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Closed-Circuit Escape Respirators Approved for Use in Mining; 42 CFR Part 84, Subpart O Compliance; Guidance for Industry; Final

This final guidance is for immediate implementation. This final guidance represents the current thinking of NIOSH on this topic.¹ It does not establish any rights for any person and is not binding on NIOSH or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the NIOSH staff responsible for this guidance. See NIOSH Docket 285 or CDC-2016-0121 in www.regulations.gov to read public comments.

I. Introduction

This final guidance 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 (C.F.R.). 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.² Beginning on May 14, 2016, manufacturers were no longer authorized to manufacture, label, or sell 10-minute escape respirators for use in mining approved pursuant to Subpart H.³

For the reasons discussed below, NIOSH is announcing that NIOSH does not intend to revoke any certificate of approval for use in mining obtained under 42 C.F.R. Part 84, Subpart H, for any escape respirators that are manufactured, labeled, or sold prior to June 1, 2019, provided that there is no cause for such revocation under 42 C.F.R. §§ 84.34 or 84.43(c), including for misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the applicable quality control requirements.⁴

II. Background

¹ An interim version of this guidance was published on the NIOSH National Personal Protective Technology website and announced in a Federal Register notice published on December 28, 2016 (81 Fed. Reg. 95623).

² 81 Fed. Reg. 7121.

³ See NIOSH final rule, Closed-Circuit Escape Respirators; Extension of Transition Period, 80 Fed. Reg. 48268 (August 12, 2015).

⁴ See 42 C.F.R. § 84.34 ("The Institute reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of this part. Such causes include, but are not limited to, misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval."); see also 42 C.F.R. § 84.43(c) ("The Institute reserves the right to revoke, for cause, any certificate of approval where it is found that the applicant's quality control test methods, equipment, or records do not ensure effective quality control over the respirator for which the approval was issued.")

Pursuant to the Federal Mine Safety and Health Act of 1977, 30 U.S.C. § 957, NIOSH is authorized to promulgate regulations to carry out its duties mandated by such Act. Under 42 C.F.R. Part 84--Approval of Respiratory Protective Devices, pursuant to 29 U.S.C. §§ 651 *et seq.* and 657(g), and 30 U.S.C. §§ 3, 5, 7, 811, 842(h), and 844, NIOSH approves respirators used by workers in mines and other workplaces for protection against hazardous atmospheres. The Mine Safety and Health Administration (MSHA) requires U.S. mine operators to supply NIOSH-approved respirators to miners whenever the use of respirators is required and co-approves respirators approved for use in mining.

The SCSR approved under 42 C.F.R. Part 84, Subpart H, and CCER approved under 42 C.F.R. Part 84, Subpart O reflect two generations of the same respirator used in certain industrial and other work settings during emergencies to enable users to escape from atmospheres that can be immediately dangerous to life and health. The SCSR/CCER is used by miners to escape dangerous atmospheres in mines.

Standards for the approval of CCERs were updated in a final rule published March 8, 2012, in which HHS codified a new Subpart O and removed only those technical requirements in 42 C.F.R. Part 84, Subpart H that were uniquely applicable to CCERs.⁵ All other applicable requirements of 42 C.F.R. Part 84 were unchanged. The purpose of these updated requirements is to enable NIOSH, respirator manufacturers, and, ultimately, respirator users, to more effectively ensure the performance, reliability, and safety of CCERs used in all workplace applications. The March 2012 rulemaking was conducted in response to decades of reports from the field, particularly underground coal mines, documenting user concerns about the inability to check Subpart H-approved SCSRs for internal damage and the damage sustained to such devices in harsh underground environments. Furthermore, incidents in which users did not receive the expected duration of breathing air were common. The former Subpart H performance rating system classified SCSRs by the duration of breathing air, and was widely known to create confusion among users. Performance duration is not fixed and is dependent on a variety of factors which might result in less protection time than the wearer expects. As HHS said in the March 2012 final rule, “[t]he ... duration rating is misleading and potentially dangerous to users.”⁶ The disaster at the Sago Mine in 2006, in which 12 miners died and another was critically injured, accelerated the promulgation of the Subpart O standards with encouragement from the United Mine Workers of America;⁷ with improved respirator functionality and a better-applied rating system, the outcome might have been different. The need for the rulemaking is discussed in greater detail in the March 2012 final rule;⁸ background documents, including public comments, are available in NIOSH Docket 005.

