

SUMMARY: These amendments provide for the importation of carcasses of quail of free-flying origin which have been eviscerated and heads and feet removed. This action will permit the entry of such carcasses from viscerotropic velogenic Newcastle disease (VVND) affected countries in the same manner that game birds are allowed entry. The effect of this action is to facilitate the importation of such quail carcasses without the risk of the introduction and dissemination of VVND into the United States. This amendment will also change the definition of "game birds" to provide for the importation of carcasses of migratory fowl other than those presently listed in the definition of "game birds." The effect of this action is to enlarge the definition of game birds to include migratory birds other than ducks, geese, pigeons and doves.

EFFECTIVE DATE: October 1, 1980.

FOR FURTHER INFORMATION CONTACT: Dr. W. J. Turner, USDA, APHIS, VS, Room 824, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, Area Code (301) 436-8379. The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing each option is available on request from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, Area Code (301) 436-8695.

SUPPLEMENTARY INFORMATION: This final action has been reviewed under the USDA procedures established in Secretary's Memorandum No. 1955 to implement Executive Order 12044 and has been classified "not significant."

Dr. M. J. Tillery, Director, National Program Planning Staffs, VS, APHIS, USDA, has determined that an emergency situation exists and it is in the public interest that the Department advise prospective importers of the revised procedures as soon as possible in order that those affected may adjust their plans accordingly. Because the quail hunting season begins in Mexico October 1, 1980, the amendments are of an emergency nature and must be placed in effect immediately in order to service the purpose intended. Therefore, pursuant to the administrative procedure provisions in 5 U.S.C. 553, good cause is found for making this final rule effective less than 30 days after publication of this document in the Federal Register.

On Friday, August 8, 1980, there was published in the Federal Register (45 FR 52818-52819) a proposed amendment to

provide for the importation of carcasses of quail of free flying origin which have been eviscerated with the heads and feet removed and also to change the definition of "game birds" to provide for the importation of migratory fowl other than those species presently listed in the definition of game birds. A 30-day comment period, which expired September 8, 1980, was provided to permit public participation in the rulemaking. A total of 88 comments were received.

Eighty-seven comments favored the amendment and agreed with the Department that such importations will not pose a danger of the introduction and dissemination of VVND into the United States.

One comment questioned whether 9 CFR 94.6 is effective in preventing the introduction of VVND into the United States through the bird carcasses. This regulation has been in effect for several years and permits the importation of carcasses of migratory game birds only when the bird carcasses have been eviscerated and heads and feet removed. It has been the Department's experience that a VVND outbreak in the United States has never been attributed to carcasses which have been imported in compliance with 9 CFR 94.6, and the Department has no reason to believe that free flying quail carcasses, if treated in the same manner as other game birds, will be carriers of VVND.

After due consideration of the comments received, this final rule is published as proposed without change.

Accordingly, Part 94, Title 9, CFR, is amended in the following respects:

1. In § 94.6(b)(4) the first sentence is amended to read:

§ 94.6 Carcasses of poultry, game birds, and other birds, parts or products thereof, and eggs other than hatching eggs; restrictions, exceptions.

* * *

(b) * * *

(4) *Game Birds*—Migratory types of birds such as ducks, geese, pigeons and doves.

* * *

2. Section 94.6(d)(1) is amended to read:

* * *

(d) * * *

(1) Carcasses of game birds and carcasses of free-flying quail (as opposed to commercial, domestic or pen-raised quail) may be imported if they have been eviscerated and the heads and feet removed.

* * *

(Section 2, 32 Stat. 792, as amended; Secs. 4 and 11, 76 Stat. 130, 132; (21 U.S.C. 111, 134c, 134f); 37 FR 28464, 28477; 38 FR 19141)

Done at Washington, D.C., this 30th day of September 1980.

R. P. Jones,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 80-30897 Filed 10-2-80; 8:45 am]

BILLING CODE 3410-34-M

Food Safety and Quality Service

9 CFR Parts 307, 350, 351, 354, 355, 362, and 381

Rate Increase for Inspection Service

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Final rule.

SUMMARY: The rates for overtime inspection, identification, certification, or laboratory service are changed to reflect increased costs associated with these programs in the upcoming fiscal year.

EFFECTIVE DATE: October 5, 1980.

FOR FURTHER INFORMATION CONTACT:

June P. Blair, Director, Finance Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-6653.

SUPPLEMENTARY INFORMATION:

Exemption From Executive Order 12044

This final action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been determined to be exempt from those requirements. Dr. Donald L. Houston made this determination because the Executive Order does not apply to matters relating to agency management.

Background

The fees relating to overtime and holiday inspection, identification, certification, or laboratory service rendered to operators of official meat or poultry establishments, importers, or exporters by the Food Safety and Quality Service, are hereby amended effective October 5, 1980, to reflect increased costs associated with these programs in the upcoming fiscal year in conformity with the requirements of the Federal Pay Comparability Act of 1970.

Accordingly, the meat and poultry inspection regulations are amended as set forth below:

PART 307—FACILITIES FOR INSPECTION**PART 381—POULTRY PRODUCTS INSPECTION REGULATION****§§ 307.5, 381.38 [Amended]**

1. The rate for overtime or holiday inspection, identification, or certification service rendered, as the case may be in accordance with the provisions of this chapter, is changed from \$15.44 per hour to \$16.76 per hour in §§ 307.5(a) and 381.38(a).

PART 350—SPECIAL SERVICES RELATING TO MEAT AND OTHER PRODUCTS

2. Section 350.7(c) is amended to read as follows:

§ 350.7 Fees and charges.

(c) The fees to be charged and collected for service under the regulations in this Part shall be at the rate of \$13.48 per hour for base time, \$16.76 per hour for overtime including Saturdays, Sundays, and holidays, and \$26.24 per hour for laboratory service, to cover the costs of the service and shall be charged for the time required to render such service. Where appropriate, this time will include but will not be limited to the time required for the travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

PART 351—CERTIFICATION OF TECHNICAL ANIMAL FATS FOR EXPORT

3. Section 351.8 is amended to read as follows:

§ 351.8 Charges for survey of plants.

Applicants for the certification service shall pay the Department for salary costs at the rate of \$13.48 per hour for base time, \$16.76 per hour for overtime, travel and per diem allowances at rates currently allowed by the Government Travel Regulations, and other expenses incidental to the initial survey of the rendering plants or storage facilities for which certification service is requested.

4. Section 351.9(a) is amended to read as follows:

§ 351.9 Charges for examinations.

(a) The fees to be charged and collected by the Administrator for examination shall be \$13.48 per hour for base time and \$16.76 per hour for overtime including Saturdays, Sundays, and holidays, as provided for in § 351.14, and \$26.24 per hour for any laboratory

service required to determine the eligibility of any technical animal fat for certification under the regulations in this Part. Such fees shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in connection therewith.

PART 354—VOLUNTARY INSPECTION OF RABBITS AND EDIBLE PRODUCTS THEREOF

5. Section 354.101(b) and (c) are amended to read as follows:

§ 354.101 On a fee basis.

(b) The charges for inspection service will be based on the time required to perform such services. The hourly rate shall be \$13.48 for base time and \$16.76 for overtime or holiday work.

(c) Charges for any laboratory analysis or laboratory examination of rabbits under this Part related to the inspection service shall be \$26.24 per hour.

PART 355—CERTIFIED PRODUCTS FOR DOGS, CATS, AND OTHER CARNIVORA; INSPECTION, CERTIFICATION, AND IDENTIFICATION AS TO CLASS, QUALITY, QUANTITY, AND CONDITION

6. Section 355.12 is amended to read as follows:

§ 355.12 Charge for service.

The fees to be charged and collected by the Administrator shall be \$13.48 per hour for base time, \$16.76 per hour for overtime, including Saturdays, Sundays, and holidays, and \$26.24 per hour for laboratory services to reimburse the Service for the cost of the inspection service furnished.

PART 362—VOLUNTARY POULTRY INSPECTION REGULATIONS

7. Section 362.5(c) is amended to read as follows:

§ 362.5 Fees and charges.

(c) The fees to be charged and collected for service under the regulations in this Part shall be at the rate of \$13.48 per hour for base time, \$16.76 per hour for overtime including Saturdays, Sundays, and holidays, and \$26.24 per hour for laboratory service to cover the costs of the service and shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in

connection therewith during the regularly scheduled administrative workweek.

It has been determined that in order to cover these increased costs of the services, to comply with the requirements of the Federal Pay Comparability Act of 1970, the hourly fees charged in connection with the performance of the services must be increased effective October 5, 1980. The need for the increase and the amount thereof are dependent upon facts within the knowledge of the Food Safety and Quality Service. Therefore, under 5 U.S.C. 553, it is found that notice and other public procedure with respect to these amendments are impracticable and unnecessary and good cause is found for making these amendments effective October 5, 1980.

Done at Washington, D.C., on: September 30, 1980.

Thomas P. Grumbly,

Administrator, Food Safety and Quality Service.

[FR Doc. 80-30095 Filed 10-2-80; 8:45 am]

BILLING CODE 3410-DM-M

NUCLEAR REGULATORY COMMISSION**10 CFR Parts, 30, 40, 70, and 150****Uranium Mill Licensing Requirements**

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rules.

SUMMARY: The U.S. Nuclear Regulatory Commission is amending its regulations to specify licensing requirements for uranium and thorium milling activities, including tailings and wastes generated from these activities. The amendments to Parts 40 and 150 take into account the conclusions reached in a final generic environmental impact statement on uranium milling¹ and the requirements mandated in the Uranium Mill Tailings Radiation Control Act of 1978, as amended, public comments received on a draft generic environmental impact statement on uranium milling,² and public comments received on proposed

¹ Copies of the final generic environmental impact statement on uranium milling (NUREG-0706) are available for public inspection and copying at the U.S. Nuclear Regulatory Commission's Public Document Room, 1717 H St NW., Washington, D.C. 20555. Copies also available from GPO Sales Program, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 and the National Technical Information Service, Springfield, Virginia 22161.

² The draft statement (NUREG-0511) was published in April 1979 (44 FR 24963).

rules published in the **Federal Register**. The amendments to 10 CFR Part 40 specify technical, surety, ownership, and long term care criteria for the management and final disposition of mill tailings. The amendments to 10 CFR Parts 30 and 70 are for consistency to require the completion of an environmental review by the NRC prior to the commencement of construction of certain other types of nuclear plants, such as uranium hexafluoride conversion plants or uranium processing and fuel fabrication plants. The amendments to 10 CFR Part 150 enumerate the authorities reserved to the Commission in Agreement States under the provisions of the Uranium Mill Tailings Radiation Control Act, and specify requirements for Agreement States to implement this Act.

EFFECTIVE DATE: November 17, 1980.

Note.—The NRC has submitted this rule to the Comptroller General for such reviews as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting and recordkeeping requirements of this rule become effective, unless advised to the contrary, accordingly reflects inclusion of the 45 day period which that statute allows for such review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT: Mr. Don F. Harmon, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (phone 301-443-5910).

SUPPLEMENTARY INFORMATION:

I. Introduction

In November 1978, the U.S. Congress enacted the Uranium Mill Tailings Radiation Control Act (UMTRCA). This Act provides a program to regulate mill tailings during uranium or thorium oreprocessing at active mill operations and after termination of operations to stabilize and control tailings in a safe and environmentally sound manner and to minimize or eliminate radiation health hazards to the public. In April 1979, the NRC published (44 FR 24963) for comment a draft generic environmental impact statement (GEIS) on uranium milling that assessed the potential environmental impacts of uranium milling operations, including the management of uranium mill tailings. The NRC wished to provide an opportunity for public participation in decisions concerning any proposed changes in NRC regulations based on that assessment.

On August 24, 1979, the Commission published in the **Federal Register** effective (44 FR 50012) and proposed (44 FR 50015) amendments to its regulations to implement the requirements of the UMTRCA and the conclusions reached

in the draft GEIS on uranium milling. In October, 1979, the NRC staff held public hearings in Denver, Colorado, and Albuquerque, New Mexico, to obtain additional public input on the proposed rule changes and the draft GEIS.

