

POLICY ISSUE NOTATION VOTE

July 11, 2002

SECY-02-0127

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PROPOSED RESPONSE TO STATE OF OHIO ON ITS ASSURED
ISOLATION STORAGE FACILITY DRAFT RULES

PURPOSE:

To request Commission review of staff's proposed response to the Ohio Department of Health, Bureau of Radiation Protection (BRP), providing comments on their proposed rules for licensing an Assured Isolation Facility (AIF) for storage of low-level radioactive waste (LLW).

BACKGROUND:

NRC staff received a February 20, 2002, letter from Mr. Robert E. Owen, BRP Manager of Technical Services, requesting review and comment on three draft Ohio rules, for an AIF, for which NRC has no comparable regulations (Attachment 1). The AIF concept involves placing LLW in a licensed, engineered facility, from which the waste could be subsequently retrieved for other dispositions, if necessary. The AIF remains under license for as long as LLW is present and relies on ongoing and continuing inspection, monitoring, and preventive maintenance. The draft Ohio rules include: (1) requirements for long-term storage of radioactive waste (not to exceed 100 years); (2) requirements for radioactive waste processing facilities; and (3) quality assurance requirements for facilities covered by the draft rules. The rules were drafted in response to a request from Ohio's Radiation Advisory Council. NRC comments were requested in concert with the Ohio public comment period that ended April 15, 2002. Pursuant to NRC staff discussion with Mr. Owen, he noted that the BRP desires NRC comment and that NRC comments would be helpful if submitted by September 7, 2002.

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Patricia Santiago, DWM/NMSS
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Ohio's LLW is currently being disposed of primarily at Barnwell, South Carolina. Some Class A LLW is disposed at Envirocare in Utah. After 2008, South Carolina is expected to limit the Barnwell disposal facility to South Carolina, Connecticut and New Jersey LLW generators (all parties to the Atlantic LLW Compact). At this time, there are no new plans to construct new disposal facilities in any of the compacts or unaffiliated States.

An assured storage/isolation facility was first described in 1995 by the U.S. Department of Energy's National Low-Level Waste Management Program, as an alternative approach to disposal for long-term management of LLW. Since that time, a number of States have expressed interest in the concept of assured storage/isolation. The Texas legislature considered bills that would have allowed for development of an AIF in 1999, and Envirocare of Texas submitted a license application which was later withdrawn. California Governor's LLW Advisory Group also had discussions with NRC on an AIF. Additionally, in 1998, technical studies were developed by the National Low-Level Waste Management Program, in response to a request from Connecticut, Massachusetts, Michigan, New Jersey, New York, and North Carolina.¹ Legal studies were later prepared for Connecticut in 2000.² NRC staff indicated, in a March 30, 2001, letter (Attachment 2) to Mr. Richard A. Ratliff, Chief, Bureau of Radiation Control, Texas Department of Health, on licensing an AIF that, "If either Texas or some other organization were to develop the requirements that would be needed to ensure long-term isolation of waste with this type of facility, NRC would be willing to provide assistance with this effort." Currently, there are no AIFs licensed or any application for an AIF under review. NRC staff plans resources in the fiscal year 2004-2005 time frame, for a rulemaking on an AIF, based on States' past interest in this LLW management concept and the uncertainty of permanent LLW disposal capacity after 2008.

DISCUSSION:

In cases where NRC has no comparable set of requirements, such as the proposed Ohio rules for an AIF, NRC would usually share the draft State rule with appropriate staff, but NRC staff would not conduct any review of the State's rules. However, in this case staff conducted a review, in part given the staff's offer in the Texas response to provide assistance "...to develop the requirements that would be needed to ensure long-term isolation of waste with this type of facility..." and to help identify issues which should be considered in development of rules for licensing an AIF storage only facility (Attachment 3). (The Ohio proposed rule only covers an AIF for LLW storage with no intent for conversion to a permanent disposal facility.) Staff's proposed response also notes that should NRC proceed, at a later date, to establish a rulemaking for an AIF facility, Ohio may need to amend any final rule it issues, to be compatible with NRC, and that such action could ultimately impact Ohio's licensees.

¹ "Licensing an Assured Isolation Facility for Low-Level Radioactive Waste," July 1998 (DOE/LLW-250a&b), National Low-Level Waste Management Program.

² "Technical Report: Assured Isolation Legal Study," April 2000, Prepared by Danaher, Tedford, Lagnese & Neal, P. C., for Connecticut Hazardous Waste Management Service.

In development of its response, staff identified and considered the following issues:

- ! The need for supplemental technical criteria, and the associated jurisdictional issues, such as the ownership of the AIF site by the Federal or State government, ownership of the material at the site, and requirements to cover the potential conversion of an AIF storage facility into a permanent disposal facility.
- ! The concern that NRC actions to help establish national regulations for an AIF may be viewed as counter to the policy underlying the Low-Level Radioactive Waste Policy Amendments Act of 1985, which focuses on disposal capacity, not storage. Further, NRC support of long-term storage (at least 100 years) may reduce incentive for compacts and unaffiliated States to develop additional disposal capacity.
- ! The likelihood that public confidence issues may arise based on where and how many AIFs are established. On one hand, an AIF may provide a more acceptable means for management of LLW with its design capabilities for later retrievability of waste for processing or disposal. However, an AIF may reduce incentive for compacts and States to develop permanent disposal capacity.
- ! The potential that some AIF concepts would permit some classes of LLW to be held in storage and then be subjected to processing, recycling or disposal at a future date. In such cases, the term of license, holding time and ability to retrieve need to be determined.
- ! The view that while State equivalents of 10 CFR Parts 30, 40, and 70 already provide sufficient authority to an Agreement State to license an AIF, issues related to long-term storage, adequate financial assurance, long-term custodians, and waste stability need to be addressed.
- ! The potential that certain AIF proposals relying on long-term storage may need a separate NRC license if the amount of special nuclear material exceeds the formula amount that an Agreement State can license under the Atomic Energy Act, NRC regulations and the State's Agreement with NRC.
- ! The need for an AIF regulation to address possible new requirements for security and protection of the AIF from sabotage and terrorist attacks after 9/11.
- ! NRC's authority over waste storage and management at a licensed reactor.

RECOMMENDATION:

The staff recommends that the attached letter be sent to Ohio.

COORDINATION:

The Office of the General Counsel (OGC) has reviewed this paper and has no legal objection. OGC is providing separately additional information to the Commission. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objection.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:

1. February 20, 2002, letter from R. E. Owen
2. March 30, 2001, letter to R. A. Ratliff
3. Draft letter to R. E. Owen

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BOB TAFT
Governor

J. NICK BAIRD, M.D.
Director of Health

February 20, 2002

Ms. Josie Piccone, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Ms. Piccone:

The attached draft rules are being submitted to you for review and comment by the NRC. The following is a summary of these rules:

Draft Rule 3701:1-54-03 Assured Isolation Facility establishes requirements for the long-term storage of radioactive waste in an assured isolation facility beyond five years, but no longer than 100 years for any given radioactive waste.

Draft Rule 3701:1-54-04 Quality Assurance establishes quality assurance requirements for facilities covered by draft rules 3701:1-54-03 and 3701:1-54-05.

Draft Rule 3701:1-54-05 Radioactive Waste Processing creates facility requirements for the processing of radioactive waste, other than a facility's own radioactive waste only.

Changes to **Rule 3701:1-54-01 Definitions** are additional definitions in clarifying new rule language in the three proposed rules. "Underlining" denotes new rule language, while "strikeouts" denote deletions.

These rules have been placed on our web site at <http://www.odh.state.oh.us>, for public review and comment. The public comment period ends April 15. They may be viewed by clicking on **Rules and Regulations**, and then clicking on **Draft Rules**.

While it is recognized that there are no corresponding rules within Title 10 of the CFR for which compatibility has been designated, it would be helpful to receive any comments that the NRC may have. It would greatly assist us, if any such comments could be received within the above comment period.

02 FEB 25 AM 9:05

STP

If there are any questions, I can be contacted at (614) 644-2732, or via e-mail at rowen@gw.odh.state.oh.us.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Owen', with a long horizontal flourish extending to the right.

Robert E. Owen
Manager of Technical Services
Bureau of Radiation Protection

cf: Roger Suppes

3701:1-54-01 **Definitions**

As used in this chapter of the Administrative Code:

- (A) "Active maintenance" means any improvements or repairs to the physical features of an AIF that are intended to preserve the ability of the facility to perform its function of isolating radioactive waste.
- (B) "AIF" means Assured Isolation Facility.
- (C) "Assured isolation" means an integrated management system for isolating radioactive waste beyond a five year period, while preserving options for its long term management through robust, accessible facilities, and planned preventative maintenance.
- (D) "Assured Isolation Facility" means the the structures and land containing the operational components of a site for the assured isolation of radioactive waste. This includes, but is not limited to, support and administrative facilities, roads and staging areas.
- (E) "Assured isolation site" means the entire plot of land on which an AIF is located, including that portion of the earth underlying the facility which is of significance to its structural stability, or is related to the environmental monitoring of the facility.
- (A)(F) "Broker" means any person who takes possession of low-level-radioactive waste solely for purposes of consolidation and shipment.
- (B)(G) "Carrier" means a person who is engaged in the transportation of low-level-radioactive waste by air, rail, road, highway, or water.
- (C)(H) "Director" means the director of health, or his a designee, or authorized representative
- (D)(I) "Disposal" or "dispose" means the permanent isolation of low-level-radioactive waste in accordance with Chapter 3748. of the Revised Code and the rules promulgated thereunder.
- (E)(J) "Generator" means a person who first produces low-level-radioactive waste, including, without limitation, any person who does so in the course of or incident to manufacturing, power generation, processing, waste treatment, waste storage, medical diagnosis or treatment, research, or other industrial or commercial activity. "Generator" does not include a patient who may discharge radioactive material in body wastes or fluids as the result of a medical procedure; however, the waste or fluids generated by such a patient are low-level radioactive waste. If the person who first produced an item or quantity of waste cannot be identified, "generator" means the person first possessing the waste who can be identified.
- (K) "Interim storage" means the storage of radioactive waste, excluding decay-in-storage, due to the absence of an accessible licensed disposal facility.
- (L) "Isolation" means the segregation and impoundment of radioactive waste in a manner that protects the environment inhabited by humans, including, but not limited to, the human food chain.
- (F)(M) "Low-level radioactive waste" means, with regard to the disposal of low-level radioactive waste, radioactive-waste that is not classified as high-level radioactive waste and that is class A, B, or C low-level radioactive waste as defined in 10 C.F.R. 61.55, as that section existed on January 26, 1983. In regard to regulatory control at locations for purposes other than a disposal facility, "low-level radioactive waste" has the same meaning as in 42 U.S.C.A. 2021 (b). Low-level radioactive waste

does not include any such waste that is owned or generated by the United States department of energy; by the United States navy as a result of the decommissioning of its vessels; or as a result of any research, development, testing, or production of any atomic weapon.

(N) "Mixed waste" is radioactive waste that contains a listed hazardous waste or exhibits a hazardous waste characteristic identified in 40 C.F.R. 261, Subpart C.

(O) "Monitoring" means evaluating the characteristics or performance of a facility or a site through systematic measurement and analysis of specific parameters.

