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DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

U. S. NUCLEAR, INC.

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February 25, 1974

Our Ref.: MSM:013

Secretary of the Commission
United States Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Staff

Gentlemen:

After thorough review of the proposed amendments to 10 CFR Part 71, we feel that certain of the Quality Assurance Requirements for Shipping are not consistent with generally accepted radiological safety and nuclear safety principles for all materials covered by 10 CFR 71. The majority of the proposed amendments are clearly addressing unique packaging problems associated with solid irradiated nuclear fuel. No sections of existing Part 71 or proposed amendments serve to differentiate between irradiated and unirradiated nuclear fuel.

An example of the need for differentiation exists in the shipment of test and research reactor fuel which is in the form of aluminum clad, uranium-aluminum alloy plate. The alloy form poses a minimal radiological hazard and a clearly definable criticality hazard which may be eliminated by effecting physical support and separation of elements in transport, this is the current basis for design of such shipping containers.

Very truly yours,

Martin S. Markowicz

Martin S. Markowicz
Plant Manager
Fuel Fabrication Division

MSM:mrh

Acknowledged 3-15-74, ers

DOCKET NUMBER PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

State of New York
ATOMIC ENERGY COUNCIL
Department of Commerce
99 Washington Avenue
Albany, New York 12210

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Acknowledged 2-20-74, ckr

February 13, 1974

DOCKETED USAEC FEB 20 1974 Office of the Secretary Public Proceedings Branch

Mr. Gordon M. Grant
Acting Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Staff

Dear Mr. Grant:

Members of the New York State Atomic Energy Council have reviewed the Proposed Amendments to 10 CFR Part 71, "Quality Assurance Requirements for Shipping Containers", prepared by the Commission's Public Proceedings Staff.

The Council supports the Commission's policy related to the need for significant upgrading of the existing requirements for quality assurance in the design, fabrication, assembly, testing, use and maintenance of Type B, large quantity or fissile material packaging for shipping and transporting licensed radioactive material. These upgraded requirements, together with an effective enforcement program, should insure the continued safe packaging and transport of radioactive materials.

Based on the Council's review, and because of the increasing importance of implementing meaningful Quality Assurance Programs in all nuclear power related matters, the Council supports the inclusion of the proposed amendments into Title 10 of the Code of Federal Regulations. We do, however, offer the attached comments which the Council believes will assist the Commission in formulating more effective amendments to 10 CFR Part 71.

We appreciate being given the opportunity to participate with the U. S. Atomic Energy Commission in this matter.

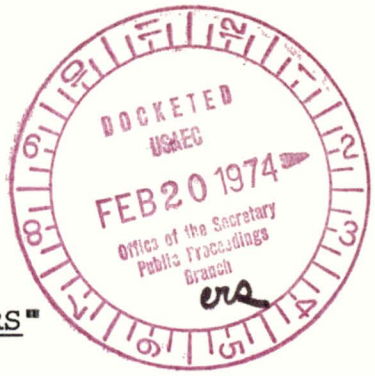
Cordially,

Neal L. Moylan

Att.

Neal L. Moylan
Chairman

cc: Members of the Atomic Energy Council
J. Bruce MacDonald, Esq.
C. Thomas Hodsdon



COMMENTS OF THE STATE OF NEW YORK ON THE U. S. ATOMIC ENERGY COMMISSION'S PROPOSED AMENDMENTS TO 10 CFR PART 71, "QUALITY ASSURANCE REQUIREMENTS FOR SHIPPING CONTAINERS"

1. Section 71.24, Quality Assurance - Paragraph (a)

The first sentence states that the applicant shall describe his Quality Assurance Program. This sentence should be updated/clarified to note that the applicant is responsible for his Quality Assurance Program, and that the Quality Assurance Program shall be described in writing.

2. Section 71.24, Quality Assurance - Paragraph (b)

This paragraph, which relates to Quality Assurance Personnel, notes only that the applicant shall identify by title and qualifications, the individual(s) in his organization responsible for assuring that shipping containers have been prepared in accordance with all applicable requirements. To insure that conflicting demands and responsibilities are not placed on Quality Assurance individual(s), and to assure that Quality Assurance individual(s) have sufficient authority, organizational freedom and independence to perform their assigned duties without being subject to improper command influence, it is recommended that the following sentence or equivalent, be added to existing paragraph (b): "Quality Assurance individual(s) shall have sufficient authority and organizational freedom to perform their functions effectively and without reservation."

3. Section 71.31, General Standards for All Packaging, Paragraph (e)

This paragraph states that the external surfaces of packaging shall, as far as practicable, be designed, fabricated and finished to facilitate decontamination. This is not considered to be comprehensive enough considering available packaging materials and existing fabrication techniques and technology in general. It is considered that the internal surfaces as well as the external surfaces should be designed to facilitate decontamination. In addition, the "as far as practicable" requirement should be qualified by adding that the packaging be designed, fabricated and finished to facilitate decontamination "as far as practicable" and at least to a specified maximum safe surface level of contamination. This maximum safe surface level of contamination should be stated in this Regulation, or other appropriate documentation should be referenced.

4. Section 71.53, Initial Determinations and Tests

It is stated that the fabricated packaging shall be "durably" marked with its model number and with a unique manufacturer's serial number. As required by other government agencies such as the U.S. Navy, Q.A. markings on accepted items should be permanent and should include the manufacturer's name or registered trademark. Thus, "durably" should be replaced with "Permanently" and manufacturer's serial number should be expanded to include his registered trademark or name.

5. Section 71.53, Initial Determinations and Tests, Paragraphs (e) and (f)

Amended paragraphs (e) and (f) state that valves and seals incorporated to meet the release limits of Section 71.36 should be tested at intervals not to exceed one year to demonstrate functioning in accordance to design. The Commission should consider making the testing time limit more restrictive than the one year interval noted. For example, it is conceivable that the seating surfaces of valves and seals could corrode together with mating seating surfaces and the set of relief valves springs could change during this extended period of time. Either of these occurrences would make valve or seal functioning in accordance with design questionable. Thus, it is recommended that these tests be required within thirty (30) days of the use of a packaging which incorporates valves or seals to meet the release limits of Section 71.36. The thirty (30) day criteria is consistent with U.S. AEC's Naval Reactors Division safety and test equipment calibration schedule, and with the philosophy of good engineering practice.

6. Section 71.54, Routine Determinations, Paragraphs (h) and (i)

Paragraph (h) states that the licensee should ascertain prior to each use of a package for shipment of licensed material that the pressure relief valve or valves only be operative. It is considered that this paragraph should be expanded to require that the licensee ascertain that the relief valve, or valves, not only be operable, but set to the design specifications required for the shipment and that the setting test has been conducted within the required time frame of the regulations. Amended paragraph (i) should be similarly expanded if the seal referred to is incorporated in the package for the purpose of meeting release limits of amended Section 71.53(f).

7. Appendix E, Section 2, Quality Assurance Program

The introduction to Appendix E and amended Section 71.24 (c) note that the Quality Assurance Program shall include maintenance and use of packaging. Section 2 in Appendix E does not establish

the Quality Assurance Program required for use (i.e., Quality Assurance required during storage or transport) or maintenance of the packaging, although it does address the Quality Assurance Program required for construction of the packaging. Thus, the Quality Assurance Program required for use and maintenance should be discussed. Akin to the overall Quality Assurance Program concept for nuclear power plants, it is considered that the Quality Assurance Program required for the addressed shipping containers should be in two distinct phases - A Quality Assurance Program for the construction of the packaging and a Quality Assurance Program for the maintenance and use (operational Quality Assurance) of the packaging.

8. Appendix E, Section 3, Design Control

a. The third sentence states that "Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the materials and components." For clarity, "materials and components" should be replaced by "materials, parts and components of the packaging."

b. The fifth sentence notes that these measures shall include the establishment of procedures for review, etc., of documents including design interfaces. This sentence should be modified to require that these procedures shall be written.

c. The sixth sentence states that the design control measures shall provide for verifying or checking the adequacy of any new design . . . ." The intent here is not clear, since checking is verification, and moreover the section does not include in its context design approval. Thus, it is considered that this sentence should be modified to read, "The design control measures shall provide for verifying and approving the adequacy of any new design . . ."

d. The seventh sentence states that the verification process shall be performed by individuals or groups other than those who performed the original design . . ." Since the design verification process will have to be performed by designated and qualified Quality Assurance personnel, it is considered that the sentence should be modified to read, "The verification process shall be performed only by appropriately designated Quality Assurance individual(s) or a group(s) . . ." In addition, a sentence should be added which annotates that the verification and approvals of any new design by other than those who performed the original design, shall be properly documented in writing in accordance with a written procedure, and evidence of their performance shall be readily apparent on each affected design document.

e. The eighth sentence discusses items to which design control measures should be applied. It is considered that design control features to facilitate decontamination should also be listed as a major item to which design control measures are applied.

f. There is no statement which annotates how design control is to be implemented by the licensee. To accomplish this, it is considered that the licensee should be required to arrange for the conduct of audits of design control systems to insure compliance with applicable regulatory requirements and the packaging design, as specified in the license.

9. Appendix E, Section 4, Procurement Document Control

This section should be expanded to note that:

a. the review and approval of procurement documents for safety-related materials, parts, and components is to be accomplished prior to placement of an order;

b. the review and approval is to be conducted by appropriately designated Quality Assurance individual(s) or a group(s) in accordance with prescribed written procedures;

c. changes to a safety-related procurement document are to be reviewed and approved in the same manner as the original document;

d. procurement documents for safety-related items should be controlled in accordance with the policy of Section 6 of Appendix E; and

e. procurement documents for safety-related items should be audited to insure compliance with applicable regulatory requirements and the packaging design, as specified in the license.

10. Appendix E, Section 5, Instructions, Procedures, and Drawings

a. The section should specify who is responsible for preparation of the written instructions, procedures and drawings.

b. The last sentence in paragraph one states that instructions, procedures or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. The term "important activities" is not considered to be definitive enough, and should be replaced by "quality related and other important use and maintenance activities."

c. No requirements are delineated concerning assurance of compliance. Thus, it is considered that a sentence should be added which states that the licensee is responsible to insure compliance by means of audits.

11. Appendix E, Section 6, Document Control

a. The first sentence states that measures shall be established to control the issuance of documents, . . ., which prescribe all activities affecting quality. The maintenance control of these documents is not addressed, and the term "prescribe all activities affecting quality" is not definitively clear. Thus, it is considered that the first sentence should be modified to read: "Written measures shall be established to control the issuance and maintenance of controlled documents, . . . which affect the quality of packaging."

b. The third sentence, which reads, "Changes to documents shall be reviewed and approved by the same organization that performed the original review and approval unless the applicant designates another organization", is incomplete since it does not address controlled documents affecting quality, incorrectly describes licensee as applicant and is misleading by designating another organization to perform the review and approval. It is recommended that this sentence be superseded by: "Changes and alterations to controlled documents affecting quality shall be made by subjecting the revised document to the same controls (review, approval for release, distribution and use) as the document which it replaces, changes or alters."

c. It is considered that this section should contain a listing of documents which are considered to be controlled. This listing should include quality assurance manuals and procedures; and, purchase documents, drawings, instructions, operating or usage procedures and maintenance procedures for equipment, materials, parts, components and activities which are safety-related.

d. The establishment and maintenance of, and responsibility for, a distribution list of controlled documents should be addressed.

e. In the second sentence "authorized personnel" should be modified to read "personnel authorized in writing."

f. Assurance of compliance with this section by the licensee should be addressed by the requirement for audits.

12. Appendix E, Section 7, Control of Purchased Material, Equipment and Services

a. In the first, third, and fifth sentences reference is made only to material and equipment. It is considered that these sections should be expanded to include "parts" as well as material and equipment.

b. The second sentence should be expanded to include review and documentary evidence prior to shipment.

c. The third sentence states that "Documentary evidence . . . shall be available prior to installation . . . and equipment." This sentence should be clarified by adding "at the installation or use site" between "available" and "prior."

d. The last sentence discusses that the effectiveness of the measures for control of purchased items should be assessed at appropriate intervals. This sentence should be expanded to note that this is accomplished by audits.

