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AMENDMENT 1
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Aseptic processing of health care products —

Part 1: General requirements

AMENDMENT 1

Traitement aseptique des produits de santé —

Partie 1: Exigences générales

AMENDEMENT 1

Reference number
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Foreword

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Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 13408-1:2008 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

Aseptic processing of health care products —

Part 1:
General requirements

AMENDMENT 1

Page vi, Introduction

In the second paragraph, replace the second sentence with the following:

> ISO/TC 198 has prepared standards for terminal sterilization of health care products by irradiation (ISO 11137 series), by moist heat (ISO 17665 series), by dry heat (ISO 20857), by ethylene oxide (ISO 11135) and by liquid chemical sterilants (ISO 14160).

Page vii, Introduction

At the end of the last sentence of the penultimate paragraph, add the word "component" so that it reads:

> "... of which process simulation studies are an essential component."

Page 1, Normative references

Delete the following reference:

> ISO 9001, *Quality management systems — Requirements*

Page 2, Normative references

Delete footnote 1 and renumber footnote 2 accordingly.

Page 3, 3.7

Delete the following:

> [ISO 13408-6:2005, definition 3.1]

Page 4, 3.14

Correct the spelling of the term to read "depyrogenation".

Page 5, 3.24

Replace the note with the following:

NOTE The required grade of cleanliness of the indirect support zone depends on the aseptic processing technologies and activities performed.

Page 7, 4.1.1

In the first sentence, replace “over all activities affecting aseptic processing” with “over all activities affecting aseptic processing (e.g. ISO 9001 and/or ISO 13485)”.

Delete the second sentence.

Page 7, 4.3.2

Replace the text with the following:

The accuracy and tolerance of all measuring instruments shall be adequate for the parameters to be measured.

Page 8, 5.2.1.2

At the end of the subclause, insert the following note:

NOTE Assessment of risk to condone poor or improper practice during aseptic processing is not appropriate.

Page 10, 5.2.4.4

Replace item a) with the following:

a) microbiological quality of the product at defined stages during the manufacturing process, alert and action levels shall be established;

Page 10, 6.1.2

Replace the second sentence of the note with the following:

Where highly potent, cytotoxic or radioactive health care products are to be processed, protection of personnel and the environment is considered an ancillary element of aseptic processing design.

Page 36, Table 1, fifth column

In the first, third and fifth rows, replace “restart validation” with “repeat initial performance qualification” to be in line with the title of Table 1.

Page 36, Table 2, fourth column

In the first, third and fifth rows, replace “revalidation” with “repeat initial performance qualification” to be in line with the title of Table 1.

Page 37, 11.1

Replace the text of 11.1 (excluding the notes) with the following:

> Where a test for sterility is required for aseptically-filled products, then this testing shall be conducted for each batch of product. The pharmacopoeia test for sterility is used when the method is applicable. Where there is no specific method in the pharmacopoeia that is applicable to a particular product, then the manufacturer of the product shall specify the method to be used.

Replace NOTE 2 with the following:

> NOTE 2 In certain jurisdictions approval of a non-pharmacopoeia test for sterility is required by the relevant competent authorities.