The Subpart O CCER standards established a classification system based on the quantity (capacity) of oxygen available in an escape respirator. For the purpose of comparing the SCSR to the CCER, a device classified as a “10-minute” SCSR under Subpart H may be approximately equivalent to a “Cap 1” unit under Subpart O, delivering between 20 and 59 liters of oxygen. A “1-hour” SCSR under Subpart H may be approximately equivalent to a “Cap 3” CCER under Subpart O, delivering at least 80 liters of oxygen. CCERs of any capacity used in mining are still required to pass the Subpart H “man test 4.” This test is used to demonstrate that CCERs used in mining will continue to meet the criteria established by MSHA in 30 C.F.R. Part 75 by providing a minimum duration of breathing air.

⁵ 77 Fed. Reg. 14168.

⁶ 77 Fed. Reg. 14168 at 14177.

⁷ See NIOSH Docket 005 for background materials related to this rulemaking, <http://www.cdc.gov/niosh/docket/archive/docket005.html>.

According to UMW, in a January 2, 2006 publication, *Report on the Sago Mine Disaster*, “[c]urrent SCSR technology is almost 20 years old. The federal and state governments, through MSHA and NIOSH, should actively pursue new SCSR technology. All stakeholders must be closely involved in the design, development and testing of these devices. The new generation of SCSRs must be longer-lasting, more reliable units...”

⁸ See 77 Fed. Reg. 14168 at 14169-14182.

Because NIOSH determined that the resulting advances in CCER performance and reliability warranted timely adoption of the enhanced standards, manufacturers were authorized to continue to manufacture, label, and sell Subpart H-approved SCSRs only until April 9, 2015. The three-year period between April 9, 2012 and April 9, 2015, was provided for manufacturers to obtain certificates of approval for CCER designs developed under the Subpart O standards. Beginning on April 10, 2012, no new applications for approval of Subpart H SCSRs have been accepted. The first approvals under Subpart O were issued for Cap 1 non-mining CCERs to Avon Protection Systems, Inc., on July 24, 2014, and Ocenco Inc., on December 2, 2014, both well ahead of the April 2015 compliance deadline.

However, manufacturers did not develop Cap 1 CCERs for use in mining or Cap 3 CCERs for use in mining or non-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 that the first approval was granted to those CCER models.⁹ Avon Protection Systems, Inc., was granted the first approval for a Cap 1 CCER for use in mining on May 13, 2015. On February 10, 2016, NIOSH issued a *Federal Register* notice announcing the first approval of a Cap 3 CCER for use in mining on January 4, 2016, issued to Ocenco. In accordance with the August 2015 final rule, respirator manufacturers were permitted to continue to manufacture, sell, and label 1-hour Subpart H-approved escape respirators until January 4, 2017. Similarly, manufacturers were permitted to continue to manufacture, label, and sell 10-minute Subpart H-approved escape respirators for use in mining until May 13, 2016.¹⁰ The manufacture, labeling, or sale of such devices subsequent to these dates, however, could result in NIOSH revoking, for cause, the certificate of approval under 42 C.F.R. §§ 84.34 or 84.43(c). 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;¹¹ however, MSHA has recently expressed concern that a market gap is imminent in the underground coal mining industry.¹²

In November 2016, the NIOSH National Personal Protective Technology Laboratory (NPPTL) had a series of communications with representatives from MSHA, the underground coal mine industry, and two respirator manufacturers concerning the current supply of person-wearable escape respirators. Specifically, all but one of the manufacturers expressed concern that, without continued authorization to manufacture, label, and sell 1-hour, person-wearable SCSRs, manufacturers would be unable to fulfill the unmet needs of the underground coal mines that require the use of 1-hour person-wearable devices to satisfy MSHA regulatory requirements.¹³

MSHA regulations require that two “approved self-rescue device or devices” each sufficient to provide at

