

Title V, New source performance standards, National emission standards for hazardous air pollutants, Maximum achievable control technology, Delegation of authority.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: October 24, 2018.

Douglas Benevento,

Regional Administrator, EPA Region 8.

[FR Doc. 2018–23631 Filed 10–29–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 192

[EPA–HQ–OAR–2012–0788; FRL–9985–79–OAR]

RIN 2060–AP43

Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; withdrawal.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is withdrawing its January 19, 2017, proposed rule addressing health and environmental protection standards under the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) that would have applied to byproduct materials produced by uranium in-situ recovery (ISR) and would have subsequently been implemented by the U.S. Nuclear Regulatory Commission and its Agreement States. The EPA is withdrawing the proposed rule for three reasons. First, the EPA, informed in part by feedback received on the proposal, has serious questions as to whether the proposed rule as written is within EPA's authority under UMTRCA. Second, the EPA no longer believes that a national rulemaking to promulgate standards is necessary at this time, as the EPA believes the existing regulatory structures are sufficient to ensure the targeted protection of public health and the environment at existing ISR facilities. Third, present market circumstances suggest that the influx of new ISR license applications that was once anticipated and that was an underlying motive for the proposal is not likely to materialize.

DATES: The proposed rule published on January 19, 2017 (82 FR 7400), entitled "Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings," is withdrawn as of October 30, 2018.

FOR FURTHER INFORMATION CONTACT:

Ingrid Rosencrantz, Office of Radiation and Indoor Air, Radiation Protection Division, Mail Code 6608T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–343–9290; fax number: 202–343–2304; email address: radiation.questions@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On January 19, 2017, the U.S. Environmental Protection Agency (EPA) proposed new health and environmental protection standards under the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) (2017 Proposal).¹ The standards proposed in that action would have applied to byproduct materials produced by uranium in-situ recovery (ISR) facilities and would have subsequently been implemented by the U.S. Nuclear Regulatory Commission (NRC) and NRC Agreement States. The EPA initially proposed new health and environmental protection standards for ISR facilities on January 26, 2015 (2015 Proposal).² However, the EPA decided to re-propose the rule on January 19, 2017, and seek additional public comment on changes to the original proposal, including changes in the regulatory framework and approach, based on public comment and new information received from stakeholders. The EPA has not finalized either of these proposals and is not doing so today. Instead, the EPA is withdrawing the 2017 Proposal, which superseded the 2015 Proposal.

II. Why is the EPA withdrawing the 2017 Proposal?

The EPA has decided to withdraw the 2017 Proposal for three reasons. First, stakeholders, including the NRC, raised significant concerns regarding the EPA's legal authority under UMTRCA to propose these standards. Based on those significant concerns, we now have serious questions concerning whether the EPA has the legal authority under UMTRCA to issue the regulations as developed in the 2017 Proposal.

Second, the EPA no longer believes that a national rulemaking to promulgate standards is currently necessary as the Agency believes the existing regulatory structures are sufficient to ensure the targeted protection of public health and the environment at existing ISR facilities. The NRC stated in its public comments that its "current regulations, at 10 CFR part 40, Appendix A, and those of the

various Agreement States, as supplemented by site-specific license conditions, guidance documents . . . and the operational experience and technical expertise of the regulatory agency staff, constitute a comprehensive and effective regulatory program for uranium in situ recovery operations (ISR) facilities." (emphasis added).

Third, present market circumstances suggest that the influx of new ISR license applications that was once anticipated, and that was motivation for the proposal, is not likely to materialize. Therefore, there is less need for the rule, which was intended to provide a more workable and efficient approach for addressing these expected new applications, compared to existing mechanisms.

A. The EPA's Legal Authority

In the 2015 Proposal, the EPA explained that it was "proposing these new standards" under its authority in section 206 of UMTRCA which "authorizes EPA to promulgate general standards for the protection of public health, safety, and the environment from radiological and non-radiological hazards associated with . . . the processing and the possession, transfer, and disposal of byproduct material at sites at which ores are processed primarily for their uranium and thorium source material content or which are used for the disposal of such byproduct material."³ Many commenters stated that this provision does not provide authority for the type of standards that the EPA proposed. Other commenters agreed with the EPA's view that UMTRCA provides authority for proposing these standards. The EPA evaluated and responded to these comments in the 2017 Proposal.⁴ Many of these same commenters subsequently submitted comments on the 2017 Proposal, arguing again that the proposed standards exceeded the EPA's authority to establish "generally applicable standards."⁵ The NRC also submitted comments stating that it does not believe EPA has the authority to develop standards of the type contained in the 2017 Proposal. Some of these commenters raised new arguments to support their position that the proposed standards exceed the EPA's authority under UMTRCA. In light of the comments provided on the various proposals, including by the NRC, the

³ 80 FR at 4163; See also 42 U.S.C. 2022(b)(1).

