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United States Department of the Interior

GEOLOGICAL SURVEY
RESTON, VA. 22092

February 22, 1982

In Reply Refer To:
EGS-Mail Stop 410

PR 60
46FR35280

(85)

DOCKET NUMBER
PROPOSED RULE PR-60
(46 FR 35280)

Hubert J. Miller
High-Level Waste Technical
Development Branch
Division of Waste Management
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Miller:

We have reviewed the proposed rule (10 CFR 60) which specifies technical criteria for disposal of high-level radioactive wastes (HLW) in geologic repositories, published in the Federal Register of July 8, 1981, regarding modifications that would be desirable to allow consideration of a repository in either the saturated or unsaturated zones. It is our opinion that appropriate modification of the following parts of the proposed rule would enable the technical criteria to apply to unsaturated as well as saturated zones.

Page 35287, Col. I. part [ii(a)]: Precise determination of the rates and quantities of expected releases from the unsaturated zone via the saturated zone to the accessible environment using differential equations to describe the flow of solutes through fractured rocks in the unsaturated zone currently is not possible. However, in some environments it can be demonstrated qualitatively that the water flux through the unsaturated zone is acceptably small and that water is unlikely to contact the waste canisters for more than brief periods, if at all; therefore such numerical modeling should not be needed to assess the performance of a repository located in that kind of environment.

Page 35289, Col 2, (2): "Performance of the engineered system - (i) containment of wastes" and (ii) control of releases." As presently stated, the first of these items requires that saturation of the repository be assumed in evaluating the potential for long-term containment by the engineered system. One of the advantages of the unsaturated zone is that well-drained rocks within it will never be saturated and thus the goals of long-term containment and very slow release rates become easier to achieve. This advantage is negated, however, with the current wording because the Department of Energy must assume full or partial saturation in its performance assessment. We suggest that the wording proposed in attachment B, pages 22-24, of the memorandum for Mr. Samuel Chilk, Nuclear Regulatory Commission from Sheldon Meyers, Department of Energy, dated November 5, 1981, may be appropriate for both these items.

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S1/1

Add: J. Donoghue - 1016 H
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Page 35290, Col. 2, paragraph 2 - (f) (2) and (3): A compelling argument for use of the unsaturated zone for a repository for HLW is predicated on the observation that this zone constitutes a major barrier to the contact of ground water with emplaced radioactive wastes. The strategy for locating a repository in the unsaturated zone is to select a repository horizon with high vertical conductivity that will allow the limited amount of recharge water reaching the repository to pass easily through this horizon into underlying units with little or no contact with the canisters of waste. Thus, "inhibition of ground water circulation in the host rock" is an undesirable condition in a repository horizon in the unsaturated zone. In the unsaturated zone, the presence of fractures or faults help to drain the repository horizon, rather than serve as possible short circuits to the biosphere, as would be the case in the saturated zone. Similarly, inhibition of ground-water flow between hydrogeologic units--is not a favorable condition between the repository horizon and underlying units in the unsaturated zone. Indeed, gravel-filled boreholes could be engineered to assure rapid drainage of water from the repository horizon in the unsaturated zone. We suggest the following addition to (f) to follow (3): In unsaturated zone environments by contrast well-drained rocks unlikely to retain perched ground water constitute favorable conditions.

Page 35290, Col. 3, (b) (6): "The existence of a fault that has been active during the Quaternary Period." This may not necessarily be an adverse condition in the unsaturated zone.

Page 35291, Col. 1, paragraph 5, (13): "Conditions in the host rock that are not reducing conditions." In the virtual absence of a transporting medium this does not appear to be an adverse condition.

Page 35293, Col. 2, paragraph 16, (i) (3): "Backfill placed in the underground facility shall be designed as a barrier" and page 35293, Col. 3, (ii), (A) "It shall provide a barrier to ground-water movement into and from the underground facility," and (ii) (c) "It shall reduce and control ground-water movement within the underground facility." In the unsaturated zone, backfill placed in the underground facility should promote ground-water movement and vertical drainage from the repository. It should not provide a barrier to ground-water movement from the repository and it should provide for vertical ground-water movement through and drainage of the underground facility.

Page 35294, Col. 2, 60.134 (f): In the unsaturated zone, water encountered during excavation is expected to drain through the repository horizon to underlying units. No purpose appears to be served by attempting to move this water to the surface. We suggest the following wording of this part might be appropriate: (f) Water control. The construction specifications shall provide that water encountered in excavations shall be controlled in accordance with design requirements for radiation control and monitoring.

On the enclosed copy of the proposed amendments to 10 CFR 60, I have marked with a felt pen the items referred to in this letter to facilitate their identification.

In summary, it appears that only relatively minor changes in the wording of the proposed rule are necessary to make it applicable to geologic repositories for the disposal of high-level wastes in both the saturated and unsaturated zones.

We shall be happy to discuss with you any questions that may be raised by our comments.

Sincerely yours,

Jack

John B. Robertson
Chief,
Office of Hazardous Waste Hydrology

Enclosure

were reviewed and published, in summary form, on March 31, 1980 (45 FR 21168). In general, the comments were supportive of the agency's efforts.

It was also at this time, March 1980, that Packers and Stockyards printed its timetable for review anticipating the publication of a specific set of regulations for review every 6 months until all regulations were considered or a total time period of approximately 5 years. Fourteen specific regulations, six policy statements and various report forms were selected for review, and comments were again solicited.

In response to the March request, 21 additional comments were received concerning the specific areas targeted for review, i.e.: (1) Current levels of required bonding; (2) proper maintenance of custodial accounts; (3) packer sales promotion policies; and (4) required annual reporting for market agencies and dealers. The agency's third Federal Register publication, dated December 31, 1980 (45 FR 87002), discussed these comments and detailed specific changes in these target areas designed to be responsive to suggestions by the industry, to lessen regulatory burdens on the industry, and to encourage competitive markets within the industry.

Present Activities

The agency has decided to accelerate the regulatory review and reform process which it has already begun. To assist the agency in achieving this end, the Deputy Administrator, Packers and Stockyards, AMS, established an internal task force in January 1981 to review each rule and regulation and to suggest changes thereto which would lessen or eliminate any regulatory burden imposed without restricting the agency's ability to enforce the Packers and Stockyards Act. An interim report of the task force has been prepared and a final report is expected by the Administrator of Packers and Stockyards Administration on August 1, 1981.