The August 24, **Federal Register** notice indicated certain of the effective rules were to: (1) govern the Commission's licensing of byproduct material (i.e., uranium mill tailings) in Agreement States; (2) provide for a general license authorizing possession of uranium mill tailings by certain persons in Agreement States to prevent existing milling operations from being in technical violation of the Atomic Energy Act; and (3) specify that individuals in Agreement States were not exempt from Commission licensing requirements governing uranium mill tailings. Legislation was enacted on November 9, 1979 (Pub. L. 96-106) to provide clarification to Sections 204(h) and 204(e) of the UMTRCA. This legislation provided that the Commission has no direct licensing authority over byproduct material licensed by Agreement States at least until November 8, 1981. Accordingly, to conform to the requirements of Pub. L. 96-106, the Commission revoked the foregoing effective rules in a **Federal Register** notice published February 26, 1980 (45 FR 12377).

II. Public Response to Draft GEIS and Proposed Rules

The Commission received ninety-nine submittals in response to the request for comments on the draft GEIS and the August 24 **Federal Register** notice. These documents were from private individuals, uranium milling companies, trade associations, state and Federal agencies, and conservation and public interest groups. In addition, about 50 individuals, representing views of the same spectrum of groups and individuals, presented statements at the Denver and Albuquerque public hearings. The NRC staff has systematically reviewed all comments received and the transcripts of the statements presented at the public hearing and has identified approximately 1500 substantive comments on the draft GEIS and proposed rule changes.

After careful consideration of all comments, the NRC staff has prepared a final generic environmental impact statement on uranium milling and the Commission has adopted the rules supported by this document. These rules are identified and discussed below. In preparing the final GEIS, the NRC has included the latest available nuclear power and uranium milling projections

obtained from the U.S. Department of Energy and has completely reviewed treatment of the following: (1) potential individual and population exposures to radioactive materials from milling activities; (2) potential health effects resulting from these exposures; (3) costs for various management and disposal alternatives; and (4) a cost benefit analysis of the effective rule changes. It also contains a new Appendix A which provides a discussion of each of the specific substantive public comments. The summary of the final GEIS provides, among other things, a general discussion of what are believed to be the major public concerns and issues raised in public comments. Appendix A and the summary of the final GEIS also contain a more detailed discussion of the significant changes appearing in the final rule changes set forth below.

Since all substantive public comments are addressed in detail in Appendix A of the final GEIS and since it is impracticable to provide here a complete summary discussion of all the complex issues raised in public comments, only those issues which the NRC staff believes cover major public concerns are discussed below.

The Commission is fully aware that Atomic Safety and Licensing Appeal Boards are now considering, in individual adjudicatory licensing proceedings and pursuant to Commission direction, issues pertaining to the environmental effects of radon releases associated with the mining and milling of uranium. It is also aware that some of the issues being adjudicated in those proceedings overlap some of the subjects which are discussed in the GEIS.

Notwithstanding its issuance at this time of a final rule imposing licensing requirements for uranium mills (including the disposal of the tailings generated in the milling process), the Commission intends that the Appeal Boards proceed to decision on all issues pending before them in the radon release proceedings. In so doing, the Appeal Boards are to base their decision on the adjudicatory record of those proceedings. To the extent, if any, that, in the judgment of the Appeal Boards, the adjudicatory record may call for findings different from those contained in the GEIS and reflected in the final rule, the Appeal Boards will be free both to make and to implement such findings in their decision.

The Appeal Boards' decision will, of course, be subject to review by the Commission either on petition of a party to the proceedings or on its own initiative. In the course of any such review, the Commission will have the

opportunity to examine any findings made by the Appeal Boards which are or might be inconsistent with those GEIS findings underlying the final rule which is now being adopted. Depending upon its resolution of the inconsistency, the Commission may then either (1) reverse or modify the Appeal Boards' decision; or (2) amend the final rule to bring it into conformity with that decision.

In determining to promulgate the final rule at this time despite the possible need for its revision following the conclusion of the adjudicatory proceedings concerned with radon releases, the Commission has heavily influenced by the consideration that prompt issuance of the rule is imperative to ensure that, by November 8, 1981, Agreement States will be able to take that action necessary to bring their byproduct and source material licensing programs into compliance with Section 2740 of the Atomic Energy Act of 1954, as amended. In this connection, although not prejudging the outcome of the pending adjudication, the Commission believes that the GEIS provides a sufficient basis for the issuance of a final rule without further delay, subject to later possible amendment.

III. Major Issues Addressed in Public Comments

Timing of Regulations

A number of commenters took the position that there is no great sense of urgency for regulations on uranium mill tailings management and mill operations. However, each year new mills are proposed and many millions of tons of tailings are generated at existing mills. As new mills are constructed and more tailings are generated, the options for dealing with tailings disposal become fewer. It is critically important that the siting and design criteria of the regulations be implemented for new facilities so that mistakes of the past are not repeated. In addition, and perhaps even more important, radioactive releases from existing mills constitute the largest potential routine releases from the nuclear fuel cycle. Therefore, it is absolutely essential that regulations, which assure that action is taken to protect the public health and safety, are promulgated promptly.

The NRC intends to promulgate the regulations recognizing that research, much of its sponsored by NRC, is still being conducted in many areas covered in the rules. The regulations are established on the basis of knowledge obtained from licensing experience and research conducted to date. Research sponsored by NRC, DOE, the industry,

and others will continue, and changes can be made to regulations if research indicates that changes are necessary or appropriate. However, the NRC considers it likely that information from this research will provide a basis for supplementing the broad criteria of the regulations with more specific regulatory guidance rather than a change in the overall objective of any criterion. In any case, the NRC considers it urgent to issue the regulations now, but expects to review them from time to time to assess whether any changes are warranted.

A number of commenters indicated that their interpretation of the UMTRCA was that EPA was required to develop standards before NRC promulgated its rules. Section 275 of the Atomic Energy Act, as amended by the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA), requires EPA to issue environmental and health standards for uranium mill tailings. However, an analysis of the Mill Tailings Act and its legislative history indicates that the Commission not only has the authority but also the immediate duty to insure that the management of uranium mill tailings is carried out in a manner that will protect the public health and safety and the environment.

Although NRC could have delayed developing regulations until EPA issued standards, that would have left unfinished the program to develop rules which NRC has been working on for nearly three years. In addition, a delay would have made it difficult, if not impossible, for the Agreement States to issue equivalent standards as required. It is clear from the UMTRCA that NRC's minimum Federal standards must be promulgated as promptly as possible so that the Agreement States will be able to have equivalent regulations in place by November 8, 1981.

NRC is aware that its regulations must be compatible with the generally applicable standards established by EPA; therefore, the NRC staff has been and will continue to coordinate closely with EPA on this matter. NRC regulations will be revised, if required, when EPA standards are issued.

Application of Regulations at Existing Sites

A number of commenters stated that tailings disposal criteria should not be applied too strictly at existing sites. Other commenters were concerned that regulations should be more specific about how the criteria will apply to these sites. In the latter case, the concern was that remedial action must be taken at existing sites where criteria are not met.

Regulations were developed recognizing that it may not be practicable to provide the same measures of conservation at existing sites as can be done at new sites where alternatives are not limited. Certain requirements in the regulations represent minimum levels of protection of public health, safety, and the environment. These requirements can and must be met in all cases. For example, requirements for minimum tailings cover, erosion protection, financial surety provisions, and the broad requirement that no ongoing active maintenance be needed to preserve the tailings isolation are mandatory in all cases. It would not be possible, on the other hand, to line the bottom of an existing tailings impoundment. Also, objectives concerning remoteness from people, providing below-grade burial, and transferring ownership of sites, may not be met to the same degree at an existing site as at a new site.

At some point, a determination, based on how a site measures up against all of the criteria, must be made as to whether the tailings should be relocated from an existing to a new site, or that, while it would be acceptable for existing tailings to be stabilized in place, tailings generated in the future should be deposited at a new location. The conditions which would lead to this determination cannot be spelled out in generic fashion in regulations because they are so variable. In any event, a full evaluation of tailings disposal and alternative sites must be completed at each milling operation and final plans formulated through a public decision making process such as is provided for by NEPA and UMTRCA.

Form of Regulations

Some commenters stated that the regulations are too specific and inflexible and, thus, restrict operators from finding new and cost effective ways to meet broad goals at any particular site. For example, some felt that regulations should only state that groundwater quality must be protected and not be specific about methods of accomplishing this. On the other hand, others considered regulations should be more specific on certain issues. For example, some wanted regulations to specify, in numerical terms, allowable hydrologic, topographic and drainage conditions.

The NRC has developed regulations mindful of the need to avoid being overly restrictive. The NRC's experiences over the past several years, working with interim tailings management performance objectives

similar in nature to the criteria contained in the following rules, has been that the industry can develop many innovative ways of achieving broad goals. Also, the NRC recognizes, as stated throughout the draft and final generic impact statements, that the problem of tailings management is highly site specific. The precise details of a program can be worked out only when unique conditions of a site are known. For example, the extent of potential groundwater impacts, or the erosion potential of a tailings disposal program depends critically upon topographic, geologic, hydrologic, and meteorologic conditions which can vary significantly from site to site. The rules have been developed with flexibility to reflect this fact.

On the other hand, the NRC has attempted to make the rules as specific as possible within the constraints noted above. This is necessary for the following reasons: (1) for fairness to applicants and mill operations in that it reduces uncertainty about what requirements are and thus allows them to plan their operations reasonably; (2) to assure consistency in application of requirements which would not occur if the rules are too broad; and (3) to ensure that a minimum level of protection is provided where there are known problems or large uncertainties about potential problems. For example, a minimum cover thickness is specified and criteria for surface stabilization are established to account for known problems which potentially threaten long term tailings cover performance.

Scope of the GEIS

There were numerous comments criticizing the "model mill" approach taken by the NRC in analyzing potential environmental impacts. More specifically, commenters pointed to various aspects of the mill that were not representative of a certain, real mill, or criticized lack of analysis of certain conditions or impacts which have arisen in specific cases.

However, as repeatedly noted in the GEIS, the factors which determine the extent of impacts from milling operations are extremely site specific. All of the variations which exist with regard to these factors could in no way be taken into account explicitly in the GEIS. The model mill and model site were described, and subsequent analysis of them was carried out, in enough detail to: (1) identify the major issues or impacts of concern with uranium milling and tailings disposal, and (2) characterize their nature and extent. Costs and benefits of alternatives for mitigating these impacts

were evaluated. The product of these analyses is as new regulation, cast primarily in the form of performance objectives which recognizes that the precise methods or combination of methods of impact mitigation can only be worked out on a case-by-case basis where all unique, site specific conditions can be accounted for.

The NRC did a comprehensive review of existing conditions in all of the current uranium milling regions in developing the model mill and site, and in performing the analysis of the GEIS in general. This was done to assure that the major differences in conditions from those assumed for the GEIS models were known in performing the analysis. Where these differences are important in terms of specific points in regulations, such as radon flux limits, the full range of variability in conditions has been explicitly evaluated to assure it is reasonable to apply the regulations at all sites.

Because major decisions concerning siting and design remain to be made for each case once needed site-specific information is available, and because of the significant and longevity of the potential hazards associated with uranium mill tailings, a comprehensive environmental assessment of each mill and tailings waste disposal operation and alternatives must be conducted. It is also essential that this alternative assessment be conducted so there is opportunity for full public scrutiny of the decision being made. NRC regulations, 10 CFR 51, assures that this is done. UMTRCA (Pub. L. 95-604) establishes a requirement that Agreement States do the same. The regulation has been designed to assure these assessments are supported by full environmental assessments and investigation of site conditions by applicants and mill operators.

In no way is the GEIS a substitute for site-specific environmental assessments.

Siting of Mills

Many commenters expressed the need to be more specific and stringent concerning siting requirements. For example, some wanted a specific definition of what would be accepted as a "remote" site, a term used in the proposed rules.