⁹ On January 29, 2015, NIOSH published an interim final rulemaking to extend the deadline to six months after the date that the first approval was granted to certain CCER models (80 Fed. Reg. 4801), but through publication of its final rule on August 12, 2015, NIOSH extended the concluding date for the transition to the Subpart O standards to one year after the date that the first approval was granted to certain CCER models. The regulatory text, promulgated at 42 C.F.R. § 84.301(a), reads: “The continued manufacturing, labeling, and sale of CCERs previously approved under subpart H is authorized for units intended to be used in mining applications with durations comparable to Cap 1 (all CCERs with a rated service time ≤20 minutes), and units intended to be used in mining and non-mining applications with durations comparable to Cap 3 (all CCERs with a rated service time ≥50 minutes), until 1 year after the date of the first NIOSH approval of a respirator model under each respective category specified.” See 80 Fed. Reg. 48268.

¹⁰ *Supra* note 2.

¹¹ The maritime market, which includes the U.S. Navy, have been quick adopters of newly-approved 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.

¹² 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.

¹³ NIOSH and MSHA received a letter on December 12, 2016 from Ocenco Incorporated stating its opposition to extension of the January 4, 2017 deadline for the sale of Subpart H-approved SCSR devices. Steven K. Berning, Ocenco Incorporated, letter to Mr. Joseph A. Main, Assistant Secretary of Labor, MSHA and [Dr.] John Howard, Director, NIOSH, December 12, 2016.

least one hour of protection be available to every person underground in a coal mine;¹⁴ at least one escape respirator of any size must be “worn or carried at all times by each person when underground.”¹⁵ Mine operators are allowed the discretion to determine whether to require miners to carry a 1-hour respirator and cache at least one additional 1-hour respirator per miner, or carry a 10-minute respirator and cache two additional 1-hour units.¹⁶ MSHA and others argue that although both CSE Corporation, of Export, Pennsylvania, and Ocenco hold approvals for Cap 3 CCERs for mining, neither is person-wearable. Both Ocenco and Avon offer approved Cap 1 mining CCERs which are person-wearable, but provide only 10 minutes of oxygen under the current approval requirements.

According to MSHA,¹⁷ in many underground coal mines, miners traveling to multiple stations underground during their shift may not presently have access to caches with 1-hour respirators (as required by MSHA regulations), and therefore must be provided with a 1-hour or Cap 3 person-wearable escape respirator to be in compliance and ensure their safety. MSHA also indicates that miners may have to search for a cache of escape respirators during an emergency, and if so, the lack of a person-worn, 1-hour SCSR or Cap 3 CCER would constitute a reduction in protection since they would have less time to find a cache. Accordingly, although the newly-approved Subpart O CCERs meet the higher performance requirements of the new standard, MSHA is concerned that the protection offered to miners currently wearing the 1-hour SRLD, the only 1-hour, belt-wearable escape respirator currently available on the market, would be diminished if they were required to switch to a Cap 1 person-wearable Subpart O CCER. MSHA further asserts that data on escape respirators deployed in underground coal mines indicate that in mines that rely on 1-hour person-wearable respirators, a substantial portion of their respirator inventory will reach the end of its service life in 2017 and 2018. According to MSHA, these will need to be replaced with additional belt-wearable 1-hour SRLDs since there are currently no available Cap 3 CCERs that are belt or person-wearable. Accordingly, MSHA has asked that NIOSH extend the deadline.

In a letter to NPPTL, CSE Corporation, manufacturer of the 1-hour belt-wearable SCSR model SRLD, reported similar concerns among its mining industry customers.¹⁸ According to CSE:

[a] large portion of the previous generation SCSR population utilized by the mining industry will reach their Service Life Date (Expire) between 2017 through to 2019. Numerous individuals from the mining industry have expressed concerns that an adequate supply of Cap 3 CCERs will NOT be available to replace the expiring SCSRs.¹⁹ [emphasis in original]

On behalf of its customers, CSE expressed two primary concerns: (1) “how to implement the new Cap 3 CCER technology under the current budgetary constraints,” and (2) “the Cap 3 CCER technology is so new that many in the mining industry have not had the opportunity to evaluate it as related to their operational needs let alone even see a new Cap 3 CCER.” CSE concluded that, “[a]s a result of these concerns, many in the mining industry have not fully issued purchase orders for either technology SCSR or Cap 3 CCER to replace the expiring SCSRs.” CSE received NIOSH approval for its Cap 3 mining CCER on March 28, 2016,²⁰ and plans to be in full production in May 2017. CSE has since informed NIOSH that it has a backlog of orders for Subpart H SCSRs, which it is unable to fill before the January

¹⁴ 30 C.F.R. § 75.1714(a), 75.1714-4.