Revised Plan

Packers and Stockyards Administration will not follow its previously published plan for regulatory review. Rather, the agency will review all currently effective regulations, policy statements and reporting requirements by the close of fiscal year 1983 (September 30, 1983). As a part of this review, effort will be made to obtain input from the affected industries, State Departments of Agriculture, and other interested persons prior to formal publication of proposals. Proposed changes and deletions will then be published in the Federal Register for comments prior to final adoption. Additionally, by September 30, 1981, the agency will publish, pursuant to the requirements of the Regulatory Flexibility Act, a listing of all rules having a significant economic impact on a substantial number of small business entities which will be reviewed during the succeeding 12 months, the proposed regulations published December 31, 1980, in the Federal Register will be reconsidered by the agency to incorporate, where appropriate, the recommendations of the task force and comments filed by the industry, and where necessary, such regulations will be republished for comment.

Done at Washington, D.C., this 1st day of July 1981.

James L. Smith,

Acting Administrator, Packers and Stockyards Administration.

[FR Doc. 81-19950 Filed 7-7-81; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 60

Disposal of High-Level Radioactive Wastes in Geologic Repositories

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The NRC is publishing proposed amendments which specify technical criteria for disposal of high-level radioactive wastes (HLW) in geologic respositories. The proposed criteria address siting, design, and performance of a geologic repository, and the design and performance of the package which contains the waste within the geologic repository. Also included are criteria for montoring and testing programs, performance confirmation, quality assurance, and personnel training and certification. The proposed criteria are necessary for the NRC to fulfill its statutory obligations concerning the licensing and regulating of facilities used for the receipt and storage of high-level radioactive waste.

DATE: Comments received after November 5, 1981 will be considered if it is practical to do so, but assurance of consideration cannot be given except for comments received on or before this date.

ADDRESS: Written comments or suggestions on the proposed amendments should be sent to the Secretary of the Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments may be examined in the U.S. Nuclear Regulatory Commission Public Document Room, 1717 H Street NW, Washington, D.C. Comments may also be delivered to Room 1121, 1717 H Street NW, Washington, D.C., between 8:15 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT:

Frank J. Arsenault, Director of the Division of Health, Siting and Waste Management, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 427–4350.

SUPPLEMENTARY INFORMATION:

Background

On December 6, 1979 the Nuclear Regulatory Commission (Commission or NRC) published for comment proposed procedures for licensing geologic disposal of high-level radioactive wastes. The licensing procedures were published in final form on February 25, 1981 (46 FR 13971). On May 13, 1980 (45 FR 31393) the Commission published for comment an Advance Notice of Proposed Rulemaking (ANPR) concerning technical criteria for regulating disposal of high-level radioactive wastes (HLW) in geologic respositories. Included with the advance notice was a draft of the technical criteria under development by the staff. The public was asked to provide comment on several issues discussed in the advance notice and to reflect on the draft technical criteria in light of that discussion. The comments received were numerous and covered the full range of issues related to the technical criteria. The tecnhical criteria being proposed here are the culumination of a number of drafts, and were developed in light of the comments received on the ANPR. It is the Commissions's belief that the regulation proposed here is one which is both practical for licensing and this notice provides a flexible vehicle for accommodating comments in that it points out alternatives and calls for comment in a number of critical plans. The Commission has prepared an analysis of the comments which explains the changes made from the ANPR, and intends to publish soon the comments and the analysis as a NUREG document. A draft of this NUREG has been placed in the Commission's Public Document Room for review. In addition, the staff has begun a program to develop guidance as to the methods that it regards as satisfactory for demonstrating compliance with the requirements of the proposed rule.

and processes that might affect the performance during the containment period.

Although both the radiation from and heat generated by the decay of the wastes have diminished about 3 orders of magnitude during the containment period, the area surrounding the emplaced wastes will not return to temperatures near those before the wastes were emplaced until after about 10,000 years. As mentioned earlier, the thermal disturbance of the area near the emplaced wastes adds significantly to the uncertainties in the calculation of the transport of the radionuclides through the geologic environment. The technical criteria are intended to compensate for uncertainties by imposing further design requirements on the waste package and underground facility, thereby limiting the source term by controlling the release rate.

Role of the Site

The Commission neither intends nor expects either containment to be lost completely at 1,000 years following emplacement or the engineered system's contribution to the control of the release of wastes to cease abruptly at some later time. However, the Commission recognizes that at some point the design capabilities of the engineered system will be lost and that the geologic setting—the site—must provide the isolation of the wastes from the environment, and has translated this requirement into a performance objective for the geologic setting. The Commission also recognizes that isolation is, in fact, a controlled release to the environment which could span many thousands of years, and that the release of radionuclides and the potential exposures to individuals which could result, should be addressed in the evaluation of a repository. A complement to the evaluation of the effects of design basis processes and events which might disrupt the repository is a projection of how the repository, unperturbed by discrete external events, will evolve through the centuries as a result of the geologic processes operating at the site. Hence, an amendment is being proposed to that portion of Subpart B of 10 CFR Part 60 which describes the contents of the Safety Analysis Report of DOE's application for geologic disposal of HLW which would require DOE to project the expected performance of the proposed geologic repository noting the rates and quantities of expected releases of radionuclides to the accessible environment as a function of time.

Retrievability

The licensing procedures of 10 CFR Part 60 were written assuming that there would be a program of testing and measurement of the thermal, mechanical, and chemical properties of the major engineered barriers to confirm their expected performance. The Commission would like to tie the requirement for retievability of the wastes to the expected time needed to execute the performance confirmation program. However, at present it appears to the Commission that neither the specific nature nor the period needed for execution of the performance confirmation program will be certain until construction of the repository is substantially complete: that is, until the actual licensing to receive wastes at a geologic repository. Hence it is difficult at this time to use the performance confirmation program as a basis for establishing a period of retrievability. Nonetheless, DOE is now making critical decisions regarding the design of geologic repositories which will have a direct effect upon how long the optio to retrieve wastes can be maintained, and upon the difficulty which will be encounted in exercising that option, should that be necessary for protection of public health and safety. Therefore, to provide a suitable objective in this regard, the proposed rule sets forth a requirement that the engineered system be designed so that the option to retrieve the waste can be preserved for up to fifty years following completion of emplacement. Thus, the waste package and the underground facility would be designed so that the period of retrievability would not be the determinant of when the Commission would decide to permit closure of the repository. Rather, the Commission would be assured of the option to let the conduct of the performance confirmation program indicate when it is appropriate to make such a decision. In particular, the Commission is concerned that the thermo-mechanical design of the underground facility be such that access can be maintained until the Commission either decides to permit permanent closure of the repository or to take corrective action, which may include retrieval.