However, the matter of tailings disposal is not a one-dimensional problem; that is, several factors must be considered simultaneously. Too much specificity would be imprudent since, for example, establishing a minimum distance to population centers might unduly constrain efforts to deal with other concerns such as protecting groundwater by avoiding aquifers of

high quality. The rules have been revised from their proposed form to clarify that the process of site selection involves optimization to the maximum extent practicable of the following general site qualities:

- remoteness from populated areas;
- hydrogeologic and other environmental conditions conducive to continued immobilization and isolation of containments from usable groundwater sources; and
- limited potential for erosion, disruption, and dispersion by natural forces.

Tradeoffs will inevitably be required in this process. In any event, siting is of paramount importance in developing optimum tailings disposal programs. The problem of tailings disposal cannot be approached with the attitude that inadequate siting features can be compensated for by design. For this reason, the rules state, as originally proposed, that in the selection of disposal sites, primary emphasis shall be given to isolation of tailings or wastes, a matter having long term impacts, as opposed to considerations of short term convenience or benefits, such as minimization of transportation or land acquisition costs.

Radon Control and Tailings Cover Requirements

Many commenters stated that the requirements for radon control should be based upon a fully quantified, incremental cost-benefit evaluation. However, the NRC staff reached a conclusion in the draft GEIS that attempting to establish tailings cover requirements on the basis of a quantified, incremental cost-benefit evaluation is unreasonable and, indeed, may be misleading.

In response to these comments, however, the NRC staff reexamined and expanded its evaluation of the strictly monetized, incremental cost-benefit methodology. Conclusions expressed in the draft statement concerning the impracticability and inappropriateness of attempting to set a radon exhalation limit solely by this method were fully reconfirmed. This is discussed more fully in Section 5.2.2 of the Summary of the final GEIS. Given the long term nature of the mill tailings hazards, and the complexity and uncertainty associated with predicting actual levels of radon emissions and impacts over the long term, it is concluded that the problem of determining tailings containment requirements cannot be reduced to the purely mathematical formulations required for the quantitative cost-benefit optimization methodology. The mathematical process

grossly oversimplifies the problem and, thus, while it appears to offer a "rational approach" to decisionmaking, it can be misleading and quite arbitrary.

One of the obvious problems with this methodology is that arguments can easily be made for virtually opposite positions (little or no control, versus absolute control or radon releases) merely by measuring potential health impacts over short or long time periods. In fact, commenters did this. The monetary worth of averting a health effect ("life loss" or "life shortening" due to cancer) is another highly subjective factor which can vary widely and, thus, make more uncertain the level of control which should be required. While arbitrary decisions might be made concerning these factors, there is no practicable way to correlate long term containment performance uniquely with costs.

The NRC staff established the proposed final tailings radon flux limit based upon an evaluation of a wide range of public health and cost factors, and the variability of site specific conditions. More specifically, these factors included evaluation of alternative radon release limits in terms of: costs for applying a final tailings cover under a full range of conditions that will occur with varying ore grades, impoundment sizes and shapes, cover material types and so on; impacts on maximum exposed individuals as they compare with existing radiation protection standards; total population exposures as they compare with population exposures from natural and technologically enhanced radon releases, both short and long term; and, radon fluxes that occur from natural soils.

In consideration of these perspectives and the problems with monetized cost-benefit evaluations, it was determined that the most reasonable residual radon emission limit would be one that would assure that tailings disposal sites are eventually returned to conditions which are reasonably near those of the surrounding environs. The radon flux limit assures that radon exhalation rates will be within the range of flux rates occurring naturally from nearby soils.

Period of Long Term Concern

Many commenters stated that tailings disposal should be viewed as a problem spanning eventually an infinite period of time, and the total number of potential health effects resulting from radon releases should be viewed in absolute terms. By integrating health effects over such periods of time, the number of calculated health effects is extremely large and, on the basis of this,

commenters urged that advanced modes of tailings disposal are warranted to provide complete or improved isolation of tailings. On the other hand, some stated that, because of the vast uncertainties involved, and the potential for development of a cure for cancer, a much shorter period such as 100 years is appropriate for evaluating the need and cost-effectiveness of controls. On this basis, much less stringent controls are urged.

The NRC has evaluated this problem and developed regulations considering the inescapable fact that the tailings will, in fact, remain hazardous for extremely long periods of time, hundreds of thousands of years. Viewing this matter as one of only short term significance because of the uncertainties involved with the long term or on the speculation that there may be a cure for cancer is unrealistic and not responsible. On the other hand, attempting to provide absolute assurances that the tailings, which are very large volume, low-specific activity wastes, will remain completely isolated for infinite time frames is impracticable and inappropriate when the potential impacts of other naturally occurring and technologically enhanced, persistent radon sources are considered.

The general conclusions about the various tailings disposal modes are summarized in Summary Section 5.2.1 and Section 12.3.3 of the final GEIS. The tailings siting and design features specified in the regulations are intended to provide a degree of isolation which is consistent with the reality that the tailings present long term hazards. These measures are those identified to be needed to account for potential failure mechanisms which can occur in the very long term. The features which are being incorporated into tailings disposal programs under the regulations are similar to those of landforms which have been known to be stable for extremely long periods of time. For example, elimination of embankment slopes by below grade burial or use of rock covering on very gentle slopes will make sites stable landforms. The latter will duplicate conditions such as those existing in alluvial deposits in Death Valley which have been stable for 20,000 years because of the "armoring" provided them by coarse rock and gravel "desert pavements." Minimum requirements on cover thickness have been specified with the knowledge that covers performance can be degraded in numerous ways.

In general, the condition of tailings disposal sites should be virtually the same as those in surrounding environs

and should remain so without active care and maintenance. Advanced tailings disposal modes such as fixation or nitric acid leaching may offer potentially improved isolation, but the improvement over what are considered adequate programs is uncertain while the costs are excessively high and other, new problems are encountered with such technologies.

Groundwater Protection

A number of separate issues were raised concerning the matter of tailings impoundment seepage and groundwater protection.

Some commenters stated that in addition to requiring control of seepage, the regulations should clearly specify that groundwater uses must be protected as there will inevitably be some seepage occurring. The NRC's intent in the proposed regulations was to protect current and potential groundwater uses and the final regulations have been drafted to explicitly state this. That is, where an aquifer below a site is initially of drinking water quality, it shall remain so during and after operations.

Others questioned whether continued seepage from impoundment would not be a problem over the very long term. Because uranium milling in the United States is conducted in semi-arid regions and evaporation rates are frequently far in excess of rainfall rates, it is not expected that seepage will be a long-term problem. There is concern about providing good seepage control primarily during the operational period when hundreds of tons of waste solutions are generated daily at an average mill. After the impoundments dry, there will be virtually no driving force for seepage. There is good reason to expect that there is, in general, little recharge of aquifers in interfluvial zones in the semi-arid milling regions, if there is any at all. It is for this reason that the NRC has accepted use of synthetic liners, the likely long term stability of which is questionable at best. Many commenters stated that the matter of groundwater protection should only be presented as a broad performance objective, and that specific methods of control should not be identified in the regulations. The concern is that the regulations will be too restrictive. In general, the NRC has identified seepage control as the most effective and positive way of protecting groundwater; methods of seepage control are identified in the regulation, but flexibility is provided to select the most appropriate ones in a case-by-case basis. (See response to the comment on the form of regulations above.)

Some commenters noted that spread of seepage contamination can occur rapidly by fractures, buried channels and other zones of high hydraulic conductivity, and stated that the GEIS and regulations should recognize this. Experience has indeed shown this concern to be valid. This has been a matter which routinely receives scrutiny by the NRC in licensing reviews and uncertainty about the existence of such discontinuous features at a site are in great measure, the reason for the NRC's conclusion that seepage prevention is the most appropriate approach to take in groundwater protection. Furthermore, the regulation has been revised to specify more clearly what site information is needed to provide an adequate understanding of hydrologic and geologic conditions which will control seepage and contaminant transport.

Finally, some stated that any area which overlies an aquifer of potential use must be avoided. As discussed above in discussions of the issue of siting, the NRC has revised the regulations to clearly indicate that one of the few most important matters which determine what is an acceptable site is the matter of groundwater protection (see the response to the siting issue above). However, a universal prohibition on siting near aquifers is inappropriate given constraints imposed in meeting other major objectives and given the seepage control measures which can be taken to effectively assure groundwater use is preserved.

Cost Estimates

Several commenters considered the cost estimates of the alternative tailings management programs presented in the draft generic environmental impact statement to be underestimated. In estimating costs in the draft, the NRC considered cost information submitted by the industry in connection with mill licensing cases, obtained quotes from vendors and suppliers, and gathered information from current literature on earthmoving and construction costs. Alternatives were clearly defined as combinations of separate unit operations, the cost of each being stated as a range. Single unit costs were selected from within the range to arrive at total costs. These total costs were consistent with those reported by the industry in actual NRC licensing cases. Where costs were particularly sensitive to assumptions made in defining alternatives, the effects of variations in assumptions on costs were clearly stated.

The NRC has reevaluated costs in the final GEIS. In doing so, the NRC

consulted other sources in addition to those consulted in preparing the draft GEIS. In general, the NRC found that costs increased by an amount attributable to inflation since the cost estimates were made for the draft GEIS document in 1978.

Environmental Impacts of Obtaining Reclamation Cover Material

Several commenters noted that considerable amounts of cover material would be required to perform final reclamation, that in some cases such material would have to be strip-mined in otherwise undisturbed areas (which would yield significant environmental impacts), and that such impacts were not addressed in the draft statement. It was further stated that this is particularly of concern at existing sites using above-grade disposal and that in some areas the depth of soil available for excavation is very limited. Under such conditions it would be necessary to excavate cover material from very large areas to obtain sufficient quantities of earth to provide reclamation in accordance with tailings cover requirements.

This final GEIS includes an assessment of the potential environmental impacts of obtaining cover material (see Section 9.3.8.4). The assessment includes analysis of what is considered by the NRC to be a potential worst-case situation wherein: (1) cover material must be obtained by strip-mining otherwise undisturbed terrain; (2) cover material must be hauled to the site from a distance of 10 miles (16 km); and (3) the average depth of soil available for excavation in the borrow area is only about 1 meter (not including about 0.5 m of topsoil which must be stripped, stored, and reapplied to revegetate the borrow area). These conditions are considered to be very conservative assumptions. Overburden or mine waste produced during local mining operations may well be available, and if so, would be suitable material provided only that it did not contain excessive radioactivity. To the extent that overburden or mine waste could be used, requirements for undisturbed soil materials would be reduced. Also, the NRC believes that adequate cover materials can be found within distances much less than 10 miles (there are over 300 sq. miles of area within a radius of 10 miles from any point), if not on the mill site itself. Furthermore, the depth of soil which may be excavated and removed will likely be much greater than 1 meter. Even in the rugged and rocky terrain of the Grants, New Mexico area

excavation depths of 15 m (60 ft.) or more are feasible.

With respect to environmental impacts, even under the very conservative assumptions described above, environmental impacts are limited; they are, at worst, comparable to those arising from mill construction with respect to air quality, land use, biota, water resources, and on the community. Given that reclamation of the borrow area will include revegetation to a natural condition, all impacts would be temporary except for the permanent alteration of topography and the irretrievable commitment of fuel burned by the trucks used to haul the cover material to the tailings disposal site. The NRC considers such impacts as small and insignificant in comparison to the benefits obtained by assuring long term physical isolation of the buried tailings and reduced residual radon emissions.

Financial Surety

Several commenters argued that self-insurance or third-party insurance should be considered as a surety mechanism. The basis for ruling out self-insurance is simply that such an arrangement would provide no additional assurance, other than that which would already exist through license requirements. Other commenters indicated that the required amount of surety coverage should be based on the licensee's costs for decommissioning and reclamation as opposed to contractor costs which include increased overhead and profit. With regard to the required amount of surety coverage, it seems obvious that the purpose of the surety mechanism is to protect the public from the possibility of a licensee's inability to perform the required decommissioning and reclamation and thus the only time when a surety would be collected would be in the event of default. A licensee's cost estimate would certainly be less than costs which an independent contractor would charge; therefore, inadequate protection would result if estimates based on licensee costs were permitted.

