Integration of FDA and NIOSH Processes Used to Evaluate Respiratory Protective Devices for Health Care Workers

Proceedings of a Workshop

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Board on Health Sciences Policy

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This Proceedings of a Workshop was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published Proceedings of a Workshop as sound as possible and to ensure that this Proceedings of a Workshop meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain privileged to protect the integrity of the process. We wish to thank the following individuals for their review of this Proceedings of a Workshop:

LISA BROSSEAU, University of Illinois, Chicago
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Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the Proceedings of a Workshop before its release. The review of this Proceedings of a Workshop was overseen by **BONNIE ROGERS,** University of North Carolina at Chapel Hill. She was responsible for making certain that an independent examination of this Proceedings of a Workshop was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of the Proceedings of a Workshop rests entirely with the rapporteurs and the institution.

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Introduction[1]

Both the Food and Drug Administration (FDA) and the National Institute for Occupational Safety and Health (NIOSH) have responsibilities for evaluating and regulating respiratory protective devices (termed "respirators" for this proceedings) for health care workers. Respirators protect the user from respiratory hazards by either removing contaminants from the air (air-purifying respirators) or by supplying clean air from another source (air-supplying respirators) (NIOSH, 2016). Respirators that are used in workplaces in the United States must be approved by NIOSH and meet standards and test results specified by regulation (42 Code of Federal Regulations [CFR] Part 84).

Respirators used by health care workers are air-purifying respirators that generally fall into three types: (1) disposable particulate filtering facepiece respirators (also termed N95s);[2] (2) elastomeric respirators, also known as reusable respirators because they use a replaceable filter (that can either be washable and able to be cleaned and disinfected or have a "disposable (rubber-like) facepiece"; or (3) powered air-purifying air respirators (PAPRs) in which a battery-powered blower moves the air through the filters (NIOSH, 2016).

This Proceedings of a Workshop focused on N95 respirators. As noted above, NIOSH certifies all N95 respirators. A subset of N95 respira-

[1]The planning committee's role was limited to planning the workshop, and the Proceedings of a Workshop was prepared by the workshop rapporteurs as a factual account of what occurred at the workshop. Statements, recommendations, and opinions expressed are those of individual presenters and participants and have not been endorsed or verified by the National Academies of Sciences, Engineering, and Medicine. They should not be construed as reflecting any group consensus.

[2]The N95 respirator is the most common of the seven types of particulate filtering facepiece respirators. This product filters at least 95 percent of airborne particles but is not resistant to oil.

tors termed "surgical N95 respirators" (also termed "surgical N95s") is designated and cleared by FDA. This subset differs from standard N95s (also termed "nonsurgical N95s") in that surgical N95s are products that have been submitted for FDA clearance and have met FDA's additional requirements related to flammability, fluid resistance, and biocompatibility.

The distinction between NIOSH approval and FDA clearance has created confusion among health care delivery organizations, health care professionals, and other end users. To improve clarity and increase efficiency, NIOSH and FDA are considering streamlining the approach for regulatory oversight and approvals for N95 respirators intended for use in health care settings. Under a streamlined approach, it is anticipated that NIOSH would determine whether the N95 filtering facepiece respirator receives approval based on specific criteria agreed upon by the two agencies. However, the evaluation of flammability, fluid resistance, and biocompatibility for N95 filtering facepiece respirators are new assessments for NIOSH as they have historically been performed by manufacturers and submitted for FDA review as a part of the agency's 510(k) pre-market notification.

To provide input to NIOSH and FDA and to discuss potential next steps to integrate the two agencies' processes to certify and approve N95 respirators for use in health care settings, a workshop was held by the National Academies of Sciences, Engineering, and Medicine (the National Academies) in Washington, DC, on August 1, 2016. The workshop was focused on exploring the strengths and limitations of several current test methods for N95 respirators as well as identifying ongoing research and research needs. The workshop resulted from discussions between FDA and NIOSH and from discussions of the National Academies' Standing Committee on Personal Protective Equipment for Workplace Safety and Health. This workshop provided the opportunity to exchange knowledge and ideas between health care professionals, policy makers, and manufacturers involved in the field of personal protective equipment for health care workers. Box 1-1 provides the statement of task for this workshop. A planning committee was appointed to organize the workshop, which brought together representatives from the user, manufacturer, distributor, and research communities, as well as from federal regulatory agencies, to discuss the topic at hand.

This Proceedings of a Workshop describes the presentations given and the topics discussed. Text included under a specific presentation is attributable to the individual presenter listed unless otherwise noted. The

BOX 1-1
Integration of FDA and NIOSH Processes Used to Evaluate Respiratory Protective Devices for Health Care Workers: A Workshop
Statement of Task

An ad hoc committee will plan and conduct a 1-day public workshop that will focus on current processes and next steps toward the integration of federal processes for respiratory protective devices for use in health care settings. The workshop, through invited speakers and participant discussion, will explore current evaluation processes and potential options for test methods and evaluation processes. The Food and Drug Administration (FDA) and the National Institute for Occupational Safety and Health (NIOSH) have responsibilities for evaluating and regulating respiratory protective devices (RPDs) for health care workers.

This workshop participants will examine the following issues regarding the current processes and next steps toward the integration of federal processes for respiratory protective devices for use in health care settings:

- Test methods—The workshop will discuss tests and testing requirements to be considered in a unified process for evaluating N95 respiratory protective devices for use in health care settings. Specifically, the following test methods and associated requirements will be discussed:
  - *Filtration performance*—The workshop will provide an overview of current test methods and identify any issues that need to be resolved.
  - *Fluid resistance* (splash and spray)—Currently, FDA requires *ASTM F1862—Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood* for validation of fluid resistance on surgical N95 respirators. The workshop will discuss the strengths and limitations of this test method and alternative test methods that could be considered.
  - *Flammability*—The workshop will discuss flammability testing and its applicability regarding all health care settings and in surgical settings as well as explore the current test method and alternative test methods that could be considered.

  - *Biocompatibility and usability*—The workshop will discuss the strengths and limitations of test methods that evaluate biocompatibility and usability, including issues of cytotoxicity, sensitization, and irritation.
- Pre-market and post-market evaluation and testing requirements—The workshop will examine the issues regarding the labeling and approval of products that exceed evaluation standards. Approaches to post-market evaluation will also be discussed.
- Third-party evaluations—Workshop participants will discuss the advantages and disadvantages of using qualified third parties to perform some of the required evaluations in the context of a unified process.
- Liability issues—Workshop participants will discuss the pros and cons for supporting various options from a liability point of view.
- Other types of respiratory protective devices—Workshop participants will discuss the issues and specific approaches that could be used to determine how other types of RPDs could be evaluated in the context of a unified process.

The committee will plan and organize the workshop, select and invite workshop speakers and discussants, and moderate the discussions. A summary of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

Following this introductory chapter, Chapter 2 presents user, manufacturer, and distributor perspectives on several issues related to N95 respirators, including how they should be tested to ensure worker safety and health and if there are challenges arising from having surgical and standard N95 respirators. Chapter 3 discusses the state of the science and potential priorities for research and standards development for filtration performance, fluid resistance, flammability, biocompatibility, and usability. Chapter 4 recounts the discussions about options for post-market surveillance. The workshop proceedings concludes in Chapter 5 with a summary of three breakout group discussions and a synopsis of the workshop's major themes and discussions.

OPENING REMARKS

In her welcome and introductory remarks, Linda Hawes Clever, chair of the National Academies' workshop planning committee and a senior physician at the California Pacific Medical Center, noted that the most important part of the workshop's objective was to ensure health care worker safety, health, and productivity. Doing so, she explained, may require surmounting barriers to the integration of federal processes regarding personal protective equipment for health care workers, and those specific to N95 respirators would be discussed at the workshop.

Maryann D'Alessandro, director of NIOSH's National Personal Protective Technology Laboratory (NPPTL), estimated that some 20 million workers use personal protective equipment, including N95 respirators, on a regular basis to protect themselves from job hazards. NPPTL, which sponsored this workshop, is charged with conducting the research and the surveillance necessary for the development and refinement of personal protective equipment standards and conformity assessment processes, and with post-market surveillance of respirators and other protective equipment.

NPPTL is also charged with conducting the certification testing on N95 and other respirators. The authority to certify respirators, she explained, dates back to the early 1900s and the Bureau of Mines, with subsequent evolutions through the 1969 Federal Coal Mine Safety and Health Act (Public Law 91-173) and the Occupational Safety and Health Act of 1970 (Public Law 91-596). NIOSH's charge is now detailed in Title 42, Part 84 of the CFR.

Today, she said, both NIOSH and FDA have authorities over a subset of N95 respirators designated as surgical N95 respirators, and these concurrent authorities have resulted in confusion in the marketplace and challenges for health care institutions. Among these, said D'Alessandro, is the duplication of efforts by the two agencies in requiring similar processes, multiple and sometimes overlapping processes for manufacturers, and confusion in the marketplace with regard to whether NIOSH, FDA, or both must approve a particular product. The approval process as it stands becomes even more complex, she added, when these products are intended for use by emergency responders because of requirements in the Public Readiness and Emergency Preparedness Act (Public Law 109-148).

As a response to these issues, NIOSH and FDA are putting together a Memorandum of Understanding (MOU) through which the two agencies will develop a process to reduce the conflicting and duplicative steps that manufacturers have to go through to obtain approval for a surgical N95

respirator. It is her hope, said D'Alessandro, that the input from this workshop will move the MOU forward. She noted that the Secretary of Health and Human Services, the FDA Commissioner, and the director of the Centers for Disease Control and Prevention (CDC) are all interested in seeing the MOU finalized and work begin on the harmonization process.

Toward that end, she stated that from her perspective the goals for the workshop were to obtain input from stakeholders on

- Test methods and other features of approval/clearance process,
- Approaches to reduce conflicting and duplicative steps,
- Pre-approval and post-approval activities, and
- Additional approaches to improve workplace safety and health.

Aftin Ross, senior project manager at FDA's Center for Devices and Radiological Health, welcomed the workshop participants and noted that the shared goal of the workshop is to "ensure that health care workers have the respiratory protective devices they need both in their day-to-day work as well as in the event of an airborne infectious disease pandemic such as H1N1 influenza in 2009." She explained that because surgical N95s fall under the authorities of both FDA and NIOSH that the agencies have been looking at ways of increasing information sharing and integrating processes and activities regarding the approvals of these respirators. Toward that end, she noted that the goals of the workshop are to

- Hear perspectives from stakeholders regarding their experiences with N95 respirators in the health care setting,
- Examine the test methods used to evaluate N95s, and
- Discuss the opportunities and challenges of integrating the NIOSH and FDA processes that aim to ensure the safety of health care workers.

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Perspectives from Users, Manufacturers, and Distributors

In the workshop's first panel session, those who use, manufacture, and distribute N95 respirators were asked to address the following in their presentations and discussions:

- What N95 respirator attributes need to be tested to ensure worker safety and health in health care settings (e.g., filtration, flammability, fluid resistance, biocompatibility, others)?
- What, if any, are the current issues being faced with having two types of N95 respirators (surgical N95s and standard N95s)?
- In your opinion, what are the priorities for research, testing, and post-market surveillance to improve N95s for health care workers' safety and health? What are the priorities to be considered in the integration of FDA and NIOSH evaluation processes for N95s?