13. Appendix E, Section 8, Identification and Control of Materials, Parts and Components

a. The second sentence states, "These measures shall assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to . . ." To clarify and update this sentence it is recommended that it be modified as follows: "These measures shall assure that permanent identification of the item is maintained by serial number, heat number, part number, or other appropriate means, either by marking on or attaching to the item, or on records clearly traceable to . . ."

b. The first sentence should be expanded to note that the measures established shall be in writing, and that identification and control should be implemented at the earliest practicable point in the fabrication process - i.e., at the subcontractor or supplier level.

c. A sentence should be added which requires that permanent identification shall be in conformance with applicable regulations, codes and standards; and, where no permanent identification method is required by regulations, codes or standards that the identification method shall conform to a manufacturing standard acceptable to the licensee.

d. Assurance of compliance with this section by the licensee should be addressed by the requirement for audits.

14. Appendix E, Section 9, Control of Special Processes

a. This section states that "Measures shall be established to assure that special processes, including welding, heat treating and non-destructive testing, are controlled by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria and other special requirements." It is considered that this sentence contains significant omissions. Thus, it is recommended that it be rewritten to read as follows: "Written measures shall be established to assure that special fabrication, production, testing, etc., special processes (i.e., welding, heat treating, non-destructive testing, cleaning, hydro-testing) are controlled and executed by personnel qualified and

authorized in writing using authorized and qualified procedures in accordance with governing or specified codes, standards, specifications or other special criteria such as that included in purchase documents."

b. The technical means for control of special processes should be addressed. It is recommended that a sentence similar to the following be added: "Control of special processes shall be by written instructions on the drawing(s), by written procedure(s), by reference to a recognized code or standard published by a national society or institute or by combinations of these with addenda."

c. Assurance of compliance with this section by the licensee should be addressed by the requirement for audits.

15. Appendix E, Section 10, Inspection

a. For clarity, the first sentence should be modified by adding "written" between "A" and Program"; and by replacing "or for" with "or on behalf of".

b. "Qualified" should be inserted before "individuals" in the second sentence.

c. The section does not address where the inspections are to be conducted, nor that they shall be documented. Thus, after the existing second sentence it is recommended that the following, or a similar, sentence be added: "Inspections should be performed at the manufacturing facility and at the installation and use site, and they shall be documented in approved, written inspection reports."

d. The fourth sentence omits sampling as an additional indirect control, does not identify monitoring as required to be documented or identify inspection as direct, and does not discuss that the intent of indirect control is to determine product quality. Thus, it is recommended that the sentence be modified to read: "If direct inspection of processed material is not feasible, indirect control by sampling or by documented monitoring of processing methods, equipment and personnel shall be employed to determine product quality."

e. The intent of the fifth sentence is unclear, and it is recommended that it be modified to read as follows: "Indirect control methods shall supplement direct inspection whenever required to verify product quality."

f. A sixth sentence should be added which addresses indirect control by means of sampling. It is recommended that it be written as follows, or similarly: "Where a sample is used to verify acceptability of a group of items the sampling procedure shall be based on recognized standard practices and shall provide adequate justification for the sample size and selection process."

g. A sentence should be added which discusses the authority to, and reasons for, "stop work" action by quality assurance or other qualified individuals. The discussion should note that "stop work" is done in order to: (1) forbid the use of quality related materials, equipment, parts or workmanship which do not conform to quality related documentation; (2) stop any quality related work in progress which is not being done in accordance with approved plans, specifications, etc.; and (3) require removal or repair of faulty quality related installation, or installation performed without direct or indirect inspections and which is impossible to inspect in place. Restart of work should also be discussed, and it should be noted in this discussion that the qualified individual or his delegate who initiated the "stop work" action may restart the work where the condition(s) causing "stop work" have been rectified to his satisfaction.

h. Assurance of compliance with this section by the licensee should be addressed by the requirement for audits.

16. Appendix E, Section 11, Test Control

a. For clarity and completeness, it is considered that the first sentence should be modified to read as follows: "A test program . . . in service is identified and documented; and that the testing is performed in accordance . . . and acceptance limits contained in the applicable package design document(s)."

b. The broad scope of the test program is not identified. Thus, it is recommended that a second sentence be added as follows: "The test program shall include as appropriate, prototype, pre-installation, pre-operational and operational testing."

c. It is considered the last sentence attempts to include documentation, review and evaluation on too general a basis, does not consider test data as well as results, and does not contain the requirement for written procedures. Thus, for clarity and completeness it is recommended that the intent of this sentence be written in two sentences as follows, or similarly: "Test data and results shall be reviewed and evaluated in accordance with written procedures to assure that test requirements and results have been satisfied. Those procedures shall include both the requirement that the evaluation be documented and that the said evaluation shall establish the basis for acceptability of the test."

d. Assurance of compliance with this section by the licensee should be addressed by the requirement for audits.

17. Appendix E, Section 12, Control of Measuring and Test Equipment

It is considered that this section should contain discussion delineating the group responsibility for control of measuring and

test equipment, and in addition, the basic requirements for a control program. Thus, it is recommended that a sentence be added which discusses that the group having physical custody and control of measuring and test equipment shall be responsible for its control, and shall provide the necessary written procedures and records required. To provide guidance for the requirements of a control program, a sentence similar to the following is suggested: "Written procedures shall be established which provide for the following as a minimum: (1) positive identification of all test and measuring equipment; (2) establishment of calibration procedures and frequency-of-calibration intervals for each type of measuring and test equipment; (3) the use of recognized standards whose calibration is traceable to the National Bureau of Standards or other recognized standards; (4) establishment and maintenance of calibration records for each inspection device to provide objective evidence that all measuring and test equipment is being calibrated and maintained in accordance with approved written procedures; and (5) provision of positive means by which no measuring or test equipment will be released to inspection personnel for quality control acceptance inspection use unless it has been calibrated and adjusted in accordance with an approved written procedure for that equipment."

18. Appendix E, Section 13, Handling, Storage and Shipping

a. For completeness the first sentence should be modified to: (1) include "Parts" as well as materials and equipment; (2) include prevention of loss as well as prevention of damage and deterioration; and (3) note that inspections are written.

b. The source of the instructions to control the handling, shipping, etc., is not discussed. Thus, a sentence similar to the following should be added: "Proper requirements for packaging, preservation, shipping, field storage and handling, cleaning, preservation, etc., of materials, parts and equipment shall be included in specifications, purchase orders and drawings in accordance with applicable codes, standards and procedures."

c. The handling, storage and shipping of critical, sensitive or high value articles should be addressed. If addressed, it should be noted that specific written procedures for the handling, storage, shipping and preservation of these articles is required.

d. Special handling tools and equipment should be addressed. It is recommended that a sentence similar to the following be added: "Special handling tools and equipment shall be provided and controlled as necessary to insure safe and adequate handling."

19. Appendix E, Section 14, Inspection, Test and Operating Status

a. In the first sentence the term "measures" should be updated to note that they are to be written.

b. Implementation of the policy of this section is not addressed. Thus, it is recommended that a sentence be added which is similar, or the same as, the following: "Written and approved procedures shall be used to implement the policies of this section."

c. It should be noted that audits in accordance with Section 18 of Appendix E are required to verify conformance with and implementation of the requirements of this section.

d. It should be noted that records of supplier and subcontractor tests and inspections are to be supplied in accordance with written instructions contained with or on procurement documents.

20. Appendix E, Section 15, Nonconforming Materials, Parts, or Components

a. The first sentence should be clarified as follows: "Written measures shall be established to identify, document and correct materials, . . . which do not conform to quality requirements . . . installation."

b. The second sentence should be clarified as follows: "These measures shall . . . written and approved procedures for . . . identification, correction, . . . affected organizations."

c. In the third sentence, "with documented procedures" should be replaced with: "with a nonconformity and disposition report system detailed by written and approved procedures."

d. Authorized deviations are not addressed. Thus, it is considered that a sentence similar to, or the same as, the following should be added: "Deviations from quality requirements are not permitted unless acceptable to the licensee in accordance with the proceedings for DESIGN CONTROL, Section 3 of this Appendix." Addressing this control procedure is considered to be of paramount importance, since it clearly establishes the procedure to prevent unauthorized quality requirement deviation at all stages of construction, installation, testing, maintenance and use.

e. It is considered that significant problem areas with quality requirements of materials, parts, or components should be reported to the U.S. AEC by the licensee. Thus, the following sentence should be added: "The licensee shall report to the Commission all significant problems in the design, construction or test of packaging. This report will clearly state the problem cause, evaluation, final disposition and measures taken to prevent recurrence."

f. It should be noted that audits in accordance with Section 18 of Appendix E are required to verify conformance with and implementation of the requirements of this section.

21. Appendix E, Section 16, Corrective Action

a. The first sentence should be clarified as follows: "Measures . . . adverse to product quality, . . ., are promptly identified and corrected in accordance with established and written procedures."

b. For clarification, the corrective action for significant adverse quality conditions referred to in the second sentence should be identified by examples of the type of permanent corrective action required. Thus, after "corrective action" in the second sentence it is considered that the following should be added: "(i.e., design change, procedure change, etc.)".

c. The last sentence only addresses the documentation and reporting of significant conditions adverse to product quality. It should, in addition, address that an evaluation of the significant condition be documented and reported.

d. It should be noted that audits in accordance with Section 18 of Appendix E are required to verify conformance with and implementation of the requirements of this section.

22. Appendix E, Section 17, Quality Assurance Records

a. To add meaning to the section, its purpose should be delineated. Thus, the following, or similar sentence should be added: "The purpose of quality assurance records is to permit reconstruction of the significant quality related events which causes any given part, material, or component to be where it is, in regard to physical position and condition, at any particular point in time."

b. The second sentence includes "design records" as an example of quality assurance records which should be maintained to furnish evidence of activities affecting quality. This is questioned, since design records (drawings, etc.) should only provide the design basis and requirements for developing documentation and subsequent activity required to furnish evidence that specified quality related activity was in fact performed. Thus, "design records" should not be included in the second sentence, but in the third sentence which lists example records which include closely related data such as qualifications of personnel and procedures.

In order to eliminate question whether quality assurance records in fact furnish evidence of activities affecting quality, or are closely-related, and since both records should be maintained, it is recommended that sentences two and three be expanded in context and combined as follows, or similarly: "The records shall include the following: records of use, results of reviews, modification records, inspection results, test results, audit plans, audit reports, records of monitoring of work performance, material analysis, personnel

qualifications, qualified procedures, qualification of equipment, purchase specifications, design drawings, and operating instructions and procedures."

b. The third sentence which addresses inspection and test records is considered to be incomplete in context, and it is suggested that it be modified as follows, or similarly: "Inspection and test records shall, as a minimum, identify by name or signature the inspector or data-recorder, the identification of parts or equipment inspected, the identification of test equipment, the fabricated process being checked, the test procedure used, the observed results, the acceptability of results, and the action taken to resolve deficiencies."

c. It should be noted that audits in accordance with Section 18 of Appendix E are required to verify conformances with and implementation of the requirements of this section.

23. Appendix E, Section 18, Audits

a. It is considered that a sentence should be added which delineates how audits are conducted, and in addition describes the scope of auditing required. Thus, a sentence should be added which is similar to, or the same as, the following: "Audits are accomplished by reviewing, in detail, selected areas of activities affecting quality and comparing the results with established criteria and objectives as stated in approved specifications, drawings, and other quality assurance program documents."

b. In order to meet the objectives of an audit program responsibility for conduct of audits has to be delineated. Since the licensee is responsible for all aspects of the quality assurance program, he should also be noted in this section to be responsible for audits.

c. That part of the second sentence which relates to the independence of the auditing personnel is not considered to be clear, and it does not describe the necessary independence required by stating: ". . . not having direct responsibilities in the areas being audited." It is recommended that this portion of the sentence be modified to read, ". . . having no administrative or functional responsibility to the quality related activity or organization being audited."

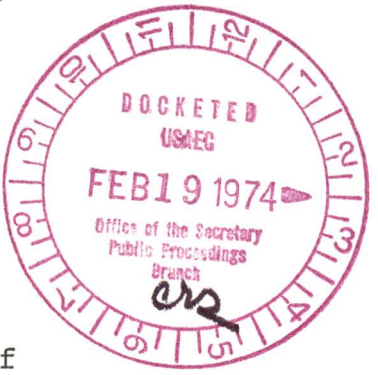
d. For completeness, the last sentence should be modified to read: "Follow-up action, including corrective action and re-audit of deficient areas, shall be taken where indicated.

