Underdosed Radiation-Sterilized Products: Factors to Consider for Dispositioning





Situation

A minimum sterilization dose (D_{ster}) of 25 kGy (SAL of 10⁻⁶) was established for a product and sent for irradiation. The product was irradiated underdosed at a minimum dose of 24.7 kGy.

Factors to Consider

Is the product still conforming to a claim of sterility (SAL of 10⁻⁶)?

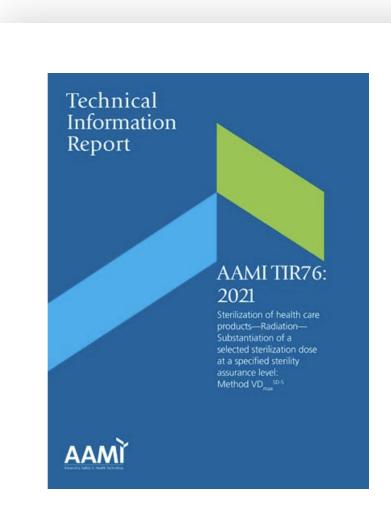
What is the potential impact to the underdosed product if released for use?

Understanding the Minimum Sterilization Dose

A minimum sterilization dose that has been established by AAMI/ISO guidelines, assumes a SAL of 10⁻⁶. Bioburden and test of sterility samples that have been irradiated at a verification dose (SAL of 10⁻¹ or SAL of 10⁻²) are performed to validate of the minimum sterilization dose (SAL of 10⁻⁶).

AAMI TIR76 provides a calculation tool that allows for calculating a verification dose based on the desired minimum sterilization dose



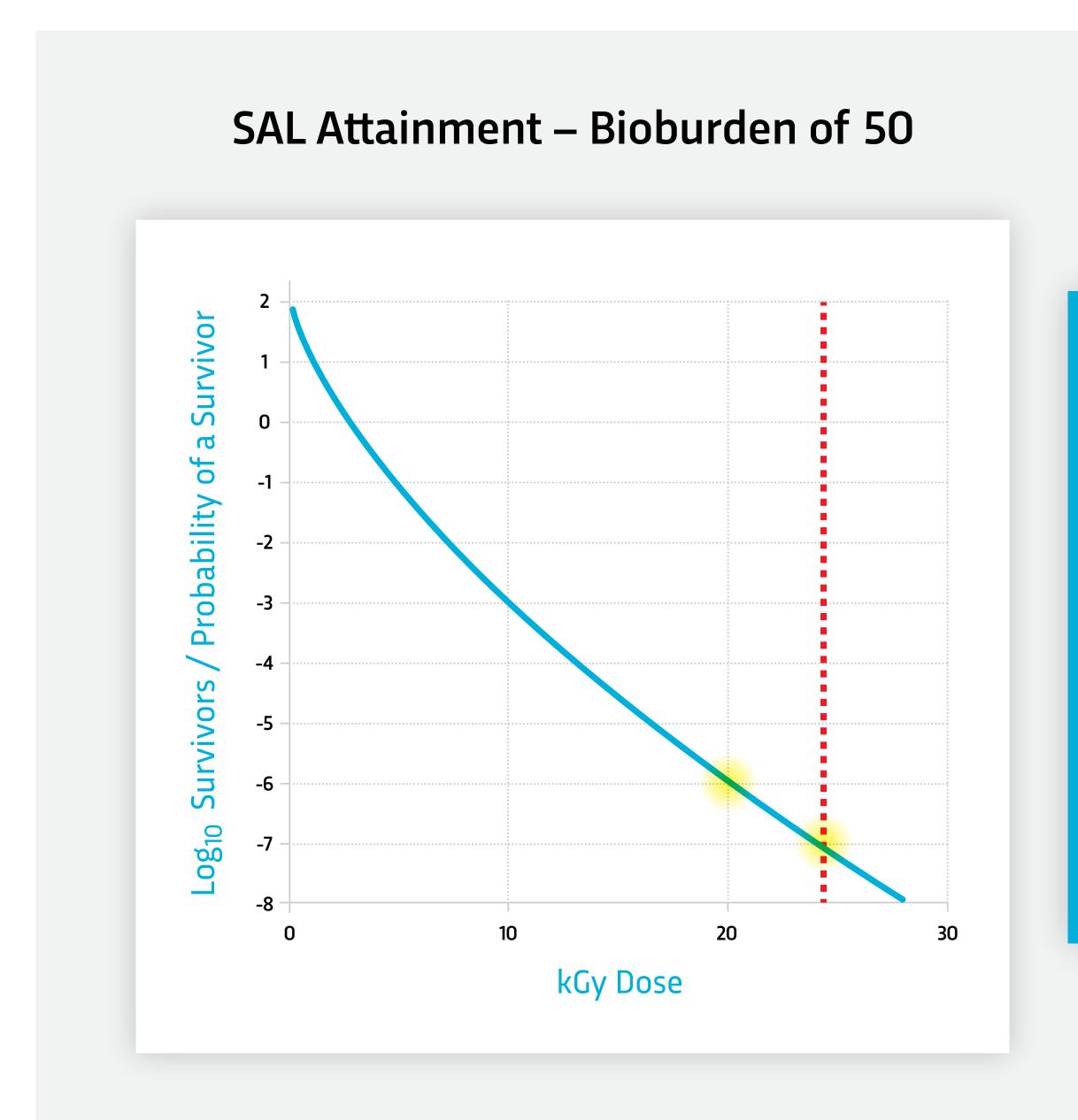


Sterilization of health care products—Radiation—
Substantiation of a selected sterilization dose at a specified sterility assurance level:

