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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.

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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. E. 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 states~~ 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.
- (H)(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.
- (H)(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.