PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Filtration Efficiency Performance of Non-NIOSH-Approved International Respiratory Protective Devices: Phase Two

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

This report summarizes the filtration performance results from the assessments that took place as a result of an Emergency Use Authorization (EUA) issued by the United States Food and Drug Administration (FDA)[1] and discusses important considerations when purchasing non-NIOSH-approved international respiratory protective devices temporarily authorized for occupational use in the United States.

NIOSH evaluations show that 26% of non-NIOSH-approved international respiratory protective devices have inconsistent filtration performance and 60% of assessments found filtration efficiencies less than 95%. The NIOSH-approved N95 filtering facepiece respirator standard is 95%.

In order to supplement the national inventory of N95 filtering facepiece respirators (FFRs) and increase the supply of available respirators, the National Institute for Occupational Safety and Health (NIOSH), part of the Centers for Disease Control and Prevention (CDC), suggested several strategies to optimize the supply of N95 respirators (CDC 2020). These guidelines include strategies for crisis capacity—those used when there is a shortage of NIOSH-approved respirators. Included within this set of strategies is the provision for the use of non-NIOSH-approved international respiratory protective devices that were manufactured under foreign standards but that incorporate performance requirements similar to NIOSH-approved N95 FFRs.[2]

Consistent with these guidelines, in March 2020, FDA issued an EUA permitting the use of specified international respirators from seven countries (FDA 2020). The United States Occupational Safety and

[1] The initial EUA issued by FDA was in effect from March 24, of 2020, through May 6, 2020. A revised EUA was issued by FDA on May 7, 2020, reducing the number of personal respiratory devices included as approved under the EUA (FDA 2020).
[2] NIOSH-approved N95 FFRs filter out at least 95% of particulate matter. The strategy to supplement the supply of NIOSH-approved N95 FFRs by temporarily allowing for the emergency use of FFRs manufactured under foreign standards includes an expectation of similar filtration efficiency.

Health Administration (OSHA) issued provisions to permit FFRs approved in these select countries to be temporarily used in the workplace (OSHA 2020).

While these international respiratory protective devices included in FDA's EUA and OSHA's enforcement guidelines have similar performance requirements compared with NIOSH-approved devices, NIOSH does not oversee the initial production, regulate sustained manufacturer quality control for these products, monitor post-market quality, or have knowledge about the product's handling and exposures after leaving the manufacturer's control. Due to the potential to have these non-NIOSH-approved international respiratory protective devices used by workers in the United States, NIOSH designed a process to assess the particulate filtration performance. The goal of the assessment was to provide consumers of personal respiratory protection devices and other interested parties a point-of-use quantitative assessment of the devices temporarily authorized for use.

As reported in the Phase One PPE CASE report (NPPTL Report Number P2020-0112), NIOSH completed 105 assessments of non-NIOSH-approved international respiratory protective devices from the start of the FDA EUA April 10, 2020 through May 6, 2020. This PPE CASE report (Phase Two) provides the results of 251 NIOSH assessments of non-NIOSH-approved international respiratory protective devices conducted from May 7 through August 17, 2020.

How NIOSH Assessed Non-NIOSH-Approved International Respiratory Protective Devices

- To address concerns regarding non-NIOSH-approved international respiratory protective devices, NIOSH developed a protocol to quickly evaluate the filtration efficiency performance of these devices. To allow for a smaller sample size and quicker turn-around time, the samples were tested using a modified version of NIOSH Standard Test Procedure TEB-APR-STP-0059.
- NIOSH received requests via formal process to evaluate non-NIOSH-approved international respiratory protective devices included on the FDA's EUA. Qualifying requests included those received from federal, state, and local government agencies; healthcare providers; employers in non-healthcare industries; public safety and first responder organizations; and universities. Requests received directly from a manufacturer, distributor, importer, or supplier were outside of the scope of this evaluation process. Requests also had to include all specified information on the request form, including, for example, the manufacturer name, the model number, and the performance standard under which the device was manufactured.
- Through the packaging and labeling, NIOSH recorded the standard to which the samples provided claimed conformance.
- The sampling protocol used to provide the devices to NIOSH was at the discretion of the outside user group making the request, however NIOSH required each requestor to submit a minimum of 10 devices per model for evaluation.

