, the manufacturer shall demonstrate that such exclusion is proper.

Quality System of KFDA

4. Quality management system

- 4.1 General requirements
- 4.2 Documentation requirements
 - 4.2.1 General
 - 4.2.2 Quality manual
 - 4.2.3 Control of documents
 - 4.2.4 Control of records

5. Management responsibility

- 5.1 Management commitment
- 5.2 Customer focus
- 5.3 Quality policy
- 5.4 Planning
 - 5.4.1 Quality objectives
 - 5.4.2 Quality management system planning
- 5.5 Responsibility, authority and communication
 - 5.5.1 Responsibility and authority
 - 5.5.2 Management representative
 - 5.5.3 Internal communication
- 5.6 Management review
 - 5.6.1 General
 - 5.6.2 Review input
 - 5.6.3 Review output

6. Resource management

- 6.1 Provision of resources
- 6.2 Human resources
 - 6.2.1 General
 - 6.2.2 Competence, awareness and training
- 6.3 Infrastructure
- 6.4 Work environment

7. Product realization

- 7.1 Planning of product realization
- 7.2 Customer-related processes
 - 7.2.1 Determination of requirements related to the product
 - 7.2.2 Examination of product related requirements
 - 7.2.3 Customer communication
- 7.3. Design and development
 - 7.3.1 Design and development planning
 - 7.3.2 Design and development inputs
 - 7.3.3 Design and development outputs
 - 7.3.4 Design and development review
 - 7.3.5 Verification of design and development
 - 7.3.6 Validation of design and development
 - 7.3.7 Control of design and development changes

8. Measurement, analysis and improvement

Quality System of KFDA

Import and Quality Management Standards Evaluation Criteria and Evaluation Sheet (Related to Paragraph 2 of Article 4)

[Attached Table 2]

1. Preparation and keeping of the Standard Manuals

The importer shall prepare the Manual of Product Specification and Manual of Import Management Standard to properly perform quality control of the imported medical device.

2. Manual of Product specification

The importer shall prepare the product specification for every product, and the product specification shall include the followings:

- A. Classification name and model name of the medical device
- B. Name of Manufacturer name and the country of production of the imported medical device;
- C. Appearance and structure, and the specification for in-house quality control testing specification of the finished product;
- D. Matters required to be mentioned on the medical device container etc. as provided in Articles 19 to 22 of the Act;
- E. Method and sequence of installation(only for medical devices requiring control of installation);
- F. Matters about method, criteria, and decision of sterilization (only for sterilized medical devices); and
- G. Enactor of the Product Specification and the date enacted(In case of amendment, the amender, the date amended and the reason for amendment shall be mentioned.)

Quality System of KFDA

3. Manual of Import Management Standard

The followings shall be included in the Manual of Import Management Standard

- A. Matters about product control and test;
- B. Matters about decision of the test result and handling of failed products ;
- C. Matters about control of the testing facilities;
- D. Means of contact with the manufacturer of the imported medical device;
- E. Checks on the manufacturing and quality control status of the manufacturer of the imported medical device; and
- F. An enactor of the Import Control Specification and the date enacted(In case of amendment, the amender, the date amended and the reason for amendment shall be mentioned.)

4. Designation of Quality Manager

The Importer shall designate 1(one) or more Quality Manager(s) per importing business, who will perform quality control services, and when 2(two) or more Quality Managers are designated, their duties shall be divided to clarify limitations of their responsibilities.

5. Duties of the Quality Manager

The quality manager shall:

- A. Keep and utilize the product specification and Import Management Standards to properly perform quality control
- B. Prepare work instruction based on the documents mentioned in sub-item A, and check and make sure that it is operated in compliance with the standards; and
- C. Ensure that the manufacturer of the imported medical device is conducting proper manufacturing and quality control.

Quality System of KFDA

6. Tasks for Quality Control of Imported Products

- A. Compliance of labeling and packaging of the imported medical device shall be checked, and the related record shall be written down.
- B. Administrative record on storage and release of the imported medical device and its accessories shall be prepared.
- C. To secure conformance of the quality control status in the manufacturing place of the imported medical device, documents that the quality control status in the manufacturing place where the imported medical device is manufactured is equivalent to the Standards for Manufacturing and Quality Management of Medical Devices of the Attached Table 3 or complies with the international standard, and shall be kept, as the one which are recognized by the government of the country of production, the agency authorized by the government of the country of production, or the KFDA Commissioner and is not later than 2(two) years(if a valid term is mentioned, the valid term shall not be exceeded).
- D. The product storage facilities shall be checked and the related record shall be written down.
- E. If the imported medical device is a secondhand one, as long as a test certificate issued by testing agency is not attached, it shall not be released.