Allied-Gulf Nuclear Services

Howard J. Larson,
President & General Manager

DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

February 11, 1974



Acknowledged 2-19-74, cys

Secretary of the Commission
U.S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Staff

Dear Sir:

Reference is made to proposed amendments to 10 CFR 71 in connection with Packaging of Radioactive Material for Transport and Transportation of Radioactive Material as published in the Federal Register, Volume 38, No. 248 on December 28, 1973.

The following general comments are offered for your consideration:

1. We are in agreement with the Commission on the need for Quality Assurance program requirements on radioactive material packaging.

2. With respect to scope of the proposed QA program requirements, we believe the following points should be considered.

   (a) The term "Shipping Containers" is used throughout the proposed amendment and is misleading. The word "Packaging" [defined in existing Section 71.4(l)] has been proven adequate and hence it should be used throughout the proposed amendment.

   (b) In the introduction of Appendix E the definition of "Packaging" is referenced and loosely quoted and then the words "...in and with which radioactive material is transported...." are added. Again, uniform use of the word "Packaging", which is defined, is important; the words "...in and with which...." will lead to misunderstanding. If it seems desirable that QA program requirements should be applied to certain components not encompassed in the definition of "Packaging", then the definition of "Packaging" should be appropriately expanded.

(c) QA program scope should be expanded to cover "repair" and "modification". Also, maintenance should be expanded to cover "preventive" and "corrective" maintenance.

3. While the proposed QA program requirements are very comprehensive, not enough attention is given to implementation. For example, in addition to the Commission reviewing the applicant's QA program and being notified 45 days in advance that fabrication will begin, the Commission and the applicant should agree on surveillance and auditing plans to be carried out during manufacturing.

4. We note that the Commission has made an attempt in §71.53 to specify certain tests and quantify related acceptance criteria. While we agree with the intent of the tests, we foresee cases in which it will be difficult, if not impossible, to carry out the tests as specified. Considering the wide variety of packaging designs and different assembly methods used by packaging suppliers, we believe specific tests and related acceptance criteria should be submitted by the applicant and approved by the Commission on a case-by-case basis. This will enable the applicant to specify and employ the most effective test methods at the proper point in manufacture without being constrained by preconceived specific regulatory tests which may be inconsistent with evolving or future packaging technology.

5. We foresee difficulty in requiring a single applicant or licensee to fulfill all the obligations and requirements included in the proposed requirements. Since other licensees may own, load, or unload the packaging, the burden of meeting Commission requirements in these areas should be placed on these licensees. As suggested below under Specific Comments, we believe this problem area can be resolved by expanding the wording in certain paragraphs to clarify respective responsibilities of "Applicant", "Owner", and "Licensee" when they are not one and the same.

Specific Comments

§71.24(b) - For reasons stated under Paragraph 5. above, an applicant will not be able to accept responsibility for assuring that the packages "...have been prepared....". Responsibility

for loading and preparation for shipment should be placed upon the licensee at the loading facility and wording should be revised accordingly.

§71.24(c) - It is suggested that the wording be changed to read: "The applicant shall identify codes and standards proposed for use in whole or in part for package....". The wording in the proposed requirements gives the impression that there exists a single code or standard which is applicable in all areas. The suggested wording recognizes the current lack of single packaging codes and standards and allows use of applicable portions of other existing codes and standards.

§71.31(e) - We agree that ease of decontamination is an important consideration and should be covered. However, interpretation and application of the requirement as written is going to be subject to individual opinion based on varying experience. To cope with this problem, it is suggested that an early attempt be made (possibly via a Regulatory Guide) to specify suitable materials and coatings, quantify finishes, and specify related decontamination techniques.

§71.41(b) - It is not clear whether the superseding license application requirement applies only to packages approved during the period September 23, 1961 to January 1, 1967, or to all packages approved prior to effective date of the proposed requirements. Also, no mention is made on how packages now in the process of review and/or manufacture will be handled.

Based on our experience since 1971, QA program requirements have been adequately implemented to the extent that application for a superseding license should not be required. With respect to packages now being manufactured, we urge the Commission to immediately identify required inspections and tests rather than delaying implementation until the effective date of the final requirements to avoid possible backfitting or modification for purposes of inspection or testing.

§71.53 - We believe that the applicant should be required to submit test specifications along with related acceptance criteria and that the Commission should review and approve such plans on a case-by-case basis along with total QA program. No attempt should be made to write such details into the regulations. If the Commission were to adopt this approach, §71.53 could become simply a listing of particular tests. These then

would become minimum requirements and an applicant's QA program would necessarily include detailed procedures, test methods, and acceptance criteria for those tests. Such an approach is completely consistent with present case-by-case review of packaging design for adequate performance and such design efforts are inseparable from those required to facilitate inspection and testing.

Notwithstanding the above general comment on §71.53, we offer the following specific comments on the proposed requirements.

(a) This paragraph would rule out the practice of lead "bonding" or "first-coating" of the shielding cavity prior to shielding cavity assembly. Such procedures are essential to heat transfer characteristics in most lead-shielded casks. In addition, some allowance must be made for testing the last weld(s) after shielding is installed. Further, it is questionable whether, in the case of uranium shielding, test prior to installation of shielding material should be a regulatory requirement or left to the manufacturer to assume the risk related to testing after installation of uranium.

(b) It appears that the intent is to cover pressure vessel or containment vessel testing in the packaging design. If this is the case, conventional ASME test criteria should be applied and suitable leak testing fluids and detection apparatus should be employed. Appropriate test sensitivity and allowable leak rates should be proposed by the applicant and approved by the Commission. Basing leak testing on Type A quantities (a curie value) is abstract and impractical and not relevant to leak-testing techniques. For example, how would a fabricator determine the allowable leak rate for PuO_2 pellets, fission products, U-237, etc.?

(c) Industry practice to date has been to prove heat dissipation adequacy by testing the prototype design, appropriate QA requirements on additional units of same design and routine observation of adequate heat dissipation capacity during life of all units of a design. We feel such practice is still adequate; testing each unit of identical design is not necessary, particularly in view of the proposed QA requirements which will assure reproduction of additional units in accordance with the original design.

With respect to testing at design heat load, allowance should be made for testing under certain abnormal conditions (loss of coolant, loss of neutron shield water) at a reduced heat load and extrapolation to the design heat load when structural deformation of the case would result from testing at the design heat load.

With respect to heat source positioning, packaging position as well as location of heat source in the packaging should be specified based on normal conditions of transport.

(d) This requirement would be hazardous, impractical, and expensive on many packaging designs. The state-of-the-art on shielding inspection is well advanced and adequate. It is based on use of modest intensity sources (readily available and safe to handle) and sensitive detection equipment which enables detection of flaws, voids, or discontinuities in shielding materials. It is not necessary to measure radiation levels and compare them with predicted values; radiation level measurements are routinely made on each shipment in accordance with DOT regulations. We would welcome the opportunity to discuss current technology in this area if the Commission staff so desires.

(e) This requirement would cause packaging suppliers to discontinue welding valves to the packaging in favor of bolting or otherwise mechanically attaching. This is highly undesirable because additional gaskets, seals, and closures are introduced into the design which introduction increases the probability of leakage. Initial "bench" testing of valve designs along with regular periodic inspection and maintenance and routine leak testing prior to shipment is adequate. Final wording of this requirement should consider recent double-containment packaging designs which enclose such valves completely within a sealed chamber thus providing the requisite containment integrity without total dependence on the valves.

(f) Because of the difficulty of carrying out the proposed periodic cycling tests with a contaminated cask and the questionable benefit for insuring leak-tightness of each individual shipment, it is suggested that the paragraph be reworded as follows: "Packaging designs incorporating seals to meet the release limits of §71.36 shall be initially qualified by passing a leak test conducted at the pressure anticipated if the package and contents were subjected to the hypothetical accident conditions specified in Appendix B".

(g) We assume this requirement is directed at reactivity control materials in which case neutron shielding materials should be excluded. Shielding materials would be covered by shielding tests under §71.53.

§71.54 - Wording of this requirement should clarify the responsibility of the licensee when he is not involved in loading operations (see Paragraph 5. above).

(h) Rupture discs, which are commonly used as relief devices, should be included.

(i) Assurance that the loading is within the rated capacity of the packaging and assurance that proper loading and leak-testing procedures are followed should be stated in this requirement.

§71.62(a) - When an applicant is not involved in loading operations, these requirements should be the responsibility of the loading facility licensee (see Paragraph 5. above).

§71.62(c) - Records of repairs and modifications should also be required.

§71.63(c) - Notification 45 days prior to fabrication by the licensee leaves room for misinterpretation. In some cases, only the applicant will be involved at that point in time. Nevertheless the Commission should receive notification. Also, fabrication should be defined to include material procurement (castings, forgings, rolling shells, etc.) so that the Commission would have the opportunity to review or witness nondestructive testing and inspections of raw materials and other components or subassemblies purchased prior to beginning construction of the principal components of the packaging.

The 5KW-15 psig criteria for notification is not an adequate index. For example, we believe the Commission would be quite interested in notification on plutonium packaging which would not be covered by these criteria. This again should be covered on a case-by-case basis; all applicants should make notification and give the Commission opportunity to decide whether it should plan on manufacturing surveillance, witnessing and/or auditing.

The following additional comments are on sections outside the proposed rule making, but, in our opinion, they are closely related to the present objective. Accordingly, they are offered for your consideration along with the above comments.

§71.12(a) & (c) - It would appear that DOT specification containers, and DOT/IAEA approved containers would be excluded from the general licensing provisions in that no QA program requirements comparable to those proposed are specified by DOT and IAEA.

§71.12(b) - In addition to requirements listed, it would appear that the general licensee must obtain some sort of certification from the specific licensee, packaging owner or packaging manufacturer that QA requirements, prior to first use were complied with and that subsequent maintenance, modification, and repairs were also carried out in accordance with such requirements.

§71.63(a) & (b) - As indicated in Paragraph 5. above, where the "Applicant", "Owner", and "Licensee" are not one and the same, it is fundamental that a licensee alone cannot perform all of the various functions in facilities of loading and unloading licensees. By the same measure, such a licensee is without power "to permit the Commission to perform..." etc., as now required by this section. Wording in this section should clarify the responsibility of the licensee when he has no control over the licensed material or the facilities of other licensees.

We trust that the foregoing comments will be helpful in formulating new requirements for packaging and transportation of radioactive material.

Sincerely yours,

Howard A. Larson

Howard A. Larson

EXXON NUCLEAR COMPANY, Inc.

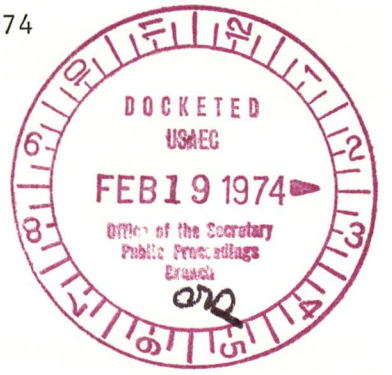
2101 Horn Rapids Road, Richland, Washington 99352

PHONE: (509) 946-9621

DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

February 13, 1974

Acknowledged 2-19-74, ORO



Secretary of the Commission
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceeding Staff

Gentlemen:

The Federal Register, Volume 38, No. 248 for December 28, 1973, contains proposed modifications to 10CFR71. Comments concerning the proposed modifications were solicited and are hereby submitted for your consideration.

Paragraph 71.41 as revised requires that casks licensed prior to January 1, 1967 be relicensed to assure compliance with the latest requirements of 10CFR71. Since the Exxon Nuclear Company feels that the proposed test and QA requirements provide additional assurance that package designs possess the necessary features required to assure safe transport of irradiated material, we endorse the intent of the proposed modification to 10CFR71.41. We believe, however, that several of the specific requirements warrant further consideration. Individual paragraphs that warrant such consideration are discussed below:

1. Paragraph 71.53(d): This paragraph requires that a test to demonstrate shielding adequacy must be completed as a portion of the final acceptance procedure for each cask. Exxon Nuclear is in full agreement with the intent of this proposed acceptance test. We do not, however, believe that testing to the design source strength is technically feasible or that this is required to assure safe cask operation. We feel that the adequacy of the shielding can be demonstrated by utilizing a source of reduced but adequate strength to allow radiation measurements to be performed exterior to the shipping container. These measurements, used as calculational benchmarks, can then be used as a basis for determining the shielding adequacy at the design source strength. An added degree of assurance is also provided through monitoring each shipment prior to release. Exxon Nuclear believes that such reduced source strength acceptance tests, combined with normal preshipment monitoring, will fulfill the intent of the proposed change.