(G)(P) "Person" means any individual, corporation, association, business enterprise, or other legal entity, either public or private, and any legal successor, representative, agent or agency of that individual, corporation, association, business enterprise, or other legal entity. "Person" also includes the United States, ~~any state~~ states, political subdivisions of ~~this or any state, states,~~ and any department, agency, or instrumentality of the United States or ~~a~~ this or another state.

(H)(Q) "Processor" means a person who treats or repackages low-level-radioactive waste received from a generator. Processor does not mean generator.

(I)(R) "Storage" or "store" means the retention of radioactive materials, including low-level-radioactive waste, prior to disposal in a manner that allows for surveillance, control, and subsequent retrieval.

(S) Temporary storage means holding radioactive waste, for a reasonable amount of time, that is either in transit, awaiting transportation, or is being prepared for transportation.

(J)(T) "Treatment" means any method, technique, or process, including storage for radioactive decay, that changes the physical, chemical, or biological characteristics or composition of any low-level-radioactive waste in order to render the waste safer for transport or management, amenable to recovery, convertible to another usable material, or reduced in volume.

(K)(U) "Waste management" means the storage, treatment, or disposal of low-level-radioactive waste.

(V) Waste processing is the act or process of treating radioactive waste.

(W) Waste processor is the person or facility that processes the radioactive waste.

3701:1-54-03 **Assured Isolation Facility**

- (A) This rule covers the licensing of the storage and safe isolation of radioactive waste over the term of a license prior to disposal in accordance with Chapter 3701:1-40 of the Administrative Code, and other rules promulgated under Chapter 3748, of the Revised Code. The requirements of this rule are in addition to those in Chapter 3701:1-40 of the Administrative Code, and other rules pursuant to Chapter 3748, of the Revised Code. All the requirements of this rule apply to all generators of radioactive waste, and those that store radioactive waste, as follows:
- (1) All of the requirements of this rule apply to an AIF used by more than one generator to hold radioactive waste for decay-in-storage or any radioactive waste generator who proposes to store radioactive waste at a location other than their currently licensed location.
 - (2) Generators that continue to hold only their own radioactive waste beyond a five year period at their currently licensed location shall apply for a license to operate an AIF and must comply with paragraphs (C)(1), (C)(2), (C)(4), (C)(5), (C)(7), (C)(9), (D)(2), (D)(3), and (E) through (N) of this rule.
- (B) The performance objectives of an AIF are to:
- (1) Protect the environment, the general public, and workers from exposures to ionizing radiation and radionuclide releases exceeding the limits and constraints delineated in Chapter 3701:1-38 of the Administrative Code.
 - (2) Keep radioactive material secure from unauthorized access or removal.
 - (3) Protect the waste and containers from the adverse effects of environmental conditions, including, but not limited to, temperature, humidity, and water.
 - (4) Use sound engineering designs and prudent procedural practices to maintain doses to workers and the general public, and radionuclide releases to the environment as low as reasonably achievable.
- (C) The contents of a license application shall provide sufficient information on the AIF, its operators, and the types of waste held, to provide reasonable assurance that the performance objectives will be met. As a minimum, the applicant shall do the following:
- (1) Submit a license application pursuant to chapter 3701:1-40 of the Administrative Code.
 - (2) Provide a description of the licensed operating activities requested, including, but not limited to:
 - (a) The location of the proposed site;
 - (b) The licensed activities involving the transportation, storage, and handling of radioactive waste;
 - (c) The types, chemical and/or physical forms and quantities of radioactive waste to be received, possessed, and stored;
 - (d) The proposed time schedules for construction and receipt of radioactive waste at the proposed AIF; and
 - (e) The estimated maximum amount of radioactive waste to be stored, both in terms of volume and activity, by radionuclide.

- (3) Describe the site suitability for storage of licensed radioactive materials for each of the following categories.
- (a) Describe and justify the location of the AIF in terms of land use. Include in the description the nearby structures present, local land usage, local populations, public facilities, local roads and traffic.
 - (b) Define the characteristics of the site by identifying and describing applicable portions of paragraph (D)(1) of this rule.
 - (c) Provide a description of the site radiological environmental monitoring program to meet the criteria in paragraph (I) of this rule. Include baseline information for the data to be collected.
 - (d) Provide an environmental assessment report required by Chapter 3701:1-40 of the Administrative Code as if that chapter also included NORM, source and special nuclear material.
- (4) Provide a complete description of the AIF, including drawings, to meet the criteria of paragraphs (D) and (E) of this rule.
- (5) Submit details on the operation of the AIF covering the topics listed in paragraph (F) of this rule.
- (6) Provide a description of the community awareness and communication program to be used.
- (a) Identify the means of communication, types of information to be provided, and when the information will be provided to:
 - (i) Notify the community of the proposed operation and licensing; and
 - (ii) Maintain community input on operational status, operational changes, and off-site emergency response capacity.
 - (b) Identify how the effectiveness of the communications will be monitored and ensured.
- (7) Submit any applicable decommissioning funding plan and financial assurance in accordance with Chapter 3701:1-40 of the Administrative Code as if that chapter also included NORM, source and special nuclear material.
- (8) Submit an emergency response plan in accordance with Chapter 3701:1-40 of the Administrative Code as if that chapter also included NORM, source and special nuclear material.
- (9) Submit the quality assurance program used in accordance with rule 3701:1-54-04 of this chapter to ensure that the maintenance and operation of the AIF meets the performance objectives, is consistent with the contents of the license application, and satisfies the requirements for the receipt, handling, emplacement and retrieval of waste in this rule.
- (D) The design of an AIF shall provide reasonable assurance that the radioactive waste will maintain its integrity and remain isolated from the environment as intended.
- (1) The overall hydrogeologic environment of the site, in combination with engineering design, shall act to minimize and control potential radioactive waste migration into surface water and ground water in the event of an accidental release. Identification and consideration of the hydrogeologic environment shall include, but is not limited to:
 - (a) Upstream drainage features such as the potential for frequent ponding and slope stability;

- (b) Characteristics of nearby rivers, streams, wetlands, or other bodies of water ;
 - (c) Distance to, and nature of, the water table and aquifer;
 - (d) Analysis of earthquake potential or other land movement and its consequences;
 - (e) The proximity to creeks or culverts; and
 - (f) Soil types under the AIF with respect to compatibility with the foundation and structural design.
- (2) No new AIF shall be located:
- (a) In a one-hundred year flood plain or a wetland; or
 - (b) In the recharge area of a sole source aquifer unless it can be demonstrated with reasonable assurance the new AIF will be designed, constructed, operated, and decommissioned without an unreasonable risk to the aquifer.
- (3) The AIF shall be constructed as designed to:
- (a) Safely handle and store the waste commensurate with the characteristics of the waste;
 - (b) Aid in fire suppression, provide filtered air ventilation, maintain environmental controls, and to the extent possible be constructed of nonflammable building materials;
 - (c) Store waste such that each individual waste container is readily retrievable and inspectable; and
 - (d) Be made of materials, and use methods, considered to ease future decontamination and decommissioning efforts.
- (4) The AIF shall include design features to aid in keeping the radioactive waste isolated. The design features must:
- (a) Minimize water infiltration and prevent any waste container from contact with water.
 - (b) Preserve the structural integrity of each waste container.
 - (c) Ensure that the site drainage and slope stability preserves the integrity of the AIF's foundation.
 - (d) Ensure that the AIF shall meet the standards prescribed in ANSI/ASCE 7-98 "Minimum Design Loads for Buildings and Other Structures" for a Category II facility as defined in the standard. Facilities that will have containers exceeding a Type A Quantity of radioactive material in normal form, as defined in Chapter 3701:1-50 of the Administrative Code, must meet the criteria for a Category III facility as defined in the standard.
 - (e) Minimize occupational and non-occupational exposures.
 - (f) Provide for site and effluent monitoring as appropriate for the AIF.
 - (g) Ensure that buildings and areas used for the storage of radioactive wastes shall have appropriate ventilation and fire protection systems to minimize the release of radioactive materials into the soil, water, or atmosphere.
 - (h) Provide facilities and equipment for repackaging leaking or damaged containers.

- (i) Ensure that the design and operation of the radioactive waste storage area shall be such that radiation levels, concentrations, and potential exposures due to airborne releases during operations are within the limits specified in Chapter 3701:1-38 of the Administrative Code and are maintained ALARA.
- (j) Ensure that the design and operation of the AIF shall be compatible with the objectives of the decommissioning funding plan for the AIF.
- (k) Ensure that the AIF shall be designed to confine spills. Independent and diverse engineering barriers shall be provided as necessary to minimize potential releases from the AIF.
- (E) The applicant shall provide a description of the site and accurate drawings of the AIF. The descriptions should address the following features, and any design features used in support of the performance objectives:

 - (1) Describe the ventilation system and how it will ensure adequate environmental controls of the storage area, including, but not limited to, heating, cooling, and humidity. Describe any applicable exhaust air filtration used.
 - (2) Describe the fire protection and suppression system to minimize the likelihood and extent of fire.
 - (3) Describe any plumbing, pipes, and/or wiring that goes through the storage or handling areas.
 - (4) Describe the physical security of the radioactive waste areas and the AIF.
 - (5) Identify radioactive waste storage areas, demonstrating where radioactive waste will be stored and how radioactive waste containers will be accessible for routine inspections.
 - (6) Describe the locations of radioactive waste handling areas, air sampling stations, effluent filters and any sources of flammable or explosive material.
 - (7) Provide a description and accurate drawing of any required special handling equipment to be employed.
 - (8) Describe the equipment installed to maintain control over the maximum concentrations of radioactive materials in gaseous and liquid effluents produced during normal operation and the means employed to keep levels of radioactive material in effluents to unrestricted areas ALARA.
 - (9) Describe the building codes and standards applied to the design and construction of the AIF.
 - (10) Describe the AIF construction, including, but not limited to, the building materials and method of construction.
 - (11) Describe the activity, volume, classification and specifications of the radioactive material to be received, possessed, and stored at the AIF.
- (F) The applicant shall describe the operations of the AIF in accordance with the radioactive waste procedures to meet the performance objectives.

 - (1) Describe the procedures to secure radioactive materials from unauthorized access and removal, including the control of access to the AIF.
 - (2) All radioactive waste ultimately subject to transportation must be stored in containers made for transportation. Describe the procedures used to verify that this requirement is met.

- (3) The commingling of radioactive wastes from different generators into a single waste container is prohibited. Describe the procedures used to verify this requirement is met.
- (4) Describe the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the occupational radiation exposure limits, and to control contamination of personnel, vehicles, equipment, buildings, and the AIF. Routine operations, inadvertent releases, and accidents must be addressed. The program description must include procedures, instrumentation, facilities, and equipment.
- (5) Submit the procedures for receipt and acceptance of waste packages. The procedures shall include examination of shipping documents, visual check of waste package, survey for removable contamination and external radiation level, identification of packages requiring remediation, corrective actions, and disposition of unacceptable packages.
- (6) Describe the program for safe placement and inspection of waste in storage and maintaining occupational exposures ALARA. The program should include periodic radiation and contamination surveys of individual packages and the storage area in general, as well as posting the storage area.
- (7) Describe the system for maintaining accurate records of radioactive materials and a current inventory of radioactive waste.
- (8) Characterize the radioactive waste to be stored in terms of:
 - (a) Volume of waste by Class (A, B, C); and
 - (b) Physical form of the waste: solid, liquid, or gas.
- (9) The AIF operator shall describe:
 - (a) The packages or containers to be used for storage of radioactive waste, any hazards the waste may pose to the packaging integrity, and the projected storage life of the packaging or containers.
 - (b) The program for periodic inspections of radioactive waste packages to ensure that they retain their integrity and containment of radioactive waste; and
 - (c) The procedures and equipment used for remote handling and repackaging damaged or leaking waste containers.
- (10) Provide the following descriptions of the equipment and procedures:
 - (a) Provide a flow diagram of radioactive waste receipt and storage operations.
 - (b) Describe the equipment and procedures used to maintain control over on-site exposures to and releases of radioactive material. Include monitoring methods, containment mechanisms, accident mitigation methods and procedures, and the corrective action process used when deviations are discovered.
 - (c) Describe the spill detection equipment and cleanup plans for the site and associated transportation of radioactive material.
- (11) Provide a description of the site radiological environmental monitoring program to meet the criteria in paragraph (I) of this rule. Include baseline information for the data to be collected.

