and shall be removed from office or employment.[23]

See Chrysler Corp. v. *Brown,* 441 U.S. 281, 301(1979) (*Chrysler*). The Trade Secrets Act applies to formal agency actions as well as actions by the agency's individual employees. Courts have found that the coverage of the Trade Secrets Act and Exemption 4 are co-extensive,[24] meaning that the Trade Secrets Act generally prohibits release of information covered by Exemption 4.[25] However, the Trade Secrets Act permits disclosure of trade secret information where ''authorized by law.'' [26] Accordingly, under the Trade Secrets Act, protected information may be released where there is statutory or regulatory authority for the agency to release it. In cases where the authorization for release is found in an agency regulation, the inquiry is whether the regulation permitting the release is authorized by law.[27]

The Commission has statutory authority to release trade secret information. While both the Federal Power and Natural Gas Acts place restrictions on an individual employee's release of information gathered in the course of examining records of a company, they permit the Commission itself to authorize such a release. The Federal Power Act provides:

The Commission shall at all times have access to and the right to inspect and examine all accounts, records, and memoranda of licensees and public utilities, and it shall be the duty of such licensees and public utilities to furnish to the Commission, within such reasonable time as the Commission may order, any information with respect thereto which the Commission may by order require, including copies of maps, contracts, reports of engineers, and other data, records, and papers, and to grant to all agents of the Commission free access to its property and its accounts, records and memorandum when requested so to do. No member, officer, or employee of the Commission shall divulge any fact or information which may come to his knowledge during the course of examination of books or other accounts, as hereinbefore provided, except insofar as he may be directed by the Commission or by a court.[28]

In addition, sections 4 and 312 of the Federal Power Act authorize the Commission ''[t]o make public from time to time the information secured hereunder and to provide for the publication of its reports and investigations in such form and manner as may be best adapted for public information and use.'' [29] Section 14 of the Natural Gas Act provides similar authorization. It states:

The Commission may permit any person to file with it a statement in writing, under oath or otherwise, as it shall determine, as to any or all facts and circumstances concerning a matter which may be the subject of investigation. The Commission, in its discretion, may publish in the manner authorized in section 312 of the Federal Power Act * * * information concerning any such matter.[30]

Because these provisions give the Commission broad discretion to release information, such release would be authorized by law under the Federal Power and Natural Gas Acts and, therefore, permitted under the Trade Secrets Act, creating an exception to the normal situation where the Trade Secrets Act prohibits release of information covered by Exemption 4. This, in turn, would permit the Commission to withhold the information from public FOIA disclosure under Exemption 4, and still disclose the information to selected individuals with appropriate restrictions on use and dissemination of that information without violating the Trade Secrets Act.

c. Exemption 7

Exemption 7 exempts from disclosure certain information compiled for law enforcement purposes.[31] For purposes of CEII, the most relevant Exemption 7 provision is 7(F), which allows information to be withheld in order to protect a person's life or physical safety. In order to invoke Exemption 7, the agency must be able to demonstrate that the document at issue involves enforcement of a statute or regulation that the agency is authorized to enforce. The Commission has very broad authority to enforce the provisions of the Federal Power Act and the Natural Gas Act. For instance, under the Federal Power Act, the Commission (1) Monitors and investigates compliance with licenses, exemptions and preliminary permits it issues; [32] (2) determines just and reasonable rates; [33] and (3) ensures compliance with the Act and regulations issued thereunder.[34] Similarly, with respect to the Natural Gas Act, the Commission has broad authority to (1) Determine whether rates and charges are just and reasonable; [35] and (2) enforce violations of the statute or regulations issued thereunder.[36] Thus, given its broad enforcement authority, much of the information the Commission collects qualifies as information collected for a law enforcement purpose. For such law enforcement information to enjoy protection under Exemption 7(F), however, the release of the information must reasonably be expected to endanger a person's life or safety.

As noted in paragraph 11 of the final rule, there have been official warnings that the energy infrastructure could be the target of terrorist attacks. Given that an attack on the energy infrastructure is a legitimate threat, the Commission concludes that release of information that could facilitate or increase the likelihood of the success of such an attack could be expected to endanger life and safety of people. The failure of a dam could cause flooding that would endanger lives, as could the explosion of a natural gas pipeline. Interruptions to gas and electric power supplies likewise could endanger lives of those reliant on power, especially in times of extreme hot or cold weather. For these reasons, information identified as CEII may qualify for protection under Exemption 7(F).

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[23] 18 U.S.C. 1905.

[24] *See, e.g., Bartholdi Cable Co.* v. *FCC,* 114 F.3d 274 (D.C. Cir. 1997); *CNA,* 830 F.2d at 1152.

[25] *CNA,* 830 F.2d at 1151.

[26] *Chrysler,* 441 U.S. at 301.

[27] *Id.*

[28] 16 U.S.C. 825(b); *see also* 15 U.S.C. 717g(b) (Natural Gas Act) and 18 CFR 3c.2(a).

[29] 16 U.S.C. 797(d), 825k.

[30] 15 U.S.C. 717m.

[31] 5 U.S.C. 552(b)(7).

[32] 16 U.S.C. 823b.

[33] 16 U.S.C. 824e.

[34] 16 U.S.C. 825m, 825o–1.

[35] 15 U.S.C. 717c.

[36] 15 U.S.C. 717s.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 165

[Docket No. 03N–0068]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its bottled water quality standard regulations by establishing an allowable level for the contaminant uranium. As a consequence, bottled water manufacturers are required to monitor their finished bottled water products for uranium at least once each year under the current good manufacturing practice (CGMP) regulations for bottled water. Bottled water manufacturers are also required to monitor their source water for uranium as often as necessary, but at least once every 4 years unless they meet the criteria for the source water monitoring exemptions under the CGMP regulations. FDA will retain the existing allowable levels for combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity. This direct final rule will ensure that the minimum quality of bottled water, as affected by uranium, combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity, remains comparable with the quality of public drinking water that meets the Environmental Protection Agency's (EPA's) standards. FDA is issuing a direct final rule for this action because the agency expects that there will be no significant adverse comment on this rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed, rule under the agency's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comments and withdraws this direct final rule. The

companion proposed rule and direct final rule are substantively identical.