2. Paragraph 71.53(f): Requires that all seals be tested for function. A cyclic test for each seal is proposed. Cyclic testing, however, is normally considered to be a destructive test. To assure that seals

which have been cycled will not fail, it is proposed that the cyclic test be performed on a random sample taken from the production lot of seals. The seals to be used on the casks should not be cycled prior to use to avoid potential failures occurring due to in-service cycling following the cyclic test.

3. Paragraph 71.53(g): The requirements of this paragraph are somewhat vague. We agree that the design efficacy of all non-fissile neutron absorbers and moderators need be demonstrated prior to use of a shipping package. Verification of the effectiveness of such neutron absorbers and moderators, however, can be obtained through the use of detailed analytical evaluations properly verified by existing critical experiment data. As written, it appears that 71.53(g) would require neutron multiplication measurements for each package loaded with fissile material both with and without the presence of the materials whose design efficacy is to be demonstrated.

4. Paragraph 71.54(h): Requires that prior to each use, all pressure relief valves must be functionally checked to demonstrate operability. We feel that functional testing of valves on a less frequent (surveillance) basis would provide the needed assurance for operability. Surveillance testing is a normal procedure to assure operability of safety release devices on other potentially hazardous containment and pressure vessels.

   A surveillance program similar to that utilized for ASME Nuclear Pressure Vessels would provide the needed confidence in the operability of relief valves.

5. Appendix E, Item 3: The proposed rules indicate that if design adequacy is determined by test, a prototype test must be run. It is not clearly stated whether the prototype test is an additional test over and above the design adequacy test. If the design adequacy test is prototypic of the final design configuration another prototype test should not be required. It is suggested that this item be clarified as noted.

Finally, the introductory remarks in the Federal Register indicate that the proposed QA requirements will apply to all Type B and Large Quantity or Fissile material packages. The proposed revisions, while specifically addressing requirements to be met for continued usage of previously licensed irradiated fuel shipping packages, do not address the QA requirements applicable to previously licensed Type B and Large Quantity or Fissile material packages. The intent of the proposed revisions to permit continued use of previously licensed packages for unirradiated fuels should be clarified.

Sincerely,

Roy Nilson
Manager, Quality Assurance
and Licensing Department

RN/ps1

DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

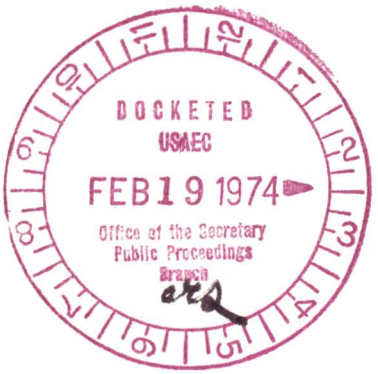
GENERAL ATOMIC

GENERAL ATOMIC COMPANY
P.O. BOX 81608
SAN DIEGO, CALIFORNIA 92138
(714) 453-1000

February 11, 1974

Acknowledged 2-19-74, ers

Secretary of the Commission
United States Atomic Energy Commission
Washington, D.C. 20545



Attention: Chief, Public Proceedings Staff

Subject: Proposed Rulemaking Notice
F.R. Docket 73-27064

Dear Sir:

General Atomic Company submits the following comments for your consideration in connection with the subject proposed rulemaking affecting 10 CFR Part 71, 38 F.R. 35490.

We are in general sympathy with the proposed regulation as it would apply toward the adoption of quality assurance requirements for shipping containers. There are a few specific areas where choices of words seem to be potential sources of doubt, and in some we believe words should be changed to permit acceptable alternatives.

General Comments

1. Under the proposed rules, a quality assurance program is to be applied to the design, fabrication, assembly, testing, maintenance, and use of a proposed package. The applicant would be required to identify codes, standards and general requirements to be imposed under its program.

The proposed rules are specific to shipping containers.

The comprehensive quality assurance programs of 10 CFR 50, RDT 2-2, Mil-Q-9858, etc., have generally complied with the Appendix E criteria. Reference to application of such a quality assurance program and the codes or standards applicable should assure the proper design fabrication and qualification testing.

The routine procedures and tests may be described with greater clarity for each individual package or package type.

2. The proposed rules seem to use "packages," "packaging," and "shipping containers" almost interchangeably, the former most often. "Shipping containers" should be deleted.

3. The leak test quantities and sensitivities prescribed are drawn with an eye toward radiotoxicity effects, and of course those are the ultimate concern for AEC and its licensees. However, a metal fabricator or inspector is likely to be able only to measure volumetric leaks and losses. Consequently, a more specific leak rate should be applied, e.g., cm^3/sec using He or Kr-85 as tracer gases.

4. The proposed rules do not seem to permit the use of an analytic model verified by some experimental results and their extrapolation as a package qualification method. In many cases where large quantities of material or significant heat loads are to be licensed, dangerous and unnecessarily expensive qualification tests would be required by the test as proposed. The wording should be changed to permit the use of tests in conjunction with appropriate models.

Specific Comments

Section 71.21(c)--The description of the proposed quality assurance program would seem to cover construction, qualification and operation and will be a required part of each application for a license. However, a detailed quality assurance program specific to a licensed package probably should cover only its routine tests, determinations, or procedures, and for the benefit of users other than the manufacturer should be simple and explicit. The presence of manufacturing and qualification procedures in a specific package's quality assurance document will cause verbosity that will not help the operator loading or testing the package on routine operations.

A suggested revision for Section 71.21(c) is:

> "(c) A description of the proposed program of quality assurance for routine operating tests and procedures as required by 71.24(a), to be made a part of the license."

Section 71.24(a) should be amended consistently with revised Section 71.21(c), deleting references to the design, fabrication, manufacturing assembly and

testing functions since those can be handled through Section 71.51 and should not be features of specific package licenses because of the interplay of specific package licenses with Sections 71.12(b)(1)(i) and (ii).

Section 71.53(c)--It is not clear if certain ambient conditions or calculations to extrapolate test results to ambient conditions are necessary for the prescribed tests.

Section 71.53(d)--It would be very difficult and hazardous to simulate a source as large as a design basis spent fuel assembly. Even low burn-up fuel assemblies would not involve equivalent sources of radiation. This coupled with the requirement of the introductory paragraph of the section that these determinations be made prior to first use of the package appears unnecessarily restrictive. It is recommended that the second sentence be changed to: "The packaging shall be loaded with a source or sources which emit radiation of a character and intensity which permit detection at the exterior of the packaging with sufficient precision that the results may be extrapolated to substantiate that the shielding meets dose rate limits for shipment when loaded with the design basis materials."

Section 71.53(f)--Because of the difficulty of carrying out the proposed cycling testing with a contaminated cask and its rather questionable benefit for insuring tightness of individual shipments, it is suggested that the paragraph be recast as follows: "Packaging designs incorporating seals to meet the release limits of §71.36 shall be qualified by passing a leak test conducted at the pressure anticipated if the package and contents were to be subjected to the hypothetical accident conditions specified in Appendix B." This change will be supplemented by the item below.

Section 71.54(i)--It is recommended that this paragraph be changed to read: "The package has been closed, sealed and leak tested in accordance with written procedures."

Section 71.54(g)--Due to the serious difficulty and additional personnel exposure involved in demonstrating the functioning of pressure relief devices and other components of neutron shield tanks, it is suggested that Section 71.53(f) be invoked, i.e., change Section 71.54(g) to read: ". . . or a liquid shielding medium have been functionally tested within 12 months per §71.53(f) and the systems . . . leak-tight."

Section 71.62(c)--It is recommended that this paragraph be made more precise. The proposed text is so inclusive that it can readily be

interpreted to require that the licensee include in its permanent records those of the reactor or other receiver which might be construed to pertain to the ". . . quality of items which have safety significance . . . ." Section 71.62(a)(10) as amended adequately covers record keeping on routine determinations.

Appendix E--Introduction--Reference is made to the Section 71.4(1) definition of packaging but the additional wording ". . . in and with which radioactive material is transported. . . ." has been added here. If it is intended that the transport vehicle be included in quality assurance provisions, certain exclusions are going to be necessary to allow procurement of vehicles. Commercially available parts such as running gear, vehicle propulsion units, and lights are not now generally subject to quality assurance requirements except for those followed anyway by the manufacturers, who are hardly likely to think it worth their while except at extremely high cost to establish and follow special programs for a handful of AEC licensees.

Our few comments are advanced in an attempt to improve the clarity of the proposed regulations and to enhance operating efficiency of them.

Very truly yours,

James P. Hogan
Attorney

JPH:gjc

DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

Nuclear Fuel Services, Inc. 6000 Executive Boulevard, Suite 600, Rockville, Maryland • 20852

A Subsidiary of Getty Oil Company

(301) 770-5510

February 12, 1974

Secretary of the Commission
U.S. Atomic Energy Commission
Washington, D. C. 20545

Attn: Chief, Public Proceedings Staff

Gentlemen:

On December 28, 1973, the USAEC announced in the Federal Register, its consideration of amendments to 10 CFR Part 71 to upgrade the requirements for quality assurance of shipping and transporting licensed radioactive materials. Nuclear Fuel Services, Inc. has reviewed the proposed amendments and offers the comments included in the attachment.

Very truly yours,

James R. Clark, Manager
Environmental Protection
and Licensing

JRC:gg
Enclosure

Acknowledged 2-19-74, ors

NUCLEAR FUEL SERVICES, INC.

Comments on Proposed Amendment to 10 CFR 71
As Published in Federal Register on December 28, 1973

1. Paragraph 71.24 - This proposed requirement could lead to unnecessary duplication of effort by licensees. NFS suggests that DOT specifications containers be approved for design and that vendors be certified for fabrication, assembly and initial testing based upon USAEC review of the vendors' quality assurance program. The licensee could then purchase such certified containers and impose his quality assurance program to the use, maintenance, and periodic testing.

2. Paragraph 71.31 (e) - The proposed requirement that the external surfaces of packaging be designed, fabricated, and finished to facilitate decontamination to the lowest practicable level is unnecessary and unwarranted. Federal regulations (49 CFR 173.397) presently exist to limit the surface contamination of packaging. Specifying that external surfaces facilitate decontamination unduly emphasizes this consideration relative to other considerations appropriate for the external surfaces of packages of Type B Large Quantity or Fissile Material. These other considerations include heat transfer, required identification marking and anti-collision devices. It should be noted that handling systems are also being designed to minimize if not preclude contact of the external surfaces with radioactive contamination.

3. Paragraph 71.53 (c) - It may not be reasonable to require a "design heat load" test under all circumstances. A well instrumented test using a fraction of the total heat load could be more meaningful under some instances; i.e., if maximum heat load could prohibit the use of some instrumentation. Since the general test plans will become a part of the safety analysis report, it should be left up to the AEC review team to review the test program recommended by the designer.

4. Paragraph 71.53 (d) - This proposed requirement may not be practicable for spent fuel shipping casks where this "type of material for which the cask is designed or an equivalent source of radiation" may never be available due to conservatism in design. The proposed change in regulations would, in effect, require the licensee to run the final acceptance test at a utility when the first fuel assembly is loaded. Even then it is quite unlikely that a maximum burnup assembly matching the cask's design point would be available. A recommended test program should be submitted by the designer and reviewed by the AEC as part of the SAR. In all cases, a check is made before each spent fuel shipment so this need not be a separate requirement.

5. Paragraph 71.53 (e) - Testing valves at accident conditions which are far above normal operating conditions could decrease their operational reliability if the same valves are then put into use. Obviously this is quite dependent upon the condition being considered, but a proof test of the type of valve(s) at or above the specified accident condition to verify design acceptability and then checking each valve actually to be used at, or slightly above, the expected operating condition should be preferred. The applicant should provide a recommendation for the approach most desirable for his proposed package, valves, and anticipated operating and accident conditions.

6. Paragraph 71.53 (g) - This should not normally be a specific requirement since such a check must be made prior to each shipment. If the design is so unique that a specific check must be made during manufacture, then the AEC should impose this as part of the acceptance testing for the specific container in question.

7. Paragraph 71.54 (g) - The requirement for this test before each shipment should be a function of the package design and not a general requirement. The check of a sealed system such as a neutron shield tank prior to each shipment could more likely cause leakage and, therefore, be more detrimental than an annual check.

