

Conformity Assessment Standards – A Necessity to Support an ISO Respirator Protective Device Standard

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In the United States, Title 42 Code of Federal Regulations, Part 84 (42CFR84) administered by the National Institute for Occupational Safety and Health (NIOSH) specifies requirements for the approval of respiratory protective devices (RPD). These requirements address: performance, design, quality assurance, packaging, labeling, user instructions, configuration management (manufacturer control of drawings and specifications), and manufacturer-acquired performance data. NIOSH exclusively conducts performance testing of RPD submitted for approval and has authority to revoke the certificate of approval for cause. NIOSH requirements for conformity assessment of respirators also include post approval conformance auditing to provide confidence that an approved respirator continues to be manufactured as approved. These audit activities include manufacturing site quality assurance audits and respirator inspections and retests. This presentation describes NIOSH 42CFR84 requirements in comparison with ISO conformity assessment guides that may be appropriate to support the ISO/TC94/SC15 RPD standard.