**STERILIZATION AND MICROBIOLOGICAL CONTROL BY IRRADIATION**

**ABSTRACT**

The irradiation sterilization of medical devices is the dominant sterilization procedure on the global sterilization market. The trend is positive because it is a sustainable procedure, operating on final packaged products, conducted with low operation costs, environmental and human friendly.

In Romania the technical base for irradiation sterilization is placed at IRASM Radiation Processing Center – part of “Horia Hulubei” National Institute for Physics and Nuclear Engineering – IFIN HH.

IRASM Center operates a multipurpose industrial irradiator also dedicated labs for validation of irradiation sterilization, materials validation at irradiation, identification of irradiated foodstuffs.

**IRRADIATOR TECHNICAL FEATURES**

* Radiation sources: Co-60
* Source rack: rectangular, split in 4 modules
* Source hoist mechanism: pneumatic
* Pool: stainless steel, 6 m high
* Biological shield (both water and concrete): calculated for 2 MCi
* Transport system: pneumatic movement, tote-box
* Internal dimensions of totes: (47 x 47 x 88) cm
* Maximum load per tote: 120 kg
* Maximum sterilization capacity (2 MCi; 25 kGy): 30 000 m3
* Dose homogeneity (package density = 0.2 tone / m3): 1.3

**QUALITY POLICY**

IRASM Center implemented and maintained a Quality Assurance System extended on all its activities. It is certified since 2002 by DQS – Germany as being in accordance with ISO9001, ISO13485 and ISO11137. Additional proves of competence belong to various IRASM entities, like GLP license and ISO17025 accreditation of microbiological laboratory, traceability of dosimetry systems to High Dose Reference Lab RISO – Denmark et al.

**APPLICATIONS**

Medical devices, raw materials and finished foodstuffs, cosmetics, pharmaceutical packages, industrial products, items belonging to cultural heritage can be treated for sterilisation and/or microbiological control at industrial level.

**ADVANTAGES**

* Processing in final packages
* The treated products are immediately released to the market
* Completely safe, quick and reproducible procedure
* No noxious chemical into the environment
* No toxic or radioactive residues left in the treated products
* No radioactive material or radioisotope appears in the procedure or left in the product
* Completely computer controlled safe and reliable procedure

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