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**U.S. FOOD & DRUG
ADMINISTRATION**

Medical Countermeasures Initiative Update

May 16, 2018

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FDA exempts certain N95 respirators from premarket notification requirements

Streamlining regulation of PPE essential to public health emergency response

Protecting the health and safety of first responders and healthcare workers is an essential part of planning for public health emergencies. Personal protective equipment (PPE) items such as respirators, protective clothing, and eye protection are standard supplies.

One type of respirator routinely used to protect both the patient and healthcare provider from the transfer of microorganisms, body fluids, and particulate material is known as an [N95 respirator](#) (pictured). N95s are single-use, disposable respiratory protective devices.



FDA and CDC's National Institute for Occupational Safety and Health ([NIOSH](#)) share regulatory oversight of N95 respirators. In a [final order](#) released on May 16, 2018, FDA is exempting certain N95s from premarket notification [510(k)] requirements, and executing a [Memorandum of Understanding](#) with NIOSH.

The final order and MOU streamline the regulation of N95s to help manufacturers easily identify, understand, and work to meet marketing requirements, and help ensure the availability of safe and effective medical products, particularly during times of increased demand, such as a public health emergency. This final action will also decrease regulatory burden on the medical device industry and will eliminate costs required to comply with certain Federal regulations.

Image: N95 face mask respirators. These respirators protect people who wear them by removing contaminants from the air. (Credit: CDC/ Debora Cartagena)

Related links:

- MCMi research - [Optimizing Respirator Decontamination to Ensure Supplies for Emergency Preparedness](#)
- MCMi research - [Investigating Decontamination and Reuse of Respirators in Public Health Emergencies](#)
- [Device Advice: Comprehensive Regulatory Assistance](#), from FDA's Center for Devices and Radiological Health (CDRH)

Ensuring data quality in BSL-4 labs

FDA course expands domestic and international collaborations in sixth year

Much of the work to develop [medical countermeasures](#) for

high-priority agents must be done in high and maximum biosafety level (BSL)-4 laboratories to prevent the agents from being released into the environment, and to provide maximum safety for the scientists.

In another sold-out class, FDA and the University of Texas Medical Branch (UTMB) convened 50 scientists and regulators from industry, academia, and government for an intensive, week-long course on ensuring data quality in maximum-containment labs.



Participants—including public health agency collaborators from eight countries—completed practice exercises while wearing full BSL-4 suits. Interactive lectures and discussions included the challenges of Ebola human clinical trials, the Animal Rule, and best practices to achieve Good Laboratory Practices (GLP) while managing BSL-4 studies.

Image: Course participants on April 26, 2018. In partnership with the National Interagency Confederation for Biological Research (NICBR), the course included lectures and tours at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and the National Institute of Allergy and Infectious Diseases (NIAID) Integrated Research Facility (IRF) in Frederick, Maryland. (Credit: UTMB)

Related links:

- **Save the date!** The [next course](#) will be held **April 8-13, 2019**, in Bethesda, MD
- Why do we hold this course? BSL-4 studies present [unique challenges](#).
- [Infographic: Biosafety Lab Levels](#), from CDC

EUA updates

Zika diagnostic test performance characteristics

- May 3, 2018: FDA has posted new tables detailing performance characteristics of Zika virus diagnostic tests (assays) currently available for use under Emergency Use Authorization (EUA). The tables include information about analytical sensitivity, along with other performance characteristics determined during EUA evaluation. [Table 1: Molecular ZIKV EUA Assays - Performance Characteristics](#) (PDF, 200 KB); [Table 2: Molecular ZIKV EUA Assays - Key Characteristics](#) (PDF, 247 KB) - *For more information, see [Zika Virus Emergency Use Authorization](#)*



Reminder:

Laboratory personnel using Zika diagnostic assays under EUA are encouraged to report performance concerns directly to FDA at CDRH-EUA-Reporting@fda.hhs.gov, in addition to reporting concerns to the manufacturer.

Information about Zika EUAs and amendments is available on the [FDA Zika virus response updates page](#). Also see the latest [CDC Zika Laboratory Guidance](#), last updated July 24, 2017.

