

Welcome to today's FDA/CDRH Webinar

*Thank you for your patience while additional time is
provided for participants to join the call.*

**Please connect to the audio portion of the webinar
now:**

U.S. Callers: 888-455-1392

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Passcode: 4373732

Importing Respirators for Health Care Personnel Use during COVID-19 Pandemic

- **John R. Powers, Jr.**, Chief, Evaluation and Testing Branch
National Personal Protective Technology Laboratory (NPPTL)
CDC National Institute for Occupational Safety and Health (NIOSH)
- **John Verbeten**, Acting Deputy Director
Office of Enforcement and Import Operations
FDA Office of Regulatory Affairs (ORA)

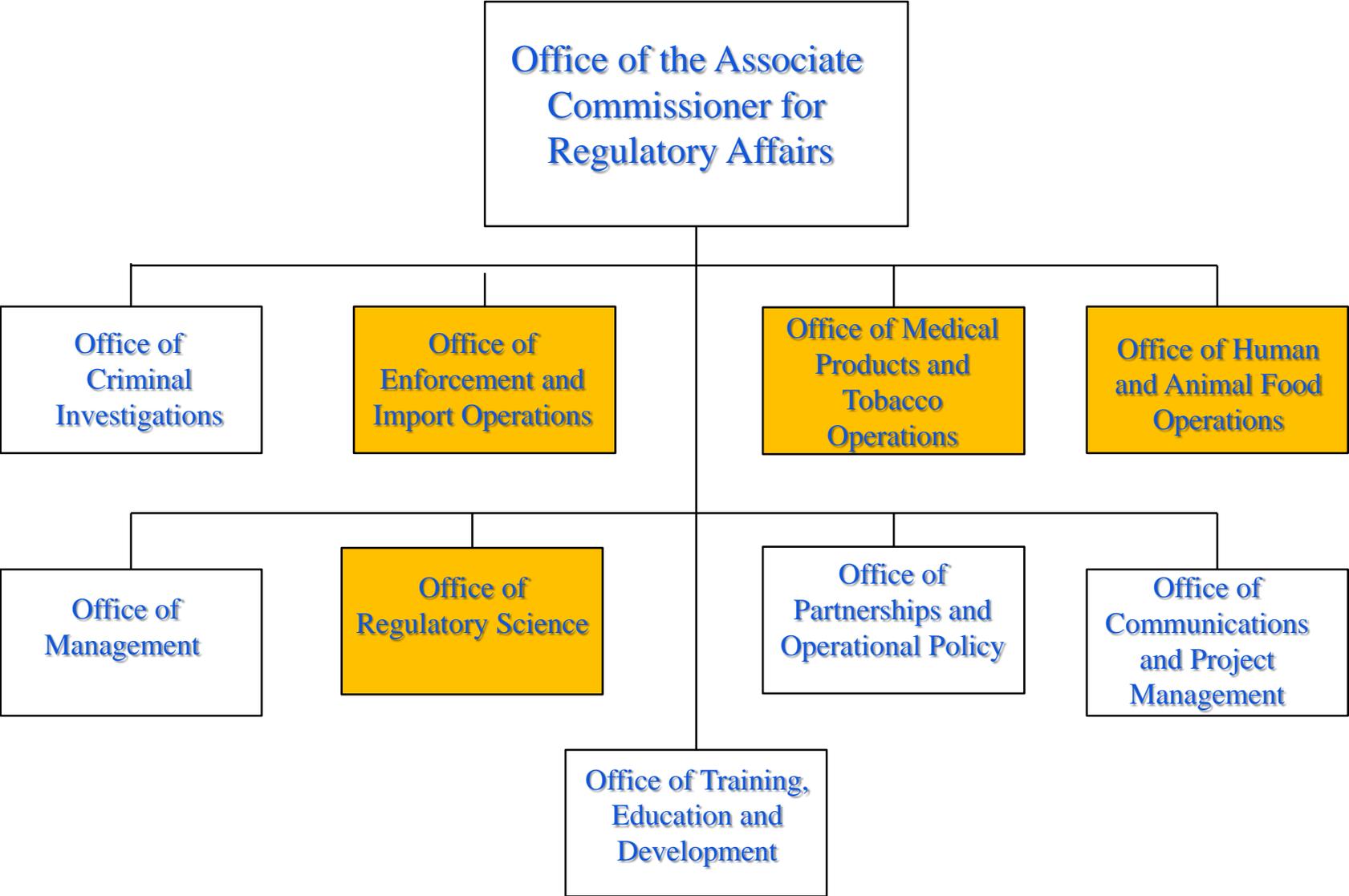
Agenda

- The FDA will speak about the importation of respirators and about their collaboration with CDC on the sampling and testing of international respirators in support of the FDA's respirator Emergency Use Authorizations.
- The CDC's National Institute for Occupational Safety and Health (NIOSH) will describe respirator testing including the modified filtration efficiency testing NIOSH completes as part of their international respirator assessments.
- Representatives from the FDA, CDC, and OSHA will also respond to questions webinar attendees may have about the safe use of respirators by healthcare personnel during the COVID-19 pandemic.

