



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket Number CDC-2016-0121; NIOSH-285]

Closed-Circuit Escape Respirators; Final Guidance for Industry; Availability

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of availability.

SUMMARY: On December 28, 2016, the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention, Department of Health and Human Services, published a notice in the Federal Register announcing the availability of an interim guidance document addressing the availability of closed-circuit escape respirators (CCERs) for purchase, and the readiness of respirator manufacturers to comply with the regulatory provisions addressing these respirators. After consideration of public comments, NIOSH has revised the guidance and now announces that NIOSH does not intend to revoke any certificate of approval for any escape respirator approved for use in mining in accordance with NIOSH regulations, that are manufactured, labeled, or sold prior to June 1, 2019, provided that there is no cause for revocation under existing NIOSH regulation.

DATES: The final guidance announced in this Federal Register notice is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Maryann D'Alessandro, NIOSH National Personal Protective Technology Laboratory, 626 Cochrans Mill Road, Pittsburgh, PA 15236; 1-888-654-2294 (this is a toll-free phone number); PPEconcerns@cdc.gov.

SUPPLEMENTARY INFORMATION: The final guidance announced in this notice addresses the availability of closed-circuit escape respirators (CCERs) for purchase and the readiness of respirator manufacturers to comply with the provisions in Part 84, Subpart O, of Title 42 of the Code of Federal Regulations (CFR). Pursuant to a Federal Register notice published on February 10, 2016, beginning on January 4, 2017, manufacturers were no longer authorized to manufacture, label, and sell 1-hour escape respirators, known in the mining community as self-contained self-rescuers (SCSRs), approved in accordance with the certification testing standards in Part 84, Subpart H.¹ Beginning on May 14, 2016, manufacturers were no longer

¹ 81 FR 7121.

authorized to manufacture, label, or sell 10-minute escape respirators for use in mining approved pursuant to Subpart H.²

In an interim guidance document published on December 28, 2016,³ NIOSH announced its intention not to revoke any certificate of approval for 1-hour escape respirators approved in accordance with 42 CFR Part 84, Subpart H, that are manufactured, labeled, or sold prior to January 4, 2018, provided that there is no cause for revocation under 42 CFR 84.34 or 84.43(c). Upon consideration of public comments submitted to the docket for this action, NIOSH has reconsidered the scope of the guidance as well as the compliance deadline.⁴ The final guidance is summarized below. The full final guidance, entitled "Closed-Circuit Escape Respirators Approved for Use in Mining, 42 CFR Part 84, Subpart O Compliance; Guidance for Industry; Final" is available on the NIOSH National Personal Protective Technology website at www.cdc.gov/niosh/npptl.

Standards for the approval of CCERs were updated in a final rule published March 8, 2012, in which HHS codified the new Subpart O and removed only those technical

² See NIOSH final rule, Closed-Circuit Escape Respirators; Extension of Transition Period, 80 FR 48268 (August 12, 2015).

³ The December 2016 guidance was announced in a [Federal Register](#) notice published on December 28, 2016 (81 FR 95623).

⁴ One public commenter asked that we extend the comment period for this action. Although we are closing the comment period for this final guidance, we are considering additional steps, such as a public meeting, to continue a dialog with stakeholders concerning the implementation of the CCER standards in 42 CFR Part 84, Subpart O.

requirements in 42 CFR Part 84, Subpart H that were uniquely applicable to CCERs.⁵ All other applicable requirements of 42 CFR Part 84 were unchanged. The purpose of these updated requirements is to enable NIOSH and the Mine Safety and Health Administration (MSHA), which co-approves respirators used in underground coal mining, respirator manufacturers, and ultimately, respirator users, to more effectively ensure the performance, reliability, and safety of CCERs used in all workplace applications.⁶

The March 2012 final rule established a sunset provision for the Subpart H standards on April 9, 2015, three years after the final rule's effective date; the three-year period was intended to provide sufficient time for manufacturers to obtain certificates of approval for CCER designs developed under the Subpart O standards. Since April 10, 2012, no new applications for approval of Subpart H SCSRs have been accepted.

However, manufacturers did not develop small capacity CCERs approved for use in mining or large capacity CCERs approved for use in non-mining and mining in time to meet the April 2015 transition deadline and, as a result, NIOSH ultimately extended the deadline to one year after the date

⁵ 77 FR 14168.

⁶ See 77 FR 14168 at 14169-14182 to read the background for this rulemaking; additional background materials as well as public comments are available in NIOSH Docket 005.

that the first approval was granted to those CCER models.⁷ Under this deadline extension formula, manufacturers were authorized to continue the manufacturing, labeling, and sale of 10-minute Subpart H escape respirators approved for use in mining until May 13, 2016 and 1-hour Subpart H escape respirators for use in mining until January 4, 2017.

The deadline extensions have contributed to the availability of new escape respirator designs which conform to the Subpart O requirements, and have addressed the needs of certain broad segments of the market for such devices;⁸ however, MSHA has recently expressed concern that a market gap is imminent in the underground coal mining industry.⁹ Further communications with stakeholders, including the underground coal mine industry and respirator manufacturers, some of whom submitted comments to the docket for this action, have indicated that the supply of Subpart O CCERs approved for use in mining are insufficient to meet the current needs of the mining industry.

In order to allow mine operators access to all of the tools necessary to protect miners, to give respirator

⁷ 80 FR 4801 (January 29, 2015).

⁸ The maritime market, which includes the U.S. Navy, have been quick adopters of newly-approved small capacity (Cap 1) CCERs (often referred to in that market as emergency escape breathing devices or EEBDs). Cap 1 CCERs which were available to replace Subpart H, 10-minute approved apparatus are being deployed in that market segment in great numbers.

⁹ Joe Main, Assistant Secretary of Labor, MSHA, letter to John Howard, Director, NIOSH, December 14, 2016. This letter is available in the docket for this guidance and corresponding Federal Register notice.

manufacturers time to develop a solution to the mine industry's desire for person-wearable Subpart O CCERs, and to ensure a smooth transition from the Subpart H to Subpart O approval standards, NIOSH does not intend to revoke any certificate of approval for escape respirators approved for use in mining in accordance with 42 CFR Part 84, Subpart H, that are manufactured, labeled, or sold prior to June 1, 2019, provided that there is no cause for revocation under 42 CFR 84.34 or 84.43(c), including misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the applicable quality control requirements.

The final guidance, available on the NIOSH National Personal Protective Technology website, does not create any new deadlines or waive any existing deadlines. The final guidance is not an interpretation of 42 CFR 84.301(a), it is a policy statement regarding NIOSH's intent to not revoke, except for cause, any certificate of approval for escape respirators approved for use in mining in accordance with 42 CFR Part 84, Subpart H, that are manufactured, labeled, or sold prior to June 1, 2019.

Thomas E. Price,

Secretary,

Department of Health and Human Services.

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