

The Relation between Sterilization Validation and Nosocomial Infection

Hideharu Shintani*

Chuo University, School of Science, 1-13-27, Kasuga Bunkyo 112-0003 Tokyo, Japan

Sterilization validation is so often considered to attain SAL (Sterility Assurance Level) of 10^{-6} , but this is not correct. The correct is to attain both simultaneously SAL of 10^{-6} and material and functional compatibility of the sterilized devices. SAL of 10^{-6} can be easily attained by using BI (Biological indicator) and D (decimal reduction value). For example it is 12D as an overkill method. On the contrary, it is quite hard to attain material and functional compatibility to the products exposed up to SAL of 10^{-6} . One typical example is the sterilization of endoscope. Endoscope is repeatedly used after sterilization, but the endoscope part to carry out biopsy is deteriorated after a few times use. So, sterilization is not conducted and HClO (pH 4-6) or only water washing is so often conducted in the exact healthcare facilities. By these methods purion, hepatitis virus or H. pylori is infected between human to human during endoscope inspection. Most easy method for sterilization of endoscope is gamma-ray irradiation. It is true that it can attain SAL of 10^{-6} in ease, but most often material and functional compatibility cannot attain. According to the author's experience (already reported), for example, artificial dialyzer was sterilized with gamma-ray up to SAL of 10^{-6} , material degraded and toxic and endocrine disrupter of bisphenol A is produced. Resemble phenomenon can be observed when exposed to polyurethane, polyurethane degraded and toxic 4,4'-methylene dianiline (MDA) produced at significant amount.

From the above it can be understood to be quite hard to attain simultaneously both SAL of 10^{-6} and material functional compatibility.

Therefore, ISO documents do not describe definitely to attain material and functional compatibility at sterilization validation and inspector may not ask for material and functional compatibility of the sterilized devices. However, in the exact status SAL of 10^{-6} and material and functional compatibility must be attained in success simultaneously. Inspectors are not trained to ask for material and functional compatibility of the sterilized devices up to SAL of 10^{-6} , so you need not be necessary as they do not ask for material and functional compatibility. But you must prepare for healthcare facilities because you are inquired how to sterilize to reuse the fragile medical devices. Officially dialyzer is not approved to use multi times and only single use is approved. On the contrary endoscope is approved to use multi uses after sterilization per each time, but right now no appropriate sterilization procedures are available and only water washing or HClO (pH 4-6) washing is currently used. Both methods are not sterilization procedures, so nosocomial infection can be observed by prion, hepatitis virus or H. pylori. They are not successfully decontaminated (sterilized) and they may cause nosocomial infection. The definite sterilization procedure to attain SAL of 10^{-6} and material and functional compatibility is keenly required in addition to diminish nosocomial infection by appropriate sterilization procedure. The sterilization is the future problem to the fragile medical devices at healthcare facilities. Right now, gas plasma sterilization is one of desirable sterilization, which the author is studied for endoscope part to conduct biopsy.

*Corresponding author: Hideharu Shintani, Chuo University, School of Science, 1-13-27, Kasuga Bunkyo 112-0003 Tokyo, Japan, Tel: +81425922336; E-mail: shintani@mail.hinocatv.ne.jp

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