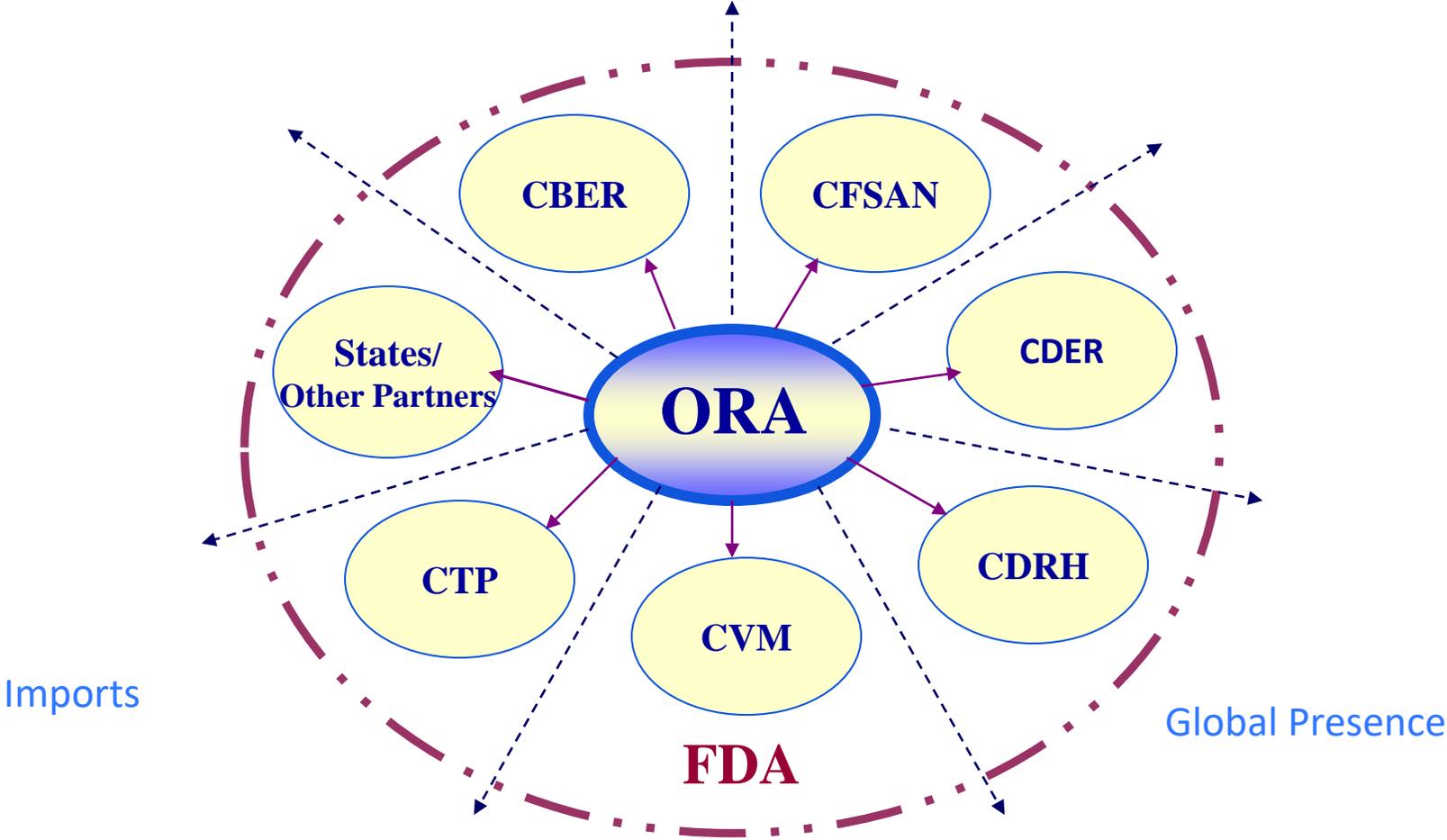
FDA Respirator Sampling Respirators for Health Care Personnel Use during the COVID-19 Pandemic

