V. Regulatory Flexibility Act Analysis

Section 3(a) of the Regulatory Flexibility Act ("RFA")[24] requires the Commission to undertake a regulatory flexibility analysis of the impact of the exceptions on a substantial number of small entities.[25] The application of the RFA to the exceptions is limited. Because the definition of QIB in Rule 144A generally is limited to those entities that in the aggregate own or invest on a discretionary basis at least $100 million in securities of unaffiliated entities ($10 million in the case of a broker-dealer), Rule 144A pertains to resales of securities to substantial investors. Although Rule 144A places no similar size restrictions on placement agents that may resell such securities, it appears that Rule 144A has been utilized by substantial U.S. broker-dealers to resell securities of substantial foreign issuers. The Chairman previously has certified that the exceptions would not have a significant economic impact on a substantial number of small entities. A copy of the certification can be obtained from Diane Mage Roberts, Securities and Exchange Commission, 450 Fifth Street, NW., Mail Stop 5–1, Washington, DC 20549.

VI. Effectiveness of Exceptions

Pursuant to 5 U.S.C. 553(d)(1), the Commission is making the exceptions effective upon publication in the **Federal Register** since the exceptions relieve restrictions from the Trading Practices Rules.

VII. Statutory Basis and Text of Rule Amendments

The amendments to Rules 10b–6, 10b–7, and 10b–8 are adopted under the Exchange Act, 15 U.S.C. 78a *et seq.*, and particularly sections 2, 3, 9(a)(6), 10(b), 13(e), 15(c), and 23(a) of the Exchange Act, 15 U.S.C. 78b, 78c, 78i(a)(6), 78j(b), 78m(e), 78o(c), and 78w(a).

[24] 5 U.S.C. 603(a)

[25] 5 U.S.C. 605(b)

List of Subjects in 17 CFR Part 240

Broker-dealers, Reporting and recordkeeping requirements, Securities, Issuers, Fraud.

For the reasons set out in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78i, 78j, 78*l*, 78m, 78n, 78o, 78p, 78s, 78w, 78x, 78*ll*(d), 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

2. Section 240.10b–6 is amended by redesignating paragraph (i) as paragraph (j) and adding a new paragraph (i) to read as follows:

§ 240.10b–6 Prohibitions against trading by persons interested in a distribution.

* * * * *

(i) The provisions of this section shall not apply to any distribution of securities of a foreign government or a foreign private issuer, as defined in § 240.3b–4, eligible for resale under § 230.144A(d)(3) of this chapter, if such securities are offered or sold in the United States solely to a qualified institutional buyer, as defined in § 230.144A(a)(1) of this chapter, or to an offeree or purchaser that the seller and any person acting on behalf of the seller reasonably believes is a qualified institutional buyer, in transactions exempt from registration under section 4(2) (15 U.S.C. 77d(2)) of the Securities Act of 1933 or § 230.144A or Regulation D (§§ 230.501–230.508) of this chapter.

* * * * *

3. Section 240.10b–7 is amended by redesignating paragraph (o) as paragraph (p) and adding a new paragraph (o) to read as follows:

§ 240.10b–7 Stabilizing to facilitate a distribution.

* * * * *

(o) The provisions of this section shall not apply to any distribution of securities of a foreign government or a foreign private issuer, as defined in § 240.3b–4, eligible for resale under § 230.144A(d)(3) of this chapter, if such securities are offered or sold in the United States solely to a qualified institutional buyer, as defined in § 230.144A(a)(1) of this chapter, or to an offeree or purchaser that the seller and any person acting on behalf of the seller reasonably believes is a qualified institutional buyer, in transactions exempt from registration under section 4(2) (15 U.S.C. 77d(2)) of the Securities Act of 1933 or § 230.144A or Regulation D (§§ 230.501–230.508) of this chapter.

* * * * *

4. Section 240.10b–8 is amended by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) to read as follows:

§ 240.10b–8 Distributions through rights.

* * * * *

(f) The provisions of this section shall not apply to any distribution of securities of a foreign government or a foreign private issuer, as defined in § 240.3b–4, eligible for resale under § 230.144A(d)(3) of this chapter, if such securities are offered or sold in the United States solely to a qualified institutional buyer, as defined in § 230.144A(a)(1) of this chapter, or to an offeree or purchaser that the seller and any person acting on behalf of the seller reasonably believes is a qualified institutional buyer, in transactions exempt from registration under Section 4(2) (15 U.S.C. 77d(2)) of the Securities Act of 1933 or § 230.144A or Regulation D (§§ 230.501–230.508) of this chapter.

* * * * *

By the Commission.

Dated: November 3, 1993.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–27556 Filed 11–12–93; 8:45 am]

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November 15, 1993

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310
Boil Treatment Drug Products for Over-the-Counter Human Use; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 82N–0054]

RIN 0905–AA06

Boil Treatment Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing that over-the-counter (OTC) boil treatment drug products are not generally recognized as safe and effective and are misbranded. This final rule applies only to topical drug products used to reduce the size of a boil or to reduce an infection related to a boil. Certain drug products used to provide relief of local symptoms (itch, pain, and discomfort) of a boil will be addressed in the rulemaking for OTC external analgesic drug products in a future issue of the Federal Register. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on OTC boil treatment drug products that have come to the agency's attention. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: May 16, 1994.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 29, 1982 (47 FR 28306), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking that would classify OTC boil ointment drug products as not generally recognized as safe and effective and as being misbranded and would declare these products to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). The notice was based upon the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by September 27, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by October 27, 1982.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, after deletion of a small amount of trade secret information.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC boil treatment drug products was published in the Federal Register of January 26, 1988 (53 FR 2198). Interested persons were invited to file by March 28, 1988, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by May 25, 1988. New data could have been submitted until January 26, 1989, and comments on the new data until March 27, 1989. Final agency action on that proposal occurs with publication of this final rule on OTC boil treatment drug products.

In the tentative final monograph, no active ingredients were proposed as generally recognized as safe and effective and not misbranded for the treatment of boils. However, the agency proposed labeling in § 358.450(b) in the event that data were submitted that resulted in the upgrading of any ingredients to monograph status in the final rule. The proposed indication was "For the temporary relief of pain and discomfort of boils."

The primary types of products used in the drug treatment of boils are: (1) Antibacterial "drawing salves" to reduce boil size and infection, and (2) anesthetics to relieve local symptoms, such as itch, pain, and discomfort. The agency stated in the tentative final monograph (53 FR 2198 at 2204) that clinical data were needed to demonstrate the "drawing action" on a boil of ingredients such as magnesium sulfate or ichthammol, and to demonstrate the antiseptic action of sulfur and phenol. The agency also stated that if new data that were submitted during the allotted 12-month comment and new data period were not sufficient to establish monograph conditions for OTC boil treatment drug products, the final rule would declare these products to be new drugs (53 FR 2199). In this final rule, the agency concludes that no active ingredient has been shown to be generally recognized as safe and effective for use as a drawing agent or antiseptic in OTC boil treatment drug products. The agency also concludes that several other ingredients are not generally recognized as safe and effective for use as a topical analgesic, anesthetic, and antipruritic in OTC boil treatment drug products. No substantive data were submitted for these ingredients.

As discussed, the labeling proposed in part 358 for OTC boil treatment drug products applied primarily to products used for the temporary relief of pain and discomfort of boils. Among the ingredients considered for this indication were several topical analgesic, anesthetic, and antipruritic active ingredients (benzocaine, camphor, juniper tar, menthol, and phenol) that are also being considered in the OTC external analgesic rulemaking. However, with the exception of benzocaine, no data were submitted supporting the use of these ingredients in the treatment of pain and discomfort associated with boils. Thus, the agency has determined that these ingredients (other than benzocaine) are not generally recognized as safe and effective for this use. The affected ingredients are listed in § 310.545(a)(5) (21 CFR 310.545(a)(5)). Data were submitted for benzocaine, and action on this ingredient is being deferred and transferred to a separate rulemaking for OTC external analgesic drug products.

In the ongoing rulemaking for OTC external analgesic drug products, general claims for OTC topical analgesic, anesthetic, and antipruritic active ingredients have been proposed in part 348 (48 FR 5852 at 5868, February 8, 1983). Proposed § 348.50(b)(2) would establish the temporary relief of pain, itching, or pain and itching as an intended use. The proposed labeling would also allow a description of several conditions that pain and itching are associated with, e.g., sunburn, insect bites, and minor skin irritations. Section 348.50(b) also includes proposed labeling for other specialized uses of analgesic, anesthetic, and antipruritic ingredients. See, e.g., proposed § 348.50(b)(5) for products used for the treatment of fever blisters and cold sores. (See 55 FR 3370 at 3382 and 3383, January 31, 1990.) The agency has determined that the appropriate place to include relief of the pain and itching of boils, if supported by appropriate data, would be proposed § 348.50(b). Accordingly, the agency is deferring a decision on benzocaine as a topical analgesic, anesthetic, and antipruritic active ingredient for relief of pain and discomfort of boils. That use of benzocaine will be discussed in the

external analgesic drug rulemaking in a future issue of the **Federal Register**. Products containing benzocaine labeled for the temporary relief of pain and discomfort of boils may continue to be marketed at this time.

This final rule declares OTC drug products containing active ingredients for the treatment of boils to be new drugs under section 201(p) of the act, for which an application or abbreviated application (hereinafter called application) approved under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 is required for marketing. In the absence of an approved application, products containing drugs for this use also would be misbranded under section 502 of the act (21 U.S.C. 352). In appropriate circumstances, a citizen petition to establish a monograph may be submitted under 21 CFR 10.30 in lieu of an application.

This final rule amends 21 CFR part 310 to include drug products containing ingredients for the treatment of boils by adding new § 310.531 (21 CFR 310.531) to subpart E. The inclusion of OTC boil treatment drug products in part 310 follows FDA's established policy for regulations in which there are no monograph conditions. (See, e.g., §§ 310.510, 310.519, 310.525, 310.526, 310.532, 310.533, and 310.534.) If, in the future, any ingredient is determined to be generally recognized as safe and effective for use in an OTC boil treatment drug product, the agency will promulgate an appropriate regulation at that time.

The OTC drug procedural regulations (§ 330.10) provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA does not use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage. In place of Category I, the term "monograph conditions" is used; in place of Category II or III, the term "nonmonograph conditions" is used.

As discussed in the proposed rule for OTC boil treatment drug products (53 FR 2198), the agency advised that it would provide a period of 12 months after the date of publication of the final monograph in the **Federal Register** for relabeling and reformulation of OTC boil treatment drug products to be in compliance with the monograph. Although data and information were submitted on ichthammol and sulfur in response to the proposed rule, they were not sufficient to support monograph conditions, and no monograph is being established at this time. Therefore, boil treatment drug products that are subject to this rule are not generally recognized as safe and effective and are misbranded (nonmonograph conditions). In the advance notice of proposed rulemaking (47 FR 26306), the agency advised that conditions for the drug products subject to this monograph would be effective 6 months after the date of publication of a final monograph in the **Federal Register**. Because no OTC drug monograph is being established for this class of drug products, the agency is adopting this 6-month effective date for the nonmonograph conditions for these drug products. Therefore, on or after May 16, 1993, no OTC drug products that are subject to this final rule may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved application.

In response to the proposed rule on OTC boil treatment drug products, one manufacturer submitted a comment and data. A copy of the comment and data received is on public display in the Dockets Management Branch (address above). Additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

I. The Agency's Conclusions on the Comment

1. The comment submitted data in support of the safety and effectiveness of benzocaine in promoting reduction in boil size and relieving pain associated with boils (furuncles) (Ref. 1). As noted above, consideration of the use of benzocaine for relief of pain associated with boils is transferred to the rulemaking for OTC external analgesic drug products. The agency is only reviewing the data as they relate to reduction in boil size in this final rule. Three studies (Florendo, Weinrauch, and Goldstein) having identical protocols were submitted. The protocol for each study prescribed a randomized, double-blind, vehicle-controlled study enrolling 30 to 50 subjects with a clinical diagnosis of boils. The active treatment contained two active ingredients, benzocaine (20 percent) and triclosan (0.35 percent), while the vehicle was stated to contain triclosan (0.25 percent) only. Subjects were examined in a dermatology clinic or private office where a clinical history was obtained and the baseline boil size was determined. Subjects were then randomly assigned to a treatment group and told to apply the medication twice daily, in the morning and evening. The first application was given in the office or clinic. Reduction in boil size was one efficacy measure in these studies. Boil size determination was supposed to be made when pain relief was first experienced and after 3 days of treatment. Reduction in boil size was the difference in diameter of the boil between baseline and the end of treatment. Change in boil diameter, percent reduction in boil diameter, and the percent of subjects with a reduction in boil size were compared for the two treatments.

The agency has determined that the data are inadequate to demonstrate benzocaine's effectiveness in reducing the size of a boil. The agency considers the study design as having a number of problems. The active treatment was a combination product with two active ingredients. To prove efficacy, a four-arm study (to include each ingredient, the combination product, and vehicle) should have been conducted. The submitted studies had no true placebo (vehicle) because the vehicle component contained triclosan 0.25 percent, a concentration 0.1 percent less than used in the active treatment. Even though this concentration is lower than that of triclosan in the active treatment, it still may have contributed to the study results because it can have antibacterial properties. Thus, beneficial results of the active treatment may have been attributable to one or both of the two active ingredients. To prove efficacy for benzocaine, a study should compare benzocaine to its vehicle without triclosan. The submitted study design was only a test of whether the combination of benzocaine and triclosan outperforms triclosan by itself in the treatment of boils. The study design did not exclude any possible beneficial effects resulting from the incorporation of triclosan into the active treatment or the vehicle.

Boil size measurements should have been made with accuracy and with diligence in a study which claimed, as one of its objectives, to influence the size of the baseline condition. There should have been exclusions for subjects on recent oral antibiotics and on systemic or intralesional corticosteroid treatment. Subjects with multiple boils in adjacent areas should not have been accepted into the studies. Carbuncles and furuncles behave very differently on a clinical basis, and the

former should not have been included in a study on boils. Carbuncles are not simple boils and should not have been included in a study on boils because these lesions behave differently and require either incision and drainage, antimicrobial therapy, or both (Ref. 2).

The Florendo study enrolled 52 subjects: 24 subjects were randomized to the placebo group, and 28 subjects were randomized to the active group. Followup data were obtained from all 52 subjects. The two treatment groups were similar with respect to sex, age, and the age and size of boils. The treatment group did have a significantly higher proportion of subjects with boils which oozed or burst than did the placebo group. Four subjects in the treatment group and five subjects in the placebo group had multiple boils. The sponsor analyzed the change in boil size both with the boil as the unit of analysis and with the person as the unit of analysis. In the latter analysis, changes in boil size were first averaged within each person.

In the sponsor's analysis, a significantly higher percentage of treatment subjects than vehicle subjects had a reduction in boil size ($p < .05$); this was true whether the analysis was by subject or by boil and whether or not boils which burst were excluded. The mean absolute reduction in boil size was greater in the treatment group than in the vehicle group in all analyses. Borderline significance was achieved ($p < .06$) in the two analyses with all boils included (whether analyzed by boil or by person). Similar findings were achieved with percentage change in boil size. The agency notes that the size of the boils was measured only to the nearest centimeter (cm). The agency believes that a more exact measurement should have been made to assess changes in size.

The Weinrauch study enrolled 51 subjects: 27 subjects were randomized to the placebo group, and 24 subjects were randomized to the treatment group. Followup data were obtained from all 51 subjects. The two treatment groups were similar with respect to sex, age, and all the baseline parameters. No subjects had multiple boils. Four boils in the vehicle group and one in the treatment group burst or oozed during the trial.

In the sponsor's analysis, when boils that burst were excluded, there was a significantly greater proportion of subjects with a reduction in boil diameter as well as a significantly greater mean absolute and percentage boil size reduction in the treatment group compared to the vehicle group. When all boils were included, the direction of these results did not change, and they did not approach statistical significance.

