Changes for the Next Version of ISO 11607

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Standard History

• Standard and Requirements Conflicts
  – Prior to harmonized ISO 11607-1 &-2
    • AAMI/ANSI/ISO 11607 vs. EN868-1
    • Local / National requirements
    • Notified Bodies vs. FDA Auditors
    • Confusion within Auditors
Standard History

• Until 1993 there were no standards or documents establishing requirements for medical device packaging

• General statements made in 21 CFR, Part 820 – Good Manufacturing Practice (cGMP)
The Early 90’s – Some Progress

• HIMA (now AdvaMed) publishes – The HIMA Reference on Sterile Packaging in 1993

• Shortly After – Work items are established for two new standards
  – EN868-1: Packaging materials and systems for medical devices which are to be sterilized
  – ISO 11607: Packaging for terminally sterilized medical devices
What was EN868-1?

- Part 1: A horizontal standard which specified general requirements for sterile packaging materials
- Supplemented by vertical standards Parts 2-10
  - Requirements for specific materials/structures
    - Sterilization wraps, papers, Tyvek®, reel materials, bags, pouches and re-usable sterilization containers, etc.
- Published in 1997
What Is ISO 11607?

• A voluntary standard which specifies the requirements for materials, package design and forming and sealing (process validation)
• The materials section essentially a modified version of 868-1 to meet ISO requirements
• The package design and forming & sealing sections written by the U.S.
• Published in 1997
• Revised in 2000 to add clauses for compliance with 868-1
What Is ISO 11607?

- The name says it all: ANSI/AAMI/ISO 11607
  - Why is it ANSI / AAMI / ISO?
  - ANSI is the official ISO secretariat
    - While it is general ANSI practice to delegate ISO committee secretariats to other US organizations, ANSI staff does administer secretariats at the request of specific industries or other ANSI constituents.
What is the Vienna Agreement?

- In January 1989 the CEN Administrative Board approved an agreement on the exchange of technical information between ISO and CEN (called the Lisbon Agreement) as a response to the ISO Council resolution 11/1987.

- Subsequently, an agreement on technical co-operation between ISO and CEN was approved by the ISO Council resolution 18/1990 and the CEN General Assembly resolution 3/1990. This agreement (called the Vienna Agreement) was published in June 1991. It is accompanied by common ISO-CEN "Guidelines for the TC/SC Chairmen and Secretariats for implementation", approved in 1992 and revised in September 1998.

- After a decade of experience, the need for the Agreement was confirmed by ISO and CEN and the present edition was confirmed by the ISO Council resolution 35/2001 and the CEN Administrative Board resolution 2/2001.
What Is ISO 11607?

• What is the Vienna Agreement?
  – Essentially, the agreement recognizes the primacy of international standards (stipulated notably in the WTO Code of Conduct). But the agreement also recognizes that particular needs (of the Single European Market for example) might require the development of standards for which a need has not been recognized at the international level. The prioritization of ISO work is also such that in some instances CEN needs to undertake work which is urgent in the European context, but less so in the international one.

  – As a result, the agreement sets out **two essential modes for collaborative development of standards**: the mode under ISO lead and the mode under CEN lead, in which documents developed within one body are notified for the simultaneous approval by the other.
Why Harmonize?

- Device Manufacturers found it difficult to comply with both standards
- Neither document read easily
- ISO 11607 did not follow normal package development flow
- EN868-1 did not cover package design, testing or process validation
- 11607 was not widely recognized in Europe
In May of 2002 ISO TC 198, WG7 met in Kyoto, Japan.
A new work item was agreed upon and established.
A new, two part ISO standard would be developed.
Part 1 – Materials & Package Design
Part 2 – Process Development & Validation
Standard would be harmonized with EN868-1
The **GOLD** Standard
11607:2006 Parts 1 and 2

- Packaging For Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging
- Packaging For Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
Part 1

• Requirements for Materials, Sterile Barrier Systems and Packaging
A Definitions Breakthrough

• Four critical definitions established which facilitated the development of the standard
  – Sterile Barrier System (SBS)
  – Pre-formed Sterile Barrier System
  – Protective Packaging
  – Package System
Sterile Barrier System

- Minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at the point of use.
Preformed Sterile Barrier System

• Sterile barrier system that is supplied partially assembled for filling and final closure or sealing. Example: Pouches, bags and open reusable containers
Protective Packaging

• Configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use.
Packaging System

Combination of the sterile barrier system and protective packaging.
Where are we now?
Where are we now?

