April 16, 2020

NC OSHERC COVID-19 Respiratory Protection Series: Session 3

GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

April 16, 2020

Updated OSHA and FDA Information - Respiratory Protection

SARS-CoV-2

Moderator: John Staley, PhD, MSEH
Speakers: Craig Colton, CIH, Pat Curran, CIH

Previous Respiratory Protection Sessions

1. How to properly Put On (Don) and Take Off (Doff) a Disposable Respirator
Aka Filtering Facepiece Respirator
SARS-CoV-2

2. Current Issues Relating to Respiratory Protection – Stockpile, Decontamination and Reuse
SARS-CoV-2

Archived and can be found at: https://osherc.sph.unc.edu/
Go to link: Registration and access to previous seminars>>

Question

Would you kindly address washable, reusable fabric masks that are impregnated with zinc and other metal.

- Does the zinc oxide pose a health concern?

- The mask in question is called a Sonomask made by Sonovia, an Israeli company
- The mask material is infused with nano-engineered zinc oxide, to provide antimicrobial protection
- We don't know if the zinc oxide poses a health concern in this instance. However, first reaction is no. Zinc oxide topical (for the skin) is used to treat diaper rash, minor burns, severely chapped skin, or other minor skin irritations.
- The TLV-TWA (occupational exposure limit) for airborne zinc oxide is 2 mg/m^3; which is a high concentration.
- If there is an apparent problem with mask after wearing/washing discontinue use.

CDC
PPE Burn Rate Calculator

The Personal Protective Equipment (PPE) Burn Rate Calculator is a Excel spreadsheet-based model that will help healthcare facilities plan and optimize the use of PPE (gowns, gloves, surgical masks, respirators, and face shields) for response to coronavirus disease 2019 (COVID-19). Non-healthcare facilities such as correctional facilities may also find this tool useful.

Last Reviewed: April 7, 2020

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html

OSHA

OSHA has issued Enforcement Guidance Pertaining to Respirators and the COVID-19 Outbreak

March 14 - Temporary Enforcement Guidance - Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak

April 3 - Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic

April 3 - Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic

April 8 – Temporary Enforcement Guidance – Expands Annual Fit Testing guidance to ALL Industries using N95 Respirators During COVID-19 Pandemic

April 13 – Interim Enforcement Response for Coronavirus Disease 2019 (COVID-19)

OSHA
Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic

April 3, 2020

- **Applies to all industries, including Health Care Providers**
- **Provides guidance on the extended use or reuse of N95 FFRs**
- **Provides guidance on the use expired N95 FFRs that were previously NIOSH approved**
- **Expired N95 FFRs generally must not be used by HCP when procedures are expected to generate aerosols or respiratory secretions**

https://www.osha.gov/memos/2020-04-03/enforcement-guidance-respiratory-protection-and-n95-shortage-due-coronavirus

Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic

April 3, 2020

- Applies to all industries, including Health Care Providers
- During shortages of N95 FFRs - air-purifying elastomeric respirators, and compatible filters certified under the following standards of other countries or jurisdictions will provide greater protection than surgical masks, homemade masks, or improvised mouth and nose covers, such as bandanas and scarves:

  Australia: AS/NZS 1716:2012

  Brazil: ABNT/NBR 13694:1996; ABNT/NBR 13697:1996; and ABNT/NBR 13698:2011

  People's Republic of China: GB 2626-2006; and GB 2626-2019

  European Union: EN 140-1999; EN 143-2000; and EN 149-2001

  Japan: JMHLW-2000

  Republic of Korea: KMOEL-2014-46; and KMOEL-2017-64

  Mexico: NOM-116-2009

https://www.osha.gov/memos/2020-04-03/enforcement-guidance-use-respiratory-protection-equipment-certified-under

Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic

April 3, 2020

All Employers should:

