



**Validation and Process Control for Electron Beam Sterilization**

**15 – 19 May, 2017**  
**4 – 8 September, 2017**

This course gives the background for understanding and implementing the requirements of the radiation sterilization standard EN ISO 11137 with focus on the dosimetric aspects of electron beam sterilization as required in

- IQ/OQ, Installation / Operational Qualification,
- PQ, Performance Qualification
- Routine monitoring and Process Control.

The emphasis of this course is on electron beam sterilization, but users of gamma sterilization will also benefit from participating. We collaborate with Sterigenics, Denmark.

- Participants will**
- calibrate dosimeters to be used in the exercises,
  - carry out IQ/OQ measurements on the 10 MeV electron accelerator,
  - perform PQ dose mapping on products irradiated at the 10 MeV accelerator,
  - make routine dosimetric process control.

Methods for selecting or substantiating a sterilization dose for medical devices are described in EN ISO 11137, part 2 and ISO TS 13004. These methods are covered by lectures and exercises based on simulated data.

Other lectures will cover biocompatibility and effects of radiation on polymers.

**Validation and Process Control for Low Energy Electron Beam Irradiation**  
**October 23-25, 2017**

This course is aimed at users of 80 – 300 keV electron beam irradiation who need traceable dose measurements for documentation of the process. The content of this low-energy course follows the same outline as the high-energy course. The special aspects of dosimeter calibration and dose measurements at low energy electron irradiation are addressed through dosimetry exercises using the Risø HDRL low energy electron accelerator.

**Lecturers: Arne Miller, Mark Bailey, Frederik Steenstrup, David Allison**

**For more information on these courses and for registration, go to**

[www.dtu.dk/nutech-hdrl](http://www.dtu.dk/nutech-hdrl) - click on “Courses”.

**Contact and information:**

Arne Miller  
 Risø High Dose Reference Laboratory  
 DTU Nutech, DK 4000 Roskilde, Denmark  
 Phone: +45 4677 4224 Fax: +45 4677 4959  
 e-mail: [armi@dtu.dk](mailto:armi@dtu.dk)