The Goldstein study enrolled 69 subjects, with 66 (38 vehicle and 28 treatment) subjects completing it. One placebo subject was excluded because his boil size was not initially recorded. Also, one subject was on another medication, which was a violation of the protocol. The two treatment groups were similar with respect to age and the baseline parameters. No subject had multiple boils. One boil in the treatment and one boil in the vehicle group burst during the trial.

No significant differences were observed with respect to change in boil size. The vehicle group had a slightly higher proportion of subjects with reduction in boil diameter (37 percent) than did the treatment group (32 percent).

The agency found that the data sheets (Ref. 1) showed a great variation in the times when boil size was measured. For some subjects, boil size was measured only during the first 4 hours; for other subjects, measurements were made only after 1 day or 3 days. Measurements were made on both day 1 and 3 for less than half of the subjects who received the drug. The inconsistency of these measurements makes the data unsatisfactory. Also, some subjects did not complete the 3-day study; they were stopped after 1 day to begin either oral administration of antibiotics or to have incision and drainage.

The study appears not to have been conducted with proper care. Boil size was measured only to the nearest cm. Boil size was not measured precisely or consistently on all subjects in a study that proposes to study changes in boil size resulting from treatment. The boil size was not recorded for several subjects (e.g., subject 2,612). There was some confusion as to the meaning of some of the data entries; for example, terms such as "1.3" for presence of pus (subject 2,654) and "patient aspirated pus after the first day" (subject 3,577). Data entries like these cast doubt on the validity and/or appropriateness of the data recording and the subjects studied.

The raw data sheets for the Goldstein study (Ref. 1) are included in the file and contain numerous inconsistencies. At least one subject with no baseline boil size measurement was included in the analysis. In conclusion, there are numerous errors and omissions in the conduct of the Goldstein study that cause the agency to conclude that the results should be discounted.

In summary, the three studies submitted were not designed properly. The data collection for these studies appears to be incomplete in many instances. The subjects were not uniformly assessed at the various time points specified in the protocol for data collection, and the data were not collected precisely. Boil size measurements appear not to have been carried out carefully, and measurements were made in an inexact manner. The design of the studies was not appropriate for a two-component (combination) product. A four-arm study (to include each component, the combination product, and the vehicle) was needed to demonstrate efficacy. The vehicle should not have contained either component of the combination product. In conclusion, none of the three studies is an adequate, well-controlled study. Benzocaine has not been shown to be effective in reducing the size of boils.

The comment subsequently informed the agency (Ref. 3) that triclosan in a concentration of 0.35 percent was in both the vehicle and in the active drug. The comment stated that it was a typographical error stating that the concentration was 0.25 percent.

The comment contended that the active preparation was not a combination product because the triclosan in the product (as an antimicrobial) does not have proven effectiveness. The comment further argued that even if triclosan were proven effective as an antimicrobial, its "contribution" as an inactive ingredient is irrelevant to the results. The comment maintained that the only active ingredient was benzocaine, whose efficacy for relief of pain was proven. The comment claimed that triclosan had two purposes in the product: (1) To help guard against spread of infection from a boil to other sites if the boil ruptured, and (2) to act as a bacteriostatic preservative.

Based on the comment's arguments (Ref. 3), the agency is now treating the comment as addressing only the claim that benzocaine is effective for relief of pain associated with boils, and that the comment is not interested in other claims being attributed to other ingredients used to treat boils. As noted above, the use of benzocaine for relieving pain associated with boils is being transferred to the rulemaking for OTC external analgesic drug products.

References

(1) Comment No. C4, Docket No. 82N–0054, Dockets Management Branch.

(2) Maibach, H. I., R. Aly, and W. Noble, "Bacterial Infections of the Skin" in Dermatology, 2d ed., edited by Moschella, S., and H. Hurley, W. B. Saunders Co., Philadelphia, pp. 612–613, 1985.

(3) Comment No. C5, Docket No. 82N–0054, Dockets Management Branch.

2. The comment included data in support of the usefulness of the ingredients ichthammol, sulfur, and triclosan in a combination product for the treatment of boils (Refs. 1 through 5). The comment also urged the agency to consider benzocaine in combination with ichthammol, sulfur, and triclosan used as antimicrobials for the treatment of boils.

The agency has reviewed the data submitted on ichthammol, sulfur, and triclosan as antimicrobials for the treatment of boils and finds they are inadequate to establish effectiveness for this use. Of the references submitted with the comment, the agency considers the following pertinent to ichthammol and sulfur: Kownatzki, Urich, and Schopf (Ref. 2) showed that ichthyol (ichthammol) induced a neutrophilic cell accumulation in an in vitro chemotaxis (Boyden) chamber. On this basis, they concluded that ichthyol has anti-inflammatory properties. Libenson et al. (Ref. 3) concluded from a laboratory experiment that elemental sulfur has antibacterial activity against streptococcal strains and to a lesser degree against *Staphylococcus aureus*. Woiwood (Ref. 4) concluded by an in vitro test that colloidal sulfur has antistaphylococcal activity in an experimental inoculation medium.

The agency finds that these references demonstrate that in laboratory (in vitro) experimental testing, ichthammol and sulfur possess certain properties that might make them useful in certain inflammatory and bacteriological conditions. However, the references submitted did not contain any human clinical studies on the use of ichthammol and sulfur for the treatment of boils. Thus, the references do not contain adequate data to establish that ichthammol and sulfur are safe and effective in the treatment of boils. The agency notes that, after the initial submission was made, the comment subsequently stated that triclosan at 0.35 percent does not have proven effectiveness as an antimicrobial (Ref. 5). The agency concludes that data from well-controlled human clinical studies are necessary to demonstrate the safety and efficacy of ichthammol, sulfur, or triclosan as antimicrobials useful for the treatment of boils. Likewise, clinical data are also needed to support any combination of ichthammol, sulfur, or triclosan with benzocaine.

References

(1) Comment No. C4, Docket No. 82N–0054, Dockets Management Branch.

(2) Kownatzki, E., S. Urich, and E. Schopf, "The Effect of a Sulfonated Shale Oil Extract (Ichthyol) on the Migration of Human Neutrophilic Granulocytes *in vitro*," Archives of Dermatological Research, 276:235–239, 1984, in Comment No. C4, vol. 3, exhibit J, Docket No. 82N–0054, Dockets Management Branch.

(3) Libenson, L. et al., "Antibacterial Effect of Elemental Sulfur," Journal of Infectious Diseases, 93:28–35, 1953, in Comment No. C4, vol. 3, exhibit J, Docket No. 82N–0054, Dockets Management Branch.

(4) Woiwood, A. J., "The Inhibition of Bacterial Growth by Colloidal Heavy Metal Sulphides and by Colloidal Sulphur," Journal of General Microbiology, 10:509–520, 1954, in Comment No. C4, vol. 3, exhibit J, Docket No. 82N–0054, Dockets Management Branch.

(5) Comment No. C5, Docket No. 82N–0054, Dockets Management Branch.

3. The comment urged the agency to consider ichthammol and sulfur as "drawing" agents alone or in combination with benzocaine. The comment submitted a large number of published references on these ingredients (Ref. 1) together with the data on benzocaine (Ref. 2) discussed in comment 1 of section I. of this document.

The agency has reviewed the references and finds they are inadequate to establish the safety and effectiveness of ichthammol or sulfur for use as a drawing agent to treat boils. Five of the references (Refs. 3 through 7) discussed ichthammol and sulfur for various indications when applied topically, but none of the references specifically discussed the use of ichthammol, sulfur, or any ingredient as a "drawing" agent. The creation of an osmotic equilibrium is postulated as the mechanism of action for drawing salves and is discussed in comment 5 of section I. of this document below. In the advance notice of proposed rulemaking on OTC boil ointment drug products, the Panel concluded that drawing salves to treat boils do not have any merit (47 FR 28306 at 28308). The agency concludes that the data submitted are not adequate to support the effectiveness of ichthammol and sulfur as "drawing" agents individually or in combination with benzocaine in treating or in reducing the size of a boil. Data from well-controlled human clinical studies are necessary to demonstrate the safety and effectiveness of ichthammol or sulfur for use as a "drawing" agent in the treatment of boils.

References

(1) Comment No. C4, vol. 3, exhibit J, Docket No. 82N–0054, Dockets Management Branch.

(2) Comment No. C4, Docket No. 82N–0054, Dockets Management Branch.

(3) Kownatzki, E., S. Urich, and E. Schopf, "The Effect of a Sulfonated Shale Oil Extract (Ichthyol) on the Migration of Human Neutrophilic Granulocytes in vitro," Archives of Dermatological Research, 276:235–239, 1984, in Comment No. C4, vol. 3, exhibit J, Docket No. 82N–0054, Dockets Management Branch.

(4) Libenson, L. et al., "Antibacterial Effect of Elemental Sulfur," Journal of Infectious Diseases, 93:28–35, 1953, in Comment No. C4, vol. 3, exhibit J, Docket No. 82N–0054, Dockets Management Branch.

(5) Woiwood, A. J., "The Inhibition of Bacterial Growth by Colloidal Heavy Metal Sulphides and by Colloidal Sulphur," Journal of General Microbiology, 10:509–520, 1954, in Comment No. C4, vol. 3, exhibit J, Docket No. 82N–0054, Dockets Management Branch.

(6) Czarnetzki, B. M., "Inhibitory Effects of Shale Oils (Ichthyols) on the Secretion of Chemotactic Leukotrienes From Human Leukocytes and on Leukocyte Migration," The Journal of Investigative Dermatology, 87:694–697, 1986, in Comment No. C4, vol. 3, exhibit J, Docket No. 82N–0054, Dockets Management Branch.

(7) Combes, F. C., "The Role of Sulfur in Dermatology," New York State Journal of Medicine, 32:1019–1023, 1932, in Comment No. C4, vol. 3, Exhibit J, Docket No. 82N–0054, Dockets Management Branch.

4. The comment noted the agency's statement in the tentative final monograph (53 FR 2198 at 2204) that "the 'drawing' action of ingredients such as magnesium sulfate or ichthammol * * * needs to be shown clinically." The comment stated that, as it understood this statement, clinical proof of any "drawing" action for benzocaine will not be required.

The comment is correct in stating that clinical proof of any "drawing" action for benzocaine is not required. No claim as a "drawing" agent has been attributed to benzocaine. Thus, the statement in the tentative final monograph on "drawing" action of ingredients such as magnesium sulfate or ichthammol did not include benzocaine. However, if a claim for "drawing" action were to be made for benzocaine, then clinical proof would be required.

5. The comment contended that magnesium sulfate and ichthammol in a boil ointment formula contribute to a "drawing" action. The comment suggested that such an action "is related to the osmotic equilibrium created at the site of application, i.e., the high fluid level of the boil versus the high solids level of the formula." The comment maintained that over a period of time and as the boil increases in fluid volume, this fluid will favor the salve formula and a decrease in boil volume will result. The comment reasoned that the "drawing" action results because the magnesium sulfate and ichthammol upset the equilibrium between the fluid

in the boil and the formula containing these and other base ingredients on the surface outside the boil.

The agency acknowledges the comment's contention and theory concerning a "drawing" action for magnesium sulfate and ichthammol. However, the comment did not submit adequate effectiveness data to support a "drawing" action for magnesium sulfate or ichthammol in the treatment of boils. The agency reviewed and evaluated the comment's submitted literature references (see comment 3 of section I. of this document) and found those references inadequate to support the effectiveness of any ingredient as a "drawing" agent.

II. The Agency's Final Conclusions on OTC Boil Treatment Drug Products

At this time, there is a lack of data from adequate and well-controlled, double-blind studies to establish that benzocaine, ichthammol, magnesium sulfate, sulfur, triclosan, or any other ingredients are effective to treat or reduce the size of boils. The agency has determined that no active ingredient has been found to be generally recognized as safe and effective for this OTC use. Treatment is defined as reducing the size of a boil or reducing an infection related to a boil. Treatment has involved the use of "drawing salves" for these purposes. These "drawing salves" contained various ingredients.

In the **Federal Register** of November 7, 1990 (55 FR 46914), the agency published a final rule in part 310 establishing that certain active ingredients that had been under consideration in a number of OTC drug rulemaking proceedings were not generally recognized as safe and effective. That final rule was effective on May 7, 1991, and included in § 310.545(a)(5) the following ingredients that had been previously considered under this rulemaking for use in the treatment of boils: Aminoacridine hydrochloride, bismuth subnitrate, calomel, camphor, cholesterol, ergot fluidextract, hexachlorophene, isobutamben, juniper tar, lanolin, magnesium sulfate, menthol, methyl salicylate, oxyguinoline sulfate, petrolatum, phenol, pine tar, rosin, rosin cerate, sassafras oil, thymol, and zinc oxide. The final rule in this document establishes that any OTC boil treatment drug product is not generally recognized as safe and effective and expands the nonmonograph ingredients to include all other active ingredients for the treatment of boils, such as benzocaine, ichthammol, sulfur, and triclosan. Therefore, any ingredient that is labeled, represented, or promoted for OTC use for the treatment of boils is considered nonmonograph and misbranded under section 502 of the act and is a new drug under section 201(p) of the act for which an approved application under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 of the regulations is required for marketing. In appropriate circumstances, a citizen petition to establish a monograph may be submitted under 21 CFR 10.30 in lieu of an application. Any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce after the effective date of this final rule that is not in compliance with the regulation is subject to regulatory action. In order to avoid duplication in listing OTC boil treatment active ingredients in more than one regulation and for ease in locating these ingredients in the Code of Federal Regulations, the agency is listing all of these ingredients in a single regulation in new § 310.531 entitled "Drug products containing active ingredients offered over-the-counter (OTC) for the treatment of boils." Accordingly, the ingredients currently listed in § 310.545(a)(5) are now being listed in § 310.531(d), and § 310.545(a)(5) is being removed. The additional ingredients covered by this final rule are being listed in § 310.531(e). This final rule does not apply to OTC drug products that contain benzocaine and that are labeled for the temporary relief of itch, pain, and discomfort of boils. The agency is deferring that use of benzocaine to the rulemaking on OTC external analgesic drug products. A paragraph is included in new § 310.531 to indicate that section does not apply to drug products that contain benzocaine labeled, represented, or promoted for OTC topical use with such external analgesic claims.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (53 FR 2198 at 2205). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC boil treatment drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC boil treatment drug products is not expected to pose such an impact on small businesses because only a limited number of products are affected. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

2. Section 310.531 is added to subpart E to read as follows:

§ 310.531 Drug products containing active ingredients offered over-the-counter (OTC) for the treatment of boils.

(a) Aminacrine hydrochloride, benzocaine, bismuth subnitrate, calomel, camphor, cholesterol, ergot fluid extract, hexachlorophene, ichthammol, isobutamben, juniper tar (oil of cade), lanolin, magnesium sulfate, menthol, methyl salicylate, oxyguinoline sulfate, petrolatum, phenol, pine tar, rosin, rosin cerate,

sassafras oil, sulfur, thymol, triclosan, and zinc oxide have been present in OTC boil treatment drug products. There is a lack of adequate data to establish general recognition of the safety and effectiveness of these or any other ingredient for OTC use for the treatment of boils. Treatment is defined as reducing the size of a boil or reducing an infection related to a boil. Treatment has involved the use of "drawing salves" for these purposes. These "drawing salves" contained various ingredients. Based on evidence currently available, any OTC drug product offered for the treatment of boils cannot be considered generally recognized as safe and effective.

(b) Any OTC drug product that is labeled, represented, or promoted for the treatment of boils is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act), for which an approved application or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any OTC boil treatment drug product is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) After May 7, 1991, any such OTC drug product that contains aminacrine hydrochloride, bismuth subnitrate, calomel, camphor, cholesterol, ergot fluid extract, hexachlorophene, isobutamben, juniper tar (oil of cade), lanolin, magnesium sulfate, menthol, methyl salicylate, oxyguinoline sulfate, petrolatum, phenol, pine tar, rosin, rosin cerate, sassafras oil, thymol, or zinc oxide initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

(e) After May 16, 1994, any such OTC drug product that contains benzocaine, ichthammol, sulfur, or triclosan initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

(f) This section does not apply to drug products that contain benzocaine labeled, represented, or promoted for OTC topical use in accordance with part 348 of this chapter.