Several other commenters questioned the availability of surety bonds under the conditions described as necessary for satisfaction of the surety requirement. Although the NRC's investigation of the situation does indicate that there seems to be resistance on the part of some bonding companies to becoming involved in issuing bonds to companies subject to government regulation, the resistance appears to be the result of a misunderstanding of the requirements of

the regulation. The surety mechanism covers specific decommissioning and reclamation activities committed to by operator in the license and is not a guarantee to satisfy an indefinite set of requirements which may be established 15 or 20 years in the future. Furthermore, the evidence indicates that the surety market is competitive since some bonds have been obtained by uranium recovery operators even recently. In addition, flexibility exists in terms of acceptable types of mechanisms to satisfy the surety requirement.

Another comment which was raised pertaining to the decommissioning and reclamation surety concerned the required term of the surety. As stated in the draft GEIS and the proposed rules, the term of the surety must be open-ended in order to provide the requisite high level of assurance. The NRC considered that unless the surety remained in force until decommissioning and reclamation activities covered by the arrangement were completed, there would be nothing to prevent the surety company from cancelling the arrangement if and when the financial stability of the licensee became questionable or at the end of milling operations when the assurance is most needed. Obviously, this would provide the public with totally inadequate protection. However, through further consideration and investigation, the NRC has learned that other types of arrangements may provide the same high level of assurance as an open-ended arrangement does. Therefore, provision has been made in the decommissioning and reclamation surety criterion to allow flexibility concerning the term of the arrangement, providing the same high level of assurance exists.

Long Term Funding

A number of comments were received concerning the requirement that an amount be paid to cover the costs of long term site surveillance. Some commenters indicated that the amount, the equivalent of \$250,000 in 1978 dollars, was too high, others stated that it was too low, and some indicated that they considered it should correlate with the size of the disposal site. The basis for the long term fund, as established in the draft GEIS, is that something on the order of an annual site inspection to confirm the integrity of the site will be all that is necessary. However, the requirement is designed so that sufficient flexibility exists to increase the required charge, if appropriate, at certain sites if it is determined that the necessary level of surveillance and site control are significantly greater than

assumed in the GEIS. For example, this might occur if fencing is determined to be necessary. However, the NRC considers that as long as some ongoing monitoring is appropriate, the nominal charge established by this requirement could hardly be reduced.

Other commenters indicated that they considered the long term fund charge should be designed like an insurance fund and cover any damage which may result from a catastrophic event. As discussed in Section 14.3 of the final GEIS, the staff considered an insurance fund to cover costs associated with unforeseen events such as catastrophic occurrences, but rejected this option on the basis that the likelihood of such an occurrence would be small and design against it would be impractical beyond that which is already required in terms of siting and design. As mentioned above, where there is significant uncertainty about long term performance, which might occur at an existing site where options for tailings disposal are limited, more than the minimum fee can be charged.

Government Land Ownership

A number of commenters inquired about how the land ownership requirements would be implemented, particularly with regard to existing facilities where UMTRCA explicitly allows for NRC discretion. Transfer of an unencumbered fee estate may be difficult to achieve since land ownership can be a complex matter, particularly in western states where it is not uncommon for surface rights, mineral rights (including oil and gas), and water rights to be conveyed as separate interests. The NRC is concerned that if complete and total transfer is required, land ownership considerations (i.e., the difficulty in assembling title to all interests) may significantly impact the selection of sites. If the ability to obtain title to land became a driving force in the site selection process, this would be wholly inconsistent with the fundamental conclusion of the GEIS, i.e., that physical isolation as opposed to institutional arrangements must be the primary means of long term control.

In addition to concluding that physical site characteristics conducive to long term stability are of overriding importance, the NRC considers that in most cases Government control of the surface rights is necessary (1) to control land uses at the disposal site which could lead to disruption of the tailings, and (2) in general, to assure ongoing surveillance is performed. Government control is also considered prudent so that in the unlikely event that remedial action at a disposal site is required, a

government agency, because it is probably the only institution which would have sufficient resources, would be available to support proper action. However, transfer of certain subsurface rights may be of less importance in providing the necessary control.

Thus, although Criterion 11 requires applicants/operators to make a serious effort to acquire all interests in the land, sufficient flexibility is maintained to permit the Commission to determine that surface ownership, by itself, of a site with characteristics conducive to long term stability may be sufficient. In addition, the Commission would require appropriate notice in the public land records that the land is being used for tailings disposal and thus, would be subject to an NRC license prohibiting the disturbance of the tailings in the exercise of any other interest in the real property.

In addition, Criterion 11 makes essentially no distinction between land ownership requirements for licenses issued before or after November 8, 1981. As discussed in Sections 12.3.11 and 13.4 of the final GEIS, the NRC has concluded that surface ownership is necessary to assure ongoing surveillance, except possibly in the case of deep mine disposal. Thus, although UMTRCA directs the Commission to specifically consider the status of land ownership at existing facilities, the NRC does not consider it reasonable to expect that any licensee or site owner would be willing to accept the onerous obligation associated with a perpetual NRC license, which would be required if land ownership is not transferred. Given these circumstances, the NRC does not expect there will be a situation where waivers to surface land ownership transfer requirements will be appropriate.

Agreement State Regulation

A number of commenters indicated that the draft GEIS failed to assess the Agreement States' programs. Others inquired as to how the new requirements would be implemented in Agreement States. The amendments to the Mill Tailings Act in 1979 clarify when the new requirements become effective in Agreement States. Generally, the States are required to implement the new requirements immediately, to the extent practicable, and to establish standards by November of 1981 which are equivalent to, or more stringent than, the minimum national standards established by the Commission. Also, the UMTRCA requires Agreement States to complete independent, documented environmental assessments in

connection with each licensing case. The need for such documents and public review is a major conclusion of the final GEIS. The Mill Tailings Act also requires the Commission to evaluate the equivalency of the Agreement State program by November 1981. A more comprehensive set of criteria to be used in review of Agreement State programs is being developed by the NRC and will be made publicly available. It is considered that a detailed evaluation of the Agreement State program is not appropriate in the GEIS; however, the general role of Agreement States and their relationship with NRC is discussed.

Exemption From Licensing Small Quantities of Byproduct Material

Some commenters suggested that small quantities of byproduct material connected with research and development should be exempted from licensing requirements. The NRC agrees that this would be desirable but is not, at this time, proposing rules to provide for either an exemption or general license (i.e., a license effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons) covering small quantities of byproduct material. In order to exempt materials from licensing requirements or issue general licenses, the Commission must determine that the quantities of materials involved will not be harmful to the health and safety of the public and to the environment. It is the NRC's understanding that the quantities of tailings generally involved in research and development activities may be as large as a few tons. The NRC notes that a quantity such as this may, among other things, result in a buildup of unacceptable radon concentrations in improperly ventilated structures. Thus, the NRC believes that additional evaluations are necessary before it can be determined what quantities of tailings can be exempted from licensing requirements or be covered under a general license. The NRC is therefore further considering this issue and plans to publish its conclusions on this subject at a later date in order not to delay issuance of the rules identified below.

In the meantime, it will be necessary for individuals conducting research and development activities using byproduct material, as defined in 10 CFR Part 40, to obtain a specific NRC license. The NRC does not believe this should be a significant administrative or costly burden on applicants since it is anticipated minimal information will be required in license applications (i.e., provisions for (1) providing proper ventilation; (2) conducting necessary

radiation safety surveys; and (3) disposal of materials to properly licensed persons). Furthermore, there are presently no fees in 10 CFR Part 170 applicable to the use of these quantities of byproduct material for research and development activities. The NRC does not plan to require fees for these licenses, at least until formal rules to 10 CFR Part 170 have been adopted. The NRC requests written comments on this matter and any additional information on specific quantities and uses to be considered for exemption or covered by a general license. The technical basis for such comments is also requested.

IV. Significant Features of Final Rules

The rules promulgated in this notice are derived from the conclusions reached in the final GEIS on uranium milling and the requirements established by the UMRCA. The major conclusions reached in the final GEIS relative to needed rule changes, stated here in broad terms, are:

1. In selecting among alternative tailings disposal sites or judging the adequacy of existing sites, consideration should be given to specific site characteristics which will assure meeting the broad objective of isolating tailings and associated contaminants from humans and the environment without ongoing active maintenance for thousands of years.

2. The "prime option" for tailings disposal is placement below grade.

3. Where full below grade burial is not practicable and tailings must be located above grade, tailings should be placed as much below grade as is reasonably achievable.

4. Methods, such as liners or dewatering, should be employed to reduce seepage of toxic materials into groundwater to the maximum extent reasonably achievable. Any seepage which might occur must not result in the deterioration of the quality of existing affected groundwater.

5. Sufficient earth cover, but not less than 3 meters, should be placed over tailings to reduce radon exhalation from buried tailings to a calculated value of not more than 2pCi/m²-sec above natural background levels. A full self-sustaining vegetative cover should be established on the earth cover or a rock cover employed to reduce to negligible amounts the potential for significant wind and water erosion of the earth cover. In arid and semi-arid regions where it is unlikely vegetation will be full and self-sustaining, rock cover stabilization is mandatory.

6. Milling operations should be conducted so that all airborne effluent releases are reduced to as low as is

reasonably achievable. To accomplish this objective, staged reclamation of tailings systems should be considered to control radon emissions and the blowing of dusts from tailings and frequent determinations of the performance of emission control devices should be made to ensure that these devices are operating at anticipated efficiencies.

7. Financial surety arrangements should be established to ensure that sufficient funds are available to cover the costs of decontamination and decommissioning the mill, mill site, and environs and for the reclamation of tailings areas.

8. Sites on which tailings are finally disposed should be controlled through ownership and custody by a government agency unless, in special cases as might occur in deep mine disposal, this is determined unnecessary.

9. Funds should be provided by each mill operator to cover the costs of long term site surveillance and any probable long term monitoring and maintenance requirements.

10. Construction of a uranium extraction facility or tailings disposal area should not commence until the NRC has completed its final environmental impact assessment required by the National Environmental Policy Act (NEPA), or an Agreement State has completed its written environmental analysis as required by UMRCA.

The UMRCA, among other things, specifies:

1. A revised definition of "byproduct material" to include tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content;

2. Ownership and custody requirements for byproduct material;

3. Provisions for requiring bonds, sureties, or other financial arrangements covering the decontamination, decommissioning, and reclamation of sites, structures, and equipment used in conjunction with byproduct material; and

4. Provisions governing Agreement State authority under Section 274 of the Atomic Energy Act.

The significant features of the new rules are discussed below. Several changes, as indicated in the above discussion and the Summary and Appendix A of the final GEIS, have been made in these rules to reflect public comments, to better clarify specific requirements, and, where practical, to provide flexibility.

1. Section 40.26 of Part 40 is amended to add a new paragraph (d) which specifies that the general license

covering tailings at active mills expires within nine months from the effective date of this amendment unless an affected licensee has submitted an application for license renewal or amendment which includes a detailed program from meeting the technical and financial criteria contained in the new Appendix A to Part 40. The Commission considers this amendment necessary to ensure that all existing mill operators who have not already done so develop acceptable programs relating to the long term disposition of tailings at active mills in a timely manner.

2. Section 40.31 of Part 40 is amended by adding a new paragraph (g) to require applicants for mill licenses to propose written specifications relating to the operation of mills and disposition of tailings or wastes to achieve requirements and objectives set forth in a new Appendix A to 10 CFR 40. As provided by paragraph (g), applicants for mill licenses must clearly demonstrate how the requirements and objectives set forth in Appendix A have been addressed; failure to clearly demonstrate how the requirements and objectives in Appendix A have been addressed will be grounds for refusing to accept an application for a license. These requirements and objectives are discussed in the following Item #3.

3. A new Appendix A entitled, "Criteria Relating to the Operation of Mills and Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for their Source Material Content," is added to 10 CFR 40. As indicated in the August 24 notice, this appendix consists of four major categories: technical criteria; financial criteria; site and byproduct material ownership criteria; and long term site surveillance criteria. These criteria are, for the most part, essentially the same as those contained in the August 24 notice except that many of the terms and provisions included in the proposed criteria have been more explicitly defined and/or clarified as recommended in public comments. Also, flexibility is provided in many cases as suggested in public comments to allow achieving an optimum tailings disposal program on a site specific basis.