John Verbeten, Acting Deputy Director
Office of Enforcement & Import Operations

Office of Regulatory Affairs



Partnership With FDA Centers and Other Regulatory Partners



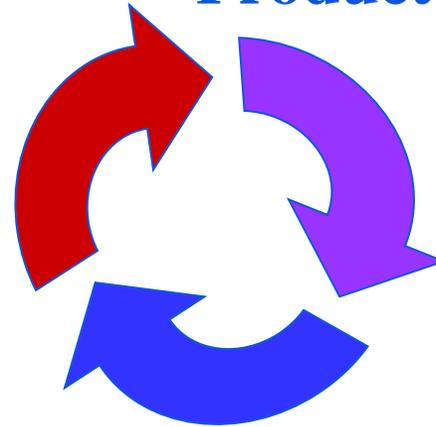
ORA Supports FDA's Core Business Functions

Pre-Market Review

Assessment of safety and effectiveness of new medical technology & safety of new food ingredients

Product Safety & Compliance

Inspection of manufacturing facilities and products to assure safety, quality, & compliance with FDA regulations



Consumer & Patient Safety

Post-marketing surveillance to ensure the safety of consumers & patients who use FDA-regulated products

FDA Sampling of Respirators During COVID-19

Supporting FDA's Emergency Use Authorizations

- Sample Non-NIOSH approved respirators manufactured in China intended for use as respirators in health care settings by health care personnel to determine whether they meet the expected 95% filtration efficiency level.
- Sampled by FDA-and then tested by CDC/NIOSH
- As set forth in the EUA, any lot or shipment of respirators that does not meet the 95% filtration efficiency level must not be distributed.

Summary of Emergency Use Authorizations for Respirators

3 Current Respirator EUAs:

- NIOSH-Approved Air Purifying Respirators for use by health care personnel in a Health Care Setting
- Imported Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (see Exhibit 1)
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (see Appendix A)

Emergency Use Authorization for Certain Respirators Manufactured in China

Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China

A disposable non-NIOSH-approved respirator manufactured in China is authorized under this EUA if it meets any of the following criteria (updated):

1. The respirator is manufactured by an entity that holds one or more NIOSH approvals, that have been verified by FDA, for FFRs, and that are produced by the NIOSH approval holder in accordance with applicable standards of authorization in another country.
2. The respirator: a) Has a registration certification, reflecting regulatory authorization, under the jurisdiction of the Chinese National Medical Products Administration (NMPA) and that is given by an appropriate provincial or municipal authority, and that has been authenticated and verified by FDA, or b) Conforms to the Personal Protective Equipment (PPE) Directive 89/686/EEC (for those placed into distribution before April 21, 2019) or that conforms to PPE Regulation (European Union (EU) 2016/425 (for those placed into distribution after April 21, 2019), as evidenced by a CE Mark, and the CE mark has been authenticated and verified by FDA.
3. The respirator was previously listed in Appendix A under the April 3, 2020 letter of authorization as an authorized respirator because it demonstrated acceptable performance to applicable standards as documented by test reports, has had particulate filtration efficiency assessed by NIOSH using a modified version of NIOSH's Standard Test Procedure (STP) TEB-APR-STP-0059 within 45 calendar days of the date of issuance of the May 7, 2020 letter, and has results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent. A respirator authorized under this EUA because it meets the above criteria (3), is no longer authorized if it has been sampled by FDA, tested by NIOSH via a modified version of STP TEB-APR-STP-0059, and results according to NIOSH that indicates one or more of the 30 sampled respirators has a filtration efficiency of less than 95%.

Emergency Use Authorization for Certain Respirators Manufactured in China: Information about Criterion Three

- Respirators previously listed in Appendix A are eligible under criterion three and must:
 - Submit information to FDA within 45 days from May 7 (June 21) as described in the EUA
 - Arrange with FDA for sampling of the product.
- As of June 22, 42 Chinese firms have been authorized and added to Appendix A via this criterion.

