are led by Regional Managers who report to the Deputy Director for ORD and are responsible for civil rights and HIPAA complaint investigations, enforcement, and outreach. ORD is responsible for responding to stakeholder calls and triaging civil rights and HIPAA complaints at intake.

C. Civil Rights Division (ATB). The Civil Rights Division is headed by the Deputy Director for Civil Rights, who reports to the Director. The Civil Rights Division oversees OCR's national civil rights program, including Section 1557 of the Affordable Care Act, as well as other federal civil rights statutes and regulations that prohibit non-discrimination on the basis of race, color, national original, sex, disability, and age; the Division also enforces provider conscience laws. The Civil Rights Division provides national leadership in OCR's enforcement and compliance activities, including advising OCR staff nationwide on case development and quality and assisting in developing negotiation, enforcement, and litigation strategies; promulgates regulations, policies, and guidance and provides technical assistance to assist covered entities with compliance; and provides subject matter expertise for public education and outreach activities to stakeholders nationwide. The Civil Rights Division also leads national civil rights compliance reviews; identifies and designs civil rights specific training programs for OCR staff; reviews challenges to OCR's regional civil rights findings; coordinates OCR's government-wide responsibilities for implementation of Age Discrimination Act requirements; and liaises with and provides civil rights technical assistance and advisory services to HHS Operating Divisions, as well as national advocacy, beneficiary, and provider groups, and to other Federal departments and agencies, including serving on intra- and interagency workgroups.

D. Health Information Privacy Division (ATC). The Health Information Privacy Division is headed by the Deputy Director for Health Information Privacy, who reports to the Director. The Health Information Privacy Division oversees OCR's enforcement of the HIPAA Privacy, Security and Breach Notification Rules, as well as the confidentiality provisions of Section 922 of the Public Health Service Act, as amended by the Patient Safety and Quality Improvement Act of 2005 (PSQIA). The Health Information Privacy Division provides national leadership in OCR's enforcement and compliance activities, including advising OCR staff nationwide on case development and quality and assisting in developing negotiation, enforcement, and litigation strategies; promulgates regulations, policies, and guidance and provides technical assistance to assist covered entities with compliance; and provides subject matter expertise for public education and outreach activities to stakeholders nationwide. The Division also identifies OCR training needs and designs HIPAA and PSQIA specific training programs for OCR staff; reviews challenges to OCR's regional offices' HIPAA investigative findings; leads national HIPAA compliance reviews, including audits; and liaises with and provides technical assistance and advisory services to HHS OPDIVS, as well as national advocacy, beneficiary, and provider groups, and to other Federal departments and agencies with respect to health information privacy, security, and breach initiatives and mandates, including serving on intra- and interagency workgroups.

III. Delegation of Authority. Pending further delegation, directives or orders by the Secretary or by the Director of the Office for Civil Rights, all delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further re-delegations, provided they are consistent with this reorganization.

Dated: December 12, 2016.

Colleen Barros,

Acting Assistant Secretary for Administration.

[FR Doc. 2016–31394 Filed 12–27–16; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Closed-Circuit Escape Respirators; Guidance for Industry; Availability

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of availability.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention, Department of Health and Human Services, announces publication of a guidance document which 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. Pursuant to a **Federal Register** notice published on February 10, 2016, beginning on January 4, 2017, manufacturers are 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 (81 FR 7121). This guidance announces that NIOSH does not intend 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 existing NIOSH regulation.

DATES: NIOSH is soliciting public comment, but is implementing this guidance immediately because NIOSH has determined that prior public participation is not feasible or appropriate. Comments must be received by February 27, 2017.

ADDRESSES: You may submit comments, identified by ''CDC–2016–0121'' by any of the following methods:

Internet: Access the Federal e-rulemaking portal at *http://www.regulations.gov.* Follow the instructions for submitting comments.

Mail: NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, OH 45226–1998.

Instructions: All submissions received must include the agency name and docket number for this guidance. All relevant comments will be posted without change to *http://www.regulations.gov* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

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: Pursuant to the Federal Mine Safety and Health Act of 1977, at 30 U.S.C. 957, NIOSH is authorized to promulgate regulations to carry out its duties mandated by such Act. Under 42 CFR part 84—Approval of Respiratory Protective Devices, NIOSH approves respirators used by workers in mines and other workplaces for protection against hazardous atmospheres.[1] The Department of

[1] The cited statutory authorities for Part 84 are 29 U.S.C. 651 *et seq.* and 657(g), and 30 U.S.C. 3, 5, 7, 811, 842(h), 844.

