Submitted Response to **Additional PortaCount® Quantitative Fit-Testing Protocols**:
Amendment to Respiratory Protection Standard

1. The **Ambient Aerosol Quantitative Fit Testing Protocol** (AAQNFT) was historically predicated, promoted and marketed as being the "Gold Standard of Fit Testing" as it designed to closely replicate the **Generated Aerosol Quantitative Fit Testing Methods** (GAQNFT) developed in the 40's & 50's. As such its exercises were patterned to reproduce the sensitivity and reproducibility of the original GAQNFT protocols. I find it difficult to see the similarity between the three (3) proposed shortened protocols to the original "*Benchmark for all Fit Testing*" in that the shortened protocol exposes the fit test technician to many more biases and variables than the GAQNFT protocol. I didn't understand how the provided peer reviewed article(s) substantially support it performs equally well at producing the equivalent sensitivity to detect poor performance in respiratory faceseal performance.
2. The AAQNFT is truly a "**Relative Measure of Mask Seal Performance**" as the actual fit factor changes (often very significantly) for any one user throughout any day or between days of fit testing. This variability is a function of the variability of ambient aerosol (challenge agent) as well as the variability of fit between each donning, variation in regards to facial hair or beard stubble growth. The assembly, use and maintenance of respirator mask adapters, their required P100 filters may also contribute to variation in measured fit factor as these components can and will degrade over periods of use and will require daily inspection and replacement eventually.
3. Historically, the AAQNFT was marketed as the "Best Method for Fit Testing" as it replicates **Wearers Talking** and real world variable breathing rate demands (ex: **Normal** and **Deep Breathing** Exercises) from the original GAQNFT. The AAQNFT has been directly marketed as the "Gold Standard for Fit Testing" as it requires a respirator wearer to breath, talk and move during the fit test regime. It seems *Highly Ironic* that the same manufacturer now wants to convince the respiratory user community that "*Talking is not any longer a Useful Exercise* (aka – It Takes too Long)" in order to, with statistical confidence, reliably capture any failures in the performance of the faceseal of the donned tight sealing respirator.
4. Looking at several samples of AAQNFT fit test data our organization and our rental clients and end user customers (purchased these systems from our organization); our experience strongly suggests that the Deep Breathing and Talking Exercises are frequently the exercises that see the lowest fit factors calculated and often are "THE Excercises" which determine whether a respirator wearer will achieve a Pass or Failure following the completion of the fit test series of exercises. I find the elimination of these exercises to be highly problematic and would like to suggest a more thorough evaluation of this change by a third party such as NIOSH-NPTL or the University of Cincinnati (Dr. Roy McKay) or Lawrence Livermore National Laboratory.
5. When the CNPQNFT was validated by NIOSH in the early 90's it was stated that it was *the only truly scientifically verifiable method of performing fit testing* as its easily calibrated and determined flow rate measurement is a direct (physical) measure of actually leakage (rate) rather than the relative value of a calculated fit factor based on a measurement of ambient aerosol concentrations which has been shown to be more prone to bias and sampling or system errors.
6. The variability of ambient aerosol is much more highly variable then the original or current GAQNFT methods do to the use of user enclosures. To address that variability AAQNFT has always relied on sampling the ambient aerosol before/after each fit test exercise and averaging those measured values then dividing that value by the mask sample concentration to calculate the individual exercise fit factor. I question the **supposed data** (from where was it collected? By whom? Who and How it was analyzed?) used to suggest that sampling ambient aerosol concentrations only twice (before the first exercise and following the last exercise)