USER PERSPECTIVE: MAYO CLINIC

Jeffrey Nesbitt, Mayo Clinic, Minnesota

The health care respiratory protection program at the Mayo Clinic is responsible for conducting annual fit testing[1] of respiratory protective devices for nurses, nurse practitioners, residents, physicians, and other personnel who care for patients in both inpatient and outpatient settings, as well as for those who work in clinical laboratories and who conduct

[1]Fit testing is the process by which the appropriate respirator model and size is identified for the respirator user. Fit testing protocols using qualitative or quantitative tests are specified by the Occupational Safety and Health Administration in 29 CFR 1910.134.

autopsies. The staff members are from 62 units at the institution that support or are part of 13 patient care units. In total, some 1,700 staff members are tested annually. Currently, explained Nesbitt, the Mayo Clinic uses eight models of N95 respirators from three manufacturers to try to achieve fit for all employees who need respirators. All of the N95s that they use are NIOSH approved. The respirators from one manufacturer are FDA-cleared surgical N95s, another are not FDA-cleared surgical N95s, and the third has a product that is not FDA-cleared but has passed the FDA-specified fluid resistance performance test (ASTM F1862—*Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood*).

From this selection, Nesbitt noted that 92 percent of the staff were able to find a respirator that passed the fit test on their faces but that the fit test process can be quite time intensive with health care workers often having to try on several makes, models, and sizes. Additionally, there are significant monetary and staff costs associated with warehousing the requisite sizes and brands for meeting operational and emergency response needs and for keeping track of the expiration dates on the respirators and restocking as needed. Record keeping is also extensive and aims to inform managers about whether their employees are medically cleared for respirator use, have been fit tested, and have received the required training in their use.

In closing, Nesbitt said that performance and comfort are the most important attributes that need to be tested to ensure worker safety and health. The main issues he sees with having two types of N95 respirators for health care workers are that it creates confusion and there is a default assumption that fluid resistance is adequate in any approved N95 product. With regard to research priorities, Nesbitt said that developing better-fitting N95 respirators would be a significant improvement for organizations with a large number of employees that use these respirators and that more research is needed to establish guidelines on the appropriate reuse of N95 respirators.

USER PERSPECTIVE: JOHNS HOPKINS UNIVERSTIY

Geeta Sood, Johns Hopkins University

As an infectious disease specialist, Sood's experience with N95 respirators comes from personal use but also from chairing her facility's infection control committee, which receives reports of medical center staff who do not use their N95s when appropriate. She explained infec-

tious disease transmission can be through direct contact, via large droplets, and also by airborne transmission of droplets less than 0.5 microns in diameter, or by some combination of those routes. Respirators are particularly useful when concerned about airborne transmission of varicella, tuberculosis, influenza, or severe acute respiratory syndrome (SARS) and are particularly useful when intubating a patient or performing a bronchoscopy, so the filtration performance of an N95 respirator is important in those settings.

Sood's main concern is that health care workers do not use N95 respirators as often as they should, and even when they do, they often do not use them appropriately. Discomfort is the main reason people do not use these respirators—she said every time she puts one on she counts the seconds before she can remove it. She noted that not all of the relevant staff at her institution get fit tested annually as required, and this is a particular challenge when someone has facial hair or experiences weight changes that make a previous fit unreliable. The availability of different sizes from different manufacturers can be a challenge when someone needs an N95 at a patient's bedside and the model and size for which that person has been fitted is not available. Even when the right respirator is available, many people do not put them on properly and can even self-contaminate the respirator. The latter is such a significant problem, said Sood, that there is a great deal of research on self-contamination in the infection control field.

In her institution, Sood noted, they use N95 respirators from two manufacturers and each comes in multiple sizes. The many options create challenges for fit testing, storage, and record keeping as noted by the prior speaker.

As far as the attributes of N95 respirators that need to be tested, Sood listed filtration ability, comfort, ease of proper use, fluid resistance, and self-contamination risks. In Sood's opinion, post-market surveillance should be prioritized, and research is needed on self-contamination and to develop respirators that are easier to implement in terms of supply, fit testing, and comfortable use.

USER PERSPECTIVE: UNIVERSITY OF MARYLAND MEDICAL CENTER

James Chang, University of Maryland Medical Center

The University of Maryland Medical Center (UMMC) is an academic medical center in Baltimore, Maryland, with approximately 9,000 staff

and faculty members. The medical center uses respiratory protection in two major scenarios, explained Chang. The first is to protect staff from airborne infectious diseases, including tuberculosis, varicella, measles, and more recently, novel pathogens, including H1N1 influenza and Middle East respiratory syndrome; and the second is for protection from airborne hazardous medications. UMMC currently uses elastomeric respirators with P100 cartridges due to supply issues that began during the H1N1 influenza pandemic. UMMC is in the process of replacing these elastomeric respirators with disposable N95s in response to user reports that it is inconvenient for mobile staff to access respiratory protection when moving between locations or patients. Also, it has been observed that staff are not always proficient at cleaning their elastomeric respirators after use. In their place, will be three different disposable N95 models and PAPRs. Chang noted that they have received somewhat surprising user feedback indicating that approximately 25 percent of those who use elastomeric respirators want to stay with their reusable respirator and not transition to the disposable N95s, citing comfort and a greater feeling of safety as the two main reasons for not switching.

Fit testing with N95 respirators is of concern to Chang. It can take him 15 minutes or longer to get an N95 respirator to fit someone properly. Proper fitting of disposable N95s can involve making several adjustments to the straps or to the respirator's position on the face and he worries that it may be challenging for that person to replicate the steps it took to achieve a reliable fit/seal when it comes time to use the respirator months later. There is no easy way for the user to know that he or she has achieved a reliable fit as the recommended fit check is highly subjective and difficult to execute. The medical center will continue to provide PAPRs for those individuals who require respiratory protection sporadically as well as those who are not fit tested successfully.

Addressing the questions specific to surgical N95s, Chang said that the three brands of N95s used at UMMC are surgical N95s. The only time that he is aware that the issues regarding surgical versus standard N95s have come up at his institution was in planning for an influenza pandemic, during which the medical center was looking at home improvement centers and industrial supply houses as potential sources for N95 respirators.

With regard to performance characteristics needed for N95 certification, UMMC does not consider flammability to be an issue. Citing the comparison between a billowing surgical or isolation gown that might come in contact with an ignition source, Chang noted that respirators worn on the face in health care settings are unlikely to be brought near an

ignition source or flame. However, fluid resistance and filtration performance are of concern particularly regarding liquid splashes. He noted that discussions regarding the U.S. Pharmacopeial Convention 800 standard for handling hazardous medications note that disposable respirators offer little protection against direct liquid splashes (USP, 2016). Chang also reiterated Sood's concern about cross contamination and wonders about the validity of antimicrobial claims from some manufacturers.

Chang concluded his comments with three suggestions to improve the effective use of disposable N95s in health care settings: develop respirators with reliable and consistent fit that have a realistic means for users to check the fit, create guidance on the resistance to hazardous medication splashes, and prepare uniform guidance on the new antimicrobial-treated N95s to determine how effective they are at preventing cross contamination with and transmission of infectious agents.

A MANUFACTURER'S PERSPECTIVE

Craig Colton, 3M

From a manufacturer's perspective, Colton noted, the N95 respirator attributes that need to be tested depend on where it will be used and the airborne hazards found in those settings. When it comes to respirator filtration performance, the scientific literature shows that bioaerosols behave the same as other aerosols in workplace settings as well as aerosols used for filter testing. However, the exposure of health care workers to bloodborne pathogens suggests that different attributes other than filtration, such as fluid resistance, are of concern. Colton said his company has also received requests for respirators to be used in health care settings that have other attributes not typically considered, such as blocking nuisance odors, including fecal odors. Flammability hazards in health care settings appear to be low and as a result, testing for flammability resistance may not be necessary for N95 respirators intended for use in health care settings. It goes back to assessing risks and location of risks, he noted. Other industries have similar issues regarding respirator attributes and the need to ensure that workers have access to the types of personal protective equipment that have the protective attributes appropriate to the tasks. Colton stated that in his opinion the current test for fluid resistance is subjective and may be a cause for concern. "There is a lot of flexibility in that particular test and we believe the test procedure can be improved by having more standardized tests," said Colton.

In regard to priorities for research, testing, and post-market surveil-

lance, he would like to see fluid resistance testing improved and validated. Research is also needed, said Colton, to understand what char- acteristics of a respirator would make it suitable for use in hot and humid environments such as one might encounter in the field as opposed to the climate-controlled conditions inside a hospital. A better understanding of the attributes that create a comfortable and tolerable respirator and how to measure those attributes is also needed. He noted that from a manufacturer's perspective, NIOSH's post-market surveillance system for respirators is more robust than the FDA system.

A DISTRIBUTOR'S PERSPECTIVE

Akhil Agrawal, American Medical Depot

Addressing supply chain issues, Agrawal noted that his company distributes products from more than 2,000 manufacturers to some 6,000 health care customers, including Department of Veterans Affairs and Department of Defense facilities. Globalization, he explained, has profoundly affected how supply chains are managed both strategically and operationally. For respirators, the main supply chain issue stated by Agrawal is that more than 90 percent of the products are not manufactured in the United States. This creates significant risks because during a true global pandemic those supplies that come from outside of the United States would likely be immediately unavailable, resulting in the U.S. supply chain being unable to meet the demand for respirators. The shortage would be further complicated by the lean inventory process employed by most health care facilities that depends on just-in-time fulfillment to meet normal operational demands for respirators and other protective equipment.

While there have been no true disruptions in the supply chain, there have been disturbances from which there are lessons to learn about the fairly "frail" supply chain for respirators noted Agrawal. These disturbances include the 2003 SARS outbreak, the 2009 H1N1 outbreak, and the 2014 Ebola outbreak. What happened during these disturbances is that health care officials placed multiple orders for respirators with multiple vendors, creating what Agrawal called an enormous amount of phantom demand accompanied by hoarding. In addition, there was a large increase in what he termed nontraditional demand from the public, clinicians, first responders, and others. As a result, the respirator manufacturers put each of the 10 major distributors (that account for 98 percent of all products moved in the health care sector) on an allocation

within 3 to 4 days. In turn, that meant that within 3 to 4 days, distributors were providing customers with 90 percent of what had been their usage over the preceding 6 months. Within a week or two, that dropped to 60 percent of a customer's historic usage, and items went on backorder after approximately 3 weeks of elevated demand. Agrawal noted that the Department of Defense's supplies were not reduced. Depending on the nature of future situations, health care facilities may have to give up part of their supplies to meet urgent needs of other facilities.