§ 310.545 [Amended]

3. Section 310.545 *Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses* is amended by removing and reserving paragraph (a)(5).

Dated: November 8, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–27917 Filed 11–12–93; 8:45 am]

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federal register

Monday
November 15, 1993

Part VIII

Environmental Protection Agency

40 CFR Part 192
Health and Environmental Standards for Uranium and Thorium Mill Tailings; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 192

[FRL–4797–8]

Health and Environmental Standards for Uranium and Thorium Mill Tailings

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is amending its general environmental regulations pertaining to uranium mill tailings disposal sites pursuant to the Uranium Mill Tailings Radiation Control Act (UMTRCA) of 1978. The amendments clarify the current rule by ensuring timely emplacement of a permanent radon barrier and by requiring appropriate monitoring for nonoperational uranium mill tailings disposal sites that are licensed by the Nuclear Regulatory Commission (NRC) or one of its Agreement States (affected Agreement States). These affected Agreement States are Colorado, Washington, and Texas, which are the states that license sites to manage uranium byproduct materials pursuant to the Atomic Energy Act (AEA). This action is related to another action by EPA to rescind its National Emissions Standard for Hazardous Air Pollutants (NESHAPs) for radon emissions from the disposal of uranium mill tailings at nonoperational sites which was promulgated on December 15, 1989, as it applies to sites licensed by the NRC or an affected Agreement State.

DATES: Effective Date: January 14, 1994.

FOR FURTHER INFORMATION CONTACT: Gale C. Bonanno, Air Standards and Economics Branch (6602J), Criteria and Standards Division, Office of Radiation and Indoor Air, Environmental Protection Agency, Washington, DC 20460, (202) 233–9219.

SUPPLEMENTAL INFORMATION:

Docket

Docket A–91–67 contains the rulemaking record. The docket is available for public inspection between the hours of 8 a.m. and 4 p.m., Monday through Friday, in room M1500 of Waterside Mall, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

Table of Contents

I. History of Regulation of Uranium Mill Tailings

A. Description of Uranium Mill Tailings

Uranium mill tailings are sand-like wastes that result from the processing of uranium ore. Tailings are stored in large surface impoundments, called piles, in amounts from less than one million tons to over thirty million tons, over areas that may cover hundreds of acres. Most piles are located in the Western United States and all piles emit radon gas, a decay product of the waste material processed at the uranium mills.

To deal specifically with the risks associated with these piles, Congress passed the Uranium Mill Tailings Radiation Control Act (UMTRCA) in 1978 (42 U.S.C. 2022, 7901–7942). In enacting UMTRCA, Congress found that uranium mill tailings may pose a potential and significant radiation health hazard to the public, and that every reasonable effort should be made to provide for the stabilization, disposal, and control in a safe and environmentally sound manner of such tailings in order to prevent or minimize radon diffusion into the environment and to prevent or minimize other environmental hazards from such tailings. See 42 U.S.C. 7901(a). Under UMTRCA, two programs were established to protect public health and the environment from the hazards associated with uranium mill tailings. One program (Title I) required the Department of Energy (DOE) to conduct the necessary remedial actions at designated inactive uranium mill tailing sites to achieve compliance with the general environmental standards to be promulgated by EPA. These sites were generally abandoned uranium processing sites for which a license issued by the NRC or its predecessor, the Atomic Energy Commission (AEC), was not in effect on January 1, 1978.

The other program (Title II) pertained to active sites, which are those that are licensed by the NRC or an affected Agreement State. Requirements for licensed sites include the final disposal of tailings, including the control of radon after milling operations cease. UMTRCA also required that EPA promulgate standards for these licensed sites, including standards that protect human health and the environment in a manner consistent with standards established under Subtitle C of the Solid Waste Disposal Act, as amended. The NRC, or the licensing Agreement State, is responsible for implementing the EPA standards at licensed uranium milling sites.

As part of NRC's 1982 authorization and appropriations, Congress amended UMTRCA on January 4, 1983. Public Law 97–415, sections 18(a) and 22(b), *reprinted in* 2 1982 U.S. Code Cong. & Admin. News at 96 Stat. 2077 and 2080. As partially amended thereby, EPA was required to promulgate standards of general applicability for the protection of the public health, safety, and the environment from radiological and nonradiological hazards associated with the processing and with the possession, transfer, and disposal of byproduct material, e.g., uranium mill tailings. Requirements established by the NRC with respect to byproduct material must conform to the EPA standards. Any requirements of such standards adopted by the NRC shall be amended as the NRC deems necessary to conform to EPA's standards. In establishing such standards, the Administrator was to consider the risk to the public health, safety, and the environment, the environmental and economic costs of applying such standards, and such other factors as the Administrator determines to be appropriate. See 42 U.S.C. 2022(b)(1).

B. EPA and NRC's UMTRCA Rulemakings

EPA is authorized to promulgate generally applicable environmental standards to govern the remediation process. 42 U.S.C. 2022(a) and 7918 (as to DOE sites); 42 U.S.C. 2014 and 2022(b) (as to NRC-licensed sites). On January 5, 1983, EPA promulgated final rules for the disposal and cleanup of the inactive uranium mill tailings sites under UMTRCA Title I (48 FR 605).

Title I requires the Department of Energy (DOE) to conduct remedial action at inactive uranium mill tailings sites to ensure compliance with EPA's regulations for properly managing uranium byproduct materials. The program for inactive sites requires the disposal of tailings and the clean-up of on-site locations contaminated with tailings. DOE is responsible for implementing the standards established by EPA, with the concurrence of the NRC, and in cooperation with the host states. The requirements developed to implement the Title I program are not the subject of today's rulemaking.

On April 29, 1983, EPA proposed standards for Title II uranium and thorium mill tailings sites (48 FR 19584). These rules were promulgated on September 30, 1983 (48 FR 45926), and are codified at 40 CFR part 192, subparts D and E. Title II applies to currently operating uranium mill tailings facilities licensed by the NRC or an Agreement State. The Title II program established requirements for the final disposal of tailings, the control of effluents into ground water, and radon emissions[1] during and after milling operations. The requirements are divided into two parts. The first part applies to the management of tailings during the active life of the pile and during the subsequent closure period, which begins after cessation of milling operations but prior to completion of final disposal, including the period of time when the tailings are drying out. The second part of the requirements specifies the standards that must be met once the piles are closed. These standards govern the design of disposal systems, and therefore guide the activities carried out during the closure period to ensure the adequacy of the final cover. For NRC licensed mill tailings sites that are being closed, subpart D calls for reclamation plans designed to control radon emissions to a flux not to exceed an average release rate of 20 pCi/m^2-s for 1000 years to the extent reasonably achievable, but in any event for at least 200 years. 40 CFR 192.32(b)(1) (i) and (ii).

Both the UMTRCA Title I and Title II standards were challenged by several parties in the Tenth Circuit Court of Appeals. On September 3, 1985, the court upheld all aspects of EPA's standards, excepting the ground water provisions of the Title I regulations at 40 CFR 192.20(a) (2)–(3). *American Mining Congress* v. *Thomas*, 772 F.2d 617 (10th Cir. 1985), *cert. denied* 426 U.S. 1158 (1986). On September 24, 1987, EPA proposed new regulations to replace those set aside (40 CFR part 192, subpart C, 52 FR 36000). The final action for that rulemaking is pending and is not affected by today's action.

On October 16, 1985, NRC promulgated rules at 10 CFR part 40 to conform the previous NRC regulations issued five years earlier to the provisions of EPA's general UMTRCA standards at 40 CFR part 192, as it affected matters other than ground water protection (50 FR 41852). On November 13, 1987, NRC promulgated final rules for ground water protection at uranium mill tailings sites that conformed to provisions of EPA's standards for ground water protection at 40 CFR part 192, subparts D and E (52 FR 43553).

Under the NRC regulations, uranium milling operations that process or dispose of uranium and thorium, and their byproduct materials, must apply to the NRC for a license. In its application for an NRC license, the owner or operator of the mill must demonstrate the expected compliance with the technical, financial, ownership and long-term surveillance requirements of NRC's implementing regulations during the siting and construction of the mill, its operation, the decontamination and decommissioning of the mill after operations cease, and the reclamation of the milling facility and its surrounding environs. In accordance with 10 CFR 40.41(e), the NRC may incorporate in any license or later amend the license to include additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of source or byproduct material as it deems appropriate or necessary to protect health or to minimize danger of life or property.

C. EPA's Clean Air Act Rulemaking

Both the UMTRCA standards promulgated by EPA in 1983 and the implementing NRC standards promulgated in 1985, failed to require or otherwise establish compliance schedules to ensure that the tailings piles would be expeditiously closed, and that the 20 pCi/m^2-s standard would be met, within a reasonable period of time. Moreover, the NRC criteria also failed to require monitoring to verify compliance with the flux standard (50 FR 41852). In response to the separate requirements of the Clean Air Act, and in light of the shortcomings of the current UMTRCA program for NRC-licensed uranium mill tailings sites, EPA promulgated standards under the Clean Air Act to ensure that the piles would be closed in a timely manner. These NESHAPs were published on December 15, 1989 (54 FR 51654) codified at 40 CFR part 61, subpart T (nonoperational) and subpart W (operational).

The NESHAP for nonoperational uranium mill tailings, codified at 40 CFR part 61, subpart T, applies to both Title I and Title II sites. The standard has three primary requirements. First, it imposes an emission limit of 20 pCi/m^2-s of radon-222 from a disposed pile, consistent with the UMTRCA standard. Second, it requires that, once a uranium mill tailings pile or impoundment ceases to be operational, it must be disposed of and brought into compliance with the emission limit within two years of the effective date of the standard (by December 15, 1991) or within two years of the day it ceases to be operational, whichever is later. If it was not physically possible for a mill owner or operator to complete disposal within that time, EPA contemplated a negotiated compliance agreement with the mill owner or operator pursuant to EPA's enforcement authority to assure that disposal will be completed as quickly as possible. Third, it requires monitoring of the disposed pile to demonstrate compliance with the radon emission limit.

As noted earlier, the numerical radon emission limit, is the same as the UMTRCA standard at 40 CFR part 192, subpart D (subpart D) (although under UMTRCA, the limit is to be met through proper design of the disposal impoundment, and is to be implemented by DOE and NRC for the individual sites, while under the CAA, the standard is an emissions limit with compliance established through monitoring). However, the two year disposal requirement and the radon monitoring requirement are not separately required by the existing UMTRCA regulations.

II. Challenge to Subpart T

A. Petitions for Reconsideration

After promulgating subpart T, EPA received petitions for reconsideration filed by NRC, the American Mining Congress (AMC), Homestake Mining Co. Among other concerns set forth in these petitions is the argument that the overlap between EPA's subpart D of the UMTRCA regulations and subpart T of the CAA NESHAP has resulted in regulations that are unnecessarily burdensome and duplicative. It was also alleged that subpart T was unlawful because it was physically impossible to come into compliance with subpart T in the time required. While these petitions remain pending before EPA (at least in

[1] The term "release" is used in 40 CFR Part 192 subpart D. EPA intends "release" as used in today's amendments to subpart D and this rulemaking to mean "emission" as that term is used in 40 CFR part 61 subpart T.

part), EPA has taken several actions to address the issues they raise.

B. Section 112(d)(9) of the Clean Air Act Amendments of 1990 (the "Simpson Amendment")

In November 1990, Congress amended the CAA and included a new section, section 112(d)(9), which authorized EPA to decline to regulate radionuclide emissions from NRC-licensees under the CAA provided that EPA found, by rule, after consultation with NRC, that the regulatory scheme implemented by NRC protects the public health with an ample margin of safety. Today's action is needed to assist EPA in making the "Simpson Amendment" finding for NRC-licensed uranium mill tailings disposal sites, as it seeks to fill the timing gaps and other concerns that underlie EPA's 1989 decision to promulgate subpart T.

C. Memorandum of Understanding Between EPA and NRC

In July of 1991, EPA, NRC and the affected Agreement States entered into discussions over the dual regulatory programs established under UMTRCA and the CAA. In October 1991, those discussions resulted in a Memorandum of Understanding (MOU) between EPA, NRC and the Agreement States which outlines the steps each party will take to both eliminate regulatory redundancy and to ensure uranium mill tailings piles are closed as expeditiously as practicable. See 56 FR 55434 (MOU reproduced as part of proposal to stay subpart T); see also 56 FR 67537 (final rule to stay subpart T). The primary purpose of the MOU is to ensure that owners of uranium mill tailings disposal sites that have ceased operation, and owners of sites that will cease operation in the future, bring those piles into compliance with the 20 pCi/m²-s flux standard as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee) with the goal that all current disposal sites be closed and in compliance with the radon emission standard by the end of 1997, or within seven years of the date on which existing operations and standby sites enter disposal status. This goal comports with Congress' concern over timing as reflected in CAA section 112(i)(3), as amended.

In accordance with the MOU, the NRC and affected Agreement States have agreed to amend the licenses of all sites whose milling operations have ceased and whose tailings piles remain partially or totally uncovered. The amended licenses would require each mill operator to establish a detailed tailings closure plan for radon to include key closure milestones and a schedule for timely emplacement of a permanent radon barrier on all nonoperational tailings impoundments to ensure that radon emissions do not exceed a flux of 20 pCi/m²-s.

D. Current Regulatory Proceedings

On December 31, 1991, EPA took several steps towards fulfilling its responsibilities under the MOU and in implementing the "Simpson Amendment" by publishing three **Federal Register** (FR) notices. In the first notice (56 FR 67537), EPA published a final rule to stay the effectiveness of 40 CFR part 61, subpart T, as it applies to owners and operators of nonoperational uranium mill tailings disposal sites. The stay will remain in effect until the Agency rescinds the uranium mill tailings NESHAP at 40 CFR part 61, subpart T, and amends the UMTRCA standards at 40 CFR part 192 to ensure that the remaining rules are as protective of public health with an ample margin of safety, as would implementation of the CAA rule being rescinded. If EPA fails to complete these rulemakings by June 30, 1994, the stay will expire and the requirements of subpart T will become effective.

In a second notice published on December 31, 1991, the Agency proposed to rescind the NESHAPs for radionuclides that appear at 40 CFR part 61, subpart T, as they apply to nonoperational uranium mill tailings disposal sites licensed by the NRC or an Agreement State (56 FR 67561).

In the third notice, EPA published an advanced notice of proposed rulemaking to amend 40 CFR part 192, subpart D (56 FR 67569) to provide for site closure to occur as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee), and appropriate monitoring requirements for nonoperational uranium mill tailings piles. These amendments would ensure timely compliance and add monitoring requirements currently lacking in the UMTRCA regulations.

EPA has tentatively concluded that with today's modifications to the general UMTRCA regulations, as properly implemented by the NRC and the Agreement States to ensure specific, enforceable closure deadlines and monitoring requirements, the NRC's regulatory program for nonoperational uranium mill tailings piles would protect the public health with an ample margin of safety. However, prior to finalizing its rule to rescind subpart T, after NRC conforms its regulations to the UMTRCA rules as modified, and all nonoperational site licenses are modified in accordance therewith, EPA currently intends to propose a finding in the **Federal Register** and provide an additional 30 day comment period on whether the NRC regulatory program protects public health with an ample margin of safety. After this occurs, EPA is likely to take final action on its proposal to rescind 40 CFR part 61, subpart T.

Consistent with their responsibilities under the MOU, as well as EPA's proposal to rescind the NESHAP at 40 CFR part 61, subpart T, NRC and the affected Agreement States have agreed to amend the licenses of all nonoperational uranium mill tailings sites to ensure inclusion of schedules for emplacing a permanent radon barrier on the tailings impoundments, as well as interim milestones. To this end, NRC and the Agreement States have already requested the licensees to voluntarily seek amended licenses and have processed those requests. Moreover, NRC and the affected Agreement States have agreed to enforce the provisions of the amended licenses to ensure compliance with the new schedules for emplacing a permanent radon barrier, including interim milestones, and to ensure (and verify) compliance with the 20 pCi/m² – s flux standard.

