How does LifeNet Health determine the dose at which allografts are terminally sterilized?

Terminal sterilization validation in accordance with ANSI/AAMI/ISO 11137 Method 2B standards was established in a study undertaken by LifeNet Health's Research and Development division using musculoskeletal allografts.[1] The Method 2B validation is a means to determine the minimum absorbed dose of radiation necessary to achieve a Sterility Assurance Level (SAL) of 10^{-6}. Based on a verification dose that is determined during the validation process, a sterilization dose that results in the probability of a viable microorganism present on one allograft in a million after gamma irradiation is calculated. By achieving a validated SAL of 10^{-6}, the U.S. Food and Drug Administration (FDA) permits a product to be labeled sterile.

In the study, samples of bone and soft tissue allografts from donors for which research consent had been granted were first aseptically processed utilizing LifeNet Health's Allowash® technology in environmentally controlled suites. Each batch contained 100 grafts that were divided into five groups of 20 grafts each and were exposed to a radiation dose between 1 and 5 kGy. Each irradiated graft was further bisected and each section subjected to microbiological testing for either aerobic or anaerobic microbes. A total of three batches of allografts were tested; all tissue samples tested were culture negative. In accordance with Method 2B, the minimum absorbed sterilization dose required to achieve an SAL of 10^{-6} was calculated to be 8.3 kGy.

The following table provides an overview of representative results of terminal sterilization validation.

Batch		1 kGy	2 kGy	3 kGy	4 kGy	5 kGy
1	Average absorbed dose	≤ 1 kGy	1.9 kGy	2.8 kGy	3.7 kGy	4.8 kGy
	Non-sterile grafts/total grafts	0/20	0/20	0/20	0/20	0/20
2	Average absorbed dose	≤ 1 kGy	1.9 kGy	3.1 kGy	4.1 kGy	5.1 kGy
	Non-sterile grafts/total grafts	0/20	0/20	0/20	0/20	0/20
3	Average absorbed dose	≤ 1 kGy	2.0 kGy	2.8 kGy	3.7 kGy	4.8 kGy
	Non-sterile grafts/total grafts	0/20	0/20	0/20	0/20	0/20
Verification Dose	Average absorbed dose	≤ 0.9 kGy	N/A	N/A	N/A	N/A
	Non-sterile grafts/total grafts	0/100	N/A	N/A	N/A	N/A

LifeNet Health routinely irradiates tissue at low temperatures and using controlled parameters to ensure that the biomechanical and biochemical properties of the tissue as needed for its intended surgical application are not compromised. LifeNet Health performs sterility dose audits at least four times each year in order to routinely control the sterilization dose. During dose audits, representative allograft samples are irradiated at the verification dose and tested for sterility. Based on the test results, the sterilization dose is accepted, augmented or reestablished to ensure that an SAL of 10^{-6} is achieved. During the dose audit, the incoming bioburden, the size and complexity of the allograft, and the manufacturing process are taken into consideration. If dose augmentation is required, it is conducted in accordance with ANSI/AAMI/ISO 11137-1.[2]

[1] Moore M, Linthurst Jones A, Gaskins B, et al. Adaptation of ANSI/AAMI/ISO 11137 method 2B sterilization validation for medical devices to tissue banking. Presented at: American Association of Tissue Banks Annual Meeting; Chicago, IL; August 2004.

[2] ANSI/AAMI/ISO 11137-1:2006. Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. May 31, 2006.

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