(12) Provide a description of the personnel training and retraining program.

(13) Each licensee shall have emergency response procedures for radionuclide incidents.

(a) If an emergency response plan is required in paragraph (C)(8) of this rule, the applicant shall provide all offsite emergency response organizations that would respond in the event of an accident a copy of the plan and allow sixty days to comment on the applicant's emergency response plan prior to submitting the plan to the director.

(b) The applicant shall submit copies of any comments received during the comment period to the director with the emergency response plan.

(14) Describe the system for maintaining inventory of receipt, storage, and transfer of radioactive waste.

(15) Describe the disposition of radioactive material and the AIF upon termination of the license.

(G) To meet the radiation safety requirements the following must be met:

(1) The safety manual shall include a description of personnel monitoring methods, training and procedures to be followed to prevent employees from ingesting or inhaling radioactive materials, and methods to keep radiation exposures ALARA;

(2) The operating manual shall include procedures to protect the integrity of the waste and waste containers during normal handling and storage conditions, and shipping radioactive materials;

(3) An emergency response manual shall include procedures to address likely minor and major accident conditions, incident response command structures, and a description of procedures for responding to emergencies, including notification of and coordination with local fire, police and medical departments;

(4) The radiation safety program shall incorporate the requirements of Chapters 3701:1-38 and 3701:1-40 of the Administrative Code, and include topics on the ALARA policy, radiation safety procedures, training, ventilation systems, air sampling, contamination control, internal exposure control and assessments, external exposure control, and instrumentation used; and

(5) The applicant shall describe the program for training personnel in procedures for packaging, handling, placement, inspection, surveying and emergency response for radioactive waste storage and transportation.

(H) Radioactive waste and materials are to be transported, handled, and stored in a safe manner to meet the performance objectives in paragraph (B) of this rule.

(1) Radioactive waste shall contain only class A, B, or C waste, determined by radionuclide activity and concentration, as provided in 10 C.F.R. 61.55 as referenced in rule 3701-39-02.1 of the Administrative Code.

(2) Radioactive waste shall meet the waste characteristics of 10 C.F.R. 61.56(a) as referenced in rule 3701-39-02.1 of the Administrative Code.

(3) No individual waste container dose rate shall exceed one-tenth mSv/hr (ten mRem/hr) at one meter or two mSv/hr (two hundred mRem/hr) on the surface.

(4) The radioactive waste shall be secured from unauthorized access and removal by individuals, and

maintained to prevent unintentional releases to the environment.

(I) "REMP" means a Radiological Environmental Monitoring Program that is used to measure and monitor radionuclides in all pathways to individuals and the general public from licensed radiological operations. All applicants shall:

(1) Describe the environmental monitoring program to provide data to evaluate potential health and environmental impacts in support of the performance objectives.

(2) Describe the action levels of radionuclides in the environment that will initiate an investigation or corrective action.

(3) Describe the plan for additional monitoring if in the event of an unintentional release of radionuclides.

(J) Records and reports shall be developed and maintained in accordance with Chapters 3701:1-38, 3701:1-40, and other Chapters of the Administrative Code promulgated pursuant to Chapter 3748. of the Revised Code, and the following:

(1) The licensee shall prepare and send statements to each generator of their own waste status, including but not limited to volume, radionuclides, activity, waste container condition, regarding prior year inventory balances, additions and withdrawals of waste from the AIF, and final inventory balance. Both the licensee and the generator shall retain copies of these reports for three years.

(2) The licensee shall prepare and send an annual summary report to the Ohio Department of Health and publish a local notice of the report's availability to the public. The report shall include, at a minimum, a summary of waste in AIF (prior year inventory balances, additions, withdrawals, and final balances), capacity utilization (volume and radionuclide license limits), incidents, environmental monitoring results, radionuclide releases to the environment, and a fiscal annual report. The licensee shall retain copies of these reports until after the license has been terminated.

(3) The annual report to the generators and the annual summary report shall be completed and submitted to the Ohio Department of Health within sixty days after the end of the calendar year.

(K) The institutional requirements include:

(1) The radioactive materials will remain under active institutional control throughout the term of the license in accordance with 10 C.F.R. 61.59(b) as referenced in rule 3701-39-02.1 of the Administrative Code.

(2) The generator of the radioactive waste shall retain title to the waste.

(3) The generator is responsible for the radioactive waste as shipped, including but not limited to the original containers and contents delivered, waste form, and radionuclide identification and quantification. The AIF operator is responsible for the waste handling and storage conditions after acceptance of the waste until its ultimate disposition.

(4) Each generator shall issue an irrevocable trust to the AIF operator to cover the cost of disposal in the event that the generator becomes bankrupt. The AIF operator must submit a copy of each trust agreement to the department. Each trust shall be reviewed and updated every five years.

(L) Financial assurance, decommissioning, and license termination requirements include:

(1) The AIF shall meet the applicable financial assurance and decommissioning requirements for unrestricted release in Chapter 3701:1-38 of the Administrative Code.

(2) The AIF shall return radioactive materials to the generator or generator's designee upon the AIF's failure to renew a license or prior to license termination.

(M) The limitations placed on an AIF include:

(1) Each license will place limitations on the aggregate radioactive waste volume as well as radionuclide quantities.

(2) An AIF license shall be renewed in accordance with Chapter 3701:1-40 of the Administrative Code. During the license renewal process, an existing licensed AIF shall verify compliance with the originally licensed structural design for the originally licensed usage. Any changes from the originally licensed usage or structural design will require a reevaluation of the entire AIF based on current standards.

(3) All users of the AIF shall contractually agree to the return of the radioactive waste to the generator, or transfer to the generator's designee licensed to receive such waste, at the end of the radioactive material storage, which may not exceed one hundred years.

(4) The operator shall not store mixed waste.

(N) Commencement of construction prior to the department issuing a license or renewal for the AIF is at the economic risk of the applicant.

3701:1-54-04 **Quality Assurance**

- (A) The purpose of this rule is to set quality assurance (QA) requirements for facilities licensed under Chapter 54 of the Administrative Code. As described in this rule, quality assurance requirements of a licensee apply to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, or modification of structures, systems, and components, and decommissioning that are important to safety.
- (B) As used in this chapter, "quality assurance" (QA) comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.
- (1) Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.
- (2) The licensee is responsible for the quality assurance requirements as they apply to the design, fabrication, and testing of a storage and/or processing facility.
- (C) The licensee, or applicant for a license, shall be responsible for the establishment and execution of the quality assurance program.
- (1) The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, but the licensee shall retain responsibility for the program. The licensee, or applicant for a license, shall clearly establish and delineate in writing the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components, which are important to safety. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.
- (2) The quality assurance functions are to:
- (a) Assure that an appropriate quality assurance program is established and effectively executed; and
- (b) Verify, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.
- (c) The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.
- (D) A quality assurance program shall meet the following:
- (1) The licensee, or applicant for a license, shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with these procedures throughout the period during which the facility is licensed. The licensee, or applicant for a license, shall identify the structures, systems, and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.
- (2) The licensee, or applicant for a license, through their quality assurance programs, shall provide control over activities affecting the quality of the identified structures, systems, and components

to an extent commensurate with the importance to safety and, as necessary, to ensure conformance with the approved design of each facility. The licensee, or applicant for a license, shall ensure that activities affecting quality are accomplished under suitably controlled conditions.

(a) "Controlled conditions" include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied.

(b) The licensee, or applicant for a license, shall take into account the need for special controls, processes, test equipment, tools and skills to attain the required quality and the need for verification of quality by inspection and test.

(3) The licensee, or applicant for a license, shall base the requirements and procedures of their quality assurance program(s) on the following considerations concerning the complexity and proposed use of the structures, systems, or components:

(a) The impact of malfunction or failure of the item on safety;

(b) The design and fabrication complexity or uniqueness of the item;

(c) The need for special controls and surveillance over processes and equipment;

(d) The degree to which functional compliance can be demonstrated by inspection or test; and

(e) The quality history and degree of standardization of the item.

(4) The licensee, or applicant for a license, shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained.

(5) The licensee, or applicant for a license, shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program must regularly review the status and adequacy of that part of the quality assurance program that they are executing.

(6) The persons and organizations performing quality assurance functions shall report to a management level that ensures that the required authority and organizational freedom, including sufficient independence from cost and schedule considerations when these considerations are opposed to safety considerations, are provided.

(a) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(b) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

(E) To meet QA design control requirements:

(1) The licensee, or applicant for a license, shall establish measures to ensure that applicable

regulatory requirements and the design basis, as specified in the license application for those structures, systems, and components to which this chapter applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

(2) The licensee, or applicant for a license, shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program.

(a) For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization.

(b) Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions.

(c) The licensee, or applicant for a license, shall apply design control measures to items such as the following:

(i) Criticality physics, radiation, shielding, stress, thermal, hydraulic, and accident analyses;

(ii) Compatibility of materials;

(iii) Accessibility for inservice inspection, maintenance, and repair;

(iv) Features to facilitate decontamination; and

(v) Delineation of acceptance criteria for inspections and tests.

(3) The licensee, or applicant for a license, shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license require prior to approval by the Department of Health.

(F) To meet QA procurement document control requirements, the licensee, or applicant for a license, shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee, or by the licensee's contractors or subcontractors. To the extent necessary, the licensee, or applicant for a license, shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this rule.

(G) To meet QA instructions, procedures and drawings requirements, the licensee, or applicant for a license, shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been

satisfactorily accomplished.

(H) To meet QA document control requirements, the licensee, or applicant for a license, shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must ensure that changes to documents are reviewed and approved.

(I) To meet QA control of purchased material, equipment, and services requirements:

(1) The licensee, or applicant for a license, shall establish measures to ensure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

(2) The licensee, or applicant for a license, shall have available documentary evidence that material and equipment conform to the procurement specifications prior to installation or use of the material and equipment. The licensee shall retain or have available this documentary evidence for the life of the facility. The licensee shall ensure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

(3) The licensee, or applicant for a license, or a designee of either, shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

(J) To meet QA identification and control of materials, parts, and components requirements, the licensee, or applicant for a license, shall establish measures for the identification and control of materials, parts, and components. These measures must ensure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item as required, throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

(K) To meet QA control of special processes requirements, the licensee, or applicant for a license, shall establish measures to ensure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

(L) To meet QA licensee inspection requirements, the licensee, applicant for a license shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Individuals other than those who performed the activity being inspected must perform the inspection. Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products cannot be carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points that require witnessing or inspecting by the licensee's designated representative, and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.