III. Legal Basis For This Action

A. Statutory Authority for Today's Action

1. Emphasis Upon Expeditious Radon Control

The crux of this action is additional regulatory means to ensure expeditious and permanent control of radon emissions from uranium mill tailings piles after active milling operations have ceased. The importance of timeliness is inherent to UMTRCA. It is evidenced by Congress' action in amending UMTRCA to require prompt EPA rulemaking action, and by the actual terms of Title II. It is also evidenced by the legislative history for Title II, contained in UMTRCA's two-part House Report, which confirms UMTRCA's purpose to require expeditious public health protection. See H. Rep. 95–1480(I) (Aug. 11, 1978) ("HR 1") (Interior and Insular Affairs Committee) and H. Rep. 95–1480(II) (Sept. 30, 1978) ("HR 2") (Interstate and Foreign Commerce Committee), reprinted in 6 1978 U.S. Code Cong. & Admin. News at 7433–7478 (UMTRCA passed the House on October 14, 1978, and was signed into law on Nov. 8, 1978).

Both parts of the House Report mirror UMTRCA's statutory language by: (1)

Making clear that UMTRCA is primarily directed to health risks associated with radon-222 releases into the environment from uranium mill tailings disposal; and (2) calling for "every reasonable effort . . . to provide for the disposal, stabilization and control in a safe and environmentally sound manner of such (uranium mill) tailings." HR 1 at 11, HR 2 at 25; HR 1 at 13. Expeditious control of disposed tailings was paramount. At Title I sites, DOE (in consultation with EPA, NRC and the host State) was required to quickly remediate disposed tailings sites "in accord with necessity for reducing the most threatening hazards first." HR 1 at 15. The same expeditiousness was expected of title II disposal sites, which should "in all cases be controlled and regulated by States and the Commission, to the maximum extent allowed by the state of the art, to insure that the public and the environment will be protected from the hazards from the tailings for as long as they remain a hazard." Id. at 17–18. To further underscore the urgent purpose, the Report states:

> The committee is convinced that *all* tailings pose a potential and significant radiation health hazard to the public. Legislation is needed *now* to stabilize and control all such tailings in a safe and environmentally sound manner and to minimize or eliminate radiation health hazards to the public. . . .
>
> The committee, however, is also convinced that it would be a grievous and costly mistake to authorize a remedial program for inactive mill sites without also enacting regulatory legislation to control the *even more serious problem at active (i.e., Title II) mill sites.*

HR 2 at 29 (emphasis added).

This intent is implemented by provisions in title II. For instance, NRC implements EPA's general standards for title II through licensing of active tailings sites, which licenses must be timely modified to conform to environmental standards. NRC licenses issued or renewed after enactment of UMTRCA must contain the terms and conditions which the NRC determines to be necessary to assure that, prior to termination of the license the licensee will comply with decontamination, decommissioning, and reclamation standards prescribed by the NRC consistent with EPA's general standards. Any license in effect on the enactment date of 42 U.S.C. 2113(a) must either contain the terms and conditions of renewal, or comply with paragraphs (1) and (2) of section 2113(a) upon the termination of the license, whichever first occurs. See 42 U.S.C. 2113(a). This provision, which went into effect upon enactment, meant that Congress expected action at each title II site within three, or at the most five years of enactment:

> For each licensee, such period (for implementing UMTRCA requirements) would be 3 years following enactment, or until the time at which the licensee's license would first be required to be renewed, whichever is the longer period * * *. In no case may such grace period be longer than 5 years following enactment of (UMTRCA).

HR 1 at 22; see also Id. at 23 (authorizing immediate expenditures by DOE and NRC on remediation).

Moreover, while timely implementation of Title II could financially or otherwise burden licensees, rather than delay implementation, Congress recognized these burdens and instructed NRC to take such hardships into account. H. Rep. No. 95–1480(I) at 44. While NRC was provided some authority to reasonably implement EPA's regulations on a site-by-site basis, it was assumed that in general the regulations would be implemented expeditiously.

The statute placed deadlines upon EPA, NRC and the Agreement States to promulgate and conform their respective regulations. See 42 U.S.C. 2021 and 2022. As noted above, EPA delay in promulgating standards led to UMTRCA's amendment in 1983, which added language requiring that EPA promulgate final Title II standards by October 1983 or lose the right to do so. 42 U.S.C. 2022(b) (as amended by Pub. L. 97–415); see H. Conf. Rep. No. 97–884 at 44–45, reprinted in 4 1982 U.S. Code Cong. & Admin. News at 3614–15 (expressing concern over EPA delay and emphasizing the importance of timeliness).

During the time period for NRC to conform its regulations to EPA's, NRC is not expected to "suspend the implementation or enforcement of its regulations." H. Conf. Rep. No. 97–884 at 45. Congress further made clear its view that UMTRCA implementation proceed immediately, going so far as to note that for title I sites "the '7-year clock' for the completion of cleanup . . . begins to run (for DOE) October 1, 1982." Id. As to title II sites, during the transition period for EPA to propose and promulgate regulations (and although its rules would be suspended during that period) "NRC is authorized to take such action as it may deem necessary, on a licensee-by-licensee basis, to protect public health, safety, and the environment." Id. at 47.

Thus, the legislative scheme is one of urgency. EPA is to promptly promulgate regulations that will promptly be implemented at each site through licensing by NRC. Radon emissions are identified as the primary threat to public health, and all tailings are to be controlled without exception.

In its February 1983 proposal for the existing UMTRCA rules, EPA took note of the January 1983 amendments to UMTRCA calling for EPA to promulgate rules or lose its authority to do so: "WE (sic) are therefore proceeding to establish these standards expeditiously." 48 FR 19585. EPA noted that of the 27 licensed uranium mills, only 16 were operating, 8 had recently closed, and others had been closed for some time. *Id.* EPA mirrored Congress in referencing radon emissions as the primary source of public health risk from these sites, and noted that radon emissions rates are currently at their peak. *Id.* EPA then listed the panoply of existing guidance materials, including the ALARA principle (that radiation exposure be limited to a level "as low as reasonably achievable"), and proposed that its UMTRCA standards "supplement" the existing guidance in a manner that

> (1) take(s) account of the tradeoffs between health, safety, and environmental and economic costs and benefits in a way that assures adequate protection of the public health, safety, and the environment; (2) can be implemented using *presently available techniques and measuring instruments;* and (3) are reasonable in terms of overall costs and benefits.

Id. at 19587 (emphasis added). In soliciting comment, EPA explicitly stated that it "*assumed (a) 15-year operating and 5-year dry-out*" period, and that the Agency was concerned about potentially significant risks to public health during those periods. *Id.* at 19600. Taken together—by basing its regulations on "presently available" means, and by expressing concern over the transition periods—EPA was assuming that compliance would occur expeditiously, without delay. While EPA recognized that there would be some lag in time before final closure could occur (i.e., to allow the tailings to dry), EPA certainly was not contemplating a period of additional or indefinite delay between ceased operations and final closure.

These purposes and assumptions were further augmented by EPA in taking final action on the rules. In listing the major provisions, EPA stated that the rule "(4) (r)equires that disposal of uranium mill tailings piles be designed so that, after disposal, radon emissions will be limited to 20 (pCi/m^2 – s)." 48 FR 45927. The tone is one of immediacy, suggesting that the requirements will apply as soon as possible, without any more delay than is necessary to implement the design

standard. This is emphasized by EPA noting the danger of lung cancer from inhaling radon emissions, a danger that exists as much today as it will later in time. *Id.* at 45928:

> Tailings pose a present hazard to human health. Beyond this *immediate* but generally limited health threat, the tailings are vulnerable to human misuse and to dispersal by natural forces for an essentially indefinite period.

Thus, EPA acted to immediately limit the present hazards and immediately halt hazards in the future by requiring that final closure expeditiously occur following ceased operations.

2. UMTRCA's Scheme and Purposes are Consistent With Today's Action Which Clarifies and Better Implements EPA's Existing Regulations

Today's action is intended to fill gaps and otherwise clarify EPA's existing regulations in order to ensure the expeditious, effective, and permanent control of radon emissions. By making minor amendments to EPA's existing regulations to explicitly require emplacement of a radon barrier as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee), interim milestones towards emplacement, and monitoring to assure that the design of the radon barrier is effective, EPA is better fulfilling Congress' purposes in enacting UMTRCA for Title II sites. As set forth above, Congress quite clearly was seeking, through UMTRCA, to protect public health from the dangers associated with radon emissions, both today and into the future, and has taken measures to require that EPA and the implementing agencies (DOE and NRC) do so expeditiously. Nothing in today's action is intended to modify the essential purposes or the essential aspects of the existing regulatory scheme; rather, EPA intends to better fulfill Congress' mandates by clarifying the existing requirements.

In promulgating the 1983 regulations, EPA intended and expected expeditious progress towards radon control once an active site ceased milling operations. EPA "assumed . . . (a) 5-year dry-out" period after milling operations had ceased, and based its regulations on that assumption. EPA did not, however, explicitly mandate a set period for drying out, in part due to the variable circumstances at each site, and also because expeditiousness was implicit to regulatory and statutory schemes, viewed as a whole.

Today's action does not seek to change EPA's rationale or scheme set forth in its 1983 rule. Rather, through minor amendments, it seeks to clarify and supplement that scheme in a manner that will better support its initial intent. Without setting forth mandatory schedules, EPA generally requires that once a site becomes nonoperational (i.e., when final closure begins), a barrier to control radon will be emplaced as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee). Interim milestones towards emplacement will support and better assure this progress, and post-emplacement monitoring will serve as confirmation that the design of the cover is working as intended.

B. Interpretive Caselaw

Judicial review of EPA's and NRC's regulations has resulted in several written opinions by the United States Court of Appeals for the 10th Circuit. Those opinions interpret UMTRCA in much the same manner as does EPA—radon control is paramount, and Congress intends that EPA and NRC promulgate regulations to protect public health in a manner that has immediate and long lasting effect. More particularly, with exception only as to matters not at issue today, the courts upheld EPA's and NRC's regulations, including the agencies' consideration of costs and benefits.

It is worthwhile to review the four opinions interpreting UMTRCA: (1) *American Mining Congress* v. *Thomas*, 772 F.2d 617 (10th Cir. 1985) ("*AMC I*") (addressing EPA's UMTRCA inactive site regulations); (2) *AMC* v. *Thomas*, 772 F.2d 640 (10th Cir. 1985) ("*AMC II*") (addressing EPA's UMTRCA active site regulations); (3) *Quivira Mining Co.* v. *NRC*, 902 F.2d 781 (10th Cir. 1989) (addressing NRC's implementing criteria); and (4) *AMC* v. *NRC*, 902 F.2d 781 (10th Cir. 1990) ("*AMC III*") (addressing amendments to NRC's implementing criteria).

1. AMC I and AMC II

The inactive site regulations at issue in *AMC I* are codified at 40 CFR part 192, subparts A-C; the active site regulations at issue in *AMC II* are codified at 40 CFR part 192, subpart D, and are the subject of this action. Stated generally, the court in *AMC I* upheld EPA's inactive site regulations under UMTRCA, except as regards a failure to adopt provisions to protect surface and groundwater. The court in *AMC II* likewise upheld EPA's active site regulations (including the groundwater protection provisions), and in so doing relied upon the extensive statutory interpretation set forth in *AMC I*.

The court in *AMC I* began its analysis with UMTRCA's statutory purposes and structure, quoting the Congressional findings at 42 U.S.C. 7901(a) (set forth above). 772 F.2d. at 621. The court also noted that the 1982 UMTRCA amendments meant that Congress strongly desired that the public health protection regulations quickly go into effect: "Anxious to institute standards for the mill tailings, Congress also provided that should the EPA miss the extended deadline, remedial action would commence using the proposed standards." *Id.* at 623 (citations omitted).

The court addressed the contention that a prerequisite to any regulations is that EPA find that uranium mill tailings present a significant risk to public health. *Id.* at 627. The court disagreed, finding that Congress had already spoken strongly on this issue:

> It would be disingenuous to hold, after reading Congress' own statement of its findings and purposes, that the EPA must make its own determination of whether radon emissions present a risk significant to warrant regulation under the UMTRCA.

Id. The court also reviewed the legislative history, and concluded that "Congress chose to consider protecting future generations by enacting the UMTRCA and requiring the *immediate stabilization and disposal of those tailings.*" *Id.* (emphasis added).

After dispensing with other less pertinent issues, the court then addressed EPA's consideration of costs and benefits. In drawing a middle course between cost-benefit "optimization" (advanced by industry), and feasibility analysis (advanced by environmental groups), the court determined only that "EPA must consider the costs involved in the regulations and, with the guidance of Congress' intent, find that these costs bear a reasonable relationship to the benefits derived." *Id.* at 632.

In *AMC II*, the court applied its analysis to the subpart D active site regulations (that EPA is today clarifying and otherwise amending). 772 F.2d at 643. The court upheld EPA's regulations in their entirety, commenting that even though EPA's cost estimates were "significant" (if accurate), "Congress placed the responsibility for evaluating them upon the EPA without imposing a specific cost-benefit requirement." *Id.* at 646.

2. Quivira Mining and AMC III

The *Quivira Mining* case involved industry challenges to NRC's 1985 UMTRCA criteria, which conform their 1980 criteria to EPA's UMTRCA regulations for active sites as

promulgated in 1983 and upheld in *AMC I* and *AMC II*, discussed above (the underlying EPA regulations are the subject of this action). Industry primarily argued that NRC had failed to properly consider costs and benefits in promulgating its 1985 criteria. 866 F.2d at 1249. The court disagreed and upheld NRC's 1985 criteria, finding that NRC's consideration of costs in its 1980 rulemaking, coupled with EPA's consideration of costs in its 1983 active site rulemaking, adequately fulfilled the relatively deferential "cost-benefit rationalization" required by UMTRCA. *Id.* at 1250, 1257–58.

Regarding NRC's reliance upon EPA's earlier consideration of costs, the court acknowledged ambiguity as to whether UMTRCA requires that NRC consider costs "anew." *Id.* at 1257. The court resolved the ambiguity in favor of NRC, deferring to the agency's reasonable construction: "It is a permissible construction of the 'due consideration' command for the NRC to accept the EPA cost-benefit analysis for the revised criteria." *Id.* at 1258.

The court in *AMC III* addressed renewed industry challenges, this time to 1987 amendments to NRC's UMTRCA criteria. 902 F.2d at 782. Among other things, industry again pressed its argument that NRC had failed to adequately consider costs and benefits under UMTRCA. *Id.* at 783. And again the court held that because EPA had properly considered costs and benefits in 1983, "NRC performed its due consideration obligation here when it conformed to the EPA's regulations it was required to adopt." *Id.* at 784.

3. Caselaw Supports This Action

The judicial interpretations set forth above are relevant to this action in two ways: (1) The *AMC I* and *AMC II* decisions affirm Congress' strong interest in the expeditious control of radon at active (i.e., NRC-licensed) uranium mill tailing disposal sites; and (2) the *Quivira Mining* and *AMC III* decisions set forth the scope of cost-benefit considerations, including the propriety of relying upon earlier efforts to the extent the regulations are not charting a new course.

This action is directed at clarifying and better effecting EPA's intent in promulgating the 1983 rules that there not be any undue delay in controlling radon emissions once a disposal site ceases milling operations. The regulatory language, including interim milestones of progress towards control and monitoring provisions, fulfill Congress' intent regarding expeditious public health protection, and are intended to better implement EPA's 1983 rules.

EPA has duly considered costs in its draft Background Information Document (BID) which addresses EPA's consideration of costs and benefits. Few if any additional costs will be incurred by site owners or operators as a result of this final action, since timely radon control has always been required. Moreover, the cost analysis which EPA conducted for its 1983 rulemaking remains relevant, since today's action encompasses amendments to the UMTRCA regulations to clarify and enhance implementation of the fundamental regulatory scheme contained in EPA's 1983 UMTRCA rules.

C. The Settlement Agreement

Two additional items further explain the legal basis and rationale for today's final action: (1) Clean Air Act section 112 (including EPA rulemaking thereunder), and (2) a litigation settlement agreement thereunder, recently entered into by EPA and the affected industry and environmental groups.