The traditional strategies for managing supply chain risk are to stockpile inventory, diversify the supply of product, identify backup suppliers, manage demand, strengthen the supply chain by working with manufacturers, and more effectively use the existing supply of product (see Table 2-1). None of these strategies would be sufficient, however, if a true pandemic situation existed, said Agrawal. "The order-of-magnitude difference for respirators and masks in terms of utilization in case of airborne pathogen transmission is so great that none of the traditional supply chain strategies that are available would ever be sufficient to meet the demand and the expectations that our 6,000 or so health care customers would have," he explained.

What is needed, he said, is innovation, and one possible solution for a pandemic situation could be one of the newly developed reusable antimicrobial respirators. While this may not be the perfect solution from a science perspective, in the event of a high-risk pandemic it may represent an acceptable solution. Agrawal wondered if there is a role for the Biomedical Advanced Research and Development Authority to play in addressing the regulatory issues, but regardless, he said there needs to be a clear path between NIOSH and FDA for approval of N95 respirators specifically and guidance regarding reusability of respirators in general.

In Agrawal's opinion, providing regulatory clarity would open up funding to innovators who would work to solve this part of the supply chain problem; and even with that, however, there would still be a need to enhance domestic production capability for respirators. He noted that there are companies that produce these materials and do the molding domestically, but they account for a small percentage of the respirators used on a normal basis in the United States.

TABLE 2-1 Traditional Strategies for Managing Supply Chain Risk

Stockpile inventory	Hold inventory that can be used to meet demand if supply is interrupted
Diversify supply	Source product from multiple vendors so that a problem with one vendor does not affect the entire supply
Backup supply	Engage an emergency supplier that is not normally used but that can be activated in the event of a supply chain problem
Manage demand	Influence demand to better match supply by encouraging consumption of products less supply constrained
Strengthen the supply chain	Work with suppliers to reduce the frequency and or severity of supply problems
Effective use of existing supply	Identify, have visibility to, and rotate the just-in-case inventory through the just-in-time demand channels

SOURCE: Presented by Akhil Agrawal, August 1, 2016.

DISCUSSION

In the discussion session with workshop participants, a number of issues regarding the use of respirators in health care settings were discussed, including issues regarding streamlining the regulatory processes. Several participants noted the potential confusion in the health care workplace regarding the use of surgical and nonsurgical N95 respirators and in addition, the complication of another type of product—surgical masks—which are not respiratory protective devices. Issues relevant to specific types of respirator testing are discussed in the following chapter.

In response to a question about how big of a problem occupational illness is in the health care setting, Sood said the numbers in normal endemic hospital functions are small and that in 10 years she has seen at most three cases of occupational transmission. Tuberculosis is very nontransmissible and while varicella has a bigger potential to pass from a patient to a staff member, most health care workers have been vaccinated and so it is seen infrequently in health care workers. In a pandemic situation, she expects these numbers to be higher. She also remarked that in her experience the biggest cause of occupational health failures is people forgetting to use respirators and face shields, which she attributed largely

to discomfort. Session moderator Barbara DeBaun from Cynosure Health noted that the health care field experienced the same challenge in the 1980s when gloves were first gaining traction in health care. "They were uncomfortable and people would not wear them because they were uncomfortable," she said.

Another issue raised by David Prezant from the New York City Fire Department was the extent of the evidence regarding expiration dates on respirators, particularly in the context of supply chain problems. He asked whether incorporating fluid resistance properties would affect the expiration date. Colton replied that there can be a number of attributes contributing to a particular respirator's expiration date, including fluid resistance, flammability, and the material from which the straps are made. Expiration dates, Colton explained, have only been added fairly recently. Although there is some scientific evidence to determine those dates—collected through a combination of accelerated aging testing and experience with specific materials—much still remains to be learned. Thus, expiration dates tend to be set toward the conservative side.

There was discussion about the use of PAPRs that have the advantage of providing both respiratory and splash protection without requiring annual fit tests; but as noted by Sood, the tradeoffs are that PAPRs are expensive and difficult to clean. She also noted that some of the hospitals in the Johns Hopkins health system tried to use PAPRs universally with little success.

The issues of fit testing came up in the discussion session with Kate Bradford from the Department of State asking if fit testing at the panelists' institutions was qualitative or quantitative. From the panelists' responses, qualitative testing is the norm for group fit testing at their institutions, and quantitative testing is used for new employees and when someone fails qualitative testing. A suggestion was made by Jonathan Rosen from AJ Rosen & Associates, LLC, to study the varying types of N95 respirators on the market today and compare their abilities to produce a good fit. Nesbitt noted that if a small number of models that would fit 90-plus percent of his staff could be identified, it would be a big boon in significantly reducing costs and logistical issues.

Rosen brought up the two Respiratory Evaluation for Acute Care Hospitals studies that NIOSH has funded. These studies demonstrated there were large gaps in complying with Occupational Safety and Health Administration (OSHA) requirements regarding respirator use in health care settings, either because staff members were not using the respirators or not wearing them correctly. He also recounted an anecdote in which an industrial hygienist was training and fitting 15 employees at a time in

short (15-minute) increments, suggesting that training and education about the use of respirators are lacking.

Mark Catlin from the Service Employees International Union said it is important to separate certification approval issues from those resulting from managers not understanding how to run a respiratory protection program. One issue he has seen is that when health care workers ask for respirators, they are told surgical masks are good enough. He also noted that NIOSH and other researchers have identified the need for health care administrators to figure out how to better run these programs. With regard to approval certification, an issue he would like to see addressed concerns the maximum length of time disposable N95s should be worn. "They are often thought of as disposable, but in the health care industry people often wear them all shift long, they take them on and off, they crease them, and they put them in pockets," noted Catlin. He said that the union's members have reported they are told that their respirators have to last for periods ranging from an entire shift to a week, a month, or an entire year because they are expensive. The panelists agreed that reusability is an issue given that many of the microorganisms of concern can be transmitted through contact with a contaminated surface such as the outside of a respirator.

James Johnson from JSJ and Associates asked the panelists to comment on the use of reusable versus disposable N95 respirators noting that in other industries, such as the radiation research laboratories where he has worked, the lab employees did not have to clean their respirator; a separate staff conducted the respirator cleaning as part of their responsibilities. Both Chang and Sood replied that infection control is a major reason for using disposable N95s (particularly as health care providers move between patients of varying risks), as well as the convenience of not having to carry a reusable respirator for an entire shift. Agrawal highlighted the issue of reusability and the potential for a positive impact on the supply chain. Rosen noted that the Joint Commission's guidance on implementing hospital respiratory protection programs highlights the Texas Center for Infectious Disease's protocols for successfully reusing N95s in the tuberculosis setting (Joint Commission, 2014).

3

Exploring the State of the Science and Potential Priorities for Research and Standards Development

Over the course of the next two panel sessions, seven speakers discussed various aspects of the state of the science and potential priorities for research and standards development in the areas of filtration performance, fluid resistance, flammability, and biocompatibility/usability. Prior to the workshop, the panelists were asked to address the following questions in their remarks:

- What improvements are needed to the tests and test methods?
- What efforts are under way to revise the standards?
- What are the research gaps and priorities?
- What are the priorities for research, test method development and refinement, and post-market surveillance of N95s to improve health care workers safety and health?
- What are the priorities to be considered in integrating FDA and NIOSH evaluation processes for N95s used in health care settings?

TESTING THE FILTER PENETRATION PERFORMANCE OF RESPIRATORY PROTECTION DEVICES

Robert Eninger, Air Force Institute of Technology

Numerous factors influence filtration efficiency (see Box 3-1), and as a result, a filter's measured filtration efficiency will depend on the test aerosol, the particle size, the way in which aerosol is measured inside and outside of the filter, and other test parameters. "If you want to compare apples to apples, all of these [different factors] must be similar between the two different test regimes to have results that are comparable," said Eninger.

BOX 3-1
Factors Affecting the Measurement of Filtration Performance

Challenge Aerosol Characteristics
- Physical state (solid, liquid)
- Particle size distribution
- Particle density
- Particle charge distribution
- Other (i.e., refractive index)

Aerosol Measurement Method
- Count, surface area, mass
- Gravimetry, photometry, etc.
- Range of detection (size and mass)
- Sensitivity and accuracy
- Response (linear, logarithmic)
- Calibration
- Filtration efficiency metric

Respirator Filter Characteristics
- Substrate
- Surface area
- Thickness
- Fiber diameter
- Surface density
- Electrical properties

Respirator Test Conditions
- Temperature
- Relative humidity
- Airflow
- Filter pre-conditioning
- Aerosol loading
- Duration
- Repetitions
- Methods of mounting/sealing

SOURCE: Presented by Robert Eninger, August 1, 2016 (Eninger, 2008).

TABLE 3-1 Filtration Test Methods

	NIOSH Certification	ASTM F2299
Particle size	MMAD 0.3 µm NaCl	0.1 µm monodisperse PSL
Particle charge	Charge neutralized	Unconditioned
Item tested	Entire respirator	Material sample
Pre-conditioning	85 percent relative humidity, 38ºC for 24 hours	None
Loading	200 mg	No specific requirement
Flow rate	85 lpm, constant	28 lpm, constant
Measurement	Mass, by light scatter	Count, by light scatter

NOTE: lpm = liters per minute; MMAD = mass median aerodynamic diameter; PSL = polystyrene latex spheres.
SOURCE: Presented by Robert Eninger, August 1, 2016.

With regard to filtration test methods, Eninger considers the NIOSH certification standards (see Table 3-1) as a more conservative set of filtration test parameters as compared to the ASTM F2299 standard included in FDA's regulatory requirements. Starting with particle size, he explained that the NIOSH certification uses sodium chloride particles with a mean particle size corresponding to the most penetrating particle size based on the principles of mechanical filtration.

The electrical charge characteristics of an aerosol can significantly influence its ability to be filtered depending on the specific filtering medium. The NIOSH test uses a charge-neutralized aerosol, creating a worst-case scenario for a filtration medium, while the ASTM method uses an unconditioned aerosol, which means that the aerosol's particles are charged to some extent. The NIOSH test uses an entire respirator that has been preconditioned for 24 hours at 38°C and 85 percent relative humidity, which represents a challenging high-humidity environment. The ASTM method tests a sample of the filtration material with no preconditioning. In addition, the NIOSH method is run until a mass of approximately 200 milligrams is deposited on the filter—a relatively large amount of mass—while there is no specific requirement for a specific mass to be tested in the ASTM method.

Flow rate is important because people respire at different rates under different workloads. The flow rate influences the residence time of particles as they pass through the filtration medium. The NIOSH method uses a constant flow rate of 85 liters per minute, which is an estimate of what a high peak inspiratory flow might be for a very active workplace,

while the ASTM method uses a constant flow rate of 28 liters per minute that may be more typical of the respiratory rate of a surgeon or other health care worker. Finally, the NIOSH method assesses the mass of particles passing through the respirator using light scattering, while the ASTM method uses light scattering to count the number of particles passing through the filter material sample.

Another ASTM test method listed in the FDA notice for N95 respirators, ASTM F2101, assesses biological filtration efficiency. This test changes two parameters from the ASTM particle filtration efficiency test: using aerosolized *Staphylococcus aureus* particles with mean diameter of approximately 3 microns and collecting the particles that pass through the filtration medium on a six-stage aerosol impactor. The collected particles are then plated out for a defined time and the number of bacterial colonies that develop on the plates are counted to produce a measure of colony-forming units per volume of air.

