

The evolution of a standard - AAMI TIR104 and beyond, Emily Craven, Boston Scientific

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This presentation looks at the drivers behind the creation of industry guidance on the transfer of health care products between radiation sterilization sources. Some information existed within ISO 11137-1 but it was unclear and incomplete. In the process of writing TIR104, the AAMI radiation sterilization working group collaborated to clarify a process to follow when assessing the transfer of doses. An overview of this framework will be presented. The resulting document and data that was published in support of this new guidance has significantly influenced the next revision of ISO 11137-1. We will examine the path forward once ISO 11137-1:2023 is published and which next steps will be of greatest benefit to our industry.