In response to the risks associated with litigation, in light of the Simpson Amendment and in order to foster a consensus approach to regulation in this area, EPA commenced discussions with NRC, the American Mining Congress ("AMC"), Homestake Mining Co., the Environmental Defense Fund ("EDF") and the Natural Resources Defense Counsel ("NRDC"). Each has a direct interest in the matter, all but NRC had challenged EPA's promulgation and/or stay of subpart T and collectively, they had historically found little common ground in this area.

As a result (and as discussed above), in October 1991, a Memorandum of Understanding ("MOU") was signed by EPA and NRC setting forth the outline to a regulatory approach that would best resolve the differences between EPA and NRC. As contemplated by the MOU, on December 31, 1991, EPA took final action to stay and propose rescission of subpart T under section 112(d)(9), and to issue an advance notice of proposed rulemaking under UMTRCA. See 55 FR 67537, 67561 and 67569. In order to preserve its rights, EDF filed a lawsuit challenging the legality of the stay. *EDF v. Reilly*, No. 92–1082 (D.C. Cir.). Litigation had previously been filed by EDF, NRDC, AMC, Homestake and others, challenging subpart T. *AMC, et al. v. EPA*, Nos. 90–1058, 90–1063, 90–1068, and 90–1074 (D.C. Cir.). NRC, AMC and Homestake had also filed an administrative petition for reconsideration of subpart T.

Discussions continued with the litigants and NRC, and in February 1993, final agreement was reached to settle the pending litigation and the administrative proceeding, avoid potential future litigation, and otherwise agree to a consensus approach to regulations of NRC-licensed nonoperational uranium mill tailings disposal sites. See 58 FR 17230 (April 1, 1993) (notice announcing settlement agreement under CAA section 113(g)). A copy of the settlement agreement is also in the docket to this action.

The settlement agreement adds comprehensive detail to, and thereby continues, the approach set forth in the MOU. If implemented, the agreement will result in the expeditious control of radon-222 emissions at nonoperational uranium mill tailings disposal sites without the delays and resource expenditures engendered by litigation and contentious administrative process. It will enable EPA to fulfill the requirement of section 112 (d)(9) that EPA find, by rule, that the NRC regulatory program protects public health with an ample margin of safety. It does this, in part, by changing EPA's UMTRCA regulations such that public health will be as well protected under UMTRCA as would implementation of subpart T under the CAA.

Under the agreement, the pending litigation will not be dismissed until after certain terms in the agreement are fulfilled. Moreover, the agreement does not legally bind or otherwise restrict EPA's rights or obligations under law; rather, by its terms (paragraph 12), there is no recourse for a court order to implement the agreement. Indeed, the only remedy for failure to meet the terms of the final agreement is activation of the underlying litigation.

This action is consistent with the settlement agreement. By clarifying and filling gaps in EPA's UMTRCA regulations, EPA may, after the other elements in the settlement agreement are also implemented, be able to make the finding necessary to rescind subpart T under section 112(d)(9). If properly implemented, a unified regulatory scheme under UMTRCA has the advantage of avoiding confusing and unnecessarily duplicative regulation, while also protecting public health with an ample margin of safety.

IV. Amendments to 40 CFR Part 192, Subpart D

A. Limited Scope

Today's amendments to the general UMTRCA regulations for nonoperational uranium mill tailings disposal sites at 40 CFR part 192,

subpart D (subpart D) fill specific regulatory gaps that currently exist in subpart D. While subpart D, as currently written, requires eventual compliance with the 20 pCi/m²-s flux standard, it does not mandate that compliance occur by a specific date. Rather, as promulgated by EPA under subpart D and implemented by NRC pursuant to its regulations at 10 CFR part 40, appendix A, a title II site licensed by NRC or an Agreement State, could indefinitely continue to emit radon at the same numerical emission limit as allowed under the CAA. It was this possibility which compelled EPA to promulgate subpart T under CAA section 112. In addition, the current UMTRCA regulations call for an impoundment design that will likely achieve compliance with the 20 pCi/m²-s flux standard for 1000, or at least 200 years, but they do not include any requirement that monitoring occur to verify the efficacy of the design. This action also fills this gap.

The amendments are not intended to substantively alter the current regulatory scheme; instead, they are merely intended to fill regulatory gaps with respect to timely compliance and appropriate monitoring. Once these gaps are filled by today's amendments and are implemented by NRC, EPA may then have the basis for rescinding subpart T, thereby avoiding unnecessarily duplicative and burdensome regulation.

The Agency's finding, pursuant to section 112(d)(9) of the Clean Air Act Amendments of 1990, that NRC's regulatory program protects the public health with an ample margin of safety must include a finding that NRC and the affected Agreement States are implementing and enforcing, in significant part, the regulations governing disposal of tailings and the operating license requirements that establish milestones for emplacement of a permanent radon barrier that will achieve compliance with the 20 pCi/m²-s flux standard on a programmatic and a site-specific basis. The Agency intends "in significant part" to mean that the Agency must find that NRC or an affected Agreement State has not failed to implement and enforce the requirements in a manner that may reasonably be expected to materially (i.e., more than de minimis) interfere with compliance with the 20 pCi/m²-s standard as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee).

EPA is also amending subpart E of 40 CFR part 192 to avoid any inference that today's minor amendments to subpart D also apply to subpart E. EPA is only addressing timing and monitoring requirements in subpart D, and amending subpart E only for clarification. EPA's subpart D timing and monitoring requirements at §§ 192.32(a)(3)(i–v) and 192.32(4)(i–ii) apply only to uranium mill tailings. Since subpart E references the subpart D standards at § 192.41, EPA believes it necessary to amend subpart E by adding § 192.41(e). This amendment is intended only to clarify that the amendments do not apply to subpart E sites, and is not intended to alter the present regulatory scheme. EPA does not intend by this minor amendment to subpart E to make a finding that the amendments to subpart D are not suitable for management of thorium byproduct material. EPA is not precluded from addressing these issues at a later time for management of thorium byproduct material.

B. Closure Requirements

EPA is amending 40 CFR part 192, subpart D to require (1) emplacement of a permanent radon barrier constructed to achieve compliance with, including attainment of, the 20 pCi/m²-s flux standard by all sites that, absent rescission, would be subject to subpart T; (2) interim milestones to assure appropriate progress in emplacing the final radon barrier; and (3) that site closure occur as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee) after the impoundments cease operation, with a goal that this occur by December 31, 1997, for those nonoperational uranium mill tailings piles listed in the MOU between EPA and NRC (at 56 FR 67568), or seven years after the date on which the impoundments cease operation for all other piles.

EPA recognizes that the UMTRCA regulatory scheme encompasses a design standard. EPA is making minor amendments to this scheme to better facilitate implementation of the regulation without fundamentally altering the current method of compliance. Sites are required to construct a permanent radon barrier pursuant to a design to achieve compliance with the 20 pCi/m²-s flux standard. The new requirement for verifying the flux with monitoring is only meant to assure the efficacy of the design of the permanent radon barrier following construction and is not intended to relieve licensees of other existing requirements.

Site control shall be carried out in accordance with a written tailings closure plan (radon), and in a manner which ensures that closure activities are initiated as expeditiously as practicable considering technological feasibility (including factors beyond the control of licensees). The tailings closure plan (radon), either as originally written or subsequently amended, will be incorporated into the individual site licenses, including provisions for and amendments to the milestones for control, after NRC or an affected Agreement State finds that the schedule reflects compliance as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee). Under the Settlement Agreement, which NRC has agreed in principle to uphold, such finding will constitute final agency action. The compliance schedules are to be developed consistent with the targets set forth in the MOU as reasonably applied to the specific circumstances of each site with a goal that final closure occur by December 31, 1997, for those nonoperational uranium mill tailings piles listed in the MOU between EPA and NRC (at 56 FR 67568), or seven years after the date on which the impoundments cease operation for all other piles. These schedules must include key closure milestones and other milestones which are reasonably calculated to promote timely compliance with the 20 pCi/m²-s flux standard. The phrase "milestones" refers to enforceable dates by which action, or the occurrence of an event, is required for purposes of achieving compliance with the 20 pCi/m²-s flux standard.

Milestones which are not reasonably calculated to advance timely compliance with the radon air emissions standard, e.g. installation of erosion protection and groundwater corrective actions, are not relevant to the (radon) tailings closure plans. In addition, today's final regulations will require that licensees ensure that radon closure milestone activities, such as wind blown tailings retrieval and placement on the pile, interim stabilization (including dewatering or the removal of freestanding liquids and recontouring), and radon barrier construction, are constructed and undertaken to achieve compliance with, including attainment of, the 20 pCi/m²-s flux standard as expeditiously as practicable considering technological feasibility.

The goal of this regulation is for existing sites, or those that become nonoperational in the future, to achieve compliance as expeditiously as practicable considering technological feasibility (including factors beyond the control of licensees) within the time periods set forth in the MOU, including

Attachment A thereto, and for new sites to achieve compliance no later than seven years after becoming nonoperational. However, if the NRC or an Agreement State makes a finding that compliance with the 20 pCi/m²-s flux standard has been demonstrated through appropriate monitoring, and after providing an opportunity for public participation, the performance of the milestone(s) may be extended. Only under this circumstance and during the period of the extension must compliance with the 20 pCi/m²-s flux standard be demonstrated each year. Additionally, licensees may request, based upon cost, that the final compliance date for emplacement of the permanent radon barrier, or relevant milestone set forth in the applicable license or incorporated in the (radon) tailings closure plan, be extended. The NRC or an affected Agreement State may approve such a request if it finds, after providing the opportunity for public participation, that (1) the licensee is making good faith efforts to emplace a permanent radon barrier constructed to achieve the 20 pCi/m²-s flux standard; (2) such delay is consistent with the definition of "available technology;" and (3) such delay will not result in radon emissions that are determined to result in significant incremental risk to the public health. Such a finding should be accompanied by new deadlines which reasonably correspond to the target dates identified in Attachment A of the MOU. (56 FR 67569)

NRC may grant an extension of time to comply with either of the following deadlines: (1) "Performance of milestones" based upon a finding that compliance with the 20 pCi/m²-s flux standard has been met, or (2) "Final compliance" beyond the date or relevant milestone based upon cost. These two bases upon which NRC may grant an extension are mutually exclusive, that is a request for a specific extension may be based on one or the other but not both grounds. If a milestone is being extended for a basis other than cost, such an extension may be granted if NRC finds that compliance with the 20 pCi/m²-s flux standard has been demonstrated using EPA Method 115 or an NRC approved alternative, and the site must continue to demonstrate compliance on an annual basis. However, if a licensee requests extension of the final compliance date (or relevant milestone) based upon cost, such an extension may only be granted if NRC finds that the three criteria specified in § 192.32(a)(3)(iii) are met. EPA believes this interpretation is consistent with the reality of annual risks from radon emissions, as well as the risks associated with allowing sites to fail to close within the two year period specified in subpart T through negotiated compliance agreements.

Any extensions of the final compliance date based upon cost will be granted on a site-specific basis. If a licensee requests an extension based upon cost, technology may not be used as a basis for granting the extension unless the costs are grossly excessive, as measured by normal practice within the industry. EPA recognizes that the emissions from the pile may exceed the 20 pCi/m²-s flux standard pending final compliance, but believes these increases will be minimal and of limited duration. In addition, such extensions will only be granted if NRC or an Agreement State finds that the emissions caused by the delay will not cause significant incremental risk to the public health. EPA believes these emissions should not exceed those emissions which could occur under subpart T if compliance agreements were negotiated. Under the circumstances, EPA believes affording authority for extensions of the final compliance date based upon cost provides adequate protection of the public health.

EPA expects the NRC and Agreement States to act consistently with their commitment in the MOU and provide for public participation on proposals or requests to (1) incorporate radon tailings closure plans or other schedules for effecting emplacement of a permanent radon barrier into licenses, and (2) amend the radon tailings closure schedules as necessary or appropriate for reasons of technological feasibility (including factors beyond the control of the licensees). Under the terms of the MOU, NRC should do so with notice timely published in the **Federal Register**. In addition, consistent with the MOU, application may be made to NRC for public participation on these matters pursuant to 10 CFR 2.206. EPA also expects the Agreement States to provide comparable opportunities for public participation pursuant to their existing authorities. While EPA desires to keep the public informed and provide for public participation, such provisions are not intended to transform the licensing (and amendment) process into notice and comment rulemaking in accordance with Administrative Procedure Act (APA) requirements.

Under the existing regulatory scheme, NRC and the affected Agreement States may have the authority to allow, at a licensee's request, a portion of a site to remain accessible, during the closure process to accept byproduct material as defined in section 11(e)(2) of the AEA, (e.g., wastes from in situ mining operations, or from groundwater corrective action programs), or to accept materials from other sources that are similar to the physical, chemical and radiological characteristics of the in situ uranium mill tailings and associated wastes. In addition, NRC and the affected Agreement States may authorize a portion of a site to remain accessible to accept section 11(e)(2) byproduct material after placement of a permanent radon barrier over a portion of a pile or impoundment. Nothing in today's action alters, ratifies, or otherwise affects this authority. However, EPA notes that, consistent with the MOU and the Settlement Agreement, such authorization shall not to be used as a method to impede emplacement of the permanent radon barrier over the remainder of the site in a manner to achieve compliance with the 20 pCi/m²-s flux standard, averaged over the entire pile or impoundment as demonstrated by the licensee's monitoring described below.

EPA does not intend to substantively alter the 1983 scheme with today's action, but instead seeks to clarify and supplement that scheme to fill a regulatory gap which currently exists. By acknowledging NRC's apparent authority to allow a portion of a site to remain accessible for disposal, EPA is acknowledging a current NRC practice. EPA believes that placement of "materials similar to the physical, chemical and radiological characteristics of uranium mill tailings and associated wastes from other sources" on a portion of an impoundment is consistent with on-going disposal activities currently authorized by NRC. See 57 FR 20525. For instance, mining uranium by using uranium solution extraction processes produces "discrete (radioactive) surface wastes" which, although they do not have the same physical form as uranium mill tailings, have historically been disposed of in uranium mill tailings impoundments. See Definition of "Byproduct Material" at 10 CFR 40.4(a–1). In addition to wastes from in situ uranium mining operations and groundwater corrective actions, wastes which arise from processing non-source material for its source material content may produce wastes which are physically and chemically similar to tailings, and may be disposed of in a tailings impoundment. For instance, the tailings produced from processing ore for its copper content may produce tailings containing greater than 0.05 percent uranium, a source material, and thus, would be subject to licensure by the

NRC. See 57 FR at 20527. EPA understands that NRC's disposal of associated wastes and other byproduct materials in uranium mill tailings impoundments will not be used as a means of circumventing other applicable regulations such as 40 CFR Part 61, subpart W. See 57 FR at 20533. Moreover, while NRC may grant such authorization, licensees may not use this authorization to avoid emplacing a permanent radon barrier and complying with the 20 pCi/m²-s flux standard. In addition, under the Settlement Agreement NRC or an Agreement State may authorize a portion of a site to remain accessible for disposal of byproduct material after placement of a permanent radon barrier provided NRC or the Agreement State makes a finding, constituting final agency action and providing for public participation, that the site will continue to achieve the 20 pCi/m²-s flux standard when averaged over the entire impoundment. Even if a portion of a site is authorized to remain accessible for disposal of byproduct materials during the closure process or after placement of a permanent barrier consistent with the Settlement Agreement, as described above, this will not cause a nonoperational uranium mill tailings disposal site to revert to an operational site as defined by 40 CFR 192.31(q).

As intended by EPA, the phrase "as expeditiously as practicable considering technological feasibility," means as quickly as possible considering: (1) The physical characteristics of the tailings and sites; (2) The limits of available technology; (3) the need for consistency with mandatory requirements of other regulatory programs; and (4) factors beyond the control of the licensee, as explained below. While this phrase does not preclude economic considerations to the extent provided by the phrase "available technology," it also does not contemplate utilization of a cost-benefit analysis in setting compliance schedules. The radon control compliance schedules are to be developed consistent with the targets set forth in the MOU as reasonably applied to the specific circumstances of each site.