Sampling



- Manufacturer arranges with FDA, for FDA to collect sample of 30 respirators.
 - Not importer or U.S. agent
- 30 respirators per sample, collected randomly across all lots in shipment of that respirator model.
 - Agreed upon between FDA & CDC/NIOSH to provide statistically significant results
- Submitted to CDC/NIOSH for analysis using a modified version of NIOSH's Standard Test Procedure (STP) TEB-APR-STP-0059
 - Assess filtration efficiency

Outcomes



- CDC/NIOSH posts results online
 - <https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html>
- Greater than/equal to 95% filtration efficiency
 - May be included in Appendix A under criterion three
- Less than 95% filtration efficiency
 - Will not be included in Appendix A under criterion three and
 - The lot or shipment of that model(s) cannot be distributed as respirators

Moving forward



- Non-NIOSH Approved Filtering Facepiece Respirators Manufactured in China that meet the eligibility criteria in the EUA are authorized for use as respirators in health care settings by healthcare personnel pursuant to CDC's recommendations.
- Products that do not meet the criteria for eligibility and are therefore not authorized under one of the FFR EUAs may be eligible for authorization as a face mask for use as source control if they meet the criteria for eligibility in the Face Mask EUA.
- FDA expects to continue a level of surveillance sampling and testing going forward

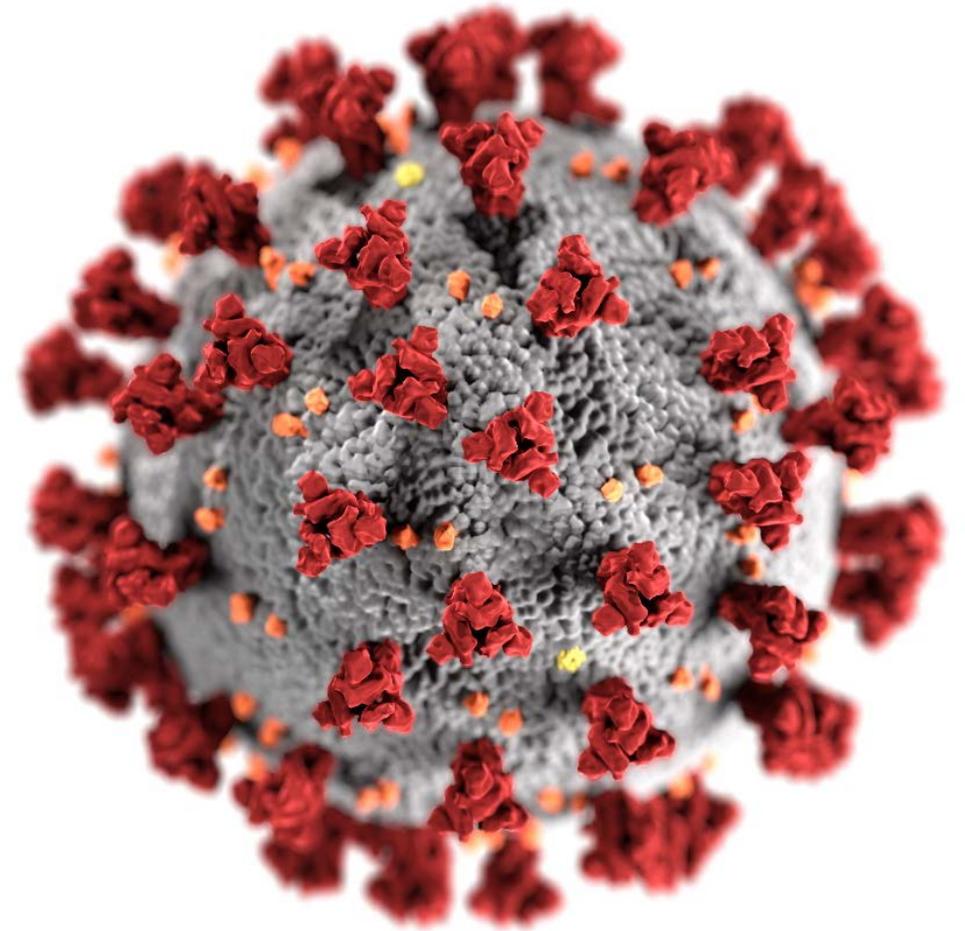


International Respirator Assessments

John Powers

Branch Chief of the Evaluation and Testing Branch (ETB)

