Global Medical Packaging Standards Update

Brief update on ISO 11607-1 and 11607-2 and ISO 16775 - Guidance document for 11607-1 and 11607-2

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Documents of Interest


Packaging for terminally sterilized medical devices –
Part 1: Requirements for materials, sterile barrier systems, and packaging, Amendment 1


Guidance on Application of ISO 11607-1 and -2
What’s Happening
with 11607-1 and 11607-2

- Amendment to 11607-1 and -2 published in fall 2014.
- It is very important to note that these changes were not made within text of document, you need to look at clauses referenced in amendment to see what has changed.
What’s Happening

with 11607

International Review of 11607-1 and 11607-2
Has Begun

US compiled comments in early 2015, these were submitted to ISO Working Group. US comments along with comments from all other voting countries were reviewed at TC198 Working Group 7 meeting in December 2015 in Berlin.
What’s Happening

with 11607-1

What happened to Comments submitted by US?

• Many minor ones were accepted.

• The most substantial comment, a proposal to rewrite sections 6 forward to start with needs of device/user and detail requirements, vs current method of starting with requirements for materials was not accepted by committee.
Current 4.4.3 Unless otherwise specified in the test methods, test samples shall be conditioned at (23 ± 1) °C and (50 ± 2) % relative humidity for a minimum of 24 h.

Comment add “unless a rational and data can be provided demonstrating that the shorter conditioning requirements have no impact on the test results”

Current 4.5.3 Documentation of compliance with the requirements may include, but is not limited to, performance data, specifications and test results from validated test methods.

Comment add “as well as validation protocols, conclusions and any necessary actions.”
What’s Happening

with 11607-1

Examples of Currently Accepted Comments

Current 5.1.7  is list of performance requirements

Comment  Add h) materials shall have microbial barrier properties which is consistent with the specified ‘acceptance criteria’ unless they meet the criterion of impermeability when evaluated per annex C.

Current 5.1.7 g  Materials shall not contain or release material known to be toxic in sufficient quantity to cause a health hazard either before, during or after sterilization under the conditions of use.

Comment  Replace toxic to align with other regulatory docs, perhaps with “carcinogenic, mutagenic or toxic to reproduction”
What’s Happening with 11607-1

Examples of Currently Accepted Comments

Current 5.2.3 Porous materials shall provide an adequate microbial barrier to microorganisms in order to provide integrity of the sterile barrier system and product safety.

Comment The 2014 revision definition of microbial barrier includes demonstrated under test conditions considering the sterilization process, handling, distribution, transport and storage.

However Definitions cannot add requirements, so that extra content will be worked in where microbial barrier is discussed.

Potential reword Porous materials shall provide an adequate microbial barrier to microorganisms demonstrated under .................in order to provide...........
What’s Happening with 11607-1

Examples of Currently Accepted Comments

Current Section 6  Design and development requirements for packaging systems

6.1 General
6.2 Design
6.3 Packaging-system performance testing
6.4 Stability testing

Comment  Add wording about Usability Testing. Clause to be finalized, perhaps “Usability testing shall demonstrate that the design requirements have been met in particular for aseptic presentation.”
What’s Happening
with 11607

What’s next

- All accepted comments and accepted with modification comments have been incorporated into a Committee Draft (CD). This draft also incorporates the amendments from 2014 into the body of the document. The initial version of this draft is currently being circulated among those who attended the Berlin meeting for review and comment.
- The Chairs of the US Working Group, the US delegates at Berlin meeting, have chosen to circulate this draft for comment to all the members of the US Mirror Group. The AAMI Packaging Committee of Sterilization Standards Committee is the US Mirror Group.
- All comments must be received by AMMI in the proper format, on the comment form, by the 1st of April in order to be considered as a US comment. Proper format means identification of clause to be changed, rationale for change, and suggested rewording.
What’s Happening with 11607

What’s next

- The Complied Comments on this CD will be resolved at ISO Working Group meeting proposed for Sept 2016. After this meeting a Committee Draft for Vote (CDV) will be circulated - likely Nov 2016-Jan 2017.

- These are initial steps in the process of drafts/ballots/resolution of comments to produce a revised 11607-1 and -2, the ISO working group has resolved that this process will be completed by Dec 2018.

- NOTE: ISO16775 will be up for reaffirmation in May 2017, the proposed revisions to 11607-1 and -2 will likely influence that ballot.
What’s Happening

with 11607

What can YOU do

• Join AAMI Working Group on Packaging

• There are several opportunities for input in near future
  • Comments on the Committee Draft in Spring 2016
  • Opinions on the submitted comments from other countries. Will be reviewed prior to Sept 2016 meeting
AAMI ISO TC198
*Working Group 7 Participation*

AAMI Packaging Working Group will meet in April 2016.

Join, Join, Join!

This is your chance to influence the next revision.

*Thank you!*