

N95 FFP – Optimizing its protection levels during pandemic

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1.0 Abstract:

N95, a term which was not common till January 2020 has suddenly registered in billions of minds in India. Today, N95 has been considered as a 'lifesaving' commodity. Ministry guidelines has listed critical clinical management staff, sanitary staff in healthcare centers, Healthcare staffs working in quarantine facilities dealing with clinical examination of symptomatic persons shall wear N95 respirators. Can a N95 mask provide its intended efficiency? This article provides an overview under what minimum protocol required for a N95 respirator user to provide protection from aerosol hazard. This article is limited to Health Care Institutions on which importance of 'Fit Testing's are briefed. However for other industries where occupational exposures to dust / aerosol particulates exists, every element of Respirator Protection Program shall be adhered.

2.0 Respirator Protection Program:

With limited statutory governance on respiratory protection requirements locally, OSHA's 1910.134 becomes the Golden Standard which shall be followed up. Some of the key elements of the Respirator Protection Program are

1. Respiratory Hazard Identification
2. Selection of Respirators
3. Medical Evaluation and Determination
4. Fit Testing
5. Maintenance & Care
6. Cleaning and Disinfecting

7. Training & Evaluation
8. Record Keeping

There are variety of respirators available today such as filtering face piece, half masks with elastomeric face piece, full face piece, Helmet / Hood and Loose –fitting face piece. N95 is technically called as 'Filtering Face Piece (FFP)'.

For successful implementation of 'Respirator Protection Program' all the above elements shall be implemented. As this article is specific to N95 FFP used in Health Care industry, fourth element of Respirator Protection Program – 'Fit Test' shall be discussed below.

3.0 'Fit Test' – Mandated approach:

Respirator Protection Program specifies that a user should initially 'Fit Test' a N95 FFP before use. Annual fit testing shall be conducted for the same user to confirm the adequacy of proper fit test or whenever a new model or type of respirator is used.

Purpose of 'Fit Test' is to confirm the fit of respirator / FFP that forms a tight seal against the user's face. For example, if a Healthcare staff is wearing a N95 FFP and have strapped one of the two bands around the head or if the staff is not in clean shave / with beard or if the size of the N95 is large compared to the facial anatomy of the user, there is all possibility that the contaminated aerosol particles can enter the users breathing airstream through the breaks in the seals or the void space around the circumference of the N95 FFP and the face of the user. This would be the mean point where the contaminated virus in the aerosol can

easily reach the respiratory system even though the user has worn a N95 FFP.

Hence, if N95 FFP is not sealed adequately with the face of the user, it will not provide its intended protection and the user may be prone for viral infection.

4.0 Types of 'Fit Test':

Two types of Fit Test protocol established by OSHA.

- 1) Qualitative Fit Test (QLFT) – PASS / FAIL fit test to assess the adequacy of respirator fit test that relies on individual's response to the test agent. The test agent could be Isoamyl Acetate, Saccharin solution aerosol, Denatonium Benzoate solution aerosol, Irritant smoke (Stannic Chloride). Among the listed, Saccharin solution and Denatonium Benzoate (Bitrex™) is commonly used for N95 FFP.
- 2) Quantitative Fit Test (QNFT) – Assessment of the adequacy of the respirator fit by numerically measuring the leakage into the respirator.

Qualitative Fit Test is considered adequate for N95 FFP. If a user PASSED qualitative fit test, it only qualifies to the specific brand / make / model and size of the FFP that was worn during the test. If the user FAILS qualitative fit test, a different size of the FFP should be tried to qualify the fit test. If an alternate brand / make / model and size to be worn by the user, a fresh 'Fit Test' with the alternate FFP have to be done to confirm successful sealing of the FFP.

5.0 Fit Testing N95 users in current pandemic situation:

All N95 users regardless of the time spent in the viral infection area, have to Qualitatively Fit Tested initially prior using the FFP. As the fit test kit supply shortage is increasing globally,

OSHA recently issued temporary guidance suspending the annual fit testing requirement of N95 filtering face piece for healthcare. However, initial fit test for health care professionals with the same model, style and size are still required. To cope up with shortage of N95 in current pandemic situation, other methods suggested such as, alternate respirators of equal or higher protection (N99 or N100 filtering face piece), reusable elastomeric respirators with appropriate filters or cartridge or powered air purifying respirators shall be provided after initial face fit testing.

6.0 'User Seal Check' not a substitute to 'Fit Test':

'User seal check' is a way to verify that the FFP is properly sealed on the users face. This exercise is carried out whenever a N95 FFP is don. The below quick instruction is for N95 FFP, however there are different 'User Seal Check' for other types of respirators too

- 1) Ensure the hands are clean and sanitized
- 2) Inspect for any tear or damage in N95 FFP, adjust and fit the N95 FFP by tightening the nose clip
- 3) Positive pressure seal check – Gently exhale to see if the face piece bulges slightly
- 4) Negative pressure seal check – Take a quick, deep breath to see if the face piece collapse slightly
- 5) If leakage is felt between the gap of the N95 FFP and user's face, readjust the fit of respirator and repeat 'User Seal Check' again
- 6) If proper seal cannot be achieve, the user should not enter the contaminated area.

User seal check is not a substitute for 'Fit Test'.

7.0 Summary:

Wearing a N95 FFP without initial 'Fit test' would not provide the expected level of protection and high probability of infectious aerosol leakage into the face piece can be expected. Health care employers should formulate Respiratory Protection Programs such that the filtering face piece / respirators selected and used shall provide the maximum protection for the users. Nevertheless in current situation, health care professionals in the pandemic viral environment shall wear N95 FFP as minimum with initial Face Fit Test done and 'User Seal Check' after the FFP is don.

Without a 'Fit Test' and 'User Seal Check', N95 FFP or other respirators cannot be expected to provide the required level of protection.

8.0 Reference:

- 1) Ministry of Health and Family Welfare – Guidelines on rational use of Personal Protective Equipment
<https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf>
- 2) Occupational Safety and Health Standards 1910.134 Respiratory Protection

<https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134>

- 3) OSHA 1910.134 Appendix A – Accepted fit test protocol
<https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA>
- 4) OSHA temporary enforcement guidance – Healthcare respiratory protection – Annual fit testing for N95 Filtering face piece during the COVID-19 outbreak
<https://www.osha.gov/memos/2020-03-14/temporary-enforcement-guidance-healthcare-respiratory-protection-annual-fit>
- 5) User Seal Check
<https://www.youtube.com/watch?v=Tzpz5fko-fg>
- 6) Strategies for optimizing the supply of N95 Filtering Face Piece during the COVID-19 response
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html>

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