

## NRC PUBLIC DOCUMENT ROOM

## NUCLEAR REGULATORY COMMISSION

[Docket No. PRM-71-5]

CHEM-NUCLEAR SYSTEMS, INC.

## Denial of Petition for Rule Making

The Nuclear Regulatory Commission's regulation, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions," 10 CFR Part 71, provides a general license in 10 CFR 71.12 to persons holding a general or specific Commission license, to deliver licensed material to a carrier for transport. The licensee must have a quality assurance program whose description has been submitted to and approved by the Commission as satisfying the provisions of 10 CFR 71.51. Further, if delivery is made in a package for which a license, certificate of compliance (Form NRC-618) or other approval has been issued by the NRC or the Atomic Energy Commission, the person using the package must have a copy of the specific license, certificate of compliance, or other approval authorizing use of the package and all documents referred to in the license, certificate, or other approval, as applicable (10 CFR 71.12(b)(1)(i)). Quality assurance requirements specific to the particular package design are specified in the package approval.

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## THE PETITION

By letter dated September 24, 1977, Chem-Nuclear Systems, Inc. filed with the Commission a petition for rule making (PRM-71-5) requesting that the Commission exempt the package owner from the requirements in 10 CFR

Part 71 that the package owner furnish the named user with the safety analysis report and blueprints of a particular container or package if (1) a user of the NRC approved container or package is named a user; (2) the named user is supplied with a copy of the license or certificate; and, (3) the named user is provided with specific procedures which have been developed by the owner of the container or package and filed with the NRC in accordance with the provisions of 10 CFR Part 71, Appendix E, "Quality Assurance Criteria for Shipping Packaging for Radioactive Material."

#### BASES FOR REQUEST

The bases for the request are set out by the petitioner as follows:

- a. Chem-Nuclear has been advised by NRC licensing staff that "all documents referred to in the license" would include the safety analysis report and blueprints of the particular container or package.
- b. In several cases, some of the information contained in the safety analysis and blueprints is regarded by Chem-Nuclear as proprietary. For competitive reasons, Chem-Nuclear wishes to limit the furnishing of this information to instances where such information is necessary and where adequate safeguards can be imposed.
- c. In all cases, the license or certificate issued by the NRC clearly defines the specific conditions for use of a particular container or package. Users of containers or packages have no

need for the safety analysis and blueprints. Providing the safety analysis and blueprints to the user can serve no useful purpose, but only create a large amount of additional paperwork for the owner of the container or package and adds to the risk of misuse of proprietary data.

- d. The need of the users for safety information can be met thoroughly by the specific procedures developed by the owner of the container or package and filed with the NRC in accordance with the provisions of Appendix E to 10 CFR Part 71.

#### REQUEST FOR COMMENTS ON PETITION

A notice of filing of petition for rule making was published in the FEDERAL REGISTER on October 6, 1977 (42 FR 54475). The comment period expired December 5, 1977. No comments were received in response to the notice.

#### PREVIOUS ACTION

On August 4, 1977 (42 FR 39364), the Commission amended 10 CFR Part 71 to add new Appendix E and upgraded quality assurance requirements that are the subject of the petitioner's request.

In the preamble to the final rule, the Commission discussed package manufacturers' submission of information on specific aspects of quality assurance:

The licensee who is an applicant for the package approval provides the descriptions of quality assurance programs governing the manufacturer and use of the package. If the package is approved by the Nuclear Regulatory Commission for use in the transportation of radioactive material, a package approval is issued which incorporates the

package description and identification, its safety evaluation, and a description of the applicant's specific quality assurance provisions for design, fabrication, assembly, testing, use, and maintenance of the package.

Clearly, the requirement in a package approval for a description of the applicant's specific quality assurance provisions is in addition to, and not in substitution for, the package's safety evaluation which is based on the safety analysis report of the package design or application.

#### WITHHOLDING FROM PUBLIC DISCLOSURE

Persons who submit to the Commission information believed to be privileged, confidential, or a trade secret are on notice (10 CFR 2.790) that it is the policy of the Commission to achieve an effective balance between legitimate concerns for protection of competitive positions and the right of the public to be fully apprised as to the basis for and effects of licensing actions, and that it is within the discretion of the Commission to withhold such information from public disclosure.

Under this policy and as a matter of licensing practice, the NRC staff issues package approvals on the basis of safety analysis reports prepared by applicants and refers to applications that contain blueprints. As a consequence, it is the general licensees delivering licensed radioactive material to a carrier for transport under the authority of 10 CFR 71.12(b) who must assure themselves and the NRC that the subject packages are as described in the package approvals. (The NRC must exercise its regulatory authority through its general licensees who use package approvals because the NRC has no general enforcement powers over package manufacturers or

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package owners unless they possess and use licensed radioactive material. They would, however, be subject to 10 CFR Part 21, "Reporting of Defects and Noncompliance.") An exemption from the requirements of 10 CFR Part 71 for furnishing the safety analysis reports and blueprints as requested by the petitioner could deny general licensees information essential to the safe use of packages to deliver licensed material to carriers for transport. In addition, for the public to be assured that general licensees comply with the terms and conditions of package approvals, the public must be apprised of the information in safety analysis reports and blueprints referred to in package approvals. Therefore, these documents cannot be exempt from public disclosure.

