

Current Activities of The Working Group on Microbiology

The Microbiology Group consists of representatives from suppliers and users of radiation services and from regulatory bodies. It discusses all aspects of microbiology related to radiation processing. Current activities include: The development of a method for the justification of 25 kGy as a sterilization dose. Assessment of the understanding and implementation of ISO and CEN radiation sterilization standards. Maintenance of The Panel's database of radiation resistances of micro-organisms.

Revision of ISO11137 and CEN 552

Sterilization using radiation is regulated by the international standard ISO11137 and the European standard CEN552. They are currently under review with the objective to restructure and harmonize these two directives. Panel Members, representing the British Standards Institute (BSI), attend ISO technical committee meetings and make progress reports back to the panel.

ISO11137-1: Part 2 – Establishing the sterilization dose, is in preparation by ISO TC 198 WG2 as a working draft (WD) for consideration at an interim meeting, to be held in London 30 October 2002. The Panel microbiology working-group plans to prepare a substantive proposal on dose setting and substantiation for product with low bio-burden (<1 organism) for presentation at this meeting.