Office of Environment, Health, Safety and Security
Operating Experience Summary

OES 2022-01 April 2022

Suspect/Counterfeit Items (S/CI): Respirators & Masks

Introduction

This Operating Experience Summary (OES) provides information on risks related to respirators and masks that are routinely used for safety applications at Department of Energy facilities and that are regulated by the United States (U.S.) Federal Government to meet various safety requirements. The increase in global demand for respirators and masks due to the COVID pandemic has also come with an increase in the production of suspect, counterfeit, and defective items in the marketplace, impacting the quality of the supply of work-related respirators and masks. The OES covers background on the prevalence of the issue, basic terms, and definitions, how to identify and report, and recommendations for dispositioning. Masks that are found to be misrepresented, substandard, fraudulent, suspect, or counterfeit are required to be reported in accordance with DOE Order (O) 414.1D, Quality Assurance, Attachment 3, Suspect/Counterfeit Items Prevention.

Background

Given the breadth and depth of DOE's missions, the undetected use of counterfeit personal protective equipment (PPE) such as safety regulated respirators and masks has the potential to pose significant near and long-term adverse consequences and safety risks to workers. Government regulated respirators and surgical masks are examples of PPE that are used to protect the wearer from particles or from liquid contaminating the face.

Increased amounts of counterfeit goods including counterfeit respirators and masks have been found in the supply chain due to supply chain shortages. Anytime there is a shortage, and this is identified within the supply chain, this leaves an opportunity for counterfeiters to meet the demand for consumers. Unfortunately, products such as respirators and other critical healthcare related PPE tend to be continuously stressed causing fluctuations in genuine supply.

Discussion

In the following, we discuss regulatory agencies, respirator types being covered in this OES, basic definitions, reporting scenarios, inspection tips, and indications of counterfeiting.

What regulating agencies are involved?

Various regulating agencies throughout the U.S. have different areas of responsibility when addressing respirators and masks including:

- **Centers for Disease Control and Prevention (CDC)** serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the American people.
    - National Institute for Occupational Safety and Health (NIOSH) and the National Personal Protective Technology Laboratory (NPPTL) are organizational components of the CDC that specifically direct, implement, and provide national guidance related to conformity assessment programs and functions (e.g., inspection, testing, certification, quality assurance, surveillance) related to PPE such as the respirators addressed in this OES.

- **Food and Drug Administration (FDA)** is responsible for advancing public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get accurate, science-based information they need to use medical products and foods to maintain and improve their health. The FDA regulates any products that may be used in a medical setting such as surgical N95 Respirators and other FDA cleared surgical masks, as discussed further in the next section.

What are the relevant respirator and mask types?

FDA-Cleared Surgical Masks are loose-fitting, disposable devices that create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. They are worn by healthcare professionals during surgery and nursing to help prevent contamination of the surgical field and/or the patient by capturing liquid droplets that are expelled by the wearer. Surgical masks are cleared for use as medical devices by the FDA, or equivalent agencies outside the U.S. They are often referred to as face masks, it is important to note that ***not*** all face masks are regulated by the FDA as surgical masks.

Filtering Facepiece Respirators (FFP) Respirators to the FFP Standard are European respirators which must meet the European standard EN 149 (current version) and have three general classes ranging from the lowest filtration at FFP1 to the highest filtration FFP3. The FFP2 respirator is the most similar to an N95 respirator with filtration rate at 94%.

N95 Respirators are respiratory protective devices designed to achieve a close facial fit and efficient filtration of airborne particles. The edges of a N95 respirator are designed to form a seal around the nose and mouth. NIOSH-certified N95 respirators are particulate respirators (filtering facepiece respirators, or FFRs) that are designed to help reduce the wearer's exposure to airborne particulate hazards. In the U.S., NIOSH tests and certifies respirators based on their physical and performance characteristics, including filtration efficiency. N95 respirators are evaluated, tested, and approved by NIOSH per the requirements in the Code of Federal Regulations 42 CFR part 84. This is a type of respirator that may be marked *NIOSH* approved and has a 95% filtration rate.