Findings

Sample Characteristics

- NIOSH completed 251 assessments of non-NIOSH-approved international respiratory protective devices following FDA's May 7, 2020, revision of its March 24, 2020, EUA.
    - Information regarding the manufacturer, model, and performance standard came from the packaging and the labels included with or on the assessed device.
    - Some samples received did not indicate the international performance standard to which the product conformed. In those cases, NIOSH classified the performance standard as "Unknown."
    - Assessments were completed on international respiratory protection devices that were largely distinct in terms of the sample of personal respiratory devices assessed; there were 170 distinct manufacturers and 177 distinct models.
- NIOSH completed assessments at the request of federal government agencies (47%), employers in non-healthcare industries (27%), state governments (12%), healthcare providers (9%), local governments (3%), individuals and organizations not classified (1%), and public safety and first responder organizations (1%).
- Of these assessments, approximately 95% of the respiratory devices used an ear loop design to secure the mask to the wearer's face; the others used a head strap design (5%).

Overall Results

- For each of the 251 requests, NIOSH evaluated the filtration efficiency for each individual unit and recorded the maximum and the minimum filtration efficiency observed and then determined whether 1) all individual units within the assessment tested above 95% efficiency; 2) all individual units within the assessment tested below 95% efficiency; or 3) there was a mixture of units, with some testing above 95% and some testing below 95%.
    - In 104 of the assessments (approximately 41%), all individual units tested above 95% particulate filtration efficiency. In 82 of the assessments (approximately 33%), all individual units tested below 95%. In the remaining 65 assessments (26%), there was a mix of units that tested above and below 95%. See Figure 1.