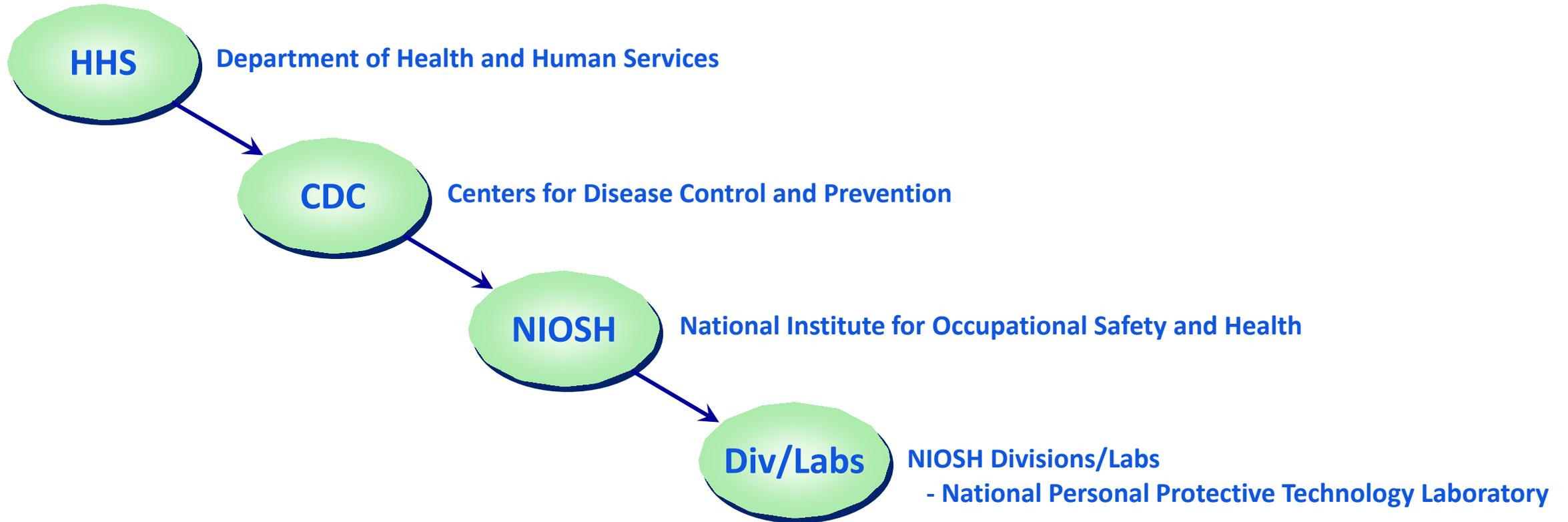
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)



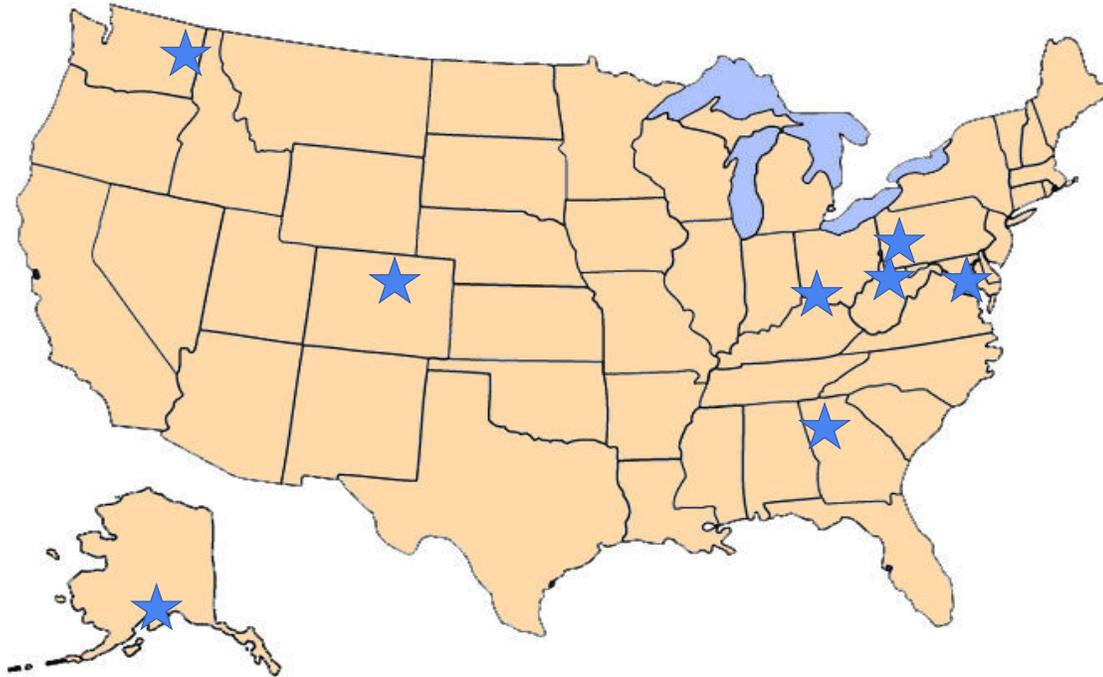
Centers for Disease Control
and Prevention
National Institute for Occupational
Safety and Health

For more information: www.cdc.gov/COVID19

Where does NPPTL fit into the federal structure?