- Implement the hierarchy of controls: elimination, substitution, engineering and administrative controls, PPE
- Acquire and use respirators in the following order:
- NIOSH-certified equipment; then
- Equipment certified in accordance with standards of other countries or jurisdictions except the People's Republic of China, unless equipment certified in accordance with standards of the People's Republic of China is manufactured by a NIOSH certificate holder; then
- Equipment certified in accordance with standards of the People's Republic of China, the manufacturer of which is not a NIOSH certificate holder; then
- Facemasks (e.g., medical masks, procedure masks).
  - Improvised masks are not PPE, ideally should be used to cover front and sides of face. When this measure is the only resort, refer to the CDC guidance at www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html.

Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic

April 3, 2020

Healthcare Employers should:

Where HCP perform procedures likely to generate aerosols or respiratory secretions are poorly controlled:

- Respiratory protection equipment certified exclusively in accordance with standards of the People's Republic of China and manufactured by companies that are not NIOSH approval holders must NOT be used unless the only feasible alternative is a facemask or improvised nose/mouth cover;
- In accordance with CDC guidance for optimizing the supply of respirators, employers should prioritize the use of N95 respirators by activity type.

Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak

April 8, 2020

Applies to ALL Industries:

- Relaxes enforcement of annual fit testing for N95 or other filtering facepiece respirators to conserve respirators
- Other requirements of the Respiratory Protection Standard such as initial fit testing, maintenance, care and training remain in effect
- Prioritize the use of fit testing equipment to high-hazard procedures
- Guidance for "equivalent fit" respirators – basic head form for size/fit

https://www.osha.gov/memos/2020-04-08/expanded-temporary-enforcement-guidance-respiratory-protection-fit-testing-n95

April 13, 2020

MEMORANDUM FOR: REGIONAL ADMINISTRATORS
STATE PLAN DESIGNEES

THROUGH: AMANDA EDENS
Deputy Assistant Secretary

FROM: PATRICK J. KAPUST, Acting Director
Directorate of Enforcement Programs

Interim Enforcement Response Plan for Coronavirus Disease 2019 (COVID-19)

- Review the respiratory protection program and any **modified** respirator policies related to COVID-19, and assess compliance with 29 CFR § 1910.134.
- Review documentation of provisions made by the employer to obtain and provide appropriate and adequate supplies of PPE.
- Determine and document whether the employer has considered or implemented a hierarchy of controls for worker protection, *i.e.*, engineering controls, administrative controls, work practices, or PPE (including a respiratory protection program).
- https://www.osha.gov/memos/2020-04-13/interim-enforcement-response-plan-coronavirus-disease-2019-covid-19

Applicable OSHA Standards

- 29 CFR § 1904, Recording and Reporting Occupational Injuries and Illness.
- 29 CFR § 1910.132, General Requirements - Personal Protective Equipment.
- 29 CFR § 1910.133, Eye and Face protection.
- 29 CFR § 1910.134, Respiratory Protection.
- 29 CFR § 1910.141, Sanitation.
- 29 CFR § 1910.145, Specification for Accident Prevention Signs and Tags.
- 29 CFR § 1910.1020, Access to Employee Exposure and Medical Records.
- Section 5(a)(1), General Duty Clause of the OSH Act.

Use of CDC recommendations

- The most current CDC guidance should be consulted in assessing potential workplace hazards and to evaluate the adequacy of an employer's protective measures for workers. Where the protective measures implemented by an employer are not as protective as those recommended by the CDC, the CSHO should consider whether employees are exposed to a recognized hazard and whether there are feasible means to abate that hazard.