Labor's Mine Safety and Health Administration (MSHA) requires U.S. mine operators to supply NIOSH/MSHA-approved respirators to miners whenever the use of escape respirators is required.

The self-contained self-rescuer (SCSR) approved under 42 CFR part 84, Subpart H, and closed-circuit escape respirator (CCER) approved under 42 CFR 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 CFR part 84—Subpart H that were uniquely applicable to CCERs (77 FR 14168). All other applicable requirements of 42 CFR part 84 were unchanged. The purpose of these updated requirements is to enable NIOSH and MSHA to more effectively ensure the performance, reliability, and safety of CCERs used in underground coal mining. 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 inspect Subpart H-approved SCSRs for internal damage and the damage sustained to such devices in harsh underground environments. Furthermore, incidents in which wearers 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'' (77 FR 14168 at 14177). 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;[2] 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 (*see* 77 FR 14168 at 14169–14182), and 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'' CCER 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 CFR part 75 by providing a minimum duration of breathing air.

Because NIOSH determined that the resulting advances in escape respirator performance and reliability warranted accelerated 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. However, manufacturers were unable to develop Cap 3 CCERs in time to meet the April 9, 2015 transition deadline and, as a result, NIOSH initiated a rulemaking to extend the deadline. On August 12, 2015, NIOSH issued a final rule extending the concluding date for the transition to the Subpart O standards to 1 year after the date that the first approval was granted to certain CCER models (80 FR 48268).[3] On February 10, 2016, NIOSH issued a **Federal Register** notice announcing the first approval of a Cap 3 CCER on January 4, 2016, issued to Ocenco Incorporated (Ocenco) of Pleasant Prairie, Wisconsin. In accordance with the August 2015 final rule, respirator manufacturers were permitted to continue to manufacture, label, and sell, 1-hour Subpart H-approved escape respirators until January 4, 2017. The manufacturing, labeling, or sale of such devices subsequent to this date, however, could result in NIOSH revoking, for cause, the certificate of approval under 42 CFR 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;[4] however, MSHA has recently expressed concern that a market gap is imminent in the underground coal mining industry.[5]

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 ability of the current supply of person-wearable escape respirators to allow the mining industry to comply with MSHA regulations. 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.[6]

MSHA regulations require that two ''approved self-rescue device or

[2] *See* NIOSH Docket 005 for background materials related to the March 2012 rulemaking, *http://www.cdc.gov/niosh/docket/archive/docket005.html.* According to UMWA, 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 . . .''

[3] *See* 42 CFR 84.301(a), which states that ''[t]he 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.''

[4] 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.

[5] 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 notice and guidance.

[6] 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.

devices'' each sufficient to provide at least one hour of protection be available to every person underground in a coal mine;[7] at least one escape respirator of any size must be ''worn or carried at all times by each person when underground.''[8] 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.[9] 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 Polymer Products, Ltd., of Cadillac, Michigan 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,[10] 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 would be diminished if they were required to switch to a 10-minute 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.

[7] 30 CFR 75.1714(a), 75.1714–4.

[8] 30 CFR 75.1714–2(b).

[9] 30 CFR 75.1714–1(a) and (b).

[10] *Supra* note 5.

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.[11] 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.[12] [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,[13] 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 4, 2017 manufacturing deadline.

Finally, a mining industry representative communicated with NPPTL to register similar concern about the availability of the SRLD.[14]

After consideration of the concerns described above, NIOSH agrees that allowing the continued manufacturing, labeling, and sale of 1-hour Subpart H SCSRs is important for the continued respiratory protection of certain underground coal miners and necessary until such time as a person-wearable Cap 3 CCER is developed to replace it. Accordingly, NIOSH has published a guidance document, entitled ''Closed-Circuit Escape Respirators; 42 CFR part 84, Subpart O Compliance; Guidance for Industry,'' on the NIOSH National Personal Protective Technology Laboratory Web site, at *www.cdc.gov/niosh/npptl.* The guidance explains the conditions under which NIOSH does not intend 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), including misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the applicable quality control requirements.[15]

This policy does not extend to any other NIOSH regulatory requirement for respirator approval in 42 CFR part 84.

To ensure that underground coal miners have sufficient MSHA-required protection during escape from hazardous atmospheres, the guidance is effective immediately. The guidance represents the current thinking of NIOSH on this topic. 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.

Dated: December 21, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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BILLING CODE 4163–19–P

[11] 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 notice and guidance.

[12] *Id.*

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

[14] 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 notice and guidance.

[15] *See* 42 CFR 84.34, which states that ''[t]he 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 CFR 84.43(c), which states that ''[t]he 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.''

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–1000]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0025

AGENCY: Coast Guard, DHS.