- (M) To meet QA test control requirements, the licensee, or applicant for a license, shall establish a test program to ensure that all testing, required to demonstrate that the structures, systems, and components will perform satisfactorily in service, is identified and performed in accordance with written test procedures that incorporate the requirements of this chapter and the requirements and acceptance limits contained in the facility. The test procedures must include provisions to ensure that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee, or applicant for a license, shall document and evaluate the test results to ensure that test requirements have been satisfied.
- (N) To meet QA control of measuring and test equipment requirements, the licensee, or applicant for a license, shall establish measures to ensure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.
- (O) To meet QA handling, storage and shipping control requirements, the licensee, or applicant for a license, shall establish measures to control, in accordance with work and inspection instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.
- (P) To meet QA inspection, test and operating status requirements:
- (1) The licensee shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the facility. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests where necessary to preclude inadvertent bypassing of the inspections and tests
 - (2) The licensee shall establish measures to identify the operating status of structures, systems, and components of the facility, such as tagging valves and switches, to prevent inadvertent operation
- (Q) To meet QA nonconforming materials, parts and components requirements, the licensee, or applicant for a license, shall establish measures to control materials, parts, or components that do not conform to their requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.
- (R) To meet QA corrective action requirements, the licensee, or applicant for a license, shall establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition identified as adverse to quality, the measures must ensure that the cause of the condition is determined and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.
- (S) To meet quality assurance record keeping requirements, the licensee, or applicant for a license, shall maintain sufficient records to furnish evidence of activities affecting quality. The records must include the following: design records, records of use, and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records must include closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the

results, the acceptability, and the action taken in connection with any noted deficiencies. Records must be identifiable and retrievable. Records pertaining to the design, fabrication, erection, facility as built diagrams, testing, maintenance, and use of structures, systems, and components important to safety must be maintained by or under the control of the licensee until the department terminates the license.

(T) To meet QA audit requirements, the licensee, or applicant for a license, shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, must be taken where indicated.

3701:1-54-05 **Radioactive Waste Processing**

- (A) This rule covers the licensing of radioactive waste processors. The requirements of this rule are in addition to those in Chapter 3701:1-40 of the Administrative Code, and other rules pursuant to Chapter 3748, of the Revised Code.
- (B) The performance objectives for a radioactive waste processing facility are to:
- (1) Protect the environment, the general public, and workers from exposures to ionizing radiation and radionuclide releases exceeding the limits and constraints delineated in Chapter 3701:1-38 of the Administrative Code;
 - (2) Keep radioactive material secure from unauthorized access or removal; and
 - (3) Use sound engineering designs and prudent procedural practices to maintain doses to workers and the general public and radionuclide releases to the environment ALARA.
- (C) A facility is exempt from the licensing requirements of this rule to process radioactive waste if:
- (1) The facility, in accordance with a specific license, processes only its own radioactive waste;
 - (2) Site decommissioning activities are conducted on-site in accordance with a specific license; or
 - (3) The facility is not required to have a decommissioning funding plan pursuant to rule 3701:1-40-17 of the Administrative Code.
- (D) The application for a radioactive waste processing facility shall provide sufficient information on the facility and its operators, and the types of waste processed, to provide reasonable assurance that the performance objectives in paragraph (B) will be met. As a minimum, the applicant shall do the following:
- (1) Submit a license application pursuant to Chapter 3701:1-40 and rule 3701-39-02.1 of the Administrative Code.
 - (2) Provide a description of the site suitability for processing radioactive waste for each of the following categories:
 - (a) The location of the facility in terms of land use. Include in the description the nearby structures present, local land usage, local populations, public facilities, local roads and traffic;
 - (b) The characteristics of the site in accordance with criteria contained in paragraph (E)(1) of this rule; and
 - (c) The site radiological environmental monitoring program (REMP) to meet the criteria in paragraph (I) of this rule. Include baseline information for the data to be collected.
 - (3) Provide a complete description of the facility, including but not limited to drawings, to meet the criteria of paragraphs (E) and (F) of this rule.
 - (4) Submit details on the operation of the facility covering the topics listed in paragraph (G) of this rule.
 - (5) Submit the quality assurance program used in accordance with rule 3701:1-54-04 of this chapter to

ensure that the construction, maintenance and operation of the facility meets the performance objectives, is consistent with the contents of the license application, and satisfies the requirements for the receipt, handling, processing and shipping of waste in this rule.

- (6) In addition to the requirements of 3701:1-40-38, provide a description of the community awareness and communication program to be used. Identify the means of communication, types of information to be provided, and when the information will be provided to notify the community of the proposed operation and licensing, and identify how the effectiveness of the communication will be monitored and ensured.
- (7) Describe the program for training personnel in procedures for packaging, handling, placement, inspection, surveying and emergency response for radioactive waste processing, storage and transportation.
- (E) The facility design, location, and site geology shall provide reasonable assurance that radioactive materials will remain isolated from the environment as intended
- (1) The overall hydrogeologic environment of the site, in combination with engineering design, shall act to minimize and control potential radioactive material migration into surface water and ground water in the event of an accidental release. Identification and consideration of the hydrogeologic environment shall include, but is not limited to:
- (a) Upstream drainage features including the potential for frequent ponding and slope stability;
 - (b) Characteristics of nearby rivers, streams, wetlands, or other bodies of water;
 - (c) Distance to the water table and aquifer;
 - (d) Analysis of earthquake potential or other land movement and its consequences; and
 - (e) Soil types under the facility with respect to compatibility with the foundation and structural design.
- (2) No facility shall be:
- (a) Located in a 100 year flood plain;
 - (b) Located in a wetland; or
 - (c) Operated where an Emergency Response Plan would be required as identified 3701:1-40-14(G) of the Administrative Code.
- (3) The facility shall be constructed to:
- (a) Safely handle and process the waste commensurate with the characteristics of the waste;
 - (b) Aid in fire suppression, provide filtered air ventilation, maintain environmental controls, and to the extent possible, be constructed of nonflammable building materials; and
 - (c) Use materials considered to ease future decontamination and decommissioning efforts.
- (4) The facility shall incorporate the following design features to aid in keeping the radioactive waste isolated.
- (a) Buildings and areas used for processing radioactive waste shall have appropriate ventilation

and fire protection systems to minimize the release of radioactive materials into the soil, water, or atmosphere.

(b) Provide facilities and equipment for repackaging leaking or damaged containers.

(c) The facility shall be designed to confine spills. Independent and diverse engineering barriers shall be provided as necessary to minimize potential releases from the facility.

(d) Any person's radioactive waste may not be held for more than ninety days before or after processing.

(F) Using both general descriptions and detailed drawings of the facility, identify the following features, and any design features used in support of the performance objectives.

(1) Describe the ventilation system and how it will assure adequate environmental controls of the processing and holding areas. Describe any applicable exhaust air filtration used.

(2) Describe the fire protection and suppression system to minimize the likelihood and extent of fire.

(3) Describe the physical security of the radioactive waste areas and the facility.

(4) Identify radioactive waste processing areas and where radioactive waste will be held. Identify how the processing areas and radioactive waste containers will be accessible for routine inspections.

(5) Describe the locations of radioactive waste handling areas, air sampling stations, effluent filters and any sources of flammable or explosive material.

(6) Provide a description and accurate drawing of any required special handling equipment to be employed.

(7) Describe the equipment installed to maintain control over the maximum concentrations of radioactive materials in gaseous and liquid effluents produced during normal operation and the means employed to keep levels of radioactive material in effluents to unrestricted areas ALARA.

(8) Identify the building codes and standards applied to the design and construction of the facility, and verify that the facility has been certified as complying with these codes.

(G) Pursuant to the requirements of paragraph (B) of this rule, describe the following.

(1) Procedures to secure radioactive materials from unauthorized access and removal, including control of access to the facility.

(2) Procedures used to ensure that all radioactive waste subject to transportation will meet transportation requirements.

(3) Radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the occupational radiation exposure limits, and to control contamination of personnel, vehicles, equipment, buildings, and the facility. Both routine operations and accidents must be addressed. The program description must include procedures, instrumentation, facilities, and equipment.

(4) Procedures for receipt and acceptance of waste packages. The procedures shall include examination of shipping documents, visual check of waste package, survey for removable contamination and external radiation level, identification of packages requiring remediation, corrective actions, and disposition of unacceptable packages.

- (5) A program for safe placement and inspection of waste and maintaining occupational exposures (ALARA) when it is not being processed. The program shall include periodic radiation and contamination surveys of individual packages;
 - (6) A program for periodic inspections of radioactive waste packages to ensure that they retain their integrity and containment of radioactive waste;
 - (7) The procedures and equipment used for remote handling and/or repackaging damaged or leaking waste containers;
 - (8) General flow diagram and detailed procedures of radioactive waste receipt, handling, processing, and storage operations;
 - (9) General flow diagram and detailed procedures of radioactive waste receipt, handling, processing, and storage operations;
 - (10) Spill detection equipment and cleanup plans for the site and associated transportation of radioactive material; and
 - (11) A system for maintaining inventory of receipt, processing, storage, and transfer of radioactive waste.
- (H) The radiation safety requirements shall include the following documents and content:
- (1) The radiation safety manual shall include a description of personnel monitoring methods, training and procedures to be followed to limit employee's exposure to radioactive materials, and methods to keep radiation exposures ALARA;
 - (2) The operating manual shall include procedures to protect the integrity of the equipment and radioactive material containment during normal handling, processing, and storage conditions, and when shipping radioactive materials; and
 - (3) An emergency response manual shall include procedures to address likely accident conditions.
- (I) The facility shall maintain a radiological environmental monitoring program (REMP), to measure and monitor radionuclides in all pathways to individuals, the environment, and the general public from radiological operations. In establishing such a program, the facility must do the following:
- (1) Identify all the possible onsite and offsite environmental radiological exposure pathways. The exposure pathways shall include but are not limited to applicable air, soil, groundwater, surface water, and vegetation. The offsite pathway exposure locations shall take into consideration meteorological, terrestrial, and emission source parameters;
 - (2) Describe the environmental monitoring program to provide data to evaluate radionuclide releases and accumulations in the environment;
 - (3) Describe the action levels of radionuclides in the environment that will initiate an investigation or corrective action; and
 - (4) Describe the plan for taking corrective measures if an unintentional release of radionuclides material is indicated.
- (J) The licensee shall:

- (1) Keep records showing the receipt, inventory, processing, transfer, and disposal of all radioactive waste; and
 - (2) Prepare and send an annual summary report to the Ohio Department of Health and publish a local notice of the report's availability to the public. The report shall include, at a minimum, a summary of radioactive waste received, processed, disposed, transferred, incidents, and environmental monitoring results. The annual summary report shall be completed and submitted within ninety days after the end of the licensee's fiscal year.
- (K) All generators shall contractually agree to the return of radioactive waste to the generator. The waste processor may dispose of the radioactive waste on behalf of the generator at a licensed disposal facility in a timely manner.

March 30, 2001

Mr. Richard A. Ratliff, Chief
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3189

Dear Mr. Ratliff:

I am responding to your letter of February 27, 2001, in which you request views on the licensing of an assured isolation facility. You forwarded a letter from Honorable Warren Chisum of Texas, in which he asks, "What requirements would be necessary, in addition to Part 61, to establish an assured isolation facility in Texas?" The Commission's policy, as described in the enclosed correspondence, has been, and continues to be, that low-level radioactive waste (LLW) should be disposed of safely as soon as possible after it is generated. Thus, the Commission strongly supports State and compact efforts to develop new LLW disposal capacity in accordance with the Low-Level Radioactive Waste Policy Amendments Act of 1985. However, in view of the many complex waste disposal issues currently facing this Nation, the Commission is open to serious consideration of any feasible and safe proposals.