DATES: This rule is effective December 8, 2003. Submit written or electronic comments by May 2, 2003. If FDA receives no significant adverse comments during the specified comment period, the agency will publish a document in the **Federal Register** no later than June 11, 2003, confirming the effective date of the direct final rule. If the agency receives any significant adverse comment during the comment period, FDA intends to withdraw this direct final rule by publication in the **Federal Register** no later than June 11, 2003. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 165.110(b)(5)(ii) as of December 8, 2003.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1640.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 7, 2000 (65 FR 76708), EPA published the Radionuclides Rule to address potential public health effects from the presence of radionuclides in drinking water. This rulemaking finalized a proposed rule that EPA published in the **Federal Register** of July 18, 1991 (56 FR 33050).

Radionuclides are radioactive elements that occur naturally in the Earth's crust or are formed as a result of cosmic ray interactions. Human activities can also add radionuclides to the environment. Radionuclides emit ionizing radiation when they radioactively decay. The potential for harmful health effects from radionuclide exposure results from the ability of ionizing radiation to chemically change molecules that make up biological tissue through a process called ionization. Studies have shown long-term exposure to radionuclides including uranium in drinking water may result in increased risk of cancer and that exposure to uranium can have adverse health effects on kidney function (65 FR 76708 at 76712–76713).

National primary drinking water regulations (NPDWRs) are issued by EPA to protect the public health from the adverse effects of contaminants in drinking water. NPDWRs specify maximum contaminant levels (MCLs) or treatment techniques for drinking water contaminants. In addition, at the same time that it issues NPDWRs, EPA publishes maximum contaminant level goals (MCLGs), which are not regulatory requirements but rather are nonenforceable health goals that are based solely on considerations of protecting the public from adverse health effects of drinking water contamination.

In the Radionuclides Rule, EPA issued an NPDWR containing an MCL for uranium. EPA retained the existing MCLs for combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity and indicated the analytical methods it approved for testing for uranium and three other contaminants. Finally, EPA published an MCLG of zero for all radionuclides. EPA's NPDWR has an effective date of December 8, 2003.

Under section 410(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349(b)(1)), not later than 180 days before the effective date of an NPDWR issued by EPA for a contaminant under section 1412 of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300g-l), FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water used for bottled water. The effective date for any such standard of quality regulation is to be the same as the effective date of the NPDWR. In addition, section 410(b)(2) of the act provides that a quality standard regulation issued by FDA shall include monitoring requirements that the agency determines to be appropriate for bottled water. Further, section 410(b)(3) of the act requires a quality standard for a contaminant in bottled water to be no less stringent than EPA's MCL and no less protective of the public health than EPA's treatment technique requirements for the same contaminant.

II. Direct Final Rulemaking

FDA has determined that the subjects of this rulemaking are suitable for a direct final rule. The actions taken should be noncontroversial and the agency does not anticipate receiving any significant adverse comment.

FDA is adopting EPA's MCL for uranium as an allowable level in the quality standard regulation for bottled water. FDA is also retaining the existing allowable levels for combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity in the quality standard regulation for bottled water. The existing allowable levels for these radionuclides in bottled water are identical to the existing MCLs for the same radionuclides in drinking water that EPA retained in their Radionuclides Rule. FDA also is specifying analytical methods for determining whether the bottled water is in compliance with the quality standards.

As a consequence of FDA's amending the quality standard for uranium in part 165 (21 CFR part 165), bottled water manufacturers are required to monitor their finished bottled water products for uranium at least once each year (part 129 (21 CFR part 129)). In addition, bottled water manufacturers are required to monitor their source water for uranium at least once every 4 years, unless they meet the criteria for the source water monitoring exemptions under the CGMP regulations (part 129).

If FDA does not receive significant adverse comment on or before May 2, 2003, the agency will publish a notice in the **Federal Register** no later than June 11, 2003, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective December 8, 2003.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or why it would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. A comment recommending a change to the rule that is in addition to the rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of the rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the

Federal Register withdrawing this direct final rule no later than June 11, 2003.

The companion proposed rule, which is in essence identical to the direct final rule, provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments on the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule, and the agency will consider the comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. EPA Standards

The SDWA, as amended in 1996, requires EPA to publish an NPDWR that specifies either an MCL or a treatment technique requirement for contaminants that may ''have an adverse effect on the health of persons,'' are ''known to occur or [have] a substantial likelihood [of occurring] in public water systems with a frequency and at levels of public health concern,'' and for which ''regulation * * * presents a meaningful opportunity for health risk reduction for persons served by public water systems'' (SDWA section 1412(b)(1)(A)). The SDWA (section 300g-l(a)(3)) also requires that EPA issue MCLGs at the same time it issues NPDWRs. MCLGs are nonenforceable health goals that are based solely on considerations of protecting the public from the adverse health effects of contaminants, and not on other considerations, such as potential costs of regulating contaminants and potential technical difficulties of achieving the health goals (59 FR 38668 at 38671). EPA sets MCLs, the enforceable contaminant levels, as close as feasible to the nonenforceable MCLGs.

In its proposed rule on radionuclides (56 FR 33050), EPA proposed comprehensive changes to radionuclides standards in drinking water. However, after conducting a review of costs, benefits, and treatment technologies, in the Radionuclides Rule, EPA established an MCL of 30 micrograms per liter (μg/L) for uranium and retained the existing MCLs of 5 picocuries per liter (pCi/L) for combined radium-226/-228, 15 pCi/L for gross alpha (excluding radon and uranium), and 4 millirem (mrem)/year for beta particle and photon radioactivity (65 FR 76708 at 76722).