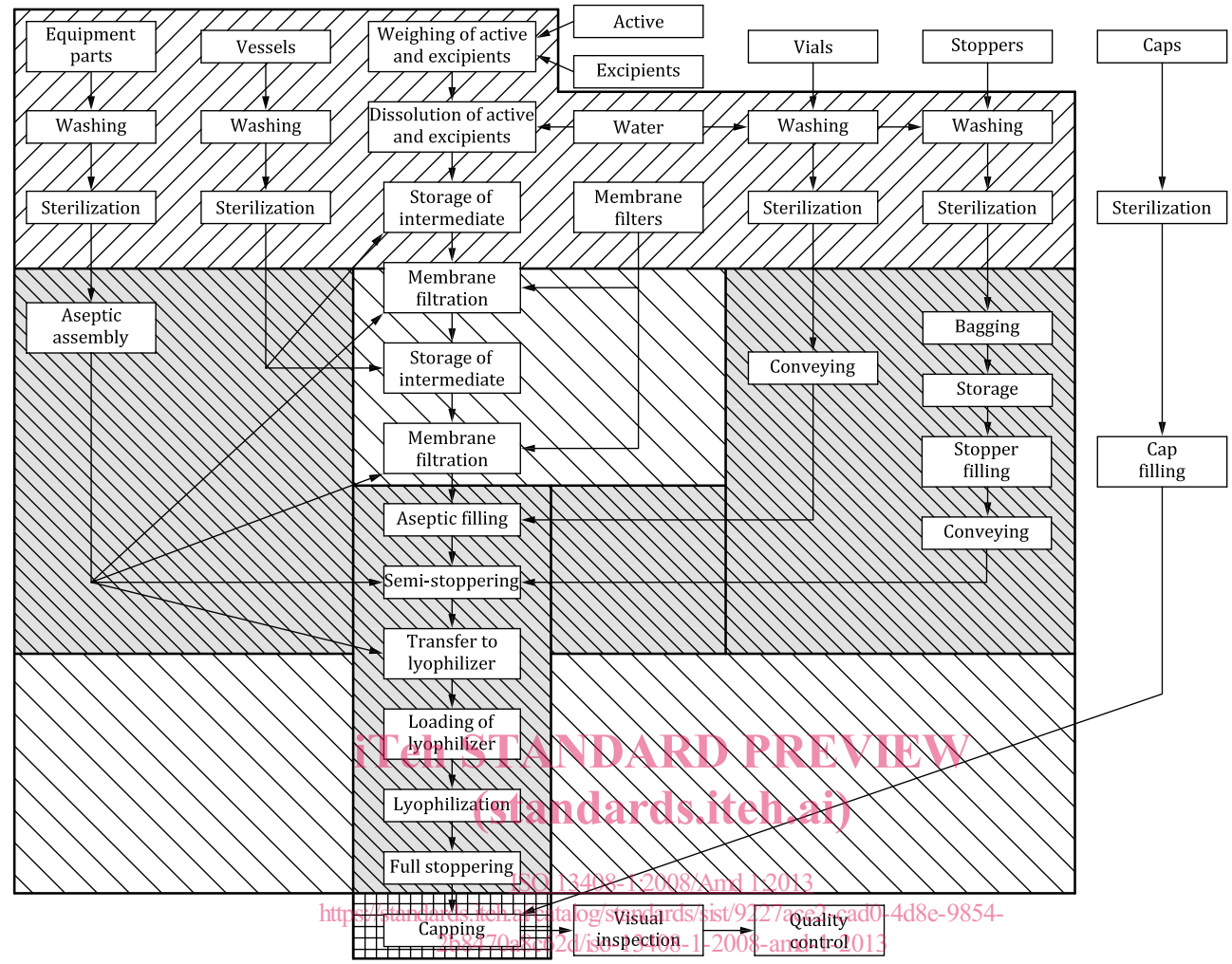
Page 37, 11.2.2

Replace "from positive units using tests for sterility" with "from positive units during tests for sterility".

In the note, replace "from positive units using tests for sterility can be found in the pharmacopoeias" with "from positive units during tests for sterility can be found in the pharmacopoeias".

Page 38, Figure A.1

Replace Figure A.1 with the following:



Key

- indirect support zone
- direct support zone outside APA
- critical processing zone
- direct support zone
- indirect support zone + grade A air flushing

Figure A.1 — Example of an aseptic process divided into unit operations

Page 41, Table D.1

In footnote b, replace “EU GMP Guide, Annex 1:2003 (drafted revision 2005)” with “EU GMP Guide, Annex 1:2009”.

Page 45, Bibliography

Insert the following new reference:

[2] ISO 9001, *Quality management systems — Requirements*

Renumber subsequent references accordingly.

Replace Reference [16] with the following:

[16] EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use (GMP), Volume 4 — Annex 1:2009 Manufacture of Sterile Medicinal Products