May 17, 2011

Mr. Stephen H. Shepherd
2135 Silver Tree Road
Claremont, CA 91711

Dear Mr. Shepherd:

I am responding to your correspondence submitted to the U.S. Nuclear Regulatory Commission (NRC or the Commission) on February 19, 2011, and titled "Petition for Rulemaking Pursuant to 10 CFR 2.206."

In your correspondence, you request that the NRC: (1) amend its regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1002, "Scope," to require that the limits on radiation exposure in 10 CFR Part 20, "Standards for Protection against Radiation," apply during the exposure of patients to radiation for the purpose of medical diagnosis or therapy except when alternative, medically effective, lower radiation or non-radiation-based diagnosis or therapy methods do not exist or cannot be used because of an emergency condition; (2) revise 10 CFR 20.1002 as may be needed to ensure that qualified physicians retain discretionary authority to prescribe a patient's exposure to radiation as a cure, treatment, or palliative; (3) evaluate whether 10 CFR Part 35, "Medical Use of Byproduct Material," requires revision or supplementation in a manner similar to the promulgation of Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low as is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," to ensure that the Commission's regulations will continue to achieve medical exposure to radiation that is as low as is reasonably achievable (ALARA); and (4) revise the regulatory position of Regulatory Guide (RG) 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be as Low as Reasonably Achievable," to state that an acceptable licensee ALARA program for medical exposures must include periodic evaluation and implementation of improvements in medical techniques and technology (including, but not limited to, implementation of robotic technology) as a necessary policy and program element.

Please note that your request is not a request under 10 CFR 2.206, "Requests for Action Under This Subpart." Rather, your submittal is a request for implementing a change to NRC regulations and for changes to regulatory guidance documents. Thus, we considered your request under 10 CFR 2.802, "Petition for Rulemaking," and against the criteria for requesting changes to regulatory guidance documents in RG 10.12, "Preparation of Petitions for Rulemaking under 10 CFR 2.802 and Preparation and Submission of Proposals for Regulatory Guidance Documents."

We have carefully reviewed your requests (1), (2), and (3) above and concluded that the information provided does not meet the Commission's criteria under 10 CFR 2.802(c) for a petition for rulemaking.

If you would like to further clarify your request in order to meet the criteria in 10 CFR 2.802, the request should include (1) the grounds for the request, (2) a description of your interest in the requested actions, (3) supporting documentation with respect to relevant technical, scientific, or other data involved that are reasonably available and other pertinent information necessary to support the actions sought, and (4) any specific cases of which you are aware where the current rule is deficient or needs to be strengthened.

We have also carefully reviewed your request (4) above, and concluded that the information provided does not meet the Commission's criteria in RG 10.12 for submitting proposals to revise regulatory guidance documents.

If you would like to further clarify your request in order to meet the criteria in RG 10.12, the request should include (1) a detailed analysis to ensure that the proposed alternatives will comply with NRC regulations and the requirements that public health and safety, the environment, and the common defense and security are adequately protected, and (2) an estimate of costs for the proposed alternatives compared with costs for the methods or positions in the existing regulatory guidance document.

Accordingly, if you wish the NRC to consider your request that the agency amend its regulations, you must supplement your correspondence of February 19, 2011, to meet the minimum content requirements for a petition for rulemaking. This information must be received by the NRC within 90 days of the date of this letter, or your request will not be docketed as a petition for rulemaking.

Please note that the NRC is in the process of revising RG 8.18 and will publish the final revision of this guide in a few months. The guide will be accessible through the NRC's public Web site under the Regulatory Guides document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML102350460. If your review of this guide indicates that the revision is missing guidance necessary to implement current NRC regulations, you may propose to the NRC that it consider a revision of RG 8.18. You must send such a request, meeting the criteria in RG 10.12, to Brian W. Sheron, Director, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you have any questions, please contact Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration, by calling 1-301-492-3667 (toll-free at 1-800-368-5642), or by e-mail to Cindy.Bladey@nrc.gov.

Sincerely,

/RA/

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. 10 CFR 2.802
2. Regulatory Guide 10.12

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10 CFR 2.802
Petition for Rulemaking

Enclosure 1

Regulatory Guide 10.12
"Preparation of Petitions for Rulemaking Under 10 CFR 2.802 and Preparation and Submission of Proposals for Regulatory Guidance Documents"

Enclosure 2