8. Paragraph 71.54 (h) - The requirement for this test before each shipment should be a function of the package design and not a general requirement. For instance, a relief valve may be a simple backup to a burst disc. In such cases, it does not see any pressure in service and, therefore, such a test would be meaningless, time consuming, and repeated disassembly could result in accidental damage to the burst disc.

9. Paragraph 71.62 (a) - The identify of "licensee" in this paragraph should be clarified. The owner of the package will probably be the holder of the license for the package while the user or shipper will perform the required tests. It is recommended that the facility that performs the routine determinations retain the records of those determinations.

10. Paragraph 71.63 (c) - The meaning of the word "fabrication" intended in this paragraph should be clarified as well as the extent of fabrication that the applicant may perform subsequent to the notification that would be required by this proposed paragraph.

11. Appendix E (3) and (11) - When a test program is used to verify a design, it should be optional as to the acceptability of using either a prototype or the actual hardware. If the test is not overly destructive, reuse of the hardware should not be prohibited. The use of the word prototype in this paragraph strongly implies a test package which could not be reused.

GENERAL ELECTRIC

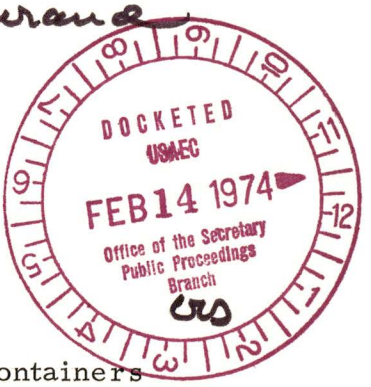
NUCLEAR ENERGY
DIVISION

GENERAL ELECTRIC COMPANY, 175 CURTNER AVENUE, SAN JOSE, CALIFORNIA 95114
Phone (408) 297-3000, TWX NO. 910-338-0116

DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

February 11, 1974

Acknowledged 2-14-74, crs



Secretary of the Commission
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Subject Quality Assurance Requirements for Shipping Containers

Dear Sir:

General Electric Company, Nuclear Energy Division, has reviewed the proposed amendments to the regulations in 10 CFR Part 71, "Packaging of Radioactive Material ... etc.," published in the Federal Register on December 28, 1973. The proposal seeks to upgrade requirements for quality assurance activities associated with the safe transport of radioactive material. General Electric does not disagree with the basic premise of strengthening quality assurance requirements for radioactive materials packaging, although neither the historical safety record of shipments nor packaging citations by Atomic Energy Commission inspections offer compelling evidence for adoption of the amendments on an emergency time scale. Accordingly, we urge careful consideration of the following comments and recommendations.

In general: (1) quality assurance requirements for packagings should be designed to meet the particular needs associated with packaging. These requirements, therefore, should be simplified, shortened and restructured to address a very important additional quality assurance matter--that of assuring the quality of the package closure; (2) all quality assurance criteria, recommendations and requirements should be collected in one place, either in Subpart D or Appendix E; (3) the regulation should provide for a licensing system in which those design features, limitations, components and procedures vital to safety are clearly identified by the applicant. Upon concurrence by the Commission, these vital points become specific license conditions for the package, subject to change only with prior Atomic Energy Commission approval.

Each of these three general points is further discussed in the attachment. In addition to these general comments, a number of proposed amendments warrant specific discussion:

1. 71.21 Change to read "... as required by Appendix E."

2. 71.24 Delete. Paragraph (a) covered by the introduction of Appendix E. Paragraph (b) is covered by Criterion 1 of Appendix E. Paragraph (c) should be included in 71.22.

3. 71.31(e) Add the clause: "except for packagings which are used for radioactive material which is completely encapsulated or otherwise used in such a manner that contamination of external surfaces is highly unlikely under normal conditions of transport."

   Packagings for unirradiated reactor fuel materials, for example, have slight, if any, potential for becoming contaminated.

4. 71.41 If adopted as proposed, paragraph (b) would require, for example, preconstruction and construction quality assurance program documentation, which is unavailable, for previously constructed spent fuel casks. We do not believe this is the Commission's intent; rather it wishes to assure those casks comply with the structural integrity requirements of Part 71 as currently effective, but prior to initiation of the upgraded quality assurance requirements.

   Accordingly, Section 71.41 should be either:

   a. made effective before the quality program, or

   b. revised to require demonstration of compliance with all pre-1974 Part 71 requirements, submission of a quality assurance plan for maintenance, repair and use, and a package cavity, closure, penetration and valve leak test completion.

5. 71.51 No comment. It is assumed Appendix E will be revised to address the quality assurance of packaging programs.

6. 71.53 The substance of the requirements of this section should be contained in the revised Appendix E. (See general comments above.)

7. 71.53(a) No comment.

8. 71.53(b) Change the end of the third sentence to read, "... where A_2 is the Type A quantity for the material to be contained as defined in Table VII of the IAEA Safety Standards, Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 revised edition."

9. 71.53(c) No comment.

10. 71.53(d) There is some doubt about the meaning of the terms "type of material for which it is designed" and "in excess of the predicted levels" in the shielding test requirement. We believe this requirement could be deleted in view of the DOT regulations which require measurement of dose rate at the surface of the package for each shipment. If there is concern that those surveys might not detect shielding cracks, voids or low density regions, the requirement would be more clearly stated by revising it to read,"... shall be loaded with a radioactive source of sufficient strength and energy level to permit detection of cracks, voids or low density regions in the shielding which could produce radiation dose rates at any point on the outer surface of the package in excess of appropriate regulatory limits."

11. 71.53(e) Revise the second sentence to read: "The test shall be conducted with the valve(s) at the temperature and pressure anticipated if the package were subjected to the hypothetical accident conditions specified in Appendix B, unless it can be shown by previously conducted calibration tests or code procedures that testing at lower temperatures will provide equivalent determination."

12. 71.53(f) No comment.

GENERAL ELECTRIC

13. 71.53(g) Delete. Neutron absorber testing would require critical array experimentation which would require Part 50 licensing. Absorbers will be examined prior to each use (71.54(b)) and 71.53(g) is therefore redundant with 71.54(b).

14. 71.54(h) Revise to read: "Any pressure relief valve(s) has not been made inoperable nor has the discharge from such valve(s) become blocked.

We would appreciate an opportunity to have industry representatives, such as the Atomic Industrial Forum's Committee on the Shipment of Nuclear Materials, meet with appropriate members of the Commission's staff to work out details of a quality assurance regulatory program in which the packaging of radioactive materials is more adequately and effectively considered.

Very truly yours,

B. D. Wilson, Manager
Radioactive Materials Safety Assurance
M/C 273, Ext. 2275

hb
enc.

GENERAL ELECTRIC

February 11, 1974

ATTACHMENT

Discussion of general comments - letter to Secretary, Atomic Energy Commission dated February 11, 1974.

I. Design the quality assurance criteria for packages.

Differences between shipping containers and nuclear reactors are legion. These differences demand different considerations in the application of quality assurance programs. Reactor internals are extremely difficult to inspect, repair or replace as compared to shipping container components. Reactors are heavily instrumented with complex redundant systems for assuring controlled criticality. Those electrical, hydraulic and pneumatic systems are made up of piping, wiring, valves, switches and electronic devices as well as mechanical apparatus, all of which are active continually.

The typical shipping container, on the other hand, is a passive structure. Once that structure is constructed, tested, inspected and approved, a completely new and different type of quality assurance program comes into being. Ineffective closure of a shipping container would constitute the greatest threat to safety. Yet, there are few, if any, Appendix E criteria that relate to that major threat without circuitous rationalization. We estimate that about 90% of the statements in the Appendix are most directly applicable to the design and construction phases of a great project, or appear to have been formulated with such a project in mind. In any case, by their preponderance, the packaging utilization phase, including refurbishment, appears overshadowed and there is more than ample reason for uncertainty as to how to apply the criteria to the package utilization phase. We suggest, therefore, a realignment and condensation of the requirements to provide a rational, understandable and useful framework for packaging quality assurance programs. The following basic outline is suggested:

1. General Criteria

   a. Quality assurance program.
   b. Quality assurance organization.

2. Package Design and Construction

   a. Design.
   b. Procurement of parts and materials.
   c. Fabrication and assembly.
   d. Preuse tests and inspection.

3. Package Use

   a. Reuse inspection.
   b. Refurbishing and repairs.
   c. Filling and closing.
   d. Closure inspection.
   e. Final preparation for transport.

II. Include all quality requirements in one place, preferably in Appendix E.

During the revision of Appendix E as indicated above, the requirements of Sections 71.24, 71.53, 71.54, 71.62(a)(10) and 71.62(c) should be included under, or with, the general statement to which each applies. For example, item 2.d., Preuse Tests and Inspection," would consist of a condensed version of the proposed item 10 of Appendix E followed by the revised Section 71.53. Paragraph 71.24(b) identifying quality assurance positions and responsibilities would be included in item 1.b., "Quality Assurance Organization." By this simple rearrangement, one's understanding of both the general and the more specific requirements in this area will be enriched. At the same time, the structural cohesiveness of the document will be improved and the possibility of overlooking an important aspect of the package quality requirements will be reduced.

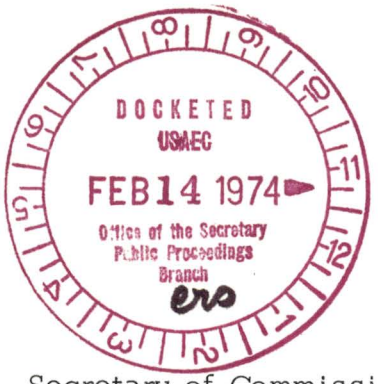
III. Revise Part 71 to provide for a more clearly defined licensing/approval system.

The transportation of radioactive materials continues to receive more attention by critics even as packaging and transport regulations become more stringent. With strengthened regulations, there appears a tendancy toward greater complexity and uncertainty in the licensing system. Uncertainty as to what kinds of information are required in applications and

how that information is to be used in package approvals would neither improve the Commission's task toward public safety nor the industry's ability to comply with the packaging regulations. A symptom of this uncertainty appears in the last paragraph under the Design Control criterion which first applies the formal review system of the applicant to packaging design changes, but immediately cautions that no changes to the licensed design can be made without Commission approval. There is no clear criterion of what the license will contain; therefore no guidance on design changes. Subpart B, "License Applications," should be revised therefore to require the applicant to identify the safety-related features of the package design (which would become license conditions) and to separate them from the detailed design description which is needed to provide a sufficient basis for evaluation of the packaging." (71.22) Similarly, only those quality assurance procedures of safety significance would be carried over as license conditions. It is not only unmanageable, but completely unwarranted for the Commission to retain prior approval authority over every statement, requirement, instruction or procedure in the applicant's quality plan as is the inference in the introduction to the December 28, 1973, proposal which reads: "Any changes in the (quality assurance) program must be approved by the Commission." Once this application dilemma is clarified, Regulatory Operations inspectors should be more effective since they will not be faced with difficult decisions of whether the licensee has made illegal (and perhaps unsafe) changes in his packaging design or his quality plan.

We recognize that this system may require a change in packaging authorizations which heretofore have attempted to provide information on package designs, not only sufficient to permit identification of the packaging and its safety-related specifications, but also sufficient to duplicate the construction.

We also realize that serious effort will be needed to establish the required changes in the licensing system. It is timely, however, to work toward these goals since the "special permit" system is currently expiring. We are confident the Commission can count on prompt cooperation from industry to bring about a practicable and sound licensing procedure to prevent perpetuation of current and projected complexities.



NL INDUSTRIES

NUCLEAR DIVISION
Nuclear Transportation Department

DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

In reply please reference
NTD-1239
February 8, 1974

Secretary of Commission
U.S. Atomic Energy Commission
Washington, D.C. 20545

Acknowledged 2-14-74, ers

Attention: Chief, Public Proceedings Staff

Reference: Proposed Rule Change 10 CFR Part 71 - Packaging of Radioactive Material For Transport and Transportation of Radioactive Material, dated Friday, December 28, 1973

Gentlemen:

Please find below our comments on the Commission's proposed rule changes which were published in the Federal Register, Vol. 38 # 248 - Friday, December 28, 1973.

Part 71.41 — It is not clear what effect the proposed changes will have on packages which are licensed and constructed subsequent to January 1, 1967 but prior to the effective date of the proposed rules change. This same concern applies to the construction of additional packages by a licensee of a package authorized by the Commission during this same interim period.