The detailed bases for the criteria in the new Appendix A are contained in the final GEIS. As noted above in preparing the final GEIS, the NRC has completely rechecked cost estimates for meeting the major criteria in Appendix A. Estimated costs were derived from information on costs submitted by applicants for licenses, experienced engineering consultants under NRC

contracts, and other information on costs available to the NRC. The Commission believes that under these criteria tailings and wastes can be disposed of at reasonable costs in a manner that the purposes and mandates of the UMTRCA will be achieved and fulfilled, respectively. Thus, the need for ongoing active care and maintenance programs to redress degradation of the tailings isolation by natural weathering and erosion forces can be essentially eliminated. In that the technical criteria relating to the siting of mills and tailings disposal areas preclude location of tailings or milling operations in an area that could be disrupted by natural events such as flooding, these criteria will ensure that the requirements of Executive Order 11988 of May 23, 1977, concerning flood plain management are met. Therefore, as well as assuring tailings isolation, flood plains will be protected.

The new Appendix A requires all mill operators to develop and submit to the NRC definitive programs meeting the technical and financial criteria in the Appendix. These programs must be submitted with license renewals or within nine months from the effective date of the appendix, whichever occurs first.

4. Paragraphs (b) of § 40.14 and (e) of § 40.32 of 10 CFR 40 are amended to require the Director of the NRC's Office of Nuclear Material Safety and Safeguards or his designee to make a positive finding on an applicant's proposed plans as meeting the requirements and objectives in Appendix A prior to commencement of construction of a mill which produces byproduct material. This finding would be that made in the final environmental impact statement (or other environmental assessment) prepared pursuant to 10 CFR Part 51. These amendments delete paragraph (b) of § 40.14 and preclude exemptions from the requirements of §§ 40.31(f) and 40.32(e) of Part 40. They also amend paragraph (e) of § 40.32 to require the denial of applications for licenses where construction is started before the appropriate environmental appraisals are completed and documented. Construction activities are likely to result in significant and long lasting environmental impacts, the propriety of which cannot be ascertained until these environmental appraisals are completed and documented. The Commission also notes in this regard that milling results in the production of large quantities of byproduct material as tailings each year. When construction of a mill begins, including its tailings disposal area,

irrevocable commitments are made regarding tailings disposal. Given that each mill tailings pile constitutes a low-level waste burial site containing long lived radioactive materials, the Commission believes that prudence requires that specific methods of tailings disposal, mill decontamination, site reclamation, surety arrangements, and arrangements to allow for transfer of site and tailings ownership be worked out and approved before a license is granted.

The Commission further notes that similar irrevocable and/or irretrievable environmental impact and resource commitments are involved in the commencement of construction of plants and facilities in which source materials are possessed and used for the production of uranium hexafluoride and commercial waste disposal by land burial. Accordingly, the requirements of the revised paragraphs (b) of § 40.14 and (e) of § 40.32 would apply to these plants and facilities.

5. The amendments to 10 CFR 30 and 70 also relate to commencement of construction of other types of plants and facilities in which byproduct and special nuclear materials are used and possessed. The Commission believes commencement of construction of these plants and facilities may also result in irreversible and irretrievable commitments of environmental impacts and resources. Therefore, the Commission believes that it is also desirable and necessary that a final environmental impact statement or assessment be completed and documented before authorizing commencement of construction. Thus, 10 CFR 30.11(b), 10 CFR 30.33(a)(5), 10 CFR 70.14(b) and 10 CFR 70.23(a)(7) are amended to conform to the foregoing amendments to 10 CFR 40.

6. A new § 150.15a is added to 10 CFR Part 150 to enumerate certain authorities reserved to the Commission under UMTRCA. Paragraph (a) is drawn directly from sections 204(f) and 202(a) of UMTRCA. Paragraph (b) is extracted from § 83 of the Atomic Energy Act of 1954, as added by § 202(a) of UMTRCA. The language of UMTRCA and its legislative history indicate that the NRC is to make the determinations under, and establish standards pursuant to, § 83, which minimum Federal standards and determinations must, under § 204(e) of the UMTRCA, be met by the Agreement States. New §§ 150.31 and 150.32 outline requirements in the UMTRCA for Agreement State regulation of tailings or activities that produce such tailings or wastes. These new sections are taken directly from

§ 274o of the Atomic Energy Act, as added by § 204(c) of the UMTRCA.

Under the provisions of the new § 150.31, an Agreement State must, after November 8, 1981, require compliance with standards for the protection of the public health, safety, and the environment from hazards associated with byproduct material which are equivalent, to the extent practicable, or more stringent than, standards in the new Appendix A of 10 CFR Part 40 discussed in Item 3 above. Before November 8, 1981, an Agreement State must require compliance with Appendix A of 10 CFR Part 40 to the maximum extent practicable. As discussed above, the provisions of the new Appendix A will require all mill operators to develop and submit detailed programs (which include appropriate supporting data, analyses, and alternatives) meeting the technical and financial criteria in the Appendix A in connection with license renewals or within nine months, whichever occurs first. The Commission believes that it is practicable for Agreement State licensees to develop and submit similar detailed programs to their respective licensing authorities in view of the length of time active milling operators have known of the basic components of these criteria and the nearly one year period before submittals are required. Therefore, the Commission expects Agreement States to immediately implement this requirement under the provisions of the UMTRCA which require Agreement States to implement equivalent standards "to the maximum extent practicable" during the interim period until November 8, 1981. The Commission notes in this regard that approval of a final acceptable plan (which may include various remedial alternatives for the management of existing tailings systems as well as alternatives for the management of tailings to be generated in the future) may take a long time following submittal of initial plans by licensees given the difficulty of the issues typically involved at existing sites. Thus, it is necessary for present mill operators to begin now to develop programs for meeting the standards in the new Appendix A to 10 CFR Part 40 rather than to delay until November 8, 1981, to develop plans and/or alternative programs for meeting the standards. Furthermore, the Commission considers it practicable now, even before final plans may have been worked out and approved, to immediately implement steps to reduce airborne effluent releases from both plant operations and tailings systems and seepage from tailings systems to levels which are as low as are

reasonably achievable as specified in the standards of the new appendix. This is also required in order to meet the EPA standards in 40 CFR 190 which must be enforced by the Commission and Agreement States by December, 1980. Therefore, it is essential that licensing action be taken now to ensure interim tailings management programs which deal with presently occurring impacts such as blowing tailings and uncontrolled seepage are worked out on an immediate basis even before complete disposal programs can be finalized.

V. Future Actions

The UMTRCA establishes certain responsibilities and authorities whereby the Environmental Protection Agency (EPA) must develop standards of general application for the protection of the public health, safety, and the environment from radiological and nonradiological hazards associated with the processing and with the possession, transfer, and disposal of byproduct materials. These generally applicable standards for nonradiological hazards must provide for the protection of human health and the environment consistent with the standards required under subtitle C of the Solid Waste Disposal Act, as amended. The Commission and any State permitted to exercise authority under § 274b.(2) of the Atomic Energy Act must apply these standards of general application in licensing actions involving byproduct material.

The EPA has not, as yet, proposed the standards described above. It is the Commission's understanding, based on NRC and EPA staff discussions, that these standards will probably not be proposed before 1981. Upon finalization of the EPA standards, it is likely that minor changes will be required in the Commission's regulations. However, to delay issuance of the rules set forth below until the final EPA standards have been issued will, in all probability, preclude sufficient time for applicable Agreement States to adopt standards which are equivalent to or more stringent than those of the Commission's by November 8, 1981, in order to meet the requirements in the UMTRCA.

VI. Regulatory Changes

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, the Uranium Mill Tailings Radiation Control Act of 1978, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Code of Federal Regulations, Parts 30, 40, 70, and 150 are

published as a document subject to codification.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

§ 30.11 [Amended]

1. Section 30.11 of 10 CFR 30 is amended by deleting paragraph 30.11(b).
2. Section 30.33 of 10 CFR 30 is amended by revising paragraph (a)(5) to read as follows:

§ 30.33 General requirements for issuance of specific licenses.

- (a) * * *
- (5) In the case of an application for a license to receive and possess byproduct material for commercial waste disposal by land burial or for the conduct of any other activity which the Commission determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

3. Section 40.1 of 10 CFR 40 is amended by revising paragraph (a) to read as follows:

§ 40.1 Purpose.

- (a) The regulations in this Part establish procedures and criteria for the

issuance of licenses to receive title to, receive, possess, use, transfer, or deliver source and byproduct materials, as defined in this Part, and establish and provide for the terms and conditions upon which the Commission will issue such licenses. The regulations in this Part do not establish procedures and criteria for the issuance of licenses for materials covered under Title I of the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021).

4. Section 40.2a of 10 CFR 40 is added to read as follows:

§ 40.2a Coverage of inactive tailings sites.

(a) Prior to the completion of the remedial action, the Commission will not require a license pursuant to this Part for possession of byproduct material as defined in this Part that is located at a site where milling operations are no longer active, if the site is designated a processing site covered by the remedial action program of Title I of the Uranium Mill Tailings Radiation Control Act of 1978. The Commission will exert its regulatory role in remedial actions primarily through concurrence and consultation in the execution of the remedial action pursuant to Title I of the Uranium Mill Tailings Radiation Control Act of 1978.

(b) The Commission will regulate byproduct material as defined in this Part that is located at a site where milling operations are no longer active, if such site is not covered by the remedial action program of Title I of the Uranium Mill Tailings Radiation Control Act of 1978. The criteria in Appendix A of this Part will be applied to such sites.

5. Section 40.3 of 10 CFR 40 is revised to read as follows:

§ 40.3 License requirements.

No person subject to the regulations in this Part shall receive title to, own, receive, possess, use, transfer, or deliver byproduct material as defined in this Part or any source material after removal from its place of deposit in nature, except as authorized in a specific or general license issued by the Commission pursuant to the regulations in this Part.

§ 40.11 [Amended]

6. Section 40.11 of 10 CFR 40 is amended by adding the words "or the Uranium Mill Tailings Radiation Control Act of 1978" following the words "Energy Reorganization Act of 1974" wherever they appear.

§ 40.13 [Amended]

7. Section 40.13 of 10 CFR 40 is amended by adding the following sentence at the end of Paragraph (a): "The exemption contained in this paragraph does not include byproduct material as defined in this Part."

§ 40.14 [Amended]

8. Section 40.14 of 10 CFR 40 is amended by deleting paragraph 40.14(b) and by inserting in its place the word "Reserved."

9. Section 40.21 of 10 CFR 40 is revised to read as follows:

§ 40.21 General license to receive title to source or byproduct material.

A general license is hereby issued authorizing the receipt of title to source or byproduct material, as defined in this Part, without regard to quantity. This general license does not authorize any person to receive, possess, deliver, use, or transfer source or byproduct material.

10. Section 40.26 of 10 CFR 40 is amended by adding a new § 40.26(d) to read as follows:

§ 40.26 General license for possession and storage of byproduct material as defined in this Part.

(d) The general license in paragraph (a) of this section shall expire nine months from the effective date of this subparagraph unless an applicable licensee has submitted, pursuant to the provisions of § 40.31 of this Part, an application for license renewal or amendment which includes a detailed program for meeting the technical and financial criteria contained in Appendix A of this Part.

11. Section 40.31 of 10 CFR 40 is amended by adding a new § 40.31(g) to read as follows:

§ 40.31 Applications for specific licenses

(g) An application for a license to receive, possess, and use source material for uranium or thorium milling or byproduct material, as defined in this Part, at sites formerly associated with such milling shall contain proposed written specifications relating to milling operations and the disposition of the byproduct material to achieve the requirements and objectives set forth in Appendix A of this Part. Each application must clearly demonstrate how the requirements and objectives set forth in Appendix A of this Part have been addressed. Failure to clearly demonstrate how the requirements and objectives in Appendix A have been

addressed shall be grounds for refusing to accept an application.

12. Section 40.32 of 10 CFR 40 is amended by revising § 40.32(e) to read as follows:

§ 40.32 General requirements for issuance of specific licenses.