Eninger said he considers NIOSH certification to be rigorous, repeatable, and a near worst-case scenario for a respirator. It does not use a biological aerosol for certification of N-type respirators. Over the past decade, researchers have revised the parameters regarding the understanding of the most penetrating particle size for a respirator. Many respirators manufactured today use electrostatically charged filtration media to increase filtration efficiency while reducing breathing resistance, creating respirators that place a lower physiological burden on users. Research has shown that the most penetrating particle size for respirators using these electrostatically charged materials shifts to 100 nanometers or less and even as low as 30 nanometers (Eninger et al., 2008). Work from NIOSH (Rengasamy et al., 2013) has shown that removing the charge from particles increases the most penetrating particle size. Other research (Harnish et al., 2013, 2016) has shown that biological particles follow the same filtration physics as do inert particles, and so the capture mechanism does not discriminate in favor of or against biological particles. These results suggest that adding the FDA requirements regarding testing for filtration performance to the NIOSH requirements would not improve the assessment of N95 filtration efficacy (Rengasamy et al., 2016).

PARTICLE PENETRATION PATHWAYS

Sergey Grinshpun, University of Cincinnati

For someone wearing a respirator there are two potential pathways for aerosol particle penetration: through the filter medium or via faceseal

leakage. The current NIOSH certification process, which measures particle concentrations inside and outside of the filter used by a respirator and assesses the filtration efficiency, addresses the first of these pathways. Over the past several decades, said Grinshpun, "industry has done a wonderful job improving the physical collection efficiency of filters, but faceseal leakage has been largely ignored or overlooked in designing new respirators or considering new configurations of facepieces."

To measure faceseal leakage, the respirator undergoes performance testing while fitted on a human subject. Measuring particle concentration inside and outside of the respirator on the user allows the determination of what is termed "total inward leakage"—the sum of the two types of particle penetration (through the filter and through the faceseal). Given the improvements made in filtration media, leakage through the faceseal can be comparable to or exceed penetration through the filter material. Thus, said Grinshpun, it becomes important to look at the relative contributions of each pathway. Assessing the relative contribution in a laboratory setting is done by fitting a manikin with a respirator and having the manikin "breathe" according to exercise-specific breathing patterns, which have been recorded when the same type of respirator was fitted on a human subject following the same set of exercises. Subtracting the filter material's contribution as determined using the NIOSH test procedure for total inward leakage yields a value that quantifies the faceseal leakage (Grinshpun et al., 2009). Studies in Grinshpun's laboratory have shown that penetration through faceseal leakage is, in fact, a major contributor to total particle penetration into the respirator and in some instances can exceed penetration through the filter material by 10-fold. Other studies (Chen and Willeke, 1992; Rengasamy and Eimer, 2012) produced similar results, as has computational modeling of total inward leakage. The latter has shown that amount of faceseal leakage is related to the ratio of the area of a leak in the faceseal to the area of the filter.

Having identified faceseal leakage as a critical factor in a respirator's particle filtration performance, Grinshpun and others have been developing novel faceseal designs to address this problem. One such effort, which aimed to improve respiratory protection against surgical smoke, came up with an elastomeric material with a shape that was designed based on the anatomy of the human face. Comparing the performance of an N95 respirator with this new type of faceseal with that of a standard N95 respirator on 10 human subjects (who were conducting simulated electric cautery surgery) showed that this new faceseal afforded greater protection against particle exposure at a statistically significant level.

Grinshpun noted that this is not the only design that companies have recently developed to address the faceseal leakage problem.

In conclusion, Grinshpun suggested that because faceseal leakage may represent a major pathway for aerosol particle penetration into respirators, particularly for those made with highly efficient filter materials, particle penetration tests for certification should include total inward leakage measurements and quantification of faceseal leakage. While there are experimental and computational methods for determining the efficiency of filtering facepiece respirators, he said that priorities for research and standard development should include the development of test methods capable of accounting for faceseal leakage. Existing NIOSH and FDA evaluation processes, Grinshpun indicated, might benefit from integrating a leakage test into the existing protocols.

FLUID RESISTANCE TESTING

Brandon Williams, Nelson Laboratories

Testing of respirators to meet the FDA criteria for fluid resistance is usually done using the ASTM F1862 test method standard, which assesses whether the synthetic blood penetrates into the layers of the respirator. The test involves dispensing synthetic blood using a pressurized cannula for a distance of 12 inches through a small hole in a target plate to which the respirator is attached. A visual inspection of the inside of the respirator for fluid penetration is then conducted. As Williams explained, the multiple layers of filtering material in some respirators can make visual identification of blood penetration difficult and sometimes requires lightly brushing a cotton swab on the inside of the device to see if there was penetration. This human factor—the force of brushing the swab against the inside of the product can be too hard or too soft—is one aspect of the test method that is subjective.

Several features of the test method approximate potential surgical exposures to blood. The pressure levels used to shoot synthetic blood at the respirator range from 80 millimeters of mercury (mm Hg) pressure to 120 to 160 mm Hg, which spans the typical human blood pressure. Williams noted that the 12-inch distance between the cannula and the respirator mimics the scenario of how close a surgeon can come to the patient during surgery. He also explained that the surface tension of the synthetic blood specified in ASTM F1862 is at the low end of the range for human blood, which mimics human blood at its most penetrating surface tension. The standard specifies that three or fewer failures are al-

lowed out of a set of 32 samples in order to pass the test. One advantage of this test aside from its simplicity, he added, is that it has been used for more than 15 years and as a result there is a significant body of data against which to compare various respirator materials and products.

ASTM F1862 is not a perfect method, however. One challenge, said Williams, is measuring surface tension accurately, and he noted that researchers at CDC have been trying to standardize surface tension measurements so that the test will produce consistent results from one laboratory to the next. "Most people purchase the test blood from the same manufacturer, yet sometimes they get different results using the same test method, so that is something that is being improved on right now," said Williams. Another challenge is that the visual inspection must occur within 10 seconds after the mask or respirator has been sprayed. He questioned whether that is a reasonable amount of time for a surgeon to remove a mask or respirator after getting sprayed with blood or if it really takes longer than that. "When the standard comes up for revision, I think that should be looked at to see if that is a reasonable expectation," said Williams. Two other disadvantages are that this is merely a penetration test and not a microbiological one, and that respirators with seams or the newer duck-billed products are difficult to test because of the low locational accuracy of the fluid-dispensing apparatus. The standard does not address how to test different areas of a respirator.

In Williams's opinion, blood penetration testing is important for surgical respirators because filtration materials have to be porous so the user can breathe, but porous products will allow for some liquid penetration. He noted that they are not aware of any other test result that could be used as an indicator for how the product will perform in the blood penetration test.

FLUID RESISTANCE TESTING AND PROTOCOLS

Steven Elliott, Food and Drug Administration

Fluid resistance is one of the elements that is assessed in FDA's 510(k) approval process for surgical N95 respirators, said Elliott. The 510(k) approval process, he added, compares new devices against those that have already been granted clearance. As discussed above, FDA recognizes consensus standard ASTM F1862 as the specific methodology to be used to test fluid resistance. The agency also recognizes ASTM F2100 as the consensus standard for performance specifications of the materials used in respirators and medical face masks.

Elliott said FDA recognizes both the strengths and limitations of the

current fluid resistance tests that the previous speaker discussed. Using the ASTM standards is voluntary—manufacturers can develop their own comparable tests—but because several stakeholders from industry, the health care sector, and FDA have had input into the development of these standards, it often turns out to be easier for manufacturers to use the ASTM methods and performance specifications. He also pointed out that FDA only requires a blood resistance test, but it recognizes that other fluids, such as caustic chemotherapy drugs, could have different properties that may require additional testing. "I am unaware of any specific clearances we have along those lines, but that is something that would be evaluated and require additional challenge conditions in the testing and possibly an entirely new test," said Elliott. Other performance claims might also result in the need for a manufacturer to use additional tests.

Elliott said that while FDA is open to changes and modifications to make the test methodology more appropriate for N95 respirators, any new procedure would have to take into account the regulatory history of these standards. He noted that any new procedure that would be incorporated into the agency's regulatory framework would need to look at performance expectations with regard to fluid resistance. "You can increase fluid resistance on any mask or respirator, but there will be some sort of tradeoff in terms of breathability and we want to make sure that we would be moving in the appropriate direction and taking in the concerns from all fronts on that," said Elliott.

FLAMMABILITY TESTING FOR RESPIRATORS

Samy Rengasamy, *National Personal Protective Technology Laboratory*

At first glance, fire hazards would not seem to be a risk to which health care workers are exposed, but in fact, said Rengasamy, when surgical fires do happen, they can be catastrophic. He noted that the Emergency Care Research Institute reports that about 600 surgical fires occur in the United States each year. Operating room fires have many sources (including electrical surgical equipment, alcohol-based agents, surgical drapes, and gases such as oxygen and nitrous oxide) and are most likely to occur during procedures such as endoscopic airway surgery, oropharyngeal surgery, tracheostomy, and cutaneous surgery.

In 2014, when NIOSH published a notice on respiratory protective devices used in health care in the *Federal Register*, issues were raised as to whether NIOSH should consider adding tests and requirements on splash and spray protection, protection against flammability hazards, and

bacterial filtration efficiency to the 42 CFR 84 conformity assessment process for respirators (HHS, 2014). To address these questions, NIOSH initiated a research project on fluid resistance and flammability of respirators and other head and face personal protective equipment. The equipment tested in this research included N95 respirators, PAPRs, hoods, surgical head covers, surgical N95 respirators, and surgical masks. The project evaluated fluid resistance for N95 and surgical N95 respirators, as well as surgical masks, using the ASTM F1862 standard method (Rengasamy et al., 2015; see description of the method above). Filtration efficiency of these devices was assessed using the NIOSH sodium chloride method and the results were compared with the FDA-required particulate filtration efficiency and bacterial filtration efficiency test methods (Rengasamy et al., 2016). The flammability testing is under way for this project and is using the Consumer Product Safety Commission (CPSC) method described in 16 CFR 1610. This test measures the time that it takes for fire to traverse across a sample of material (positioned at a 45 degree angle) once it has been ignited. The average burn time for a set of five samples is used to assign a material to a flammability class. Class 1 materials (normal flammability) are less likely to burn and take longer than 3.5 seconds to burn.[1] The average burn time for Class 3 materials is less than 3.5 seconds for plain surface textile fabrics. FDA recommends that surgical masks and respirators be made from Class 1 and Class 2 materials and requires a flammability warning notice if Class 3 materials are used.