Equipment Shortages

- The outbreak is resulting in shortages of:
  - N95 filtering facepiece respirators FFRs)
  - Other disposable respirators
  - Surgical masks
  - Fit-testing supplies and equipment
  - Health services by fit-testing companies and by medical providers for respirator evaluations are severely limited

Employer Good Faith Efforts, in this order:

Hierarchy of Controls

- Eliminate workplace hazards
- Then engineering controls
- Administrative controls
- Safe work practices to prevent worker exposures to respiratory hazards
- Respirators – obtaining the most appropriate ones

Respiratory Protection Standard

- For general guidance, CSHOs should refer to CPL 02-00-158, *Inspection Procedures for the Respiratory Protection Standard*, June 26, 2014, at www.osha.gov/enforcement/directives/cpl-02-00-158.
- During an inspection, CSHOs will evaluate whether healthcare or emergency response workers, who are expected to perform very high and high risk exposure tasks, are using respirators (i.e., N95 or better).
- ***Appropriate respiratory protection is required for all healthcare personnel providing direct care for patients with suspected or confirmed cases of COVID-19.*** For additional guidance, see *COVID-19 Hospital Preparedness Assessment Tool*, www.cdc.gov/coronavirus/2019-ncov/hcp/hcp-hospital-checklist.html.

Written program with worksite specific procedures covering:

- Respirator selection
  - Allows non-NIOSH approved respirators
  - Enforcement directives establish priorities based on existing shortages
  - Selecting different respirator models could require an update to the program
  - If using PPE of different sources: NIOSH, expired, other countries etc., need to establish selection rules matching the task with the equipment
  - Review documentation of provisions made by the employer to obtain and provide appropriate and adequate supplies of PPE
  - See Enforcement Memos

Written program with worksite specific procedures covering:

- Medical evaluations - not required annually
  - Initial, and follow-up (if required)
  - Employee reports medical signs and symptom related to ability to use the respirator
- Fit testing procedures
  - Initial fit test prior to use when a different respirator (size, style model or make)
- Procedures for routine and foreseeable emergency situations
  - The hierarchy of the respirators you are using at your facility

Written program with worksite specific procedures covering:

- Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding and otherwise maintaining respirators
  - Employers must address the circumstances under which a disposable respirator will be considered contaminated and not available for extended use or reuse
  - When respirators are being re-used, employers should pay particular attention to workers' proper storage of the FFRs in between periods of reuse.
  - Decontaminating FFR procedures?
  - Maintenance of elastomeric respirators?
  - Maintenance of powered air purifying respirators (PAPRs)?
  - Do not comingle. The following should be stored separately:
    - NIOSH-certified equipment
    - Equipment that was previously NIOSH-certified but that has surpassed its manufacturer's recommended shelf life
    - Equipment certified under standards of other countries, and equipment that was previously certified under standards of other countries but that has expired

Written program with worksite specific procedures covering(cont.):

- Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators
  - Some laboratories may now be using these
- Training of employees in the respiratory hazards to which they are exposed
  - Review employee training records, including records related to COVID-19 exposure prevention or in preparation for a pandemic
- Training of employees in proper respirator use
  - CSHOs should confirm that workers perform a user seal check each time they don a respirator, regardless of whether it is a NIOSH-certified device or device certified under standards of other countries
  - Do not use a respirator on which they cannot perform a successful user seal check
    - See 29 CFR § 1910.134, Appendix B-1, *User Seal Check Procedures*

Written program with worksite specific procedures covering:

- Training of employees in the proper use of respirators
- CSHOs will determine if the employer has trained workers to understand:
  - If the structural and functional integrity of any part of the respirator is compromised, it should be discarded
  - If a successful user seal check cannot be performed, another respirator should be tried to achieve a successful user seal check
  - Over time, components such as the straps, nose bridge, and nose foam material may degrade, which can affect the quality of the fit and seal
- CSHOs should assess whether the employer has trained employees on the proper sequence of procedures for donning/doffing to prevent self-contamination
  - *See* www.cdc.gov/niosh/npptl/pdfs/PPE-Sequence-508.pdf.