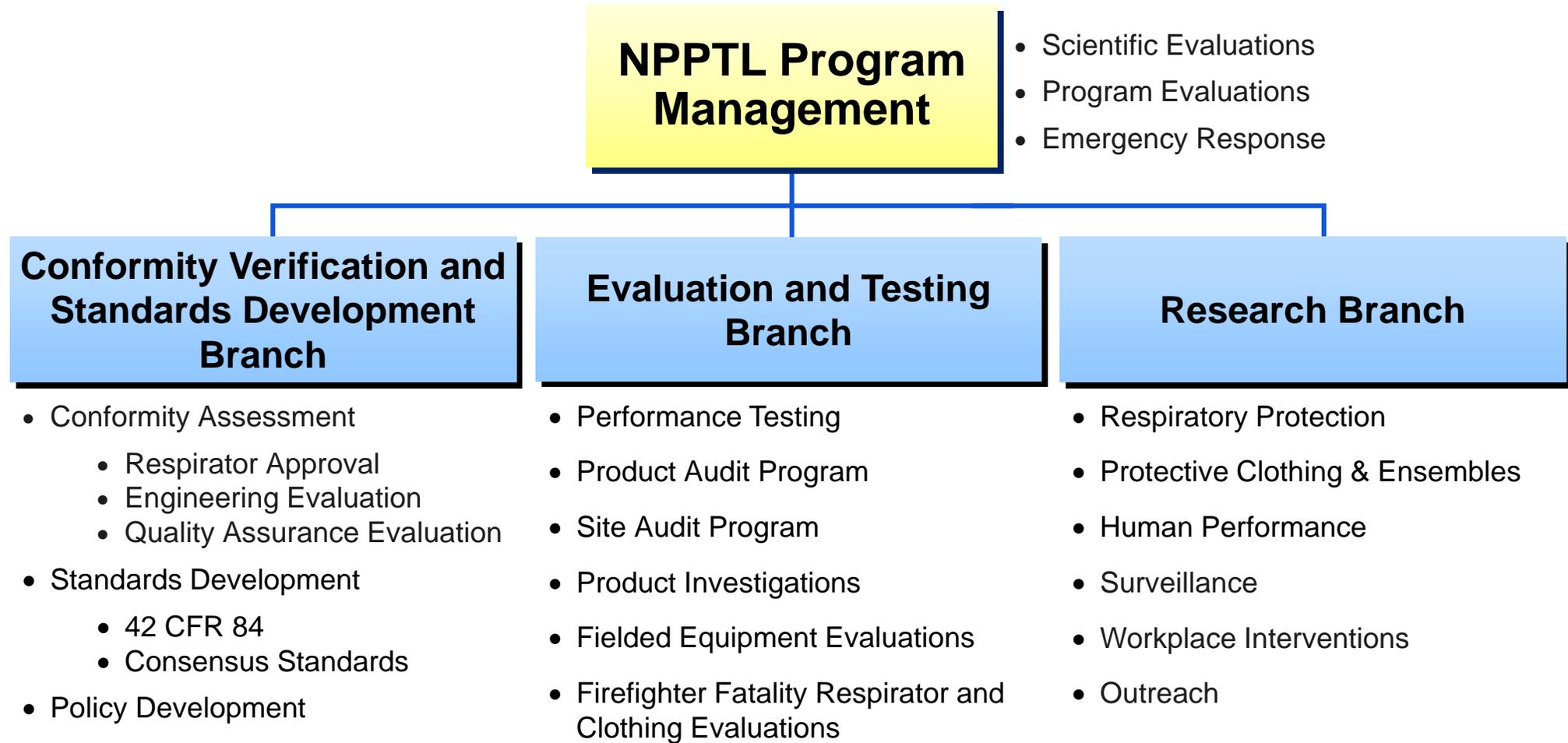


NIOSH Divisions & Laboratories



- Office of the Director, NIOSH
- Division of Field Studies & Engineering (DFSE)
- Division of Safety Research (DSR)
- Division of Science Integration (DSI)
- Division of Compensation Analysis and Support (DCAS)
- Health Effects Laboratory Division (HELD)
- National Personal Protective Technology Laboratory (NPPTL)
- Office of Extramural Programs (OEP)
- Pittsburgh Mining Research Division (PMRD)
- Respiratory Health Division (RHD)
- Spokane Mining Research Division (SMRD)
- Western States Division (WSD)
- World Trade Center Health Program Division (WTC)

