Guidelines for the Development, Validation and Routine Control of Industrial Radiation Processes - DTU Orbit (25/12/2018)

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Radiation processing has become a well accepted technology on the global market, with uses ranging from the sterilization of medical devices to polymer cross-linking and curing to the irradiation of selected food items. Besides these well established uses, new radiation technology applications are emerging for environmental remediation and the synthesis of advanced materials and products. Quality assurance is vital for the success of these technologies and requires the development of standardized procedures as well as the harmonization of process validation and process control. It is recognized that the degree of implementation of a quality management system and its associated procedures is quite different in developed and in developing IAEA Member States, which might become a trade barrier between them. The present guidelines have been developed following requests by Member States to provide guidance towards fulfilling the requirements of international standards regarding the development, validation and routine control of radiation processes in the health care field. Although these requirements refer specifically to medical devices, the present publication offers generalized advice relevant for any radiation process.

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