(e) In the case of an application for a license to possess and use source and byproduct material for uranium milling, production of uranium hexafluoride, commercial waste disposal by land burial or for the conduct of any other activity which the Commission determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Part 51 of this chapter, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such a conclusion shall be grounds for denial of a license to possess and use source and byproduct material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

13. Section 40.41 of 10 CFR 40 is amended by revising § 40.41 (c) and (e) to read as follows:

§ 40.41 Terms and conditions of licenses.

(c) Each person licensed by the Commission pursuant to the regulations in this part shall confine his possession and use of source or byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part shall carry with it the right to receive, possess, and use source or byproduct material. Preparation for shipment and transport of source or byproduct

material shall be in accordance with the provisions of Part 71 of this chapter.

(e) The Commission may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of source or byproduct material as it deems appropriate or necessary in order to:

- (1) Promote the common defense and security;
- (2) Protect health or to minimize danger of life or property;
- (3) Protect restricted data;
- (4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the act and regulations thereunder.

14. Section 40.51 of 10 CFR 40 is revised to read as follows:

§ 40.51 Transfer of source or byproduct material.

(a) No licensee shall transfer source or byproduct material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of paragraphs (c) and (d) of this section, any licensee may transfer source or byproduct material:

- (1) To the Department of Energy
- (2) To the agency in any Agreement State which regulates radioactive materials pursuant to an agreement with the Commission or the Atomic Energy Commission under section 274 of the Act;

(3) To any person exempt from the licensing requirements of the Act and regulations in this part, to the extent permitted under such exemption;

(4) To any person in an Agreement State subject to the jurisdiction of that State who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemptions;

(5) To any person authorized to receive such source or byproduct material under terms of a specific license or a general license or their equivalents issued by the Commission or an Agreement State;

(6) To any person abroad pursuant to an export license issued under Part 110 of this chapter; or

(7) As otherwise authorized by the commission in writing.

(c) Before transferring source or byproduct material to a specific licensee of the Commission or an Agreement State or to a general licensee who is

required to register with the Commission or with an Agreement State prior to receipt of the source or byproduct material, the licensee transferring the material shall verify that the transferee's license authorizes receipt of the type, form, and quantity of source or byproduct material to be transferred.

(d) The following methods for the verification required by paragraph (c) of this section are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of source or byproduct material to be transferred, specifying the license or registration certification number, issuing agency and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of source or byproduct material to be transferred, specifying the license or registration certification number, issuing agency and expiration date: Provided, That the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

(5) When none of the methods of verification described in paragraphs (d)(1) to (4) of this section are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the source or byproduct material.

15. Section 40.61 of 10 CFR 40 is revised to read as follows:

§ 40.61 Records.

(a) Each person who receives source or byproduct material pursuant to a license issued pursuant to the regulations in this part shall keep records showing the receipt, transfer, and disposal of such source or byproduct material.

(b) Records which are required by the regulations in this part or by license

condition shall be maintained for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, such records shall be maintained until the Commission authorizes their disposition.

(c)(1) Records of receipt of source or byproduct material which must be maintained pursuant to paragraph (a) of this section shall be maintained as long as the licensee retains possession of the source or byproduct material and for five years following transfer, or disposition of the source of byproduct material.

(2) [Reserved]

(3) Records of transfer of source or byproduct material shall be maintained by the licensee who transferred the material until the Commission authorizes their disposition.

(4) Records of disposal of source or byproduct material shall be maintained in accordance with § 20.401(c) of this chapter.

(5) If source or byproduct material is combined or mixed with other licensed material and subsequently treated in a manner which makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, evaluative techniques such as first-in-first-out may be used for purposes of the records retention requirements of this paragraph.

(d)(1) Records which must be maintained pursuant to this part may be the original or reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations.

(2) If there is a conflict between the Commission's regulations in this part, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part for such records shall apply unless the Commission, pursuant to § 40.14, has granted a specific exemption from the record retention requirements specified in the regulations in this part.

16. Section 40.62 of 10 CFR 40 is revised to read as follows:

§ 40.62 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect source or byproduct material and the premises and facilities wherein source or byproduct material is used or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

17. Section 40.63 of 10 CFR 40 is revised to read as follows:

§ 40.63 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part, including tests of:

- (a) Source or byproduct material;
- (b) Facilities wherein source or byproduct material is utilized or stored;
- (c) Radiation detection and monitoring instruments; and
- (d) Other equipment and devices used in connection with the utilization and storage of source or byproduct material.

18. Appendix A is added to 10 CFR 40 to read as follows:

Appendix A to Part 40

Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for Their Source Material Content.

Introduction. Every applicant for a license to possess and use source material in conjunction with uranium or thorium milling, or byproduct material at sites formerly associated with such milling, is required by the provisions of § 40.31(g) to include in a license application proposed specifications relating to milling operations and the disposition of tailings or waste resulting from such milling activities. This appendix establishes technical, financial, ownership, and long term site surveillance criteria relating to the siting, operation, decontamination, decommissioning, and reclamation of mills and tailings or waste systems and sites at which such mills and systems are located. As used in this appendix, the term "as low as is reasonably achievable" has the same meaning as in paragraph 20.1(c) of 10 CFR 20 of this Chapter.

In many cases, flexibility is provided in the criteria to allow achieving an optimum tailings disposal program on a site specific basis. However, in such cases the objectives, technical alternatives, and concerns which must be taken into account in developing a tailings program are identified. As provided by the provisions of § 40.31(g), applications for licenses must clearly demonstrate how the criteria have been addressed.

The specifications shall be developed considering the expected full capacity of tailings or waste systems and the lifetime of mill operations. Where later expansions of systems or operations may be likely (for example, where large quantities of ore now marginally uneconomical may be stockpiled), the amendability of the disposal system to accommodate increased capacities without

degradation in long term stability and other performance factors shall be evaluated.

Detailed programs meeting the technical and financial criteria in this Appendix, including appropriate supporting data, analyses, and alternatives, shall be developed by existing uranium milling licensees and filed with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, in connection with license renewal applications or within nine months from the effective date of this Appendix, whichever occurs first.

I. Technical Criteria

Criterion 1—In selecting among alternative tailings disposal sites or judging the adequacy of existing tailings sites, the following site features, which will determine the extent to which a program meets the broad objective of isolating the tailings and associated contaminants from man and the environment during operations and for thousands of years thereafter without ongoing active maintenance, shall be considered:

- remoteness from populated areas;
- hydrologic and other natural conditions as they contribute to continued immobilization and isolation of contaminants from usable groundwater sources; and
- potential for minimizing erosion, disturbance, and dispersion by natural forces over the long term.

The site selection process shall be an optimization to the maximum extent reasonably achievable in terms of these features.

In the selection of disposal sites, primary emphasis shall be given to isolation of tailings or wastes, a matter having long term impacts, as opposed to consideration only of short term convenience or benefits, such as minimization of transportation or land acquisition costs. While isolation of tailings will be a function of both site and engineering design, overriding consideration shall be given to siting features given the long term nature of the tailings hazards.

Tailings shall be disposed of in a manner that no active maintenance is required to preserve conditions of the site.

Criterion 2—To avoid proliferation of small waste disposal sites and thereby reduce perpetual surveillance obligations, byproduct material from in situ extraction operations, such as residues from solution evaporation or contaminated control processes, and wastes from small remote above ground extraction operations shall be disposed of at existing large mill tailings disposal sites; unless, considering the nature of the wastes, such as their volume and specific activity, and the costs and environmental impacts of transporting the wastes to a large disposal site, such offsite disposal is demonstrated to be impracticable or the advantages of onsite burial clearly outweigh the benefits of reducing the perpetual surveillance obligations.

Criterion 3—The "prime option" for disposal of tailings is placement below grade, either in mines or specially excavated pits (that is, where the need for any specially constructed retention structure is eliminated).

The evaluation of alternative sites and disposal methods performed by mill operators in support of their proposed tailings disposal program (provided in applicants' environmental reports) shall reflect serious consideration of this disposal mode. In some instances, below grade disposal may not be the most environmentally sound approach, such as might be the case if a high quality groundwater formation is relatively close to the surface or not very well isolated by overlying soils and rock. Also, geologic and topographic conditions might make full below grade burial impracticable; for example, bedrock may be sufficiently near the surface that blasting would be required to excavate a disposal pit at excessive cost, and more suitable alternate sites are not available. Where full below grade burial is not practicable, the size of retention structures, and size and steepness of slopes of associated exposed embankments, shall be minimized by excavation to the maximum extent reasonably achievable or appropriate given the geologic and hydrologic conditions at a site. In these cases, it must be demonstrated that an above grade disposal program will provide reasonably equivalent isolation of the tailings from natural erosional forces.

Criterion 4—The following site and design criteria shall be adhered to whether tailings or wastes are disposed of above or below grade:

(a) Upstream rainfall catchment areas must be minimized to decrease erosion potential and the size of the maximum possible flood which could erode or wash out sections of the tailings disposal area.

(b) Topographic features should provide good wind protection.

(c) Embankment and cover slopes shall be relatively flat after final stabilization to minimize erosion potential and to provide conservative factors of safety assuring long term stability. The broad objective should be to contour final slopes to grades which are as close as possible to those which would be provided if tailings were disposed of below grade; this could, for example, lead to slopes of about 10 horizontal to 1 vertical (10h:1v) or less steep. In general, slopes should not be steeper than about 5h:1v. Where steeper slopes are proposed, reasons why a slope less steep than 5h:1v would be impracticable should be provided, and compensating factors and conditions which make such slopes acceptable should be identified.

(d) A full self-sustaining vegetative cover shall be established or rock cover employed to reduce wind and water erosion to negligible levels.

Where a full vegetative cover is not likely to be self-sustaining due to climatic or other conditions, such as in semi-arid and arid regions, rock cover shall be employed on slopes of the impoundment system. The NRC will consider relaxing this requirement for extremely gentle slopes such as those which may exist on the top of the pile.

The following factors shall be considered in establishing the final rock cover design to avoid displacement of rock particles by human and animal traffic or by natural processes, and to preclude undercutting and piping:

- shape, size, composition, and gradation of rock particles (excepting bedding material average particles size shall be at least cobble size or greater);

- rock cover thickness and zoning of particles by size; and
- steepness of underlying slopes.

Individual rock fragments shall be dense, sound, and resistant to abrasion, and shall be free from cracks, seams, and other defects that would tend to unduly increase their destruction by water and frost actions. Weak, friable, or laminated aggregate shall not be used. Shale, rock laminated with shale, and cherts shall not be used.

Rock covering of slopes may not be required where top covers are very thick (on the order of 10m or greater); impoundment slopes are very gentle (on the order of 10 h:1v or less); bulk cover materials have inherently favorable erosion resistance characteristics; and, there is negligible drainage catchment area upstream of the pile and good wind protection as described in points (a) and (b) of this Criterion.

Furthermore, all impoundment surfaces shall be contoured to avoid areas of concentrated surface runoff or abrupt or sharp changes in slope gradient. In addition to rock cover on slopes, areas toward which surface runoff might be directed shall be well protected with substantial rock cover (rip rap). In addition to providing for stability of the impoundment system itself, overall stability, erosion potential, and geomorphology of surrounding terrain shall be evaluated to assure that there are not ongoing or potential processes, such as gully erosion, which would lead to impoundment instability.

(e) The impoundment shall not be located near a capable fault that could cause a maximum credible earthquake larger than that which the impoundment could reasonably be expected to withstand. As used in this criterion, the term "capable fault" has the same meaning as defined in § III(g) of Appendix A of 10 CFR 100. The term "maximum credible earthquake" means that earthquake which would cause the maximum vibratory ground motion based upon an evaluation of earthquake potential considering the regional and local geology and seismology and specific characteristics of local subsurface material.

(f) The impoundment, where feasible, should be designed to incorporate features which will promote deposition. For example, design features which promote deposition of sediment suspended in any runoff which flows into the impoundment area might be utilized; the object of such a design feature would be to enhance the thickness of cover over time.