7. Corrective actions

Upon a complaint of the quality of the medical device, the importer shall prepare relevant procedure for the quality manager to clarify the cause and take a corrective action, and execute it.

Quality System of KFDA

8. Record

The importer shall prepare and control the following records:

- A. Record of quality control services for the imports mentioned in the above item 6
- B. Record of corrective actions
- C. Record of tests
- D. Record of laboratory and control of testing facilities
- E. Record of sterilization
- F. Record of installation control
- G. Record of training
- H. Other record of handling of tasks by this standard

9. Training

The Importer shall establish training plan for quality control toward staffs and prepare them in a document in order to effectively perform their tasks and secure the quality of the imported medical device.

Quality System of KFDA

Indication Criteria for Approval of Compliance with the Manufacturing and Quality Management Standards for Medical devices (Related to Article 7-3)

[Attached Table 4]

A. Mark Indicating Approval of Compliance

1) Design

2) Dimensions: Width * Length = 1 * 0.83

3) Color code : Phantom color 2736CVC

B. Indication and specification

1) The indication for approval of compliance may use diversified dimensions (on condition of the same ratio) and colors in compliance with characteristics and packing material of the product on the basis of the dimensions and color mentioned in Sub-item A, however, the indicated design shall not be changed.

2) The indication method for approval of compliance mentioned in Sub-item A may be affixed to one or all of the container, case, packing, and attached document in compliance with the mentions under Article 19 to 21 of the 「Medical device Act」.



Quality System of CE/MDD

Medical Device Directive 93/42/EEC

Article 9 Classification

Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX.

Article 11 Conformity assessment procedures

Conformity assessment of Class III medical devices

1. In the case of devices falling within Class III, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); or

(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:

(i) the procedure relating to the EC verification set out in Annex IV;

Or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance).

Quality System of CE/MDD

Conformity assessment of Class IIa medical devices

2. In the case of devices falling within Class IIa, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure relating to the EC declaration of conformity set out in Annex VII, coupled with either:

(a) the procedure relating to the EC verification set out in Annex IV;

Or

(b) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance);

Or

(c) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

Instead of applying these procedures, the manufacturer may also follow the procedure referred to in paragraph 3 (a).

Quality System of CE/MDD

Conformity assessment of Class IIb medical devices

3. In the case of devices falling within Class IIb, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); in this case, point 4 of Annex II is not applicable; or

(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:

(i) the procedure relating to the EC verification set out in Annex IV;

Or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance);

