INTERNATIONAL STANDARD

ISO 13408-6

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AMENDMENT 1
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Aseptic processing of health care products —

Part 6: Isolator systems

AMENDMENT 1

Traitement aseptique des produits de santé —

Partie 6: Systèmes isolateurs

AMENDEMENT 1

Reference number
ISO 13408-6:2005/Amd.1:2013(E)

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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 13408-6:2005 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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Aseptic processing of health care products —

Part 6:
Isolator systems

AMENDMENT 1

Foreword, last paragraph

Add the following to the list of parts:

— *Part 7: Alternative processes for medical devices and combination products*

Page 1, Clause 2

Replace “ISO 13408-1:1998” with “ISO 13408-1:2008”.

After ISO 13408-4 and ISO 13408-5, delete “:—[1)]”.

Delete footnote 1.

Page 1, Clause 3

In the boilerplate text, replace “ISO 13408-1:1998” with “ISO 13408-1:2008”.

Delete definitions 3.1 bio-decontamination, 3.2 design qualification, 3.3 isolator, 3.8 separative device, 3.9 surrounding environment, 3.13 worst-case conditions.

Renumber terms accordingly.

Page 2, 3.7, risk assessment

Replace “[ISO 14971:2000, 2.15]” with “[ISO 14971:2007, definition 2.18]”

Page 3, 4.1.1

Replace “ISO 13408-1:1998” with “ISO 13408-1:2008”

Page 4, 5.1.2, Note 2

In the last line, delete the word “surrounding”.

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Page 6, 5.6.2.1

In the last line of the text and in the note, replace “surrounding environment” with “indirect support zone”.

Page 6, 6.1.1

In the first paragraph replace “a clean zone” with “an indirect support zone”.

In the second paragraph delete “(surrounding environment)”.

Page 8, 7.3.4.2

Replace “can be removed” with “shall be removed to defined levels”.

Page 8, 7.4.1.2 h)

Replace “biocontamination” with “bioburden”.

Page 9, 7.4.3.2

Replace list item a) with the following:

a) installation of a cabinet specific for hydrogen peroxide;

At the end of the list add the following:

h) personnel exposure limits.

Page 10, 7.4.6.2

Replace the text with the following:

Residues of the bio-decontaminating agent shall be removed to an acceptable level after bio-decontamination.

NOTE The acceptable level of residual bio-decontaminating agent should be based on risk assessment of the effect residues would have on:

— operator safety,

— products or components, or

— subsequent processes.

Page 11, 8.2

In the second paragraph delete “(e.g. in ISO 9001:2001)”.

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Page 13, 8.5.1.3

Replace the first sentence with the following:

Other points that shall be addressed include but are not limited to:

Page 13, 8.5.3.1

Replace the first sentence with the following:

Pre-requisite information for the bio-decontamination process shall be obtained by performing cycle development and, where relevant, shall include temperature studies, vapour distribution studies, biological challenges and aeration.

Add the following note:

NOTE Consider the cycle development studies.

Page 14, 8.5.4.2

Replace "ISO 13408-1:1998, Clause 17, for media fill studies" with "ISO 13408-1:2008, Clause 10, process simulation".

Page 14, 9.2.1

Delete "ISO 10648-2 and".

Page 15, 9.5.2

Replace "should" with "shall".

Page 15, 9.6.2

In the first sentence replace "should" with "shall".

Add "HEPA" before filter in the third and fourth sentences so that it reads:

HEPA filters shall undergo testing upon installation and periodically thereafter. Tests on HEPA filters shall include filter integrity and airflow velocity.

Page 15, 10.2

At the end of the second sentence, before the list, add "but not be limited to".

Page 17, Bibliography

Delete References [1] and [15].

In Reference [6], replace "ISO 14971:2000" with "ISO 14971:2007".

Replace Reference [7] with the following:

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ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*[2)]

Replace footnote 2 with the following:

Guidance on the designation of a medical device to a product family and processing category is under preparation as ISO/TS 17665-3.

After existing Reference [7], add the following:

ISO/TS 17665-2, *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1*[2)]

Replace Reference [10] with the following:

USP 35 *The United States Pharmacopeia and National Formulary 30, 2012*

Replace Reference [17] with the following:

USP 35 <1208> *Sterility testing — Validation of Isolator Systems*

Add the following reference:

ICH Q9, *Quality risk management*

Delete all web links in references and renumber references accordingly.

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