EPA has added an additional definition in the final rule to clarify ambiguities surrounding use of the term "permanent radon barrier." That term is now defined as "the final radon barrier constructed to achieve compliance with, including attainment of, the limit on releases of radon-222 in § 192.32(b)(1)(ii)."

The term "available technology" includes technologies and methods for emplacing a permanent radon barrier on nonoperational uranium mill tailings disposal sites, but does not include extraordinary measures or techniques that would impose grossly excessive costs as measured by practice within the industry (or one that is reasonably analogous), and provided there is reasonable progress towards emplacement of the permanent radon barrier (such as, by way of illustration only, unreasonable overtime, staffing or transportation requirements, etc. considering normal practice in the industry; laser fusion of soils, etc.). To determine whether costs are grossly excessive, the closure cost estimate contained within the licensee's (radon) tailings closure plan may be used as a baseline. However, costs which are determined to be greater than the estimated costs contained in the plan will not automatically be considered grossly excessive.

The phrase "factors beyond the control of the licensee" includes factors causing delay in the schedule in the applicable license for timely emplacement of the permanent radon barrier to achieve compliance with the 20 pCi/m²-s flux standard (and 10 CFR part 40, appendix A, criteria 6) despite the good faith efforts of the licensee to achieve compliance. These factors may include, but are not limited to, physical conditions at the site; inclement weather or climatic conditions; an act of God; an act of war; a judicial or administrative order or decision, or change to the statutory, regulatory, or other legal requirements applicable to the licensee's facility that would preclude or delay the performance of activities required for compliance; labor disturbances; any modifications, cessation or delay ordered by state, federal or local agencies; delays beyond the time reasonably required in obtaining necessary governmental permits, licenses, approvals or consent for activities described in the (radon) tailings closure plan proposed by the licensee that result from agency failure to take final action after the licensee has made a good faith, timely effort to submit legally sufficient applications, responses to requests (including relevant data requested by the agencies), or other information, including approval of the tailings closure plan by NRC or the affected Agreement State; and an act or omission of any third party over whom the licensee has no control.

The term "operational" means that a uranium mill tailings pile or impoundment is being used for the continued placement of uranium byproduct material or is in standby status for such placement. A tailings pile or impoundment is operational from the day that uranium byproduct material is first placed in the pile or impoundment until the day final closure begins. When final closure begins a site is no longer in operation as that term is defined in 40 CFR 61.251(e) and 40 CFR 61 subpart W no longer applies. The closure plan contains a description of how final closure will be conducted. See 40 CFR 264.111.

C. Appropriate Monitoring

After emplacement of a permanent radon barrier designed and constructed to achieve compliance with, including attainment of, the 20 pCi/m²-s flux standard, the licensee shall conduct appropriate monitoring and analysis of the radon flux through the barrier. This monitoring will verify that the design of the permanent radon barrier is effective in ensuring that emissions of radon-222 will not exceed compliance with the 20 pCi/m²-s, as contemplated by 40 CFR 192.32(b)(1)(ii). Appropriate monitoring shall be conducted pursuant to the procedures described in 40 CFR part 61, appendix B, method 115, or any other measurement method proposed by a licensee and approved by NRC or the affected Agreement State as being at least as effective as EPA Method 115 in demonstrating the effectiveness of the permanent radon barrier in achieving compliance with the 20 pCi/m²-s flux standard.

EPA intends that the permanent radon barrier be designed to ensure sustained compliance with the 20 pCi/m²-s flux standard by all sites, but does not propose continuous emissions monitoring. Rather, a single monitoring event may well suffice to verify the design of the permanent radon barrier to ensure continued compliance.

If the NRC or an Agreement State extends the time for performance of milestones after making a finding that compliance with the 20 pCi/m²-s flux standard has been demonstrated by appropriate monitoring, compliance with the 20 pCi/m²-s flux standard must be demonstrated each year during the period of the extension.

When a site's tailings closure plan (radon) provides for phased installation of the radon barrier, the licensee will be allowed to conduct radon flux monitoring for each portion of the tailings area on which the radon barrier has been placed by conducting flux monitoring on the closed portion as described above.

V. Discussion of Comments and Response to Comments From NPR

A public hearing on the notice of proposed rulemaking (NPR) (58 FR

32174, June 8, 1993) was held in Arlington, Virginia on June 21, 1993. Representatives from NRC and AMC testified at the hearing. Written comments were also received from EDF, AMC, NRC, the Texas Water Commission (affected Agreement State), a few companies and an individual. To the extent they are specifically restricted to EPA's modifications to its UMTRCA regulations, the comments have been evaluated by the Agency, and a summary and response are set forth below. Some comments, not addressed here, are directed to EPA's earlier promulgation of subpart T, a rulemaking decision that is not being revisited by the amendments to subpart D. EPA responded to many of those comments when the Agency promulgated subpart T. The comments have also been repeated in subsequent petitions to reconsider that action, which are pending before the Agency. These petitions might be addressed or otherwise resolved should 40 CFR part 61, subpart T be rescinded.

1. General

In response to the NPR, environmental groups and industry generally support the proposed amendments to the regulations promulgated under UMTRCA at 40 CFR part 192 subpart D. Various commenters suggested specific revisions to the proposed regulation and preamble, as well as to the draft Background Information Document (BID). EPA has carefully reviewed all comments and suggested revisions; revising the regulation, preamble and BID where deemed appropriate.

2. Section 112(d)(9) of the Clean Air Act, as Amended ("Simpson Amendment")

Comment: The Simpson Amendment "mandates" EPA to eliminate duplicative regulation under the Clean Air Act if the NRC regulatory program adequately protects the public health.

Response: EPA disagrees with the commenters' assertion that the Simpson Amendment is mandatory. The Simpson Amendment, section 112(d)(9) of the CAA, authorizes EPA to decline to regulate radionuclide emissions from facilities licensed by the NRC or Agreement States, under section 112 of the CAA, provided that EPA determines, by rule, after consultation with NRC, that the regulatory scheme implemented by NRC protects the public health with an ample margin of safety.

3. NRC Regulatory Scheme

Comment: The existing NRC regulatory program protects the public health with an ample margin of safety and provides sufficient basis for EPA to rescind 40 CFR 61 subpart T pursuant to the Simpson Amendment; specifically, EPA's timing and monitoring concerns, the subject of these amendments, are adequately addressed in NRC's regulations at 10 CFR part 40 and Appendix A thereto. The Memorandum of Understanding (MOU) between EPA and NRC merely serves to strengthen NRC's authority under the existing regulatory program.

Response: EPA is conducting a separate rulemaking on the issue of rescission of the CAA radionuclide NESHAP at 40 CFR 61 subpart T, and the adequacy of the existing NRC regulatory program as a basis for such rescission will be addressed in that rulemaking. For a discussion of EPA's view on whether the current NRC regulatory program protects the public health with an ample margin of safety, and would thus support rescission of subpart T, see EPA's proposal to rescind subpart T, 56 FR 67561 (December 31, 1991). Comments on the adequacy of the current NRC regulatory program to support rescission of subpart T will be addressed in that rulemaking, and are not relevant to the regulatory changes adopted today.

EPA does not believe that NRC's current regulations at 10 CFR part 40 and appendix A of part 40 adequately address EPA's concerns on timing and monitoring. Both EPA's UMTRCA regulations (40 CFR part 192 subpart D) and NRC's implementing regulations did not require placement of covers by specific dates or verification that radon flux through the covers met the flux standard. These issues led to EPA's promulgation of the CAA NESHAP at 40 CFR part 61 subpart T. EPA promulgated subpart T in 1989 to address the timing issue and provide for verification of the 20 pCi/m^2-s flux standard, noting that "(S)ome piles have remained uncovered for decades emitting radon. (A)lthough recent action has been taken to move toward disposal of these piles, some of them may still remain uncovered for years" (54 FR 51683, December 15, 1989).

Although commenters suggest that 10 CFR 40.63, and 10 CFR 40.42(c)(2) (iv), (i), and (iii) adequately address EPA's timing and monitoring concerns, neither EPA's general standards nor NRC's implementing criteria compel sites to proceed toward final closure by a certain date. Moreover, neither EPA's general UMTRCA regulations, nor NRC's implementing criteria require appropriate monitoring to demonstrate the efficacy of the closure design to ensure compliance with the 20 pCi/m^2-s standard. In fact, as indicated in footnote 1 to 40 CFR 192.32(b)(1) promulgated in September 1983, the flux standard was expressly intended as a design standard, for which monitoring after installation was not required. (48 FR 45947, October 7, 1983). Thus, EPA believes that the UMTRCA standards should be amended to include timing requirements and a provision to confirm that the radon flux through the cover meets the flux standard.

Comment: It appears EPA is acknowledging and concurring in NRC's regulation of "similar byproduct material."

Response: EPA is recognizing a current NRC practice that allows a portion of a site to remain accessible for disposal in the preamble of the NPR. EPA believes that placement of "materials similar to the physical, chemical and radiological characteristics of uranium mill tailings and associated wastes from other sources" on a portion of an impoundment is consistent with on-going disposal activities currently authorized by NRC. See 57 FR 20525. Nothing in today's action is intended to ratify, alter or otherwise affect this authority.

4. EPA's Legal Rationale for the Proposed Amendments

Comment: Some commenters claim that EPA's discussion of the legislative scheme mischaracterizes the potential problem involved. These commenters objected to use of terms such as "urgency" and "immediacy," as there was no significant increase in public health risk without long term exposure to radon emissions at the levels projected.

Response: The commenter misunderstands the Agency's discussion of the legislative scheme. As described in the proposal, Congress placed great emphasis on expeditious action by EPA to impose controls on the disposal of the uranium mill tailings. This is reflected most dramatically in Congress' decision to remove EPA's authority to issue standards under 42 U.S.C. 2022(b) if EPA failed to promulgate final title II standards by the end of October 1983. In addition, Congress was clearly concerned that EPA standards lead to the expeditious control of radon emissions from uranium mill tailings piles. The relevant case law reflects this interpretation of the statute. See section III supra for a more detailed discussion of these points.

Congress believed that uranium mill tailings presented a major threat to public health, based on the extremely long radioactive decay process

associated with these piles. They amounted for all practical purposes to a "perpetual hazard." H. Rep. No. 95–1480, 95th Cong., 2nd Sess. 11, reprinted in 1978 U.S. Code Cong. & Ad. News 7433. Given the long term nature of the problem, and the prior history of minimal federal regulation of mill tailings piles, Congress required that "every reasonable effort be made by the States, the Federal Government, and private industry to provide for the disposal, stabilization, and control" of such mill tailings. H. Rep. No. 95–1480, 95th Cong., 2nd Sess. 13, reprinted in 1978 U.S. Code Cong. & Ad. News 7435. The regulatory changes adopted today are in line with this goal—they will require the control of radon emissions through expeditious emplacement of a permanent barrier. Today's regulations implement Congressional intent, and in no way contradicts the fact that uranium mill tailings present a long term threat to the public health.

5. Rescission of Subpart T

Comment: A few commenters expressed concern and suggested that EPA is not committed to rescinding subpart T.

Response: The amendments to subpart D are related to EPA's action to rescind subpart T, the NESHAP for radon emissions from the disposal of uranium mill tailings at nonoperational sites which was promulgated on December 15, 1989, as applied to NRC-licensees. EPA has demonstrated its commitment to avoid duplicative regulation of these sites and to ensure uranium mill tailings disposal piles are closed as expeditiously as practicable by executing the MOU with NRC (and the affected Agreement States) and the settlement agreement with EDF, NRDC, AMC, and Homestake Mining Co. The MOU and the settlement agreement provide the regulatory approach for this action. EPA has also proposed rescission of subpart T. See 56 FR 67561 (December 31, 1991).

EPA believes that today's amendments eliminate an existing deficiency in the regulatory scheme, and may enable EPA to rescind subpart T, providing a single consistent framework which can be implemented by NRC. EPA has tentatively concluded that the amendments to subpart D, if effectively implemented and enforced by NRC and the Agreement States to ensure specific enforceable closure deadlines and monitoring requirements, may enable EPA to make the finding required by the Simpson Amendment. EPA reiterates its commitment to the terms of the MOU and the settlement agreement.

Comment: EPA should rescind subpart T simultaneously with today's action.

Response: EPA is not rescinding subpart T with today's action. EPA is not prepared at this time to make the finding pursuant to the Simpson Amendment that the public health is protected with an ample margin of safety at this time. EPA does not intend to take final action on the proposed rescission of subpart T until after NRC and the Agreement States complete the license amendments as specified in the MOU and NRC conforms its implementing regulations to today's amendments to subpart D, and other conditions of the MOU occur. EPA plans to publish an additional notice in the **Federal Register** and provide for a 30 day comment period on whether the NRC regulatory program protects public health with an ample margin of safety, including whether: (1) EPA has effectively promulgated appropriate revisions to 40 CFR part 192, subpart D; (2) NRC's regulations at 10 CFR part 40, appendix A, either already adequately and appropriately implement the revisions to EPA's regulations, or may reasonably be expected to do so prior to rescission of subpart T; (3) the revision of NRC and Agreement State licenses reflect these new requirements; and (4) any judicial challenge to EPA or NRC regulations which is pending that presents a significant risk of interference with full compliance with the MOU and the settlement agreement.

6. Settlement Agreement

Comment: The regulatory program for nonoperational uranium mill tailings sites is best served by EPA adopting the proposed regulations to the extent the proposal is consistent with the settlement agreement executed between EPA, EDF, NRDC, AMC, Homestake Mining Co., and individual site owners (NRC agreed in principle by letter).

Response: The agreement adds comprehensive detail to, and continues the approach set forth in the MOU executed between EPA and NRC in October 1991. The settlement agreement settles the pending litigation and administrative proceeding, avoids potential future litigation, and otherwise provides a consensus approach to regulation of NRC-licensed nonoperational uranium mill tailings disposal sites. See 58 FR 17230 (April 1, 1993).

EPA believes this action is consistent with the settlement agreement. By clarifying and filling gaps in EPA's UMTRCA regulations, EPA may, after the other elements in the settlement agreement are also implemented, be able to make the finding necessary to rescind subpart T under the Simpson Amendment. The agreement does not legally bind or otherwise restrict EPA's rights or obligations under law; rather, by its terms (paragraph 12), there is no recourse for a court order to implement the agreement.

Comment: Proposed rule § 192.32(a)(3)(ii) which addresses the extension of performance milestones and the final compliance date based on cost is confusing because it combines two separate provisions of the settlement agreement. The commenter recommends separate sections in the regulation to clarify any confusion surrounding this provision. The commenter also interpreted proposed § 192.32(a)(3)(ii) such that a site need not meet the 20 pCi/m²-s standard in all cases before any extension of either interim or final deadlines may be granted by NRC or an Agreement State.

Response: EPA agrees with the commenter that § 192.32(a)(3)(ii) as proposed is confusing because it combines the two separate instances in which extensions of milestones may be granted by the NRC or an Agreement State. EPA has revised the final regulation to incorporate the extension provisions in two separate paragraphs in § 192.32(a)(3) (ii) and (iii), to more fully reflect the intent of the settlement agreement described above.

EPA generally agrees with the commenter's interpretation of § 192(a)(3) (ii) and (iii) that a site need not satisfy the 20 pCi/m²-s standard in all cases before NRC or an Agreement State may approve any extension of the interim milestone or the final closure date. Section 192(a)(3) (ii) and (iii) are based upon the regulatory approach set forth in settlement agreement paragraphs III.2.i. and III.2.j., and they establish the criteria for granting an extension when a site meets the 20 pCi/m²-s standard and the criteria for an extension of the final compliance date or relevant milestone based upon cost. The criteria for an extension based upon cost does not include the requirement that the site meet the 20 pCi/m2-s standard. However, it does include other criteria designed to protect the public health.