¹⁵ 30 C.F.R. § 75.1714-2(b).

¹⁶ 30 C.F.R. § 75.1714-1(a) and (b).

¹⁷ *Supra* note 9.

¹⁸ Scott Shearer, CSE Corporation, letter to Maryann D’Alessandro, Director, NPPTL, Subject: Cap 3 Closed-Circuit Escape Respirators Transition Plan, November 4, 2016. This letter is available in the docket for this guidance and corresponding *Federal Register* notice.

¹⁹ *Id.*

²⁰ See NIOSH National Personal Protective Technology Laboratory Certified Equipment List, https://www2a.cdc.gov/drds/cel/cel_form_code.asp.

4, 2017 manufacturing deadline.

Finally, a mining industry representative communicated with NPPTL to register similar concern about the availability of the SRLD.²¹

In addition to the communications discussed above, which were received prior to the development of the December 27, 2016 version of this guidance, Ocenco submitted a comment to the docket for this action to request the inclusion of Subpart H 10-minute SCSRs in this guidance, asserting that NIOSH's decision not to revoke certificates of approval for 1-hour respirators approved under Subpart H is arbitrary, puts Ocenco at a competitive disadvantage, and impedes mine operators' ability to choose the most suitable escape respirators for their specific environment. Mine operators who employ the Ocenco Subpart H 1-hour SCSR typically deploy Ocenco Subpart H 10-minute SCSRs to be belt-worn by miners and cache their Ocenco 60-minute SCSRs.

NIOSH also received comment from three other stakeholders who were largely supportive of the improved standards in Subpart O. Two commenters, both representing the underground coal mining industry, suggested that while full compliance with Subpart O, including the sunset of the standards in Subpart H, is a worthwhile and achievable goal, manufacturers must have more time for the development of Subpart O CCERs that are able to be comfortably and safely worn by miners for a full work shift. According to those commenters, allowing the continued manufacturing, labeling, and sale of Subpart H devices only until January 2018 would not allow sufficient time for their replacement with suitable Subpart O devices.

III. Scope of This Final Guidance

This final guidance applies to those respirator manufacturers engaged in the manufacturing, labeling and sale of all escape respirators approved for use in mining in accordance with the approval standards in 42 C.F.R. Part 84, Subpart H.

IV. Closed-Circuit Escape Respirators Approved for Use in Mining; 42 CFR Part 84, Subpart O -- Compliance Policy

NIOSH developed the standards in Subpart O over the course of many years of research in order to respond to the concerns of the various industries that employ these devices. While the Subpart O standards are intended to substantially improve respiratory protection for miners and other workers escaping environments immediately dangerous to life and health, NIOSH is confident that escape respirators approved to the Subpart H standards continue to be protective of those who need to rely on them in such emergency situations. NIOSH recognizes that, although our goal to advance the science is formalized by the promulgation of Subpart O, the development of this technology is an ongoing process ultimately driven by the respirator manufacturers in response to the needs of particular environments, or even particular escape scenarios, as communicated in this case by MSHA and mine operators.

In order to allow mine operators access to all of the tools necessary to protect miners, to give respirator 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 Subpart H to Subpart O, NIOSH does not intend to revoke any certificate of approval for escape respirators approved for use in mining in accordance with 42

²¹ Allen Dupree, Contura Energy, letter to Maryann D'Alessandro, November 23, 2016, Subject: Concerns regarding SCSR Rule. This letter is available in the docket for this guidance and corresponding *Federal Register* notice.

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 C.F.R. §§ 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.

This final guidance does not create any new deadlines or waive any existing deadlines. This final guidance is not an interpretation of 42 C.F.R. § 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 C.F.R. Part 84, Subpart H, that are manufactured, labeled, or sold prior to June 1, 2019.

This policy does not extend to any other NIOSH regulatory requirement for respirator certification and approval in 42 C.F.R. Part 84.

V. Contact for Further Information

For further information, please 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). Information requests can also be submitted by e-mail to *PPEconcerns@cdc.gov*.