NPPTL Organizational Structure



Conventional Operations: The Respirator Approval Program



Conventional Operations: N95 FFR Testing

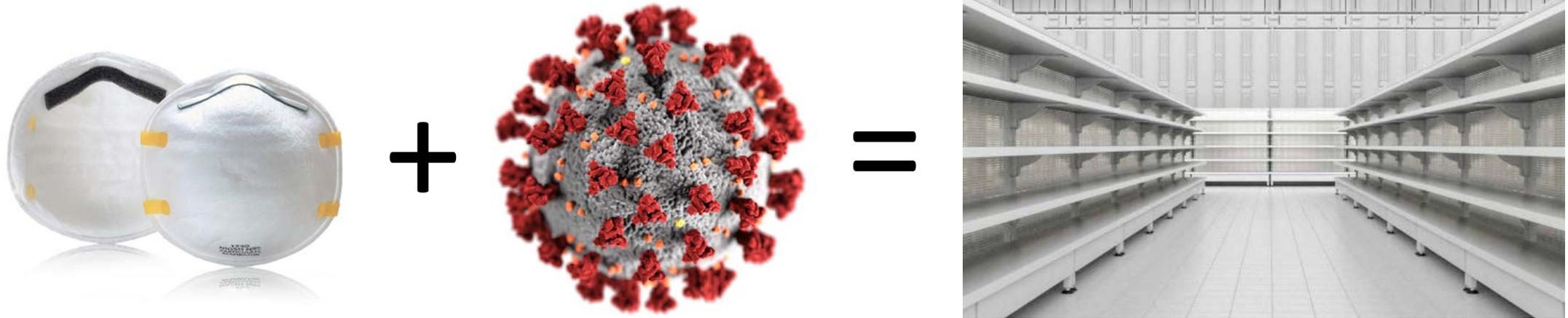
Standard Test Procedures:

- TEB-APR-STP-0003, Determination of Exhalation Resistance (3 samples)
- TEB-APR-STP-0007, Determination of Inhalation Resistance (3 samples)
- TEB-APR-STP-0059, Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators (20 samples)

TEB-APR-STP-0059 Requirements:

- Pre-condition all 20 samples in humidity chamber at 85% +/- 5% relative humidity for 25 +/- 1 hours.
- Flow Rate of 85 +/- 4 Lpm
- Particle size distribution will be a count median diameter of 0.075 +/- 0.020 micron and a geometric standard deviation not exceeding 1.86.
- Aerosol concentration not exceeding 200 mg/m³.
- First 3 samples are fully loaded.
- Remaining 17 samples are loaded according to filter type.

Conventional Operations with COVID-19



COVID-19 Operations: International Respirators

Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes

- U.S.: 42 CFR 84
- Europe: EN-149-2001
- China: GB2626-2006
- Australia/New Zealand: AS/NZ-1716:2012
- Korea: KMOEL-2017-64
- Japan: JMHLW – Notification 214, 2018

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-20 06)	P2 (AS/NZ 1716:2012)	Korea 1 st Class (KMOEL - 2017-64)	DS (Japan JMHLW- Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min

Credit: 3M Technical Bulletin, May, 2020, Revision 4

<https://multimedia.3m.com/mws/media/17915000/comparison-ffp2-95-filtering-facepiece-respirator-classes-tb.pdf>



COVID-19 Operations: International Respirator Strategies

Respirators Approved Under Standards Used in Other Countries That Are Similar to NIOSH-Approved N95 Filtering Facepiece Respirators

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13698:2011	PFF2	N95
		PFF3	N99 or lower
People's Republic of China	GB 2626-2006 GB 2626-2019 GB19083-2010	KN/KP95	N95
		KN/KP100	N95
Europe	EN 149-2001	P2	N95
		P3	N99 or lower
Japan	JMHLW-2000	DS/DL2	N95
		DS/DL3	N99 or lower
Korea	KMOEL-2017-64	Special 1st	N95
		N95	N95
Mexico	NOM-116-2009	R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower
		R100	R100 or lower
		P100	P100 or lower



COVID-19 Operations: International Respirators



COVID-19 Operations: International Respirator Assessment

Modified Test Procedure:

- Assessment of Filter Penetration Performance for Non-NIOSH Approved Respirators – NPPTL Assessment to Support the COVID-19 Response (10 samples)

Modified TEB-APR-STP-0059 Requirements:

- **No pre-conditioning.**
- Flow Rate of 85 +/- 4 Lpm
- Particle size distribution will be a count median diameter of 0.075 +/- 0.020 micron and a geometric standard deviation not exceeding 1.86.
- Aerosol concentration not exceeding 200 mg/m³.
- **All 10 samples are run for a 10 minute duration, regardless of filter type.**
- Maximum penetration recorded for each respirator.

