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Mallinckrodt Medical, Inc.

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OFFICE OF SECRETARY
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BRANCH

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #PRM-35-9
Washington, DC 20555

Dear Mr. Secretary:

Permit the following comments to serve as support for the Petition for Rulemaking filed by the American College of Nuclear Physicians (ACNP), and the Society of Nuclear Medicine (SNM). The recent revision to 10 CFR 35 regulations (April, 1987) governing the medical use of byproduct materials adversely impacts the practice of nuclear pharmacy, and ultimately compromises the character of health care. As well, these regulations restrict patient access to optimal (and cost effective) diagnostic and therapeutic procedures.

Mallinckrodt Medical, Inc., (an operating unit of Mallinckrodt, Inc.) operates a group of free standing nuclear pharmacies throughout the United States. These radiopharmacies provide diagnostic and therapeutic radioactive materials to hospitals and clinics under the authority of NRC and/or agreement state regulations. Under the present constraints of the revised 10 CFR 35 regulations, these nuclear pharmacies are unable to provide radiopharmaceuticals to physicians who prescribe usage of these drugs beyond that stated within the manufacturers package insert. As well, these regulations prohibit the radiopharmacist from reconstituting complexes that would be more useful to optimal patient diagnosis. It's clear, thus that 10 CFR 35 regulations do interfere with the practice of medicine in these circumstances. In that the NRC's Medical Policy statement clearly offers that no regulation promulgated by the NRC is intended to interfere with the practice of medicine, a revision of such regulations is warranted.

As an additional point, 10 CFR part 20 (20.1) (C) denotes that "should...maintain radiation exposures, as low as reasonably achievable." Currently the constraints of 10 CFR 35 do not permit the distribution of optimal radiopharmaceuticals to physicians, thus suboptimal studies must be performed at higher radiation doses to the patient. As well, repetition of less suitable procedures provide added radiation exposure to patients - contrary to the ALARA philosophy espoused in 10 CFR part 20.

In summary, practices which are approved under FDA regulations and state medical and pharmacy laws are unduly restricted by compliance criteria of 10 CFR 35 regulations. These constraints result in suboptimal delivery of health care, as well as compromise the implementation of nuclear medicine research. Revisions in 10 CFR 35 should be undertaken to amend this shortfall.

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The following statement of consideration is offered.

NRC regulations 10 CFR 32.72 and 10 CFR 32.73 should be revised to allow the compounding of radiopharmaceuticals under the practice of pharmacy regulations in accordance with requirements of the Food and Drug Administration and applicable state requirements.

In that free standing radiopharmacies licensed under 10 CFR 32.72 and 10 CFR 32.73 operate under licenses that have a clause more restrictive than the regulations, the license document takes precedent. In these circumstances the licenses should be amended, without charge to the licensee, to permit the reconstitution of radiopharmaceuticals in accordance with manufacturers instructions, and the compounding of radiopharmaceuticals under the practice of pharmacy regulations in accordance with requirements of the Food and Drug Administration and applicable state requirements.

In closing we urge the revision of NRC 10 CFR part 35 regulations and support the Petition for Rulemaking forwarded by the ACNP/SNM.

Sincerely,

Steve A. Spinosi
Manager, NMA Medical Physics Operations
Diagnostic Imaging Services
Mallinckrodt Medical, Inc.

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cc: P. J. Early
W. K. Fadling