Surgical N95 Respirators are commonly used in healthcare settings. They are both certified by NIOSH as an N95 respirator and cleared by the FDA as a surgical mask. These products are frequently referred to as medical respirators, healthcare respirators, or surgical N95s. This is a type of respirator that may be marked *NIOSH* approved and *FDA* cleared as a surgical mask. This is not typically seen on respirators certified by other countries' standards. Surgical N95 respirators must also be capable of meeting American Society for Testing Materials (ASTM) F1862 (current version) which is a standard test method standard for resistance of medical facemasks to penetration by synthetic blood, so this may also be marked on the packaging and mask. This test is required because during certain medical procedures, a blood vessel may occasionally be punctured, resulting in a high-velocity stream of blood impacting a protective medical facemask.

KN95 Respirators are respirators similar to an N95 but are not NIOSH certified. They are manufactured to the Chinese standard GB2626 (current version). The filtration performance requirements are similar to NIOSH requirements, but KN95 respirators are NOT to be marked as "NIOSH" approved since they have NOT been tested or validated by NIOSH. A good reference to compare the standards for KN95 and N95 is provided by 3M: "Comparison of FFP2, KN95, and N95 Filtering Facepiece Respirator Classes," and the subsequent table from this bulletin is included in the Attachment to this OES.

KF Respirators are respirators regulated by the Korean Food and Drug Administration (similar to the FDA) and have three general levels of respirators available for use**:** KF80, KF94, and KF99. KF80 has 80% filtration, KF94 has 94% filtration, and KF99 has 99% filtration. Typically, the KF94 is used in a medical setting and is the most similar to the N95 respirator used in the U.S.

What typical definitions are used when referring to the status of respirators and masks?

Counterfeit respirators and masks are products that are falsely marketed and sold as being government safety regulated or tested and may not be capable of providing appropriate respiratory protection to workers. Counterfeit indications are often confirmed through various means of validation and testing.

Defective or Nonconforming respirators and masks are products that were provided by a manufacturer that have an abnormality that may impair quality due to inadequate design, quality escape during production, damage during shipping/handling and storage, or other controllable causes.

Suspect respirators and masks are products for which there are indications that the item may not be genuine. Testing or validation may not have been performed yet to confirm the item is counterfeit or validation of the item is inconclusive. Indications may include but are not limited to:

- Lack of information on packaging (missing manufacturer information)
- Conflicting information between packaging, certificates, and product (i.e., states NIOSH certified on box but no NIOSH markings on exterior of mask)
- Indications that the item is poor quality (i.e., appearance of low quality: packaging, texturing, labeling, etc.)
- Item smells strong of chemicals or smells odd
- Misspellings or incorrect logos

Reporting Scenarios

The following scenarios are provided to aid users with examples of potential S/CI respirators and masks, and when and how to report them.

Scenario #1: Misrepresented NIOSH respirator
Your site received an order of KN95 respirators that are marked as "NIOSH Approved." After looking through the NIOSH Certified Equipment List, it appears that the mask manufacturer is misrepresenting the mask as being NIOSH approved when it is NOT.

Scenario #2: Respirator is on CDC Counterfeit List
The site inspected the respirator accordingly by following guidance on the CDC website "Counterfeit Respirators/Misrepresentation of NIOSH Approval." During the inspection, it was noted that the respirators received were listed on this website as counterfeit.

Scenario #3: Suspect *FDA cleared* Surgical Masks
The site received what appeared to be *FDA cleared* surgical masks that are certified for healthcare use (i.e., surgical masks are regulated under 21 CFR 878.4040). After inspection of the packaging of the masks the inspector noted numerous spelling and grammatical errors and some conflicting information regarding the regulations and test standards. The item appears to be suspect. After further investigation, the inspector finds that the company is not a U.S. company, and the masks were likely not tested.