Method VD_{max} SD-S

Background on Underdosed Product

- Minimum sterilization dose of 25 kGy
- Utilizing the Calculation Tool in AAMI TIR76
- Recent dose audit Bioburden of 50 CFU = verification dose of 8.7 kGy
- Recent dose audit delivered a verification dose within the +/-10% range of 8.7 kGy
- Disposition of product with existing data can support the minimum sterilization dose $D_{ster} = 24.7 \text{ kGy for a SAL } 10^{-6}$

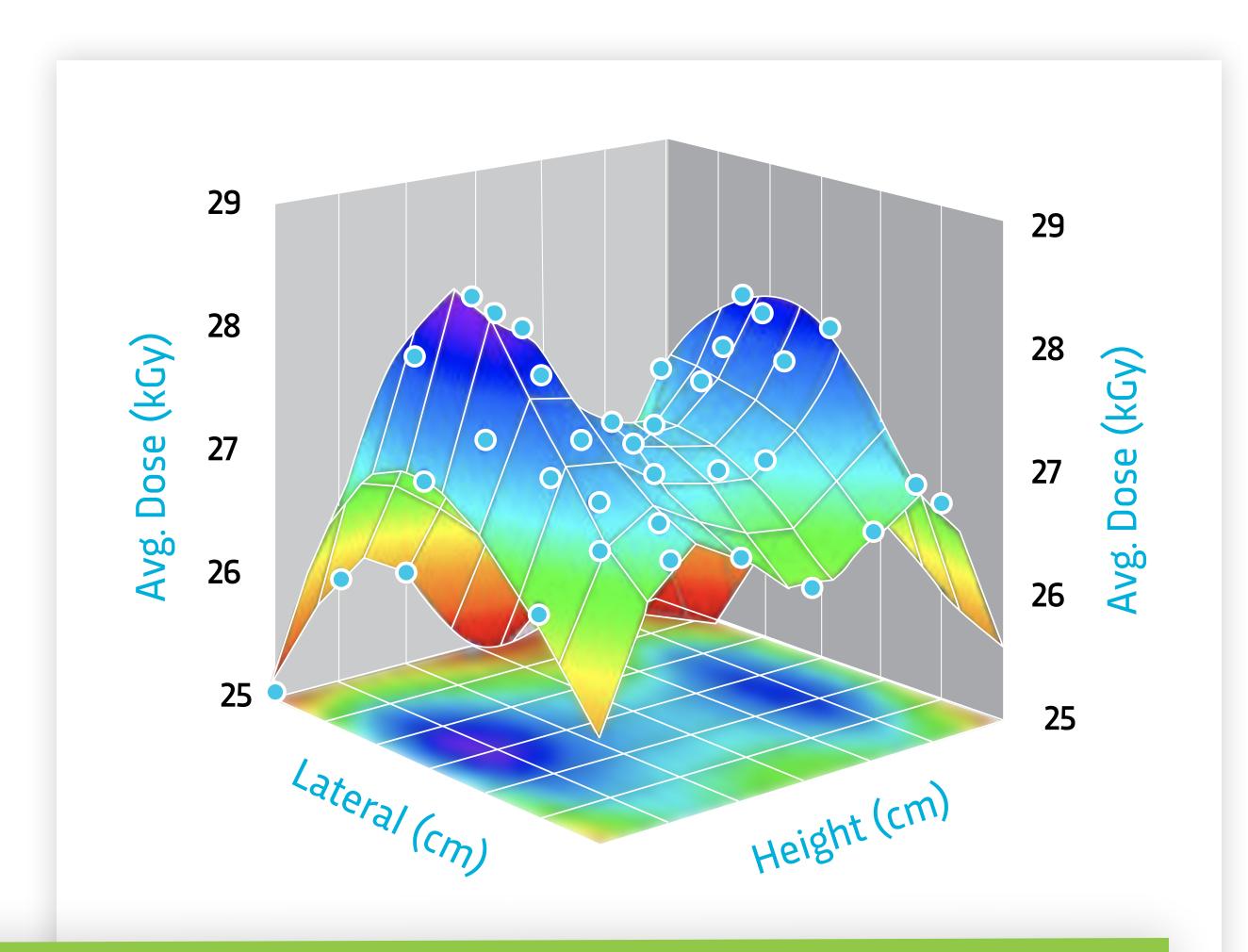


A SAL of 10⁻⁶ is attained at ~20 kGy with a highly resistant model population (Population C) which underpins Method 1 and Method VD_{max} of ISO 11137-2

At a minimum dose of **24.7 kGy**, the attained SAL is better than **10**⁻⁷







What percentage of product receives the min dose?

Based on the chart above, you can visualize the **10%** of product achieves **24.7 kGy** as shown in the red areas. That remaining amount across the dose distribution then characterizes that 90% of product achieves greater than **25 kGy**.

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