As it is now structured, the rule would require in effect that the repository design be such as to permit retrieval of waste packages for a period of up to 110 years. The components of this total period are as follows: the first waste packages to go in the repository are likely to be in place about thirty years before all wastes are in place; thereafter, a 50-year period is required by the rule; finally, a retrieval schedule is suggested of about the same time as the original construction plus emplacement operations—another 30-odd years. Since it is probably not practical to adjust the retrievability design aspects of the repository according to the order of emplacement of the waste packages, the 110-year requirement will apply to all of the waste. The Commission is particularly interested in comments on the degree to which this requirement will govern the thermal and mechanical design of the repository and on whether some shorter period would be adequate or whether there are other ways than an overall retrievability requirement to preserve options before permanent closure. The Commission does not want to approve construction of a design that will foreclose unnecessarily options for future decisionmakers, but it is also concerend that retrievability requirements not unnecessarily complicate or dominate repository design.

The retrievability requirement does not specify the form in which the wastes are to be retrievable or that wastes are "readily retrievable." The requirement is simply that all the wastes be retrievable during a period equal to the period of construction and emplacement. DOE's plans for retrieval are specifically requested as part of its license application and the practicability of its proposal will be considered by the Commission. Waste may be retrieved upon NRC approval of a DOE application or upon order by NRC, or otherwise, where authorized by DOE's license.

Human Intrusion

Some concern has been raised on the issue of human intrusion into a geologic repository. Human intrusion could conceivably occur either inadvertently or deliberately. Inadvertent intrusion is the accidental breaching of the repository in the course of some activity unrelated to the existence of the repository, e.g., exploration for or development of resources. For inadvertent intrusion to occur, the institutional controls, site markers, public records, and societal memory of the repository's existence must have been ineffective or have ceased to exist. Deliberate or intentional intrusion, on the other hand, assumes a conscious decision to breach the repository; for example, in order to recover the high-level waste itself, or exploit a mineral associated with the site.

Historical evidence indicates that there is substantial continuity of

are met without prescribing standards for the major elements of a repository.

In relation to the first and the third alternatives that are briefly discussed above, Alternative 2 appears to offer a reasonable and practical compromise. In addition to retaining the single overall performance standard in Alternative 1 as the final performance objective, this approach establishes the minimum performance objectives for each of the 3 major barriers of the repository. While this approach limits the repository designer's flexibility, it is clear that meeting these minimum design goals would substantially enhance the Commission's confidence that the final EPA standard will be met. Therefore, the Commission prefers a technical rule established upon this approach.

It should be noted that, in the event that the Commission decides to adopt the Alternate 1 approach in the final rulemaking, portions of the proposed rule (e.g., the section on requirements for the geological setting) would have to be further studied and possibly revised. In addition, it is possible that further public comments would have to be sought.

Major Features of the Proposed Rule

1. *Overall Description.* The proposed technical criteria have been written to address the following: performance objectives and requirements for siting, design and construction of the repository, the waste package, confirmation of repository performance, quality assurance, and the training and certification of personnel. As appropriate, these topics are divided in turn to address separately requirements which apply during construction, waste emplacement, and after permanent closure (decommissioning) of the repository. Although the licensing procedures indicate that there would be separate subparts for siting and design requirements, viz. Subparts E and F, respectively (cf. § 60.31(a)(2)), the NRC now believes that the site and design are so interdependent that such a distinction is artificial and misleading. For example, although the requirement to place the underground facility at a minimum depth of 300 meters is clearly a design requirement, it is manifested as a siting requirement since unless the site has a host rock of sufficient thickness at sufficient depth, the above design requirement cannot be met. Hence the proposed Subpart E to 10 CFR Part 60 contains both site and design requirements.

To enable the Commission to reach a finding as to whether the generally applicable environmental standard for disposal of HLW is met and that public health and safety will be protected, a careful and enhaustive analysis of all the features of the repository will be needed. That analysis necessarily must be both qualitative and quantitative although the analysis can and will be largely quantitative during the period that greatest reliance can be placed upon the engineered system. Thereafter, although the issues of concern, and certainly the physics of a repository itself, do not change, the numerical uncertainties begin to become so large that calulations become a weak indicator of expected repository performance.

In sum, the technical criteria perform two tasks. First they serve to guide DOE in siting, designing, constructing, and operating a repository in such a manner that there can be reasonable confidence that public health and safety will be protected. Second, they serve to guide DOE in those same areas in such a manner that there can be reasonable confidence that the analyses, needed to determine whether public health and safety is protected, can be performed.

2. *Performance Objectives.* The design and operation of the repository are prescribed to be such that during the period that wastes are being emplaced and performance assessed, exposure to workers and releases of radioactivity to the environment must be within limits set by the Commission and the EPA. Further, the repository is to be designed so that the option can be preserved to retrieve the emplaced wastes beginning at anytime up to 50 years following completion of emplacement. Following permanent closure, the repository must perform so that releases are within the limits prescribed by the generally applicable environmental standard which will be set by the EPA. Further, the design of the repository must include a waste package and an underground facility, as well as the site, as barriers to radionuclide migration.

The performance of the engineered system (waste package and underground facility) following permanent closure is specified to require containment of the wastes within the waste package for at least 1000 years following closure, when temperatures in the repository are substantially elevated, and control of the release of nuclides to the geologic environment thereafter.

Transuranic waste (TRU) may be disposed of in a geologic repository. Since transuranic waste does not generate significant amounts of heat, there is no advantage to containment for any specified period. Hence, the requirement for TRU waste is simply a controlled release equivalent to that for HLW, provided they are physically separated from the HLW so that they will not experience a significant increase in temperature.

Although a minimum 1,000-year containment and a maximum one part in 100,000 release rate will satisfy these criteria, the Commission considers it highly desirable that wastes be contained as long thereafter as is reasonably achievable, and that release rates be as far below one part in 100,000 as is reasonably achievable.