An assured isolation facility, as originally described by its authors,¹ is intended initially to be a storage facility. Later, based on its performance, it could be converted to a disposal facility, subject to the requirements in effect at that time. Its authors describe it as a LLW management concept different from Part 61 near-surface disposal facilities. Instead of relying on site features to help in isolating waste like Part 61, an assured isolation facility relies more heavily on engineered barriers and "institutional controls," or the monitoring and maintenance of the facility, far into the future. Reliance on such controls is limited by Part 61 requirements to 100 years after facility closure. The assured isolation concept also preserves future options (such as the ability to remove waste and dispose of it elsewhere). Disposal of waste in 10 CFR Part 61 facilities is intended to be permanent and there are no requirements for retrievability. These important differences notwithstanding, an assured isolation facility has many of the characteristics and features of modern disposal facilities--concrete buildings and overpacks for wastes, an above-ground design, an extensive monitoring and maintenance program to ensure continued performance of the facility, and so forth. Although similar to or nearly identical to a disposal facility in its design, suitable licensing criteria for such a facility that protect public health and safety and the environment have not been defined. In the following response, we offer three different approaches for licensing an assured isolation facility for your consideration.

Approach 1-- Storage under 10 CFR Parts 30, 40 & 70. The Commission believes that Texas has the authority to license an assured isolation facility for storage of LLW in renewable terms and to defer a decision on its ultimate disposition to the future. We note that the Texas Natural Resources Conservation Commission (TNRCC) had a report prepared for it last summer that includes licensing approaches for assured isolation.² Although NRC has not reviewed this

¹ "Assured Storage Facilities: A New Perspective on LLW Management" by W. Newberry, T. Kerr, D. Leroy, Radwaste Magazine, v.2, no.5, pp.13-22, September 1995.

² "Texas Compact Low-Level Radioactive Waste Generation Trends and Management Alternatives Study," Rogers and Associates Engineering Branch of URS. RAE-42774-019-5407-2. August 2000.

report, the initial licensing of such a facility for the possession and storage of LLW (under your equivalent to 10 CFR Parts 30, 40 and 70) is relatively straightforward from a public health and safety point of view, with the exception of issues associated with financial assurance for ultimate disposal and whether (and when) the facility would be considered permanent disposal. Converting the facility to a disposal facility at some time in the distant future is one of the options addressed in the TNRCC report. Issues would need to be addressed by Texas in the initial licensing, such as funding for removal and ultimate disposal of the waste if the facility was not or could not be licensed for disposal in the future. Texas would also need to determine whether such a facility meets the terms and obligations of the Texas Compact law. Finally, Texas would also need to examine how current regulatory limits on the possession of special nuclear material (SNM) might apply to an assured isolation facility. It is possible that an NRC license would also be required to possess SNM in a facility licensed by Texas, since the amounts of SNM might exceed those which Texas can license under its agreement with NRC. While obtaining a second license for possession of these materials is possible, it would be an added complication. If the State were to choose this approach, we would encourage you to coordinate resolution of issues with NRC.

Approaches 2 & 3- Disposal under 10 CFR Part 61: It would also be possible to license an assured isolation facility under Texas rules equivalent to NRC's disposal regulations in 10 CFR Part 61, while still preserving many of the desirable features of assured isolation. Such a facility, while licensed for disposal, could still incorporate the following:

- a robust engineered facility with concrete buildings and overpacks for waste;
- recoverability or retrievability of the waste for disposal elsewhere at some future time;
- institutional controls for the indefinite future, although reliance on such controls in our regulations is limited to 100 years; and
- funding sufficient for the long-term care program (such funding could potentially cover the removal of the waste and disposal elsewhere).

The engineered barriers would be relied on, at least in part, to meet our regulations, while other features, such as retrievability and funding for disposal in another facility, could be added at the discretion of the State. There are two basic alternatives for licensing under Texas disposal regulations equivalent to those in 10 CFR Part 61. The approach depends upon the design chosen for assured isolation.

Approach 2 -- 10 CFR Part 61 near-surface disposal. If an assured isolation facility were to be eventually covered with earth, it would be considered a near-surface disposal facility. This facility would be subject to the general performance objectives in 10 CFR Part 61, Subpart C, and to the detailed technical requirements that are contained in 10 CFR Part 61, Subpart D for near-surface disposal. The Commonwealth of Pennsylvania had planned such a facility at one

time, and had put into place regulations compatible with 10 CFR Part 61. The proposed facility included recoverability of the waste and an institutional control program lasting more than 100 years. The facility was to remain uncovered for a long period of time for monitoring and then would have been covered with earth after it was closed. Because of the earthen cover, a facility such as this could be licensed under your detailed technical requirements for near-surface disposal equivalent to those in 10 CFR Part 61, Subpart D. We do not believe that any additional requirements from a safety perspective would be needed for such a facility. If Texas wanted to preserve certain features of assured isolation that are not mandated by 10 CFR Part 61, it could, at its discretion, specify an institutional control period longer than 100 years and contingency funds to remove the waste and dispose of it elsewhere at some future time.

Approach 3 -- 10 CFR Part 61 above-ground disposal. This approach for licensing would be for a facility that would not be covered with earth at any time in the future. Such a facility is considered to be an "above-ground" disposal facility, and while covered by 10 CFR Part 61, there are no detailed requirements for such a design in our regulations. It is not considered to be "near-surface disposal" and would not be subject to the well-developed requirements in 10 CFR Part 61 for near-surface disposal. The above-ground disposal concept is similar in some respects to entombment of low-level radioactive waste from nuclear power reactors in the containment building after cessation of operations. NRC is currently investigating whether a rulemaking is needed or desirable for entombment, and that effort may be useful if Texas pursues above-ground disposal. (See All Agreement States Letter STP-01-017, Request for Comments on an Advance Notice of Proposed Rulemaking and a Draft Rulemaking Plan Concerning an Entombment Options for Power Reactors, dated March 7, 2001.) When NRC amended 10 CFR Part 61 in 1993 to cover above-ground facilities, we noted that detailed technical criteria would need to be developed if such a facility were to be proposed. NRC has no plans to promulgate regulations for only one possible above-ground facility. If either Texas or some other organization were to develop the requirements that would be needed to ensure long-term isolation of waste with this type of facility, NRC would be willing to provide assistance with this effort. We have enclosed our 1993 final rule on above-ground facilities for your information. The lack of specificity in our regulations would provide some flexibility for the State in terms of what the criteria might be.

Finally, we note that there may be SNM implications for Approaches 2 and 3 depending on the amount of SNM stored at any one time prior to disposal.

We would be pleased to discuss these issues further. Please contact me or Spiros Droggitis of my staff at 301-415-3340 for further information.

Sincerely,

/RA/

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 19, 1999

The Honorable Gary L. Walker
Texas House of Representatives
District 80
P.O. Box 2910
Austin, Texas 78768-2910

Dear Mr. Walker:

I am responding to your March 4, 1999, letter requesting the views of the Nuclear Regulatory Commission (NRC) on assured storage (or assured isolation) as an alternative to disposal of low-level radioactive waste (LLW). Our views on assured storage remain the same as those expressed in my May 9, 1996 letter to David Leroy of Idaho. The Commission policy has been, and continues to be, that LLW should be disposed of safely as soon as possible after it is generated. Thus, the Commission strongly supports State and compact efforts to develop new LLW disposal capacity in accordance with the Low-Level Radioactive Waste Policy Amendments Act of 1985. The Commission also is aware that there are a variety of complex waste disposal issues currently facing this Nation, many of which are within the purview of the Atomic Energy Act. In particular, in view of the many challenges in the area of site decommissioning that are tied closely to the availability of safe and economic means of managing LLW, the Commission is open to serious consideration of any feasible and safe proposals.

We also recognize that a few States have expressed interest in the assured storage concept. If a State came to the Commission directly seeking our views on the feasibility of assured storage, we would evaluate the request in accordance with our regulatory responsibilities. This evaluation would have to address several complex issues associated with assured storage, such as when does assured storage constitute disposal, what financial assurance would be required during the storage period, and how would current regulatory limits on the possession of special nuclear material apply to an assured storage facility.

Because no one has applied to the NRC for a license to construct and operate an assured storage facility, *per se*, the NRC has not licensed an assured storage facility. However, the NRC has licensed numerous commercial nuclear facilities that included LLW storage as an integral component of other nuclear activities. We do not consider assured storage to be the equivalent of permanent disposal of LLW. By its very nature, assured storage is considered a temporary facility. If it were intended to be permanent, we would review an application for such a facility under our requirements for LLW disposal in 10 CFR Part 61. As I stated in my letter to Mr. Leroy, the NRC would need to determine which regulations to apply in reviewing an application to construct an assured storage facility. The applicable safety requirements would vary based on the nature of the proposal and the potential risks to the public and the environment.

I trust that this response will be useful to Texas in your consideration of assured storage and safe management of LLW. If the NRC can be of further assistance, please do not hesitate to contact us.

Sincerely,

A handwritten signature in cursive script, appearing to read "Shirley Ann Jackson".

Shirley Ann Jackson

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56 FR 61352
Published 12/3/91
Effective 6/20/91

Standards for Protection Against
Radiation; Correction

See Part 20 Statements of
Consideration

57 FR 55062
Published 11/24/92
Effective 12/24/92

Clarification of Statutory Authority for
Purposes of Criminal Enforcement

See Part 11 Statements of Consideration

requirements for low-level radioactive waste (LLW) disposal facilities. These amendments clarify that these regulations also apply to the licensing of above-ground disposal facilities; replace the phrase "quality control program" in these regulations with the phrase "quality assurance program," tailored to LLW disposal; update the Paperwork Reduction Act Statement in the regulations, and identify the correct NRC recipient of copies of the licensee's annual reports. The changes are intended to simplify LLW disposal facility licensing interactions for NRC, the NRC Agreement States, and potential applicants for LLW disposal licenses.

EFFECTIVE DATE: July 22, 1993.

ADDRESSES: Copies of the regulatory analysis, the environmental assessment and finding of no significant impact, and the comments received on the rule may be examined at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mel Silberberg, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 492-3810.

SUPPLEMENTARY INFORMATION:

Background

The NRC published a proposed rule in the *Federal Register* on March 6, 1992, (57 FR 8093-8096) that proposed to make four specific changes to 10 CFR part 61 (hereafter referred to as "part 61" or "the regulation"). Part 61 sets out licensing requirements, licensing procedures, and performance objectives for the land disposal of LLW waste. A review of part 61 against the backdrop of current State and Compact efforts to site and develop LLW disposal facilities identified the need to modify the regulations as follows: (1) Clarify that 10 CFR part 61 also applies to above-ground disposal facilities; (2) replace the phrase "quality control program" in § 61.12(j) with the phrase "quality assurance program," tailored to LLW disposal; (3) update the Paperwork Reduction Act Statement in § 61.8; and (4) identify the correct NRC recipient of copies of the licensee's annual reports. A 30-day comment period expired on April 6, 1992. Comments were received from six respondents.