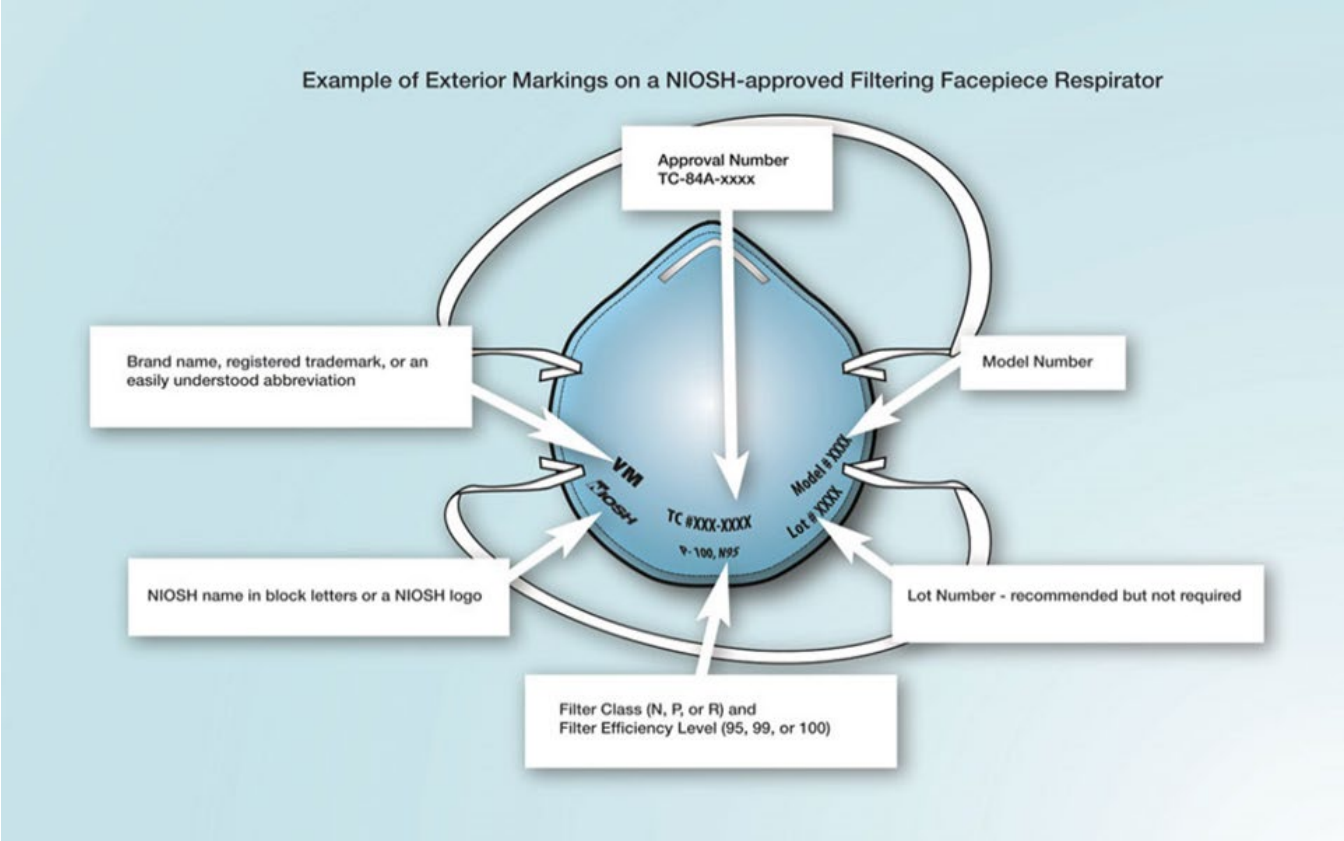
In all three scenarios, the items should be reported by emailing counterfeit@hq.doe.gov. By contacting this email address, the DOE Office of Inspector General (OIG) and S/CI Subject Matter Expert (SME) will review the information and address any questions. For reporting process information reference DOE O 414.1D.

Reporting to the DOE Occurrence Reporting and Processing System (ORPS) is only required if items are found in use, after passing incoming inspection, and/or their failure could result in a loss of safety function or present a hazard to health and safety.

Mask Inspection Tips

Inspection Tip: How to Identify a NIOSH-Approved Respirator:

NIOSH-approved respirators have an approval label on or within the packaging of the respirator (i.e., on the box itself and/or within the users' instructions). Additionally, an abbreviated approval is on the FFR itself. You can verify the approval number on the NIOSH Certified Equipment List (CEL) or the NIOSH Trusted-Source page to determine if the respirator has been approved by NIOSH. NIOSH-approved FFRs will always have one the following designations: N95, N99, N100, R95, R99, R100, P95, P99, P100.



Indications 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
- Check the respirator approval markings using the Example of Correct Exterior Markings on a NIOSH-Approved Filtering Facepiece Respirator graphic.