3. *Siting Requirements.* Although no specific site suitability or exclusion requirements are given in the criteria, stability and minimum groundwater travel times are specified as required site characteristics. ALARA (as low as reasonably achievable) principles have not been applied to the natural features of a site because they are not amenable to modification once a site is chosen. However, the technical criteria do identify site characteristics considered favorable for a repository as well as characteristics which, if present at the site, may compromise site suitability and which will require careful analysis and such measures as may be necessary to compensate for them adequately. The impact of these characteristics on overall performance would be site specific. Thus, the Commission has judged that these should not be made absolute requirements. Presence of all the favorable characteristics does not lead to the conclusion that the site is suitable to host a repository. Neither is the presumption of unsuitability because of the presence of an unfavorable characteristic incontrovertible. Rather, the Commission's approach requires a sufficient combination of conditions at the selected site to provide reasonable assurance that the performance objectives will be achieved. If adverse conditions are identified as being present, they must be thoroughly charaterized and analyzed and it must be demonstrated that the conditions are compensated for by repository design or by favorable conditions in the geologic setting.

The Commission has not included any siting requirements which directly deal with population density or proximity to population centers. Rather, the issue has been addressed indirectly through consideration of resources in the geologic setting. The Commission believes this to be a more realistic approach given the long period of time involved with geologic disposal. Nonetheless, the Commission invites comment on whether population related siting requirements should be included in the final rule and how they might be implemented.

"Floodplain" means the lowland and relatively flat areas adjoining inland and coastal waters including flood prone areas of offshore islands and including at a minimum that area subject to a one percent or greater chance of flooding in any given year.

"Geologic repository" means a system for the disposal of radioactive wastes in excavated geologic media. A geologic repository includes (1) the geologic repository operations area, and (2) the geologic setting.

"Geologic repository operations area" means an HLW facility that is part of a geologic repository, including both surface and subsurface areas, where waste handling activities are conducted.

"Geologic setting" or "site" is the spatially distributed geologic, hydrologic, and geochemical systems that provide isolation of the radioactive waste.

"High-level radioactive waste" or "HLW" means (1) irradiated reactor fuel, (2) liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel, and (3) solids into which such liquid wastes have been converted.

"HWL facility" means a facility subject to the licensing and related regulatory authority of the Commission pursuant to Sections 202(3) and 202(4) of the Energy Reorganization Act of 1974 (88 Stat. 1244).[2]

"Host rock" means the geologic medium in which the waste is emplaced.

"Important to safety," with reference to structures, systems, and components, means those structures, systems, and components that provide reasonable assurance that radioactive waste can be received, handled, and stored without undue risk to the health and safety of the public.

"Indian Tribe" means an Indian tribe as defined in the Indian Self-Determination and Education Assistance Act (Public Law 93-638).

"Isolation" means inhibiting the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits.

"Medium" or "geologic medium" is a body of rock characterized by lithologic homogeneity.

"Overpack" means any buffer material, receptacle, wrapper, box or other structure, that is both within and an integral part of a waste package. It encloses and protects the waste form so as to meet the performance objectives.

"Public Document Room" means the place at 1717 H Street NW., Washington, D.C., at which records of the Commission will ordinarily be made available for public inspection and any other place, the location of which has been published in the Federal Register, at which public records of the Commission pertaining to a particular geologic repository are made available for public inspection.

"Radioactive waste" or "waste" means HLW and any other radioactive materials other than HLW that are received for emplacement in a geologic repository.

"Site" means the geologic setting.

"Site characterization" means the program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of a particular site relevant to the procedures under this part. Site characterization includes borings, surface excavations, excavation of exploratory shafts, limited subsurface lateral excavations and borings, and in situ testing at depth needed to determine the suitability of the site for a geologic respository, but does not include preliminary borings and geophysical testing needed to decide whether site characterization should be undertaken.

"Stability" means that the nature and rates of natural processes such as erosion and faulting have been and are projected to be such that their effects will not jeopardize isolation of the radioactive waste.

"Subsurface facility" means the undergound portions of the geologic repository operations area including openings, backfill materials, shafts and boreholes as well as shaft and borehole seals.

"Transuranic wastes" or "TRU wastes" means radioactive waste containing alpha emitting transuranic elements, with radioactive half-lives greater than five years, in excess of 10 nanocuries per gram.

"Tribal organization" means a Tribal organization as defined in the Indian Self-Determination and Education Assistance Act (Public Law 93-638).

"Underground facility" means the undergound structure, including openings and backfill materials, but excluding shafts, boreholes, and their seals.

"Unrestricted area" means any area, access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

"Waste form" means the radioactive waste materials and any encapsulating or stabilizing materials, exclusive of containers.

"Waste package" means the airtight, watertight, sealed container which includes the waste form and any ancillary enclosures, including shielding, discrete backfill and overpacks.

3. Section 60.10 is revised to read as follows:

§ 60.10 Site characterization.

(a) Prior to submittal of an application for a license to be issued under this part the DOE shall conduct a program of site characterization with respect to the site to be described in such application.

(b) Unless the Commission determines with respect to the site described in the application that it is not necessary, site characterization shall include a program of in situ exploration and testing at the depths that wastes would be emplaced.

(c) As provided in § 51.40 of this chapter, DOE is also required to conduct a program of site characterization, including in situ testing at depth, with respect to alternative sites.

(d) The program of site characterization shall be conducted in accordance with the following:

(1) Investigations to obtain the required information shall be conducted to limit adverse effects on the long-term performance of the geologic repository to the extent practical.

(2) As a minimum the location of exploratory boreholes and shafts shall be selected so as to limit the total number of subsurface penetrations above and around the underground facility.

(3) To the extent practical, exploratory boreholes and shafts in the geologic repository operations area shall be located where shafts are planned for repository construction and operation or where large unexcavated pillars are planned.

(4) Subsurface exploratory drilling, excavation, and in situ testing before and during construction shall be planned and coordinated with repository design and construction.

4. Paragraphs (c)(1), (c)(3), and (c)(13) of § 60.21 are revised to read as follows:

§ 60.21 Content of application.

* * * * *

[2] These are DOE "facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from activities licensed under such act [the Atomic Energy Act]" and "Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive wastes generated by [DOE], which are not used for, or are part of, research and development activities."

Ownership and Control of the Geologic Respository Operations Area

Sec.

60.121 Requirements for ownership and control of the geologic repository operations area.

Additional Requirements for the Geologic Setting

60.122 Favorable conditions.
60.123 Potentially adverse conditions.
60.124 Assessment of potentially adverse conditions.

Design and Construction Requirements

60.130 General design requirements for the geologic repository operations area.
60.131 Additional design requirements for surface facilities in the geologic respository operations area.
60.132 Additional design requirements for the underground facility.
60.133 Design of shafts and seals for shafts and borenoles.
60.134 Construction specifications for surface and subsurface facilities.

