

Microbiological Resistance / Population C, Martell Winters, Nelson Labs

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Population C, also called the Standard Distribution of Resistances (SDR), has been the microbiological benchmark for radiation sterilization since the early 1980s. The development of the SDR should be understood by industry and it provides insights into how the SDR, and associated dosing tables, can be used when investigating sterilization dose establishment or dose audit failures and aberrant bioburden data. Also, analysis of the SDR reveals a potential Achilles heel which is currently being discussed in the industry and is prompting additional guidance that is being proposed in the review of ISO 11137-1.