Written program with worksite specific procedures covering (cont.):

- Procedures for regularly evaluating the effectiveness of the program
  - Are employees following the new changes you have made to your program

FDA

Emergency Use Authorization

EUA

FDA-EUA
Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators - March 24, 2020

https://www.fda.gov/media/136403/download?from=groupmessage&isappinstalled=0

- FDA concluded that certain imported disposable FFRs that are not NIOSH-approved are appropriate to protect the public health or safety
- Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English
- These models will be new to the USA
  - OSHA TEG requires initial fit test
  - Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes, 3M Technical Data Bulletin, January, 2020, Revision 2
  - Summarizes the performance requirements of FFRs from around the world

    https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf

Disposable FFRs that meet a given performance standard with acceptable product classifications
https://www.fda.gov/media/136403/download

Jurisdiction	Performance Standard	Acceptable product classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894	YES
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
Japan	MHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1st	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

Disposable FFRs that meet a given performance standard with acceptable product classifications

https://www.fda.gov/media/136731/download

Authorized Imported, Non-NIOSH Approved Respirators Manufactured

Manufacturer	Respirator Model(s)	Country of Manufacture
3M	8205	Japan
3M	8822	South Korea
3M	9320+	UK, Singapore, Turkey
3M	9322+	UK, Singapore, Turkey
Dromex	Model 1020	South Africa

Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China April 3, 2020

Authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators.

Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China

Appendix A: Authorized Respirators

https://www.fda.gov/media/136664/download

Appendix A: Authorized Respirators
https://www.fda.gov/media/137021/download

Manufacturer	Respirator Model(s)	Country of Manufacture
3M	9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552, 9552	China
Allmed	KN95 Particulate Respirator LP220002	China
AOK Tooling Ltd. (aka Shenzhonghai Medical)	20130040, 20130045A, 20180021, 20130038, 20190019	China
Bei Bei Safety Co Ltd	B702, B702V, B704, B704V	China
Bei Bei (Dong Shan) Protective Supplies Co., LTD	B707	China
BYD Precision Manufacture Co. Ltd.	BYD KN95 Particulate Respirator (Model Number: DG3101)	China
Changsha JNEYL Medical Equipment Co., Ltd	JN-9501	China
Chengde Technology Co.	KN95 (PM 2.5) Protective Mask	China

FDA – Emergency Use Authorizations For Decontamination of N95 Respirators

Currently there are 3 FDA – EUAs issued for the decontamination of N95 FFRs:

- Battelle Memorial Institute –March 28 and revised March 29, 2020

https://www.fda.gov/media/136529/download

- Steris Corporation – April 9, 2020

https://www.fda.gov/media/136843/download

- Advanced Sterilization Products – April 11, 2020

https://www.fda.gov/media/136884/download

FDA – Emergency Use Authorizations For Decontamination of N95 Respirators

All 3 Decontamination Systems use Hydrogen Peroxide Vapor

All use “Compatible” respirators: N95 respirator with no cellulose materials or N95-equivalent respirators (Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators)

FDA – Emergency Use Authorizations For Decontamination of N95 Respirators

Battelle Memorial Institute –March 28 and revised March 29, 2020

https://www.battelle.org/inb/battelle-ccds-for-covid19-satellite-locations/

- Decontamination system provides for up to 20 decontamination cycles per compatible N95 respirator
- Each system can decontaminate up to 80,000 respirators per day

- Establishes procedures for contaminated respirator collection, labelling and information to healthcare facilities and providers
- Battelle must operate the decontamination system and shall not distribute to third parties

FDA – Emergency Use Authorizations For Decontamination of N95 Respirators

Steris Corporation – April 9, 2020

- STERIS V-PRO 1 Plus, maX, and maX2 Sterilizers
- 10 N95 FFRs per cycle
- Each N95 FFR can go through 10 decontamination cycles
- Single user reuse – the same HCP should use the same respirator after decontamination

https://www.steris.com/healthcare/steris-decontamination-solutions-for-compatible-n95-or-n95-equivalent-respirators