Summary and Analysis of Public Comments

Two of the letters came from States, one from a citizens group, one from an environmental consulting company, one from a LLW facility developer, and one from a private citizen. Three of the

respondents provided no actual comments but only wrote to indicate their support for the proposed rulemaking. Two of the actual commenters, the State of Illinois and the consulting company, objected to certain provisions of the proposed rule and provided comments on those provisions. The objections raised by these two commenters focused on the change which clarifies that part 61 also applies to above-ground LLW disposal facilities. The developer commented on a part of the rule that was not being revised. One of the commenters raised a concern about shallow land burial that was not germane to this rulemaking.

Issue: Abandonment of the Systems Approach

The State of Illinois and the consulting company expressed concern that the proposed amendments to clarify the applicability of part 61 to above-ground disposal amounted to more than simple clarification. These two commenters took the view that the proposed amendments constituted a significant change in, or even abandonment of, the regulatory concept that was the foundation of part 61 and referred to as the "systems approach." The consulting company stated that two of the basic concepts of the systems approach in part 61 were that "the site should make a significant contribution to the long-term isolation of the wastes," and "as reliance on the long-term performance of engineered features decreases over time, reliance on the site must increase over time in order to compensate." The same commenter stated that the site would play a significantly less important role in assuring the long-term isolation of the waste for above-ground disposal facilities without soil covers than it would for disposal facilities built into the ground with soil covers. The commenter stated that there would have to be overwhelming reliance on the above-ground engineered structures not only to contain the wastes over the short term, but to provide long-term isolation as well. The commenters argued that this situation is an abandonment by NRC of the system approach to LLW disposal.

Response

The systems approach to safe disposal of LLW was and still is the foundation of licensing under part 61. The NRC is not abandoning that regulatory concept in the process of clarifying that part 61 can be used to license above-ground disposal facilities. In pursuing the concept of the systems approach during the development of part 61, NRC

58 FR 33886
Published 6/22/93
Effective 7/22/93

10 CFR Part 61

RIN 3150 - AE00

Licensing Requirements for Land
Disposal of Radioactive Wastes

AGENCY: Nuclear Regulatory
Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations containing licensing

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assumed that for LLW disposal facilities to meet the performance objectives in subpart C, there would have to be an integrated performance of all of the disposal system components (i.e. the site, the waste form, the engineering or facility design, the operation, and the closure of the facility). Each component of the disposal system would make some particular contribution to the containment or isolation of the waste, albeit dependent upon the particular design. As an integrated system the components would work with each other to protect the public health and safety. This assumption applies to any LLW disposal facility, whether it is in the ground or above-ground. As noted in the Statement of Considerations for the proposed rule, technical criteria, analogous to those presently in 10 CFR part 61 but specific to above-ground disposal, do not exist. Nor is the NRC providing either technical criteria or guidance for above-ground disposal designs in this rulemaking. It is expected that should NRC receive an application for above-ground disposal, criteria will be developed on a case-by-case basis.

In any case, whether an LLW facility is in the ground or above ground, it will have to meet the part 61 performance objectives to be licensed for LLW disposal, and performance assessments will evaluate the interactions of the site, design, etc., to determine if they will result in a safe facility.

Issue: NRC Promotion of an Unproven and Questionably Safe Disposal Technology

The public health and safety implications of the proposed action were also a major concern to the consulting company. That commenter objected to the proposed rule on the grounds that the NRC could not ensure that the public health and safety would be protected because the Agency had not evaluated the safety of an above-ground disposal facility over the 500 years during which there would be a radiological hazard at such a facility. The commenter also asserted that the NRC had not demonstrated through the proposed rule that an overall disposal system of such a design could, with reasonable assurance, meet the performance objectives of subpart C, as such a facility would be required to do before an LLW license could be granted. In addition, the commenter stated that above-ground disposal technology was not specifically evaluated in the Environmental Impact Statement (EIS) for the existing part 61 and noted that no additional assessment was offered as part of the proposed rulemaking. From

this commenter's perspective, by proposing the changes to authorize the use of above-ground disposal, NRC is promoting an unproven and questionably safe disposal technology.

Response

The structure of part 61 is that all land disposal facilities must meet the performance objectives of subpart C. The subpart C performance objectives are the safety objectives, intended to protect the general population from releases of radioactivity, to protect individuals from inadvertent intrusion, and to protect individuals during facility operations. The licensee application for any LLW land disposal facility must demonstrate compliance with these objectives. If NRC received a license application for an above-ground facility, NRC would perform a safety evaluation as a necessary part of the licensing process to determine if the required performance objectives would be fulfilled. NRC's analysis and evaluation for such a facility would be based on site-specific information and data obtained during the licensing process to assess compliance with the performance objectives. Additionally, in accordance with 10 CFR 51.80(a), the NRC will prepare an EIS for the facility as it is required to do for any LLW disposal facility license issued under 10 CFR part 61.

Issue: Lack of Technical Requirements for Above-Ground Disposal—More Complicated Licensing Process

The two commenters who objected to the proposed rule also objected because it did not contain technical requirements for above-ground disposal. Part 61 contains detailed technical requirements specifically for near-surface disposal facilities but no equivalent technical requirements for above-ground facilities are present in the existing part 61, nor were any proposed through the rulemaking. The commenters maintain that it is not desirable to promulgate a rule extending the applicability of Part 61 to above-ground disposal facilities without appropriate technical guidance.

The consulting company also objected to the proposed rule because the commenter believes that NRC's intentions to develop technical requirements after an application is received would increase uncertainty and complicate, rather than simplify, the licensing process. The commenter stated that developing the requirements at the same time a license application is under review would expose the license review to undesired debate about the adequacy of the regulations and the

manner in which they were developed. The commenter argued that NRC should develop the technical requirements for above-ground disposal now, as part of this rulemaking.

Response

The NRC continues to support its earlier decision not to issue technical criteria for above-ground disposal with this rulemaking. While some States have considered above-ground disposal, no State has actually decided to build such a facility. Thus, NRC may not even receive an application to license an above-ground facility. Therefore, NRC believes that it is a more efficient use of NRC resources to develop technical criteria when there are actual plans for an above-ground facility rather than speculate at this time as to how such a facility might be designed.

Although the decision to defer development of the technical criteria for an above-ground disposal facility will introduce some uncertainty into the licensing process, the Commission does not believe that this deferral will substantially interfere with the development of a license application for such a facility or the NRC review of such a license application. As noted previously, the performance objectives of subpart C must still be met, and furthermore, the near-surface disposal requirements currently in § 61.50, § 61.51, and § 61.52 may be useful to a potential license applicant in preparing a license application for an above-ground disposal facility.

Issue: Increased Regulatory Uncertainty for Above-Ground Disposal

The consulting company expressed concern that if an Agreement State receives an application for above-ground disposal and NRC has not developed technical requirements, the Agreement State will have to develop its own technical requirements which could be different from those developed by another Agreement State or by the NRC. The commenter's view is that the differences in requirements could raise issues that would ultimately have to be resolved by NRC or by the courts.

Response

NRC recognizes that different States and the NRC might utilize different technical criteria appropriate to the particular design proposed to them. The NRC will provide assistance to the extent practical to facilitate States' efforts in developing and utilizing criteria. In any case, as noted previously by the Commission, the performance objectives of subpart C must still be met. Any differences in technical approaches

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should not give rise to proceedings before NRC or the Courts.

Issue: LLW Licensing on an Ad Hoc Basis

According to one of the commenters, the proposed changes which include facility review and criteria development on a case-by-case basis, raise the specter of above-ground disposal facilities that are designed, licensed, constructed, operated, and closed, on an ad hoc basis. The commenter believes such licensing would be a retreat to the method of licensing used before the promulgation of part 61.

Response

The NRC does not believe that the term "ad hoc" accurately describes the licensing decisions it will make on above-ground disposal. NRC has dealt with and will continue to deal with many specific licensing issues on a case-by-case basis. However, since the promulgation of part 61, the licensing process for LLW disposal is directed at attaining reasonable assurance that the licensed facility will meet the performance objectives of subpart G. Granted there will likely be new and different issues associated with licensing an above-ground facility, but NRC will deal with these issues as it has in the past, making sure that adequate conservatism has been incorporated in the design or the siting of the facility to ensure the public safety.

Issue: Not Disposal but Long-Term Storage

One of the commenters objected to the concept of above-ground disposal as nothing more than a 500-year hold-for-decay, storage facility. The commenter notes that long-term storage of LLW is inconsistent with Commission policy. The commenter urged NRC to make a clear case that an above-ground disposal facility without an earthen cover is substantially different from a 500-year storage facility.

Response

The NRC would not treat an above-ground disposal facility as a storage facility. A performance assessment would need to demonstrate long-term performance and stability as required by part 61. The facility would be licensed as a permanent disposal facility and would be evaluated for compliance with the Performance Objectives in subpart C.

Issue: Lack of Public Role in the Regulatory Process

Another issue raised was that the approach NRC intends to use to license

above-ground disposal will not ensure adequate opportunity for public involvement in the regulatory process. The commenter noted that in the proposed rule NRC specified its intent to develop technical requirements for above-ground disposal facilities after an application is received and on a case-by-case basis. The commenter assumed that such an approach would not afford the public the opportunity to be actively involved in the development and review of such requirements.

Response

There has been opportunity for public participation in the establishment of the performance objectives in subpart C, which were established by rulemaking. In addition, there will be opportunity for the public to be involved in the regulatory process related to licensing an above-ground disposal facility. As discussed previously, the technical review criteria for an above-ground disposal facility will be developed on a case specific basis after a license application is received for such a facility. On a case specific basis the Commission will determine what mechanism to use to establish the technical requirements for the facility license and the method for involving the public in the development of such requirements. In similar situations where the technical criteria for licensing has not been established by rule, the Commission has provided an opportunity for parties to the hearing on the license application for the facility, the opportunity to comment on the licensing criteria. This occurred in the Envirocare license application for a specialized high-volume, low-activity thorium and uranium waste disposal facility (58 FR 2939) 1991 and in the Louisiana Energy Services license application for the design, construction, and operations of unique uranium enrichment facilities. (58 FR 23310) 1991.

Participation by a member of the public in the licensing process is described in NUREG-1274 including procedures for compliance with 10 CFR part 2, NRC's "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders." Federal Register Notices (FRN) are published when an application is tendered, when an application is determined to be acceptable for docketing, when the Draft Safety Evaluation Report (DSER) and Draft Environmental Impact Statement (EIS) are completed, and when public hearings are scheduled. NRC will also publish a Notice of Intent to issue a license and a Notice of Issuance. The public, States, tribes, and local

governments can petition to participate in the licensing process and can request hearings to provide further involvement.

Issue: Shallow Land Burial Facilities Could be Considered Geologic Repositories

The developer commented that the second sentence of the definition "land disposal facility" which reads, "For purposes of this chapter, a geologic repository as defined in part 60 is not considered a land disposal facility" might be construed to preclude shallow land burial as a permissible method for LLW disposal. The commenter noted that while the exclusion of geologic repositories is supposed to decouple LLW facilities from deep geologic facilities for high-level waste (HLW) disposal, the definition of geologic repository in part 60 (NRC's HLW disposal regulations) is very general, and that a "shallow land burial facility" for LLW could be considered a geologic repository under the part 60 definition.