The commenter also noted that NRC or an Agreement State may extend the date for emplacement of the radon barrier based on "factors beyond the control of the licensee," as that term is implicit in the definition of "as expeditiously as possible." EPA understands that under subpart D's provisions there is no bar to NRC or an Agreement State reconsidering a prior decision establishing a date for

emplacement of the radon barrier that meets the standard of "as expeditiously as possible." Such reconsideration could, for example, be based on the existence of factors beyond the control of the licensee, or on a change in any of the various factors that must be considered in establishing a date that meets the "as expeditious as practicable" standard of § 192.32(a)(3)(i). However EPA stresses that such a change in circumstances would not automatically lead to an extension. It would be incumbent on NRC or an Agreement State to evaluate all the factors relevant under § 192.32(a)(3)(i) before it could change a previously established milestone or date for emplacement of the final barrier, and any new date would have to meet the standard set out in § 192.32(a)(3)(i). Finally, NRC's and Agreement States' authority to reconsider previously established milestones or dates would include authority to shorten or speed up such dates, as well as extend them. EPA also expects that public participation consistent with that level of participation provided in the MOU and the settlement agreement will be afforded the public by NRC and the Agreement States in amending the licenses due to "factors beyond the control of the licensee," or for any other basis.

7. Proposed Amendments

7.1. Prescriptiveness of Proposed Amendments

Comment: One commenter suggested that EPA's amendments were more prescriptive than they should be given EPA's authority to promulgate general environmental standards. Specifically, the details of particular licensing processes should be left to the NRC and Agreement States.

Response: The regulations adopted today are within EPA's UMTRCA authority, and do not impermissibly infringe on NRC and the Agreement States.

As spelled out by Congress when it amended the Atomic Energy Act in 1978, EPA "shall, by rule, . . . promulgate . . . standards of general application for the protection of the public health, safety, and the environment" from hazards associated with uranium mill tailings at active processing or disposal sites. 42 U.S.C. 2022(b)(1).[2] Congress also required that the NRC conform its requirements to these standards, 42 U.S.C. 2022(b)(1), and assigned responsibility for the implementation and enforce-ment of EPA's UMTRCA standards to the NRC, in the licensing activities, and to the Agreement States. 42 U.S.C. 2022(e). The text of the statute thus indicates that Congress intended to grant broad, general authority to EPA in setting standards under UMTRCA, limited only by the requirement that they be of "general application" and that they be aimed at the "protection of the public health, safety, and the environment."

The legislative history for UMTRCA provides important additional insight into Congressional intent on the limits of this standard setting authority, stemming from the assignment of different responsibilities to EPA and the NRC. Congress intended that EPA's "standards and criteria should not interject any detailed or site-specific requirements for management, technology or engineering methods on licensee or on the Department of Energy." See H.Rep. No. 95–1480, 95th Cong., 2nd Sess. 17, reprinted in 1978 U.S. Code Cong. & Ad. News 7433, 7439. Also see the House Report at 46, 1978 U.S. Code Cong. & Ad. News 7473 ("The committee stresses that the EPA standards are not to be site-specific"). From this, it is clear that EPA is to establish criteria or standards that are generally applicable, but should not promulgate requirements that dictate the specific management, technology, or engineering methods required at specific sites.

Viewing EPA's authority in this light, the revisions to subpart D promulgated herein clearly fall within the range of standards authorized by Congress. They are not site-specific, and instead apply to any and all sites subject to subpart D. The regulations define when a permanent radon barrier has to be placed on the site, and require appropriate monitoring. A written plan detailing the steps for closure in compliance with these standards is to be incorporated into the individual site license, including a schedule for key closure milestone activities. The regulations also set out the criteria for extensions of these milestones. None of these requirements are site specific, and they do not dictate the management, technology, or engineering methods required for any specific site.

The revisions adopted herein do provide for site-specific variability in their application. For example, in implementing the standard of "as expeditiously as practicable considering technological feasibility," EPA expects that different sites will establish different schedules and dates for emplacement of the permanent radon barrier. This site-specific variability, however, does not transform the generally applicable standard into an unlawful site-specific standard. These site-specific results stem from the application of the general standard to the variety of circumstances found at different sites. Likewise, EPA's criteria for an extension of a milestone or for keeping sites open during or after the closure process establish general standards applicable to all sites. While not all licensees are expected to seek such extensions or authority, any such request will be measured against the generally applicable standard in these regulations. The substantive and procedural requirements for such extensions or authorizations are designed to establish generally applicable requirements that EPA believes will best ensure the proper consideration of all relevant factors in acting on such a request.

The relevant case-law supports EPA's belief that it has authority to adopt these standards and criteria. In *AMC I*,[3] the court reviewed among other things a rule allowing exceptions from the general standards for inactive sites. That regulation authorized such exceptions for the implementing agencies so long as the selected remedial action came as close to meeting the otherwise applicable standard as was reasonable under the circumstances. This provision clearly allowed site-specific variability, based on the peculiar circumstances of a site. The court upheld this regulation as generally applicable standards were in place and, if necessary, a court could determine in a specific case whether an exception was reasonable. The court's main concern was whether EPA had promulgated general standards that would apply to a case or had delegated such authority to the implementing agency. It was satisfied that EPA had acted lawfully, as EPA had promulgated a general standard applicable absent an exception, and had promulgated what amounted to a general standard applicable in those limited situations involving exceptions.

In this case, EPA has likewise promulgated a generally applicable standard, along with detailed criteria applicable for those limited circumstances where an exception is sought. EPA's requirements clearly provide an adequate basis for a court to determine, for example, in a specific case whether an extension for emplacement of the permanent radon barrier was properly granted. In fact,

[2] Congress granted similar authority to EPA with respect to inactive sites selected by the Department of Energy under Title I of UMTRCA. 42 U.S.C. 2022(a).

[3] *American Mining Congress* v. *Thomas*, 772 F.2d 617 (10th Cir. 1985) (addressing EPA's UMTRCA regulations for inactive sites).

EPA's general criteria for evaluating such exceptions would appear to be much more like a generally applicable standard than the broad authority for exceptions approved in *AMC I*, and should therefore easily meet the threshold established by that court.

7.2. Seven Year Goal

Comment: The MOU goal specifying closure of nonoperational uranium mill tailings sites by the end of 1997, or within seven years of the date on which existing operations and standby sites enter disposal status is not a regulatory requirement.

Response: The primary purpose of the MOU is to ensure that owners of uranium mill tailings disposal sites that have ceased operation and are not in standby status, and owners of sites that will cease operation in the future, bring those piles into compliance with the 20 pCi/m²-s flux standard as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee). That is the regulatory requirement adopted herein. EPA's and NRC's goal is that all current disposal sites be closed and in compliance with the radon emission standard by the end of 1997, or within seven years of the date on which existing operations and standby sites enter disposal status. EPA believes this regulatory requirement is fully consistent with the goals expressed in the MOU.

In accordance with the MOU, the NRC and affected Agreement States have amended the licenses of most sites whose milling operations have ceased and whose tailings piles remain partially or totally uncovered. Pursuant to the MOU and the regulations adopted today, the amended licenses require each mill operator to establish a detailed tailings closure plan for radon to include key closure milestones and a schedule for timely emplacement of a permanent radon barrier on all nonoperational tailings impoundments to ensure that radon emissions do not exceed a flux of 20 pCi/m²-s.

This action amends 40 CFR part 192, subpart D to require (1) emplacement of a permanent radon barrier by all sites that, absent rescission, would be subject to subpart T; (2) interim milestones to assure appropriate progress in emplacing the final radon barrier; and (3) that site closure occur as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee) after the impoundments cease operation. EPA believes that this regulatory approach is consistent with the goal in the MOU that this occur by December 31, 1997, or seven years after the date on which operating impoundments cease operations.

7.3. Permanent Radon Barrier

Comment: The term "permanent" should be revised to read "final radon barrier" to distinguish the barrier used to comply with the standard from any interim barriers placed during the closure process.

Response: EPA believes the term "permanent radon barrier" to be appropriate. However, to clarify any ambiguities surrounding use of this term, "permanent radon barrier" has been defined to mean "the final radon barrier constructed to achieve compliance with, including attainment of, the limit on releases of radon-222 in § 192.32(b)(1)(ii)."

7.4. Tailings Closure Plan (Radon)

Comment: It is essential that the Tailings Closure Plan (Radon) be incorporated in individual site licenses and that the plan contain a schedule for compliance.

Response: EPA agrees with this comment, and both the proposed and final regulations reflect this requirement. EPA understands that the NRC and affected Agreement States have amended most of the licenses of sites whose milling operations have ceased and whose tailings piles remain partially or totally uncovered pursuant to the MOU executed between EPA, NRC and the affected Agreement States. Pursuant to the MOU and the regulations adopted today, these license amendments should establish a detailed tailings closure plan for radon, including key closure milestones and a schedule for timely emplacement of a permanent radon barrier on all nonoperational tailings impoundments to ensure that radon emissions do not exceed a flux of 20 pCi/m²−s. These schedules must include key closure milestones and other milestones which are reasonably calculated to promote timely compliance with the 20 pCi/m²−s flux standard. The phrase "milestones" refers to enforceable dates by which action, or the occurrence of an event, is required for purposes of achieving compliance with the 20 pCi/m²−s flux standard. Milestones which are not reasonably calculated to advance timely compliance with the radon air emissions standard, e.g. installation of erosion protection and groundwater corrective actions, are not relevant to the tailings closure plans (radon).

7.5. Monitoring

Comment: It is not accurate to refer to a "monitoring" requirement, since a single event is sufficient.

Response: Today's amendments require that monitoring occur after construction of the permanent radon barrier. Subpart T requires monitoring to occur only once to demonstrate compliance with the standard. EPA believes that conducting a single test and analysis of the radon emissions through the radon barrier typically will be sufficient to verify that the design of the permanent radon barrier is effective in ensuring that emissions of radon-222 do not exceed 20 pCi/m²-s as required by § 192.32(b)(1)(ii). Each tailings closure plan (radon) will establish the amount of testing and analysis required.

Comment: The timing of the monitoring requirement is ambiguous. Response: Today's amendments require monitoring to verify the efficacy of the design of the permanent radon barrier upon emplacement of such barrier. The details on timing of the monitoring requirement are left to NRC.

Comment: EPA's specification of Method 115 in the monitoring requirement limits flexibility.

Response: 40 CFR 192.32(a)(4)(i) requires monitoring to be conducted using either EPA Method 115 or any other measurement method proposed by a licensee that NRC approves as being at least as effective as Method 115 in demonstrating the efficacy of the permanent radon barrier. (emphasis added) EPA believes that this regulation does not unduly restrict flexibility as it provides for alternative methods.

Comment: EPA's Method 115 references another document, "Radon Flux Measurements on Gardiner and Royster Phosphogypsum Piles Near Tampa and Mulberry, Florida" (EPA 520/5–85–029), which should be readily available.

Response: This document is available for public inspection and is included in Docket A–91–67 which contains the rulemaking record for this action. The docket is available for public inspection between the hours of 8 a.m. and 4 p.m., Monday through Friday, in room M1500 of Waterside Mall, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

8. Amendment of 40 CFR 192 Subpart E

Comment: In addition to amending subpart D, EPA should amend 40 CFR 192 subpart E to exclude the application of the subpart D amendments to the subpart E requirements for disposal of thorium mill tailings.

Response: EPA agrees and is amending subpart E by adding a new

§ 192.41(e) to clarify EPA's intent that the subpart D timing and monitoring requirements at §§ 192.32(a)(3)(i–v) and 192.32(4)(i–ii) apply only to uranium mill tailings. This amendment is necessary as subpart E references the subpart D standards in 192.41, the only purpose of this amendment is to clarify that the amendments to subpart D do not apply to subpart E sites, and is not intended to alter the present regulatory scheme under subpart E. By amending subpart E, EPA is not making a determination that the timing and monitoring requirements imposed for subpart D sites would be improper for subpart E sites. This rulemaking is only intended to address subpart D sites, and is not intended to make substantive decisions concerning subpart E sites. The amendment to subpart E is designed to do no more than preserve the status quo, without prejudging or prejudicing the appropriateness of any future modifications to subpart E.

9. NRC Waiver Authority and Citizens Suits Provisions

Comment: NRC waiver authority and the lack of citizens suits provisions under UMTRCA provide insufficient basis for EPA to rescind subpart T.

Response: As noted previously, EPA is conducting a separate rulemaking on the issue of rescission of the CAA radionuclide NESHAP at 40 CFR 61 subpart T, and the adequacy of the existing NRC regulatory program as a basis for such rescission will be addressed in that rulemaking. For a discussion of EPA's view on whether the current NRC regulatory program protects the public health with an adequate margin of safety, and would thus support rescission of subpart T, see EPA's proposal to rescind subpart T, 56 FR 67561 (December 31, 1991). Comments on the adequacy of the current NRC regulatory program to support rescission of subpart T will be addressed in that rulemaking, and are not relevant to the regulatory changes adopted today.

10. Technical

10.1. EPA's Risk Analysis Set Forth in the Background Information Document (BID)

Comment: EPA's risk analysis set forth in the BID is flawed because the "potential risk from radon emitted during the two-year period (December 15, 1989—December 15, 1991) cannot be meaningfully compared to potential increased risks from radon emitted until sites are closed according to the dates set forth in the MOU."

Response: The purpose of this rulemaking is to incorporate the timing and monitoring provisions of subpart T into EPA's UMTRCA regulations, thereby potentially providing the basis for eventual rescission of subpart T. It is reasonable to assume the baseline risks and costs are those that would have resulted had the piles been covered by December 15, 1991, pursuant to subpart T. The modeling period used for both the baseline and for covering the piles by the MOU dates is from December 15, 1991 to December 15, 2061. This period does not include the time between promulgation, December 15, 1989, and the date the piles were to be covered, December 15, 1991.

Comment: EPA based its analysis of the health risk posed by uranium mill tailings disposal sites on a number of studies dealing with miners, however, the evaluation of the working level month (WLM) dosimetry for that population is not correct. BEIR IV was not sufficiently critical of the data on which it based its analysis of the risk of inhaling radon daughters, specifically it overestimated the risk to Swedish iron miners, and to the Beaverlodge and Ontario uranium miners.

Response: EPA relied on the National Academy of Sciences' BEIR IV report and the 1987 report by the National Institute for Occupational Safety and Health (NIOSH) in addition to other relevant studies in its risk analysis. Given the broad uncertainty inherent in the risk assessment, any potential overestimate would not change EPA's conclusion on the risk from mill tailings. In fact, the conclusion of one of the studies cited in the comments, a reassessment of the Beaverlodge uranium miners, states: "[u]nless new studies significantly reduce the range of uncertainty, there is little justification for changing the limits for exposure to radon * * * progeny * * * for occupational exposures." *Review of Risk Estimates for Inhalation of Radon Progeny by Miners: Presentation by the Atomic Energy Board of Canada (AEBC) before the ICRP Main Commission*, Nov. 1992.

Comment: The radon emissions from uncovered subpart T uranium mill tailings piles is not a significant risk to the public health.

Response: In this rulemaking EPA is not revisiting the determinations made in either the subpart T or UMTRCA rulemakings that uranium mill tailings piles need to be covered to protect the public health. In addition, the court in *AMC I* made it clear there was no requirement that EPA show a significant risk from uranium mill tailings prior to regulation of the tailings. *American Min. Congress* v. *Thomas*, 772 F.2d 617, 629 (10th Cir. 1985).

10.2. Extensions

Comment: Extensions of time and the practical aspects of closure occurring on schedule are not addressed in the BID accompanying the proposed rule.

Response: Any attempt to model extensions in the closure dates agreed to in the MOU would require the arbitrary selection of those piles to be granted extensions and choices of closure dates. There is no limit to the number of these combinations. EPA believes that the better procedure is to develop the model based on the dates in the MOU, and to recognize that extensions in the closure dates would increase total emissions and reduce present value costs.

10.3. Correlation Between 1 pCi/g of Radium to the Radon Flux

Comment: The BID relies on a false assumption that a concentration of radium of 1 pCi/g will result in 1 pCi/m^2-s radon flux from the tailings.

Response: EPA recognizes that the one-to-one radium to radon correlation is an approximation. However, there is no scientific consensus on what the value should be. Numerous factors enter into estimating the emanation rate. The rate varies according to tailings characteristics such as grain structure, grain size and moisture content. It also is affected by meteorological conditions such as temperature and barometric pressure. The impact of these factors on the emanation rate is not well understood. The rate can be expected to vary across individual piles, and from pile to pile. The Agency considered it prudent to assume a rate the tailings would be expected to exhibit at the time they are dry, prior to constructing the cover.

