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Response to the proposed new fit testing protocol Docket No. OSHA-2015-0015, RIN-1218-AC94

Please allow me to preface my response/comments in regards to the new proposed protocol referenced above by stating that I possess excess of sixteen-years of experience on the subject. This field experience includes the fit-testing of many thousand subjects as well as training hundreds of others as fit-test operators. This experience is wide and varied, including a broad range of respirator manufacturers, models and/or types of respirators as well as fit-test methods in an equally broad range of settings/environments. This experience also includes a broad range of applications and regulatory environments (OSHA, MSHA, CBRNE, NFPA).

I do not agree with acceptance of the proposed new protocols by OSHA for the reasons detailed in the following;

In addressing multiple specific questions raised by OSHA I would like to make the following statements as a result of reading the manufacturers manual, application notes (both found on the manufacturers website) and the Docket No. OSHA-2015-0015, RIN 1218-AC94.

1. Were the three studies described in the peer-reviewed journal articles well controlled and conducted according to accepted experimental design practices and principles?

   I respectfully submit that they were too controlled and did not allow for variables encountered by fit test providers when conducting fit testing in real world settings as opposed to the controlled environment of the test chamber utilized for their studies. As such I question the validity of a test performed under a single, controlled set of test conditions vs real world testing performed under varying conditions that include Different Particle Concentration Ranges, Natural Particles vs Generated Particles and/or variation of Particle Counts during the actual fit-test being performed. I refer to the manufacturers own documents to bolster my statements;

PortaCount® Manual p/n 6001868, Revision P, March 2015, Precautions for Fit Testing located on Page 3 states the following; “Fit Testing with Generated Aerosols – The PortaCount® Pro fit tester is designed to operate using microscopic particles in ambient air. It can measure particle concentrations and fit factors when generated aerosols (like corn oil, salt or DOP) are used; however, these aerosols may cause the PortaCount Pro fit tester to need more frequent cleaning and calibration.” *This implies that the device is subject to variables introduced as a result of Generated Aerosols vs Naturally Occurring (no particle generation in use) ambient particles. In addition, I seek further clarification as to the need and/or schedule for more frequent cleaning and calibration. I also question if it creates different maintenance methods and/or schedules why any test studies did not account for these issues.*

PortaCount® Academy Tips & Tools Troubleshooting Guide, Application Note RFT-018 (A4) states the following on page 3, under the heading of Fit Test Fails (overall fit factor is less than minimum pass level); “In environments with naturally occurring (no particle generation in use) ambient particle concentrations exceeding 8,000 pt/cc (as per use with full- & half-mask, P100 fit testing) or 800 pt/cc (as per use with N95 fit-testing) you may need to increase the fit test protocol purge times. The purge time allows the PortaCount fit tester to clear the tubing in between mask and ambient particle samples. 1. Go to **Database I Edit I Protocol Table** 2. Increase the ambient purge from 4 to 6 seconds – increased time allows for stable ambient concentration. 3. Increase the respirator purge from 11 to 15 seconds – increased time allows for complete mask purge at high particle concentration.” *If the study had been performed in real-world settings, with their varying environmental conditions, this issue could have presented itself, but by choosing a controlled environment that did not contain this known, real-world issue, this issue was not seen nor was it addressed in the protocol. I respectfully submit that the studies and any subsequent proposed protocol(s) should provide for suitable ambient and respirator purge durations to address the full range of particle concentrations that the device is recommended for use in instead of selecting a duration based on the optimum conditions that were selected for the studies and then modifying for applications that while less than optimum are within the advertised acceptable range for the equipment.*

2. Were the results of the three studies described in the peer-reviewed journal articles properly, fully, and fairly presented and interpreted?

   I respectfully do not agree that they were, as real-world fit-testing is not conducted in a test chamber, under optimum conditions. By conducting the studies in a sealed chamber vs the real world they should have replicated the complete range of range of acceptable conditions published for the equipment including the known

conditions that they acknowledge can affect the unit's operation. I do however feel that under the specific set of conditions that the tests were performed that they were presented well but are not representative of the environment that most fit-testing occurs in. I question how their outcome would have varied should they have been performed over a range of typical environments one would encounter on a day to day basis in the field.

In addition, I believe the decision to remove the grimace exercise out of convenience, is inexcusable and invalidates the studies as it does not compare either the letter or spirt of the existing protocols and regulation. I will address it more so in my response to question # 10.

