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Challenges in Iodine-125 Sources Production for Cancer Treatment

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There is a great challenge the implantation on assurance quality system in the brachytherapy sources production. It involves tofulfill the Good Manufacturing Practices (GMPs) requirements, involving the process validation and of all supporting activities such as cleaning and sanitization. The purpose of this work was to execute a process validation in the iodine-125 seeds production on Radiation Technology Center located at IPEN- Brazil. Besides this, the sanitization was to evaluate the effectiveness of different surface cleaning products, determining the best to reduce radiological contamination to acceptable levels during the sources production, according to legislation. The fabrication process was performed three times for evaluation. The parameters evaluated in this study were: the source welding efficiency and the leakage tests results (immersion test). The welding efficiency doesn't have an established parameter, since is visually evaluated by the operator, and the leakage detection has to be under 5 nCi / 185 Bq, accordingly with the ISO 9978. In the relation of sanitization, it was established a cleaning program for three production lots of iodine 125 seeds using three types of sanitizers: Lot 1 with extran 1/1 (v/v), Lot 2 with hydrogen peroxide 6% and Lot 3 with sodium hydroxide 1M. Each lots contained seven iodine 125 seeds and was immersed in the sanitizer for 1 hour and then two washes with distilled water. An activity detected in each lots does not exceed 0,2 kBq (~5nCi). The observed values on process validation were: 75% welding efficiency and 32% leakage detection. Although established values for the global efficiency aren't available in the literature, the results showed high consistency and acceptable percentages, especially when other similar manufacturing processes are used in comparison (average 85-70% found in the literature for other similar metallic structures). According to results of sanitization, the best choice for remove de surface contamination was peroxide hydrogen. Further testing should ensure the sanitizer's choice is based not only on the removal of surface contamination, but also this sanitizer does not leave residues requiring further rinsing with distilled water. Those values will be important data when drafting the validation document and to follow the Good Manufacturing Practices (GMPs).