⁴ 82 FR at 7418–7419, 7421–7422.

⁵ 42 U.S.C. 2022(b)(1) uses the phrase "standards of general application," while 42 U.S.C. 2022(b)(2) uses the term "generally applicable standards." We use these terms interchangeably throughout the action.

¹ 82 FR 7400.

² 80 FR 4156.

EPA now has serious questions as to whether we have the legal authority to finalize the standards that were proposed in the 2017 Proposal.

Most of the commenters' objections to the EPA's application of its authority under UMTRCA in the 2015 Proposal centered around the meaning of the phrase "standards of general application" in the statutory provision. Commenters opposing the proposed standards stated, "the proposed rules were legally invalid and felt the EPA was overreaching its authority under UMTRCA by proposing standards that are too detailed and prescriptive."⁶ These commenters stated that the EPA "was redefining what UMTRCA established as the EPA's role to set general standards" since these commenters did not believe UMTRCA provided the EPA with the authority to set standards that included "any prescriptive implementation requirements."⁷ Other commenters that supported the 2015 Proposal stated that "the proposed standards were an appropriate application of the EPA's authority under the UMTRCA."⁸

In its response to the many comments opposing the EPA's proposed application of its authority, the EPA in the 2017 Proposal indicated that it "disagree[d] with those commenters who believe the EPA has redefined its role or overreached its authority in developing the new standards for ISR facilities."⁹ The EPA stated that "the new standards proposed in this action would apply the same requirements to all ISR facilities and would establish general requirements . . . [that] the regulatory agency would be responsible for implementing. . . on a site-specific basis through the licensing process and would retain the authority to determine when an ISR license can be terminated."¹⁰

Several stakeholders, including the NRC, subsequently submitted comments on the 2017 Proposal, again stating that the proposed standards could not be reasonably classified as "generally applicable standards" under UMTRCA and thus was outside EPA's authority. In the 2017 Proposal, the EPA identified the proposed standards as falling into one of three different categories: (1) "Constituent concentration standards;" (2) "initial stability standards;" and (3) "long-term stability standards."¹¹ In its comments, the NRC asserted the initial

and long-term stability standards "are not generally applicable standards but are implementation criteria, and as such, encroach upon NRC's authority and impair the NRC's ability to effectively regulate its ISR licensees."¹² The NRC also raised several new significant legal arguments in its comments to support its position that had not been previously raised with EPA.¹³ For example, the NRC argues that "EPA's authority to promulgate generally applicable standards, at least for radiological material, is prescribed by what is essentially EPA's organic authority, namely, the Reorganization Plan No. 3 of 1970 (Reorganization Plan)."¹⁴ The NRC asserts that "the Reorganization Plan provided EPA with an express transfer of AEA authority to set generally applicable standards 'for the protection of the general environment from radioactive material,'" and that the Reorganization Plan "expressly prescribed this standard setting authority by defining the term 'standards' to mean 'limits on radiation exposures or levels, or concentrations or quantities of radioactive material'—essentially, numerical limits."¹⁵ NRC further asserts that UMTRCA's legislative history shows that "Congress was aware of and considered [this standard-setting authority in the Reorganization Plan] when it enacted UMTRCA in 1978" and that "Congress structured UMTRCA's grant of authority to the EPA Administrator upon this very provision."¹⁶ The NRC points to several excerpts from the legislative history to support its claim that Congress intended "that EPA's generally applicable standards under UMTRCA, for both radiological and non-radiological materials, be in the form of numerical limits, namely, limits on concentrations of radiological and non-radiological material, quantities of such material, or allowable doses or levels to individuals from such material."¹⁷

