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U.S. Regulatory Commission
Secretary
Washington, D.C. 20555
Attention: Docketing and Service Branch

Mallinckrodt Medical, Inc.
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RE: ACNP/SNM Petition for Rulemaking, Docket No. PRM-170-3

In response to the Nuclear Regulatory Commission's (NRC) request for public comment on a petition for rulemaking, Docket No. PRM-170-3, filed by the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) to amend its regulations governing the licensing, inspection, and annual fees charged to its licensees, the following comments are offered.

In an era where medical cost containment is of paramount importance to the nuclear medical community in order to assure the continuity of the health care services it offers, a licensee's ability to control future cost is virtually lost when faced with the exorbitant expense of the NRC's annual fees. Furthermore, the entire nuclear medicine industry has been unfairly burdened as a result of the sizable annual expenditures in order to just maintain a NRC license.

These user fees, and the propensity for additional fee increases, will continue to threaten the financial capacity of some licensees to maintain their NRC license, both of those licensees providing radiopharmaceuticals to the nuclear medicine industry and those who are practicing within the medical discipline of nuclear medicine.

As an industry leader and major supplier of radiopharmaceutical products, Mallinckrodt Medical, Inc. has also experienced the immense financial burden of maintaining radioactive materials licenses as a result of the extraordinary annual fees and fee increases over the past two years to which our research and development laboratories, manufacturing operations, and numerous nuclear pharmacy operations are subjected. The NRC user fees have pressured Mallinckrodt Medical operations to offset these astonishing expenses via product price increases to our customers, thereby further inflating cost in this already struggling healthcare economic environment.

We understand the reaction of the NRC to increase the user fees in order to recover its budgetary authority as mandated by the Omnibus Budget Reconciliation Act of 1990. However, the resulting impact to the nuclear medicine community will discourage any further growth and development of this medical discipline as a result of these costs. Since the initiation of the fee increases and the ensuing annual fees, hundreds of nuclear medicine licensees have terminated their radioactive materials license. It is only reasonable to conclude that the fees generated by the remaining licensees will not meet the anticipated budgetary requirements sought by the NRC. Do we prepare again for a larger fee increase in order for the NRC to continually reconcile the budget requirement as licensees terminate their licenses?

Any additional fee increases will only serve to further negatively impact the nuclear medicine industry as this financial accountability is anticipated to force other licensees to terminate their license. Likewise, as Agreement State legislation provides a similar mechanism for budgetary reconciliation, the anticipated result will be the same, thus, compounding the detrimental effects to the nuclear medicine community. This cyclic endeavor to raise licensing fees is not proving to be a successful option in order to meet the eminent budgetary requirement and is only resulting in the abandonment of the nuclear medicine profession.

Those licensees which remain committed and possess the financial capacity to continue the practice of nuclear medicine will be continually faced with the challenge to off-set the additional operating costs brought on by the NRC's annual users' fees which are anticipated to continue to escalate. These costs must be absorbed and ultimately they will be by the end user as a non-reimbursable expense in the practice of nuclear medicine, thereby further raising their operating costs and possibly threatening the licensees continued existence and the quality of health care provided.

The impact of these high user fees goes beyond just a direct financial impact to the nuclear medicine community. A patient, for example, quite possibly will be denied the choice to select a preferred health care facility because nuclear medicine services are no longer offered as a result of the financial requirements to maintain a radioactive materials license. Also, aside from restricting health care facility choices, the considerable cost of user fees are putting the development of the nuclear medicine industry at a disadvantage in the current competition between medical modalities.

The medical community already faces the enigma of health care cost and aggressive measures for containment. The anticipation of more licensees terminating their licenses and the likelihood of ensuing fee increases to meet budgetary commitments is a realistic dilemma having a detrimental effect on the nuclear medicine community and the health care which it provides. The amendment to the NRC regulations governing the licensing, inspection, and annual fees charged to its licensees is resulting in a substantial economic impact to the nuclear medicine community.

The petition for rulemaking filed by the ACNP/SNM for the reevaluation of user fees details specific issues deserving further consideration. In the interest of fostering continued growth in the practice of nuclear medicine, it is imperative that the NRC consider the proposal of the ACNP/SNM petition for rulemaking.

Sincerely,



Warren K. Fadling,
Director DIS/NMA

WKF/eeb