Good morning. I am John Martonik, acting Director of the Health Standards Programs Directorate of the Occupational Safety and Health Administration and I am here to present OSHA's comments on the 42 CFR Part 84 particulate filter testing proposal that NIOSH has proposed as the first module of a comprehensive revision of the existing respiratory certification standards in 30 CFR 11.

First, OSHA would like to congratulate NIOSH on the publication of this first module of the 42 CFR Part 84 revision. However, this very important first step in the updating of the respirator certification standards is only the beginning of the process of revising respirator certification. OSHA supports your efforts in this area and hopes that NIOSH will be able to expedite the rulemaking process to quickly produce a much needed final standard to bring respirator certification out of the past and into the present decade while containing flexibility to address future needs.
OSHA understands why NIOSH chose to utilize a modular format for revising the respirator certification standards in the interest of making these revisions as expeditiously as possible. However, the overall respirator certification standards that NIOSH finally adopts are of vital importance to OSHA. It is important for OSHA to know what NIOSH will be using for approval criteria for each of the various types of respirators under the new 42 CFR Part 84 provisions, particularly for gas and vapor respirators and SCBAs, modules that NIOSH will be addressing much later in this modular rulemaking process. It is important that OSHA understand what NIOSH will be requiring for certification, as it will impact what OSHA requires in the selection of certified respirators for hazardous chemicals.

As NIOSH knows, OSHA is also in the process of revising its own respiratory protection standard, 29 CFR 1910.134; a standard which relies on the respirator certification standards established by NIOSH. OSHA and NIOSH are coordinating regulatory efforts to attain consistency and utilize our resources efficiently. OSHA has
a particular interest in the issue of assigned protection factors, an area that NIOSH will be addressing in the second module of this respirator certification revision. The NIOSH protection factor review will have an important impact on a critical part of our proposal, and OSHA encourages NIOSH to expedite its work in this area. The issue of protection factors is of great practical importance to the respirator user community, and OSHA is anxious that NIOSH proceed with this next phase of its rulemaking agenda.

OSHA has been asked to comment on whether a respirator that meets the requirements for filter penetration contained in the NIOSH proposed 42 CFR Part 84 standard would be acceptable for use against M. tuberculosis exposures. At this time, OSHA believes that a respirator that meets the new NIOSH test criteria for class A, B, or C, would be acceptable for use against TB. However, there are issues other than filter efficiency that must be addressed before a respirator can safely be used for TB. The respirator must be able to be fit tested on the wearer to demonstrate that faceseal leakage is no more than 10%. Second, the respirator must be able
to fit different face sizes and characteristics, which can usually
be met by the respirator being available in three respirator sizes.
Lastly, and importantly, the respirator must be able to be fit
checked by the wearer each time it is put on to ensure proper
facepiece fit before entry into TB exposed areas. The NIOSH 42 CFR
Part 84 filter testing criteria meet only the first of the CDC
criteria for respirator use with TB, that the filter exhibit filter
leakage of 5% or less, a filter efficiency of 95% or greater. OSHA
plans to promulgate a standard regulating occupational exposures to
TB. In the process of rulemaking, OSHA will publish a proposed
standard and obtain public review and comment. OSHA expects all
aspects of respirator use will be evaluated in this process.

In order to optimize the possibility that a respirator will
achieve its assigned protection factor, that respirator must be
chosen by the use of fit testing. NIOSH has so far left out of its
certification proposal the evaluation of fit testing procedures and
programs. As a part of respirator certification, the manufacturer
submits its respirator use instructions for the respirator wearer,
including any fit check procedure the manufacturer recommends for its respirators. NIOSH currently does not review this material for the adequacy or appropriateness of any fit check the manufacturer recommends. Some manufacturers believe that since NIOSH received their use instructions as part of the certification process, therefore NIOSH has reviewed them for adequacy, and approves of the fit check method. A respirator which cannot adequately be fit checked by the wearer prior to entry into a hazardous atmosphere has a reduced chance of obtaining its assigned protection factor. NIOSH needs to evaluate all the manufacturers use instructions, including any fit check or fit testing recommendations, before issuing a certification for that respirator.

At this time, OSHA has no specific comments on the provisions of the particulate filter testing revision. OSHA supports NIOSH in the need for updating the filter testing provisions to reflect current state of the art testing procedures and equipment. The NIOSH proposal has made extensive changes in the filter testing requirements and test equipment from those in the original 30 CFR
11 standards, and NIOSH should present supporting data and explanations for those changes as part of the rulemaking record. For example, why did NIOSH choose sodium chloride as its solid test particle, and neutralized dioctyl phthalate (DOP) as its liquid test particle at a challenge concentration of 200 mg/m³? It is also not clear how combination respirators such as a supplied air respirator with particulate cartridges for escape would be tested.

OSHA supports NIOSH in its revision of the respirator certification standards, and encourages NIOSH to proceed with all the modules in its rulemaking agenda in an expeditious manner to produce a new 42 CFR Part 84 standard that will address the needs of the respirator community for many years into the future.