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Research Letter

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Abstract

Additively manufactured respirators (AMRs) made using rigid plastic can be fitted with repurposed filter media to yield a wearable mask capable of passing a quantitative fit test with criteria set for commercial, N95 health care particulate respirators. This has been verified through an evaluation study assessing AMR masks fabricated using open-source design files and a commercial fused-filament fabrication machine, using N95 filter cloth and a P100 respirator cartridge. A few examples of filter media not designed for human respiratory protection were also evaluated in an AMR mask but did not demonstrate filtering sufficient to pass the N95 test criteria. All attributes of an AMR mask system must be considered during design and when testing performance, including the mask frame, gasket, and the cord used to secure the mask to the face. AMR masks are not the same as commercially available respiratory masks. If AMR masks are used as personal protective equipment (PPE) during a crisis when there is a shortage of regular PPE it is important that wearers are fully informed of the differences, tradeoffs, and risks associated with their use. Quantitative fit testing and proper training on how to don and doff the AMR mask are important to help achieve the best possible outcome when they are used.

Introduction

Emergency response personnel and health-care workers around the world are facing severe shortages of important personal protective equipment (PPE) that is needed for their own safety, the safety of patients, and the safety of the public.[1] To address this situation maker communities are spontaneously forming around the world with the goal of creating small-scale fabrication shops, mostly using additive manufacturing (AM) 3-dimensional plastic filament printers, to produce PPE for local and regional use, including face shields, goggles, and respirators.[2] Noteworthy in these efforts is the use of small-scale AM equipment (3-dimensional (3D) printers); an outcome from this interest has been a rapid proliferation of open source stereolithographic computer aided design files (.STL file format) that contain the standardized design information needed for machine users to print these components. While the printing process is straightforward and quickly yields parts, challenges still remain in relation to the need to source additional materials to allow their use, such as clear plastic sheet for use with face shields and goggles, and filter material for respirators.

In the case of respirators, unresolved questions exist in relation to technical performance due to mask shape, caused because the masks are rigid and not form fitting, mask sealing, which is influenced by the choice and application of gasket materials, and the possible use of inferior filter materials. Prior work has shown that skilled health care personnel had a 92.2% pass rate during initial fit testing with flexible, elastomeric half-mask respirators (EHMRs).[3] Unfortunately, no similar data exists for how well less-trained responders can adapt to using *ad hoc* rigid AM respirators (AMRs). The fact that no standards or even guidelines exist to aid in the selection and application of flexible gaskets with AMRs compounds this problem. In relation to the choice of filter material, most discussion relates to cutting good N95 masks into subparts to cannibalize filter material for use in the AMRs. This approach is questionable in terms of optimally using a scarce resources, and in many cases may not be feasible due to unavailability of the N95 material. Discussions in on-line maker community forums also describe the use of other materials instead of N95 cloth, such as high-efficiency particulate air (HEPA) filters, vacuum cleaner bags, or even clothing.[2,4] Laboratory evaluations of the filtering abilities of these materials show they are inferior to the N95 standard but do have some filtration capability, ranging from 69% in a test with a cotton T-shirt to 94% for a test with a vacuum cleaner bag; this level of performance may be deemed acceptable in some communities under extreme conditions.[5]

The goal of this study was to explore methods affecting the fit of AMRs, compare AMR performance using different filter materials, and to evaluate the feasibility of using a P100 cartridge in an AMR. N95 masks are the standard of use in health care PPE.[6] They are tested to demonstrate they are capable of keeping out at least 95% of airborne challenge particles in an environment, the "N" prefix indicates they are not capable of resisting oil. The P100 filter cartridge is rated to filter out 99.97% of airborne challenge particles, where the "P" indicates it is oil proof. It is interesting to consider the use of P100 filter cartridges in hasty-made AMRs because P100 filters are widely available and robust, they are commonly used in industries where hazardous materials are encountered. At Idaho National Laboratory P100 filter cartridges are used in all operations where there is a potential to encounter airborne radioactive particulate contamination. They are similarly used at other U.S. National Laboratories involved in work with nuclear materials, and at commercial nuclear power plants.