Waste Package Requirements

60.135 Requirements for the waste package and its components.

Performance Confirmation Requirements

60.137 General requirements for performance confirmation.

Subpart F—Performance Confirmation

60.140 General requirements.
60.141 Confirmation of geotechnical and design parameters.
60.142 Design testing.
60.143 Monitoring and testing waste packages.

Subpart G—Quality Assurance

60.150 Scope.
60.151 Applicability.
60.152 Implementation.
60.153 Quality assurance for performance confirmation.

Subpart H—Training and Certification of Personnel

60.160 General requirements.
60.161 Training and certification program.
60.162 Physical requirements.

Subpart E—Technical Criteria

§ 60.101 Purpose and nature of findings.

(a)(1) Subpart B of this part prescribes the standards for issuance of a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area. In particular, § 60.41(c) requires a finding that the issuance of a license will not constitute an unreasonable risk to the health and safety of the public. The purpose of this subpart is to set out performance objectives and site and design criteria which, if satisfied, will support such a finding of no unreasonable risk.

(2) While these performance objectives and criteria are generally stated in unqualified terms, it is not expected that complete assurance that they will be met can be presented. A reasonable assurance, on the basis of the record before the Commission, that the objectives and criteria will be met is the general standard that is required. For § 60.111, and other portions of this subpart that impose objectives and criteria for repository performance over long times into the future, there will inevitably be greater uncertainties. Proof of the future performance of engineered systems and geologic media over time periods of a thousand or many thousands of years is not to be had in the ordinary sense of the word. For such long-term objectives and criteria, what is required is reasonable assurance, making allowance for the time period and hazards involved, that the outcome will be in conformance with those objectives and criteria.

(b) Subpart B of this part also lists findings that must be made in support of an authorization to construct a geologic repository operations area. In particular, § 60.31(a) requires a finding that there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and disposed of in a repository of the design proposed without unreasonable risk to the health and safety of the public. As stated in that paragraph, in arriving at this determination, the Commission will consider whether the site and design comply with the criteria contained in this subpart. Once again, while the criteria may be written in unqualified terms, the demonstration of compliance may take uncertainties and gaps in knowledge into account, provided that the Commission can make the specified finding of reasonable assurance as specified in paragraph (a) of this section.

§ 60.102 Concepts.

(a) *The HLW facility.* NRC exercises licensing and related regulatory authority over those facilities described in section 203 (3) and (4) of the Energy Reorganization Act of 1974. Any of these facilities is designated an *HLW facility.*

(b) *The geologic repository operations area.*

(1) This part deals with the exercise of authority with respect to a particular class of HLW facility—namely a *geologic repository operations area.*

(2) A *geologic repository operations area* consists of those surface and subsurface areas that are part of a geologic repository where radioactive waste handling activities are conducted. The underground structure, including openings and backfill materials, but excluding shafts, boreholes, and their seals, is designated the *underground facility.*

(3) The exercise of Commission authority requires that the geologic repository operations area be used for *storage* (which includes *disposal*) of *high-level radioactive wastes (HLW).*

(4) HLW includes irradiated reactor fuel as well as reprocessing wastes. However, if DOE proposes to use the geologic repository operations area for storage of *radioactive waste* other than HLW, the storage of this radioactive waste is subject to the requirements of this part. Thus, the storage of *transuranic-contaminated waste (TRU),* though not itself a form of HLW, must conform to the requirements of this part if it is stored in a geologic repository operations area.

(c) *Areas adjacent to the geologic repository operations area.* Although the activities subject to regulation under this part are those to be carried out at the geologic repository operations area, the licensing process also considers characteristics of adjacent areas. First, there is to be an area within which DOE is to exercise specified controls to prevent adverse human actions. Second, there is a larger area, designated the *geologic setting* or *site* which includes the spatially distributed geologic, hydrologic, and geochemical systems that provide isolation of the radioactive waste from the accessible environment. The geologic repository operations area plus the geologic setting make up the *geologic repository.* Within the geologic setting, particular attention must be given to the characteristics of the host rock as well as any rock units surrounding the host rock.

(d) *Stages in the licensing process.* There are several stages in the licensing process. The *site characterization* stage, though begun before submission of a license application, may result in consequences requiring evaluation in the license review. The *construction stage* would follow, after issuance of a construction authorization. A *period of operations* follows the issuance of a license by the Commission. The period of operations includes the time during which *emplacement* of wastes occurs; and any subsequent period before permanent closure during which the emplaced wastes are *retrievable* and *permanent closure,* which includes final backfilling of subsurface facilities, sealing of shafts, decontaminating and dismantling of surface facilities. Permanent closure represents the end of active human activities with the geologic repository operations area and engineered systems.

significant, such as: (1) rights arising under the general mining laws; (2) easements for right-of-way; and (3) all other rights arising under lease, rights of entry, deed, patent, mortgage, appropriation, prescription, or otherwise.

(b) *Establishment of controls.* Appropriate controls shall be established outside of the geologic repository operations area. DOE shall exercise any jurisdiction and control over surface and subsurface estates necessary to prevent adverse human actions that could significantly reduce the site or engineered system's ability to achieve isolation. The rights of DOE may take the form of appropriate possessory interests, servitudes, or withdrawals from location or patent under the general mining laws.

Additional Requirements for the Geologic Setting

§ 60.122 Favorable conditions.

Each of the following conditions may contribute to the ability of the geologic setting to meet the performance objectives relating to isolation of the waste. In addition to meeting the mandatory requirements of § 60.112, a geologic setting shall exhibit an appropriate combination of these conditions so that, together with the engieered system, the favorable conditions present are sufficient to provide reasonable assurance that such performance objectives will be met.

(a) The nature and rates of tectonic processes that have occurred since the start of the Quaternary Period are such that, when projected, they would not affect or would favorably affect the ability of the geologic repository to isolate the waste.

(b) The nature and rates of structural processes that have occurred since the start of the Quaternary Period are such that, when projected, they would not affect or would favorably affect the ability of the geologic repository to isolate the waste.

(c) The nature and rates of hydrogeological processes that have occurred since the start of the Quaternary Period are such that, when projected, they would not affect or would favorably affect the ability of the geologic repository to isolate the waste.

