

Title: Use of Sterilized Goggles within the Aseptic Processing Area					
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## Use of Sterilized Goggles within the Aseptic Processing Area

### **Introduction**

This document will discuss the requirement for goggle use within Aseptic Processing Areas (APA) as well as products and processes that are available to assist sites in complying with established requirements. Suggested elements of a sterile goggle program are also considered.

This guidance provides background information forming the basis for the requirement for sterilized goggles and discusses goggle availability, sterilization compatibility, and program considerations.

### **Rationale & Recommendations**

United States based APA sites first encountered regulatory concern from the Medicines and Healthcare products Regulatory Authority (MHRA) requiring the use of sterilized goggles within APA manufacturing operations for any aseptically manufactured product exported for use in Europe.

The FDA has supported the use of sterilized goggles as supported within its' Guidance document "Guidance for Industry – Sterile Drug Products Produced by Aseptic Processing", published in September 2004. This guidance indicates that gown articles worn within the aseptic processing area should be sterilized and further specifies goggles as part of this sterile ensemble.

FDA 483 citations have been issued to aseptic pharmaceutical sites where goggles have been sanitized with isopropyl alcohol prior to use as opposed to being sterilized.

As with every other article that comprises the sterile gown, it is interpreted that use of a newly sterilized pair of goggles would need to be donned with every gowning. As the human element is the greatest contamination contributor, the aseptic quality of the garments meant to act as the particulate barrier between human and environment must be maintained at the highest levels.

Goggles should be chosen, in part, based on their ability to contain particles shed by the wearer as well as not release any contaminating particles or fibers from the goggle itself. The need for goggles to be sterile within the APA is supported by the following principles. First and foremost, the criticality of the aseptic filling environment requires every other gown component to be sterile at the time of donning, including boots that touch the floor and are maintained well below line surfaces.

component for any re-usable goggle due to the direct ability to properly re-sterilize (e.g. ETO). FDA 483 citations have also been issued for lack of goggle cleaning programs when used in the APA.

### **Re-Usable Goggle Considerations**

If reusable goggles are chosen, the decision to sterilize on site depends on the sterilization technology available, goggle component compatibility, and the commitment to develop, document and maintain an overall goggle sterilization program. This program needs to:

- 1) Include a use number tracking mechanism based on a validated and documented ability of the goggles to perform as specified,
- 2) Be able to maintain the safety of the operators wearing them.

Tracking in the gowning industry is often accomplished through the use of bar coding. For instance, one vendor has accomplished the tasks of tracking and particle containment by placing a bar-code on the low particulate material used to cover the elastic strap of the goggle. The development of a tracking program is necessary if goggles are to be re-sterilized as goggle materials deteriorate during the sterilization process. The effects differ based on sterilization technology as well as the materials of construction for each specific goggle type. Goggles have been identified that are compatible with steam, ETO, and gamma irradiation sterilization. When re-sterilization is performed by a vendor, that vendor maintains the responsibility of tracking.

With the increasing expectations for use of goggles that are sterile, numerous suppliers are in the process of developing goggles that can withstand higher numbers of sterilization cycles for re-use before final disposal. Some models have the ability to change the lenses.

### **Definition of Sterilization – Risk Analysis**

While ethylene oxide, gamma irradiation and steam sterilization are the most documented and utilized forms of sterilization, other means of surface sterilization have been successfully documented and used in house for surface sterilization.

Vapour phase hydrogen peroxide (VHP), hydrogen peroxide/paracetic acid, and other surface sterilants may potentially produce a goggle that meets sterility assurance requirements. These techniques have been shown to be capable of surface sterilization for other applications that have not required a typical terminal sterilization sterility assurance level (SAL). As these methods are not first line sterilants for the purpose of sterilizing goggles, studies would need to be performed and documented on an individual basis to ensure all materials are compatible with the sterilization technique chosen for proper functionality within the APA and to show that all surfaces are sterilized. These methods should have formal validation and documentation.

### **Cautions**

Few goggle materials can withstand autoclave conditions. Gamma irradiation causes a discoloration effect and increased brittleness on the goggles after numerous sterilization cycles, depending on dosage and exposure. Ethylene oxide leaves residuals that, when not properly de-gassed, can have undesirable irritation effects on the user. The ETO residuals build with each additional sterilization cycle, even with