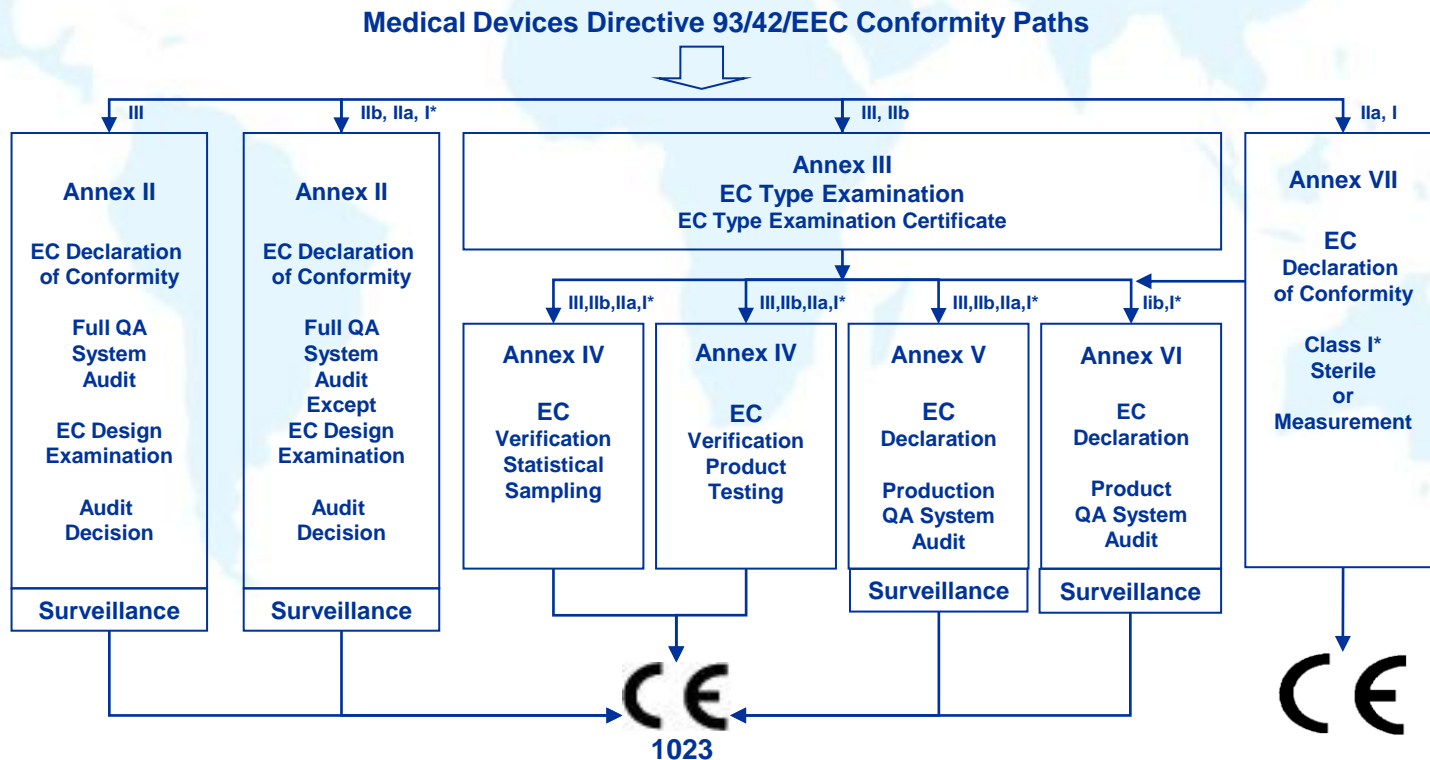
Or

(iii) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).

Quality System of CE/MDD

Conformity assessment of Class I medical devices

5. In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.



Quality System of CE/MDD

ANNEX II **EC DECLARATION OF CONFORMITY (Full quality assurance system)**

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- the name and address of the manufacturer and any additional manufacturing site covered by the quality system,
- all the relevant information on the product or product category covered by the procedure,
- a written declaration that no application has been lodged with any other notified body for the same product-related quality system,
- the documentation on the quality system,
- an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,
- an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,

Quality System of CE/MDD

— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

Quality System of CE/MDD

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

— the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,

— the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform,

— where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

(c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:

Quality System of CE/MDD

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

— the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,

— the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform,

— where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

Quality System of CE/MDD

(c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular:

- a general description of the product, including any variants planned, and its intended use(s),
- the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full,
- the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed,
- if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,
- a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device,
- a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC (1),
- the solutions adopted as referred to in Annex I, Chapter I, Section 2,
- the pre-clinical evaluation,
- the clinical evaluation referred to in Annex X,
- the draft label and, where appropriate, instructions for use.

Quality System of CE/MDD

(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:

- the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,
- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

4. Examination of the design of the product (Only apply to product in Class III)

5. Surveillance

7. Application to devices in Classes IIa and IIb.

7.1. In line with Article 11(2) and (3), this Annex may apply to products in Classes IIa and IIb. Section 4, however, does not apply.

Quality System of CE/MDD

ANNEX V **EC DECLARATION OF CONFORMITY** **(Production quality assurance)**

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- the name and address of the manufacturer
- all the relevant information on the product or product category covered by the procedure,
- a written declaration that no application has been lodged with any other notified body for the same products,
- the documentation on the quality system,
- an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,
- an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,

Quality System of CE/MDD

— an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them:

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.

Quality System of CE/MDD

It shall include in particular an adequate description of:

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular:

— the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned,

— the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform,

— where the manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

(c) the inspection and quality assurance techniques at the manufacturing stage and in particular:

— the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

— the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

Quality System of CE/MDD

(d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

4. Surveillance

6. Application to devices in Class IIa

In line with Article 11(2), this Annex may apply to products in Class IIa, subject to the following:

6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Directive.

6.3. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken.

6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3.

