Progress towards Harmonization of the ISO and CEN Medical Packaging Standards

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Topics

- The background
- The current standards
- The differences
- Progress towards harmonization
The Standards

The standards are:

- **Europe**
  EN 868 series “Packaging materials and systems for medical devices which are to be sterilized”

- **Rest of the World**
  ISO 11607 “Packaging for terminally sterilized medical devices”
Terminally Sterilized Medical Devices

- Device placed in packaging material
- Package - sealed
  - sterilized
  - distributed
  - stored
  - aseptically opened
Background

**EN 868 Series**

- CEN/TC102/WG4 started work in 1988
- **Purpose:**
  - To provide guidance on how to comply with the essential requirements of the Medical Device Directive that relate to packaging materials
  - To harmonize a number of existing material specific national standards
Background

ISO 11607

• ISO/TC198/WG7 started work in the early 1990’s
• Purpose
  ➔ To provide guidance on materials, pack formation and the final package
  ➔ To meet the concerns of people outside of Europe about the EN 868 material specific standards Parts 2 to 10
EN 868 Series of Standards

- Only apply in Europe

- EN 868-1 is:
  - Horizontal standard
  - Mandatory

- Other standards in the series (EN 868 Parts 2 to 10) are:
  - Voluntary
  - Vertical (i.e. material specific)
EN 868 Series of Standards

EN 868-1 is:

- “Horizontal” standard - specifies the requirements for all medical packaging materials
- Mandatory - provides guidance on how to meet the essential requirements of the Medical Device Directive (93/42/EC) that relate to packaging

- Users must ensure that they meet all requirements relevant to their application
EN 868 Requirements

- Compatible with conditions during production and subsequent use (e.g. temp. and pressure)
- Compatible with intended sterilization process
- Ensure the safety of both the patient and the user
- Suitable for intended use (design)
  - Physical protection
  - Microbial protection
  - Protection against chemicals, gases, moisture, UV light, static discharge, etc.
EN 868 Requirements

- No significant toxicity
- Biocompatible (if necessary)
- User requirements
- Maintain sterility (Shelf life)
- Compatible with labelling
EN 868 Series of Standards

EN 868 Parts 2 to 10 are:

- Vertical
  - Detailed specifications for a number of commonly used materials and systems
  - Specify limits for properties such as air permeance, wet and dry strength, water repellency, pore diameter, pH

- Use is optional

- Can be used to satisfy one or more, but not all, of the requirements detailed in EN 868 - 1
EN 868 Series of Standards

“Packaging materials and systems for medical devices which are to be sterilized -

EN 868 - 1 General requirements
EN 868 - 2 Sterilization Wrap (CSR Wrap)
EN 868 - 3 Paper (for steam sterilization)
EN 868 - 4 Paper bags
EN 868 - 5 Paper/Film pouches and reels
EN 868 - 6 Paper (for ETO or irradiation sterilization)
EN 868 - 7 Adhesive coated paper (for heat sealable packs to be ETO or irradiation sterilized)
EN 868 - 8 Reusable containers
EN 868 - 9 Uncoated nonwovens (polyolefines)
EN 868 - 10 Adhesive coated nonwovens (polyolefines)”
ISO 11607 - Status

- Used in many countries outside of Europe
- ISO standards are voluntary
- Countries can choose whether they wish to adopt an ISO standard as a National standard
- They can then decide whether the standard should be voluntary or mandatory
- In USA the ANSI standard is voluntary but FDA inspectors use it as a guidance document which means that it is effectively mandatory
ISO 11607 - Structure

• Contains three main sections:
  – Packaging materials (Section 4)
  – Package forming and sealing (Section 5)
  – Final (product) package (Section 6)

• Originally drafted as three separate standards but these were combined before publication because of the large amount of duplication
EN 868 v ISO 11607 - Main Differences

(1) **Additional topics in ISO 11607** - The ISO standard has sections concerning package formation & sealing and the final package. The CEN standard does not

(2) **Additional topics in the EN 868 series** - The CEN series includes the material specific (vertical) standards EN 868 - Parts 2 to 10. The ISO standard has no such requirements

(3) **Allocation of responsibilities** - ISO 11607 identifies who is responsible for the various activities. EN 868-1 does not
1. **Additional topics covered by ISO 11607**

1.1 **Package formation & sealing.** This is not included in the CEN standards because:
   - The EC mandate was for a material standard. CEN guidelines state that such standards shall be concerned with the product and not the production line
   - These requirements are covered by the Medical Device Directive

1.2 **Final package.** Not specifically included in the CEN standards but EN 868-1 does cover some of the requirements when addressing material design.
EN 868 v ISO 11607 - Main Differences

(2) Additional topics in the EN 868 series
- Vertical standards were prepared to harmonize existing national standards in the various member states of the EU.
- In many cases, the old standards contained slightly different requirements for materials to be used for the same application.
- Without EN 868 Parts 2 to 10, the old standards would have continued to be used
- ISO 11607 contains more details of material requirements than EN 868-1 because the CEN series deals with them in EN 868 Parts 2 to 10
EN 868 v ISO 11607 - Main Differences

(3) Allocation of responsibilities

- The ISO standard allocates responsibilities for the various activities:
  - The “Producer” is responsible for manufacturing the packaging material and/or system
  - The “Manufacturer” is responsible for packaging and/or sterilizing the medical device

- EN 868-1 does not allocate responsibilities because CEN guidelines state that a materials standard shall be concerned with the requirements of the product and not who performs the tests to confirm whether it complies
• **Hospitals** are required to meet ISO 11607 whereas EN 868-1 allows them to use other means to demonstrate conformity.

