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

CHAIRMAN

June 6, 1997

The Honorable Richard Burr
Subcommittee on Energy and Power
Committee on Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Burr:

I am responding to your letter of May 9, 1997. In that letter, you asked about the Nuclear Regulatory Commission's (NRC) process for determining whether to withhold, from public disclosure, certain information in the spent fuel storage and transportation area, claimed by applicants as proprietary, pursuant to 10 CFR 2.790. The staff working in this area have been careful to ensure that the requirements of 10 CFR 2.790 are implemented appropriately, ensuring that a balance is maintained between the public's right to know and legitimate proprietary claims of applicants and licensees.

When the staff receives a request to withhold information, technical reviewers from the appropriate disciplines consider the information to determine whether the information claimed as proprietary, in whole or in part, meets the standards in the regulation. The owner of the information must state in an affidavit why the owner believes the information to be proprietary.

Upon concluding its review, which generally takes 30 days, the staff may decide that all, part, or none of the information submitted meets the standards set out in 10 CFR 2.790. The Office of the General Counsel reviews the staff's conclusions before they are released. If any information is to be withheld from the public, the applicant or licensee normally is asked to submit nonproprietary versions of the material to NRC, if feasible.

In your letter, you mention a specific concern about the protection of non-applicants from the disclosure of information that the non-applicants might view as proprietary to them. Our regulations at 10 CFR 2.790(b)(1) require that the entity which owns the information submit the affidavit stating why it believes the information to be proprietary. If portions of a submittal to the Commission contain information owned by an entity, other than the applicant, the other entity also is required to submit an affidavit and each entity must identify the portions of the information it owns.

As indicated in Section 2.790, it has been NRC's goal to minimize the amount of proprietary information withheld from the public. One very effective tool used in the storage and transportation area has been the requirement that useful detailed nonproprietary versions of proprietary drawings be submitted and be made available to the public, in our Public Document Room (PDR) in Washington, DC, and in a series of Local PDRs (LPDRs) around the country. For spent fuel transportation and storage casks, these drawings are often key to understanding the design. The LPDRs are generally near nuclear power plants, major fuel cycle facilities, and in several of the communities in the vicinity of Yucca Mountain, Nevada. The staff's letter documenting its decision regarding whether the information is, in fact, proprietary also is placed in

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the PDR and LPDRs. Should an applicant or licensee disagree with the staff's determination, it may withdraw the material, in which case the material would not be used to make a licensing or certification decision and would be returned to the applicant or licensee without public disclosure. See 10 CFR 2.790(c).

In the case of applications for certification of storage casks, pursuant to the general licensing requirement of Part 72, public access to all information used in the certification decision is ensured in another way. If an applicant requests certification of a storage cask for use by general licensees, a rulemaking is required to include the cask on the List of Approved Spent Fuel Storage Casks found at 10 CFR 72.214. At the time of rulemaking, all information the staff uses for making its certification decision is made publicly available, whether previously determined to be proprietary or not.

For applications for site-specific independent spent fuel storage installations pursuant to Part 72, which do not involve rulemakings, challenges to staff proprietary determinations can be made through the adjudicatory processes available via raising contentions to an Atomic Safety and Licensing Board. In this case intervenors would have the opportunity to challenge NRC proprietary determinations. If the proprietary determinations are upheld, intervenors may nevertheless gain limited access to the proprietary information for litigation on the merits by signing protective agreements or being subject to protective orders in the proceeding. See 10 CFR 2.790(b)(6). In this way, the proprietary information may be used in the adjudicatory proceeding as necessary and yet be protected from public disclosure.

Your letter also asks about design work developed by a vendor while under contract to a government sponsor. Such work is considered to be publicly available information, unless other contractual arrangements are made at the inception of a project. This policy would be followed in the spent fuel storage and transportation area if, for example, an application for certification of a transportation, storage, or dual-purpose spent fuel cask, were based on design work funded through the U.S. Department of Energy's multi-purpose canister program (now cancelled). Assuming the existence of no contractual agreement to the contrary, the staff would find all such information to be available to the public.

I am aware of no recent concerns raised by members of the public regarding excessive withholding of information by NRC in the area of spent fuel storage and transportation. Should this become a problem in the future, appropriate corrective action will be taken.

Sincerely,

Shirley Ann Jackson

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CHAIRMAN

June 16, 1998

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The Honorable Richard Burr
United States House of Representatives
Washington, D.C. 20515-3305

Dear Congressman Burr:

I am responding to your letter dated April 10, 1998, in which you expressed concerns about possible changes in the U.S. Nuclear Regulatory Commission's (NRC) 10 CFR Part 35, "Medical Use of Byproduct Material." In particular, you posed specific questions: "Has the NRC conducted any risk assessment to determine which procedures fall into low risk versus high risk categories prior to developing and publishing a proposed rule?" and " Why hasn't the Commission undertaken such activity prior to publishing a proposed rule?"

As a result of NRC's Strategic Assessment and Rebaselining efforts, the staff formed the Nuclear Byproduct Material Risk Review Group to develop a risk-informed, graded approach to regulating many material uses, including medical. The group's final recommendations are expected in the fall of 1998 and will be considered by the staff during the Part 35 rulemaking process. The Commission is currently in the rulemaking process to restructure Part 35 into a risk-informed, more performance-based regulation. In so doing, the Commission has drawn on the extensive assessments that have been conducted over the last few years, including a 1993 internal senior management review; the external review conducted by the National Academy of Sciences, Institute of Medicine; and the Commission's Strategic Assessment and Rebaselining process. On the basis of these assessments, the Commission directed the staff to proceed with rulemaking on an expedited basis and to provide increased opportunities for public input in the development process.

The program for revising Part 35 and the associated guidance has provided more opportunity for input from potentially affected parties (the medical community and the public) through formal Federal Register notices; facilitated public workshops; public meetings of the working and steering groups; meetings with medical professional societies and boards; and the public release via the Internet of draft regulatory language as a "strawman" for public comment. Over 200 comment letters have been received to date. The staff is reviewing information from all sources to become as informed on the risks of diagnostic and therapeutic procedures as possible. The draft proposed rule, which the Commission will be reviewing in June, has benefitted from these interactions and reflects numerous changes from the existing requirements. Such changes include a regulatory burden reduction for diagnostic uses including

Originated by: [DFlack, NMSS]

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requiring fewer license amendments and less prescriptive quality control requirements. After the Commission approves the proposed rule for comment, the staff will conduct additional public workshops to solicit input prior to finalizing the rule.

I trust this responds to your concerns. If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Shirley Ann Jackson