Methods

Several AMRs were made using an open source STL file for a design referred to as the "Montana Mask" (MM) (Fig. 1) and a design from LaFactoria3D (LF3D); a Fusion3 F400 (Fusion3 SD Printers, Greensboro, N.C.) fused-filament fabrication 3D printer was used for the MM and a FlashForge Creative Pro (FlashForge USA, City of Industry, Calif.) printer was used for the LF3D.[7,8] The Montana Mask incorporates a rigid mask frame that has a square hole in front of the nose and mouth, and a removable window pane that fits into this hole, the LaFactoria3D mask is similar. The user places the filter material over the square opening in the frame and then presses the window frame through the filter and into the hole. This process securely captures the filter fabric frame behind the window pane, with the fabric serving as the gasket at the joint between the frame and window. As a baseline test, measurements were also made using a commercial N95 mask (3M N95 Model 1860; 3M, St. Paul. Minn.; Fig. 3).

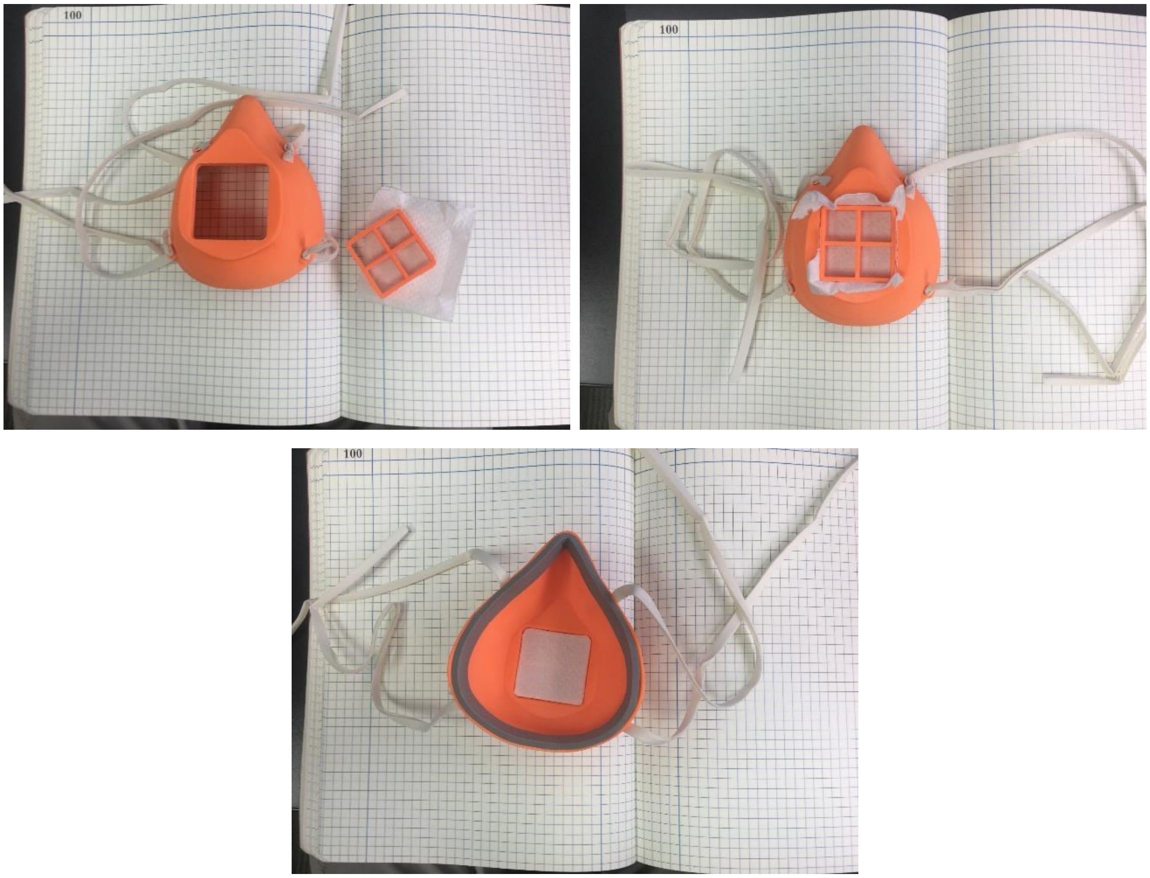

Fig. 1 Photos of an MM (made using orange filament) showing the view from the outside with the window pane next to the frame (upper left), the view from the outside with the window pane installed in the frame with a filter (upper right), and a view from the inside with the window pane and a filter installed (bottom).

