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

Keck Center of the National Academies
500 5th Street, NW, Room 100
Washington, DC

August 1, 2016

Workshop Objective:

- Assure 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:
  - NIOSH – Certification of all N95 respirators with tests including for filtration performance
  - FDA – Approval of surgical N95 respirators, which in addition to NIOSH certification also meet FDA requirements regarding flammability, fluid resistance, and biocompatibility

7:45 – 8:30 a.m. **Breakfast, Available in Keck Atrium, 3rd floor**
(Breakfast tickets available for committee and speakers in Room 101)

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: *Barb DeBaun*

9:00 – 9:05 Panel Introductions
9:05 – 9:55 Presentations

- *Jeff Nesbitt*, Mayo Clinic
- *Geeta Sood*, Johns Hopkins Bayview Medical Center
- *Jim 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 **BREAK**

10:30 – Noon **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 – 11:15 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 underway 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 heatlh care settings?

12:00 – 12:45 p.m. **Lunch – Atrium (3rd floor)**

(Blue lunch tickets available for speakers and committee; sign ticket and give to cashier)

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 underway 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 – 2:40 p.m. **Panel 4: Options for Post Market Surveillance**
Facilitator: *Dan Shipp*

2:00 – 2:05 Panel Introductions
2:05 – 2:20 Presentation
- *Jeff Peterson*, NPPTL

2:20 – 2:40 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?

2:40 – 3:00 p.m. **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 3 to 5 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 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**