Events

- **New! May 21, 2018:** [Bio. Chem. and Health Security Luncheon](#) (Washington, DC), 12:00 – 1:30 p.m. ET, hosted by the National Academies of Sciences, Engineering, and Medicine (NASEM) – Greg

Measer, regulatory counsel in FDA's Office of Counterterrorism and Emerging Threats ([OCET](#)), will discuss FDA's initiative to build a national capacity for post-dispensing monitoring and assessment of medical countermeasures. In-person only; registration is required. *Related:* [Medical Countermeasure Monitoring and Assessment](#)

- **May 22, 2018:** [Public Workshop of the Committee on the Use of Elastomeric Respirators in Health Care](#) (Washington, DC), hosted by NASEM - topics include decision-making and implementation in emergencies.
- **May 24, 2018:** [FY 2018 Generic Drug Regulatory Science Initiatives Public Workshop](#) (Silver Spring, MD and [webcast](#)) - FDA will take information obtained from the public workshop into account in developing fiscal year 2019 regulatory science plans.
- **June 15, 2018:** [2nd NIH-FDA Joint Agency Microbiome Meeting](#) (College Park, MD and webcast) - This meeting will present ongoing microbiome research being undertaken at the NIH and FDA. Advance [registration](#) required.
- **June 25-26, 2018:** [2018 Center for Biologics Evaluation and Research \(CBER\) Science Symposium](#) (Silver Spring, MD and webcast) - participants will discuss scientific topics related to the regulation of biologics, and highlight science conducted at CBER by showcasing how scientific research informs regulatory decision-making. Topics include emerging and re-emerging diseases, and new technologies. [Register](#) to attend in-person or online by **June 18, 2018**; early registration recommended because seating and webcast connections are limited.
- **August 13-14, 2018:** [Pediatric Medical Device Development public meeting](#) (Silver Spring, MD and webcast), to identify strategies to enhance the medical device ecosystem to cultivate development and innovation of devices that serve the unique needs of pediatric populations. To attend in-person, register by **3:00 p.m. ET August 6, 2018**.

Information for industry

- Revised guidance for establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps) - [Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products: Guidance for Industry](#) (PDF, 86 KB) - This guidance updates information in the March 2016 guidance by:
 1. providing findings from more recent epidemiological studies including impact on public health;
 2. reporting new data that informs the potential for transmission of ZIKV;
 3. discussing the current status of availability of ZIKV tests;
 4. updating sexual contact risk factors;
 5. updating when an area is considered to have an increased risk for ZIKV transmission; and,
 6. providing additional scientific references

This update supports the continuation of recommendations to screen living donors of HCT/Ps for risks of infection with ZIKV based on geographic areas with risk. *Also see* [Zika Virus Response Updates from FDA - Safety of the Blood Supply](#) (May 2, 2018)

More: [MCM-Related Guidance by Date](#)

In case you missed it

- In a new [Director's Corner Podcast](#) (audio and transcript available), FDA Center for Drug Evaluation and Research (CDER) Director Dr. Janet Woodcock discusses [Breakthrough Therapy designation](#), which is designed to speed drug development and the regulatory review process for promising new therapies. (May 9, 2018)
- New online training course - [Food Defense Awareness for the Intentional Adulteration Rule](#) - This

free course was designed specifically for individuals that are required to take a food defense awareness course to meet the requirements of the FSMA Final Rule for [Mitigation Strategies to Protect Food Against Intentional Adulteration](#) (21 CFR Part 121) (IA Rule). Individuals who complete the online module will be able to generate a certificate of completion from the website. Also see [Food Defense](#), and [Protecting the Food Supply from Intentional Adulteration, such as Acts of Terrorism](#) (May 8, 2018)

- [Advancing the Science of Nanotechnology in Drug Development](#) - The use of nanotechnology in products regulated by the FDA has been ongoing for several decades and has included foods, cosmetics, medical devices and drugs. Within the purview of CDER, there is great diversity in drug products containing nanomaterials. (April 27, 2018)
- From the National Science Foundation - Federal partners (including FDA) [release Interagency Strategic Plan for Microbiome Research](#) - view the [FY 2018-2022 plan](#) (PDF, 816 KB) (May 1, 2018)
- From HHS - [HHS partners to develop new treatment for seizures caused by nerve agents](#) - Uncontrollable seizures are a devastating result of exposure to nerve agents and can be deadly or lead to permanent brain damage. (April 27, 2018)
- From HHS/ASPR TRACIE - [Mass Distribution and Dispensing of Medical Countermeasures \(MCMs\) Topic Collection](#) - Provides links to federal, state, local, and tribal programs and resources, lessons learned, plans, tools, and templates, courses, and guidance that can help planners address the need to effectively distribute and administer MCMs to a large number of persons in a short period of time, particularly through mass dispensing efforts led by public health authorities. (May 2018)
- From NIH - [NIAID-Sponsored Trial of a Universal Influenza Vaccine Begins](#) (May 4, 2018), and [Despite Mutations in Makona Ebola Virus, Disease Consistent](#) (May 8, 2018)



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