Third-party marketplace potential indications of counterfeiting:

- If a listing claims to be “legitimate” and “genuine,” it likely is not
- Look for bad grammar, typos, and other errors
- Mixing up names/logos
- Domain squatting type activity (misspell the domain)
- An odd privacy policy page and/or broken links
- Seller has a lot of items in stock when other sellers do not (i.e., there are shortages)

Recommendations

DOE maintains a S/CI Working Group (SCIWG). The SCIWG has developed the following recommendations to aid in training, inspection and disposition of masks and respirators:

1) Individuals performing procurement, inspection, or are actively using N95, KN95, or surgical masks for use other than for COVID protection should be familiar with this OE document.

2) Individuals should work closely with their site ES&H, Operating Experience, and/or Industrial Hygiene organizations during any inspections, testing, or dispositions of masks.

3) Disposition processes should follow the steps outlined in DOE O 414.1D. Typically, once a DOE/National Nuclear Security Administration (NNSA) site has received a release of the masks for disposition by the DOE OIG, the site may disposition the S/CI using their local processes or procedures.

   Masks released by the OIG for disposition by the site may still be used for COVID protection if appropriately evaluated. The evaluation, which must be documented, should consider the following:
   - Safety impact: How will the item be used, and will personnel safety be impacted?
   - Validation: How were the items validated for safety for the use case that they will be used? Note that previous testing on items may have been conducted by the NPPTL.
   - Marking/Segregation: How will the items be marked and/or segregated to prevent them from being used in an incorrect application?
   - Items must be marked to prevent the use in a safety environment (i.e., an environment that is not just for COVID prevention).

   Once it is feasible or cost efficient to replace the items with genuine products, they should be replaced and disposed of.

Conclusion

Respirators and masks are regulated by a government entity (i.e., FDA or CDC/NIOSH.) DOE/NNSA sites that identify S/CI respirators and masks should reported to the DOE S/CI SME and DOE OIG at counterfeit@hq.doe.gov.

References

3M Technical Bulletin Date: February 2021, Rev. 6, Comparison of FFP2, KN95, and N95 Filtering Facepiece Respirator

Counterfeit Respirators/Misrepresentation of NIOSH Approval

Fraudulent COVID-19 Products FDA Warning Letters list by company

NPPTL Respirator Assessments to Support the COVID-19 Response (lists international testing of NIOSH and Non-NIOSH approved respirators, displays list of counterfeit respirators and test results)
NIOSH Certified Equipment List

Understanding the Difference- Infographic for respirator vs mask use

The Office of Environment, Health, Safety and Security (EHSS), Office of ES&H Reporting and Analysis publishes OES's to promote safety throughout the DOE Complex by encouraging the exchange of lessons-learned information among DOE facilities.

Please contact Gabrielle Holcomb at 240-255-8299 or Gabrielle.Holcomb@hq.doe.gov for questions regarding this OES.

Attachment: Comparison of FFP2, KN95, and N95 Filtering Facepiece Respirator Classes

The following information is taken directly from a 3M Technical Bulletin, "Comparison of FFP2, KN95, and N95 Filtering Facepiece Respirator Classes" February 2021, Rev. 6.

As shown in the following summary table, respirators certified as meeting these standards can be expected to function very similarly to one another, based on the performance requirements stated in the standards and confirmed during conformity testing. Based on this comparison, it is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class, and Japan DS2 FFRs as "similar" to US NIOSH N95 and European FFP2 respirators, for filtering non-oil-based particles such as those resulting from wildfires, PM 2.5 air pollution, volcanic eruptions, or bioaerosols (e.g., viruses). However, prior to selecting a respirator, users should consult their local respiratory protection regulations and requirements or check with their local public health authorities for selection guidance.

Certification/ class (Standard)	N95 (NIOSH-42 CFR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS2 (Japan JMHLW-Notification 214, 2018)	PFF2 ABNT/NBR 13.698. 2011
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%	≥ 94%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl	NaCl and paraffin oil or dioctyl phthalate
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min	95 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	N/A
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)	≤ 70 Pa (at 30 L/min)≤ 240 Pa (at 95 L/min)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min	Varied – see above
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)	≤ 300 Pa
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min	160 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec	Leak rate ≤30 cm^3/min
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa	-250 Pa
CO_2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%