Part 71.53(a) — The proposed shielding chamber test is not compatible with the fabrication procedures necessary to construct a spent fuel shipping container. To construct a package to the point where a pressure test could be performed on the assembled shielding chamber, prior to installing the shielding, would result in detracting from other safety aspects of the package such as thermal performance in the case of bonded lead shielding and thermal barrier in the case of uranium shielding. It is recommended that the regulation be written such that the licensee has a choice of methods or freedom to use a combination of methods to satisfy the requirement of leak testing. Some of the methods which could be considered are (1) X-ray examination of all accessible welds, (2) liquid penetrant or magnetic particle inspection of those welds not accessible for X-ray examination, (3) helium leak test, (4) pressure test (for those designs where fabrication procedures

are compatible with pressure testing prior to installation of shielding).

Part 71.35(b) The regulation seems to be directed to the testing of two different chambers. One contains radioactive material and the other does not. Part 71.35 (a) deals with the shielding chamber which indicates that (b) is address to a third chamber which does not contain radioactive material.

It is recommended that this third chamber be more specifically defined since there is the possibility of interpreting the regulation as establishing the test pressures to be used to satisfy the requirements of 71.35(a).

The regulation should stipulate that the required tests are performed on the completed package.

Part 71.35(c) Design heat load should be defined as the approved package decay heat load. Add in first sentence after " design heat load", "under normal conditions of shipment",.

Recommend the following be added to the last sentence. "It is not necessary that the geometry of the heat source duplicate the geometry of the actual heat source."

Part 71.35(d) In the case of spent fuel an equivalent source will represent a substantial quantity of source material, both gamma and neutron, that a fabricator would be required to have in order to comply with the requirements as written. This seems to be putting the license and/or the fabricator in an unnecessary position of safeguarding and handling a large quantity of source material when existing regulations and industry practice (which can more readily be made a regulatory requirement) provide the assurance that the design and construction of the cask does result in an effective shield. Maximum allowable radiation dose rates as well as the requirement to insure by examination that the external radiation levels are within the allowable limits is presently required by 49 CFR Part 71.393. As for initial determination of shielding integrity the procedure has been to place a colomated source on one side of the shielding wall with appropriate counting instrumentation opposite the source on the outside of the shielding wall. By moving the source and counter over the shielded wall a count rate is recorded and compared against an established count rate which is acceptable for the shield thickness being inspected.

Part 71.35 (e) The last sentence should be revised so that the requirement is directed to relief valves which are part of the primary containment system. All other valves to be pressure tested at ambient temperatures at intervals not to exceed one year.

Part 71.35 (f) Suggest using the words flange joint or closure joint instead of seal since it is the entire joint design that is being tested.

The yearly tests would be performed to confirm the condition of joint has not deteriorated rather than to reconfirm the seal design.

Part 71.54(h) The initial determination tests along with the requirement to repeat such tests at least once a year should give adequate assurance of proper valve function. Routine determination should be limited to a visual examination of the installed valve for any evidence of damage which may result in the valve being inoperable.

Part 71.63(c) The regulation needs clarification on the following points. (1) Does prior to fabrication mean prior to ordering material or prior to actual construction. (2) Is it the intent of this regulation to restrict the licensee or the applicant for a license from starting fabrication of a package prior to receiving AEC authorization for use of the package. (3) Does this apply to the fabrication, by a licensee, of all subsequent units of a package which has AEC authorization.

The above comments are also relivent to Appendix E (11).

To permit a licensee to start fabrication of a package prior to AEC approval does not seem to contradict the intent of the regulations. The burden is on the licensee as to showing documented evidence that the constructed package is in accordance with the AEC approved design. The documented evidence is a product of the Quality Assurance Program. The licensee would not be a licensee unless he had demonstrated to Regulatory Operations that a Quality Assurance Program in accordance with Appendix E was established and in operation.

Very truly yours,

G. L. Stukenbroeker

G.L. Stukenbroeker
Manager
Nuclear Transportation

DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

AMERICAN INSURANCE ASSOCIATION

85 John Street
New York, N.Y. 10038
(212) 433-4400

February 7, 1974

Secretary of the Commission
U. S. Atomic Energy Commission
Washington, D. C. 20545

Att: Chief, Public Proceedings Staff

Dear Sir:

Mr. John Langhaar, a member of the N-14 Committee on the Packaging and Transportation of Radioactive and Fissile Materials, is submitting comments to you on the proposed revision 10CFR71 Federal Register Vol. 38, No. 248, Friday, December 28, 1973 entitled, "Quality Assurance Requirements for Shipping Containers." The comments are enclosed with this letter. They represent Mr. Langhaar's own views. We have not given this full committee consideration. We are anxious to get this to you before the deadline.

Sincerely yours,

Carmela Vitarco, Secretary

Arthur Spiegelman
Vice President
Engineering and Safety

Attachs.

DOCKETED
USAEC
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Office of the Secretary
Public Proceedings
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Acknowledged

2-11-74 ers

OSR 25-58

FEB 4 1974

E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED

ATOMIC ENERGY DIVISION
WILMINGTON, DELAWARE 19898

cc: R. H. Jones

February 1, 1974

Mr. M. Stewart Fastman
Eng. & Safety Dept.
American Insurance Assn.
85 John St.
New York, N. Y. 10038

Dear Mr. Fastman:

As discussed with you on the phone, enclosed are my comments, and also comments by R. H. Jones who is a member of N 14.12, on the proposed rule making, 10 CFR Part 71, Federal Register Vol. 38, No. 248, Friday, December 28, 1973, "Quality Assurance Requirements for Shipping Containers". It is recommended that these comments if approved by Art Spiegelman and with such editing as he considers appropriate, be forwarded to the AEC by N 14. The deadline is February 11, 1974. The letter should be addressed to

Secretary of the Commission
U. S. Atomic Energy Commission
Washington, D. C. 20545
Attn: Chief, Public Proceedings Staff

Very truly yours,

John W. Langhaar

John W. Langhaar

JWL/jd
enc.

- comments by one of the members of N-14. We have not had time to get this full committee consideration but we are optimistic to get it to you before the deadline.

COMMENTS ON PROPOSED AMENDMENTS TO 10 CFR PART 71
"QUALITY ASSURANCE REQUIREMENTS FOR SHIPPING CONTAINERS"

FEDERAL REGISTER VOL. 38, NO. 248 - DECEMBER 28, 1973

The proposed amendments appear generally acceptable. We are in accord with the principle that current emphasis in the field of regulations for shipping radioactive materials should be on assuring compliance with the intent of the regulations.

There are some details for which we believe the objective could be accomplished by simpler and more practical means, and others for which the intent should be clarified. Following are comments and recommendations for your consideration.

(1) 71.24(b) It is not clear whether the words "prepared in accordance with all applicable requirements" is intended to include design and fabrication, or refers only to the operating procedures of loading, testing, etc.

(2) 71.53(b) A leak test sensitivity of A x 10^{-6} per hour, which we suppose will become A_2 x 10^{-6} per hour in the near future, would be unnecessary and impractical in some cases. For example, for a water solution containing 5 Ci/cm3 of lead-210, with A_2 = 0.2 Ci, the value A_2 x 10^{-6} per hour would correspond to 1.3 x 10^{-11} cm3/sec. of solution, or one drop in 120 years. If it is assumed for purposes of illustration that the liquid is at 15 psig and 50°C, the corresponding sensitivity of test expressed in conventional units, as for the helium-mass spectrometer test and based on data in the draft of ANSI-N 14.5, would be 2 x 10^{-10} atm cm3/sec. The ANSI standard would recommend a test sensitivity better by a factor of 2 in order to be reasonably sure of detecting the leak, which in this case would be 1 x 10^{-10} atm cm3/sec. However, the ANSI recommendation also is that the most sensitive test ever required is 5 x 10^{-8} atm cm3/sec, to detect a leak of 1 x 10-7 atm cm3/sec.

The reason for not requiring a leak test sensitivity better than 5 x 10^{-8} atm cm3/sec. is that leaks smaller than 10^{-7} atm cm3/sec are rarely found in practice. Such small leak paths are readily plugged and in the case of liquids, would often require a high pressure to overcome surface tension. The corresponding leak path diameter is calculated to be in the range of 1 to 2 microns, This may be compared with about 10 microns for the smallest particle visible to the naked eye, or 35 microns which is the calculated size for the sensitivity of test proposed by the ISO. (The US voted against the ISO proposal). The helium-mass spectrometer test is normally useful only for leak rates greater than 10^{-8} atm cm3/sec, or perhaps 10-9 under well-controlled

conditions. It should perhaps be noted also that 100% assurance can never be provided with respect to leakage or many other aspects of container performance. The characteristics observed in a test are not necessarily duplicated in practice. A high degree of confidence is the best that can be expected.

(3) 71.53(c) The first and second sentences are essentially the same, except for 5 watts in the first and 5 kilowatts in the second. Clarification is needed. We assume that the test could consist of loading the container with the intended contents for the first shipment, and making the observations of the type required in IAEA regulations, paragraph 739(a), provided the contents generate the "design heat load". In fact, if IAEA 739(a) is adopted, there will be no need for the proposed 71.53(c).

A lower limit of 5 watts is so low as to appear unintended. Regardless of the lower limit, performance of a test is often not justified from an engineering standpoint. The upper limit for radioactive contents is frequently imposed not by heat dissipation, but by some other parameter such as physical dimensions, shielding, criticality, or chemistry of the contents. Thus, for example, packaging which by calculation could safely dissipate 10 kw might be approved only for contents generating a maximum of 5 kw.

Even when a test is justified, a sound engineering evaluation can be made using a heat load less than the design heat load. The latter point is especially important when actual radioactive contents are used for the test, because such contents are nearly always less than the design maximum. The test in this case provides basic data for reliable extrapolation of results.

Thus it is proposed that 71.53(c) might read: "If the decay heat load from the approved contents exceeds 75% of the maximum heat load demonstrated by calculation to be in compliance with (.....specific paragraphs of the regulations.....), then the adequacy of the package to safely dissipate heat from the approved contents shall be demonstrated by test. The heat source used in the test may be the actual loading for the first shipment or may be some other heat source, but in any case shall have a heat output sufficient for reliable prediction of actual performance with approved contents."

(4) 71.53(d) We would understand this to permit using the first loading for the test, and to permit a smaller number of curies of gamma or neutron source because the "type of material" is not necessarily the same quantity of material. With respect to normal transport, the adequacy of shielding is already required to be checked before each shipment because of the dose rate limits.

It would seem that the additional regulatory concern would then be the thickness and integrity of shielding to meet requirements in the hypothetical accident. Clarification is recommended, for example in the following manner:

"If packaging incorporates shielding to meet dose rate limits, the effectiveness of the shielding shall be demonstrated by test. The source, which may be the contents for the first shipment, shall be of sufficient strength and suitable geometry to demonstrate that the shielding is of the required thickness and distribution for the approved contents in normal transport and under hypothetical accident conditions. Gamma shielding and neutron shielding may be tested and evaluated separately."

(5) 71.53(e) In many cases some damage to the valve would result from testing at the temperature corresponding to the hypothetical accident, even though such damage would be acceptable in the accident. It should be permissible to perform standard tests, making suitable allowance or adjustment for temperature and pressure. Rupture discs cannot be so tested, but should be replaced if there is evidence of corrosion or damage.

Containers which are out of service for more than a year, as is the case for many casks, should be exempt from the "one year" test interval provided a test is made less than one year before any off-site shipment.

(6) 71.53(f) Leakage rates may be affected by temperature, pressure, vibration, impact, slight variations in O-rings and gaskets, seating pressure and other factors. As noted in connection with 71.53(b), the best that can be expected is a high degree of assurance, and this may be provided by tests at a lower pressure than the hypothetical accident pressure. Sometimes leakage decreases at high pressure. The design should of course from an engineering standpoint be adequate for the expected pressure.

The containment system might suffer some permanent deformation at the hypothetical accident pressure and still meet the regulatory requirements, but routine testing at such pressure would be inappropriate.

The recommendations of the ANSI-N 14.5 proposed standard with regard to procedures for and frequency of testing are suggested for consideration.

(7) 71.53(g) The relationship of this to section 71.53(d) is not clear.