Other commenters disputed the EPA's authority to adopt regulatory requirements that they alleged could not reasonably be considered "generally applicable standards." For example, the Uranium Producers of America (UPA) argued that the proposed standards "exceed[s] EPA's jurisdictional authority as set forth by UMTRCA."¹⁸ UPA further criticized the "new

prescriptive post-operational monitoring time and data requirements and new prescriptive post-restoration requirements" as an "impermissible attempt by EPA to direct the compliance of ISR operations."¹⁹ The Texas Commission on Environmental Quality (TCEQ) raised the same objection, requesting that the EPA withdraw those particular requirements "because they exceed EPA's authority to promulgate standards."²⁰ TCEQ stated that UMTRCA "confers the NRC and Agreement State programs . . . , not EPA, with authority to implement and enforce EPA's standards," and then asserted the EPA's "proposed rules . . . go beyond the promulgation of standards and address how those standards should be implemented and enforced."²¹

Other stakeholders submitted comments in support of the 2017 Proposal, reiterating their position that they believe the EPA has the authority to propose these types of "generally applicable standards" under UMTRCA.

Based on the discussion above, EPA now has serious questions concerning whether we have the legal authority to issue the regulations as proposed in the 2017 Proposal. In conjunction with the grounds for withdrawal discussed below, this uncertainty as to our authority weighs in favor of withdrawing the 2017 Proposal.

B. Health and Environmental Protection Justification for the Rule

When EPA initiated this rulemaking, there was already an effective system in place providing environmental oversight of ISR operations. As we explained in the 2015 Proposal, "in 1983, EPA originally promulgated regulations at 40 CFR part 192, Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings, in response to the statutory requirements of the Atomic Energy Act [AEA] of 1954, as amended by the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA)."²² The 2015 Proposal further stated: "Requirements currently applicable to active uranium processing and disposal sites, including ISR sites (*i.e.*, Title II sites) can be found in subpart D of 40 CFR part 192 (hereafter "subpart D"). Subpart D contains provisions for managing uranium byproduct materials during and following the processing of uranium ores, and restoration of

¹² EPA-HQ-OAR-2012-0788-0312 (comments of the Nuclear Regulatory Commission) at 11.

¹³ EPA-HQ-OAR-2012-0788-0312, pp. 8–21.

¹⁴ *Id.* at pg. 12.

¹⁵ *Id.*

¹⁶ *Id.* at pg. 13.

¹⁷ *Id.* at pg. 14.

¹⁸ EPA-HQ-OAR-2012-0788-0380 (comments of Uranium Producers of America) at 7.

¹⁹ *Id.*

²⁰ EPA-HQ-OAR-2012-0788-0302 (comments of the TCEQ) at 3.

²¹ *Id.* at 3–4.

²² 80 FR 4161.

⁶ 82 FR at 7418.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ 82 FR 7405.

disposal sites following any such use of those sites.”²³

In the 2015 Proposal, under the heading “Why does EPA believe new standards are necessary?” the Agency stated: “We believe that ISR-specific standards are necessary because uranium ISR operations are very different from conventional uranium mills and the existing standards do not adequately address their unique aspects. In particular, we believe it is necessary to take a longer view of groundwater protection than has been typical of current ISR industry practices. Although the presence of significant uranium deposits typically diminishes groundwater quality, current industry practices for restoration and monitoring of the affected aquifer may not be adequate to prevent either the further degradation of water quality or the more widespread contamination of groundwater that is suitable for human consumption.”²⁴

In response to both proposals, the EPA has received numerous comments questioning the need or benefits of the rule. For example, in the 2017 Proposal the EPA noted that “Industry commenters and others say that there is no need for this rule because the EPA has not identified an instance in which an ISR operation has contaminated a source of drinking water.”²⁵ In the 2017 Proposal, the EPA also said: “Focusing on the area of surrounding or adjacent aquifers, the EPA acknowledges that the Agency does not have sufficient information to document a specific instance of contamination of a public source of drinking water caused by an ISR . . . [however,] the Agency remains concerned that the lack of data does not demonstrate that no contamination is occurring The monitoring requirements in this proposal address the issue of lack of data.”²⁶ (emphasis added). In its comments on the 2017 Proposal, UPA refers to the above statement: “EPA acknowledges there is *no evidence* of harm. . . . The EPA provides no evidence to contradict [NRC’s findings].” By contrast, the Natural Resources Defense Council (NRDC) asserts that its comments “demonstrate impacts to ISL mined aquifers . . . such that the groundwater is substantially degraded and there will be long-term harm to crucial natural resources.”²⁷ As is evidenced by the comments, the debate is nuanced and

complicated and reflects differing views on the available data.