Fig. 2 Photo of the inside of two LF3D masks.

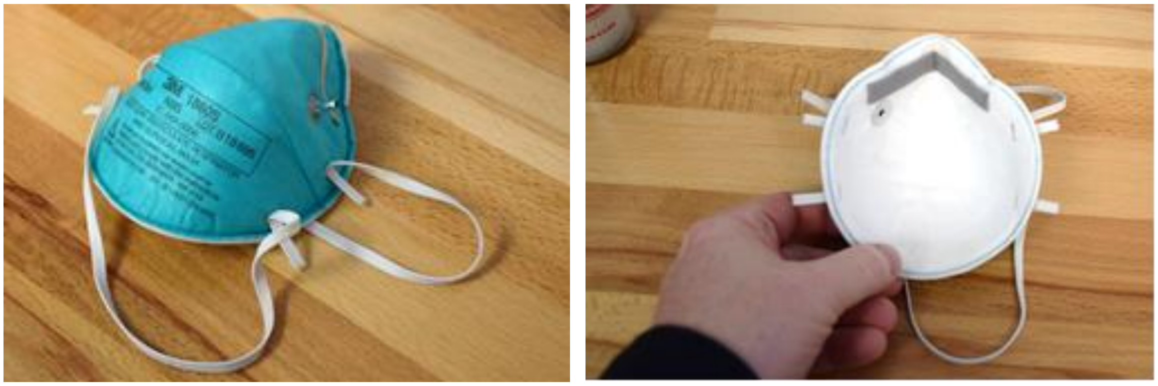

Fig. 3 Photos of the outside (left) and inside (right) of a 3M N95, model 1860, health care particulate respirator and surgical mask, note that a test nipple has been attached to this mask.

Printing for the Montana Mask was done using 1.75-mm diameter acrylonitrile butadiene styrene (ABS) polymer filament from Raise 3D (Irvine, Calif.) Machine settings used a layer height of 0.2 mm; an infill of 30%; a print speed of 58 mm s^{-1}; a print temperature of 235 C; and a bed temperature of 110 C. Print settings for the LaFactoria3D mask included use of 1.75 mm diameter ABS filament; a layer height of 0.25 mm; an infill of 20%; a print speed of 31 mm s^{-1}; a print temperature of 220 C; and a bed temperature of 110 C. After fabrication, commercial weather stripping foam (M-D Building Products, Inc., Oklahoma City, Ok.) was used as a face seal with the MM mask, two sizes were studied: medium (13-mm wide by 6.4-mm thick), and large (13-mm wide by 10-mm thick). A rubber "D-seal" automobile-style gasket (17-mm wide by 9.5-mm thick) was used with the LF3D mask, it was secured with silicone glue. Multiple filter cloths were evaluated including a) material cut from a commercial N95 mask; b) paper cut from a commercial domestic vacuum cleaner bag; c) paper cut from a commercial HEPA-filter vacuum filter assembly; and d) cloth taken from a disposable polypropylene PPE garment. Additionally, a special adapter window was fabricated for the Montana Mask that had a mounting hole to allow attachment of a P100 respirator filter cartridge (Fig. 4). To ensure a tight fit between the window and frame when using the P100 filter, cloth tape was pressed over the window-frame joint, on both the outside and inside of the mask.