3. Did the three studies treat outliers appropriately in determination of the exclusion zone?

   No comment

4. Will the two proposed protocols generate reproducible fit-testing results?

   Not necessarily should conditions vary outside of those utilized in the controlled environment(s) in the studies. In addition to the issues raised previously I question what affect(s) could be seen when testing subjects who themselves or whose clothing is a source of particulate such as dusts, vehicle exhaust, etc? e.g. a worker in a dusty environment such as a coal mine, cement kiln, grain silo, etc could effectively increase particle counts as a result of particles being liberated from their clothing as a result of the prescribed exercises and that these swings in particle count could be both rapid as well as significant in nature. By eliminating the ambient sample during half of the tests, I question how they can account with accuracy for such conditions encountered in real-world settings?

5. Will the two proposed protocols reliably identify respirators with unacceptable fit as effectively as the quantitative fit-testing protocols, including the OSHA-approved standard PortaCount® protocol, already listed in appendix A of the Respiratory Protection Standard?

   I question the choice of the study's authors in removing the Grimace exercise and will address it more thoroughly in my answer to question # 10.

   I also question the potential suitability for use in applications that contain particles below the range "0.02 to greater than 1 micrometer" specification found in the specifications on page 78 of the manufacturers manual, PortaCount® Manual p/n 6001868, Revision P, March 2015. I would like to pose a question asking if this technology is suitable for use in applications that include either Nanoparticles or

Ultrafine particles in sizes below the published size limit of 0.02um (20 nm) and how it compares to the other OSHA-accepted protocols in appendix A that utilize Controlled Negative Pressure (CNP) technology. I would propose that the CNP's use of air as it's challenge agent vs aerosols is a more stringent method due to the smaller physical size of the challenge agent. An O2 molecule is approximately 0.12nm or roughly 167 times smaller than the smallest particle able to be seen by the Portacount® (0.02um/20nm) detailed in the manufacturer's published specification referenced above. The disparity in the size of the challenge agent utilized between the two technologies should allow the Controlled Negative Pressure Technology to see and/or identify much smaller leaks. As such, I think that the protocols related to the controlled negative pressure are potentially better suited for applications protecting against environments that contain or potentially contain Nanoparticles or Ultrafine particles <20nm than any of the PortaCount® protocols accepted or proposed. I would welcome a through peer reviewed study on the subject to offer clarity on this potential concern.

6. Did the protocols in the three studies meet the sensitivity, specificity, predictive value, and other criteria contained in the ANSI/AIHA Z88.10-2010, Annex A2, Criteria for Evaluating Fit Test Methods?

   No Comment

7. Are the specific respirators selected in the three studies described in the peer-reviewed journal articles representative of the respirators used in the United States?

   No, I question why none of the Filtering Facepiece styles selected did not include those equipped with an exhalation valve? The use of an exhalation valve in a Filtering Facepiece adds comfort for the wearer by reducing the humidity level in the mask and as such many will select it over a standard Filtering Facepieces without them.

8. Does the elimination of certain fit-test exercises (e.g., normal breathing, deep breathing, talking) required by the existing OSHA-approved standard PortaCount® protocol impact the acceptability of the proposed protocols?

   Yes. While the frequency rate for normal breathing, deep breathing, and talking is shown as 3% in their study, it is still too high. While the number sounds small the severity of the risks and hazards imposed by an ill-fitting mask are extreme. I for one would not want to be part of the acceptable loss ratio set forth by the study and protocol authors. I would submit that if the author(s) had to select 3% of their friends and/or family members for repeated exposure to carcinogens or other workplace hazards that they too would question if 3% is insignificant.

9. Is the test exercise, jogging-in-place, that has been added to the Fast-Full and Fast-Half protocols appropriately selected and adequately explained? Should the jogging exercise also be employed for the Fast-FFR protocol? Is the reasoning for not replacing the talking exercise with the more rigorous jogging exercise in the Fast-FFR protocol (as was done in Fast-Full and Fast-Half) adequately explained?

   When it comes to fit-testing an accurate fit-test trumps speed and convenience. As such I agree with the selection of a more rigorous protocol. When it comes to the use of a N95 or other filtering facepiece not being used in a motion such as jogging, that I do not agree with. It is my experience that of the different types of respirators with the exception of SCBA's being utilized by Fire Fighting and related applications that the filtering facepiece type is the one that is more often than not used in dynamic applications as a result of it not being as hot, bulky and uncomfortable to wear. Assuming that the hazards can be addressed by a filtering facepiece, wearers if given a choice between wearing a filtering facepiece with exhalation valve vs a standard half mask elastomeric respirator will typically select the filtering facepiece due to its lighter weight and smaller profile.