Edition 2007 versus 2000 (Am1:2003)

- **Edition 2007 adds or modifies definitions for**
 - **In vitro diagnostic medical devices**
 - **life-cycle**
 - **post-production**
 - **residual risk**
 - **risk estimation**
 - **risk evaluation**
 - **risk management**
 - **top management**
 - **use error**
 - **verification**

Edition 2007 versus 2000 (Am1:2003)

- **Edition 2007 expand definitions for medical device and includes:**
 - **tools**
 - **machines**
 - **implants**
 - **In vitro reagents**
 - **calibrators**
 - **software**
 - **life supporting or sustaining devices**
 - **devices for disinfection of medical devices**
 - **devices for in vitro examination of specimens derived from the human body**

Edition 2007 versus 2000 (Am1:2003)

- **2007 Block diagram of Risk Management Process is expanded and includes:**
 - additional Risk Controls
 - separate block for Residual Risk
 - Risk Management Report and
 - Production and Post-Production Information

- **2007 dropped Sec. 3.1 on National or Regional Regulatory Requirements**

Edition 2007 versus 2000 (Am1:2003)

- **2007 added Sec. 3.2 on the Risk Management Process**
- **2007 Risk Management File Sec. 3.5 expanded to include:**
 - **Risk Analysis**
 - **Risk Evaluation**
 - **Implementation and Verification of Risk Control Measures**
 - **Assessment of Acceptability of Residual Risks**

Edition 2007 versus 2000 (Am1:2003)

- **2007 changed the former sec. 4.1 „Risk Analysis Procedure“ to „Risk Analysis Process“**
- **Fig. 2 in ed. 2000 called „Overview of risk management activities as applied to medical devices“ has been dropped out and moved to Annex B**

Edition 2007 versus 2000 (Am1:2003)

- **2007 added Sec. 3.2 on the Risk Management Process**
- **Sec. 4.3 was changed from “Identification of Know or Foreseeable Hazards” to “Identification of Hazards”**

Edition 2007 versus 2000 (Am1:2003)

- **Sec. 4.4 changed from “Estimation of the Risk for each Hazard” to “Estimation of the Risk for each Hazardous Situation”**
- **2007 changed Sec. 6.2 from “Option Analysis” to “Risk Control Option Analysis”**

Edition 2007 versus 2000 (Am1:2003)

- **2007 changed Sec. 6.6 from “Other generated hazards” to “Risks arising from risk control measures”**
- **2007 changed Sec. 6.7 from “Completeness of risk evaluation” to “Completeness of risk Control”**
- **2007 changed Sec. 7 from “Overall residual risk evaluation” to “Evaluation of overall residual risk acceptability”**

Edition 2007 versus 2000 (Am1:2003)

- **2007 clarifies Section 8 to indicate that elements required within the “Risk Management Report”:**
 - **Appropriate implementation of the Risk Management Plan**
 - **Acceptability of overall residual risk**
 - **Methods to obtain relevant production and post-production information are appropriate and are in place**

Edition 2007 versus 2000 (Am1:2003)

- **2007 changed Sec. 9 from “Post production information” to “Production and post-production information”**

Annexes in 2007 edition

Annex A - Rationale for requirements

This annex is a revision of previous Amd1:2003 to provide understanding of rationale for revised requirements in 2007 edition

Annex B - Overview of the risk management process for medical devices

This annex contains modification of former figure 2 and elaborations about it from 2000 ed.

Annexes in 2007 edition

Annex C – Questions that can be used to identify medical device characteristics that could impact on safety

Several questions were added and enhanced

Annex D – Risk concepts applied to medical devices

Extensive enhancements provide additional guidance on overall risk management concepts.

This annex is a significant revision of Annex E of previous 2000 ed.

Annexes in 2007 edition

Annex E – Examples of hazards, foreseeable sequences of events and hazardous situations

This annex provides significant enhancements to concept model and the relationship between hazards, events, hazardous situations, and harm. It was Annex D in 2000 ed.

Annex F – Risk management plan

This is new annex provide content guidance for developing of the risk management plan.

Annexes in 2007 edition

Annex G – Information on risk management techniques

This annex was Annex F in 2000 ed.

Annex H – Guidance on risk management for in vitro diagnostic medical devices

This annex was significantly expanded to provide guidance on application of risk management to in vitro diagnostic medical devices. Former 1-page Annex B in 2000 ed. was extended to 17-page guidance document.

Annexes in 2007 edition

Annex I – Guidance on risk process for biological hazards

This annex was enhanced from original Annex C in 2000 ed., addressing toxicological hazards

Annex J – Information for safety and information about residual risk

This new annex provides guidance related to communication of safety and residual risk information

Annexes in 2007 edition

Annex G (Other standards that contain information related to the elements of risk management described in this International Standard) included in 2000 ed. was dropped out.

A light blue world map is centered in the background of the slide.

Thank you.

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