In addition to the public stakeholder comments mentioned above, most importantly, the NRC, the agency tasked with implementing the program, weighed in on the debate, stating in its public comments that “the NRC staff has concluded that its application of the 10 CFR part 40, Appendix A regulations to ISR facilities meets the AEA standard of ‘adequate protection’ of public health and safety and the environment. . . .”²⁸

In considering these factors, as well as the presence of an existing program that the NRC (the implementing agency) believes is sufficient, and the lack of expected growth and status of the industry as described further in the next section of this withdrawal action, the EPA believes that the reasonably envisioned public health and environmental benefits of the proposed rulemaking are limited and do not warrant EPA proceeding with its proposed rulemaking. The existing regulatory structures, adequately address the current environmental concerns.

C. Current and Anticipated Market Conditions

Finally, the EPA believes that market forces themselves have lessened the need for such a rule. Initially, several factors, including the expected growth in this industry, led the EPA and the NRC to believe that regulation of ISR activities could be more workable and efficient if the EPA issued standards of general application specific to the ISR facilities that the NRC would incorporate into its own regulations and implement through its licensing activities.²⁹ When these efforts began, the NRC expected as many as 23 ISR license applications for new facilities,

expansions, and restarts.³⁰ This expected influx of ISR license applications is no longer anticipated.

The NRC is currently reviewing license applications for only three expansions of ISR facilities and, for the next five years, the NRC expects only one license application for an expansion of one ISR facility and one license application for one new ISR facility.³¹ Compared to the expected influx of ISR license applications, and the 15 ISR facilities owned by 10 companies at the time of the 2017 Proposal, at the end of 2017 only approximately six ISR facilities were operating,³² with production down 17% compared to late 2016.³³ According to the U.S. Energy Information Administration (EIA), “Domestic Uranium Production Report,” 4th Quarter 2017, there are no ISR facilities reported as operating in Texas, with Alta Mesa, Hobson, La Palangana reported as on “standby.” Additional ISR facilities in New Mexico, Texas, and Wyoming have been licensed but have not operated and only one has undergone development.

The proposal of generally applicable national standards by EPA was driven partly by the expectation of a significant number of new facilities (which would have also applied to operating wellfields at existing facilities), making these proposed ISR-specific standards a more immediate prerequisite to achieving the efficiency across all regulatory programs that the NRC acknowledged could be gained by a “regulatory regime . . . specific to ISRs.”³⁴ Today, the EPA questions whether this expected growth in operating ISR facilities is likely to be realized.

Given this change in circumstances, completion of this rule is no longer expected to achieve the regulatory efficiency that was sought when this rulemaking effort began. The NRC and the NRC Agreement States currently regulate, through existing licenses, the limited number of operating ISR facilities and such an approach has been workable in practice for this number of

²⁸ EPA–HQ–OAR–2012–0788–0312 at 1.

²⁹ EPA–HQ–OAR–2012–0788–0006 (“Regulation of Groundwater Protection at *In Situ* Leach Uranium Extraction Facilities,” Nuclear Regulatory Commission Memorandum COM/JSM–06–0001, January 17, 2006) at 2 (“ . . . the recent rapid rise in uranium prices and mining claims would indicate a significant future potential for new ISL facilities.”); 80 FR at 4167 (“In recent years, NRC has recognized the desirability of ISR-specific regulations. . . . [T]he Commission determined in 2006 that the appropriate action was ‘initiation of a rulemaking effort specifically tailored to groundwater protection programs at *in situ* leach (ISL) uranium recovery facilities.’”); 82 FR at 7420 (“In addition, the NRC acknowledges that efficiency could be gained by codifying its longstanding effective regulatory regime into regulations specific to ISRs. As described in the original proposal, this rulemaking was initially prompted by the NRC’s conclusion that ISR-specific rules are needed to create a more workable and sustainable regulatory framework for this activity, and is not based on any specific instances of identified contamination.”).

³⁰ EPA–HQ–OAR–2012–0788–0405 (“Uranium Recovery Licensing Activities,” Presentation of the Nuclear Regulatory Commission) at 10.

³¹ Expectations for number of future licenses based on NRC/EPA telephone conversation on November 28, 2017.