At the time of this workshop, Rengasamy and his colleagues had tested 11 N95 models and 8 surgical N95s, and all of the models passed the flammability test. Many of the samples, he said, did not ignite at all and some ignited but self-extinguished. Others did burn but with an average burn time exceeding 3.5 seconds. Comparable results were obtained and confirmed by a third-party independent laboratory. Rengasamy noted that 7 out of 11 N95 models met the FDA requirements for fluid resistance and flammability testing, as did all 8 surgical N95s. The take-home messages, he said, are that NIOSH has the capacity to perform the 16 CFR 1610 flammability testing and that there may be several N95

[1]16 CFR 1610 states that plain surface textile fabrics that have a burn time of 3.5 seconds or more are classified as Class 1, normal flammability; for raised surface textile fabrics, Class 1 is used for those with a burn time of more than 7 seconds. For raised surface textile fabrics, intermediate flammability (Class 2) is defined as a burn time of 4 to 7 seconds. Class 2 does not apply to plain surface textile fabrics. Class 3 (rapid and intense burning) materials are those that "exhibit rapid and intense burning, are dangerously flammable and shall not be used for clothing."

models on the market that meet FDA requirements but that have not been submitted to FDA for clearance. This could provide more models of N95s that meet FDA criteria that are available for emergency use during the infectious disease seasons, said Rengasamy.

FLAMMABILITY TESTING: TEST METHODS AND STANDARDS

Roger L. Barker, North Carolina State University

FDA cites three standards with respect to the flammability of surgical N95 respirators, said Barker. The first, developed originally in the 1950s by CPSC[2] and described above by Rengasamy, is used in testing apparel worn in the United States. This standard stipulates a test method that has been used for more than 60 years so there are extensive data. CPSC has established three classes of flammability based on the rate of burn propagation in that test. FDA also cites National Fire Protection Association standard 702, which is similar to the CPSC standard and was actually withdrawn in 1986 in deference to the CPSC standard, and Underwriters Laboratory 2154, which measures the level of atmospheric oxygen required to propagate flame when the ignition is caused by electrical surgical laser. As far as Barker could determine, this latter test is not readily available. He noted that all clothing materials, even those treated to be flame-resistant, will burn if a high-intensity heat source is applied to them in the presence of sufficiently elevated oxygen levels.

Having spent much of his academic career developing test methods to look at thermal protection for protective clothing, Barker said one thing he knows to be true is that there are many variables, such as the ignition source and oxygen level, that can affect and determine flammability beyond the material itself. He also pointed out that all of the recognized test methods look solely at the filtration material, not the entire respirator. Many different metrics can be used to describe flammability, including ease of ignition, burning rate, heat release, thermal stability, and others. Barker said that the tests focus on the flammability of the product's materials and not on the way in which the material is put into use (e.g., the form of the products such as respirators, masks, and gowns), which can affect the outcome of a material's burning behavior.

With regard to what he believes to be the most important considerations for assessing a flammability test method or whether it is even nec-

[2]This standard is alternatively referred to as 16 CFR 1610 and CPSC CS-191-53.

essary, Barker said the first is to understand the flammability hazards in surgical and nonsurgical environments as they relate to the exposures that could occur to the user wearing a respirator. "When you do that, what you are able to do is more accurately match the flammability requirement with the potential hazard in a reasonable and practical type of way with a goal of ensuring safety," said Barker. Two other considerations are the need for uniformity in reporting test results so that there is clarity about the class to which a material belongs, and the importance of risk assessment that accounts for the entire landscape of the factors that might affect the functional performance of the respirator or other product. As noted above, FDA has stated that surgical N95s should use materials that meet Class 1 or Class 2 flammability standards.

EVALUATING BIOCOMPATIBILITY

BiFeng Qian, Food and Drug Administration

As had already been discussed, surgical N95 respirators are Class II medical devices subject to FDA's 510(k) review to ensure they address the performance and safety issues described in a 2004 FDA guidance document for surgical masks (FDA, 2004). According to this document, biocompatibility is an expected element of surgical N95 respirators (as it is with many other medical devices), and in September 2016, FDA issued a new guidance document on biocompatibility evaluation (FDA, 2016).

Biocompatibility evaluation of a medical device, said Qian, should first consider how the device will contact the body and how long it will remain in contact with the body. Based on their intended clinical use and the FDA 2004 guidance document for surgical masks (FDA, 2004), surgical N95 respirators are classified as surface devices that contact intact skin for a limited duration. Biocompatibility evaluation also needs to consider the primary material used as well as all of the other ingredients, including plasticizers, additives, crosslinkers, reagents, colorants, inks, adhesives, surfactants, detergents, antimicrobial coatings, process contaminants, and sterilant residues. All surgical N95 respirators seeking 510(k) clearance, Qian added, should address biocompatibility concerns for cytotoxicity, skin irritation, and dermal sensitization as specified in the FDA-recognized test standard for a surface device, intact skin contact, and limited duration use (International Organization for Standardization [ISO] standard 10993-1). In addition, if the surgical N95 respirator is to be sterilized, the sterilization residues should be examined to ensure

that requirements are met for the ISO 10993-7 acceptance criteria for limited exposure devices.

Qian provided an overview of the four consensus standards that FDA recognizes for testing biocompatibility (see Box 3-2). These evaluations are supposed to be conducted on the final product, representative samples from the final product, or materials processed in the same manner as the final product, including sterilization. Biocompatibility testing based on manufacturing raw materials or unfinished device parts may have limitations and is generally not accepted by FDA without solid justification. Evaluations should cover all device components with the potential to contact patients or users and not be limited to the inner layer. "In the worst clinical use condition, chemical residues may leach out from other layers and come into contact with the patient or user," Qian explained. FDA, she added, considers that addition of a color additive to a medical device is a significant change to the device. If a surgical N95 respirator has more than one color type, each color type needs to be assessed for biocompatibility.

In some cases, sponsors may conduct biocompatibility testing on a different device. If so, the sponsor will need to justify the switch and include a certification stating that the test article is identical to the proposed medical device in its final finished form in formulation,

BOX 3-2
FDA-Recognized Consensus Standards for Biocompatibility Testing

- **In vitro cytotoxicity testing:** ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity.
- **Skin irritation or intracutaneous reactivity testing:** ISO 10993-10:2010. Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization.
- **Sensitization testing:** ISO 10993-10:2010. Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization.
- **EtO residuals testing:** ISO 10993-7:2008(R)2012. Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals.

SOURCE: Presented by BiFeng Qian, August 1, 2016 (FDA, 2016).

processing, sterilization, and geometry, and that no other chemicals, such as plasticizers, fillers, additives, cleaning agents, and mold release agents, have been added. In other instances, the surgical N95 respirator may be identical to a previously cleared device in terms of the materials, chemicals, and processes, including sterilization. If this cleared respirator has established a history of safe use in the intended application and user population, the sponsor may provide a material certification statement for comparison to the previously cleared device in lieu of new biocompatibility testing.

FDA may have additional concerns about biocompatibility, Qian noted, if a surgical N95 respirator has additional specific issues, including having materials known to be associated with significant health problems, having antimicrobial or other specific coatings, if it is intended to be used in biologically vulnerable populations, or if it contains special labeling claims. Based on those concerns, FDA may request additional testing or information.

As a final note, Qian said biocompatibility of a medical device may need to be reevaluated if changes are made to the device (including changing the source or specification of the materials used in the product or how it is manufactured, packaged, or sterilized), if there is a change in product shelf life or intended use, or if there is any evidence that the product may produce adverse effects when used in humans. "Based on the assessment of potential impact of the changes, new biocompatibility testing may or may not be warranted," said Qian.

DISCUSSION

The discussion following the presentations focused on the range of tests outline in FDA and NIOSH requirements and criteria.

Particle Filtration Testing

James Zeigler, from J.P. Zeigler, LLC, asked the panelists if they knew of any examples where respirators were tested for viral penetration in the same way that personal protective clothing fabrics have been tested. Williams said he was unaware of anyone conducting such a test on an N95 respirator, although it has been done on surgical masks.

In response to a question about priorities for integrating the FDA and NIOSH certification processes, Eninger replied that if the goal is to look at filtration for purposes of determining filtration efficiency, then testing

with an inert particle is adequate. He said that one drawback of the ASTM test is that it does not utilize test conditions that are well controlled in other areas, such as the electrostatic condition of the aerosol or the loading of the filter. He noted that additional research is not warranted because methods already exist for dealing with these variables and implementing those methods should be the next step.

Elliott clarified that the ASTM specifications regarding filtration efficiency are not FDA methods. Rather, when FDA clears an N95 surgical respirator, it works with NIOSH in terms of certification. Terrell Cunningham from FDA added that FDA only clears NIOSH-certified N95 respirators. FDA confirms that the respirator has a valid NIOSH certification number and therefore has met the particle filtration efficiency standards and the other NIOSH requirements. Then FDA looks at whether the product also meets the biocompatibility, flammability, and fluid resistance standards and, if so, the product could be approved as a surgical N95 respirator. If the surgical N95 respirator is proposed to have an antimicrobial additive, then FDA imposes additional requirements because of the concern that chemically attaching or embedding an antimicrobial could affect a filter's barrier performance. Biocompatibility would also be a concern with an antimicrobial respirator.

Williams noted that NIOSH will be publishing a paper showing that if an N95 respirator passes NIOSH testing, it is close to guaranteed that it will pass bacterial and particle filtering efficiency testing. However, passing the bacterial and particle filtering efficiency tests does not guarantee passing the NIOSH testing protocol. Elliott then explained that the expectation at FDA is that an N95 respirator submitted for FDA clearance as a surgical N95 will have been certified by NIOSH to pass the differential pressure and particle filtration efficiency tests, but with regard to bacterial and viral filtration efficiency, data from those tests will be necessary for FDA's review.

Elizabeth Claverie-Williams from FDA pointed out that whether a device requires bacterial and viral testing has to do with its intended use. "Whatever claims the sponsor makes as related to the performance and effectiveness of the device will drive the types of tests that we will require in order to support those claims," she explained. In response to a question about who certifies a nonsurgical N95 that someone would wear in a tuberculosis isolation room, for example, Claverie-Williams said that if the product is not designated as a surgical N95, then it is solely approved by NIOSH; FDA is not involved in the approval process for standard N95s.

Grinshpun noted that "a particle is a particle" and that the important

characteristic of particles with regard to testing is their aerodynamic, not actual, size. Aerodynamic size, he said, accounts for the fact that bacterial and viral particles may not be perfect compact spheres such as the test particles used for testing filtration efficiency.

Jeffrey Peterson from NIOSH's NPPTL explained that when NIOSH receives products that have an antimicrobial or infection control claim, they talk with the manufacturer and coordinate with FDA to ensure that the product is undergoing the appropriate tests to meet the FDA criteria.

Fluid Resistance Testing

James Chang noted that blood and body fluid splash is a significant challenge in protecting health care workers. David Prezant agreed and noted that fluid exposures are also a major occupational health issue for paramedics and emergency medical technicians and these exposures raise the potential need for prophylactic therapy for HIV or other infections. Prezant also raised an issue having to do with the fact that the ASTM test protocol uses a narrow stream of fluid directed at the respirator, but first responders and health care workers wearing a respirator are more likely to be struck by a fine mist from coughing or a large fluid mix from vomiting rather than a jet of blood. If that is the case, he wondered why such testing is required when the best protection would be afforded by a face shield. In Prezant's opinion, face shields, not fluid-resistant N95s, are the solution.