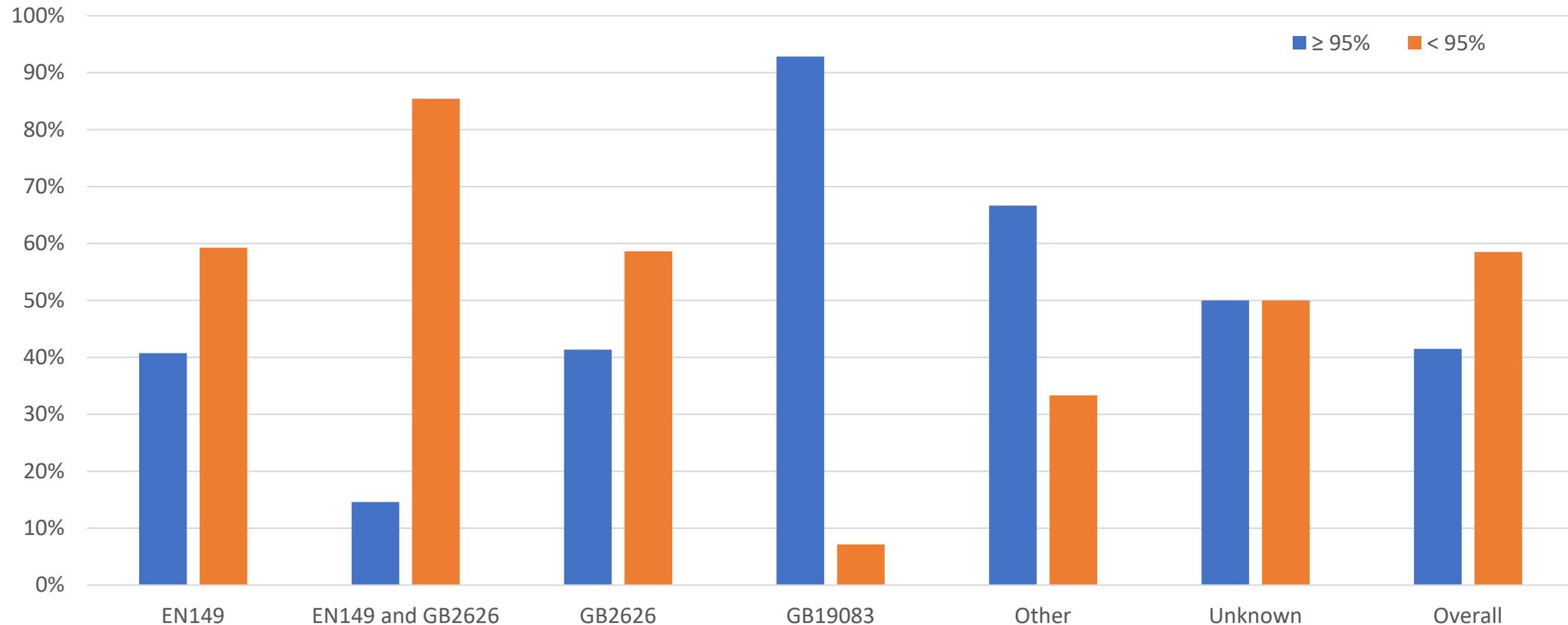
International Respirator Assessment Results

Distribution of Completed Assessments by International Standard

International Standard	Number of Assessments Completed	Percent
EN149	27	10%
EN149 and GB2626	48	17%
GB2626	162	57%
GB19083	14	5%
Other	21	7%
UNKNOWN	10	4%
Total	282	100%

International Respirator Assessment Results

Assessment Results by International Standard



International Respirator Assessment Results

Ear Loops versus Head Straps/Bands

- 91% have Ear Loops
- Only 9% have Head Straps/Bands

OSHA 1910.134 Requirements

- Must develop and implement a Respiratory Protection Program
- Proper respirator selection, medical evaluations, and training
- Appendix A – Fit Test Procedures

International Respirator Assessment Results

- <https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html>



Check these additional resources

[The NIOSH Certified Equipment List \(CEL\)](#)

[Respirator User Notices](#)

[Counterfeit Respirators / Misrepresentation](#)

[CDC Crisis Capacity Strategies for Optimizing N95s](#)

[Understanding the Use of Imported Non-NIOSH-Approved Respirators](#)

Disclaimer:

Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services.



Questions?

CDRH-COVID19-SurgicalMasks@fda.hhs.gov

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at:

<http://www.fda.gov/training/cdrhlearn>

Under Heading: Specialty Technical Topics; Sub-heading: Personal
Protective Equipment (PPE)”

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