(d) The nature and rates of geochemical processes that have occurred since the start of the Quaternary Period are such that when projected, they would not affect or would favorably affect the ability of the geologic repository to isolate the waste.

(e) The nature and rates of geomorphic processes that have occurred since the start of the Quarternary period are such that, when projected they would not affect or would favorably affect the ability of the geologic repository to isolate the waste.

(f) A host rock that provides the following groundwater characteristics—(1) low groundwater content; (2) inhibition of groundwater circulation in the host rock; (3) inhibition of groundwater flow between hydrogeologic units or along shafts, drifts, and boreholes; and (4) groundwater travel times, under pre-waste emplacement conditions, between the underground facility and the accessible environment that substantially exceed 1,000 years.

(g) Geochemical conditions that (1) promote precipitation or sorption or radionuclides; (2) inhibit the formation of particulates, colloids, and inorganic and organic complexes that increase the mobility of radionuclides; and (3) inhibit the transport of radionuclides by particulates, colloids, and complexes.

(h) Mineral assemblages that, when subjected to anticipated thermal loading, will remain unaltered or alter to mineral assemblages having increased capacity to inhibit radionuclide migration.

(i) Conditions that permit the emplacement of waste at a minimum depth of 300 meters from the ground surface. (The ground surface shall be deemed to be the elevation of the lowest point on the surface above the disturbed zone.)

(j) Any local condition of the disturbed zone that contributes to isolation.

§ 60.123 Potentially adverse conditions.

The following are potentially adverse conditions. The presence of any such conditions may compromise site suitability and will require careful analysis and such measures as are necessary to compensate for them adequately pursuant to § 60.124.

(a) *Adverse conditions in the geologic setting.*

(1) Potential for failure of existing or planned man-made surface water impoundments that could cause flooding of the geologic repository operations area.

(2) Potential, based on existing geologic and hydrologic conditions, that planned cnstruction of large-scale surface water impoundments may significantly affect the geologic repository through changes in the regional groundwater flow system.

(3) Potential for human activity to affect significantly the geologic repository through changes in the hydrogeology. This activity includes, but is not limited to planned groundwater withdrawal, extensive irrigation, subsurface injection of fluids, underground pumped storage facilities, or underground military activity.

(4) Earthquakes which have occurred historically that if they were to be repeated could affect the geologic repository significantly.

(5) A fault in the geologic setting that has been active since the start of the Quaternary Period and which is within a distance of the disturbed zone that is less than the smallest dimension of the fault rupture surface.

(6) Potential for adverse impacts on the geologic repositroy resulting from the occupancy and modification of floodplains.

(7) Potential for natural phenomena such as landslides, subsidence, or volcanic activity of such a magnitude that large-scale surface water impoundments could be created that could affect the performance of the geologic repository through changes in the regional groundwater flow.

(8) Expected climatic changes that would have an adverse effect on the geologic, geochemical, or hydrologic characteristics.

(b) *Adverse conditions in the disturbed zone.* For the purpose of determining the presence of the following conditions within the distrubed zone, investigations should extend to the greater of either its calculated extent or a horizontal distance of 2 km from the limits of the underground facility, and from the surface to a depth of 500 meters below the limits of the repository excavation.

(1) Evidence of subsurface mining for resources.

(2) Evidence of drilling for any purpose.

(3) Resources that have either greater gross value, net value, or commercial potential than the average for other representative areas of similar size that are representative of and located in the geologic setting.

(4) Evidence of extreme erosion during the Quaternary Period.

(5) Evidence of dissolutioning of soluble rocks.

(6) The existence of a fault that has been active during the Quaternary Period.

(7) Potential for creating new pathways for radionuclide migration due to presence of a fault or fracture zone irrespective of the age of last movement.

(8) Structural deformation such as uplift, subsidence, folding, and fracturing during the Quaternary Period.

(9) More frequent occurrence of earthquakes or earthquakes of higher

evacuation of personnel during an emergency.

(ii) The geologic repository operations area shall be designed to include onsite facilities and services that ensure a safe and timely response to emergency conditions and that facilitate the use of available offsite services (such as fire, police, medical and ambulance service) that may aid in recovery from emergencies.

(6) *Utility services.*

(i) Each utility service system shall be designed so that essential safety functions can be performed under both normal and emergency conditions.

(ii) The utility services important to safety shall include redundant systems to the extent necessary to maintain, with adequate capacity, the ability to perform their safety functions.

(iii) The emergency utility services shall be designed to permit testing of their functional operability and capacity. This will include the full operational sequence of each system when transferring between normal and emergency supply sources, as well as the operation of associated safety systems.

(iv) Provisions shall be made so that, if there is a loss of the primary electric power source or circuit, reliable and continued emergency power is provided to instruments, utility service systems, and operating systems, including alarm systems. This emergency power shall be sufficient to allow safe conditions to be maintained. All systems important to safety shall be designed to permit them to be maintained at all times in a functional mode.

(7) *Inspection, testing, and maintenance.* The structures, systems, and components important to safety shall be designed to permit periodic inspection, testing, and maintenance, as necessary, to ensure their continued functioning and readiness.

(8) *Criticality control.* All systems for processing, transporting, handling, storage, retrieval, emplacement, and isolation of radioactive waste shall be designed to ensure that a nuclear criticality accident is not possible unless at least two unlikely, independent, and concurrent or sequential changes have occurred in the conditions essential to nuclear criticality safety. Each system shall be designed for criticality safety under normal and accident conditions. The calculated effective multiplication factor (k_{eff}) must be sufficiently below unity to show at least a 5% margin, after allowance for the bias in the method of calculation and the uncertainty in the experiments used to validate the method of calculation.

(9) *Instrumentation and control systems.* Instrumentation and control systems shall be designed to monitor and control the behavior of engineered systems important to safety over anticipated ranges for normal operation and for accident conditions. The systems shall be designed with sufficient redundancy to ensure that adequate margins of safety are maintained.

(10) *Compliance with mining regulations.* To the extent that DOE is not subject to the Federal Mine Safety and Health Act of 1977, as to the construction and operation of the geologic repository operations area, the design of the geologic repository operations area shall nevertheless include such provisions for worker protection as may be necessary to provide reasonable assurance that all structures, systems, and components important to safety can perform their intended functions. Any deviation from relevant design requirements in 30 CFR, Chapter I, Subchapters D, E, and N will give rise to a rebuttable presumption that this requirement has not been met.