Response

NRC staff believes that this comment reflects a misunderstanding regarding NRC's proposed changes to the definition of "land disposal facility," and it addresses an issue which is outside of the intended scope of the rulemaking. From the developer's comments, it could be that the developer incorrectly believed that the second sentence of the definition was being added, or at least changed, as part of NRC's proposed revision to part 61. However, neither was the case. The language identified in this comment is already part of the definition of "land disposal facility" in part 61 and has been since the original rule was promulgated in 1982. For purposes of presenting the entire definition as it would appear when the revisions were promulgated, the NRC staff included the second sentence in what was referred to as the proposed definition for "land disposal facility" for the proposed rulemaking. Even though NRC was not proposing to add or change that sentence, NRC staff considered the developer's comment to determine if the wording of the second sentence could be used to exclude typical shallow land burial as an acceptable design for disposal of LLW.

The staff does not believe that there should be any difficulty in differentiating between a geologic repository that is licensed under the requirements of part 60 for disposal of HLW and a land disposal facility licensed under the requirements of part 61 for disposal of LLW. The definition of a geologic repository must be read

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within the context of the purpose and scope of 10 CFR 60.1. This section applies to a geologic repository that is only licensed to the U.S. Department of Energy (DOE) in accordance with the Nuclear Waste Policy Act of 1982. Moreover, § 60.1 specifically states that part 60 "does not apply to any activity licensed under another part of this chapter." Therefore, a shallow land burial facility licensed under part 61 would not come within the scope of § 60.1, but instead would fit within the scope of part 61. The staff concludes that no change is required to the second sentence in the definition for "land disposal facility" in part 61 to address the developer's comment.

Based on the analysis of public comments and further staff review, the staff has prepared this final rule. As described below, there are some editorial differences between the proposed definition for "land disposal facility" and the definition to be promulgated in the final rule.

Discussion of the Revisions

I. Amend the definition of "land disposal facility" in § 61.2 to clarify that the term refers to LLW disposal facilities which are on or protrude through the earth's surface and do not have an earthen cover, in addition to those that are in the ground and have an earthen cover. The purpose of this change is to clarify the regulatory applicability of part 61 to the licensing of "above-ground" disposal designs like the "above-ground vault," in particular, and the applicability of the performance objectives of part 61 to these designs.

The definition of "land disposal facility" offered in the proposed rule read "land disposal facility" means the land, buildings, and equipment which are intended to be used for the disposal of radioactive wastes on the surface or into the subsurface of the land. For purposes of this Chapter, a 'geologic repository' as defined in part 60 is not considered a 'land disposal facility'."

For the final rule, the wording of the definition of "land disposal facility" has been modified slightly from the language of the proposed definition in order to better clarify that part 61 can be used by NRC to license above-ground LLW disposal facilities. The final definition of land disposal reads "land disposal facility means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this Chapter, a "geologic repository" as defined in part 60 is not considered a "land disposal facility." In the final definition, the words "on the surface or into the subsurface of the

land" have been deleted to eliminate confusion regarding the kinds of facilities to which these terms apply. The word "structures" has been added since that term better describes the types of engineered features likely to be constructed at an above-ground LLW disposal facility. The Commission believes the final definition is not a substantive change but a modification to simplify the definition so that it is easier to understand.

At this time, the NRC is not issuing specific technical criteria for above-ground disposal facilities that are analogous to the near-surface disposal requirements of §§ 61.50(a), 61.51(a), and 61.52(a) of subpart D because of the special technical characteristics of above-ground disposal facilities. Only those portions of the regulation that apply generically to "land disposal facilities" are directly applicable to the licensing of above-ground disposal facilities. Specifically, this means that the overall performance objectives of subpart C will apply to above-ground disposal facilities, as well as the part 61 administrative and procedural requirements, the environmental monitoring requirements, the financial assurance requirements, the waste transfer and manifest requirements, and the general institutional requirements.

Establishing the applicability of the subpart C performance objectives to above-ground disposal is particularly important. Any applicant for a license for an above-ground disposal facility under part 61 will have to demonstrate to the NRC that the proposed facility can meet the same safety requirements and dose limits that apply to any LLW disposal facility that has an earthen cover. The demonstration of compliance will have to address the unique features of the above-ground design, the special technical considerations associated with those features, their potential health and safety consequences, and reconcile them with the subpart C performance objectives.

Even though some of the requirements in subpart D are only applicable to near-surface disposal, the Commission still believes they would be useful to a prospective license applicant as guidance for planning an above-ground facility and to the NRC or Agreement States in the development of technical requirements for such facilities.

To provide further clarification regarding the applicability of part 61 to the licensing of above-ground disposal facilities, NRC also is amending the "Disposal Facility" discussion in the Concepts Section—61.7. The change to § 61.7(a)(1) clarifies the distinction made by the NRC between near-surface

disposal and above-ground disposal, to emphasize that near-surface LLW disposal facilities built partially or totally above-grade have protective earthen covers, while similar facilities constructed without earthen covers are considered to be "above-ground disposal facilities."

NRC is not providing either technical criteria or guidance for above-ground disposal designs with these amendments. It is expected that, should NRC receive an application for above-ground disposal, criteria will be developed on a case-by-case basis.

II. Replace the term "quality control program" in § 61.12(j) with the term "quality assurance program, tailored to LLW disposal." The purpose of this change is to clarify what steps an applicant for an LLW disposal facility license must take in order to assure that the facility will perform as intended, and also to assure that the necessary records and documentation are available for evaluation and performance assessment by NRC or an Agreement State at the time of license submittal. Quality assurance is a broad term that encompasses quality control and also includes managerial controls and audits.

III. Revise § 61.8 to indicate that the NRC requested and obtained OMB approval for the information collection requirements in part 61. Under the OMB guidelines that were in effect when the original part 61 was issued, OMB approval of the part 61 information collection requirements was not necessary because the regulation was expected to affect less than 10 licensees. Subsequently the OMB guidelines changed, and part 61 was no longer exempt from the OMB approval requirement. Accordingly, NRC submitted part 61 for OMB review and obtained the OMB clearance that is required by the Paperwork Reduction Act. The purpose of this change is to update § 61.8 to correctly reflect this approval.

IV. Revise § 61.80(i)(1) to identify the correct NRC headquarters recipient of copies of the annual report.

Issue of Compatibility for Agreement States

Under existing NRC policy and guidelines, two of the changes adopted in this rulemaking would be matters of compatibility for the NRC Agreement States. The change to the definition of land disposal facility in § 61.2 is a matter of Division I compatibility, and the "QC" to "QA" change in § 61.12(j) is a matter of Division II compatibility. This means that those Agreement States that have assumed NRC's regulatory authority for the disposal of LLW under

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section 274 of the Atomic Energy Act (AEA) of 1954, as amended, normally would be required to incorporate the new definition of "land disposal facility" essentially verbatim directly into their State regulations for LLW disposal. However, States who have already selected a disposal technology and adopted a more narrow regulatory definition of "land disposal facility" to reflect that selected technology, will not be required to amend their regulatory definition to conform to this revision, provided the selected technology falls within the scope of 10 CFR part 61 and the definition is not inconsistent with the NRC definition.

The incorporation of the Division II change is also required; however, the Agreement States have more flexibility than for the Division I change. For the Division II change, the language adopted need not be identical to the NRC regulations, but the effect cannot be less stringent.

Based on the existing guidelines, the changes would have to be incorporated within 3 years after this final rule is issued.

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969 as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule is not expected to have a significant effect on the quality of the human environment and, therefore, an environmental impact statement is not required. Three of the proposed changes—the "quality control" to "quality assurance" change in § 61.12(j), the update of the Paperwork Reduction Act Statement in § 61.8, and the correction of the organizational inconsistency in § 61.80(i)(1) are the types of actions described in categorical exclusion § 51.22(c)(2). As such they are considered by the Commission to be corrective and nonsubstantive in nature and will not have an impact on the environment. The remaining changes, which clarify the applicability of part 61 to the licensing of above-ground LLW disposal, also will not have an impact on the environment in that these amendments do not change the required level of overall performance for LLW disposal facilities. Furthermore, any environmental impact of operating such a facility will be addressed as a part of the licensing action for that specific facility under 10 CFR part 51. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document

Room, 2120 L Street NW (Lower Level), Washington, DC. Single copies of the environmental assessment and the finding of no significant impact are available from Mark Haisfield, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3877.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0135.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the alternatives considered by the Commission and explains the decision to revise part 61. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC. Single copies of the analysis may be obtained from Mark Haisfield, (301) 492-3877.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The changes made to part 61 in this rule will only affect those entities that decide to apply for a license to build and operate an LLW disposal facility. In the Low-Level Radioactive Waste Policy Act of 1980 (LLRWPA) and the Low-Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPA), Congress mandated that the individual States or groups of States called compacts should provide the LLW disposal capacity for the LLW generated within each of their borders. Thus the licensees for LLW disposal facilities will either be States or private operators which are not small entities under the size standards established by the Nuclear Regulatory Commission on November 6, 1991 (56 FR 56871). In addition, this rule will not have a significant economic impact because the changes to part 61 are clarifying in nature, and only a small number of licensees are likely to be affected.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule, and therefore,

that a backfit analysis is not required for this final rule because these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 61

Criminal penalty, Low-level waste, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 61.

58 FR 52406
Published 10/8/93
Effective 11/8/93

Whistleblower Protection for Employees of NRC-Licensed Activities

See Part 19 Statements of Consideration

58 FR 54646
Published 10/22/93

Whistleblower Protection for Employees of NRC-Licensed Activities: Correction

See Part 19 Statements of Consideration

58 FR 67657
Published 12/22/93
Effective 1/1/94

Standards for Protection Against Radiation; Removal of Expired Material

See Part 20 Statements of Consideration

60 FR 15648
Published 3/27/95
Effective 3/1/98

Low-Level Waste Shipment Manifest Information and Reporting

See Part 20 Statements of Consideration

"Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.5°C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

"State" means any State, Territory, or possession of the United States, Puerto Rico, and the District of Columbia.

"Stability" means structural stability.

"Surveillance" means observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.

"Tribal Governing Body" means a Tribal organization as defined in the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450).

"Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Waste Policy Act, that is radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste).

§ 61.3 License required.

(a) No person may receive, possess, and dispose of radioactive waste containing source, special nuclear, or byproduct material at a land disposal facility unless authorized by a license issued by the Commission pursuant to this part, or unless exemption has been granted by the Commission under § 61.6 of this part.

(b) Each person shall file an application with the Commission and obtain a license as provided in this part before commencing construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license.

§ 61.4 Communications.

Except where otherwise specified, all communications and reports concerning the regulations in this part and applications filed under them should be addressed to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Communications, reports, and applications may be delivered in person at the Commission's Offices at 2120 L Street, NW., Washington, DC, or 11555 Rockville Pike, Rockville, Maryland.

§ 61.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be considered binding upon the Commission.

§ 61.6 Exemptions.

The Commission may, upon application by any interested person, or upon its own initiative, grant any exemption from the requirements of the regulations in this part as it determines is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest.

§ 61.7 Concepts.

(a) *The disposal facility.* (1) Part 61 is intended to apply to land disposal of radioactive waste and not to other methods such as sea or extraterrestrial disposal. Part 61 contains procedural requirements and performance objectives applicable to any method of land disposal. It contains specific technical requirements for near-surface disposal of radioactive waste, a subset of land disposal, which involves disposal in the uppermost portion of the earth, approximately 30 meters. Near-surface disposal includes disposal in engineered facilities which may be built totally or partially above-grade provided that such facilities have protective earthen covers. Near-surface disposal does not include disposal facilities which are partially or fully above-grade with no protective earthen cover, which are referred to as "above-ground disposal." Burial deeper than 30 meters may also be satisfactory. Technical requirements for alternative methods may be added in the future.

