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Is IQ/OQ/PQ Part of Irradiation Process Control?

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Regulations and ISO standards applicable for medical devices require that validation of a process shall be performed. In fact, both the U.S. Quality System Regulation 21 CFR Part 820 and ISO 13485:2012 have explicit elements requiring the manufacturer to perform tasks associated with IQ, OQ and PQ.

Only after performing IQ, OQ, PQ successfully with a desired result and established documents that verify each phase, the production can get underway. This defined discipline for process validation has proven to be the ideal way to guarantee the best quality production and this, constantly over time.

During production, process control is the phase involved in ensuring the process is stable and consistently operating at the target level of performance with variations which have been set accordingly during OQ and PQ.

Relevant documents adapted to the radiation processing industry, such as ISO 11137-3, ISO14470, ISO/ASTM51649, ISO/ASTM51702, ISO/ASTM51608, ISO/ASTM52303, AAMI/TIR 29 describe the purpose and the experiments to be conducted during IQ, OQ, PQ and routine control of the process of irradiation.

The purpose of this presentation is to show actual results of irradiation plant qualification following the mentioned standards/guides and an approach for routine process control.

Preliminarily to those results, the dosimetry system calibration step and a dose measurement inter comparison conducted within the RLA 1013 004 ARCAL project, will be addressed since OQ/PQ results are mainly based on absorbed dose measurements.

Country/Organization invited to participate

France

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