• **Various Definitions** for example:
  “Primary system that provides a microbial barrier”
  – ISO calls this the “Final Package”
  – CEN calls it the “Primary Pack”

• **Conditioning** of test samples is mandatory in EN 868-1 but not in ISO 11607.
EN 868 v ISO 11607 - Other Differences

• **Sterilization** Both standards require the materials to be compatible with the specified sterilization process but EN 868-1 references the CEN sterilization standards. Activities to harmonize these CEN standards with the equivalent ISO ones are underway.

• **Microbial Barrier** EN 868-1 states that a final pack test is the target but, until such a test becomes available, testing of single components (e.g. materials, seals, etc.) is acceptable. ISO 11607 does not differentiate between the two routes i.e. you can continue to use single component testing even if a final pack test becomes available.
Progress towards Harmonization

1993 (Ottawa) - CEN and ISO working groups accepted that they would not be able to develop a single standard at that time. They agreed to prepare separate documents and review the situation after publication.


• Compliance of a packaging material/system with either one of these standards did not necessarily mean that it would meet the requirements of the other.

• ISO working group started to consider how to harmonize the two standards
Progress towards Harmonization - Stage 1

- This retained the original requirements of ISO 11607 but provided details of the CEN requirements at those points in the text where the standards differed.
- All these occur in Section 4 “Packaging materials”

April 2002 - ISO secretariat issued FDIS for voting but had replaced details of the CEN requirements with:
- Brief references to EN 868-1
- References to an unwritten ISO Technical Report

• They had not understood the rationale behind the document
• Not approved (voted down)
Progress towards Harmonization - Stage 1

May 2002  ISO/TC198/WG7 requested that the secretariat reinstate the original version of the FDIS and send it out for voting

August 2002 - Revised FDIS issued that incorporated all but one of the original changes

• Received 100% positive vote
• Not published yet
May 2002 (Kyoto) ISO/TC198/WG7 decided to start work on a new version of ISO 11607 that would fully harmonize the ISO and CEN standards. They agreed to:

1. Contact CEN/TC102 to get their agreement to form a joint working group with an ISO lead. - This was accepted by the CEN group
2. Have representatives from CEN/TC102/WG4 and ISO/TC198/WG7 to jointly lead the project
3. Divide the standard into two parts:
   - Part 1 covering materials and the final package to satisfy the requirements of the EC Mandate
   - Part 2 dealing with package forming and sealing
4. Reference the CEN material specific standards EN 868-2 to 10 in a similar way to that adopted in EN 868-1
5. Omit any allocation of responsibilities
6. Form a small task group from within the ISO working group to draft the initial documents
Progress towards Harmonization - Stage 2

Feb 2003 Initial drafts completed and sent to members of CEN/TC102/WG4 and ISO/TC198/WG7 with a request for comments by 1 May 2003

June 2003 Joint meeting of the two working groups in Frankfurt to prepare Committee Drafts

1 July - 1 Oct 2003 Drafts to be circulated for ballot

Dec 2003 Results of ballots to be reviewed at meetings of ISO/TC198/WG7 and ISO/TC198 in New Orleans

Early 2004 Documents to be issued for joint ISO/CEN enquiry ballots
Proposals for the New Standards

• Documents are Committee Drafts. Therefore not available to the general public. However, we need to get as wide a range of views from the industry as quickly as possible

• Contact your national representatives on CEN/TC102/WG4 and ISO/TC198/WG7 if you would like to see them
Proposals for the New Standards

1. Two parts:
Packaging for terminally sterilized medical devices
– Part 1: Requirements for materials, sterile barrier systems and packaging
– Part 2: Requirements for forming, sealing and assembly processes

N.B. Part 2 will include pouches, etc. produced by sterile packaging manufacturers as well as those formed by medical device manufacturers when packing their products

2. Part 1 references the CEN material specific standards EN 868 Parts 2 to 10 in the same way as EN 868-1
Proposals for the New Standards

3. No allocation of responsibilities

4. Introduces the definition “Sterile Barrier System” to replace “Final package” (ISO 11607) and “Primary pack” (EN 868-1).

N.B. This term is used by EUCOMED in their campaign for primary medical packaging to be excluded from the requirements of the Packaging & Packaging Waste Directive (94/62/EC)

5. Hospitals that place terminally sterilized medical devices on the market are included
The Target

A single (global) standard for packaging for terminally sterilized medical devices to be published during 2004