Because uranium is a kidney toxin as well as a carcinogen, EPA chose an MCL for uranium, expressed in μg/L, that is protective of both kidney toxicity and carcinogenicity (65 FR 76708 at 76716). Analytical methods approved by EPA for uranium monitoring include activity and mass concentration analyses. If uranium is determined by activity-type methods, a 0.67 pCi/μg conversion factor is used to convert activity to mass concentration (65 FR 76708 at 76725).

IV. FDA Standards

A. The Agency's Approach to the Bottled Water Quality Standards Established Under Section 410 of the Act

Under section 401 of the act (21 U.S.C. 341), the agency may issue a regulation establishing a standard of quality for a food under its common or usual name, when in the judgment of the Secretary of Health and Human Services such action will promote honesty and fair dealing in the interest of consumers. On November 26, 1973 (38 FR 32558), FDA established a quality standard for bottled water that is set forth in § 165.110.

Producers of bottled water are responsible for assuring, through appropriate manufacturing techniques and sufficient quality control procedures, that all bottled water products introduced or delivered for introduction into interstate commerce comply with the quality standard (§ 165.110(b)). Bottled water that is of a quality below the prescribed standard is required by § 165.110(c) to be labeled with a statement of substandard quality. Moreover, any bottled water containing a substance at a level that causes the food to be adulterated under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) is subject to regulatory action, even if the bottled water bears a label statement of substandard quality.

FDA has traditionally fulfilled its obligation under section 410 of the act to respond to EPA's issuance of NPDWRs by amending the quality standard regulations for bottled water introduced or delivered for introduction into interstate commerce to maintain compatibility with EPA's drinking water regulations. In general, FDA believes that, with few exceptions, EPA standards for contaminants in drinking water are appropriate as allowable levels for contaminants in the quality standard for bottled water when bottled water may be expected to contain the same contaminants.

FDA generally has not duplicated the efforts of EPA in judging the adequacy of MCLs or treatment techniques in NPDWRs for contaminants when determining their applicability to bottled water in order to protect the public health. FDA believes that, in general, it would be redundant for FDA to reevaluate the drinking water standards prescribed by EPA. Further, because bottled water is increasingly used in some households as a replacement for tap water, consumption patterns considered by EPA for tap water can be used as an estimate for the maximum expected consumption of bottled water by some individuals. Therefore, FDA's view is that generally in cases where bottled water is subject to the same contaminants as tap water, FDA should establish a standard of quality levels in bottled water at the same levels that EPA establishes as MCLs for such contaminants in tap water.

B. Quality Standard for Radionuclides

The quality standard for bottled water, as set forth in § 165.110(b)(5)(i), prescribes that bottled water shall not contain: (A) combined radium-226/-228 activity in excess of 5 picocuries per liter of water, (B) gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water, and (C) beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year. The quality standard for bottled water, however, does not currently prescribe an allowable level for uranium.

With the exception of uranium, FDA's existing allowable levels for radionuclides (i.e., combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity) in the bottled water quality standard are the same as EPA's existing MCLs for the same radionuclides in drinking water that EPA retained in the Radionuclides Rule. Therefore, FDA will not change the existing allowable levels for these radionuclides in bottled water.

FDA has evaluated the MCL for uranium established by EPA for drinking water. FDA concludes that EPA's MCL for uranium, as a standard of quality level for bottled water, is adequate for the protection of public health. Certain waters used for bottled water may be expected to contain uranium; thus, FDA believes that adopting EPA's MCL for uranium will ensure that the quality of bottled water is equivalent to the quality of public drinking water that meets EPA standards.

Therefore, FDA is establishing in a new paragraph (b)(5)(i)(D) in § 165.110, an allowable level for uranium of 30 micrograms per liter of water.

C. Analytical Methods for Radionuclides

In the Radionuclide Rule, EPA listed the analytical methods that it had approved for use by public water systems to determine compliance with the radionuclide MCLs (i.e. for uranium, combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity) (65 FR 76708 at 76724). FDA is revising § 165.110(b)(5)(ii) by incorporating by reference EPA approved analytical methods (65 FR 76708 at 76725) for determining compliance with the quality standard for uranium activity in bottled water. FDA is also revising § 165.110(b)(5)(ii) by incorporating by reference EPA approved analytical methods for determining compliance with the quality standard for combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity in bottled water (65 FR 76708 at 76725). FDA believes that these methods are sufficient to use for determining the level of uranium in bottled water.

D. Monitoring Provisions of CGMP Regulations for Bottled Water

FDA has established CGMP regulations for bottled water in part 129. Under § 129.35(a)(3)(i), source water must be analyzed by the plant as often as necessary, but at least once every 4 years for radiological contaminants. Therefore, once the rule becomes effective, bottlers will be required to test their source water as often as necessary but at least once every 4 years for uranium, combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity, unless the bottlers meet the provisions in § 129.35(a)(4) for source water monitoring exemptions. Further, to ensure that a plant's production complies with applicable standards, § 129.80(g)(2) requires radiological analysis by the plant, at least annually, of a representative sample from a batch or segment of a continuous production run for each type of bottled water produced during a day's production. Therefore, once this rule becomes effective, bottlers will be required to test their finished bottled water products at least once a year for uranium, combined radium-226/-228, gross alpha particle radioactivity, and beta particle and photon radioactivity. In addition, bottled water must comply with the allowable levels for radionuclides in the quality standard for bottled water (§ 165.110(b)(5)(i)) unless the label bears a statement of substandard quality under § 165.110(c). As stated in § 165.110(d), bottled water is deemed adulterated if it contains a substance at a level considered injurious to health under section 402(a)(1) of the act (21 U.S.C. 342).

V. Environmental Impact

The agency has determined under 21 CFR 25.32(a) 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.

