Preparer:	Reviewer:	Approver:
10/5/2016	10/5/2016	1/26/2017
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LTFE Policy

1. PURPOSE

This policy document is intended to clarify the application of Title 42 Code of Federal Regulations (42 C.F.R.) § 84.310, "Post-approval testing," paragraph (c), by offering a more precise explanation of the tests the National Institute for Occupational Safety and Health (NIOSH) expects to perform in fulfillment of this requirement.

2. SCOPE

This policy applies to all closed-circuit escape respirators collected for NIOSH post-approval testing under 42 C.F.R. § 84.310(c).

3. REFERENCES

42 C.F.R. § 84.310(c) Post-Approval Testing – NIOSH will conduct such testing pursuant to the methods specified in §§ 84.303 through 84.305, except as provided under paragraph (d) of this section.

42 C.F.R. § 84.310(d) Post-Approval Testing – The numbers of units of an approved CCER to be tested under this section may exceed the numbers of units specified for testing in §§84.304 and 84.305.

4. BACKGROUND

Originally developed as a research program under the Bureau of Mines (BOM), what is now commonly referred to as the Long-Term Field Evaluation (LTFE) is the basis for the post-market testing of CCERs required under Title 42, Code of Federal Regulations, Part 84, Subpart O (hereafter referred to as Subpart O) https://www.gpo.gov/fdsys/pkg/CFR-2015-title42-

vol1/pdf/CFR-2015-title42-vol1-part84-subpartO.pdf. Information gained from the BOM research program established the need to evaluate fielded CCERs on an ongoing basis in order to ensure their continued safety and viability as emergency life support, after they have been exposed to harsh environments such as those found in mining. The testing done in prior years served as a prototype for the testing specified in Subpart O, in establishing both the technical basis for class viability and the need for post-market evaluations.

In a rulemaking conducted in March 2012[1] to update the standards for the testing of CCERs, NIOSH failed to clarify that human-subject trials would not be conducted on post-market respirators. NIOSH employs human subjects only when new or modified devices are presented for approval evaluation. The human subject trials are included as a final check of functionality in the as-used (worn by a human being) mode of operation. In essence, the overall performance of a respirator design found to be in compliance with the battery of bench tests specified in Subpart O is deemed to be "well characterized." The inclusion of human subject tests addresses the goal of ensuring that no aspect of a well characterized design is compromised by, nor fails to adequately accommodate, the needs of the human/device interaction. Once so established, there is no need to re-evaluate the apparatus on human subjects unless something in the design is changed.

NIOSH conducts post-market (fielded unit) evaluations using only the bench tests specified in 42 C.F.R. §§ 84.303 - 84.305, in accordance with § 84.310(c). Bench testing eliminates the potential for human subjects to suffer adverse effects from defective CCERs. Post-market tests are by their nature exploratory; in the event that a fielded unit has been compromised by exposure to the deployment environment in a way that makes its operation unsafe but not obvious by inspection, we want that discovery to occur using a machine rather than a human test subject. Further, using human subjects constrains the number of fielded units NIOSH is able to test, due to the logistical complexity and higher cost of coordinating human subjects. Conducting fewer tests, in turn, affects the statistical validity of the results of post-market testing, and allows for a more effective LTFE program.

5. POLICY

Respirators tested in fulfillment of the requirements established at 42 C.F.R. § 84.310(c), are subjected only to bench tests prescribed in Subpart O. No respirators tested in the fulfillment of these requirements are evaluated through the human-subject tests which require the subject to actually breathe through the respirator. All ventilation and metabolic requirements will be evaluated by employing an Automated Breathing and Metabolic Simulator (ABMS).

[1] Notice of Final Rule published in the Federal Register 8 March 2012, pp. 14167-14197, titled "Approval Tests and Standards for Closed-Circuit Escape Respirators"

NIOSH will correct the regulatory text in Subpart O to clarify the agency's intent with regard to CCER post-approval testing protocols in an upcoming rulemaking.

6. REQUIRED APPROVALS

6.1 The required approvals should be completed, via email, in the following order, with the appropriate revision made in between each approval level:

- 6.1.1 Author is assigned by Branch Chief or seeks verbal approval from Branch Chief to create policy document.
- 6.1.2 Create policy document.
- 6.1.3 Branch Chief approval
- 6.1.4 NPPTL ADS approval
- 6.1.5 NPPTL Director approval

6.2 Once the above approvals are complete, the policy will be submitted to the Health Communication Specialists for posting on the NPPTL website.