Determining the Feasibility of Using International Organization for Standardization Voluntary Consensus Standards for Verification of Respiratory Protective Devices

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Abstract
The National Personal Protective Technology Laboratory (NPPTL), a division of the National Institute for Occupational Safety and Health (NIOSH), has actively participated in standards development for respiratory protective devices since the International Organization for Standardization (ISO) formed the Technical Committee (TC94/SC15): Personal Safety – Protective Clothing and Equipment – Respiratory Protective Devices in 2002. Active participation in national and international standards development is essential for meeting current and future regulatory obligations of the Institute. Additionally, there is a need for global harmonization of standards given the potential economic advantages provided by international standards to the manufacturers and users of respirators. NPPTL completed a feasibility study to begin to assess the potential cost and benefits to the use of ISO standards for conformity assessment of respiratory protective devices. The study considered the ISO standards and draft standards for test methods (ISO 16900 series) and performance requirements (ISO 17420 series), using industrial air-purifying respirators, or unassisted filtering devices, as an initial case study. The study is expected to aid in the estimation of potential costs to NIOSH of adopting ISO test methods and in developing a roadmap for capturing the full economic costs and benefits to all stakeholders involved. The analysis identified 61 different evaluations that would be needed under ISO, including 24 special application evaluations. The assumptions and methods used to complete the study based on conceptual specifications of the ISO respiratory standards will be discussed.