

## **Issues and Guidance for Changing Radiation Modalities or Sites in Radiation Processing**

Mark A. Smith, Ph.D., CHP  
Ionaktis, LLC

Commercial irradiators generally use one of three modalities: gamma, electron beam, or x-ray. If an irradiated product is transferred from being irradiated in one modality to another, or in some cases to another irradiator using the same modality, there is potentially a difference in radiation interactions within the product that can make a difference in the desired outcome. There must be means of identifying the radiation characteristics that may possibly cause such a difference and in assessing the magnitude and significance of such differences. For healthcare product sterilization, which falls under the scope of ISO-11137-1 “Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices”, the Association for Advancement of Medical Instrumentation (AAMI) developed a Technical Information Report (TIR) to establish a basis for evaluation and provide guidance. TIR-104, “Guidance on transferring health care products between radiation sterilization sources,” was published in 2022 and contains a description of the process that should be followed in assessing changes of radiation modalities or sites. This presentation will summarize the content of TIR-104 and discuss the significance of radiation parameters in the assessment of change.