10.4. Equilibrium Factor

Comment: EPA does not accurately address the equilibrium factor in the BID.

Response: EPA uses a nominal value of 0.5 (rather than the 0.4 value used by the National Council for Radiation Protection (NCRP)) for the indoor equilibrium factor for radon entering houses directly from underground (see Technical Support Document for the 1991 Citizen's Guide to Radon, pp. 2–32, 33). However, when a house is located downwind from the radon source, ingrowth of radon decay products will occur, and some of these decay products will infiltrate the house. As the radon and its decay products move downwind, ingrowth will continue until an equilibrium between continued ingrowth and loss of decay

products due to ground deposition and participation scavenging is achieved. Therefore, the equilibrium fraction will increase with time, and with distance traveled, until a maximum is reached. This equilibrium will be maintained indefinitely. At a wind speed of 3.5 m/s, this maximum is calculated to be reached at about 20,000 meters (or about 12.5) miles. Since most of the population exposed to radon from the uranium mill tailings piles is more than 12.5 miles downwind, the value used in the BID is believed to be appropriate.

Comment: EPA's discussion of the equilibrium factor in the BID does not address support of the theoretical estimates utilized by monitoring data.

Response: The decay of radioactive materials such as radon is well understood. The diffusion of radon in the atmosphere is also well known; however it is a very complex phenomena. It is traditionally accepted that the atmospheric dispersion of radon and its decay products be modeled because of the difficulty of measuring their concentrations at points long distances downwind from sources such as mill tailings piles. EPA's dispersion models are based on accepted scientific principles and have received peer review. Given the difficulty inherent in the measurement of radon and its decay products in the atmosphere, we see little justification in requiring the extraordinary efforts that would necessarily be expended in accumulating monitoring data on emissions from mill tailings piles.

10.5. Moisture Content of Type B Soil

Comment: The 7.5 percent value for moisture content of type B soil used in EPA's BID should be revised to 6 percent to be consistent with NRC's Regulatory Guide 3.64.

Response: EPA used a moisture content of 7.5 percent for type B soil in estimating the emanation of radon through earthen covers on mill tailings piles. This assumed moisture content for type B soil has been used in all of EPA's rulemakings under UMTRCA and the CAA since 1983. The diffusion of radon through covers is a very complex phenomena that is affected by a large number of variables. For example, a small change in the assumed porosity of the cover material, a change within NRC's accepted range of these values (NUREG/CR–3533), would change the estimated emanation rate to a greater extent than would a change in the assumed moisture content from 7.5 percent to 6 percent. Given the sensitivity of the estimated diffusion rate to variation in the input parameters, EPA does not believe that a change to NRC's default value of 6 percent for the moisture content for type B soil is warranted.

10.6. Computer Codes Used to Assess Health Effects

Comment: It appears EPA is modifying existing regulations without benefit of rulemaking by discussing "Cap–88–EPA" in the BID, since "Comply-R" was the computer code used to assess health effects under the current CAA regulations (NESHAPs).

Response: The computer code "Comply-R" was not used in the 1989 NESHAPs rulemaking for estimating health risks from uranium mill tailings piles. EPA used "AIRDOS" for estimating the health risks from these piles in the 1989 rulemaking, which gives results essentially the same as "Cap–88–EPA."

10.7. Evaporation Ponds

Comment: Some commenters strongly support allowing evaporation ponds to remain open after emplacement of the permanent radon barrier.

Response: EPA received many comments to the Advanced Notice of Proposed Rulemaking (ANPR) noting that evaporation ponds should be excluded from the expeditious cover requirement. EPA reiterates that the Agency does not intend the expeditious radon cover requirement to extend to areas where evaporation ponds are located, even if on the pile itself, to the extent that such evaporation pond is deemed by the implementing agency (NRC or an affected Agreement State) to be an appropriate aspect to the overall remedial program for the particular site. Rather, the evaporation pond area may be covered to control radon after it is no longer in use and ready for covering. EPA believes the overall public health interest in comprehensively resolving the problems associated with each site is best served by requiring that the radon cover be expeditiously installed in a manner that does not require interruption of this aspect of remediation. Moreover, the ponds themselves serve as an effective radon barrier. EPA believes that provided all other parts of the pile are covered with the radon barrier, compliance with the 20 pCi/m^2-s standard will result, and this will be maintained by covering the evaporation pond area when it is no longer in use.

11. Miscellaneous

11.1. Amending UMTRCA

Comment: One commenter objects to an apparent EPA request to amend UMTRCA to include timing requirements.

Response: EPA did not intend to request that UMTRCA be amended when it stated in the preamble to the proposed rule "[T]hus the Agency believes that UMTRCA should be amended * * * in order to find that the NRC program protects the public with an ample margin of safety * * *". EPA was referring to the proposed amendments to the UMTRCA regulations promulgated by EPA at 40 CFR 192 subpart D.

11.2. Provisions for the Impacts of Flooding at the Sites

Comment: EPA has not duly considered the possible implications of the current Midwest flooding on uranium mill tailings disposal sites, particularly one site located near the Colorado River.

Response: The MOU and this rule are directed to timely compliance with the 20 pCi/m^2-s flux standard and not erosion protection and groundwater remediation. This rulemaking addresses changes to the UMTRCA regulations which EPA believes are requisite to a finding that the NRC regulatory program protects the public health with an ample margin of safety. Milestones which are not reasonably calculated to advance timely compliance with the 20 pCi/m^2-s standard, e.g. installation of erosion protection and groundwater corrective actions, are not relevant to the tailings closure plans (radon) and are not the subject of this action. EPA does not intend today's amendments to subpart D to address groundwater and erosion protection concerns and in addition understands that no nonoperational uranium mill tailings disposal site was in jeopardy due to the recent flooding in the Midwest. EPA understands NRC and the Agreement States consider the possibility of flooding at a particular site in reviewing the site's reclamation and closure plan. Furthermore, EPA understands that the magnitude of floods considered by the NRC are based upon the probable maximum flood, or the probable maximum precipitation event. These events generally have a much lower probability of occurrence and larger magnitude for a given drainage area than the events that occurred in the Midwest this year. Design practices for protecting uranium mill tailings covers from erosion are described in NRC's *Design of Erosion Protection Covers for Stabilization of Uranium Mill Tailings Sites* (1990).

VI. Miscellaneous

A. Paperwork Reduction Act

In light of NRC's conforming regulations and any recordkeeping regulations adopted thereunder, and the designation in UMTRCA of NRC and Agreement State authority to implement and enforce such regulations, any issues under the Paperwork Reduction Act are properly considered by NRC in its conforming regulations.

B. Executive Order Requirements

This action was submitted to the Office of Management and Budget (OMB) under Executive Order 12291, which was revoked by Executive Order 12866 on September 30, 1993. This action was not classified as "major" under Executive Order 12291. Therefore, the Agency did not prepare a Regulatory Impact Analysis (RIA). OMB completed their review under Executive Order 12866. OMB's written comments (if any) are available in the public docket.

C. Regulatory Flexibility Analysis

Section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603, requires EPA to prepare and make available for comment an "initial regulatory flexibility analysis" which describes the effect of this rule on small business entities. However, section 605(b) of the Act provides that an analysis not be required when the head of an Agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

It was found in the 1989 rule for 40 CFR Part 61, subpart T that there was no significant impact on small business entities. There has been no change in this finding, since no new tailings piles have been constructed since 1989. Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), EPA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 40 CFR Part 192

Air pollution control, Environmental protection, Groundwater protection, Hazardous constituents, Hazardous materials, Radiation protection, Radium, Radon, Thorium and Uranium.

Dated: October 29, 1993.

Carol M. Browner,

Administrator.

Part 192 of chapter I, subchapter F of title 40 of the Code of Federal Regulations is amended as follows:

PART 192—[AMENDED]

1. The authority citation for part 192 continues to read as follows:

Authority: Sec. 275 of the Atomic Energy Act of 1954, 42 U.S.C. 2022, as added by the Uranium Mill Tailings Radiation Control Act of 1978, Public Law 95–604, as amended.

Subpart D—[Amended]

2. Section 192.31 is amended by adding new paragraphs (k), (l), (m), (n), (o), (p), and (q) to read as follows:

§ 192.31 Definitions and cross-references.

* * * * *

(k) *As expeditiously as practicable considering technological feasibility* means as quickly as possible considering: the physical characteristics of the tailings and the site; the limits of available technology; the need for consistency with mandatory requirements of other regulatory programs; and factors beyond the control of the licensee. The phrase permits consideration of the cost of compliance only to the extent specifically provided for by use of the term "available technology."

(l) *Permanent Radon Barrier* means the final radon barrier constructed to achieve compliance with, including attainment of, the limit on releases of radon-222 in § 192.32(b)(1)(ii).

(m) *Available technology* means technologies and methods for emplacing a permanent radon barrier on uranium mill tailings piles or impoundments. This term shall not be construed to include extraordinary measures or techniques that would impose costs that are grossly excessive as measured by practice within the industry or one that is reasonably analogous, (such as, by way of illustration only, unreasonable overtime, staffing or transportation requirements, etc., considering normal practice in the industry; laser fusion, of soils, etc.), provided there is reasonable progress toward emplacement of a permanent radon barrier. To determine grossly excessive costs, the relevant baseline against which cost increases shall be compared is the cost estimate for tailings impoundment closure contained in the licensee's tailings closure plan, but costs beyond such estimates shall not automatically be considered grossly excessive.

(n) *Tailings Closure Plan (Radon)* means the Nuclear Regulatory Commission or Agreement State approved plan detailing activities to accomplish timely emplacement of a permanent radon barrier. A tailings closure plan shall include a schedule for key radon closure milestone activities such as wind blown tailings retrieval and placement on the pile, interim stabilization (including dewatering or the removal of freestanding liquids and recontouring), and emplacement of a permanent radon barrier constructed to achieve compliance with the 20 pCi/m^2-s flux standard as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee).

(o) *Factors beyond the control of the licensee* means factors proximately causing delay in meeting the schedule in the applicable license for timely emplacement of the permanent radon barrier notwithstanding the good faith efforts of the licensee to achieve compliance. These factors may include, but are not limited to, physical conditions at the site; inclement weather or climatic conditions; an act of God; an act of war; a judicial or administrative order or decision, or change to the statutory, regulatory, or other legal requirements applicable to the licensee's facility that would preclude or delay the performance of activities required for compliance; labor disturbances; any modifications, cessation or delay ordered by state, Federal or local agencies; delays beyond the time reasonably required in obtaining necessary governmental permits, licenses, approvals or consent for activities described in the tailings closure plan (radon) proposed by the licensee that result from agency failure to take final action after the licensee has made a good faith, timely effort to submit legally sufficient applications, responses to requests (including relevant data requested by the agencies), or other information, including approval of the tailings closure plan by NRC or the affected Agreement State; and an act or omission of any third party over whom the licensee has no control.

(p) *Operational* means that a uranium mill tailings pile or impoundment is being used for the continued placement of uranium byproduct material or is in standby status for such placement. A tailings pile or impoundment is operational from the day that uranium byproduct material is first placed in the pile or impoundment until the day final closure begins.

(q) *Milestone* means an enforceable date by which action, or the occurrence of an event, is required for purposes of achieving compliance with the 20 pCi/$m^2 - s$ flux standard.

3. Section 192.32(a) is amended by redesignating paragraphs (a)(3) and (a)(4) as paragraphs (a)(5) and (a)(6), and by adding new paragraphs (a)(3) and (a)(4), to read as follows:

§ 192.32 Standards.

(a) * * *

(3) (i) Uranium mill tailings piles or impoundments that are nonoperational and subject to a license by the Nuclear Regulatory Commission or an Agreement State shall limit releases of radon-222 by emplacing a permanent radon barrier. This permanent radon barrier shall be constructed as expeditiously as practicable considering technological feasibility (including factors beyond the control of the licensee) after the pile or impoundment ceases to be operational. Such control shall be carried out in accordance with a written tailings closure plan (radon) to be incorporated by the Nuclear Regulatory Commission or Agreement State into individual site licenses.

(ii) The Nuclear Regulatory Commission or Agreement State may approve a licensee's request to extend the time for performance of milestones if, after providing an opportunity for public participation, the Nuclear Regulatory Commission or Agreement State finds that compliance with the 20 pCi/m²−s flux standard has been demonstrated using a method approved by the NRC, in the manner required in 192.32(a)(4)(i). Only under these circumstances and during the period of the extension must compliance with the 20 pCi/m²−s flux standard be demonstrated each year.

(iii) The Nuclear Regulatory Commission or Agreement State may extend the final compliance date for emplacement of the permanent radon barrier, or relevant milestone, based upon cost if the new date is established after a finding by the Nuclear Regulatory Commission or Agreement State, after providing an opportunity for public participation, that the licensee is making good faith efforts to emplace a permanent radon barrier; the delay is consistent with the definition of "available technology" in § 192.31(m); and the delay will not result in radon releases that are determined to result in significant incremental risk to the public health.

(iv) The Nuclear Regulatory Commission or Agreement State may, in response to a request from a licensee, authorize by license or license amendment a portion of the site to remain accessible during the closure process to accept uranium byproduct material as defined in section 11(e)(2) of the Atomic Energy Act, 42 U.S.C. 2014(e)(2), or to accept materials similar to the physical, chemical and radiological characteristics of the in situ uranium mill tailings and associated wastes, from other sources. No such authorization may be used as a means for delaying or otherwise impeding emplacement of the permanent radon barrier over the remainder of the pile or impoundment in a manner that will achieve compliance with the 20 pCi/m²−s flux standard, averaged over the entire pile or impoundment.

(v) The Nuclear Regulatory Commission or Agreement State may, in response to a request from a licensee, authorize by license or license amendment a portion of a pile or impoundment to remain accessible after emplacement of a permanent radon barrier to accept uranium byproduct material as defined in section 11(e)(2) of the Atomic Energy Act, 42 U.S.C. 2014(e)(2), if compliance with the 20 pCi/m²−s flux standard of § 192.32(b)(1)(ii) is demonstrated by the licensee's monitoring conducted in a manner consistent with § 192.32(a)(4)(i). Such authorization may be provided only if the Nuclear Regulatory Commission or Agreement State makes a finding, constituting final agency action and after providing an opportunity for public participation, that the site will continue to achieve the 20 pCi/m2−s flux standard when averaged over the entire impoundment.

(4)(i) Upon emplacement of the permanent radon barrier pursuant to 40 CFR 192.32(a)(3), the licensee shall conduct appropriate monitoring and analysis of the radon-222 releases to demonstrate that the design of the permanent radon barrier is effective in limiting releases of radon-222 to a level not exceeding 20 pCi/m²−s as required by 40 CFR 192.32(b)(1)(ii). This monitoring shall be conducted using the procedures described in 40 CFR part 61, Appendix B, Method 115, or any other measurement method proposed by a licensee that the Nuclear Regulatory Commission or Agreement State approves as being at least as effective as EPA Method 115 in demonstrating the effectiveness of the permanent radon barrier in achieving compliance with the 20 pCi/m²−s flux standard.

(ii) When phased emplacement of the permanent radon barrier is included in the applicable tailings closure plan (radon), then radon flux monitoring required under § 192.32(a)(4)(i) shall be conducted, however the licensee shall be allowed to conduct such monitoring for each portion of the pile or impoundment on which the radon barrier has been emplaced by conducting flux monitoring on the closed portion.

4. Section 192.32(b)(1), footnote number 1 is revised to read as follows:

§ 192.32 Standards.

* * * * *

(b) * * *

(1) * * *

[1]The standard applies to design with a monitoring requirement as specified in § 192.32(a)(4).

Subpart E—[Amended]

5. Section 192.41 is amended by revising the introductory text and adding paragraph (e) to read as follows:

§ 192.41 Provisions.

Except as otherwise noted in § 192.41(e), the provisions of subpart D of this part, including §§ 192.31, 192.32, and 192.33, shall apply to thorium byproduct material and:

* * * * *

(e) The provisions of § 192.32(a) (3) and (4) do not apply to the management of thorium byproduct material.

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