The Move to Combine CEN and ISO Medical Packaging Standards

Paul Fielding
DuPont de Nemours (Luxembourg) sarl, Bristol, UK

Long-held plans for a universally accepted international standard are showing signs of progress and hopes are high that this could become a reality by 2004.

Initial disagreement
Progress is now being made towards the development of a joint European and international standard for packaging materials for terminally sterilised medical devices. Failure to agree in the early 1990s led to the European standards body, CEN, and the International Organisation for Standardisation (ISO) publishing separate standards in 1997. CEN Technical Committee (TC) 102 Working Group (WG) 4 developed EN 868-1 Packaging Materials and Systems for Medical Devices that are to be Sterilised, which is mandatory in Europe, whilst ISO TC 198 WG 7 drafted ISO 11607 Packaging for Terminally Sterilised Medical Devices, which is used in many other countries. In addition to a number of relatively minor differences concerning issues such as test methods and definitions, the main differences between the two standards are:
• EN 868-1 refers to a number of voluntary material-specific standards (EN 868 Parts 2 to 10)
• EN 868-1 is only concerned with packaging materials and to some extent pack design, whereas ISO 11607 also covers pack formation and the final pack
• ISO 11607 allocates responsibility for the various activities, EN 868-1 does not.

This means that packaging complying with the ISO standard cannot automatically be used in Europe. It must still be checked against EN 868 Part 1.

Working through the differences
ISO TC 198 WG 7 first started to consider how to go about combining the two standards in 1997. Its first step was to draft a new version of ISO 11607, which left the requirements unchanged, but provided the reader with details of the CEN requirements at those points in the text where there are differences. These all occur in the materials section of the standard. The new draft was finally passed to the ISO Secretariat in the summer of 2000 and was eventually sent out for ballot in April 2002. Regrettably, the ISO Secretariat had replaced details of the CEN requirements with brief references to the CEN standard and a recommendation that the reader should refer to an unwritten ISO Technical Report that was to explain the differences. It subsequently emerged that this was partly because the Secretariat objected to the use of CEN material in an ISO document, and also because it did not really understand its purpose. Not surprisingly, the document was voted down and in August 2002 the Secretariat had to issue a revised Final Draft International Standard incorporating all but one of the original changes. This received a 100% positive vote.

In the meantime ISO TC 198 WG 7 has been working on the next stage of the project. The issues that need to be resolved are:
• How to reference CEN standards EN 868 Parts 2 to 10 in the ISO standard. Some people outside Europe see these material-specific standards as a barrier to trade, whereas people inside Europe view them as voluntary standards that simply provide examples of materials, which have proved successful for many applications over a number of years.
• The European Commission’s mandate for EN 868-1 called for a materials standard. CEN guidelines require that the standard should be concerned with the product and not...
with the production line. This means that CEN will be unable to accept the ISO section dealing with package formation. Modifications would also be required to the section concerned with the final package.

Some people outside Europe see these material-specific standards as a barrier to trade.

- CEN guidelines state that the standard shall be concerned with the requirements for the product and not who should perform the tests to confirm whether it complies.
- In May 2002, in Kyoto, Japan, ISO TC 198 WG 7 decided that an ISO 11607 standard incorporating EN 868-1 would have to
- reference the CEN vertical standards EN 868-2 to 10 in a similar way to that adopted in EN 868-1
- be divided into two separate documents, one covering materials plus the final pack to satisfy the Commission’s mandate and the other dealing with the formation of the pack.
- omit any allocation of responsibilities.

ISO TC 198 WG 7 agreed to form a small task group to prepare initial draft versions of the documents that would serve as a starting point for a joint CEN–ISO working group. At the same time it issued a formal invitation to CEN TC 102 to participate in the project and this has now been accepted. When completed, the drafts will be circulated to all members of ISO TC 198 WG 7 and CEN TC 102 WG 4. It is then hoped that a joint meeting will be held in early June 2003 to review the comments.

The road towards a universally accepted international standard for medical packaging has not been an easy one. However, everyone has had plenty of time since the two standards were first published in 1997 to not only reconsider the issues, but also to gain experience in using them. It is hoped that this will mean that rapid progress can now be made.

Paul Fielding is the lead UK representative on ISO TC 198 WG 7, ISO TC 198 WG 7 and CEN TC 102 WG 4 and Packaging Consultant for Tyvek Medical Packaging, DuPont de Nemours (Luxembourg) Sarl, 3 Druid Road, Stoke Bishop, Bristol BS9 1LJ, UK, tel. +44 117 9 626 940, e-mail: paul.fielding@lux.dupont.com