

COMPARISON OF AAMI METHODS FOR SETTING OF MINIMUM STERILIZATION DOSE WITH IRRADIATION

TECHNICAL TIP #23

The Association for the Advancement of Medical Instrumentation (AAMI) generates numerous standards and guidelines used by professionals in the healthcare industry. Occasionally, the AAMI Standards board will provide additional guidance to specific standards in the form of a Technical Information Report (TIR). These TIRs reflect common industry practices that evolve from an accumulated process knowledge base.

In the last few years many changes have occurred to the guidance documents we have all followed to set minimum sterilization doses. With the completion of ANSI/AAMI/ISO 11137:2006 and the addition of AAMI TIR 33, many options were placed in the hands of the healthcare industry. Significant changes, such as bringing VD_{max}^{25} into an ISO document, the additional of a VD_{max}^{15} option, and incorporation of single lot validation for Method 1, have eliminated or reduced the need to use older AAMI or AAMI/ISO documents such as TIR 27, 15844 and 13409. These changes have also made the familiarity with the current ANSI/AAMI/ISO documents even more critical to the needs of the healthcare industry.

While this document is not intended to be an exhaustive comparison of old versus new guidelines, we wanted to bring together in a chart format a comparison of the methods available as starting point when preparing to review these documents for the first time as they apply to your specific product needs or requirements. This TechTip will look at dose setting, while a companion document will look at dose audits in the same format.

Please see page two of this TechTip for a comparison of gamma dose determination methods.

References:

1. ANSI/AAMI/ISO 11137-1:2006. Sterilization of health care products – Radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.
2. ANSI/AAMI/ISO 11137-2 :2006. Sterilization of health care products – Radiation-Part 2: Establishing the sterilization dose.
3. ANSI/AAMI/ISO 11137-3:2006. Sterilization of health care products – Radiation-Part 3: Guidance on dosimetric aspects.
4. AAMI TIR 33:2005. Sterilization of healthcare products- Radiation-Substantiation of a selected sterilization dose- Method VD_{max} .

Gamma Dose Determination Method Comparison

Method		Method 1	Method 2A	Method 2B	VD _{max} ¹⁵	VD _{max} ^{17.5}	VD _{max} ^{20.0}
Max CFU		1,000,000	N/A	N/A	1.5	9	45
Lowest Possible Dose	Verification	1.3 kGy (10 ⁻²)	2 (10 ⁻²)	1 (10 ⁻²)	0.5* (10 ⁻¹)	0.6* (10 ⁻¹)	0.7* (10 ⁻¹)
	Sterilization (10 ⁻⁶)	0.1-0.9 CFU: 11.0 kGy ----- >1 CFU: 14.2 kGy	8 kGy	10 kGy	15 kGy	17.5 kGy	20 kGy
Number of Samples	Bioburden	3 lots/10 each	None	None	3 lots/10 each	3 lots/10 each	3 lots/10 each
	Sterility	100	640 (3 lots, 20 each, per dose)	580 (3 lots, 20 each, per dose)	10	10	10
Dose Determination Method	Verification Dose	Per Table	2 kGy Incremental: 9 doses	1 kGy Incremental: 8 doses	Per Table	Per Table	Per Table
	Sterilization Dose	Per Table	Calculated	Calculated	15 kGy	17.5 kGy	20 kGy
Sterility Passing Criteria		≤ 2 positive	≤ 2 positive	≤ 2 positive	≤ 1 positive	≤ 1 positive	≤ 1 positive
SIP Allowed		Yes	Yes	No	No	If bioburden ≥ 1	If bioburden ≥ 1

Method		VD _{max} ^{22.5}	VD _{max} ^{25.0}	VD _{max} ^{27.5}	VD _{max} ^{30.0}	VD _{max} ^{32.5}	VD _{max} ^{35.0}
Max CFU		220	1000	5000	23,000	100,000	440,000
Lowest Possible Dose	Verification	0.8* (10 ⁻¹)	0.9* (10 ⁻¹)	4.6** (10 ⁻¹)	5.0** (10 ⁻¹)	5.4** (10 ⁻¹)	5.8** (10 ⁻¹)
	Sterilization (10 ⁻⁶)	22.5 kGy	25 kGy	27.5 kGy	30 kGy	32.5 kGy	35 kGy
Number of Samples	Bioburden	3 lots/10 each	3 lots/10 each	3 lots/10 each	3 lots/10 each	3 lots/10 each	3 lots/10 each
	Sterility	10	10	10	10	10	10
Dose Determination Method	Verification Dose	Per Table	Per Table	Per Table	Per Table	Per Table	Per Table
	Sterilization Dose	22.5 kGy	25 kGy	27.5 kGy	30 kGy	32.5 kGy	35 kGy
Sterility Passing Criteria		≤ 1 positive	≤ 1 positive	≤ 1 positive	≤ 1 positive	≤ 1 positive	≤ 1 positive
SIP Allowed		If bioburden ≥ 1	If bioburden ≥ 1	If bioburden ≥ 1	If bioburden ≥ 1	If bioburden ≥ 1	If bioburden ≥ 1

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