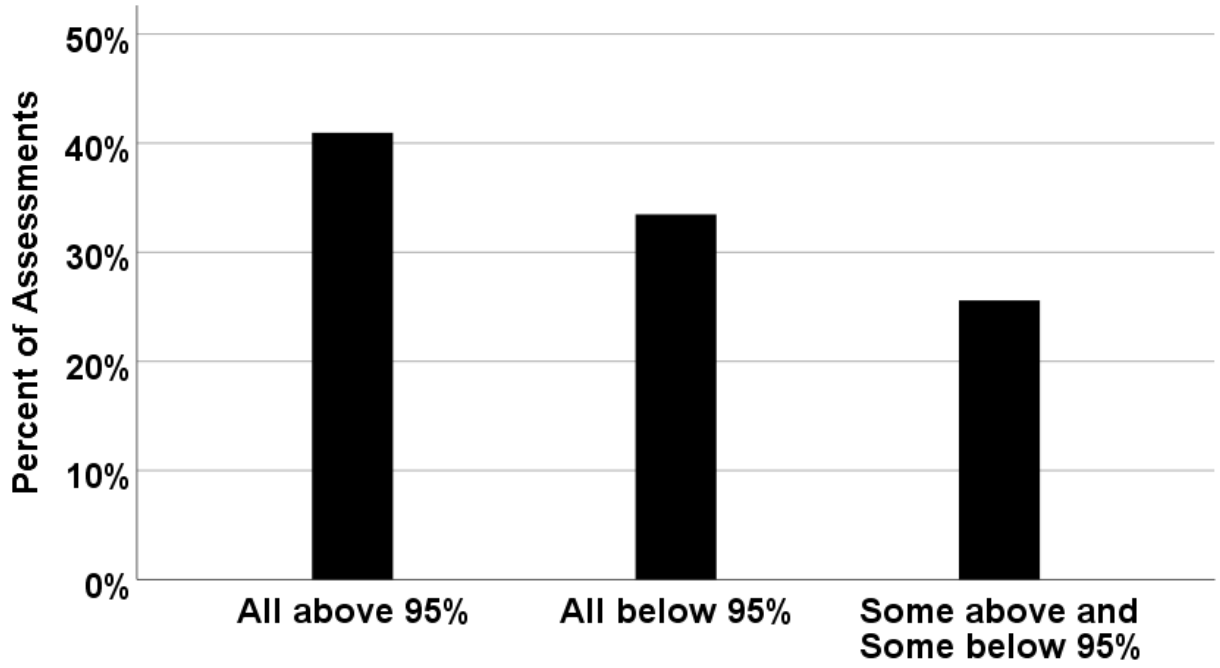

Figure 1: Overall Filtration Efficiency Results

Results by International Standard

- Table 1 presents filtration results by international standard. It shows the numbers and relative percentages of assessments that were categorized as all units above 95%, all units below 95%, and a mix of units above and below 95% by international standard.
    - **Highest Performing Filtration Efficiency International Respirators Assessed.** All units from 9 of 10 assessments (90%) conducted on devices that claimed conformance with GB19083-2010 (an international standard originating from China) tested above 95%. All units from one of the two assessments (50.0%) conducted on devices that claimed conformance with KMOEL-2017-64 (an international standard originating from Korea) tested above 95%.
    - **Lowest Performing Filtration Efficiency International Respirators Assessed.** All units from the 1 of 1 assessment (100%) conducted on devices that claimed conformance with GB/T 32610-2016 (an international standard originating from China) tested below 95%. All units from 7 of 17 assessments (78%) that claimed conformance with EN149-2001 (an international standard originating from Europe) tested below 95%. All units from 22 of 39 assessments (56%) that claimed to conform with both EN149-2001 and GB2626-2006 (international standards originating in Europe and China, respectively) tested below 95%.

Table 1: Summary Filtration Results by International Standard Claimed

Standard	NIOSH/NPPTL Assessment Results	Number of Assessments	Approximate Percentage of Assessments for Each Standard
Europe EN149-2001	All above 95%	6	35%
	All below 95%	7	41%
	Some above and some below 95%	4	24%
Europe/China EN149-2001 & GB2626-2006	All above 95%	9	23%
	All below 95%	22	56%
	Some above and some below 95%	8	21%
China GB/T 32610-2016	All above 95%	0	0%
	All below 95%	1	100%
	Some above and some below 95%	0	0%
China GB19083-2010	All above 95%	9	90%
	All below 95%	0	0%
	Some above and some below 95%	1	10%
China GB2626-2006	All above 95%	77	44%
	All below 95%	50	29%
	Some above and some below 95%	48	27%
Korea KMOEL-2017-64	All above 95%	1	50%
	All below 95%	0	0%
	Some above and some below 95%	1	50%
Unknown	All above 95%	2	29%
	All below 95%	2	29%
	Some above and some below 95%	3	42%

Variability Within Individual Assessments

- When facing respiratory hazards in the workplace, end users must be able to trust that individual respirator units, which are labeled and packaged identically, provide a consistent level of performance. (See 42 CFR Part 84 for explanation of quality requirements NIOSH-approved respirators, where a consistent unit-to-unit filtration efficiency is required.)
- In this context, an assessment of filtration efficiency variation through an analysis of the range within individual assessments is important because the range indicates the level of filtration performance consistency that can be expected from one unit to the next when the units are labeled and packaged consistently.
- As noted previously, each individual assessment tested at least 10 different units submitted with the same label and packaging. There were 251 assessments conducted.