VI. Economic Impact

A. Regulatory Impact Analysis

FDA has examined the economic implications of this direct final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this direct final rule is not a significant regulatory action as defined by Executive Order 12866.

1. The Need for Regulation

In the Radionuclides Rule, EPA published an NPDWR establishing an MCL for uranium. Under section 410 of the act, when EPA issues a regulation establishing an MCL for a contaminant in public drinking water, FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health. FDA's standard of quality regulations must also include appropriate monitoring requirements. Of the radionuclide standards addressed in EPA's final rule, only the uranium requirement does not have a current standard of quality regulation for bottled water. If FDA does not issue a standard of quality regulation by 180 days before the effective date of EPA's NPDWRs or make a finding that such a regulation is not necessary to protect the public health, the NPDWRs become applicable to bottled water.

2. Regulatory Options

FDA considers three options for this analysis:

Option 1. FDA does not establish a uranium quality standard regulation or make a finding that it is not necessary to protect the public health because uranium is not found in water used for bottled drinking water. Bottled water producers would be subject to the requirements set forth in the NPDWR for uranium.

Option 2. FDA establishes a uranium quality standard regulation. Bottled water producers would be subject to allowable levels in § 165.110 and CGMP monitoring requirements in §§ 129.35 and 129.80.

Option 3. Bottled water producers are not subject to either an FDA quality standard regulation or an EPA NPDWR for uranium.

Note on Option 3: Since water used for bottled water comes from sources that likely contain some level of naturally occurring uranium, section 410(b)(1) of the act does not allow this option. The act specifies two alternatives: ''promulgate a standard of quality regulation under this subsection,'' or find that ''such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems * * * but not in water used for bottled drinking water.'' However, the Office of Management and Budget cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. Our analysis finds that option 3 does not have the highest net benefits.

Therefore, even if option 3 were permissible, the statute does not preclude the option with the highest net benefits.

Assumptions and Estimations Applicable to all Options

For the purposes of this analysis, FDA makes the following assumptions:

- Option 3, which has zero costs and benefits, will be considered the baseline for this analysis.
- The regulatory options we consider will have no organoleptic effect on the final bottled water product, and thus no impact on sales due to product quality. The cost of the regulation will be limited to the direct cost of testing, recordkeeping, and possible treatment technology investment or other compliance activity.
- Bottled water producers market their products based on meeting government safety testing requirements. However, any change in sales resulting from successful marketing either transfers revenue from one producer to another with no net loss to society, or causes increased sales of bottled water, which would mitigate the cost of this regulatory effort.
- Both the EPA NPDWR and the FDA standard of quality regulations will compel facilities to comply with the new uranium standard. Therefore, FDA assumes that options 1 or 2 will not differ in terms of the number of illnesses avoided or the burden placed on facilities compelled to adopt treatment technology. However, EPA and FDA do have differing monitoring requirements.
- *The number of facilities*: Approximately 1,550 plants produced bottled water in 1998 (63 FR 25764, May 11, 1998). According to another database search conducted in 2002, the industry contains only 914 plants that would be subject to these rules. The 2002 count may not include bottled water services to business, but the decrease in facilities may also be a result of industry consolidation (Ref. 1). Because of this uncertainty, we use both totals to define our uncertainty interval.
- *Facilities out of compliance*: As in the EPA NPDWR analysis, we estimate the baseline incidence of facilities out of compliance by using the EPA's National Inorganics and Radionuclides Survey (NIRS). EPA took the results of the concentration of radionuclides found in the NIRS and extrapolated to the expected percent of municipal water facilities that would be out of compliance—by type and population served—for various uranium levels. Since most bottled water facilities that do not use a public water source use ground water, and are relatively small when compared to municipal water plants, we assume that the percent of bottled water plants out of compliance with the uranium standard is approximately the same percent as the number of ground water municipal plants that serve less than 500 people. EPA used two methods to extrapolate the NIRS results to all facilities. Using both approaches, small ground water facilities have by far the largest estimated out of compliance percentages, so this is a conservative assumption. Table 1 of this document presents the four possible numbers of facilities out of compliance, using our two bottled water facility counts and EPA's two percentage estimates for groundwater facilities.[1] The lowest and the highest number of facilities identified here (8–22 facilities) will be used as the out of compliance uncertainty interval for cost calculations.

TABLE 1.—NUMBER OF FACILITIES POTENTIALLY OUT OF COMPLIANCE WITH THE URANIUM STANDARD

Total Number of Facilities	EPA Method 1 (1.4% out of compliance)	EPA Method 2 (0.9% out of compliance)
1550	22	14
914	13	8

Cost Calculations under Options 1 and 2

This cost analysis is separated into two sections: Possible compliance activity that firms may have to undertake to meet the uranium standard, and monitoring requirement for all facilities. Between 914 and 1,550 facilities may have to adopt a test for the uranium standard, and between 8 and 22 facilities may also have to take measures to come into compliance with the uranium standard. Uranium testing is a standard procedure that is available in many labs around the country. Firms can choose among many types of treatment options to come into compliance, including water softening/iron removal, point-of-use reverse osmosis, point-of-use anion exchange/activate alumina, blending, or finding an alternative source.

Compliance costs. FDA assumes that all facilities will come into compliance under options 1 and 2, so the relative ranking of options 1 and 2 is not affected by compliance cost calculations. In their 2000 NPDWR analysis, EPA estimated compliance investment needed per volume of water treated (here presented as per 83,000 gallons, which is the annual per household water use estimate used by EPA) for each of their extrapolation methods mentioned above, for each facility size category, and for several different uranium standards. However, they did not directly estimate the compliance cost of the 30 µg/L standard considered here. We use an average of the compliance costs per gallon between the 40 and 20 µg/L standard levels for which costs were estimated directly tested by EPA. We also assume that each facility out of compliance is of average size. According to EPA's per capita total water use estimates applied to bottled water, an average bottled water facility processes as much water as a municipal system serving between 42 and 72 households, so we use the compliance cost estimated for groundwater facilities serving between 100 and 500 people, which is the closest category EPA presents.