#### GROUND FOR DENIAL

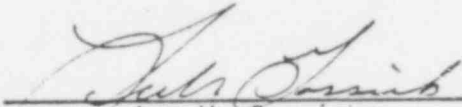
The Commission has given careful consideration to this petition for rule making (PRM-71-5) and has decided to deny the petition on the grounds that: (1) The requirement in a package approval for a description of the applicant's specific quality assurance provisions is in addition to, and not in substitution for, the package's safety evaluation which is based on the safety analysis report of the package design or application; and (2) The right of the public to be fully apprised as to the bases (e.g., safety analysis reports and blueprints) for licensing under 10 CFR 71.12(b) outweighs the concern of Chem-Nuclear Systems, Inc. for protection of a competitive position that may be set out in a safety analysis report or blueprint.

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A copy of the petition for rule making and the Commission's letter of denial are available for public inspection at the Commission's Public Document Room at 1717 H Street NW., Washington, D C.

Dated at Bethesda, Maryland this 30th day of May,  
1979.

For the Nuclear Regulatory Commission.

  
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Lee V. Gossick  
Executive Director for Operations

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

MAY 24 1978

PRM 71-5

MEMORANDUM FOR: Files

FROM: Neil S. Landau, Transportation & Product Standards  
Branch, Office of Standards Development

SUBJECT: SCHEDULING AND VALUE IMPACT APPRAISAL FOR INITIATION  
OF SD TASK TP-805-3 (PRM-71-5)

This memorandum has been prepared in accordance with the November 13, 1975 directive from R. B. Minogue on "Value Impact Appraisal and Scheduling for Task Initiation."

The proposed Scheduling of this task is directed at completing it in the shortest reasonable time, considering its priority and the press of other business. Discussions with the other NRC Offices involved in resolving the petition (NMSS, ELD, IE) indicate that no substantive disagreements exist. NRC policy will not be altered if the petition is denied as the staff recommends.

10 CFR Part 2, Subpart H, and SD Office policy mandate prompt action on petitions for rulemaking. In accordance with these policies PRM-71-5 has been discussed among the NRC staff members, who recommend denying the petition.

The petition for rulemaking submitted by John L. West on behalf of Chem-Nuclear Systems, Inc. contains two parts, both directed at protecting the competitive position of a package owner. One part asks to amend 10 CFR 71.12(b) to require that a package owner supply a generally licensed user only with necessary information which can be safeguarded from use by competitors. Currently §71.12(b) requires the owner furnish all documents referenced on the package approval. Second, the petition asks that the user's need for safety related information be met by supplying the user with specific procedures developed by the owner filed in accordance with Appendix E to 10 CFR Part 71.

Discussions with the licensing staff (FCMS, Transportation Branch) indicate that all information from a package owner required for package approval is necessary to ensure safe package use. Section 71.12(b) now requires that the owner supply all this information to users. ELD staff members have indicated that the NRC already has procedures, given in 10 CFR §2.790, for protecting proprietary information. Therefore, since the

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regulations require only necessary safety related information be supplied to package users, and since the regulations contain adequate procedures to allow the owner to safeguard proprietary information, the staff recommends denying the first part of PRM-71-5.

The request that specific procedures submitted to satisfy Appendix E of 10 CFR 71 be provided to users in lieu of the safety analysis and blueprints for the container, cannot be met. Appendix E does not require the submission of specific procedures; it only requires that an approved quality assurance program is established. Since there are no specific procedures associated with this Appendix, we must deny the portion of the petition requesting their use.

Because the staff believes that protecting the public health and safety requires a container user have available all safety related information, and that existing regulations provide adequate ways for a container owner to protect proprietary information, we see no grounds for granting this petition. The only alternative to denial is for the petitioner to withdraw the petition. He will be informed of the staff recommendation, and of the option of withdrawal.

The costs of denying this petition for rulemaking include possible costs to package owner through the loss of certain competitive advantages, and costs to owners and the NRC involved with filing and processing requests for withholding proprietary information. Benefits of denial include sustaining the current level of public health and safety, and general savings in time and money from maintaining the status quo.

Costs of granting PRM-71-5 would be NRC time and effort dealing with comments to proposed rule changes, NRC costs to change its regulations and licensing procedures, and possible costs in public health and safety. Benefits from approving the petition would consist primarily of elimination of possible harm to a package owner's competitive position. Approval could also reduce his administrative costs arising from filing requests to protect proprietary data.

*Neil S. Landau*

Neil S. Landau  
Transportation & Product Standards Branch  
Office of Standards Development

Enclosure 2

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