Current activities: TIR 22 and ISO TIR 22
TIR 22 reissued with …

• Two new annexes
  – Annex J – for Healthcare providers
  – Annex K – to define worst case
    • Much of this work contributed by the SPMC.
Report of the meeting of ISO/TC 198/WG 07, Packaging Working Group
3-4 November 2008

San Francisco Hilton Financial District;
United States
Hilton conference room facilities

March 3-5, 2009
www.healthpack.net
Our room with a view of buildings across the street

March 3-5, 2009
www.healthpack.net
The meeting was attended by 16 delegates from 9 countries.

1. Anna Boman, Sweden
2. Simone Christophe, France
3. Ramona Conner, USA
4. Paul Fielding, United Kingdom
5. Nick Fotis, USA
6. Tim Galekop, The Netherlands
7. Akira Hashimoto, Japan
8. Victoria Hitchins, USA
9. David Johnson, Belgium
10. Jackie Daly Johnson, USA
11. Stefan Manhart, Germany
12. Fangon Michael, France
13. F.W. Oertmann, Germany
14. Vera Settemayer, Germany
15. Dianne Trudeau, Canada
16. Christian Wolf, Germany
The meeting was opened by Tim Galekop who welcomed the experts to the meeting of ISO/TC 198/WG 7 in San Francisco.

The members were informed that Mike Scholla, the Convener of ISO/TC 198/WG 7, was ill and could unfortunately not attend this meeting.

The meeting was therefore lead by Tim Galekop.
• The draft agenda was accepted. The members then noted the report of the last meeting in Sydney, April 2005, on which no comments have been received.

• Attention was drawn to item 10 of the report referring to the subject acceptance criteria for the inclusion of test methods in the next revision of ISO 11607-1 and -2 and it was mentioned that the systematic review of ISO 11607-1 and-2 will be launched in 2009.
• Initially, Tim Galekop gave a presentation about the development and content of the International and European standards on packaging materials and their relation to European Directives. He highlighted the special needs of end-users in healthcare facilities and requested the Standards Committees to consider these needs appropriately.

• In this context, the newly approved work item *Guidance on ISO 11607* will be of fundamental importance.
Review of the results of the ballot of the New Work Item Proposal *Guidance on the application of ISO 11607-1 and ISO 11607-2, Packaging for terminally sterilized medical devices*

- The participants then noted the positive voting result of the NWIP at ISO but also at CEN level and that CEN/TC 102 had agreed to proceed with this work item under the Vienna Agreement with an ISO lead.
A new part 3? No!

- The participants discussed the envisaged publication type.
- It was agreed that
  - the work item should result in a purely "educational" guidance document to ISO 11607-1 and ISO 11607-2;
  - the guidance should address industry and end-users;
  - the work item should not be designated Part 3 of the series ISO 11607 but should rather be published "outside" the series ISO 11607 in order to have a clear formal separation between "requirements" and "guidance".
TIR 22 Annex J – the cornerstone

• The document AAMI TIR 22 and the Amendment to that Technical Report offered by the US delegation as first working drafts have been received with thanks. In particular, the Annex J of AAMI TIR 22 including the Guidance for healthcare facilities was discussed in more detail.

• It was agreed that this Annex needs to be amended by taking into consideration the Guideline for the validation of the sealing process prepared by the DGSV as well as several other comments made at the meeting.
This work has been designated to a Task Force comprising:

- from the end-user-side
  - Wim Renders (to be confirmed), Anne Bank (to be confirmed),
  - Ramona Conner and Diane Trudeau; and

- from the industry
  - Christian Wolf, David Johnson, Jackie Daley-Johnson (Leader of the Task Force), Tim Galekop and F. Oertmann.

The following tasks have been assigned:

- Tim Galekop and Christian Wolf will amend Annex J based on the comments made at the meeting.
- David Johnson will provide the section for the guidance on wrapping, see also AAMI ST 79),
- Friedrich Oertmann will provide the section for the guidance on containers.
Task force timing

• The experts agreed to provide their input by mid December 2008 to the leader of the Task Force.
  – The outcome of the work of the Task Force will also be made available to the members of the complete working group. All members of ISO/TC 198/WG 7 were encouraged to submit further comments as well as national guidelines relating to both the Guidance section for healthcare facilities as well as to the Guidance section for the industry.

• The next meeting of the complete Working Group has not been scheduled yet.
Revision of the European Directives on Medical Devices – Impact on EN ISO 11607

• The members of WG 7 were informed about the amendment of the European Directives on Medical Devices and the current activities of CEN/TC 102 which is preparing an Amendment to EN ISO 11607-1 in order to address the applicable modified Essential Requirements of the Directive 93/42/EC.
  – This Amendment will only modify the Table ZA.1 of EN ISO 11607-1 – i.e. only this very specific European element - but not the "body" of the standard. The corresponding update of the "body" of the Standards needs to be done under the Vienna Agreement with an ISO lead and ISO/TC 198/WG 7 has now been asked by CEN/TC 102 to agree on this approach. It was also noted that no changes were necessary in EN ISO 11607-2.