Criterion 5—Steps shall be taken to reduce seepage of toxic materials into groundwater to the maximum extent reasonably achievable. Any seepage which does occur shall not result in deterioration of existing groundwater supplies from their current or potential uses. The following shall be considered in order to accomplish this objective:

- installation of low permeability bottom liners (Where synthetic liners are used, a leakage detection system shall be installed

immediately below the liner to ensure major failures are detected if they occur. This is in addition to the groundwater monitoring program conducted as provided in Criterion 7. Where clay liners are proposed or relatively thin in-situ clay soils are to be relied upon for seepage control, tests shall be conducted with representative tailings solutions and clay materials to confirm that no significant deterioration of permeability or stability properties will occur with continuous exposure of clay to tailings solutions. Tests shall be run for a sufficient period of time to reveal any effects if they are going to occur (in some cases, deterioration has been observed to occur rather rapidly after about nine months of exposure)).

- mill process designs which provide the maximum practicable recycle of solutions and conservation of water to reduce the net input of liquid to the tailings impoundment.

- dewatering of tailings by process devices and/or in-situ drainage systems (At new sites, tailings shall be dewatered by a drainage system installed at the bottom of the impoundment to lower the phreatic surface and reduce the driving head for seepage, unless tests show tailings are not amenable to such a system. Where in-situ dewatering is to be conducted, the impoundment bottom shall be graded to assure that the drains are at a low point. The drains shall be protected by suitable filter materials to assure that drains remain free running. The drainage system shall also be adequately sized to assure good drainage.)

- neutralization to promote immobilization of toxic substances.

Where groundwater impacts are occurring at an existing site due to seepage, action shall be taken to alleviate conditions that lead to excessive seepage impacts and restore groundwater quality to its potential use before milling operations began to the maximum extent practicable. The specific seepage control and groundwater protection method, or combination of methods, to be used must be worked out on a site-specific basis. Technical specifications shall be prepared to control installation of seepage control systems. A quality assurance, testing, and inspection program, which includes supervision by a qualified engineer or scientist, shall be established to assure the specifications are met.

While the primary method of protecting groundwater shall be isolation of tailings and tailings solutions, disposal involving contact with groundwater will be considered provided supporting tests and analyses are presented demonstrating that the proposed disposal and treatment methods will not degrade groundwater from current or potential uses.

In support of a tailings disposal system proposal, the applicant/operator shall supply information concerning the following:

- The chemical and radioactive characteristics of the waste solutions.
- The characteristics of the underlying soil and geologic formations particularly as they will control transport of contaminants and solutions. This shall include detailed information concerning extent, thickness, uniformity, shape, and orientation of underlying strata. Hydraulic gradients and

conductivities of the various formations shall be determined.

This information shall be gathered from borings and field survey methods taken within the proposed impoundment area and in surrounding areas where contaminants might migrate to usable groundwater. The information gathered on boreholes shall include both geologic and geophysical logs in sufficient number and degree of sophistication to allow determining significant discontinuities, fractures, and channelled deposits of high hydraulic conductivity. If field survey methods are used, they should be in addition to and calibrated with borehole logging. Hydrologic parameters such as permeability shall not be determined on the basis of laboratory analysis of samples alone; a sufficient amount of field testing (e.g., pump tests) shall be conducted to assure actual field properties are adequately understood. Testing shall be conducted to allow estimating chemi-sorption attenuation properties of underlying soil and rock.

- Location, extent, quality, capacity and current uses of any groundwater at and near the site.

Furthermore, steps shall be taken during stockpiling of ore to minimize penetration of radionuclides into underlying soils; suitable methods include lining and/or compaction of ore storage areas.

Criterion 6—Sufficient earth cover, but not less than three meters, shall be placed over tailings or wastes at the end of milling operations to result in a calculated reduction in surface exhalation of radon emanating from the tailings or wastes to less than two picocuries per square meter per second. In computing required tailings cover thicknesses, moisture in soils in excess of amounts found normally in similar soils in similar circumstances shall not be considered. Direct gamma exposure from the tailings or wastes should be reduced to background levels. The effects of any thin synthetic layer shall not be taken into account in determining the calculated radon exhalation level. If non-soiled materials are proposed to reduce tailings covers to less than three meters, it must be demonstrated that such materials will not crack or degrade by differential settlement, weathering, or other mechanism, over long term time intervals. Near surface cover materials (i.e., within the top three meters) shall not include mine waste or rock that contains elevated levels of radium; soils used for near surface cover must be essentially the same, as far as radioactivity is concerned, as that of surrounding surface soils. This is to ensure that surface radon exhalation is not significantly above background because of the cover material itself.

Criterion 7—At least one full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental

impacts of operation; and to detect potential long term effects.

Criterion 8—Milling operations shall be conducted so that all airborne effluent releases are reduced to levels as low as is reasonably achievable. The primary means of accomplishing this shall be by means of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practicable measures have been taken to control emissions at the source.

Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are reduced to the maximum extent reasonably achievable and to avoid site contamination. The greatest potential sources of offsite radiation exposure (aside from radon exposure) are dusting from dry surfaces of the tailings disposal area not covered by tailings solution and emissions from yellowcake drying and packaging operations.

Checks shall be made and logged hourly of all parameters (e.g., differential pressures and scrubber water flow rates) which determine the efficiency of yellowcake stack emission control equipment operation. It shall be determined whether or not conditions are within a range prescribed to ensure that the equipment is operating consistently near peak efficiency; corrective action shall be taken when performance is outside of prescribed ranges. Effluent control devices shall be operative at all times during drying and packaging operations and whenever air is exhausting from the yellowcake stack. Drying and packaging operations shall terminate when controls are inoperative. When checks indicate the equipment is not operating within the range prescribed for peak efficiency, actions shall be taken to restore parameters to the prescribed range. When this cannot be done without shutdown and repairs, drying and packaging operations shall cease as soon as practicable. Operations may not be re-started after cessation due to off-normal performance until needed corrective actions have been identified and implemented. All such cessations, corrective actions, and re-starts shall be reported to the appropriate NRC regional office as indicated in Criterion 8A, in writing, within 10 days of the subsequent restart.

To control dusting from tailings, that portion not covered by standing liquids shall be wetted or chemically stabilized to prevent or minimize blowing and dusting to the maximum extent reasonably achievable. This requirement may be relaxed if tailings are effectively sheltered from wind, such as may be the case where they are disposed of below grade and the tailings surface is not exposed to wind. Consideration shall be given in planning tailings disposal programs to methods which would allow phased covering and reclamation of tailings impoundments since this will help in controlling particulate and radon emissions during operation. To control dusting from diffuse sources, such as tailings and ore pads where automatic controls do not apply, operators shall develop written operating procedures specifying the methods of control which will be utilized.

Criterion 8A—Daily inspections of tailings or waste retention systems shall be conducted by a qualified engineer or scientist and documented. The appropriate NRC regional office as indicated in Appendix D of 10 CFR Part 20, or the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, shall be immediately notified of any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas, and/or of any unusual conditions (conditions not contemplated in the design of the retention system) which if not corrected could indicate the potential or lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

II. Financial Criteria

Criterion 9—Financial surety arrangements shall be established by each mill operator prior to the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the mill and site and for the reclamation of any tailings or waste disposal areas. The amount of funds to be ensured by such surety arrangements shall be based on Commission-approved cost estimates in a Commission-approved plan for (1) decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and (2) the reclamation of tailings and/or waste disposal areas in accordance with technical criteria delineated in Section I of this Appendix. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and evaluates alternatives for mitigating these impacts. The surety shall also cover the payment of the charge for long term surveillance and control required by Criterion 10. In establishing specific surety arrangements, the licensee's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the Commission may accept financial sureties that have been consolidated with financial or surety arrangements established to meet requirements of other Federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long term site surveillance and control, provided such arrangements are considered adequate to satisfy these requirements and that the portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long term funding charge is clearly identified and committed for use in accomplishing these activities. The licensee's surety mechanism will be reviewed annually by the Commission to assure that sufficient funds would be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any

increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability shall be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time (e.g., five years) yet which must be automatically renewed unless the surety notifies the beneficiary (the Commission or the State regulatory agency) and the principal (the licensee) some reasonable time (e.g., 90 days) prior to the renewal date of their intention not to renew. In such a situation the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least 60 days for the regulatory agency to collect.

Proof of forfeiture must not be necessary to collect the surety so that in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above would have to be clearly stated on any surety instrument which is not open-ended, and must be agreed to by all parties. Financial surety arrangements generally acceptable to the Commission are:

- (a) Surety bonds;
- (b) Cash deposits;
- (c) Certificates of deposit;
- (d) Deposits of government securities;
- (e) Irrevocable letters or lines of credit; and
- (f) Combinations of the above or such other

types of arrangements as may be approved by the Commission. However, self insurance, or any arrangement which essentially constitutes self insurance (e.g., a contract with a state or federal agency), will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

Criterion 10—A minimum charge of \$250,000 (1978 dollars) to cover the costs of long term surveillance shall be paid by each mill operator to the general treasury of the United States or to an appropriate State agency prior to the termination of a uranium or thorium mill license.

If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in Criterion 12, (e.g., if fencing is determined to be necessary) variance in funding requirements may be specified by the Commission. In any case, the total charge to cover the costs of long term surveillance shall be such that, with and assumed 1 percent annual real interest rate, the collected funds

will yield interest in an amount sufficient to cover the annual costs of site surveillance. The total charge will be adjusted annually prior to actual payment to recognize inflation. The inflation rate to be used is that indicated by the change in the Consumer Price Index published by the U.S. Department of Labor, Bureau of Labor Statistics.

III. Site and Byproduct Material Ownership

Criterion 11—A. These criteria relating to ownership of tailings and their disposal sites become effective on November 8, 1981, and apply to all licenses terminated, issued, or renewed after that date.

B. Any uranium or thorium milling license or tailings license shall contain such terms and conditions as the Commission determines necessary to assure that prior to termination of the license, the licensee will comply with ownership requirements of this criterion for sites used for tailings disposal.

C. Title to the byproduct material licensed under this Part and land, including any interests therein (other than land owned by the United States or by a State) which is used for the disposal of any such byproduct material, or is essential to ensure the long term stability of such disposal site, shall be transferred to the United States or the State in which such land is located, at the option of such State. In view of the fact that physical isolation must be the primary means of long term control, and Government land ownership is a desirable supplementary measure, ownership of certain severable subsurface interests (for example, mineral rights) may be determined to be unnecessary to protect the public health and safety and the environment. In any case, however, the applicant/operator must demonstrate a serious effort to obtain such subsurface rights, and must, in the event that certain rights cannot be obtained, provide notification in local public land records of the fact that the land is being used for the disposal of radioactive material and is subject to either an NRC general or specific license prohibiting the disruption and disturbance of the tailings. In some rare cases, such as may occur with deep burial where no ongoing site surveillance will be required, surface land ownership transfer requirements may be waived. For licenses issued before November 8, 1981, the Commission may take into account the status of the ownership of such land, and interests therein, and the ability of a licensee to transfer title and custody thereof to the United States or a State.

D. If the Commission subsequent to title transfer determines that use of the surface or subsurface estates, or both, of the land transferred to the United States or to a State will not endanger the public health, safety, welfare, or environment, the Commission may permit the use of the surface or subsurface estates, or both, of such land in a manner consistent with the provisions provided in these criteria. If the Commission permits such use of such land, it will provide the person who transferred such land with the right of first refusal with respect to such use of such land.

E. Material and land transferred to the United States or a State in accordance with

this Criterion shall be transferred without cost to the United States or a State other than administrative and legal costs incurred in carrying out such transfer.

F. The provisions of this Part respecting transfer of title and custody to land and tailings and wastes shall not apply in the case of lands held in trust by the United States for any Indian tribe or lands owned by such Indian tribe subject to a restriction against alienation imposed by the United States. In the case of such lands which are used for the disposal of byproduct material, as defined in this Part, the licensee shall enter into arrangements with the Commission as may be appropriate to assure the long term surveillance of such lands by the United States.

IV. Long-Term Site Surveillance

Criterion 12—The final disposition of tailings or wastes at milling sites should be such that ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections shall be conducted by the government agency retaining ultimate custody of the site where tailings, or wastes are stored to confirm the integrity of the stabilized tailings or waste systems and to determine the need, if any, for maintenance and/or monitoring. Results of the inspection shall be reported to the Commission within 60 days following each inspection. The Commission may require more frequent site inspections if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

§ 70.14 [Amended]

19. Section 70.14 of 10 CFR 70 is amended by deleting paragraph 70.14(b) and by inserting in its place the word "Reserved."