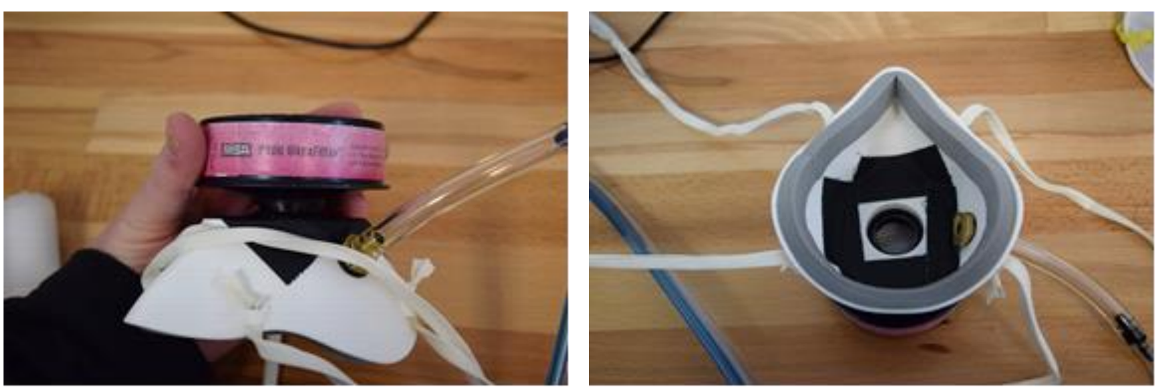

Fig. 4 Photos of the outside (left) and inside (right) of the MM mask fit with a P100 cartridge filter.

Performance testing was enabled by drilling a small hole into the side of the masks where a brass nipple fitting was secured using a rubber gasket, to ensure a leak-tight connection. This nipple allowed for a plastic tube to be attached to the mask as a sample port, connecting the inside environment of the mask to a PortaCount Pro+ Respirator Fit Tester 8038 (TSI Incorporated, Shoreview, Minn.). The instrument was factory calibrated, and the calibration was verified on-site the day of use. Testing was done in a small room where paraffin candles were lit to produce a low-concentration, smoke-particle environment (Fig.

5). The instrument draws in air through the sample tube to test the air particle density in the breathing area (smoke dust particles that leak into the mask through the filter, through the mask frame, or around the gasket) while simultaneously drawing in air from a co-located tube that ends just outside the mask. The machine quantifies the concentration of microscopic dust (smoke) particles in both air streams and determines the ratio between the two, this ratio is referred to the Fit Factor. For a person wearing a mask to pass an N95 fit test this ratio (outside concentration / inside concentration) must be 100 or greater (meaning the air inside the respirator is 100 times cleaner than the air outside the respirator). Measurements made during respirator fit testing are not a guarantee of how a user will don and wear a mask at other times. For this testing a zero baseline verification and maximum Fit Factor check were performed prior to use, a zero test was also completed with an in-line HEPA filter prior to testing, ensuring a clean system that was contaminant free.

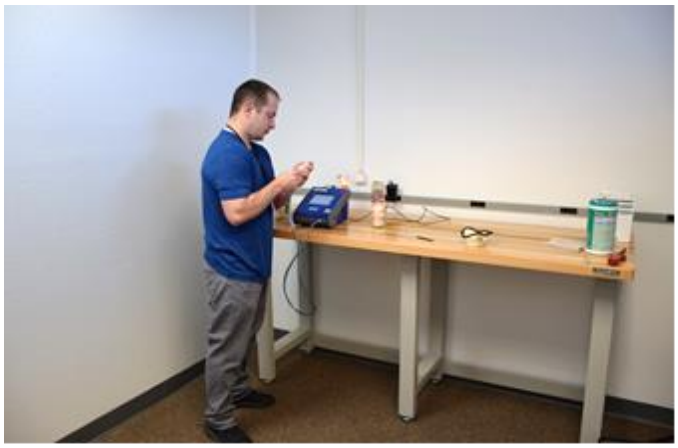

Fig. 5 Set up and calibration of the PortaCount Pro+ Respirator Fit Tester 8038.

Preliminary baseline trials (Fig. 6) were performed of different mask implementations by having the mask wearer breathe normally for approximately 60 seconds. If the observed Fit Factor during this baseline test indicted the mask was providing respiratory protection then additional tests were conducted. If the mask performance was deficient the user was allowed to readjust the mask and try again, to get the best possible face-to-mask seal. When follow-on tests were warranted they consisted of deep breathing, breathing while moving the head side to side, breathing while moving the head up and down, breathing while talking out loud, breathing while bending up and down at the waist, and then normal breathing (Fig. 7). Scores exceeding 200 are reported as 200+.