Elliott agreed this was a good point, and said FDA would never argue that a respirator alone would be the appropriate choice for personal protection from workplace hazards across the entire range of possible uses or in every contamination situation possible. Williams said in his opinion, testing fluid resistance using a high velocity stream would be a worst-case scenario.

Howard Cohen from the Yale School of Public Health wondered if the test for fluid resistance is putting up an unnecessary barrier that limits the supply of respirators that would afford particle protection—the predominant role for these respirators—for the majority of health care workers, both on a routine and emergency basis. Elliott agreed this was a fair point and suggested that one solution would be to require a different device for fluid protection in situations where fluid protection is important. However, the current regulations do not make that distinction because surgical N95 respirators are regulated as surgical apparel, where the expectation is that there would also be barrier protection against bodily fluids. Prezant noted that any health care worker concerned about

fluid exposure would don a face shield and not depend on a surgical N95 respirator because the respirator only covers a small portion of the face.

Zeigler noted that in his opinion having a requirement for fluid resistance is creating a false sense of security and could result in breathability and air flow problems given that fluid resistance is tied to air flow. James Johnson said Zeigler's comment points to the need for research on how these respirators are used in practice in operating suites and other areas of the hospital.

Flammability Testing

In clarifying the need for flammability testing of N95s for use in health care settings, Cohen mentioned that the specific occupational hazards need to be more carefully assessed.

Nesbitt and Chang noted that they view flammability resistance as a low-priority issue for health care respirators. Prezant also questioned the extent to which fires related to respirators are happening in operating rooms or endoscopy suites. These discussions led to comments about the need for increased hazard assessment efforts in the health care environment to more fully examine the hazards that are present where N95 respirators are used. Mark Shirley from Sutter Health noted that he and other workshop planning committee members had done some exploration of the literature and experiences regarding surgical fires and had not found evidence of filtering facepiece respirators being involved with fires. He emphasized the risk-assessment needs regarding the flammability of respirators and noted that is an area of opportunity for further research and guidance for health care professionals.

In response to questions about the methodology of the flammability test, Barker noted that this is a long-standing and reproducible methodology.

Biocompatibility Testing

Responding to questions about whether biocompatibility is an attribute that FDA and NIOSH need to address as part of the MOU, Chang and Sood both said that biocompatibility should be considered, particularly for respirators that have specific additions, such as antimicrobial properties. Craig Colton said that biocompatibility is an important attribute that manufacturers assess for respirator products in all industries, including health care. Biocompatibility testing, as noted by Qian, is not limited to respirators used in the operating room if the respirator is claimed to be a medical device. Peterson added that even though nonsur-

gical N95s do not require FDA clearance, they still need to meet NIOSH's requirement that a device worn by a wearer cannot cause any harm to the wearer. "We deem that as the manufacturers' responsibility and that when they submit the application they have done their due diligence in actually performing that work" said Peterson. Colton said one reason 3M has a toxicology department is to ensure that none of its products with intended human use has a biocompatibility issue regardless of whether or not the product will be submitted for FDA clearance.

Maryann D'Alessandro pointed out that NIOSH has not had any reports of biocompatibility issues with nonsurgical N95s and that the agency has a certified product investigation process and audit process that would follow up on any reported issues. Jennifer Goode from FDA added that the tests used to assess biocompatibility are well understood and consistently conducted. "When we see differences in results, it is usually not because it is at one test lab or another," said Goode. "It is because there is something that is in the final product that somebody did not anticipate. When we see a toxicity for a normally used material, it is because something happened either from the supply or in the manufacturing."

Cunningham then explained that FDA's expectation is that NIOSH would not issue a certification of a surgical N95 respirator until it had conferred with FDA and confirmed that FDA was also reviewing the product. The important point, he added, is that NIOSH and FDA do coordinate the review and labeling of these products. Similarly, Peterson pointed out that when NPPTL receives an application for a respirator that does have an impregnated antimicrobial agent, it notifies the company filing for certification that it needs to notify FDA as well and submit a 510(k) application. "We would not take action on issuing approval until that request has been received by FDA and validated against their requirements," said Peterson. He added that NIOSH and FDA keep each other informed about deficiencies that turn up during the certification process and that the two agencies work together on product labeling.

Cecile Rose from the University of Colorado Denver said it appears based on the presentations and discussion that it makes sense for manufacturers to do biocompatibility testing as opposed to having it done by NIOSH or FDA. Cohen, commenting on the importance of biocompatibility and flammability testing, agreed with Rose and said, "it appears to me that these are two issues that could be well handled by the manufacturer by saying these are standards that you must meet, which is really what FDA does." If there is an issue, he said, FDA or NIOSH would investigate as opposed to adding a requirement for biocompatibility and flammability testing to the NIOSH certification test.

Qian pointed out that biocompatibility applies to both the patient and the health care workers. Goode added details on this, noting that the ISO 10993-1 standard is currently undergoing revision and that FDA does have regulatory authority for medical devices that are primarily in contact with the clinician as well as those in contact with the patient. Joyce Lee, a toxicologist at Halyard Health, agreed that examining irritation and sensitization are important both for the patient and the clinician.

Overarching Comments

Andrew Levinson from OSHA noted that the protective value of an unworn respirator is zero and that this is "really the first time that NIOSH is looking at an industry-specific respirator standard that would be just for health care usage." Given that, he wondered if there was a need to have standards for user acceptability criteria such as heat and moisture buildup and breathing resistance that would strike a balance between adequately protecting people but not overly protecting them with a respirator that is uncomfortable and less likely to be worn. Mark Shirley agreed that is an important concern from an end-user's perspective and balancing protection. Usability, said Shirley, should be part of a risk assessment that each organization needs to conduct to ensure the appropriate equipment is worn and that employees understand how to put it on and take it off. Geeta Sood agreed with this last idea and said, "From a user's point of view, I would much rather have a simple, easy-to-use mask that would not be fluid-resistant but that would allow people to use it and not have as much user error."

With regard to expiration dates, Prezant asked if anyone has ever tested these products to see if they have the same flame resistance, fluid resistance, and biocompatibility over time. Barker noted the need for this type of research and emphasized that the degradation of flammability performance in textiles can occur over time. Qian said devices with materials that may degrade over time need more testing to evaluate the expiration date. Johnson said the biggest factor in the degradation of performance would likely be how the products are stored. D'Alessandro added that research is under way at NPPTL to look at these issues and the main finding so far has been that filtration performance is not affected over time, but the bands that secure the respirator on the face and the foam around nose bridges do degrade.

4

Options for Post-Market Surveillance

The workshop's final panel session discussed various aspects of post-market surveillance and included the following:

- An overview of current processes for post-market surveillance of N95 respirators and other similar types of devices
- Discussion of suggested considerations for improving post-market surveillance

As an introduction to the one presentation in this session, Daniel Shipp from the International Safety Equipment Association explained that conformity assessment—the process of demonstrating that a product or process meets regulatory requirements—does not stop with regulatory clearance. Quality assurance monitoring is a critical aspect of post-market surveillance that aims to ensure that every item coming off a production line is exactly like the one that was approved. So, too, is assessing what happens to a product once it is in the hands of users and feeding that information back into testing and evaluation.

OVERVIEW OF THE NIOSH RESPIRATOR APPROVAL PROGRAM AND POST-MARKET ACTIVITIES

Jeffrey Peterson and James Harris, National Personal Protective Technology Laboratory

Under the provisions of 42 CFR 84, NIOSH is authorized to approve respirators. The regulatory specifications include performance requirements as well as the criteria for the quality assurance program relevant to manufacturing respirators. Peterson noted that because NIOSH is author-

ized to approve completely assembled respirators (and not respirator components or subassemblies), it is easy to track actual configurations and identify critical performance characteristics of NIOSH-approved N95s. In the approval process, NIOSH first conducts an initial engineering review to ensure that the request for certification matches all of the accompanying documentation, including product drawings and the quality assurance system specifications. The product is then sent to the laboratory for testing, and concurrently NIOSH conducts a quality assurance review that delves into the manufacturing processes and procedures. A final review includes comparing the manufacturer's test results with those obtained by NIOSH's laboratory and finalizing the labeling, which then leads to an issued approval. Currently, the respirator approval program deals with 98 approval holders comprising 119 manufacturing sites in more than 20 countries. In an average year, said Peterson, NIOSH receives approximately 400 approval requests and grants approximately 250 new approvals.

Post-marketing surveillance begins once a product is approved and it includes visiting every manufacturing site on a biennial basis to make sure the sites are complying with 42 CFR 84 requirements, their own quality assurance protocols, and the documentation that was submitted with the manufacturer's application for respirator approval. Peterson said this inspection is important because inspectors do find changes in the product or manufacturing process that were not submitted to NIOSH after the initial approval, resulting in required corrective action. NIOSH also conducts audits on products it purchases on the open market or that it receives from manufacturers. Additionally, NIOSH can open an investigation in response to complaints.

Peterson explained that NIOSH is developing a new audit approach that will expand the number of product audits and will ensure that the agency tests at least one product from every manufacturer, rather than the prior process of testing 40 to 50 products selected by NIOSH from the certified equipment list. The new audit procedure will broaden the scope of the program so that the wide range of respirators are included.

Additional product audits and evaluations, he added, are conducted based on emerging issues and stakeholder needs, said Peterson. These include

- Increased filtering facepiece respirator audits during pandemics and other disease outbreaks,
- Evaluations of self-contained breathing apparatus to support the Fire Fighter Fatality Investigation and Prevention Program,

- Near-miss evaluations to support the International Association of Fire Fighters, and
- Evaluations of closed-circuit escape respirators to support the Mine Safety and Health Administration and the U.S. Navy.

Other point-of-use evaluations are also being explored, he said, and NIOSH has a new effort under way to evaluate stockpiled products to see if the agency can assist stockpile holders in making decisions on inventory that may be coming close to its expiration date or with other issues.

In the event of receiving a complaint about a respirator or failing an inspection, NIOSH initiates a certified product investigation process (CPIP). The purpose of this type of investigation, explained Peterson, is to ensure the quality of NIOSH-approved respirators by promptly investigating and resolving reports of product nonconformance issues. A CPIP also works with the manufacturer to understand and document the problem; assess any corrective actions that manufacturer has taken to correct the problem; and ensure the manufacturer takes steps to address inventory units, field units, and future production. In most cases, NIOSH wants the approval holder to conduct a failure modes and effects analysis. "Without that, it gets to be a bit tricky to really understand whether or not the root cause has been defined," said Peterson.

Reports that trigger a CPIP come in to NIOSH via many routes, including self-reports from approval holders as well as from users and service organizations and during product audits. Examples of nonconformance issues include performance failures, a failure to maintain quality control requirements, misleading advertising, and manufacturing under a private label without prior approval from NIOSH. What is important about the CPIP, Peterson explained, is that NIOSH oversees the investigation but it does not conduct the investigation.