- For each individual assessment, NIOSH calculated the range in the filtration efficiencies of the units by subtracting the lowest observed filtration efficiency from the highest observed filtration efficiency. This range provides an indication of how consistent the unit-to-unit filtration properties were within each individual assessment.
    - For example, in a single assessment, if the highest filtration recorded was 95% and the lowest was 30%, the range would equal 65% (95 minus 30). With a range such as this, the end user could not have confidence in the consistency of the level of protection.
- Approximate quartiles within the 251 assessments suggested that
    - 67 (27%) had a greater than 15% range in filtration efficiencies
    - 54 (21%) had a 5%–15% range in filtration efficiencies
    - 77 (31%) had a 1%–5% range in filtration efficiencies
    - 53 (21%) had a 0%–1% range in filtration efficiencies
- Table 2 reports the highest and lowest ranges observed among assessments based on the reported international standard.
    - Across the 251 assessments, the lowest range in filtration results was 0.06%, corresponding to a sample of 30 units from a non-NIOSH-approved respirator that claimed conformance with China standard GB2626-2006; the maximum filtration observed was 100% and the minimum was 99.94%.
    - Across the 251 assessments, the highest range in filtration results was 86.75%, corresponding to a sample of 10 units that claimed to conform with both EN149-2001 and GB2626-2006, standards originating from Europe and China respectively; the maximum filtration observed was 92.05% and the minimum was 5.30%.

Table 2: Highest and Lowest Range in Filtration Efficiency Performance Within Assessments by International Standard Claimed

Standard	Lowest Range in Filtration Efficiency (%)	Highest Range in Filtration Efficiency (%)	Number of Assessments
Europe EN149-2001	0.18	78.00	17
Europe/China EN149-2001 & GB2626-2006	0.13	86.75	39
China GB/T 32610-2016	30.80	30.80	1
China GB19083-2010	0.26	5.46	10
China GB2626-2006	0.06	71.50	175
Korea KMOEL-2017-64	0.09	6.93	2
Unknown	0.40	67.42	7
Overall	**0.06**	**86.75**	**251**

NOTE: The values reported in the table reflect the range of filtration efficiency observed within each assessment. Lower values represent lower filtration efficiency variability while higher values represent higher filtration efficiency variability.

Conclusion

The results of these assessments suggest that there was considerable range in filtration efficiency for most of the models assessed. Further, in 33% of the assessments, all units tested below 95%.

During Phase One of NIOSH's international assessments, NIOSH primarily assessed international respiratory devices that were included in FDA's March 27, 2020 EUA. Based in part on these results (reported in NPPTL Report Number P2020-0112), on May 7, 2020, FDA removed 57 respirators from its International EUA list (FDA 2020). Approximately half (47%) of NIOSH assessments completed during Phase Two were performed at the request of federal agencies continually investigating the efficiency of incoming non-NIOSH-approved international respiratory protective devices and the possibility of continually revising the FDA EUA.

While filtration efficiency shows how well the filter media performs, users must ensure a proper fit is achieved. This assessment procedure provides useful information about the filtration efficiency of respiratory protection devices that may be used by workers in national emergency situations; however, it is not equivalent to the standard test procedure used to evaluate NIOSH-approved N95 respirators. Therefore, the values reported on the international assessment results – not NIOSH-approved webpage only provide an indication of filtration efficiency and confirm neither that the product performs equivalently to a NIOSH-approved N95 nor that it conforms with the standard requirements claimed by the manufacturer.

International Respiratory Protective Device Assessment: Phases One and Two Summary and Comparison

As noted in the Phase One PPE CASE report (NPPTL Report Number P2020-0112), NIOSH completed 105 assessments of non-NIOSH-approved international respiratory protective devices between the start of the FDA EUA and May 6, 2020. The current PPE CASE report (Phase Two) summarized 251 NIOSH assessments conducted from May 7, 2020, through August 17, 2020.

Figure 2 shows a side-by-side comparison of the results between Phase One and Two. Table 3 summarizes the number of assessments that fell into each filtration efficiency category.