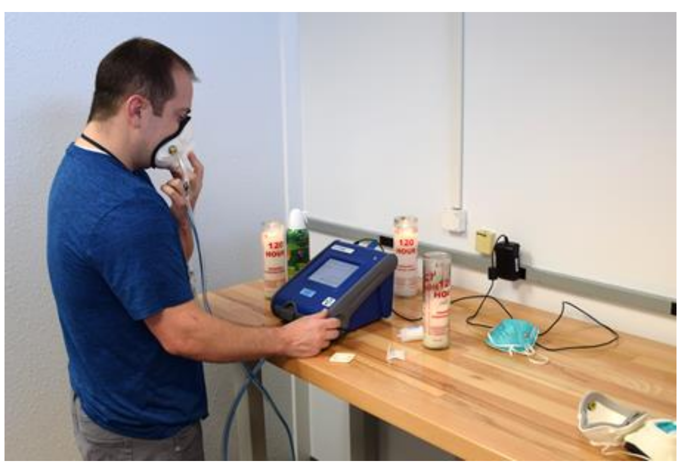

Fig. 6 Baseline trial fit test for the LF3D mask.

Fig. 7 Fit testing with the MM AMR during normal breathing (left) and bending over (right).

Results

Nine separate fit test evaluations were performed, the results from these tests are summarized in Table 1. The LF3D mask was not able to achieve a passing score during multiple baseline tests. One possible reason could have been leaking at the mask/filter joint, a second possible reason might be attributable to the rubber gasket used with the LF3D mask. During the fit test the rubber gasket was observed to be stiff, it may not have had enough compressibility to form a complete and reproducible seal to the face; this precluded the use of the LF3D mask in follow-on testing but should not be interpreted as a failure of the LF3D AMR rigid mask frame. Initial testing with the MM mask showed good results but leakage due to an incomplete face seal impacted performance. This further emphasized the need for gasket pliance and compressibility. The MM gasket was switched to the large foam gasket; performance with the large gasket and elastic was also marginal, but when fabric cord was used to secure the mask it was possible to form a compete seal to the face. The importance of using fabric cord was likely due to the heavier mass of the MM mask (56 g) vs the N95 mask (10 g), the fabric cord keeps the mask pressed to the face better than the elastic cord. None of the 'alternative' filter material options were shown capable of providing significant particulate filtering to meet the N95 standard.

Table 1 Commercial N95 and AMR mask fit test results.

	Fit Factor Test Scores								
Test	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Mask	N95	LF3D	MM	MM	MM	MM	MM	MM	MM
Gasket	None	Rubber	Medium foam	Large foam	Large foam	Large foam	Large foam	Large foam	Large foam
Filter	N95	N95	N95	N95	N95	PP	VB	HEPA	P100
Attachment	Elastic	Elastic	Fabric cord	Elastic	Fabric cord	Fabric cord	Fabric cord	Fabric cord	Fabric cord
Normal breathing	139	3.7	85	86	200+	6.6	2.2	5.4	200+
Deep breathing	200+	NT	150	87	200+	NT	NT	NT	200+
Side to side	200+	NT	81	95	200+	NT	NT	NT	200+
Up and down	200+	NT	95	79	200+	NT	NT	NT	200+
Talking out loud	200+	NT	68	23	200+	NT	NT	NT	200+
Bending up and down	200+	NT	129	114	200+	NT	NT	NT	200+
Normal breathing	200+	NT	132	120	200+	NT	NT	NT	200+
Total score	189	NT	98	66	200+	NT	NT	NT	200+

NT: not tested further
N95: 3M NIOSH N95 Filter Model 1860
PP: 3-layers of polypropylene cloth taken from a disposable anti-contamination lab smock
VB: filter cloth taken from a commercial, domestic-use vacuum cleaner bag (Arm & Hammer Odor Eliminating Vacuum Bag, Part 62601, Church and Dwight Co., Inc., Ewing, N.J.)
HEPA: filter cloth taken from a commercial, industrial use vacuum cartridge labeled as "HEPA" by the manufacturer (RIGID VF6000 HEPA Material Wet/Dry Vac Filter, Rigid Wet/Dry Vacs, St. Louis, Mo.)
P100: an MSA P100 UltraFilter cartridge (MSA, Cranberry Township, Penn.)

