

## **Materials and Methods**

### **Respirators**

Two models of European CE-marked FFP1 FFRs, and two models each of NIOSH certified N95 FFR, P100 FFR and ER models with N95 filters were tested in the study. Respirator models were selected based on the commonly used models in NIOSH studies, and the availability of the devices in the market. The CE-marked FFR models were selected based on their availability. The manufacturers and models are shown in parentheses: FFP1 (Blackrock and 3M Model 8710E), N95 FFR - (3M Model 1870 and Sperian Model N1105; Small, Medium/Large and Extra-Large sizes), P100 FFR - (Sperian Model P1130; Small, Medium/Large and Extra-Large sizes) and 3M Model 8293), and ER (with N95 rated filters) (North Model 7700-30; Small, Medium and Large sizes) and MSA Model Comfo Classic; Small, Medium and Large sizes). The two models of FFP1 FFRs were labeled as A and B, N95 FFRs as C and D, P100 FFRs as E and F, and ERs as G and H, in a random manner. The FFP1 FFR category is certified at 80% filter efficiency. NIOSH approves the N95 FFRs and P100 FFRs, and ERs with replaceable N95 filters at 95, 99.97 and 95 percent efficiencies, respectively.

### **NaCl and Corn Oil Aerosol Test Chambers**

The TIL values for corn oil and NaCl aerosols were measured in two separate chambers. The dimensions of the corn oil aerosol chamber are 3.05 X 3.05 X 2.74 meters. Corn oil aerosol is generated using the MSP Corporation Model 2045-S High Output Aerosol Generator (MSP Corp. Shoreview, MN). The aerosol generator injects corn oil aerosol into the vertical section of a 20.3 cm in diameter duct approximately 213 cm upstream of a horizontal header connected to the intake plenum. The corn oil aerosol/air mixture flows into the corn oil chamber through four vents (0.3 X 2.1 meters) equally spaced on the aerosol inlet plenum. The dimensions of the NaCl aerosol chamber are 2.43 X 3.05 X 2.74 meters. NaCl aerosol is generated using a 2% salt solution by an SFP Services (Dorset, UK) 4100/250F single collision atomizer with an integral fan. The air supplied by the fan conveys the NaCl aerosol into the chamber through a 20.3 cm in diameter duct to the chamber, approximately 5.8 meters downstream of the NaCl aerosol generator. The two chambers share a common air lock entryway. The interior/exterior walls are covered with fiberglass reinforced plastic (Class C Fire Rating) facilitating ease of cleaning.

### **Test Subjects**

Ten subjects tested each respirator model and the NIOSH bivariate panel was used for placement of test subjects in specific face length by face width cells. The bivariate panel has ten cells and covers face lengths from 98.5 mm to 138.5 mm and face widths from 120.5 mm to 158.5 mm. Of the eight models of respirators tested in the present study, four models were in three different sizes while the others were one-size-fits-all type. The NIOSH Human Subjects Institutional Review Board approved this study and all subjects gave written consent to participate.

### **Fit Testing**

Subjects were fit tested in a room adjacent to the TIL test chambers prior to TIL testing. A PortaCount® Pro+ (Model 8038, TSI, Inc. Shoreview, MN), with the N95-Companion mode turned off, was used to measure the FF. Test subjects were instructed to don the respirator in accordance

with the information supplied by the respirator manufacturer. The test administrator tried to ensure that the subjects followed the information supplied by the respirator manufacturer including the instructions when donning the device to complete the user seal check. The test subjects were allowed to adjust the respirator before fit testing. Subjects performed the eight exercises described in the standard OSHA fit test protocol. The eight exercises were performed in the following order: 1) normal breathing, 2) deep breathing, 3) turn head side to side, 4) move head up and down, 5) speak out loud (recitation of the 'rainbow' passage), 6) reach for floor and ceiling, 7) grimace, and 8) normal breathing. The duration of time for each exercise is approximately one minute for a total of eight minutes for the test. At the end of the test, the PortaCount calculates the FF for each individual exercise ( $FF_i$ ) and provides a harmonic mean (FF) for seven exercises, excepting the grimace exercise. After fit testing, the subject continued to wear the respirator, with the sampling tube removed. After a five-minute break, the subject was tested for measuring TIL.

### **TIL Measurement Using Test Subjects**

All subjects participated in the TIL testing, irrespective of passing or failing the fit test. The rationale for this is to understand whether all subjects passing or failing the fit test consistently yield relatively lower or higher TIL values expected for the different categories of respirators. The subject was not allowed to adjust the respirator fit until the completion of the TIL test in the two test chambers. Five subjects were tested in the NaCl aerosol chamber first and then continued testing in the corn oil aerosol chamber. The other five subjects were tested in the reverse order. After the test subject entered the chamber, the sample tubing was connected to the respirator and the subject stood on the non-moving treadmill for about two minutes to keep the equipment ready for measurement. The test subject performed the exercise regimen continuously as specified in the ISO16900-1<sup>(17)</sup> (Annex B, Table 2). The TIL for each exercise and for the entire test regimen was measured. After completing the exercise regimen, the sampling tube was removed and the test subject exited the chamber, continued to wear the device without any adjustment or repositioning for a resting period of 5-10 minutes, and then entered the second test chamber for testing. The sampling tube was connected to the respirator. The subject continued testing in the second testing chamber following the same exercise regimen as in the previous chamber. A continuous sampling method was used to measure the in-mask and test chamber aerosol concentrations. In the case of NaCl aerosol testing, the aerosol sample was withdrawn at 1 liter per minute and was mixed with filtered air at 1 liter per minute (used to reduce the relative humidity of the exhaled sample) at a distance of 22 cm downstream of the sample point. The upstream and downstream aerosol samples of NaCl aerosol and corn oil aerosol were measured using a flame photometer (SFP Services, Type 1250) and a light scattering photometer (TSI 8587A), respectively. A LabVIEW program collected the data and provided the overall TIL value for the two aerosols.