a. Pressure differentials between building areas, opening/closing of doors & windows, cycling of heating and air conditioning systems HVAC commonly influence the (relative) fit factors calculated. Swings in ambient on many occasions will be severe enough to force the termination of fit testing until a consistent background of 1,000 particles/cc (70 particles/cc for Filtering Facepiece Respirators FFR's) can be maintained or generated using aerosol generators.
b. Variation in the type or quality of water used in aerosol generators can dramatically influence the operation and potential maintenance downtime of AAQNFT systems. Tap water high in minerals and salts can produce much large ambient background concentrations which can foul or choke off the sample from the Condensation Nucleus Counter (CNC) as salt or mineral particles will agglomerate in the throat or inlet to the laser diode counting chamber and can even influence the flow rate of the sampling system if users do not perform the recommended annual cleaning & calibration of these systems.
c. Humidity conditions can influence the duration of operation as the isopropanol will require more frequent replenishment in lower (winter or arid regions) humidity conditions.
d. The current generation of CNC system used in AAQNFT has a higher flow rate to improve its sensitivity to ambient aerosol. A larger alcohol wick was incorporated in its design to accommodate the potential for more rapid evaporation and hence need to replenish the alcohol.
e. Condensation of particles as well as IPA liquid occurs at higher rates do to this change in CNC design. IPA liquid has been found to be transferred through the sampling and has accumulated within the switching valve mechanism of the current CNC systems. Changes in supplier valve materials have caused a noticeable increase in the failure of switching valves to function correctly during fit testing. It has been discovered that the IPA liquid can leach plasticizers from the valve material resulting in its swelling or changing durometer which results in these valve's "Sticking" which initially may not be readily detectable but likely results in the dilution or oversampling of either the ambient or mask sample concentration of particles. Eventually, the failure of the valve forces the user to terminate the use of the CNC and require it be returned for service. I suspect that shortening of fit test protocols will significantly impact the ability of fit test technicians to detect these issues or other issues related to actual fit test respirator facepiece, its components, the required mask adapter kits, the internal sampling tube, metal clip & suction cups as well as the respirators P100 filters which generally will eventually fail do to leakage.
f. It is interesting to consider that the high variability of ambient aerosol is what caused TSI to (at the request of a Canadian Consultant) develop a "Smaller, Battery-Operated version of the PortaCount for site investigations related to Indoor Air Quality". This customer and numerous others had long communicated their amazement to TSI of the sensitivity of the Condensation Nucleus Counter (CNC) incorporated into the original Model 8010 and the then improved versions of the Model 8020 and the N95 Companion. Merely moving around a room you could see very large swings in the concentration of ambient aerosols. This variation could be also seen at a fixed location by observing its response over an extended period of use. The P-Trak CNC product which resulted from this request continues to be used for IAQ and Ultrafine Particle Detection (UFP).

7. Our organization's rental division has experience renting all of the AAQNFT (PortaCount) and CNPQNFT (QuantiFit) systems to users across the United States in all sectors of both public & private enterprises (Construction, General Industry, ESH Consulting, Oil/Gas, Refinery, Chemical, Healthcare, Research,

and Governmental Agencies). Our support staff has uniformly found a much larger need to respond to support calls for the AAQNFT compared to the CNPQNFT. Common issues with the selection of location to perform fit testing (ambient aerosol suitability and variability), the familiarization of the fit test technician with the required Daily Check Procedures and how to troubleshoot issues with either setup or actual conduct of the fit test protocol. Some of our users performing large quantities of fit testing found the reliability at some point required the maintenance, use or rental of a back-up system as these down-time issues could complete derail the effort to comply with their organizations requirements to complete annual fit tests for all of their required use wearers.

8. Our organization's experience has also suggested the CNPQNFT is a much more conservative measure of face to faceseal performance (or the presence of facial leakage). The fit factors generated are generally always smaller (it's easier to detect the leakage of air molecules (CNP) versus an form of ambient aerosol (AA)) and in nearly every instance of a failure to pass the CNPQNFT the result is a detectable issue or problem with the condition, maintenance or even selection of mask for the respirator wearer. More than one user has stated to our staff that they could actually perform a fit test on some tight short length beards with the AAQNFT and get a PASSING FIT FACTOR. Conversely, at nearly no time have we experienced that any person with any notable beard growth is ever able to pass the CNPQNFT protocol. Again, the sensitivity of the CNPQNFT to detect mere air molecules rather than a select (limited) size distribution of ambient aerosol as is done using the AAQNFT methods.
9. I question the size and representativeness of the small population of respirator users as well as likely a very small sample of the wide range of tight sealing respirators that were used in the Articles published in the ISRP journal to support the contention that this revised and significantly altered and shortened protocol continued to show statistically significant equivalence to the original GAQNFT protocols.
10. For these and several less technical issues (what message are we sending to the regulated community if the protocol is revised to merely shorten its duration without confidence that the revised protocol will not result in a significant increase in respirator wearers who actually receive a false sense of protection while being allowed to wear respirators that do not truly provide protection levels equivalent to or in excess of the Assigned Protection Factors for the category of protection being required for any subsequent exposures) I strongly suggest that the data provided with the revised proposal do not adequately substantiate the equivalent or minimum amount of certainty to assure the protection of the respirator user(s) and his or her organization(s) ethical, tactical or practical objectives. I therefore suggest that this revised proposal not be accepted for inclusion into 29 CFR 1910.134 Appendix A.