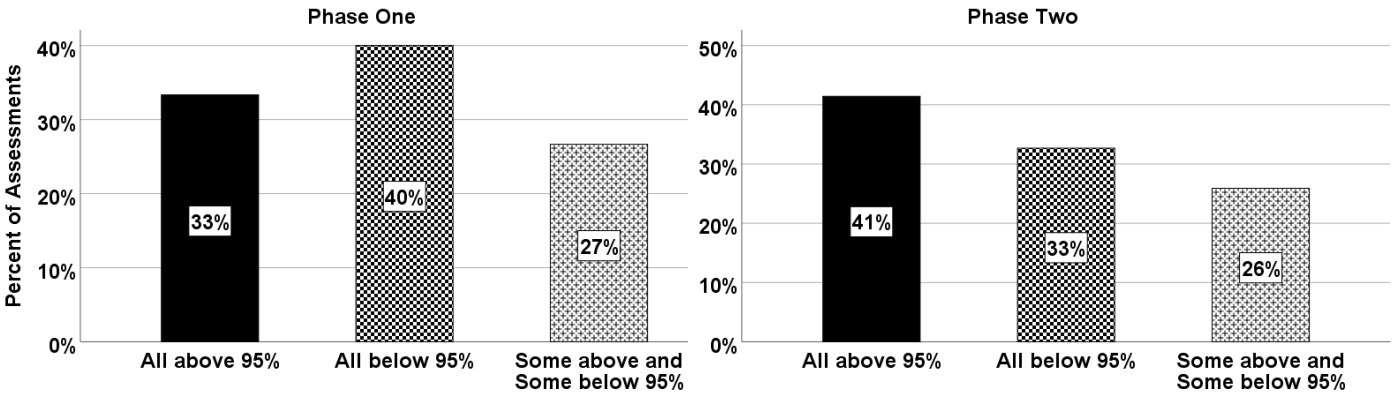

Figure 2: Side-by-Side Summary and Comparison of Phase One and Phase Two Results

Table 3: Phase One and Phase Two Comparison and Summary

	Phase One	Phase Two	Comparison	Phases One and Two Combined
All units tested were above 95%	33% (35)	41% (104)	8% Increase	39% (139)
All units tested were below 95%	40% (42)	33% (82)	7% Decrease	35% (124)
Some units above and some below 95%	27% (28)	26% (65)	1% Decrease	26% (93)
Total number of assessments	105	251		356

As shown in Figure 2 and Table 3, an 8% increase was observed for the category of assessments in which each unit tested above 95% filtration efficiency. There was also a 7% decrease for the category of assessments in which each unit tested below 95% filtration efficiency. These changes may have resulted, in part, from the awareness raised by the NIOSH assessments in Phase One and the transparent and timely information-sharing of assessment results between FDA and NIOSH.

Table 3 also shows the results of the assessments when Phase One and Two are combined (Number of Assessments = 356). In total, in 39% of the assessments (n=139) all units tested above 95% filtration efficiency, in 35% of the assessments (n=124) all units tested below 95% filtration efficiency, and in 26% of the assessments (n=93) some units tested above and some tested below 95% filtration efficiency. These summary statistics suggest that the level and consistency of filtration efficiency of the international respiratory protection devices assessed remain concerning.

What the User/Purchaser Can Do When Purchasing Non-NIOSH-Approved International Respiratory Protective Devices

- Healthcare organizations should review the FDA EUAs before purchasing any non-NIOSH-approved international respiratory protective devices.
- Purchasers should review the NIOSH Respirator Assessment Results webpage before purchasing respirators that claim to meet the standards identified in Table 1.
- Purchasers should refer to the following guidance to evaluate respirators from other countries to determine whether they are counterfeit or provide substandard protection: Factors to Consider When Planning to Purchase Respirators from Another Country, Including KN95 Respirators from China and Understanding the Use of Imported Non-NIOSH-Approved Respirators.

Get More Information

For more information related to personal protective equipment, visit the NIOSH website.

Find NIOSH products and get answers to workplace safety and health questions:

1-800-CDC-INFO (1-800-232-4636) | TTY: 1-888-232-6348
CDC/NIOSH INFO: cdc.gov/info | cdc.gov/niosh/npptl
Monthly NIOSH eNews: cdc.gov/niosh/eNews

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