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After reviewing the notice of proposed rulemaking for adding two new modified PortaCount® quantitative fit-testing protocols to the Respiratory Protection Standard and the associated references, I would recommend that the new methods not be adopted because the three supporting studies described in the peer-reviewed journal articles were not conducted in a manner that would be predictive of how the PortaCount® would perform using ambient aerosols.

The PortaCount® was designed and marketed to be used for conducting quantitative fit tests using room aerosols, whereas the supporting studies were conducted in a test chamber using a generated aerosol. Concentrations of room aerosols are typically about $1x10^3$ p/cc, whereas in these studies the average challenge concentrations were about $2x10^4$ p/cc. In their landmark paper, daRosa, et al. (1991) found that particle count can affect measured PortaCount® fit factors. More importantly, in the modified protocols the exercise fit factors are calculated using the average of the challenge concentrations measured at the beginning and end of the entire fit test. While this may be justifiable for sampling in a test chamber where the concentration can be expected to be relatively constant, it is not a reasonable assumption when sampling ambient aerosols which can be highly variable.

I would recommend that the protocols not be accepted until these validation tests are conducted using ambient aerosols, and preferably by independent investigators.

da Roza RA, Biermann AH, Foote KL, McCormack C, and Sachett CR. (1991) Evaluation of PortaCount for Determining Respirator Fit Factors, Part III: Human Subject Tests and Comparison with an Aerosol Photometer. J. Int. Soc. Resp. Prot. 9(3):22-38.