10. Was it acceptable to omit the grimace from the Reference method employed in the studies evaluating performance of the proposed fit-testing protocols? Is it appropriate to exclude the grimace completely from the proposed protocols, given that it is not used in the calculation of the fit factor result specified under the existing or proposed test methods? If not, what other criteria could be used to assess its inclusion or exclusion?

    I seriously question the choice of the study and protocol authors in removing the Grimace exercise. I do concur with their statement that it cannot be consistently applied and with their statement that the fit-factor if measured should not be used in calculation of the fit factor. I do however feel that the study authors have missed the reason that the exercise is in the current protocol(s) and have made a mistake so flawed that it cannot be overlooked or overcome, by not including the Grimace out of convenience in their study and the subsequent proposed protocol(s). I believe the primary importance of its inclusion in the current protocol was misinterpreted. My interpretation is that that the importance of the grimace is not in the fit factor achieved during this step of the protocol but instead in the ability of the mask to re-seal after this exercise which goes to the respirators proper fit. I believe this to be accurate due to the standard being written in such a way as to place the emphasis on the re-sealing of the mask and not the fit factor achieved during this exercise. To find agreement with my statement one doesn't have to look further than the manufacturers written manual - PortaCount® Manual p/n 6001868, Revision P, March 2015, page 37, Exercise Name; Grimace, Description; "Grimace by smiling and/or frowning to create a leak in the respirator

face seal. This exercise will often result in a failed fit factor, which is why the OSHA standard allows you to exclude that fit factor. When performing the grimace, you are intentionally creating a break in the face seal in order to see if the mask re-seals itself afterwards. Successful re-sealing is proven by achieving a passing fit factor on the next exercise. Notes: The OSHA protocol includes special provisions for the grimace exercise. It is allowed to be 15 seconds long and the resulting fit factor may be discarded (excluded) before calculating the overall fit factor. This is allowed because the grimace exercise is done in order to make sure that the mask reseats itself before the next exercise." As such the study authors justification to remove the grimace out of convenience does not out-weigh its importance in determining if the mask can/will re-seal after the seal is broken and furthermore by excluding it from their study of the existing protocol they have not performed a study that effectively compares the effectiveness of the original protocol to the proposed protocol. It is a partial study that appears to value convenience over a complete and through comparison of the two protocols by taking exception with the original protocol.

11. The protocols in the three studies specify that participants take two deep breaths at the extreme of the head side-to-side and head up-and-down exercises and at the bottom of the bend-forward exercise. According to the developers of these protocols, the deep breaths are included to make the exercises more rigorous and reproducible from one subject to the next. Are these additional breathing instructions adequately explained in the studies and in the proposed amendment to the standard? Are the reasonable and appropriate?

    No comment

12. Does OSHA's proposed regulatory text for the two new protocols offer clear instructions for implementing the protocols accurately?

    No, this is not the fault of OSHA but instead of the developers of this protocol. This is the result of not addressing the known issues of fit-testing in high ambient concentrations detailed in the manufacturers Application Note - PortaCount® Academy Tips & Tools Troubleshooting Guide, Application Note RFT-018 (A4) states the following on page 3, under the heading of Fit Test Fails (overall fit factor is less than minimum pass level); "In environments with naturally occurring (no particle generation in use) ambient particle concentrations exceeding 8,000 pt/cc (as per use with full- & half-mask, P100 fit testing) or 800 pt/cc (as per use with N95 fit-testing) you may need to increase the fit test protocol purge times. The purge time allows the PortaCount fit tester to clear the tubing in between mask and ambient particle samples. 1. ***Go to Database I Edit I Protocol Table*** *2. Increase the ambient purge from 4 to 6 seconds – increased time allows for stable ambient concentration. 3. Increase the respirator purge from 11 to 15 seconds – increased*

time allows for complete mask purge at high particle concentration." If the study had been performed in real-world settings, with their varying environmental conditions, this issue could have presented itself, but by choosing a controlled environment that did not contain this known, real-world issue it was not seen nor was it addressed in the proposed protocol. I respectfully submit that the studies and any subsequent proposed protocol(s) should provide for sufficient ambient and respirator purge duration to address the full range of particle concentrations that the device is recommended for use in instead of selecting a duration based on the optimum conditions that were selected for the studies controlled environment and then trying to modify the protocol for applications that while less than optimum are within the advertised acceptable range of the device.