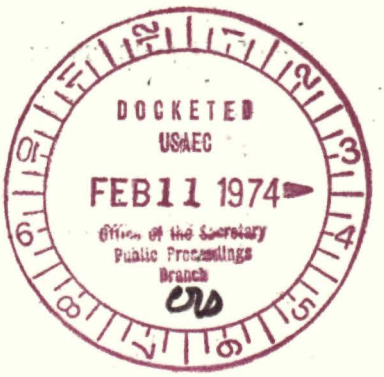
(8) 71.54(h) Some advice is needed on how to check pressure relief valves, and on whether rupture discs are included. Actual opening of a relief valve entails the possibility of failure to reseat adequately. Determination of the pressure at which the valve opens and closes is not appropriate, and seems to fall within the province of 71.53(e).

ADVANCED TECHNOLOGY DEPARTMENT

January 25, 1974

J. LANGHAAR

cc CF Goodner
GF Holmes
NC Shirley
CW Smith
EF Stell
BD Wilson



AN Tschaeche
Administrator-Licensing
M/C 273 Ext. 2235

Subject: Comments on Proposed 10 CFR 71 Rule Changes

The following are ATD - Fuel Recovery Product Section comments on the subject rule changes:

71.24(c) Change entirely to read, "The applicant shall identify the recognized codes and standards proposed for package design, fabrication, assembly, testing, maintenance, and use where they exist. In the absence of recognized codes and standards, the applicant will describe the basis and rationale used to formulate the package Quality Assurance Plan."

71.41(b) Change the end of the first sentence as follows,"... superceding license for the use of such packages in accordance with the following:

(i) Packages must be shown to comply with the September 30, 1972 version of 10 CFR 71.
(ii) A Quality Assurance Plan must be written encompassing package maintenance, repair and use.
(iii) Prior to first use under the new license, the package cavity, closure, penetrations and valves must be visually inspected and leak tested at 1.5 times the design pressure.

If the licensee fails to do so..."

71.53(b) Change the end of the third sentence to read, "... where A_2 is the Type A quantity for the material to be contained as defined in Table VII of the IAEA Safety Standards, Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 revised edition."

(d) Eliminate the first sentence and modify the second sentence as follows:

"If packaging incorporates shielding to meet dose rate limits, the integrity of the shielding will be demonstrated by test. A radioactive source of sufficient strength and energy level together with a detector system of sufficient sensitivity shall be utilized to scan or probe the shielding for cracks, voids or low density regions which could produce radiation streaming in excess of permitted levels. As an alternative, the packaging may be loaded with..."

(e) Add the following sentence to the paragraph:

Annual testing of valves and pressure relief valves may be ~~tested~~ CONDUCTED at room temperature provided correlation to accident temperature set point is in accordance with recognized code procedures or previously conducted calibration tests.

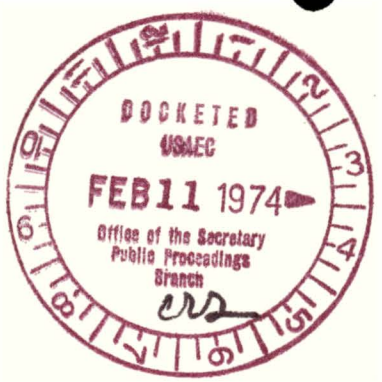
(g) Delete entire paragraph.

Comment: These items are important to safety and their fabrication, assembly, inspection, repair and use will be part of the QA plan. There is no reasonable test of the "Design efficacy" short of a critical array experiment.

71.54(h) Delete sentence and substitute:
Any pressure relief valve or valves have not been rendered inoperable or blocked from discharge downstream from such valve or valves.

R.H. Jones, Sr. Engineer
Licensing & Transportation
M/C 160 | Ext. 6551

/la



NL INDUSTRIES

DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

NUCLEAR DIVISION
WILMINGTON PLANT

February 8, 1974

Secretary of Commission
U. S. Atomic Energy Commission
Washington, D. C. 20545

Acknowledged
2-11-74, ers

Attention : Chief, Public Proceedings Staff

Gentlemen :

Following are NL Industries, Inc., Wilmington Plant, comments to the proposed amendments to 10 CFR 71 as published in the Federal Register Friday, December 28, 1973.

71.41 Does not cover packages manufactured between January 1, 1967 and the present. Are we to assume these do not require re-licensing or must they also be reviewed on an individual basis since many obviously do not meet the proposed new requirements.

71.53 (a) These paragraphs seem to ignore a problem inherent in some packages.

1. The requirement to test the shield cavity prior to installation of shielding presents a problem in two specific cases.

(A) When a bond is required between lead shielding material and the inner and outer walls of the shield cavity, it becomes necessary to apply by hand a bonded layer of lead material to the inside of the outer cylinder and the outside of the inner cylinder. This must be done prior to assembly of the cylinders. This layer of bonded lead effectively prevents testing the cavity per the proposed new regulation.

Foot of West Street Wilmington, Delaware 19801 (302) 656-1661
Division of NL INDUSTRIES, INC.

71.53 (a) (continued)

(B) Often when depleted uranium shielding is specified it is necessary to apply a spray coating of copper to the walls of the shield cavity to prevent iron-uranium eutectic. The copper coating can only be applied properly before assembly of the inner and outer cylinders. This effectively invalidates the new test specified in the proposed regulation.

An alternate would be to test the inner and outer cylinders prior to application of lead or copper and prior to assembly by special fixturing and helium leak testing. Helium leak test would appear to be readily accomplished and should be perfectly satisfactory. The welds could also be radiographed for structural integrity. The final assembly welds could remain uncoated and be tested after assembly by means of helium leak test.

71.53 (b) It should be made clear that this paragraph applies only to the compartment which provides primary containment for the material being shipped. It could possibly be misinterpreted to mean shielding material chamber in the case of depleted uranium shielding.

71.53 (c) The words "design heat load" could be interpreted to mean the actual spent fuel limiting to thermal capacity. Suggest "simulated design heat load" or words to that effect.

71.53 (d) Current procedures in use for testing shielding are designed to test shield integrity rather than shield effectiveness. To provide an "equivalent source of radiation" would seem to necessitate the actual use of spent fuel for testing. This seems unrealistic.

71.53 (e) Believe this paragraph should be clarified to differentiate between relief valves and closure valves. It should also consider bolted valves versus welded valves.

71.53 (f) Some seals are not reuseable. The paragraph as written would seem to prohibit the use of such seals.

71.53 (g) It would seem the normal neutron moderators, such as water, have been adequately tested in the past and that perhaps only specific basket design must be tested for each new container.

We believe these items should be thoroughly reviewed and resolved prior to amending the regulations.

Other than the items specified, we believe the proposed changes provide needed criteria to assure safe transport of radioactive material.

Very truly yours,

F. J. Bush, Jr.
Manager

/ls

DOCKET NUMBER
PROPOSED RULE PR-71 (38 FR 35490)
Quality Assurance

Battelle
Columbus Laboratories
505 King Avenue
Columbus, Ohio 43201
Telephone (614) 299-3151
Telex 24-5454

February 8, 1974

Secretary of the Commission
U.S.A.E.C.
Washington, D.C. 20545

Attention Chief Public Proceedings Staff

Dear Sir:

Acknowledged 2-11-74 ers

This letter concerns the proposed rule-making published in the Federal Register December 28, 1973, regarding the addition to the regulations of a Quality Assurance Program (QAP) to be applied to nuclear material shipping containers.

In general we feel that the application of this proposed program will decidedly increase the safety aspects of transporting nuclear materials. From our long experience in designing, constructing, and handling this type of equipment we would like to make the following comments, which we feel would improve the program:

(1) Personnel Qualifications - Each reference to people involved in the program, the term "qualified" should be added. Our experience indicates that the effectiveness of a Quality Assurance Program is determined by the knowledge and capabilities of the personnel involved. Perhaps minimum standards of education and/or experience might be established to aid people who wish to qualify for these positions. Special training programs might be provided to help prospective personnel meet the standards established for the Quality Assurance Program.

(2) Material Marking - Permanent marking for all parts used in the construction and operation should be employed wherever possible. Electric pencil etching is a preferred method since letter/number stampings can cause stress concentrations in sensitive materials.

(3) Relicensing of Casks Constructed Before 1967 - Section 71.41, which requires that previously constructed packages be modified to comply with this program, virtually rules out the use of these packages. It is not possible to retrofit this Quality Assurance Program to equipment of this type. In most cases, very little information is available on construction

material specifications, and the reports of QAP tests are not normally kept as permanent records.

To permit the continued use of older containers, an extensive testing program might be employed to ensure adequate safety. This testing program should be conducted after final modifications that may have been made expressly to meet the test requirements. In addition, a completely new SAR would be required for each cask. Because of the way in which the proposed new rules are written, the fate of any cask that cannot be shown to meet all of the quality-control requirements is left to the subjective judgment of the cask review team, which is constantly changing.

Again may I say that for the most part, we feel this proposed Quality Assurance Program is good and should greatly increase the confidence of the public in the safety of handling nuclear materials.

Very truly yours,

Elmer C. Lusk

Elmer C. Lusk
Nuclear and Flow Systems Section

ECL:ckg

Airmail

ATOMIC ENERGY COMMISSION

[10 CFR Part 71]

PACKAGING OF RADIOACTIVE MATERIAL FOR TRANSPORT AND TRANSPORTATION OF RADIOACTIVE MATERIAL UNDER CERTAIN CONDITIONS

Quality Assurance Requirements for Shipping Containers

The Atomic Energy Commission has under consideration amendments to its regulations in 10 CFR Part 71 "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions," to upgrade requirements for quality assurance in the design, fabrication, assembly, testing, use and maintenance of packagings for shipping and transporting licensed radioactive material. The amendments would also revoke, subject to a timely application for reapproval, the present authority to use certain shipping casks for solid irradiated nuclear fuel which had been approved under criteria used before the current standards were developed.

Under the proposed amendments which follow, each licensee subject to 10 CFR Part 71 would be required to assess the adequacy of his quality assurance program against the upgraded standards and requirements, and to make whatever changes are required to comply with those standards and requirements. AEC would verify compliance with the standards through its licensing and inspection programs. Each applicant for a license or license amendment under 10 CFR Part 71 would be required to describe his quality

assurance program to be applied to the design, fabrication, assembly, testing, maintenance and use of his proposed packaging. The applicant would further be required to identify the codes, standards and general requirements to be imposed under the program. Within this framework, the licensee would be required to document his quality assurance program in detailed written procedures and requirements, and follow those procedures and requirements in his operations. The adequacy of the detailed written documents and the licensee's implementation of them would be determined through the Commission's compliance program. That adequacy will be judged in part on the complexity and proposed use of the package under consideration, and on the complexity and importance to safety of its components.

The quality assurance requirements proposed here would apply to a licensee's design, fabrication, assembly, testing, use and maintenance of a Type B, Large Quantity or Fissile material package which he constructs for himself or has someone else construct for him. In the case of a licensee using a package approved for another licensee's use, in accordance with the general license provisions of present §71.12, the quality assurance requirements of the licensee for whom the package was first approved must be followed in the use, testing and maintenance of the package by the second licensee. Any changes in the program must be approved by the Commission.

A new provision would require notification of the Commission's Directorate of Regulatory Operations before fabrication is begun of

packaging with certain heat loads or anticipated internal pressures. This would facilitate communication between the licensee and the Commission's regulatory staff to resolve any differences on the adequacy of the quality assurance program before significant expenditures and irretrievable effort are committed to packaging of such importance.

To assure that external contamination of packages is kept as low as practicable, a new provision would require that external surfaces of packaging be designed and finished to facilitate decontamination.

Authority to use certain shipping casks for solid irradiated nuclear fuel is contained in § 71.41 of Part 71 "Previously constructed packages for irradiated solid nuclear fuel." This authority applies to shipping casks approved after September 23, 1961 and constructed by January 1, 1967, when the current package standards system was first adopted in the United States. Under these proposed amendments, any such casks still in use must be shown to comply with current package standards, either in their present condition or after modification.

Pursuant to the Atomic Energy Act of 1954, as amended, and section 553 of title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 71 is contemplated. All interested persons who desire to submit written comments or suggestions for consideration in connection with the proposed amendments should send them to the Secretary of the Commission, U.S. Atomic Energy Commission, Washington, D. C. 20545, Attention: Chief, Public Proceedings Staff,

by February 11, 1974. Copies of comments on the proposed amendments may be examined at the Commission's Public Document Room at 1717 H Street, N. W., Washington, D. C.

1. Paragraph (c) of § 71.21 is amended to read as follows:

§ 71.21 Contents of application

* * * *

(c) A description of the proposed program of quality assurance as required by § 71.24.