The extrapolation methods used to construct the uncertainty intervals explained above affect both the percent of facilities out of compliance and the total amount of uranium that would need to be removed to come into compliance. Therefore, the per volume costs will be different under EPA's different estimation methods even for identically sized facilities. As mentioned previously, firms can choose among many types of treatment options. Our central value of uncertain compliance cost estimates is based on EPA's study of technology adoption for previous standards and their decision tree analysis, and our uncertainty interval is defined by the least (alternative sourcing) and most (point-of-use methods) expensive options being adopted by every one of the 8–22 facilities assumed to be affected.

Table 2 of this document summarizes these calculations. Considerable economies of scale exist in water treatment, but EPA only estimates the effect of economies of scale between their grouped size categories. Therefore, within the EPA size category we are assuming applies to bottled water, total treatment cost depends only on the amount of water treated, even though it is probable that larger facilities within this class have a lower per volume cost of treating their water. Also, for these options we base estimates of the amount of bottled water treated per facility not on our uncertain number of facilities but

[1] This is actually a percentage out of compliance for all facilities, but the percentage is dominated by small groundwater facilities. Above an MCL of 40 µg/L, no facilities other than groundwater facilities serving less than 500 people were predicted to be out of compliance. Since EPA did not directly estimate compliance percentages for the EPA MCL of 30 µg/L, we must assume that the number of facilities that are not small groundwater and are out of compliance would be negligible.

on a fixed total estimate of bottled water production in the United States. Therefore, except for rounding, our compliance cost estimate is not dependent on the number of facilities. We do expect that fewer facilities treating a larger amount of water would lead to lower per volume costs, but our most accurate estimate cannot take this into account, and this uncertainty does not affect the ranking of alternatives. We assume costs are incurred every year indefinitely into the future. The annual volume of bottled water consumed in the United States increased by an average of 7 percent over the past 11 years (Ref. 3), but again since the cost of treating water is subject to considerable economies of scale (Ref. 2) we assume that per year compliance costs will be roughly constant in the future. The discount rate used is 7 percent. We use the average of all four estimates of the middle value to construct the measure of central tendency, and the average of the two rounded lowest values and the two rounded highest values to construct the uncertainty interval. According to this analysis, total present value compliance costs will average approximately $1,085,000, with a range of $61,000-$2,660,000 for both options 1 and 2.

TABLE 2.—COMPLIANCE COST FOR EPA METHODS 1 AND 2

EPA Calculation Method	No. of Facilities	Cost /83,000 Gallons ($)	Cost Per Facility ($)	Total Annual ($)	Present Value ($)
1	22	100 (10–190)	4,200 (300–7,900)	92,000 (7,000–174,000)	1,406,000 (107,000–2,660,000)
1	13	100 (10–190)	7,200 (500–13,400)	94,000 (7,000–174,000)	1,437,000 (107,000–2,660,000)
2	14	80 (10–190)	3,600 (300–7,900)	50,000 (4,000–111,000)	764,000 (61,000–1,697,000)
2	8	80 (10–190)	6,000 (500–13,400)	48,000 (4,000–107,000)	734,000 (61,000–1,636,000)

Monitoring Costs. FDA has collected several estimates for uranium testing cost, ranging from $25-$150 per sample.[2] We will use the average of these testing costs of $105 as a most likely value and the entire range to define uncertainty. EPA and FDA required testing frequencies under options 1 and 2 differ substantially, as explained below.

Option 1 (EPA) Testing Frequency. Under the EPA testing regime, the 914 or 1,550 facilities would have to adopt a test for the uranium standard. According to the Radionuclides Rule (65 FR 76708 at 76711), all facilities would have to first perform four consecutive quarterly samples. We assume that bottled water facilities would test these samples in the first year after adoption. Based on the average results of these samples, facilities would have to sample once every 3 years (average greater than 50 percent of MCL), once every 6 years (average less than 50 percent of MCL), or once every 9 years (not detected). We assume one-third of facilities would fall in each of these categories, and that future tests would be uniformly distributed across years; for example, one-third of the facilities that only have to test once every 3 years will conduct the test in any one year.

Option 2 (FDA) Testing Frequency. Under § 129.35(a)(3), bottled water producers are required to test their source water for radiological contaminants at least once every 4 years unless exempted from such testing under § 129.35(a)(4). For example, one possible exemption is that the 25 percent of bottled water facilities that use a public water source already subject to EPA regulations may substitute public water system testing results for source water testing. We assume that no facilities that use a public water source will need to test their source water for uranium, and that all bottled water producers using nonpublic water will need to test their source water. All bottled water producers are required to test their final bottled water product for radiological contaminants at least once per year under § 129.80(g)(2).

Table 3 of this document presents the calculations for each option. The low bound is calculated by the low facility count multiplied by the low testing cost estimate, the high bound is calculated by the high facility count multiplied by the high testing cost estimate, and the middle value is the average of the low and high facility counts multiplied by the average of the testing cost estimates. Multiplying all low and high estimates together probably renders the low and high bounds extremely unlikely, but since we do not have a probability distribution associated with these values we have no other method of defining uncertainty. The present value is calculated as if all testing were to be continued indefinitely, with a discount rate of 7 percent.

TABLE 3.—MONITORING COST ESTIMATES

Options	Year 1 tests	Year 1 Cost ($)	Subsequent year tests	Subsequent year cost ($)	Present Value ($)
Option 1 (EPA)	4	517,000 (91,000–930,000)	.61	79,000 (14,000–142,000)	1,645,000 (291,000–2,956,000)
Option 2 (FDA)	1.19	154,000 (27,000–277,000)	1.19	154,000 (27,000–277,000)	2,353,000 (416,000–4,229,000)

[2] A private lab called General Engineering Laboratories (GEL) in Charleston, SC, provides uranium testing of private wells at a cost of $25 per sample: http://www.scdhec.net/eqc/water/html/urtest2.html, accessed August 15, 2002. The New Hampshire Department of Environmental Services charges $140 per uranium test: http://www.des.state.nh.us/factsheets/ws/ws-3-11.htm, accessed August 15, 2002. The Maine Health and Environmental Testing Laboratory charges $150 per uranium test: http://www.state.me.us/dhs/etl/pubgd99w.html, accessed August, 15, 2002.