§ 60.131 Additional design requirements for surface facilities in the geologic repository operations area.

(a) *Facilities for receipt and retrieval of waste.* Surface facilities in the geologic repository operations area shall be designed to allow safe handling and storage of wastes at the site, whether these wastes are on the surface before emplacement or as a result of retrieval from the underground facility. The surface facilities shall be designed so as to permit inspection, repair, and decontamination of such wastes and their containers. Surface storage capacity is not required for all emplaced waste.

(b) *Surface facility ventilation.* Surface facility ventilation systems supporting waste transfer, inspection, decontamination, processing, or packaging shall be designed to provide protection against radiation exposures and offsite releases as provided in § 60.111.

(c) *Radiation control and monitoring.*—(1) *Effluent control.* The surface facilities shall be designed to control the release of radioactive materials in effluents during normal and emergency operations. The facilities shall be designed to provide protection against radiation exposures and offsite releases as provided in § 60.111.

(2) *Effluent monitoring.* The effluent monitoring systems shall be designed to measure the amount and concentration of radionuclides in any effluent with sufficient precision to determine whether releases conform to the design requirement for effluent control. The monitoring systems shall be designed to include alarms that can be periodically tested.

(d) *Waste treatment.* Radioactive waste treatment facilities shall be designed to process any radioactive wastes generated at the geologic repository operations area into a form suitable to permit safe disposal at the geologic repository operations area or to permit safe transportation and conversion to a form suitable for disposal at an alternative site in accordance with any regulations that are applicable.

(e) *Consideration of decommissioning.* The surface facility shall be designed to facilitate decommissioning.

§ 60.132 Additional design requirements for the underground facility.

(a) General criteria for the underground facility.

(1) The underground facility shall be designed so as to perform its safety functions assuming interactions among the geologic setting, the underground facility, and the waste package.

(2) The underground facility shall be designed to provide for structural stability, control of groundwater movement and control of radionuclide releases, as necessary to comply with the performance objectives of § 60.111.

(3) The orientation, geometry, layout, and depth of the underground facility, and the design of any engineered barriers that are part of the underground facility shall enhance containment and isolation of radionuclides to the extent practicable at the site.

(4) The underground facility shall be designed so that the effects of disruptive events such as intrusions of gas, or water, or explosions, will not spread through the facility.

(b) *Flexibility of design.* The underground facility shall be designed with sufficient flexibility to allow adjustments, where necessary to accommodate specific site conditions identified through in situ monitoring, testing, or excavation.

(c) *Separation of excavation and waste emplacement (modular concept).* If concurrent excavation and emplacement of wastes are planned, then:

(1) The design shall provide for such separation of activities into discrete areas (modules) as may be necessary to assure that excavation does not impair waste emplacement or retrieval operations.

(b) *Shaft and borehole seals.* Shaft and borehole seals shall be designed so that:

(1) Shafts and boreholes will be sealed as soon as possible after they have served their operational purpose.

(2) At the time of permanent closure sealed shafts and boreholes will inhibit transport of radionclides to at least the same degree as the undisturbed units of rock through which the shafts or boreholes pass. In the case of soluble rocks, the borehole and shaft seals shall also be designed to prevent groundwater circulation that would result in dissolution.

(3) Contact between shaft and borehole seals and the adjacent rock does not become a preferential pathway for water.

(4) Shaft and borehole seals can accommodate potential variations of stress, temperature, and moisture.

(5) The materials used to construct the seals are appropriate in view of the geochemistry of the rock and groundwater system, anticipated deformations of the rock, and other in situ conditions.

(c) *Shaft conveyances used in radioactive waste handling.*

(1) Shaft conveyances used to transport radioactive materials shall be designed to satisfy the requirements as set forth in § 60.130 for systems, structures, and components important to safety.

(2) Hoists important to safety shall be designed to preclude cage free fall.

(3) Hoists important to safety shall be designed with a reliable cage location system.

(4) Hoist loading and unloading systems shall be designed with a reliable system of interlocks that will fail safely upon malfunction.

(5) Hoists important to safety shall be designed to include two independent indicators to indicate when waste packages are in place, grappled, and ready for transfer.

§ 60.134 Construction specifications for surface and subsurface facilities.

(a) *General requirement.* Specifications for construction shall conform to the objectives and technical requirements of §§ 60.130 through 60.133.

(b) *Construction management program.* The construction specifications shall facilitate the conduct of a construction management program that will ensure that construction activities do not adversely affect the suitability of the site to isolate the waste or jeopardize the isolation capabilities of the underground facility, boreholes, shaft, and seals, and that the underground facility is constructed as designed.

(c) *Construction records.* The construction specifications shall include requirements for the development of a complete documented history of repository construction. This documented history shall include at least the following—

(1) Surveys of underground excavations and shafts located via readily identifiable surface features or monuments;

(2) Materials encountered;

(3) Geologic maps and geologic cross sections;

(4) Locations and amount of seepage;

(5) Details of equipment, methods, progress, and sequence of work;

(6) Construction problems;

(7) Anomalous conditions encountered;

(8) Instrument locations, readings, and analysis;

(9) Location and description of structural support systems;

(10) Location and description of dewatering systems; and

(11) Details, methods of emplacement, and location of seals used.

(d) *Rock excavation.* The methods used for excavation shall be selected to reduce to the extent practicable the potential to create a preferential pathway for groundwater or radioactive waste migration or increase migration through existing pathways.

(e) *Control of explosives.* If explosives are used, the provisions of 30 CFR 57.6 (Explosives) issued by the Mine Safety and Health Administration, Department of Labor, shall be met, as minimum safety requirements for storage, use and transport at the geologic repository operations area.

(f) *Water control.* The construction specifications shall provide that water encountered in excavations shall be removed to the surface and controlled in accordance with design requirements for radiation control and monitoring (§ 60.131(c)).

(g) *Waste handling and emplacement.* The construction specifications shall provide for demonstration of the effectiveness of handling equipment and systems for emplacement and retrieval operations, under operating conditions.

Waste Package Requirements

§ 60.135 Requirements for the waste package and its components.

(a) *General requirements of design.* The design of the waste package shall include the following elements:

(1) *Effect of the site on the waste package.* The waste package shall be designed so that the in situ chemical, physical, and nuclear properties of the waste package and its interactions with the emplacement environment do not compromise the function of the waste packages. The design shall include but not be limited to consideration of the following factors: solubility, oxidation/reduction reactions, corrosion, hydriding, gas generation, thermal effects, mechanical strength, mechanical stress, radiolysis, radiation damage, radionuclide retardation, leaching, fire and explosion hazards, thermal loads, and synergistic interactions.