2. Section 71.24 is amended to read as follows:

§ 71.24 Quality assurance

(a) The applicant shall describe his quality assurance program to be applied to the design, fabrication, assembly, testing, maintenance and use of the proposed packaging. Appendix E, "Quality Assurance Criteria For Shipping Containers For Radioactive Material" sets forth the requirements for quality assurance programs for packaging. The description of the program shall include a discussion of how the applicable requirements of Appendix E will be satisfied.

(b) The applicant shall identify, by title and qualifications, the individual(s) in his organization responsible for assuring that packages of radioactive materials to be delivered to a carrier for transport have been prepared in accordance with all applicable requirements.

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(c) The applicant shall identify the codes and standards proposed for package design, fabrication, assembly, testing, maintenance and use.

3. A new paragraph (e) is added to § 71.31 to read as follows:

§ 71.31 General standards for all packaging

* * * *

(e) The external surfaces of packaging shall, as far as practicable, be designed, fabricated and finished to facilitate decontamination.

4. Section 71.41 is amended to read as follows:

§ 71.41 Previously constructed packages for irradiated solid nuclear fuel.

(a) Notwithstanding any other provisions of this subpart, a package, the use of which has been authorized by the Commission for the transport of irradiated solid nuclear fuel on or after September 23, 1961, and which has been completely constructed prior to January 1, 1967, shall be deemed to comply with the package standards of this subpart for that purpose, except as otherwise provided in paragraph (b).

(b) The holder of the specific license providing the authority specified in paragraph (a) shall, within 6 months after (the effective date of this section), file a consolidated application for a superseding license for the use of such packages in accordance with this part. If the licensee fails to do so, the provisions of paragraph (a) and the

authority granted by the license to deliver the material to a carrier for transport in such packages shall expire at that time. The Commission may issue a new license superseding the existing license, may confirm the existing license with or without modification, or may deny the application in whole or in part and terminate the existing license in whole or in part. If modification of the design of a package being used under the authority of this section in effect prior to (effective date of these amendments) is proposed by a licensee in his application for a superseding license in accordance with this paragraph, the licensee shall designate in his application the time period needed to modify the package(s) after approval by the Commission.

5. Section 71.51 is amended to read as follows:

§ 71.51 Establishment and maintenance of a quality assurance program

The licensee shall establish, maintain and execute a quality assurance program satisfying each of the criteria specified in Appendix E "Quality Assurance Criteria for Shipping Containers For Radioactive Material."

6. Section 71.53 is amended to read as follows:

§ 71.53 Initial determinations and tests

Tests shall be performed or determinations made, prior to the first use of a package, to satisfy the requirements of this section and of the license. After determining that the packaging has been fabricated in

accordance with the design approved by the Commission, the packaging shall be conspicuously and durably marked with its model number, as specified in the license, and with a unique manufacturer's serial number.

(a) If a completely sealed shielding chamber is necessary to demonstrate compliance with the requirements of this part, its leak-tightness shall be demonstrated by test, appropriate for the shielding material to be contained, during the fabrication of the packaging and before the shielding chamber is filled with shielding material. This test shall be performed while possible leakage points are accessible for repair and before any leak paths can be plugged with shielding material. If leakage is indicated, the leaks shall be located and repaired, and the test repeated. The leak test of the shielding chamber may be performed after the addition of the shielding material whenever such procedure provides higher assurance of shielding chamber leak-tightness than the test otherwise specified in this paragraph.

(b) If a completely sealed chamber is necessary to demonstrate compliance with the requirements of this part, its leaktightness and structural integrity shall be demonstrated by test, appropriate for the material to be contained. The chamber shall be pressurized to 1.5 times the sum of the maximum normal operating pressure and any differential pressure below mean sea-level atmospheric pressure to which it may be subjected in transit, or to 11 psig, whichever is greater, and the

pressure maintained for at least 10 minutes. If the chamber will contain radioactive material, the leak test shall have a minimum sensitivity of $A \times 10^{-6}$ per hour, where A is the Type A quantity for the material to be contained. If the chamber will not contain radioactive material, the leak test shall be sufficiently sensitive to detect any leakage beyond that determined to be acceptable under § 71.35. If any leakage above those rates, or any mechanical deformation beyond that determined to be acceptable under § 71.35 is shown, corrective action shall be taken and retesting performed.

(c) If the decay heat load from the approved contents of a package is greater than 5 watts, the adequacy of the package design to safely dissipate the design heat load shall be demonstrated by test. If the decay heat load is greater than 5 kilowatts, each package shall be demonstrated by test to safely dissipate the design heat loads. The heat source used in the test shall be the design heat load and shall be placed in the normal position for heat generation.

(d) If packaging incorporates shielding to meet dose rate limits, the effectiveness of the shielding shall be demonstrated by test. The packaging shall be loaded with the type of material for which it is designed, or an equivalent source of radiation, and the entire outer surface shall be surveyed for radiation in excess of the predicted levels.

(e) If packaging incorporates one or more valves to meet the release limits of § 71.36, the functioning of each individual valve to be used shall be demonstrated by test to function according to its design. The test shall be conducted with the valve(s) at the temperature and pressure anticipated if the package were subjected to the hypothetical accident conditions specified in Appendix B. In conducting the test, it is not necessary that the entire package be subjected to the test conditions. This test shall be repeated at intervals not to exceed one year.

(f) If packaging incorporates one or more seals in its closure system to meet the release limits of § 71.36, the functioning of each individual seal to be used shall be demonstrated by test to function according to its design. The test shall be conducted at the pressure anticipated if the package were subjected to the hypothetical accident conditions specified in Appendix B. Unless the seal is to be replaced after each use, the test shall include cycling (opening and closing) of the seal closure for a number of times appropriate for the intended use of the seal. This test shall be repeated at intervals not exceeding one year.

(g) If packaging incorporates neutron moderators or non-fissile neutron absorbers, the design efficacy of these materials shall be demonstrated by test or examination.

7. New paragraphs (g), (h) and (i) are added to § 71.54 to read as follows:

§ 71.54 Routine determinations.

Prior to each use of a package for shipment of licensed material the licensee shall ascertain that the package with its contents satisfies the applicable requirements of Subpart C and of the license, including determinations that:

* * * *

(g) Space provided for contained expansion of liquid coolant or a liquid shielding medium is adequate, auxiliary devices important to the containment of liquid coolant or a liquid shielding medium are functioning properly, and the systems for the liquid coolant and the liquid shielding medium are leaktight.

(h) The pressure relief valve or valves are operable.

(i) The package has been closed and sealed in accordance with written procedures.

8. In § 71.62 a new paragraph (c) is added and paragraph (a)(10) is amended to read as follows:

§ 71.62 Records

(a) The licensee shall maintain for a period of 2 years after its generation a record of each shipment of fissile material or of more

than a type A quantity of radioactive material, as defined in § 71.4 (q), in a single package, showing, where applicable:

* * * *

(10) Results of the determinations required by § 71.54.

* * * *

(c) The licensee shall maintain, during the life of the packaging to which they pertain, sufficient quality assurance records to furnish documentary evidence of the quality of items which have safety significance, and of services affecting such quality, including records of the results of the determinations required by § 71.53, and of monitoring, inspection and auditing of work performance during the design, fabrication and assembly of the packaging.

9. A new paragraph (c) is added to § 71.63 to read as follows:

§ 71.63 Inspections and tests

* * * *

(c) The licensee shall notify the Director of Regulatory Operations, U. S. Atomic Energy Commission, Washington, D. C. 20545, at least 45 days prior to fabrication of a package to be used for the shipment, in that single package, of radioactive material having a decay heat load in excess of 5 kW or with an operating pressure in excess of 15 psig.

10. A new Appendix E is added to read as follows:

APPENDIX E - QUALITY ASSURANCE CRITERIA FOR SHIPPING CONTAINERS FOR RADIOACTIVE MATERIAL

Introduction: In accordance with § 71.24, every applicant for a license or license amendment for use of a shipping container (packaging) is required to describe his quality assurance program, and every licensee is required by § 71.51 to establish and maintain a quality assurance program for the design, fabrication, assembly, testing, use and maintenance of each packaging. Packaging is defined in § 71.4(1), and includes all receptacles, wrappers, components, and supplementary equipment in and with which radioactive material is transported.

This appendix establishes quality assurance requirements which apply to all activities affecting the components of the packaging which are significant to safety. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining, repairing, and modifying.

As used in this appendix, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. 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.

1. ORGANIZATION

The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to other organizations the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility therefor. The authority and duties of persons and organizations performing quality assurance functions shall be clearly established and delineated in writing. Such persons and organizations shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. In general, assurance of quality requires management measures which provide that the individual or group assigned the responsibility for checking, auditing, inspecting, or otherwise verifying that an activity has been correctly performed be independent of the individual or group directly responsible for performing the specific activity.

2. QUALITY ASSURANCE PROGRAM

The licensee shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. The quality assurance program shall be documented by written procedures or instructions, and shall be carried out in accordance with those procedures throughout the period during which packaging is used. The licensee

shall identify the material and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated function of these organizations. The quality assurance program shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied. The program 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.

The licensee shall base the requirements and procedures of his quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) The importance of malfunction or failure of the item to safety;

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

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

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

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

The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

3. DESIGN CONTROL

Measures shall be established to assure that applicable regulatory requirements and the package design, as specified in the license, for those materials and components to which this appendix applies, are correctly translated into specifications, drawings, procedures and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the materials and components.

Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures shall provide for verifying or checking the adequacy of any new design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualification testing of a prototype unit under the most adverse design conditions. Design control measures shall be applied to items such as the following: criticality physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair; and delineation of acceptance criteria for inspections and tests.

Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license require Commission approval.

4. PROCUREMENT DOCUMENT CONTROL

Measures shall be established to assure that applicable requirements of this part which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee or by his contractors or subcontractors. To the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this part.

5. INSTRUCTIONS, PROCEDURES AND DRAWINGS

Activities affecting quality in the fabrication, use and maintenance of packaging shall be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. These shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Procedures shall be established for opening, loading, closing and preparing packages for transport to assure that, prior to delivery to a carrier for transport, all applicable conditions of approval, such as limits on the fissile content, weight and heat generation rate, are met and that each package is properly closed.

6. DOCUMENT CONTROL

Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another organization. Changes in the conditions specified in the license require Commission approval.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall 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. Documentary evidence that material and equipment conform to the procurement specifications shall be available prior to installation or use of such material and equipment. This documentary evidence shall be retained by or be available to the licensee and shall

be sufficient to identify the specific requirements met by the purchased material and equipment. The effectiveness of the measures for control of purchased material, equipment and services shall be assessed by the licensee or his designee at appropriate intervals.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

Measures shall be established for the identification and control of materials, parts, and components. These measures shall assure that identification of the item is maintained by heat number, part 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 shall be designed to prevent the use of incorrect or defective materials, parts and components.

9. CONTROL OF SPECIAL PROCESSES

Measures shall be established to assure 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.

10. INSPECTION

A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity

to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected. Examination, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when quality control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work shall not proceed without the consent of its designated representative, are required, the specific hold points shall be indicated in appropriate documents.

11. TEST CONTROL

A test program shall be established to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. The procedures shall include provisions for assuring that all prerequisites for the given test

have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted to maintain accuracy within necessary limits.

13. HANDLING, STORAGE AND SHIPPING

Measures shall be established to control the handling, storage, shipping, cleaning and preservation of materials and equipment to be used in packaging in accordance with instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels and temperature levels shall be specified and provided.

14. INSPECTION, TEST AND OPERATING STATUS

Measures shall be established 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 packaging.

These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent by-passing of such inspections and tests. Measures shall also be established for indicating the operating status of components of the packaging, such as by tagging valves and switches, to prevent inadvertent operation.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

16. CORRECTIVE ACTION

Measures shall be established to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

17. QUALITY ASSURANCE RECORDS

Sufficient written records shall be maintained to furnish evidence of activities affecting quality. The records shall 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 shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the licensee shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

18. AUDITS

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including re-audit of deficient areas, shall be taken where indicated.

(Secs. 53, 62, 81, 161; Pub. Law 83-703; 68 Stat. 930, 932, 935, 948, as amended (42 U.S.C. 2073, 2092, 2111, 2201).)

Dated at Washington, D. C. this 19th day of December 1973.

FOR THE ATOMIC ENERGY COMMISSION.

Gordon M. Grant
Acting Secretary of the Commission