

Memorandum

To: SFG CLIENTS

From: THE SMITH-FREE GROUP

Date: MAY 20, 2020

RE: FEMA & 3M N95/KN-95/KN-90 PPE Briefing

Michael Brock, FEMA Region 10: We've received a lot of questions about different types of masks and PPE and 3M has generously offered to host us for this briefing.

Chris Spicoli, 3M: Since the end of March I've been embedded with FEMA's Supply Chain Task Force and they've done a tremendous job getting PPE where it's needed. There's a lot of confusion in the market about the KN-95 and KN-90 products. The President directed us to import the KN-90 and KN-95 products back in April and FEMA has been distributing those masks since then. We have a 3M laboratory engineer on the call with us, Nicky McCulloch, and she is one of the world's foremost disposable respirator experts.

Nicky McCulloch, 3M: CDC has strategies for optimizing respiratory protection, and they have three different supply strategies: one with respirators in plentiful supply, one with respirators in short supply, and one with severe shortages of supply. The CDC and OSHA allow the use of the N-95 respirators beyond their shelf life in the last scenario, as well as the use of respirators from other countries. They allow limited reuse of N-95s and facemasks in some circumstances.

The FDA has put out two emergency use authorizations, which allow people to use certain brands of Chinese respirators. The performance standard for N-95 respirators are set by NIOSH, the title N-95 refers to the filter performance—they must be 95% efficient or greater for particles of all sizes. They're tested with salt particles in a very specific size range at 85 meters per minute flow rate, which is a breathing rate you might experience with jogging. There are also limits on inhalation and exhalation resistance.

The KN-95 is the Chinese standard, and it's very similar to the US standard. China uses the NIOSH standard as the basis of their standard and testing conditions are very similar. Filter performance is 95% or greater tested with salt at 85 meters per minute. They can have no more than 8% total inward leakage and they test on subjects of all ages representative of the country's population. Additionally, to pass the KN-95 test in China they have to fit Chinese faces. Chinese faces are generally differently structured than the diverse range of faces we see in the United States.

China has another classification of respirators, KN-90. They are very similar to KN-95 except they only have filtration efficiency of 90%. This is a globally approved standard, Europe and Australia use the KN-90 standard but the United States does not. OSHA and CDC do not recognize KN-90 as similar to N-95 but they have authorized emergency use of KN-90 for now.

- **KN-95:** Very similar to NIOSH N-95, 95% filtration efficiency. Generally white, two different types of attachments: ear loops and headbands. Ear loops are common in China but not in the United States, but they are common on surgical masks. The FDA approves both types for emergency use. OSHA requires that workers using respirators in the United States have training with fit and use. Workers

must be fit-tested and KN-95 are designed for Chinese faces, so some U.S. workers may not pass the fit test. If a worker does not pass the fit test, KN-95 is not considered a respirator but can still be considered a facemask.

- KN-90: KN-90's do not meet the NIOSH N-95 standard. They can be used as face masks and are authorized for emergency use. They have 90% filter rate and are recognized as respirators in China, but OSHA and CDC have specified that these should be considered face masks.

Resources: [3m.com/airlift](https://www.3m.com/airlift) contains detailed charts about different types of respirators being imported and links to training materials. [3M.com/coronavirus](https://www.3m.com/coronavirus) has information about fit testing, selection and use of respirators, and general questions about respirators.

Q & A

- We were told that the KN-95's distributed by the State of Oregon were no longer sufficient medical purposes.
 - Nicky McCulloch: The FDA emergency use authorization lists all ninety approved Chinese manufacturers. NIOSH did find that a lot of KN-95s were substandard, they removed seventy-five manufacturers and there are now only ninety approved.
- Due to scarcity we are looking at decontamination methods for our N-95 masks. What research is 3M doing on this?
 - Nicky McCulloch: We have a technical bulletin on the [3M.com/coronavirus](https://www.3m.com/coronavirus) website that talks about safe decontamination methods that don't damage filters or headbands. These respirators are designed to be disposable so bands can stretch out and nose clips can become fatigued. If workers can't get a good seal they shouldn't use it anymore.
- Are there different sizes of KN-95s? The sizes just aren't working for our people and we've only got one size. Is there a list of approved KN-95 suppliers?
 - Nicky McCulloch: Appendix A of the FDA Emergency Use Authorization lists the approved KN-95 manufacturers. Most KN-95's only come in one size and Chinese faces tend to be larger than U.S. faces, I've been studying Chinese faces and doing respirator development with and in China for twenty-three years. 3M's KN-95 products are designed for the Chinese markets and will not fit every American face.
- The most recent date for the FDA Appendix A hasn't been updated since May 7, is that up to date?
 - Nicky McCulloch: I believe so.
- So KN-95's that are not on the FDA Appendix list should only be considered facemasks?
 - Nicky McCulloch: Yes. NIOSH also lists masks they've tested that came back with substandard results, and you can actually mail them ten of your respirators and they will test them for you.
- When do you expect the supply of domestically manufactured N-95 respirators to stabilize?
 - Chris Spicoli: We're producing about 35M N-95's a month and will ramp that up to 90M per month in October, and we will produce about 1.1B annually domestically in the coming years. Everything we produce is being distributed immediately; we are not holding any stock so please be cautious of distributors claiming to have millions of 3M respirators in their possession.
- Is there a universally fitting model you're focusing on producing?

- Nicky McCulloch: We are ramping up production across several different models including a horizontal flat fold platform, which has high levels of fit compatibility.
- Will a second wave of pandemic in Asia impact supply in the United States?
 - Chris Spicoli: That's a question for the State Department; it becomes an issue of negotiating supply between governments.
- Can we use N-95 respirators that expired eight years ago but are in good condition?
 - Nicky McCulloch: Yes, NIOSH research indicates that expired respirators still meet their standards. Be aware of the head straps and nose clip deteriorating.
- Is there proof of any N-95 respirator stopping COVID-19?
 - Nicky McCulloch: Respirators are designed to reduce exposure to airborne particles. When air goes through a filter media, 95% of particles will be filtered out. So the exposure to particles overall is reduced by 95%. Testing has shown that respirators filter out bacteria and viruses in the air just as efficiently as salt, silica or dust particles. Respirators are not designed to be disease prevention devices; they are designed to be particle exposure reduction devices. There are historical examples of hospitals using respirators faring much better than those who don't, but this is due to an overall reduction of particle exposure, not because it kills viruses.
- Can city governments order directly from 3M?
 - Chris Spicoli: Absolutely.