(2) Near-surface disposal of radioactive waste takes place at a near-surface disposal facility, which includes all of the land and buildings necessary to carry out the disposal. The disposal site is that portion of the facility which waste is used for disposal of waste and consists of disposal units and a buffer zone. A disposal unit is a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the disposal unit is usually a trench. A buffer zone is a portion of the disposal site that is controlled by the licensee and that lies under the site and between the boundary of the disposal site and any disposal unit. It provides controlled space to establish monitoring locations which are intended to provide an early warning of radionuclide movement, and to take mitigative measures if needed. In choosing a disposal site, site characteristics should be considered in terms of the indefinite future and evaluated for at least a 500 year time frame.

Mr. Robert E. Owen
Manager of Technical Services
Bureau of Radiation Protection
Ohio Department of Health
246 North High Street
P. O. Box 118
Columbus, OH 43216-0118

Dear Mr. Owen:

I am responding to your letter of February 20, 2002, in which you requested our views on the proposed Ohio regulations for licensing of an assured isolation facility.¹ I want to stress that the Commission's policy has been, and continues to be, that LLW should be disposed of safely in a permanent disposal facility as soon as possible after it is generated. Thus, the Commission strongly supports State and Compact efforts to develop new LLW disposal capacity in accordance with the Low-Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPA). The Commission is also aware that there are a variety of complex waste disposal issues, many of which are within the purview of the Atomic Energy Act, that continue to face the States and the Nation. In particular, there are many challenges, in the area of site decommissioning, that depend, for their safe resolution, on the availability of safe and economic means of managing LLW. The Commission is open to serious consideration of feasible and safe proposals and recognizes the need to assist the States in efforts that could include assured isolation facilities, which will help manage LLW. These facilities would permit relatively short-lived radioactive wastes to decay during isolation and then be recycled or disposed of at a future date, not to exceed a specified period of time. Although assured isolation is a LLW management tool, concerns about ultimate disposal must be reviewed, since storage for a period of 100 years raises additional complex issues, such as financial assurance, responsible parties and/or their successors, waste stability, and the LLRWPA requirement to establish additional permanent disposal capacity for LLW.

In the past, several States expressed interest in the assured isolation concept. The questions that will need to be considered include, in part, a common definition for assured isolation, and what financial assurance mechanisms would be required during the storage period and for ultimate disposal. As a separate matter, other issues need to be considered, such as how current State and U.S. Nuclear Regulatory Commission (NRC) regulatory limits on the possession of special nuclear material apply to an assured isolation facility, or how other program elements under review and development, such as stewardship and financial assurance, impact the final outcome of a proposed regulation for assured isolation. We had anticipated a need for rulemaking on

¹Assured isolation is a low-level radioactive waste (LLW) management concept, and the associated facility is not permanent nor near-surface disposal, as defined in 10 CFR Part 61.

assured isolation as an interim measure to manage LLW, until permanent disposal facilities are developed. We currently anticipate initiation of this effort in the fiscal year 2004-2005 time frame. We also recognize that the Commission, in the past, noted it would provide assistance to a State or other organization that developed requirements for an assured isolation facility.

In the next decade, permanent LLW disposal capacity may not be available and this would not be in the best interest of the public. Therefore, it is timely to consider your proposal, as it could be a helpful foundation which other Agreement States could use in their development of similar operable rules. We are providing the enclosed general comments as a technical consultation to you for your consideration. These comments are not all-encompassing and are provided for assistance, should you continue to develop regulations separately for assured isolation. Please note that should NRC proceed at a later date to develop assured isolation facility rules with extensive public and stakeholder involvement, that might require Ohio to amend its rule, to be compatible with NRC, depending on the compatibility category.

We would be pleased to discuss these issues and comments. Please contact me or Dr. Stephen Salomon of my staff at 301-415-3340.

Sincerely,

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure:
As stated

GENERAL COMMENTS ON THE OHIO DRAFT RULES FOR ASSURED ISOLATION

These comments are not all-encompassing, and are provided for general assistance if Ohio develops regulations for assured isolation. It should be noted that the NRC has authority and jurisdiction over an Assured Isolation Facility (AIF) on a reactor site, at least until such time as the reactor is decommissioned and the reactor license is terminated. Thus, the comments that follow are directed to AIFs that are not on reactor sites.

Draft Rule 3701:1-54-03 through 05; Assured Isolation Facility; Quality Assurance; and Radioactive Waste Processing

1. The definitions should be reviewed by other Federal agencies, to include the U.S. Environmental Protection Agency and the U.S. Department of Transportation. Some definitions should be revised [e.g., the definition for assured isolation should be limiting (not beyond 100 years) so as not to suggest this could be permanent disposal]. The 100-year provision in 1-54-03 (M)(3) is not direct enough to address this concern. Further, since the proposed regulation is intended to be specific to storage, the interim storage definition should not specifically include disposal. Consequently, the statement "... due to the absence of an accessible licensed disposal facility" should be revised or deleted from the interim storage definition. The definition of temporary storage states, "...for a reasonable time" and would be more useful if specific criteria were included to define what is considered reasonable. A definition for the term "institutional control," as it appears in Chapter 3701:1-54-03(K)(1), should be provided, relevant to assured isolation, and to distinguish use of the term as it is commonly applied to closed disposal sites.
2. In follow up to Comment 1, the definition for "waste management" includes disposal. Since, this definition provides interpretation for any other use of the term "management" as it applies to waste in these proposed requirements, clear distinction should be made that disposal is not included when the term "management" is used elsewhere, in the regulation, in reference to waste at an AIF. As a specific example, the definition of "assured isolation" states, "...means an integrated management system for isolating radioactive waste..." and can be interpreted as including disposal as part of the management system for this AIF waste.
3. Add clarification to (A) that the proposed regulations should be specific on when the 100-year period begins. The regulations should clearly state this is for an AIF, not for a permanent disposal facility.
4. Add (B) to (A)(2), since performance objectives should apply to all generators requiring an AIF license.
5. The regulation requires all generators to apply and operate an AIF if they will store waste longer than 5 years, in (A)(2). This could create thousands of AIFs with a significant potential for inadequate financial assurance and no incentive for disposal. Numerous bankruptcies may result. Consequently, this regulatory approach may not be consistent with the LLRWPA. Further, it is not clear how this would apply; as currently written, the regulation might be read to apply to both Ohio licensees and to NRC licensees at reactor sites. The regulation should be modified to make it clear that it applies only to Ohio licensees.

ENCLOSURE

6. Views of the Midwest Compact on the proposal should be sought to determine any legal restrictions on development of this rulemaking. Assured isolation is not permanent disposal and does not satisfy requirements of the LLRWPA. Consequently, any future National program definition and regulatory interpretation associated with assured isolation facilities may necessitate significant restructuring of existing State regulatory programs for State, commercial, and/or privately owned facilities.

7. It seems likely that these new regulations will be coordinated with State requirements for environmental impact review and assessment for both assured isolation and disposal facilities. We expect that there will be resulting changes to the proposed definitions and regulations. Specifically, submittal of environmental information for review is typically required for new licenses, renewals, certain amendments, decommissioning, and other significant safety or facility changes. Further, an environmental review would also assure that such timely issues as site surveillance and security are reviewed for increased public confidence, with regard to potential and/or perceived threats. Additionally, NRC's future decisions will likely address Federal requirements for implementing the National Environmental Policy Act (NEPA) and prevention of segmentation (i.e., the dividing of a single overall plan into separate segments without a significant environmental impact, for the purpose of evading NEPA requirements) for initial environmental reviews related to storage of waste (i.e., assured isolation) versus subsequent potential impacts resulting from disposal of the same waste.

8. Since the potential exists to exceed special nuclear material amounts that Ohio can license under the Atomic Energy Act, NRC regulations and its Agreement with NRC (August 31, 1999), the regulation should limit such material, by reference to the amounts authorized under Ohio authority, and then refer an applicant to 10 CFR. Other provisions on segregating classes of waste and controls should be more specific.

9. The provision for returning waste to the generator in Chapter 3701:1-54-03(L)(2) raises questions on who maintains ownership-level responsibility for the waste until the waste reaches a permanent disposal site -- and how a generator or its successors would ensure financial assurance for its disposal, up through the 100 years permitted for assured isolation. The financial assurance provisions in (L) are limited and should be more specific, including: (1) provisions for specifying a 3-year time period for review of the mechanisms and costs (3 years planned for the revised NRC financial assurance requirements that are scheduled to be published in June 2002); (2) provisions specifying that when an AIF cannot provide adequate assurance, then within 90 days, the original generator or generator's designee should retrieve the waste and provide for final disposal; and (3) the addition of backup financial assurance provisions to address the potential for orphan waste where, for example, the original generator of waste stored in the AIF files in bankruptcy or terminates its business before the end of the AIF storage term. Also revise Chapter 3701:1-54-05 (K).

10. Review of the provision for emergency response was limited to the wording provided in 3701:1-54-01(C)(8). Depending on the AIF inventory, an emergency response plan may not be sufficient or may not be needed, since the plan requirements are detailed in the referenced Chapter 3701:1-40. Further, the requirements of the plan may not be sufficient if the requirements do not address radioactive material or packaging at the end of the typical life cycles. (E.g., will

consequences be worse through 100 years?) These requirements should specifically address recoverability.

11. Security, as identified in Chapters 3701:1-54-03(E)(4) and 3701:1-54-03(F)(1), should not be limited to unauthorized access and removal, using the traditional interpretation of this terminology as it applies to radioactive materials storage.

12. The regulation needs to also address possible new requirements for security and protection of the AIF from sabotage and terrorist attacks after 9/11.

13. Chapter 3701:1-54-03(F)(2) states, "All radioactive waste ultimately subject to transportation must be stored in containers made for transportation." If waste is being stored until retrieved and relocated to a permanent disposal site, all the waste will be subject to transportation for disposal and may be stored in transportation containers. We question if this is the best storage mechanism. Further, at the end of the expected 100-year maximum storage period, transportation requirements and containers may be significantly different from current requirements.

14. The description for waste processing facilities provided in Chapter 3701:1-54-05(E) states, "The facility design, location, and site geology shall provide reasonable assurance that radioactive materials will remain isolated from the environment as intended." Specific design considerations are also listed. However, climate characteristics of an area should also be considered during design (e.g., tornadoes, ambient temperature ranges, and wearing/cracking from winter-ice formation). The same comment applies to the AIF design considerations specified in Chapter 3701:1-54-03(D). Other hazards should also be addressed (e.g., chemical and formation of explosive gases may need evaluation).

15. The regulation states robust engineering designs; however, it is not clear that they are incorporated into the regulation and more specification may be needed. In addition, it is not clear how the rulemaking will be implemented. There is a need for guidance on reviews of applications to ensure consistency of approach at different facilities, and to ensure consideration of a risk-informed approach.

16. Similarly, additional considerations of the above comments are needed for the Quality Assurance and Radioactive Waste Processing regulations.

17. Guidance documents that may accompany the proposed requirements were not available to include with our review. We recommend the development of specific guidance for the implementation of AIF related requirements that will address, for example, specific areas, expected practices, and acceptable criteria (e.g., acceptable leak detection systems; guidelines assuring that stored waste can be inspected; etc.).

