

Miller, Diane M. (CDC/NIOSH/EID)

From: Larry Green [lgreen@bio-md.com]
Sent: Wednesday, January 28, 2009 5:56 PM
To: NIOSH Docket Office (CDC)
Subject: ref: Docket 0148, Air-Fed Ensembles

We feel that the standard for Air-fed Ensembles should be written to allow for other respirator combined garments.

By writing the specification to allow garments without gloves and/or boots these additional types of garments could be covered by the standard. Garments for use in environments where glove and boot attachment is necessary would be so constructed.

Respirators are frequently used in conjunction with jump suits, surgical smocks and the like. While these combinations generally work, there are instances where using separately designed systems together causes difficulties with the use protocols in certain environments.

Many of these environments may not require the containment afforded by attached gloves and boots.

It is intuitive that having the hood attached to the neck of the suit will provide a more secure seal than the overlaps afforded with separate components.

One example is the Surgical Toga (distributed or manufactured by Syntech Intl, Stryker Instruments, Stackhouse, DePew and possibly others). This combines a Loose fitting respirator hood with a surgical gown for ease of Donning and Doffing. Per FDA requirements, these do not require attached gloves or boots. In typical surgical use protection is only required from the knees up and the surgeons use the gloves which fit correctly to provide the dexterity required. The gloves are available in many more sizes than normal glove sizes. The FDA has specifications for some aspects of these products. Most of these and others commonly adhered to would fall in line with, or be enhanced by, the standards being proposed for Air-Fed Ensembles.

Some of the proposed requirements, such as the minimum pressure, may not be applicable to certain of these of garments. Others may be overly stringent for lessor hazards but we have not performed an evaluation of this.

Larry Green
Syntech, Intl.