• Changes affect Part 1 section 7 Information to be provided.
  – Some felt that they were currently covered under 7.2 local requirements.
Revision of the European Directives on Medical Devices – Impact on EN ISO 11607

• Three areas specific to packaging labeling
  – (Sec 13.3) For devices imported into the community, the label shall contain the name of the authorized representative where the manufacturer does not have a registered place of business in the Community.
  – (Sec 13.6 h…) If a device bears an indication that the device is for single use, information on the characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be reused …
  – (Section 13.6.q) date of issue or the latest revision of the instructions for use.

Per Directive 2007 / 47/ EC
Revision of the European Directives on Medical Devices – Impact on EN ISO 11607

• Taking into consideration that the systematic review of ISO 11607-1 will be initiated in 2009, the following was agreed:

  – A proposed text for a Draft Technical Amendment on ISO 11607-1, prepared by the Convenor and the Secretariat, will be sent to the members of ISO/TC 198/WG 7 for comment by the end of November 2008.

  • The content of this proposed Technical Amendment will be based on the amended Essential Requirements listed in document
Revision of the European Directives on Medical Devices – Impact on EN ISO 11607

- The agreed text for the Draft Technical Amendment will be put on hold until the results of the systematic review of ISO 11607-1 are known.

- Based upon the result of the Systematic Review ISO/TC 198/WG 7 will then decide on the most appropriate action (e.g. to forward the agreed draft Technical Amendment, unchanged, to answer the enquiry or to supplement it by other items that might appear as the result of the Systematic Review).
Post ISO meeting

Additional items of interest

• The Working group did not respond to a CEN request for additional help in validating additional test methods

• An update was held for AAMI Working group members via teleconference
  – Very well attended
  – A method of contributing suggested changes to the 11607 parts 1 and 2 documents was established at the AAMI website.
Where are we headed?
The biggest single change

- At the ISO meeting in Australia in 2007, the Working group, under Mike Scholla’s urging, adopted the following direction

  - Only test methods that have repeatability and reproducibility data should be included in the Annex B.
An opportunity to clarify / improve
An opportunity to clarify / improve

• Example:

3.11
**preformed sterile barrier system**
sterile barrier system (3.22) that is supplied partially assembled.  

EXAMPLE  Pouches, bags, and open reusable containers.  

[ISO/TS 11139:2006]

3.12
**product**
result of a process  

[ISO 9000:2000]

NOTE  For the purpose of sterilization standards, product is taken to be composed of sub-assembly(ies) and health care product(s).  

[ISO/TS 11139:2006]

3.13
**protective packaging**
configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use  

NOTE  Adapted from ISO/TS 11139:2006.
An opportunity to clarify / improve

• Example 2:

6.4.2 Stability testing shall be performed using real-time aging.

6.4.3 Stability testing, using accelerated aging protocols, shall be regarded as sufficient evidence for claimed expiry dates until data from real-time aging studies are available.

6.4.4 Real-time and accelerated aging tests should begin simultaneously.

NOTE Stability testing and performance testing are separate entities. Performance testing evaluates the interaction between the packaging system and the products in response to the stresses imposed by the manufacturing and sterilization processes and the handling, storage and shipping environment.
An opportunity to clarify / improve

• Example 3:

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.
An opportunity to clarify / improve

- Spreadsheet available on line

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<th>Comments and secretariat observations</th>
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<th>Document: AAMI/ANSI/ISO 11607-01</th>
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* This form is being used as a running compilation of comments for possible revisions to the next version of 11607-1 standard. If you have comments on sections which need to be revised, please fill out the form and submit to Hao Choe at AAMI (hchoe@aami.org), so that the comments may be compiled and used during the next revision of the standard.

www.aami.org/committeecentral/
How can you help?
How can you help?

• Think through the past couple of years –
  – When has a requirement caused a discussion within your company? With Quality? With Regulatory?
  – What requirements do you think could be made clearer?
  – What changes to an Annex would be good?
How can you help?

• Send your changes in via the AAMI website
  – AAMI.org  Committee Central  WG7
• Plan to attend the next AAMI meeting –
  – Baltimore, MD
  – June 8,9,10
    • Date & time for WG7 meeting not yet finalized.
Thank you!