FDA – Emergency Use Authorizations For Decontamination of N95 Respirators

Advanced Sterilization Products – April 11, 2020

https://web.asp.com/covid-19

- The STERRAD Sterilizer cycles to be used in decontamination of compatible N95 respirators are: STERRAD 100S Cycle, STERRAD NX Standard Cycle, and STERRAD 100NX Express Cycle
- 10 N95 FFR per cycle
- Each N95 FFR can go through 2 decontamination cycles
- Single user reuse – the same HCP should use the same respirator after decontamination

FDA News Release April 12, 2020: FDA issued an EUA that has the potential to decontaminate approximately 4 million N95 or N95-equivalent respirators per day in the U.S. There are approximately 9,930 STERRAD Sterilization systems in approximately 6,300 hospitals across the U.S. Each can reprocess approximately 480 respirators per day.

NIOSH News
April 14, 2020

- NIOSH published "Approval Tests and Standards for Air- Purifying Particulate Respirators"
- Interim Final Rule with comments
- Creates an new class of **P**owered **A**ir-**P**urifying **R**espirator (PAPR)
  - PAPR100
    - PAPR100-N Not for use against oil-based aerosols
    - PAPR100-P Strongly resistant to oil aerosols
- Effective date: April 14, 2020
- Comments due by August 12, 2020

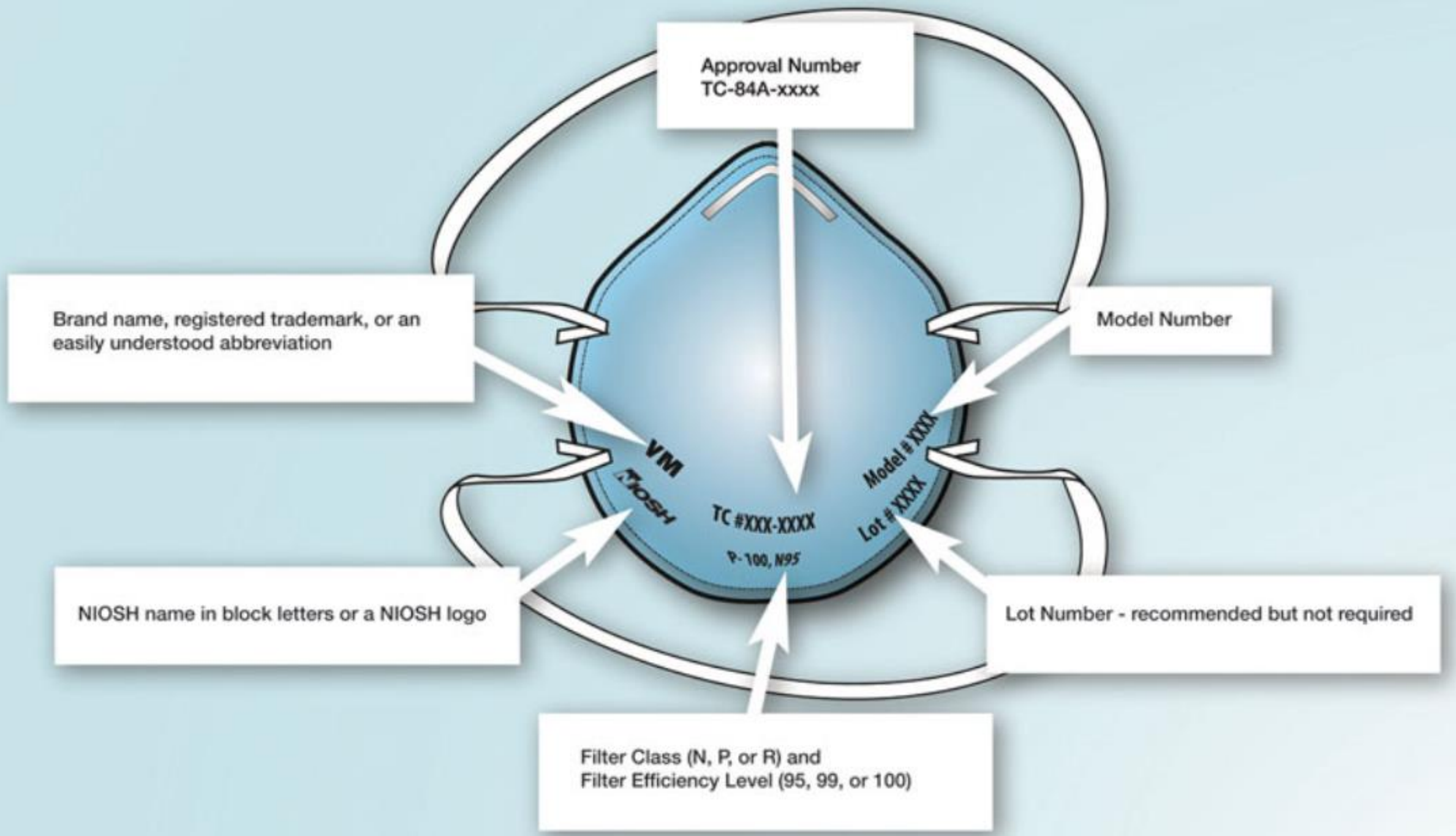
Counterfeit/Misrepresented Respirators Revisited

