April 14, 2014

NIOSH Docket Office
Robert A. Taft Laboratories
MS-C34
4676 Columbia Parkway
Cincinnati, OH 45226

Re: National Institute for Occupational Safety and Health (NIOSH) Notice of Request for Comment; Respiratory Protective Devices Used in Healthcare [CDC−2014−0005, Docket Number NIOSH−272]

To Whom It May Concern:

The Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) appreciate the opportunity to provide input to NIOSH in response to the request for comment on *Respiratory Protective Devices Used in Healthcare*.

SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in healthcare epidemiology and infection prevention. The Society promotes infection prevention by supporting science, research, guidelines, expert guidance, education, antimicrobial stewardship and transparency in public reporting related to healthcare associated infections.

The IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases (ID). IDSA's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the U.S. and abroad.

The primary intent of this request for comment appears to be a desire to harmonize requirements for all respiratory protective devices (RPDs) across two agencies: NIOSH and FDA. The rationale outlined for such an intervention is that in the event of a pandemic, healthcare institutions may be forced to purchase RPDs that would not meet FDA standards of impermeability, variable aerosol and inflammability.

We support streamlined approval of respirators as well as clarity, transparency, and harmonization of regulatory requirements. We are primarily interested in adequate filtration characteristics and impermeability (fluid resistance). From an infection prevention/employee health perspective, impermeability is very important as there are relatively frequent instances of splashes in the non-operating room (OR) setting, including wound irrigation and handling of blood and other body fluids (e.g. paracentesis, pleurocentesis) during routine medical care and non-OR procedures. Fire resistance is a rare requirement outside the OR.

We also offer comments on the questions # 1, 2, and 4 as posed in the request for comment:

1. Do healthcare stakeholders anticipate expanding the use of RPDs to include elastomeric air purifying respirators and/or Powered Air Purifying Respirators (PAPRs)?

SHEA and IDSA anticipate that healthcare facilities, particularly in suburban or rural communities and those with low tuberculosis (TB) incidence, will increase the use of elastomeric RPD and PAPRs (especially the latter) to avoid the annual fit testing to meet aerosol transmissible disease (ATD) requirements. Many facilities with low incidence of TB—and therefore infrequent need for respirators for routine care—have opted for PAPR-only policies as a cost-effective alternative to cumbersome annual fit-testing of hundreds of employees enrolled in their respiratory programs. While elastomeric RPDs are not frequently used in routine healthcare, they are one of the preferred strategies to protect health care personnel during pandemics or other large-scale events involving ATD as they are reusable by the same person. As a result, they are being stockpiled by some institutions. It is therefore critically important that regulatory requirements for respirators are clarified so that healthcare facilities can adequately prepare for and respond to a pandemic or large outbreak.

2. For protections appropriate for RPDs to be used in surgical and/or nonsurgical healthcare environments, should NIOSH consider adding tests and requirements to the 42 CFR Part 84 conformity assessment process for splash/spray protection (fluid resistance) per ASTM F1862:2000a, or other appropriate standards? NIOSH seeks evidence related to the performance of existing products (NIOSH-approved, but not FDA-cleared as a medical device) against this standard and the prevalence and characteristics of actual sprays/splashes faced by healthcare workers during nonsurgical patient care.

NIOSH should consider adding tests and requirements, or other appropriate standards, for splash/spray protection (fluid resistance), as this is a clear hazard during routine, non-OR patient care. Splashes and sprays (e.g. from a severed artery, cough, or sneeze) are generally known to be a major source of body substance exposures. Smaller volume blood splashes during line placement or removal, IV removal, cerebrospinal fluid splashes during lumbar punctures, peritoneal fluid splashes during peritoneal dialysis, or paracentesis, are also common events. Although the standard recommendation for these procedures is a surgical mask, we acknowledge that many providers will use the mask most accessible at the time of the procedure and that these procedures must sometimes be performed on patients in airborne isolation. As such, appropriate standards should be set to ensure that RPDs are impermeable.

4. For RPDs to be used in surgical and/or non-surgical healthcare environments, should NIOSH consider adding optional, supplemental filtration testing (e.g., ASTM F2101–01 (Bacterial Filtration Efficiency) and ASTM F1215:1989 (Particulate Filtration Efficiency)) in addition to the existing NIOSH filter requirements in 42

CFR Part 84? NIOSH requests evidence related to the performance of existing products (NIOSH-approved, but not FDA-cleared as a medical device) against these alternative filter test methods and the prevalence and characteristics of airborne exposures faced by healthcare workers during patient care (i.e., non-surgical activities). NIOSH seeks comparative results for testing against such candidate supplemental standards versus test results achieved in the existing filter efficiency tests of 42 CFR Part 84.

While we do not have specific evidence to share, in general, we believe that additional testing for filtration requirements is unnecessary. We would be happy to review and provide feedback should NIOSH offer evidence for review through the public comment process.

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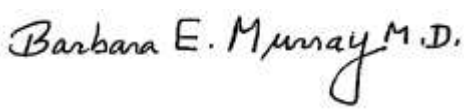
Once again, thank you for the opportunity to provide comments. Should you have any questions please contact Melanie Young, SHEA Director of Policy & Strategic Initiatives (703-299-0761 / myoung@shea-online.org) or John Billington, IDSA Sr. Program Officer for Health Policy (703-299-0015 / jbillington@idsociety.org).

Sincerely,

Dan Diekema, MD, FSHEA, FIDSA
President, SHEA



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