Possible follow-up actions include issuing a recall order, asking manufacturers to retrofit equipment, and issuing notices to users. Typically, such notices are issued by the manufacturer after review by NIOSH and a link to the notice is posted on the NIOSH website. On occasion, said Peterson, NIOSH will issue a notice that covers units from multiple approval holders or when it cannot agree with the approval holder that one is needed or on what the notice should say. If the CPIP involves a surgical N95 respirator, NIOSH also notifies FDA. In some instances, NIOSH will issue a stop sales notice so that the product is off the market while the CPIP is ongoing. In extreme cases where a resolution is not foreseeable, NIOSH will rescind an approval or the manufacturer will voluntarily request a rescission.

Before closing a CPIP, NIOSH poses the following questions:

- Has the approval holder properly identified the cause of the nonconformance?
- Has the approval holder developed effective corrective actions to resolve nonconformance?
- Has the approval holder successfully addressed inventory units, field units, and future production?

When NIOSH determines an investigation can be closed, it sends the approval holder a CPIP closing letter.

Aside from inspections and audits, NPPTL provides technical assistance to users, labor organizations, other government agencies, contractors, and the general public on questions, including expiration dates and proper selection and use of respirators. "We try to address each and every one of these within three days of receipt," said Peterson. NPPTL disseminates information on standard test procedures through its website, issues letters to manufacturers on policy changes and clarifications, informs users about product failures or recalls, provides a certified equipment list and a trust source list through its website, informs all customers of new initiatives at NIOSH, and alerts stakeholders about other corrective measures that are under development.

DISCUSSION

A wide range of issues on post-market surveillance were discussed. Linda Hawes Clever asked if there have been any post-marketing surveillance complaints to FDA about surgical N95 respirators, and Peterson replied that there have been no more than two reported over the past 5 to 7 years. Over the same time period, there has been an increase in issues with manufacturers not following their quality assurance systems or having deficiencies in their system that have allowed products that are not in compliance with requirements to enter the market. There have been no reports, however, of any adverse consequences resulting from those deficiencies.

Responding to a question about stockpiling, Susan Moore from NPPTL said she is working on a project that will attempt to create a stockpile partnership for filtering facepiece respirators and surgical gowns. The partnership would include state hospital stockpiles, the CDC strategic national stockpile, manufacturing associations and manufactur-

ers, major suppliers, and distributors. Currently, she and her colleagues are examining the storage conditions for the stockpiled protective equipment in the United States as stockpile storage conditions can vary across states. The next step will be to initiate a study to test products from five facilities and multiple manufacturing models to determine how different products made from different materials perform over time in storage. One goal of this study is to give manufacturers more confidence in the shelf lives of their products. The availability of products that were initially stockpiled after September 11, 2001, will likely provide a wealth of information about product longevity.

Peterson responded to a question about NIOSH's legal authority to take regulatory action against a manufacturer by noting that NIOSH does not have broad enforcement authority. When it issues a stop sell request, the manufacturer's response is voluntary. NIOSH can move to revoke certification, triggering a legal process, if the problem proves to be large or if the manufacturer does not comply with NIOSH's requests. Andrew Levinson said OSHA does have regulatory authority in that it can cite employers using non-NIOSH-certified respirators because that is a violation of OSHA standards and OSHA inspectors do enforce those standards. Elizabeth Claverie-Williams added that FDA has ongoing post-market surveillance for all regulated medical devices, including surgical N95s. The agency's Office of Compliance investigates any post-marketing issues that arise regarding use of medical devices. Such issues can include outbreaks of infectious disease, although she noted there have been no such reports connected to surgical N95 use. If such an issue did arise, FDA would work with NIOSH, OSHA, CDC, the Joint Commission, and the affected hospitals to address the problem.

When asked for ideas on how post-market surveillance could be improved, Peterson said the main limitation today is one of resources. One suggestion, he said, would be to create an easy-to-use Web portal where users could report problems they experience with specific products. D'Alessandro said that NPPTL is looking into working with FDA's MedWatch (a system where users can report issues with medical devices), and the laboratory has recently posted a standards database for personal protective equipment (PPE) as a first step toward becoming the nation's PPE clearinghouse. The ultimate plan, she said, is to have an app or other vehicle that could link into this clearinghouse and enable users to submit reports that would be linked to specific products. Mark Shirley commented that MedWatch is the gold standard in health care for reporting incidents, one with which health care providers are quite familiar. He noted, though, that the challenge with disposable respirators is

that users are more likely to simply throw a defective one away and get a new one rather than report it. He suggested an effort to educate end users, safety professionals, and infection control practitioners on the need to report issues would be fruitful.

5

Potential Next Steps and Priorities

Prior to the workshop's final session, workshop participants split into three breakout groups to discuss one of three topics and address specific tasks assigned to each group. The topics and tasks were

- Breakout 1—Next Steps in Research for Improving Test Methods
  - Identify research gaps for test methods used to evaluate N95 respirators for use by health care workers
  - Identify three to five research priorities
  - Outline next steps for filling the research gaps
- Breakout 2—Issues in Improving and Streamlining the Integration of FDA and NIOSH Processes for N95s Used in Health Care Settings
  - Identify outstanding issues in the integration of FDA and NIOSH processes
  - Discuss the strengths and weaknesses of various approaches to testing (i.e., third-party testing, government lab testing, manufacturer attestation of testing) as relevant to N95s used in health care settings
  - Identify priorities and delineate potential next steps for completing the integration of the evaluation processes
- Breakout 3—Priorities for Health Care Workers
  - Discuss whether the attributes needed for respiratory protection for health care workers differ from the attributes needed for respiratory protection for other workers (e.g., agriculture, industry)
  - Identify priorities for improving N95s for use by health care workers

After each breakout group's facilitator reported on the discussions to the entire workshop, an open discussion followed.

NEXT STEPS IN RESEARCH FOR IMPROVING TEST METHODS

Howard Cohen, Yale School of Public Health

Cohen noted four areas warranting further research that were discussed during the breakout session. The first area concerned inward leakage of respirators, which the group said should be part of aerosol testing. NIOSH is working on the total inward leakage issues, and that the American National Standards Institute (ANSI) has formed a committee to develop a total inward leakage standard that NIOSH could potentially adopt. The group discussed whether 0.3 micron diameter particles are the most penetrating particle for N95 respirators because N95 filters do not solely rely on mechanical filtration. Cohen reported that there was agreement that the current NIOSH test method is more than adequate to demonstrate whether the filter medium is effective.

There was general agreement in the group, Cohen reported, on the need to conduct hazard assessment for fluid resistance. He noted that more information is needed on the fluid hazards that health care workers deal with and to inform decisions regarding the utility of the ASTM test method. "It is unknown whether this jet of synthetic blood is appropriate for testing the hazards," said Cohen. Research in this area could lead to better test methods or verification that the current test methods are adequate. The discussion on fluid resistance also noted that any test methodology needs to focus on the entire respirator and protective equipment ensemble, not just the filter or solely the respirator.

Flammability was the third topic of discussion, and many in the group agreed that the current test, developed by the CPSC, is adequate. The group discussed the risk of flammability regarding N95 respirators but many participants did not see this as a high-priority issue given the information the group was aware of regarding operating room fires. The discussion group participants did acknowledge that they would not want respirators to be flammable but felt that this is a test that manufacturers could conduct and provide the approving federal agency with the data.

Similarly, Cohen noted that the group discussed the importance of biocompatibility testing as an area where manufacturers can conduct the testing and provide the data. Cohen noted that several in the group said that biocompatibility testing "could be done without NIOSH having to

adapt new test procedures and could be done by simply asking manufacturers to show the data that they have done on this type of testing." According to some breakout group participants, most manufacturers already do biocompatibility testing to avoid liability issues.

Jim Johnson, a member of this breakout group, added that the potential to harmonize the FDA and NIOSH processes looks promising to him based on what he had heard at the workshop. Cohen said he would go one step further and say that not only is harmonization possible, but that it can be achieved without manufacturers having to have two types of N95s (standard and surgical). The end result, he said, would be to have a larger number of respirators available in the market and not having users and purchasers trying to separate out surgical and nonsurgical (standard) N95s. In a discussion on the need for hazard assessment, David Prezant noted that he did not see the value of hazard assessment focused on N95s. In his opinion, a hazard assessment will show either there is no problem, in which case testing does not need to be done because there is no risk supporting the epidemiology, or that there is a huge problem, in which case one would not rely on N95 respirators to solve it. For example, if fluid penetration is a huge problem, a face shield would be in order. If flammability was a huge problem, a flame-retardant hood would be in order.

ISSUES IN IMPROVING AND STREAMLINING THE INTEGRATION OF FDA AND NIOSH PROCESSES FOR N95S USED IN HEALTH CARE SETTINGS

Kerri Rupe, College of Nursing, University of Iowa

This group's robust discussion, Rupe reported, centered on the goal of having one N95 respirator for use in the health care setting and on the current confusion about what the designation of surgical N95 means for users. Participants differed in their views of whether surgical N95s are intended only for use in surgical suites and similar health care settings or if they are intended to be used throughout all health care environments. Rupe noted that, in general, the group agreed that the respirators should continue to be certified by NIOSH and felt that flammability and biocompatibility testing could be done by the manufacturers with data provided to NIOSH, similar to what is done now with the FDA clearance process. In such a scenario, NIOSH could add requirements for flammability and biocompatibility testing. Many in this group agreed that biocompatibility and flammability appear to be minor issues in the health

care setting, as was also mentioned in the first breakout report. This group also discussed that OSHA has a broader set of standards that apply to workers across industries and that there are a range of personal protective products that are considered in meeting worker protection needs.

PRIORITIES FOR HEALTH CARE WORKERS

Cecile Rose, University of Colorado Denver

With regard to the question of whether the attributes needed for respirators for health care workers are different than for workers in other industries and professions, Rose reported that there was general agreement in this group that there are not many differences in terms of the respirators themselves or in the attributes needed for health care workers versus those in other industries. What is different, however, is the culture of safety in health care that puts the patient ahead of the worker. In addition, the hazardous exposures in health care settings are often unpredictable and hard to monitor. As she noted, it is the difference in measuring for microbial bioaerosols versus measuring for coal mine dust.

The priorities that individual participants in the breakout group identified for improving N95s for use by health care workers included a need to improve comfort, fit, and usability and to finalize a total inward leakage test. There was strong support in this breakout group to improve training and education on the proper use of N95s, which will require management commitment to respiratory protection and worker involvement, and for addressing the issues raised earlier in the workshop around fit testing, particularly its time-consuming nature. The group discussed concerns about communication that occurs while wearing respirators and ensuring that a properly fitted respirator does not impede communication between health care workers and patients.

A high-priority research area for many participants in this group was the nonuse of respiratory protection in health care. It is important, these participants noted, to determine if failure to use a respirator when warranted is related to risk perception, respirator accessibility, comfort, or all of the above. Rose noted that the group discussed the areas for more research and guidance on respirator reuse. “When and when not to reuse the respirators remains a problem,” said Rose. Some breakout participants also noted that while standards are wonderful, they are not of much use if there is no enforcement. “If people are not doing fit testing properly, then we are not doing a good enough job thinking about this,” said Rose. What could help, she said, was to link programs for respiratory protection with surveillance programs for reporting cases.

