ENVIRONMENTAL IMPACTS OF GAMMA VS X-RAY IRRADIATION STERILIZATION

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Single-use technologies (SUT) used for biopharmaceutical manufacturing require irradiation sterilization before the production of biologic drug products. The primary source of radiation is Cobalt-60 gamma. A rapid increase in SUT sterilization demand and a forecasted shortage of gamma sterilization capacity has spurred the adoption and validation of X-ray as an alternate irradiation technology. While cost, capacity, and efficacy are all considerations in the adoption of X-ray, another factor is sustainability. This study presents the first comprehensive comparison of the environmental impacts of both irradiation technologies using life cycle assessment (LCA) methodology. The functional unit selected for this study is the sterilization of one metric ton of SUT materials at a standard packed density of 0.2 g/cm³ to a target dose of 25 kGy. Four scenarios were modeled at two facilities, Libertyville in the United States and Däniken in Switzerland, both employing gamma and X-ray sterilization techniques. The results reveal a significant disparity in environmental impacts across these scenarios, primarily due to differences in process energy intensity and regional energy mixes. Libertyville's X-ray sterilization demonstrated significantly higher environmental impacts mainly due to its high energy intensity and predominantly fossil-based energy mix. Conversely, gamma sterilization at the Däniken facility, supported by a hydroelectric and nuclear power energy mix, has a much lower energy intensity, and exhibited the lowest impacts across all categories. When comparing global warming potential (GWP) values for the distinct scenarios, the Libertyville X-ray scenario had the highest GWP value of 152.3 kg of CO2-eq. Däniken gamma showed the lowest GWP value (0.39 kg CO2-eq.). A sensitivity analysis showed that GWP for all scenarios is most sensitive to electricity consumption. This study underscores that environmental sustainability should be a priority when evaluating sterilization operations. Specifically, the choice of regional energy sources should be a chief consideration to minimize impacts.

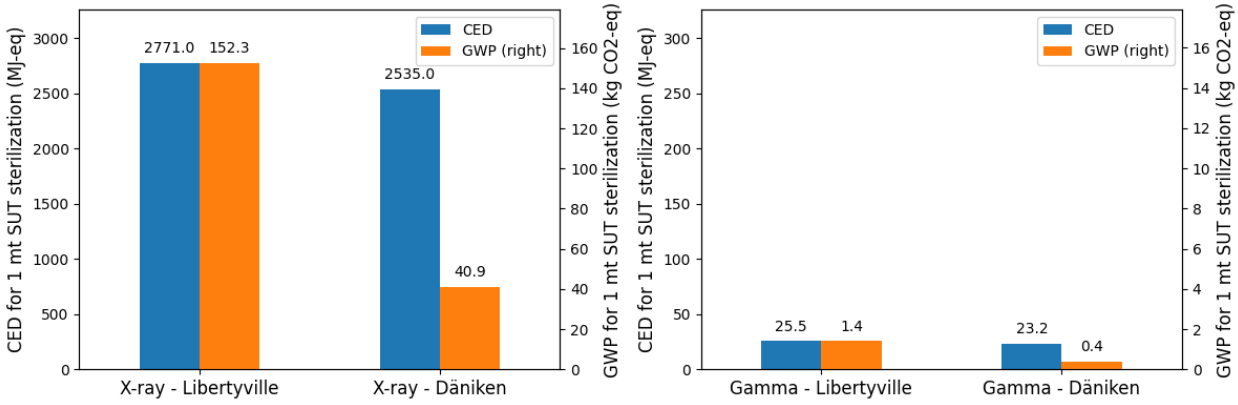

Figure 1 – LCA results for cumulative energy demand (CED, blue) and global warming potential (GWP, orange) for sterilization methods in Libertyville and Däniken Steris locations. Note: the gamma plot axes (right) are at 1/10th the scale of the X-ray plot axes (left).