(2) *Effect of the waste package on the underground facility and the natural barriers of the geologic setting.* The waste package shall be designed so that the in situ chemical, physical, and nuclear properties of the waste package and its interactions with the emplacement environment do not compromise the performance of the underground facility or the geologic setting. The design shall include but not be limited to consideration of the following factors: solubility, oxidation/reduction reactions, corrosion, hydriding, gas generation, thermal effects, mechanical strength, mechanical stress, radiolysis, radiation damage, radionuclide retardation, leaching, fire and explosion hazards, thermal loads, and synergistic interactions.

(b) *Waste form requirements.* Radioactive waste that is emplaced in the underground facility shall meet the following requirements:

(1) *Solidification.* All such radioactive wastes shall be in solid form and placed in sealed containers.

(2) *Consolidation.* Particulate waste forms shall have been consolidated (for example, by incorporation into an encapsulating matrix) to limit the availability and generation of particulates.

(3) *Combustibles.* All combustible radioactive wastes must have been reduced to a noncombustible form unless it can be demonstrated that a fire involving a single package will neither compromise the integrity of other packages, nor adversely affect any safety-related structures, systems, or components.

(c) *Waste package requirements.* The waste package design shall meet the following requirements:

(1) *Explosive, pyrophoric, and chemically reactive materials.* The waste package shall not contain explosive or pyrophoric materials or chemically reactive materials that could interfere with operations in the underground facility or compromise the ability of the geologic repository to satisfy the performance objectives.

operating, maintaining, monitoring, repairing, modifying, and decommissioning.

§ 60.152 Implementation.

DOE shall implement a quality assurance program based on the criteria of Appendix B of 10 CFR Part 50 as applicable, and appropriately supplemented by additional criteria as required by § 60.151.

§ 60.153 Quality assurance for performance confirmation.

The quality assurance program shall include the program of tests, experiments and analyses essential to achieving adequate confidence that the emplaced wastes will remain isolated from the accessible environment.

Subpart H—Training and Certification of Personnel

§ 60.160 General requirements.

Operations that have been identified as important to safety in the Safety Analysis Report and in the license shall be performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operation. Supervisory personnel who direct operations that are important to safety must also be certified in such operations.

§ 60.161 Training and certification program.

The DOE shall establish a program for training, proficiency testing, certification and requalification of operating and supervisory personnel.

§ 60.162 Physical requirements.

The physical condition and the general health of personnel certified for operations that are important to safety shall not be such as might cause operational errors that could endanger the public health and safety. Any condition which might cause impaired judgement or motor coordination must be considered in the selection of personnel for activities that are important to safety. These conditions need not categorically disqualify a person, so long as appropriate provisions are made to accomodate such defect.

Dated at Washington, D.C. this 2nd day of July, 1981.

Samuel J. Chilk,

Secretary of the Commission.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Human Prescription Drugs in Oral Dosage Forms; Proposed Exemption From Child-Resistant Packaging of All Unit-Dose Forms of Potassium Supplements Containing Not More Than 50 Milliequivalents of Potassium Per Unit-Dose

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to amend the current exemption from special packaging under the Poison Prevention Packaging Act of 1970 for potassium supplements in effervescent tablet form, each tablet containing not more than 50 milliequivalents of potassium, to cover all unit-dose forms of the drug containing not more than 50 milliequivalents of potassium per unit-dose. The Commission is taking this action based on the absence of adverse experience from ingestion by children of potassium supplements in all forms, including powdered and liquid potassium.

DATES: Comments on this proposed exemption should be submitted by September 8, 1981. If the Commission issues a final regulation concerning the exemption, the Commission proposes that the exemption be effective on the date the final regulation is published in the Federal Register.

ADDRESS: Comments should be addressed to the Office of the Secretary, CPSC, 1111 18th St., NW, Third Floor, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT: Virginia White, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207, (301) 492-6453.

SUPPLEMENTARY INFORMATION:

Background

Regulations issued under the Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C. 1471-1476) establish child-protection packaging requirements for human oral prescription drugs in order to protect children from serious personal injury or illness resulting from handling, using, or ingesting these substances.

On September 30, 1980 the Commission issued a final exemption to the child-resistant packaging regulations for prescription drugs in oral form (16 CFR 1700.14(a)(10)) for potassium supplements in individually-packaged effervescent tablets, each tablet containing not more than 50 milliequivalents (mEq) of potassium (44 FR 34968). The Commission took this action based on the absence of adverse experience with effervescent potassium tablets and on test data indicating that their effervescence inhibits ingestion in dangerous amounts. In the same Federal Register document the Commission also announced its intention to reopen the issue of a possible exemption for all unit dose forms of potassium supplements, including powdered and liquid forms as well as individually-wrapped tablets. The Commission decided to reopen the issue based on correspondence with a manufacturer of powdered potassium (Berlex Laboratories) who contended that there is an inconsistency between denial of its earlier petition (PP 75-11) requesting an exemption from special packaging for powdered potassium chloride in individual packets and the proposal of an exemption for the 50 mEq effervescent tablet.

The Commission denied PP 75-11, along with similar requests from Abbott Laboratories and Mead-Johnson Laboratories for exemption of potassium chloride powder, on August 21, 1975. That denial was based on experimental evidence indicating that potassium chloride powder, administered to rabbits in amounts equivalent to ingestion of one to three packets of the drug by a small child, caused severe gastric irritation and injury in the animals, as well as in the lack of human experience data with this drug.

The Commission also earlier denied a petition from Warren-Teed Pharmaceuticals, Inc. (PP 74-42) for exemption of its liquid potassium supplements in unit dose form. (The liquid form of potassium is used almost exclusively in hospitals and other institutions but is also available for home use.) The Commission denied that petition based on the lack of adequate human experience data, at the time, with which to evaluate childhood ingestion; the fact that the products were highly flavored; and an evaluation of toxicity data indicating that five unit does vials (100 mEq potassium) might produce toxic effects in a small child.

Grounds for Exemption

Based upon additional information, data, and human experience generated since the 1975 denial of the petitions for exemption of potassium chloride powder and liquid potassium supplements, the Commission is now proposing to exempt from special packaging all unit dose forms of potassium supplements, including unit dose vials of liquid potassium