The final concern that Rose raised based on her group's discussion was on stockpiling and the availability of respirators in the event of a pandemic. The discussion, Rose said, pointed to the importance of focusing on the day-to-day operations as they relate to planning and stockpiling. She said that participants in the group had ongoing concerns about making sure that the pandemic and stockpiling issues are not lost in the challenge of running a health care system. Rupe noted that participants in her breakout group expressed the same concern about stockpiling and accessibility issues as they relate to a pandemic. Several participants in her group wondered how the regulatory issues could be streamlined to provide better access to respirators during a pandemic.

DISCUSSION

Clever opened the general discussion by calling out stockpiling as a main research and implementation priority, particularly with regard to storage, reuse, and expiration issues. James Zeigler added distribution to be another component of the bigger issue of getting respirators where they are most needed during a pandemic, noting the supply chain problems that arose after the September 11, 2001, attacks. Clever agreed and called this a national security issue given that 90-some percent of the respirators and materials that go into respirators are made overseas. Jonathan Rosen noted that the stockpiling issue goes beyond supplying the needs of health care workers as evidenced by the problems with mold exposure that homeowners and volunteers experienced after Hurricane Katrina.

Anugrah Shaw from the University of Maryland, Eastern Shore, said that comfort and fit are universal issues for all respirators, regardless of whether they are for use in health care or by pesticide applicators. She suggested that many of the issues discussed at the workshop could be examined at a universal level with an emphasis on those used in the health care setting. "I think that would add to the overall ability to be able to respond to these questions," said Shaw. Clever added that broadening the scope of the discussion could provide the opportunity to bring a new set of voices and ideas to the table that might lead to new solutions.

Along the lines of bringing new ideas to the table, Mark Shirley proposed issuing a global challenge with prize money, such as the one issued in response to Ebola that resulted in an innovative containment suit developed at Johns Hopkins University. "That sort of thing might help spur some innovation," said Shirley. "There are many groups out there that are small, but smart and creative. Why not challenge them with some

priorities?" Clever added that such a challenge might identify new approaches to improving the respirator seal, perhaps even borrowing a solution from nature. "There are answers there. We have to figure out how to excavate or imagine them," said Clever.

Cohen also stressed the importance of improving the seal components so that they can fit a wider range of facial structures. "Once you do that, you reduce your fit testing needs," said Cohen. Sergey Grinshpun, who discussed one approach to a universal seal in his earlier presentation in the workshop, said there are a myriad of different materials available today that would mimic the changing shape of the face and provide a better, more universal seal. He also noted that filter material efficiencies are so good today that collection efficiency could be maintained while improving comfort and reducing the pressure drop across the filter, which would by itself reduce faceseal leakage.

Clever asked for some clarification on whether hazard assessment is a priority research topic. Cohen answered that it is because it determines the attributes that are truly necessary to protect workers but also emphasized that there are often multiple types of protective equipment being used by workers so it is important to consider the options, protective ensembles, and tradeoffs in the requirements. It could be, he said, that meeting flammability and fluid resistance standards is compromising other functions of the respirator, such as the pressure drop across the faceseal. David Prezant stated that he is not against risk assessment, but what he is against is waiting for a risk assessment to be finished before NIOSH and FDA harmonize approval processes for N95 respirators. Risk assessment could point to protective needs that would not mean the need for new respirators or respirator requirements but for different protective ensembles to protect health care workers and different tests to assess performance of the ensembles.

The discussion raised a few additional points. D'Alessandro pointed to the importance of highlighting the supply and distribution issue and sustaining efforts to study and address that problem. Rosen highlighted a 2013 paper by Janssen and colleagues that notes how education and training on respirator fitting for health care workers does work (Janssen et al., 2013). He also raised a question that hospitals are struggling with as to whether everybody in a hospital should receive protective equipment training to prepare for a pandemic or if training should be limited to specified individuals. An unidentified participant suggested that labeling of the respirators that noted which tests the product had passed could be an area in which harmonization would be relatively easy.

To finish the discussion, Clever reviewed what she believed were the key messages from the day's proceedings:

- Ensuring the health of health care workers is paramount.
- Reducing confusion and duplication, which means increasing the use of respirators and decreasing waste, is an important priority.
- Harmonization and integration are needed, and it will take goodwill and intent on the part of FDA and NIOSH to make that happen.
- Major challenges include respirator comfort, fit, faceseal integrity, contamination, effectiveness, stockpiling, expiration dates, supply lines, and hazard assessment.
- Increasing the opportunities to provide feedback on issues regarding respirator performance is critical and NPPTL's post-market surveillance program and FDA's MedWatch system could both contribute to that effort.

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A

Workshop Agenda

Integration of FDA and NIOSH Processes Used to Evaluate Respiratory Protective Devices for Health Care Workers: A Workshop

Keck Center of the National Academies of Sciences, Engineering, and Medicine
500 Fifth Street, NW, Room 100
Washington, DC

August 1, 2016

Workshop Objective:

- Ensure health care worker safety, health, and productivity by discussing potential next steps to integrate federal processes (FDA and NIOSH) used to certify and approve N95 respiratory protective devices for use in health care settings.

Starting Points:

- All participants are familiar with the FDA and NIOSH approval and certification processes. Background materials outlining these processes have been provided to all workshop participants. The workshop will focus on potential next steps and priorities for harmonization:
  - FDA—Approval of surgical N95 respirators, which in addition to NIOSH certification also meet FDA requirements regarding flammability, fluid resistance, and biocompatibility

- NIOSH—Certification of all N95 respirators with tests, including for filtration performance

7:45 – 8:30 a.m. **Breakfast, Available in Keck Atrium, 3rd floor**

8:30 – 8:40 a.m. **Welcome and Introductions**
Linda Hawes Clever, Chair, Workshop Planning Committee

8:40 – 9:00 a.m. **Goals for the Workshop**
Maryann D'Alessandro, National Personal Protective Technology Laboratory (NPPTL)
Aftin Ross, Food and Drug Administration (FDA)

Discussion

9:00 – 10:20 a.m. **Panel 1: Perspectives from Users, Manufacturers, and Distributors**
Facilitator: *Barbara DeBaun*

9:00 – 9:05 Panel Introductions
9:05 – 9:55 Presentations
- *Jeffrey Nesbitt*, Mayo Clinic
- *Geeta Sood*, Johns Hopkins University
- *James Chang*, University of Maryland Medical Center
- *Craig Colton*, 3M
- *Akhil Agrawal*, American Medical Depot

9:55 – 10:20 Discussion

Issues for Presentations and Discussion:
- What N95 respirator attributes need to be tested to assure worker safety and health in health care settings (e.g., filtration, flammability, fluid resistance, biocompatibility, others)?

- What, if any, are the current issues being faced with having two types of N95 respirators (surgical N95s and standard N95s)?
- In your opinion, what are the priorities for research, testing, and post-market surveillance to improve N95s for health care workers' safety and health? What are the priorities to be considered in the integration of FDA and NIOSH evaluation processes for N95s?

10:20 – 10:30 a.m. **BREAK**

10:30 a.m. – 12:00 p.m. **Panel 2: State of the Science and Priorities for Research and Standards Development—Filtration Performance and Fluid Resistance**
Facilitator: *Jim Johnson*

10:30 – 10:35 Panel Introductions
10:35 – 11:35 Presentations
10:35 – 11:05 Filtration Performance
- *Robert Eninger*, Air Force Institute of Technology
- *Sergey Grinshpun*, University of Cincinnati

11:05 – 11:35 Fluid Resistance
- *Brandon Williams*, Nelson Laboratories
- *Steven Elliott*, FDA

11:35 – 12:00 Discussion

Issues for Presentations and Discussion:
- What improvements are needed to the tests and test methods? What efforts are under way to revise the standards?
- What are the research gaps and priorities?
- What are the priorities for research, test method development and refinement, and

post-market surveillance of N95s to improve health care workers' safety and health? What are the priorities to be considered in integrating FDA and NIOSH evaluation processes for N95s used in health care settings?

12:00 – 12:45 p.m. **Lunch, Available in Keck Atrium, 3rd floor**

12:45 – 2:00 p.m. **Panel 3: State of the Science and Priorities for Research and Standards Development—Flammability and Biocompatibility/Usability**
Facilitator: *Mark Shirley*

12:45 – 12:50 Panel Introductions
12:50 – 1:35 Presentations
12:50 – 1:20 Flammability
- *Samy Rengasamy*, NPPTL
- *Roger Barker*, North Carolina State University

1:20 – 1:35 Biocompatibility/Usability
- *BiFeng Qian*, FDA

1:35 – 2:00 Discussion

Issues for Presentations and Discussion:
- What improvements are needed to the tests and test methods? What efforts are under way to revise the standards?
- What are the research gaps and priorities?
- What are the priorities for research, test method development and refinement, and post-market surveillance of N95s to improve health care workers safety and health? What are the priorities to be considered in integrating FDA and NIOSH evaluation processes for N95s used in health care settings?

2:00 – 2:45 p.m. **Panel 4: Options for Post-Market Surveillance**
Facilitator: *Dan Shipp*

2:00 – 2:05 Panel Introductions
2:05 – 2:20 Presentation
- *Jeffrey Peterson and James Harris*, NPPTL

2:20 – 2:45 Discussion

Issues for Presentations and Discussion:
- Overview of current processes for post-market surveillance of N95 respirators and other similar types of devices
- Examples from other devices/processes
- What are suggested considerations for improving post-market surveillance?

2:45 – 3:00 p.m. **Break and Move to Breakout Sessions**

3:00 – 4:15 p.m. **Breakout Sessions**

Breakout #1—Next Steps in Research for Improving Test Methods (Room 100)
Facilitator: *Howard Cohen*

Tasks for the breakout group:
- Identify research gaps for test methods used to evaluate N95 respirators for use by health care workers
- Identify three to five research priorities
- Outline next steps for filling the research gaps

Breakout #2—Issues in Improving and Streamlining the Integration of FDA and NIOSH Processes for N95s Used in Health Care Settings (Room 103)
Facilitator: *Kerri Rupe*

Tasks for the breakout group:

- Identify outstanding issues in the integration of the FDA and NIOSH processes
- Discuss the strengths and weaknesses of various approaches to testing (i.e., third-party testing, government lab testing, manufacturer attestation of testing) as relevant to N95s used in health care settings
- Identify priorities and delineate potential next steps for completing the integration of the evaluation processes

Breakout #3—Priorities for Health Care Workers (Room 106)
Facilitator: *Cecile Rose*

Tasks for the breakout group:

- Discuss whether the attributes needed for respiratory protection for health care workers differ from the attributes needed for respiratory protection for other workers (e.g., agriculture, industry)
- Identify priorities for improving N95s for use by health care workers

4:15 – 4:30 p.m. **Break and Move to Plenary Session**

4:30 – 5:30 p.m. **Plenary Session, Keck 100**
Facilitator: *Linda Hawes Clever*

Reports on Potential Next Steps and Priorities

Public Comments

Closing Remarks

5:30 p.m. **ADJOURN**

B

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