20. Section 70.23 of 10 CFR 70 is amended by revising paragraph (a)(7) to read as follows:

§ 70.23 Requirements for the approval of applications.

(a) * * *

(7) Where the proposed activity is processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, commercial waste disposal by land burial, or any other activity which the Commission determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available

alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusions shall be grounds for denial to possess and use special nuclear material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

PART 150—EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES UNDER SECTION 294

21. Section 150.15a of 10 CFR 150 is added to read as follows.

§ 150.15a Continued Commission authority pertaining to byproduct material.

(a) Prior to the termination of any Agreement State license for byproduct material as defined in § 150.3(c)(2) of this Part, or for any activity that results in the production of such material, the Commission shall have made a determination that all applicable standards and requirements pertaining to such material have been met.

(b) After November 8, 1981, the Commission reserves the authority to establish minimum standards regarding reclamation, long term surveillance (i.e., continued site observation, monitoring and, where necessary, maintenance), and ownership of byproduct material as defined in § 150.3(c)(2) of this Part and of land used as a disposal site for such material. Such reserved authority includes:

(1) Authority to establish such terms and conditions as the Commission determines necessary to assure that, prior to termination of any license for byproduct material as defined in § 150.3(c)(2) of this Part, or for any activity that results in the production of such material, the licensee shall comply with decontamination, decommissioning, and reclamation standards prescribed by the Commission; and with ownership requirements for such materials and its disposal site;

(2) The authority to require that prior to termination of any license for byproduct material as defined in

§ 150.3(c)(2) of this Part, or for any activity that results in the production of such material, that title to such byproduct material and its disposal site be transferred to the United States or the State in which such material and land is located, at the option of the State (provided such option is exercised prior to termination of the license);

(3) The authority to permit use of the surface or subsurface estates, or both, of the land transferred to the United States or a State pursuant to paragraph (b)(2) of this section in a manner consistent with the provisions of the Uranium Mill Tailings Radiation Control Act of 1978, provided that the Commission determines that such use would not endanger the public health, safety, welfare, or the environment;

(4) The authority to require, in the case of a license for any activity that produces such byproduct material (which license was in effect on November 8, 1981) transfer of land and material pursuant to paragraph (b)(2), of this section, taking into consideration the status of such material and land and interests therein, and the ability of the licensee to transfer title and custody thereof to the United States or a State.

(5) The authority to require the Secretary of the Department of Energy, other Federal agency, or State, whichever has custody of such property and materials, to undertake such monitoring, maintenance and emergency measures as are necessary to protect the public health and safety and other actions at the Commission deems necessary to comply with the standards promulgated pursuant to the Uranium Mill Tailings Radiation Control Act of 1978; and

(6) The authority to enter into arrangements as may be appropriate to assure Federal long term surveillance (i.e., continued site observation, monitoring, and where necessary, maintenance) of such disposal sites on land held in trust by the United States for any Indian tribe or land owned by an Indian tribe and subject to a restriction against alienation imposed by the United States.

22. Section 150.31 of 10 CFR 150 is added to read as follows:

§ 150.31 Requirements for Agreement State regulation of byproduct material.

(a) Prior to November 8, 1981, in the licensing and regulation of byproduct material, as defined in § 150.3(c)(2) of this Part, or of any activity which results in the production of such byproduct material, an Agreement State shall require compliance with the requirements in Appendix A of 10 CFR

40 of this Chapter to the maximum extent practicable.

(b) After November 8, 1981, in the licensing and regulation of byproduct material, as defined in § 150.3(c)(2) of this Part, or of any activity which results in the production of such byproduct material, an Agreement State shall require:

(1) Compliance with requirements in Appendix A of 10 CFR 40 of this Chapter established by the Commission pertaining to ownership of such byproduct material and disposal sites for such material; and

(2) Compliance with standards which shall be adopted by the Agreement State for the protection of the public health, safety, and the environment from hazards associated with such material which are equivalent, to the extent practicable, or more stringent than, standards in Appendix A of 10 CFR 40 of this Chapter adopted and enforced by the Commission for the same purposes, including requirements and standards subsequently promulgated by the Commission and the Administrator of the Environmental Protection Agency pursuant to the Uranium Mill Tailings Radiation Control Act of 1978; and

(3) Compliance with procedures which:

(i) In the case of licenses, under State law include:

(A) An opportunity, after public notice, for written comments and a public hearing, with a transcript;

(B) An opportunity for cross examination; and

(C) A written determination by the appropriate State official which is based upon findings included in such determination and upon the evidence presented during the public comment period and which is subject to judicial review;

(ii) In the case of rulemaking, provide an opportunity for public participation through written comments or a public hearing and provide for judicial review of the rule;

(iii) Require for each licensing action which has a significant impact on the human environment a written analysis by the appropriate State agency (which shall be available to the public before the commencement of any such proceedings) of the impact of such licensing action, including any activities conducted pursuant thereto, on the environment. Such analysis shall include:

(A) An assessment of the radiological and nonradiological impacts to the public health of the activities to be conducted pursuant to such licenses;

(B) An assessment of any impact on any waterway and groundwater resulting from such activities;

(C) Consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted pursuant to such license; and

(D) Consideration of the long term impacts, including decommissioning, decontamination, and reclamation impacts associated with activities to be conducted pursuant to such license, including the management of any byproduct material, as defined in § 150.3(c)(2) of this Part; and

(iv) Prohibit any major construction activity with respect to such material prior to complying with the provisions of paragraph (c)(3) of this section. As used in this paragraph the term "major construction activity" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(c) No Agreement State shall be required under paragraph (b) to conduct proceedings concerning any license or regulation which would duplicate proceedings conducted by the Commission.

23. Section 150.32 of 10 CFR 150 is added to read as follows:

§ 150.32 Funds for reclamation or maintenance of byproduct material.

(a) The total amount of funds an Agreement State collects, pursuant to a license for byproduct material as defined in § 150.3(c)(2) of this Part or for any activity that results in the production of such material, for reclamation or long term maintenance and monitoring of such material, shall after November 8, 1981, be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of such license. Such funds include, but are not limited to, sums collected for long term surveillance (i.e., continued site observation, monitoring and, where necessary, maintenance). Such funds do not however, include monies held as surety where no default has occurred and the reclamation or other bonded activity has been performed.

(b) If an Agreement State requires such payments for reclamation or long

term surveillance (i.e., continued site observation, monitoring and, where necessary, maintenance), the payments must, after November 8, 1981, be sufficient to ensure compliance with those standards established by the Commission pertaining to bonds, sureties, and financial arrangements to ensure adequate reclamation and long term management of such byproduct material and its disposal site.

(Secs. 11.e(2), 81, 83, 84, 161b, 161o, 161x, 274; Pub. L. 83-703 as amended by Title II of Pub. L. 95-604, 68 stat. 919 et seq. 92 Stat 3021 et seq. (42 U.S.C. 2014e(2), 2111, 2113, 2114, 2201b, 2201x, 2021))

Dated at Washington, D.C., this 26th day of September 1980.

For the Nuclear Regulatory Commission,
Samuel J. Chilk,
Secretary of the Commission.

[FR Doc. 80-30597 Filed 10-2-80; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Human Prescription Drugs in Oral Dosage Forms; Exemption of Isosorbide Dinitrate in Sublingual and Chewable Forms Containing Not More Than 10 Milligrams of Isosorbide Dinitrate From Child-Protection Packaging Requirements

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: In this document the Commission issues an exemption from child-protection packaging requirements for isosorbide dinitrate in sublingual and chewable dosage forms containing not more than 10 milligrams of isosorbide dinitrate.* An exemption for sublingual and chewable dosage forms containing not more than 5 milligrams of isosorbide dinitrate is currently in effect. Based upon the absence of past adverse experience resulting from ingestion of isosorbide dinitrate, the Commission believes that child-protection packaging for the larger dosage forms is unnecessary to protect children from serious illness or injury. In addition, the Commission believes that an exemption is justified because of the seriousness of the consequences should administration of this medication be delayed by

accessibility problems due to special packaging.

EFFECTIVE DATE: This amendment is effective October 3, 1980.

FOR FURTHER INFORMATION CONTACT: Charles Jacobson, Directorate for Compliance and Enforcement, Consumer Product Safety Commission, Washington, D.C. 20207, (301) 492-6400.

SUPPLEMENTARY INFORMATION:

Background

On September 28, 1979, the Commission proposed an exemption from the child-resistant packaging regulations under the Poison Prevention Packaging Act of 1970 (PPPA) for sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 10 milligrams (mg) or less (44 FR 55892).

Isosorbide dinitrate-containing drugs are generally used to relieve the pain associated with an angina attack (constriction of a blood vessel supplying oxygen to the heart). The principal adverse effect associated with such drugs is that because they dilate the blood vessels, the drugs can produce a drop in blood pressure that can result in a feeling of weakness or fainting and a loss of consciousness. However, as soon as the patient is placed in a reclining position with the feet raised, consciousness usually returns immediately.

Oral human prescription drugs containing over 5 mg of isosorbide dinitrate are currently subject to the Commission's child-protection packaging requirements, set forth at 16 CFR 1700.14(a)(1). Sublingual and chewable forms of isosorbide dinitrate in dosage units of 5 mg or less are exempted from these requirements at 16 CFR 1700.14(a)(10)(ii).¹ That exemption was granted at a time when only 5 mg dosage strengths for the drug were manufactured. Since that time, a few manufacturers, including Ives Laboratories, the petitioner in this matter, have produced 10 mg tablets in response to the fact that some angina patients require a higher dose of medication to control symptoms. For the reasons stated below, the Commission has decided to issue an exemption for sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 10 mg or less. The Commission, therefore, has revised the existing exemption for isosorbide dinitrate by

setting a higher dosage level for exemption.

Grounds for Exemption

As was noted in the proposed exemption, Ives Laboratories contends that the same grounds which justified an exemption for isosorbide dinitrate in 5 mg sublingual and chewable forms support the request for a 10 mg exemption level. The 5 mg exemption was based on the following facts: (1) The difficulty and delay that a patient might experience in trying to open a child-resistant closure while under the stress of an angina attack could result in serious consequences; (2) the sublingual form of nitroglycerin previously had been exempted for the same accessibility reasons; (3) the data revealed no reported cases of serious illness or injury to young children accidentally ingesting isosorbide dinitrate.

A search of the most current data sources available to the Commission staff reveals a continued lack of serious illness in young children who have accidentally ingested isosorbide dinitrate. Data from the National Clearinghouse for Poison Control Centers (NCPCC) indicate that of the 322 reported ingestions by children under 5 years of age from 1969 through 1978, 18 children reportedly manifested some symptoms, for which 12 were hospitalized.

Data collected by six poison control centers under contract with the Commission during the years 1976 through 1977 reveal 9 reported ingestions of isosorbide dinitrate by children, with only one case of nausea and vomiting. None of these 9 children was hospitalized. The amounts ingested in these cases ranged from one-half to 23 tablets (the child ingesting 23 tablets (50-55 mg) reportedly did not show any symptoms).

The National Electronic Injury Surveillance System (NEISS) Comment File for 1973 through December, 1979 contains six incidents of children under five years of age ingesting isosorbide dinitrate. All of the children were treated and released from the hospital.

The Commission's consumer complaint files and death certificate files contain no reports associated with isosorbide dinitrate as of February, 1980.

The Commission staff also conducted a toxicological evaluation of isosorbide dinitrate. As was discussed in the proposal document, the Commission staff has assumed that a toxic dose of isosorbide dinitrate would be greater than 1 gram (or greater than 100-10 mg tablets). This assumption is based upon

* A majority of Commissioners—Chairman King and Commissioners Pittle, Staller, and Zagoria—approved issuance of the final exemption. Commissioner Sloan dissented and has issued a separate opinion which is on file in the Office of the Secretary of the Commission.

¹ On November 20, 1974, the Commission published a document in the *Federal Register* (39 FR 40761) issuing an exemption for sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 5 milligrams or less.