Discussion

Quantitative performance testing has shown that a properly-fit AMR mask frame holding quality filter material can be worn and pass a fit test at a level equivalent to a commercial N95 particulate respirator mask for protection against airborne particulates. AMR masks may be able to fill a role during crisis conditions when emergency responders might otherwise go without any respiratory protection if access to traditional N95 masks becomes unavailable. The rigid nature of the AMR frame necessitates the use of a soft and flexible gasket, to accommodate differences between the shape of the frame and the shape of the face. To ensure a good seal with the face the use of fabric cord or string may perform better then elastic cloth typically found with N95 masks. A fit test serves an important role for a new wearer to learn how to wear the mask and confirm it fits the face. Due thought should be used before deciding to cannibalize a good N95 mask to harvest materials for use in AMR masks, this is an extreme course of action. Qualified, certified P100 cartridge filters could be used with AMR masks as an alternate to N95 fabric without impacting existing stocks for N95 masks. Care must be taken when selecting and using non-traditional filer materials with AMR masks. All users of AMR masks should be properly informed of the limitations and risks associated with the use of improvised PPE.

Observations:

- For the test conditions of this study a rigid AMR mask, coupled with N95 filter material, was shown to be able to be worn securely with a mask-to-face seal comparable to a commercial N95 health care particulate respirator mask, based on the results of quantitative fit testing.
- A P100 UltraFilter cartridge can be fit to the AMR mask, using a window adapter, to achieve N95-level respiratory protection; the larger surface area of the P100 filter made breathing through the P100 cartridge easier and less tiring than for the case when the N95 cloth was used in the AMR.
- The AMR mask requires more practice to properly apply and get a good face seal than the N95 mask.
- The AMR rigid mask used here is less accommodating to different face sizes than the cloth N95 masks, both larger and smaller frames would be needed in order to allow proper fitting to a larger population.
- The AMR mask is less comfortable to wear than cloth N95 masks.
- It is more difficult to speak and maintain a good fit with the rigid AMR mask than it is with the cloth N95 mask.
- Three, possibly four cloth inserts can be harvested from the 3M 1860 mask, depending upon how the material is cut.
- Thicker, foam-like gasket material appears to be better than thinner foam, or more rigid rubber-like material; compressibility to allow the gasket to conform to the face is thought to be important in bridging the gap between the rigid body of the AMR mask and the skin.
- The extra weight of the AMR mask frame suggests that elastic cloth ribbon (from an N95 mask) may not be sufficient to keep the mask in place and ensure a good seal in some cases, fabric cord or string should be considered instead.
- Care must be taken when tying the knot in fabric cord, to ensure the mask does not become loose from the face.
- Alternative filter materials, even when labeled as HEPA-filter grade, may not provide respiratory protection comparable to a commercial N95 mask; other household materials may provide relatively little respiratory protection.
- Care must be taken in the selection of alternative filter material to ensure the wearer can still breath easily, some filter materials may have too much resistance to air flow to allow long-term, or possible even short-term use.
- Cloth tape can be placed on the inside and outside of the AMR window pane/frame joint to aid in sealing the mask but the longevity of this solution has not been evaluated.
- The AMR frame combined with the P100 cartridge had a weight of 129 g, further suggesting the need to use cordage instead of elastic cloth to secure the mask to the face.
- It may be possible to use a heat source (e.g., hair dryer) to soften a rigid AMR mask frame so that it can better mold to the shape of an individual's face, this may need to be done prior to the application of the sealing gasket.

Recommendations:

- Users of AMR masks should be informed that AMR masks have not yet been comprehensively tested and demonstrated effective outside of a laboratory setting.
- Users of AMR masks should receive instruction on how to don and doff the AMR mask.
- Users of AMR masks should be given a fit test, ideally a quantitative fit test, by a person trained in the selection of AMR masks so they use a mask size correct for their face size and shape, and so they can learn how the mask works and learn what a proper face seal feels like.

- Serious consideration of operational tradeoffs should be given before an unused N95 mask is cannibalized to produce filter inserts for AMR masks, only under extreme circumstances would this be justified.
- Care must be used in the selection of non-N95 filter materials to ensure adequate particulate respiratory protection is afforded by the use of the AMR mask when these materials are used, this selection process can be aided by using a fit test machine to quantify filter performance. When available, P100 filter cartridges may prove useful as an alternate filter in AMR masks

Additional work is needed to:

- Evaluate the impact of perspiration inside the mask, moisture might degrade the gasket seal and compromise mask performance.
- Evaluate methods for cleaning and sterilizing the mask, and generate guidelines for implementation.
- Assess the respiratory protection value of other materials besides N95 mask cloth.

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