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Editorial Open Access

Validation Study of Nitrogen Gas Plasma Exposure Based on ISO Documents (Mainly ISO TC 198 and 194 Documents)

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There are so many ISO documents to understand and utilize for validation study and routine control. Biological indicator (BI) is the essential items to conduct sterilization validation and routine control. ISO 11138-1 and ISO 14161 are the major ISO documents to read for both BI manufacturer and BI user, respectively. In ISO 11138-1, BI manufacturer must utilize BI with 10^6 CFU (colony forming unit)/carrier as an initial population in validation study. In routine control, it is approved to use 10^5 CFU/carrier BI in ISO 11138-1.

In ISO 14161 BI user need not imitate BI manufacturer and less than 10^6 CFU/carrier BI is approved to use for validation study and routine control. According to ISO 14161 for BI user, initial population using validation study and routine control must be identical. To the BI user, there are 4 sorts of sterilization validation procedure and routine control. They are half-cycle methods, over-kill methods, combined BI/bioburden method and absolute bioburden method (ISO 14161 Annex, Normative). BI with an initial population of 10^6 CFU/carrier must be used at validation study for BI manufacturer in ISO 11138-1, but BI user can select to use commercial available BI of more than 10^3 CFU/carrier as BI with an initial population for validation study and routine control in ISO 14161. Approved SAL (sterility assurance level) was defined to be 10^{-6} and this is unchanged for both BI user and BI manufacturer. In that means, from initial population to SAL of 10^{-6}, survivor curve must be straight and tailing curve should not be observed (Figures 1 and 2). Gas plasma BI, *Geobacillus stearothermophilus* ATCC 7953 is not the spore causing tailing and present straight survival curve from initial population of 10^6 CFU/carrier to SAL 10^{-6}, therefore inactivation kinetics is the first order and *D* (decimal reduction) value can be calculated from the dose or min to decrease 1 log. Chemical indicator (CI) is not approved to use in validation study and only BI is approved to use for evaluation of sterilization validation study. CI is not approved to use in validation study and only approved to use as a support in routine control in ISO 11140-1 and 14161.

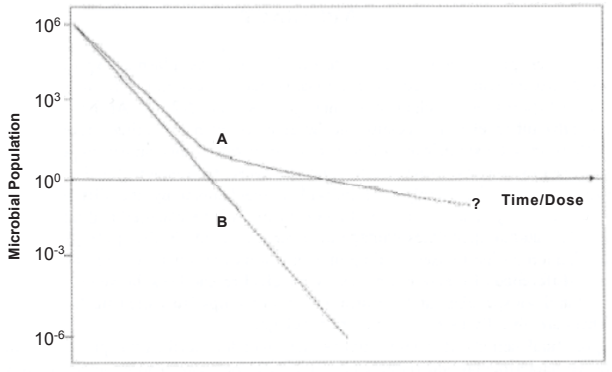

Figure 1: Straight survivor curve (B) and curved tailing survivor curve (A), the presence of curved tailing survivor curve (A) must be avoided.

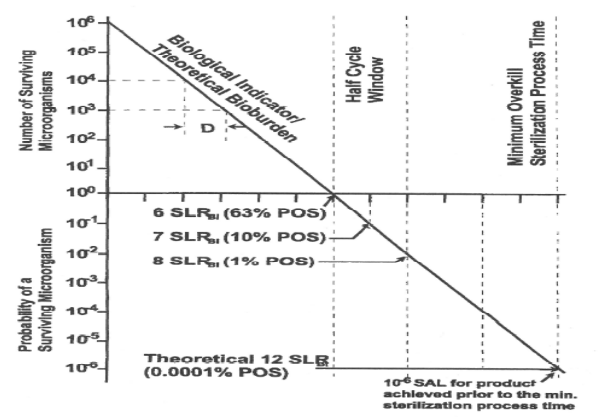

Figure 2: Necessity to attain a SAL of 10^{-6} and straight survivor curve from the initial population to a SAL of 10^{-6}, SLR stands spore log reduction, POS stands possibility of survival 10^6 CFU/carrier to SAL of 10^{-6} must be straight line to attain reproducible *D* value.

ISO documents

I am a Japan delegate of ISO TC 198 and 194. TC means Technical committee. TC 198 covers sterilization of healthcare products. TC 194 covers biological and clinical evaluations of medical devices. As I have been discussed and published ISO relative books and papers, so based on these experience and knowledge, this editorial is prepared. In the current status there is no ISO document covering gas plasma sterilization.

Gas plasma sterilization is useful sterilization procedure to easily attain sterility assurance level (SAL) of 10^{-6} and material/functional compatibility simultaneously. This is because gas plasma penetration depth is quite shallow (10-20 nm), so material does not deteriorate so easily contrary to the existing sterilization procedures [1]. Current sterilization validation requires SAL of 10^{-6} and material/functional compatibility simultaneously. If this requirement strictly addresses to the existing sterilization procedures, no sterilization procedures are available, so this requirement of simultaneous attainment of SAL of 10^{-6} and material/functional compatibility is tentatively neglected. For example, our experiment comparing material compatibility among gamma-ray, autoclaving and ethylene oxide gas sterilization was also significant deterioration of the material of polyurethane [2] and if this result addresses to the real requirement of sterilization validation, no sterilization procedure was available right now, therefore sterilization validation is the results of compromise.

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Therefore, if gas plasma sterilization can be realized, the existing sterilization procedures must be strictly addressed to obtain both SAL of 10^{-6} and material/functional compatibility. In that meaning inspection is more strict and sterilization validation will be more tough because gas plasma sterilization has a benefit to obtain both in success.

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