³² U.S. Energy Information Administration: “Domestic Uranium Production Report.” 4th Quarter 2017 (February 8, 2018). The operating facilities are Crow Butte in Nebraska and Lost Creek, Nichols Ranch, Ross, Smith Ranch-Highland and Willow Creek, all in Wyoming. Cameco subsequently curtailed production at the Crow Butte and Smith-Ranch Highland facilities (see <http://www.cameco.com>).

³³ World Nuclear News, 20 November 2017.

³⁴ 82 FR 7420. See footnote 29 for a more complete citation.

²³ 80 FR 4163.

²⁴ 80 FR 4164.

²⁵ 82 FR 7404.

²⁶ 82 FR 7404.

²⁷ EPA–HQ–OAR–2012–0788–0380 at 2; EPA–HQ–OAR–2012–0788–0390 (comments of the NRDC) at 4.

facilities. We do not see a need for the EPA to continue investing its resources to complete this rule to develop a “more workable and sustainable regulatory framework” as originally anticipated when we proposed these ISR-specific standards, especially where current production is reduced and little or no growth is expected in the near future. The statutory authorities providing for this ongoing regulatory and licensing function remain unchanged. Thus, the appropriate regulatory authorities may decide on a case-by-case basis to revise their own pre-existing regulations based on these authorities if they deem it necessary to assist with their management of ISR facilities in a particular state or local area.

In addition, we find support for our decision to withdraw the proposed rule in the NRC’s comments on the 2017 Proposal. As explained above, the EPA developed the proposed standards partly based on its understanding, after consultation with the NRC, that the anticipated growth in the number of ISR facilities highlighted a need for standards specific to ISR facilities, rather than continuing to apply standards that were originally written to address surface disposal of uranium mill tailings.³⁵ However, the NRC expressed the following view in its public comments on the proposed rulemaking:

The NRC’s current regulations, at 10 CFR part 40, Appendix A, and those of the various Agreement States, as supplemented by site-specific license conditions, guidance documents (e.g., NRC’s “Standard Review Plan for In Situ Leach Uranium Extraction License Applications,” NUREG-1569), and the operational experience and technical expertise of the regulatory agency staff, constitute a comprehensive and effective regulatory program for uranium in situ recovery operations (ISR) facilities.³⁶

Considering the prevailing economic conditions affecting current and projected production, which leads the NRC now to expect significantly fewer future license applications, as opposed to the large increase that it expected at the time the rulemaking process was initiated (which was motivation for the proposal), we conclude that withdrawing this proposal is appropriate.

III. Statutory Authority

The statutory authority for this notice is provided by section 275 of the Atomic

Energy Act (AEA), as added by section 206 of UMTRCA (42 U.S.C. 2022) and the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*).

IV. Impact Analysis

Because the EPA is not promulgating any regulatory requirements, there are no compliance costs or impacts associated with today’s final action.

V. Statutory and Executive Order Reviews

Today’s action does not establish new regulatory requirements. Hence, the requirements of other regulatory statutes and Executive Orders that generally apply to rulemakings (e.g., the Unfunded Mandate Reform Act) do not apply to this action.

Dated: October 18, 2018.

Andrew R. Wheeler,

Acting Administrator.

[FR Doc. 2018–23583 Filed 10–29–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS–5528–ANPRM]

RIN 0938–AT91

Medicare Program; International Pricing Index Model for Medicare Part B Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Advance notice of proposed rulemaking with comment.

SUMMARY: We are issuing this advance notice of proposed rulemaking (ANPRM) to solicit public comments on potential options we may consider for testing changes to payment for certain separately payable Part B drugs and biologicals (hereafter called “drugs”). Specifically, CMS intends to test whether phasing down the Medicare payment amount for selected Part B drugs to more closely align with international prices; allowing private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and changing the 4.3 percent (post-sequester) drug add-on payment in the model to reflect 6 percent of historical

drug costs translated into a set payment amount, would lead to higher quality of care for beneficiaries and reduced expenditures to the Medicare program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS–5528–ANPRM. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–ANPRM, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–ANPRM, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Hillary Cavanagh, 410–786–6574 or the IPI Model Team at IPIModel@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

³⁵ 82 FR at 7402–3; 80 FR 4164–7.

³⁶ EPA–HQ–OAR–2012–0788–0312 at 1.