- **When NIOSH becomes aware of counterfeit respirators or those misrepresenting NIOSH approval on the market, we will post them here to alert users, purchasers, and manufacturers**
- https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

Signs that a respirator may be counterfeit:

- No markings at all on the filtering facepiece respirator
- No approval (TC) number on filtering facepiece respirator or headband
- No NIOSH markings
- NIOSH spelled incorrectly
- Presence of decorative fabric or other decorative add-ons (e.g., sequins)
- Claims for the approval for children (NIOSH does not approve any type of respiratory protection for children)
- Filtering facepiece respirator has ear loops instead of headbands

Example of Exterior Markings on a NIOSH-approved Filtering Facepiece Respirator



This is an example of a misrepresentation of a NIOSH-approval. G & F Products is not a NIOSH approval holder or a private label holder. (4/9/2020)

Any respirators being sold as Maskin are no longer NIOSH approved. They are counterfeit or they are no longer compliant to the NIOSH approval. (4/9/2020)

North Carolina Occupational Safety and Health Education & Research Center

These are examples of counterfeit respirators using Shanghai Dasheng Health Products Manufacture Co. Ltd's (SDH) NIOSH approval number, TC-84A-4329, without their permission. Please note these respirators have ear loops. The NIOSH-approved SDH model does NOT have ear loops. These respirators are not NIOSH approved. (3/31/2020)

This is an example of a counterfeit respirator. Raxwell is not a NIOSH approval holder or private label holder. They are using Shanghai Dasheng Health Products Manufacture Co. Ltd's (SDH) NIOSH approval number, TC 84A-4329, without their permission. (3/31/2020)

Mask vs Respirator

What's included?

•Clean Air Mask 2.0

•1 Advanced N95 Air Filter 2.0

Performance and Technical Specifications

	Clean Air Mask 2.0	Industrial Mask	Surgical Mask	Fashion Mask
5-layer filter technology, tested for for various international standards	✓	✓	✗	✗
Fit all types of faces	✓	✗	✗	✗
Shapeable nose-clip to secure sealing	✓	✗	✗	✗
2x exhalation valves for comfortable breathing	✓	✗	✗	✗
Adjustable earloops for a personal fit	✓	✗	✗	✗
Long Lasting & replaceable filters	✓	✗	✗	✗
Breathable cloth	✓	✗	✗	✗
2x Advanced N99 filters included	✓	✗	✗	✗

Thank You!

Please contact johnstaley@unc.edu for questions about this presentation.