3. Benefits of the Regulatory Options

FDA assumes that both option 1 and option 2 would compel all bottled water facilities to come into compliance with the 30 μg/L uranium standard. Uranium carries two distinct risks: An increased risk of cancer and kidney toxicity. In addition, treatment technologies put in place to remove uranium will also reduce the concentration of other bottled water contaminants. However, EPA was unable to quantify the effect of uranium on kidney toxicity and the effect of uranium treatment technology on cocontaminants due to lack of information, and FDA has not found any information made available that would allow the quantification of these effects since EPA's 2000 analysis.

Cases of Cancer Avoided

Exposure. According to the *Bottled Water Reporter*, Americans consumed a per capita average of approximately 73.8 liters of bottled water in 2001 (Ref. 3). This is approximately 18 percent of the per capita consumption of water from all sources estimated by the EPA (Ref 2). Bottled water consumption has been increasing at a rate of approximately 7 percent per year in the United States over the past 11 years, and this trend may continue (Ref 3).

Risk and Valuation of Risk. In September 1999, EPA updated a series of coefficients they developed to express the incremental lifetime risk of cancer morbidity or mortality per unit of intake. They then combined this per unit risk to the average and 90th percentile annual and lifetime intake of water from all sources (including bottled water, but they adjusted for bottled water that did not originate in the municipal water supplies they regulated) to calculate: (1) The total morbidity and mortality cancer risk due to drinking water containing uranium, and (2) the reduction in risk due to their proposed NPDWR for uranium. We adjust these values based on our calculation of the average annual intake of bottled water described above. The mortality risk coefficient per ug of uranium ingested is 3.97E–11, and the morbidity coefficient is 6.13E–11 (Ref. 4). In other words, for each g of uranium ingested the lifetime risk of getting cancer increases by approximately 6 in 100 billion, while the lifetime risk of dying from cancer increases by approximately 4 in 100 billion.

This risk estimate is applied to the decrease in Uranium ingested due to options 1 and 2. Between 0.9 percent and 1.4 percent of bottled water is expected to initially have uranium concentrations over 30 μg/L. Based on 2001 total bottled water consumption, this translates into between 49 million and 76 million gallons of bottled water possibly above the standard. In the Radionuclides rule, EPA expected that the reduction in uranium concentration in the out of compliance municipal water facilities would yield an annual decrease in the number of new fatal and nonfatal statistical[3] cancer cases of 0.82 from an affected number of gallons of approximately 73 million.

For the calculations below, we assume that every bottled water consumer has an equal chance of drinking water from a facility that would be out of compliance with the standard. This makes the calculation much simpler, and since the mortality and morbidity risk coefficients are linear and are not based on past exposure, the total reduction in risk is identical. If out-of-compliance bottled water facilities have uranium concentrations roughly equal to the EPA estimates, then applying this assumed reduction and the total annual per capita consumption attributable to the affected bottled water facilities yields a total number of fatal and nonfatal cancer cases avoided of between 0.55 and 0.85 per year for both options 1 and 2. We use a 6 percent growth rate to take into account an increase in exposure and population, in relation to the 7 percent discount rate used for the cost calculations. We also assume that the cancer mortality will occur 20 years in the future. The central estimate is somewhat sensitive to these assumptions, so we test different assumptions in the net benefits section below. Using standard valuation techniques for cancer morbidity and mortality yields an expected present value benefit of between $8,700,000 and $13,500,000. The calculations summary is in Table 4 of this document.

TABLE 4.—BENEFITS CALCULATIONS

Options	Cases of Cancer Avoided: EPA Method 1	Cases of Cancer Avoided: EPA Method 2	Present Value ($) of Annual Cancer Cases (low-high)	Total Present Value ($) (low-high)
1 and 2	.85	.55	629,000 (494,000–764,000)	11,112,000 (8,731,000–13,493,000)

A final source of uncertainty we need to account for is the upper and lower bound estimated by EPA for their cancer risk coefficients. In the 2000 analysis, EPA assumes an uncertainty cancer risk interval extending one order of magnitude above and below their risk coefficients. Applying this uncertainty interval to the benefits we have already calculated yields a final benefits interval of between $870,000 and $135,000,000. Although EPA does not include a probabilistic confidence interval associated with this additional source of uncertainty, they do state that the central tendency values they use for their main calculations are more likely (Ref. 2).

Sensitivity to Assumptions and Uncertainty: Benefits

These benefits calculations are subject to considerable uncertainty. The uncertainty interval used in the analysis is due to the uncertainty in the incidence and concentration of naturally occurring uranium and uncertainty in the uranium risk coefficients. However, the main uncertain benefits that we do not quantify are; (1) The reduction in kidney disease due to reducing uranium concentration in bottled water, and (2) the reduction in cocontaminants due to the adoption of treatment technologies for uranium. Therefore, the quantified cancer benefits probably underestimate the true positive impact of the uranium standard.

4. Net Benefits

Table 5 below presents the total costs and benefits for all three options:

[3]A statistical cancer case refers to expectations. For example, if this risk of contracting cancer sometime during one's life increases for each person by 1 in a million, and the affected population consisted of 1 million people, it is expected that the number of eventual cancer cases observed would increase by 1. However, 1 is only the measure of central tendency in a distribution of effects.

TABLE 5.—COSTS AND BENEFITS

Options	Total Costs ($) (low-high)	Total Benefits ($) (low-high)
1 (EPA Monitoring Requirement)	2,930,000 (352,000–5,616,000)	11,112,000 (8,731,000–13,493,000)
2 (FDA Monitoring Requirement)	3,438,000 (477,000–6,889,000)	11,112,000 (8,731,000–13,493,000)
3 (No Action Taken)	0	0

In the most likely central values in the distribution of cost and benefits, EPA option 1 has positive net measured benefits and FDA option 2 has positive net measured benefits. The ranking of option 1 and 2 depends completely on the frequency of required testing: FDA would require an average of 1.19 tests per year per facility, while EPA, after a series of four tests, would only require an average of .61 test per year per facility. We tested the effects of 5 percent–7 percent discount rates and 15–30 year delays in cancer onset in our benefits calculations, and both options still yield positive net benefits. The choice of the discount rate or time period before onset does not affect the relative ranking of options 1 and 2.

The range of uncertainty between costs and benefits overlaps, but many of the determinants of the range of uncertainty affect both costs and benefits equally, so low costs are associated with low benefits and high costs are associated with high benefits. The exception to this is the uncertainty in the cancer risk coefficient; since this interval is not probabilistic, FDA cannot estimate a probability that this rule will have negative net or positive net benefits for any of these options. However, FDA does consider our central estimates the most likely outcomes. Also note the potentially large benefits from a reduction in kidney toxicity and cocontaminants that we were not able to quantify, which could also affect the size and range of the net benefits.

Finally, our cost-best analysis reaches a different result than EPA's 2000 radionuclide analysis, which concluded that testing for uranium in water destined for human consumption has negative net quantifiable benefits (65 FR 76708). The reason for the difference between our results and EPA's results is that most of the costs of the EPA rule are applied to water that will not be consumed. People do not drink the vast majority of water treated by municipal facilities. Most of that water is used for cleaning, waste disposal, and outdoor uses. In contrast, almost all bottled water is used for human consumption. In fact, a typical bottled water facility processes as much water for drinking as a much larger municipal water facility. Consequently, fewer bottled water facilities would have to incur compliance costs to afford the same level of protection for water consumed as assumed in the EPA analysis.

B. Small Entity Analysis

Under section 603(a) of the Regulatory Flexibility Act, for any proposed rule for which the agency is required by section 553 of the Administrative Procedure Act or any other law to publish a general notice of proposed rulemaking, the agency is required to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency has published, in the companion proposed rule published elsewhere in this **Federal Register**, an initial regulatory flexibility analysis. Because the companion proposed rule is a proposed rule for which a general notice of proposed rulemaking is required, and therefore, is subject to the Regulatory Flexibility Act, the agency will consider any comments it receives on the initial regulatory flexibility analysis in the companion proposed rule when deciding whether to withdraw this direct final rule.

FDA has examined the economic implications of this direct final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this rule would have a significant economic impact on a substantial number of small entities.

FDA feels that the flexibility allowed in source testing requirements under option 2 in the impact analysis is the maximum amount of flexibility possible in this regulation. FDA is not establishing exemptions for final product testing since there is a need to test for naturally occurring uranium, which could be present in all source water.

According to the latest database search across the bottled water industry mentioned above, approximately 72 percent of firms qualify as small by the Small Business Administration (SBA) standard of having less than 500 full-time-equivalent employees. We assume that all SBA small firms operate a single facility for the purposes of this analysis. Since all facilities must adopt uranium testing, between 658 and 1,116 small firm facilities will incur a testing burden. Assuming the same distribution of size among out of compliance plants means that between 6 and 16 small facilities will incur the more costly burden of devoting resources to bring their water into compliance with the uranium standard issued in this rule. Table of this document presents the average and maximum annual costs attributable to this rule for each small firm.

TABLE 6.—ANNUAL AVERAGE AND MAXIMUM COSTS PER FIRM

Category	Average ($)	Maximum ($)
Monitoring	125	179
Compliance	5,246	13,383
Total	5,400	13,600

Most small firms will only incur a $125 (1.19 tests per year at an average cost of $105 per test) uranium testing cost, although a few may incur up to $179 (1.19 tests per year at an average cost of $150 per test) in annual testing costs, which is 0.03 percent of the $580,000 annual revenue of the median small bottled water firm. If a small firm operates more than one facility, testing costs would be multiplied by the number of facilities they operate. However, between 6 and 16 small firms will incur an average of $5,400 in total costs, and may incur as much as $13,600 in total costs if for some reason they need to adopt the most expensive treatment option, although FDA considers this unlikely. The average treatment cost estimates represent .9 percent of median annual small firm sales, but could be as much as 2.3 percent of annual sales. However, 75 percent of the total reduction in cancer incidence of this rule is due to these small firms lowering the amount of uranium in their water, so it is essential that they adopt some sort of treatment technology.

C. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4), requiring cost-benefit and other analyses, in section 1531 (a) defines a significant rule as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any 1 year.'' FDA has determined that this direct final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VII. Paperwork Reduction Act

FDA tentatively concludes that this direct final rule contains no collections

of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive Order requires agencies to ''construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a)(1) provides that ''no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce-(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g)* * *'' FDA has interpreted this provision to apply to standards of quality (21 CFR 100.1(c)(4)). Although this rule has preemptive effect in that it would preclude States from issuing requirements for uranium levels in bottled water that are not identical to the allouable level for uranium as set forth in this rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act.

Section 4(c) of the Executive Order further requires that ''any regulatory preemption of State law shall be restricted to the minimum level necessary'' to achieve the regulatory objective. Under section 410 of the act, not later than 180 days before the effective date of an NPDWR issued by EPA for a contaminant under section 1412 of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300g-1), FDA is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water used for bottled water. Further, section 410(b)(3) of the act requires a quality standard for a contaminant in bottled water to be no less stringent than EPA's MCL and no less protective of the public health than EPA's treatment techniques required for the same contaminant. On December 7, 2000, EPA issued an NPDWR containing an MCL for uranium (65 FR 76708). FDA has determined that the MCL for uranium that EPA established for public drinking water is appropriate as a standard of quality for bottled water, and is issuing this regulation consistent with section 410 of the act.

Further, section 4(e) of the Executive Order provides that ''when an agency proposed to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' Given the statutory framework of section 410 of the act for bottled water, EPA's issuance of an MCL for uranium in public drinking water provided notice of possible FDA action for a standard of quality for uranium in bottled water. FDA did not receive any correspondence from State and local officials regarding a uranium standard for bottled water subsequent to EPA's NPDWR on the MCL for uranium. Moreover, FDA is not aware of any States that have requirements for uranium in bottled water that would be affected by FDA's decision to establish a bottled water quality standard for uranium that is consistent with EPA's standard for public drinking water. In addition, we are providing an opportunity for State and local officials to comment on FDA's standard of quality for uranium in bottled water in the context of this rulemaking. For the reasons set forth previously in this document , the agency believes that it has complied with all of the applicable requirements under the Executive order.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with Executive order 13132.

IX. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or elctronic comments regarding this document. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

X. Effective Date

The agency intends to make the direct final rule effective December 8, 2003. The agency will publish a confirmation notice for the direct final rule in the **Federal Register** no later than 180 days before the effective date. The agency is providing 180 days before the effective date to permit affected firms adequate time to take appropriate steps to bring their product into compliance with the standard imposed by the new rule.

XI. References

1. Hamon, J., ''Bottled Water Industry, 2001'' Special Industries Spotlight, January 2001. Available at www.merger.com.

2. Industrial Economics, Inc., *Economic Analysis of the Radionuclides National Primary Drinking Water Regulations*. Available from the Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency. November 2000.

3. Rodwan, J. G., ''The 2001 Stat: Bottled Water Sales Reach New Heights,'' *Bottled Water Reporter*, p. 14–20, April/May 2002.

4. Eckerman, K., R. Leggett, C. Nelson, J. Pushkin, and A. Richardson, *Cancer Risk Coefficients for Environmental Exposure to Radionuclides*, Federal Guidance Report No. 13, 1999. (EPA 402–R–99–001). Note that FDA used the risk coefficients as adjusted and reported in Ref. 2 of this document in order to be consistent with the EPA radionuclide impact analysis.

List of Subjects in 21 CFR Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 165 is amended as follows:

PART 165—BEVERAGES

1. The authority citation for 21 CFR part 165 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 343–l, 348, 349, 371, 379e.

2. Section 165.110 is amended by adding paragraph (b)(5)(i)(D) and by revising paragraph (b)(5)(ii) to read as follows:

§ 165.110 Bottled water.

* * * * *

(b) * * *

(5) * * *

(i)* * *

(D) The bottled water shall not contain uranium in excess of 30 micrograms per liter of water.

(ii) Analyses conducted to determine compliance with the requirements of paragraph (b)(5)(i) of this section shall

be made in accordance with the methods described in the applicable sections of ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., may be obtained from the American Public Health Association, 1015 15th St. NW., Washington, DC 20005. Copies of the methods incorporated by reference in this paragraph (b)(5)(ii) may also be examined at the Office of the **Federal Register**, 800 North Capital St. NW., suite 700, Washington, DC, or at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD.

(A) Combined radium-226/-228 shall be measured using the following methods:

(*1*) Method 7500–Ra B—''Precipitation Method,'' which is contained in ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(*2*) Method 7500–Ra D—''Sequential Precipitation Method,'' which is contained in ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(B) Gross alpha particle radioactivity shall be measured using the following method: Method 7110 C—''Coprecipitation Method for Gross Alpha Radioactivity in Drinking Water,'' which is contained in ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(C) Beta particle and photon radioactivity shall be measured using the following methods:

(*1*) Method 7500–Sr B—''Precipitation Method,'' which is contained in ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(*2*) Method 7500–^{3}H B—''Liquid Scintillation Spectrometric Method,'' which is contained in ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(*3*) Method 7120 B—''Gamma Spectroscopic Method,'' which is contained in ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(D) Uranium shall be measured using the following methods:

(*1*) Method 7500–U B—''Radiochemical Method'' which is contained in ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(*2*) Method 7500–U C—''Isotopic Method'' which is contained in ''Standard Methods for the Examination of Water and Wastewater,'' 20th Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

* * * * *

Dated: February 26, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–4971 Filed 2–27–03; 11:42 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

33 CFR Part 52

[OST Docket No. 2002–13439; Notice 2002–1]

RIN–2105–AD19

Coast Guard Board for Correction of Military Records; Procedural Regulation

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: The Department is revising and reissuing the procedural regulations of the Coast Guard Board for Correction of Military Records (Board) in order to clarify application procedures; to explain applicants' legal rights and burden of proof; to provide more time and flexibility for applicants to improve their applications; and to facilitate timely decision making by the Board.

EFFECTIVE DATE: April 2, 2003.

FOR FURTHER INFORMATION CONTACT: Dorothy J. Ulmer, Chair, Board for Correction of Military Records of the Coast Guard, C–60, Office of the General Counsel, U.S. Department of Transportation, 400 7th Street SW.; Washington, DC 20590. Telephone: (202) 366–9335.

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users may download a copy of this final rule at the following Internet addresses: *http://dms.dot.gov; http://www.access.gpo.gov; http://www.archives.gov/federal_register.* An electronic copy may also be obtained by using a computer, modem, and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661.

Background

The Secretary of Transportation, acting through the Board for Correction of Military Records of the Coast Guard, is authorized by section 1552 of title 10 of the United States Code to correct the military records of active duty, reserve, retired, and discharged Coast Guard military personnel who apply for a correction of an error or injustice in their records.

The Board's current rules at 33 CFR Part 52 have become disorganized over time by amendments and have several shortcomings that may negatively affect the Board's applicants and the timeliness of the Board's decisions. This revision of 33 CFR Part 52 is intended