May 27, 1998

NOTE TO: Hugh L. Thompson, Jr., DEDR

FROM: Myron Pollycove, M.D.

SUBJECT: REVISION OF 10 CFR PART 35 REQUIREMENTS FOR NOTIFICATION FOLLOWING A MEDICAL EVENT

ACMUI, Barry Siegel and I agree that the current reporting requirement should be revised to require a licensee to inform only NRC of a medical event. The March 20, 1998 paper for the Commissioners from L. Joseph Callan includes the discussion that supports this revision:

> "The majority of the comments received on notification following a medical event (including those of two "patient rights advocates"), indicated that there should not be an NRC requirement for patient and/or referring physician notification in the case of a medical event. Individuals who do not favor patient notification assert that there are no other areas of medicine in which there is a Federal requirement for patient notification and that an NRC requirement for patient notification is contrary to the 1979 Medical Policy Statement [by intruding into the practice of medicine]. According to some of the ACMUI members and the NRC medical consultant advising the Working Group, patient notification of medical events should occur as part of the patient-physician "fiduciary" relationship, in which it is the "standard of care" for a physician to provide the patient with complete and accurate information. Members of the medical community have pointed out that they view the "fiduciary" relationship between the patient and physician as different from that between a licensee and an individual receiving a dose in excess of the 10 CFR Part 20 limits. In addition, some members of the medical community particularly object to the requirement, in 10 CFR 35.33(a)(4)(i)-(ii), for licensee to provide the informed individual with a copy of the licensee's report to the Commission (or a similar report,) believing that the report greatly magnifies the significance of the event when, in fact, a medical event could be of minimal safety significance."

The next paragraph of the paper cites Attachment 5 (enclosed) as supporting current requirements for patient notification. However, all examples cited in Attachment 5 are mistakes that harm the patient. Part 35, on the other hand, does not restrict "medical events" to mistakes that harm patients. The majority of previous "misadministrations" reported to the NRC did not harm the patient. The question to be considered carefully is whether more harm than benefit would result from retaining current reporting requirements in Part 35. In Attachment 5, Wu, et.al., "To Tell the Truth", JGIM:12, p.771 lists potential harms of disclosure to the patient:

> "Patients may be harmed by learning that a mistake was made in their care. The knowledge may cause alarm, anxiety, and discouragement. It may destroy patients' faith and confidence in the physician's ability to help them. Patients may become disillusioned with the medical profession in general. This may cause them to decline beneficial treatments, or decrease their adherence to beneficial treatments, or decrease their adherence to beneficial treatment regimens or habits.
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> Not all patients want to know everything about their medical care. Some would rather not be burdened with the complexities of their illness. The well-meaning disclosure of potentially serious, but inconsequential mistakes may cause unwelcome confusion. In some cases, patients may feel they would be better off not knowing that a mistake had been made in their care. As the *American College of Physicians Ethics Manual* states, "society recognizes the 'therapeutic privilege' which is an exemption from detailed disclosure when such disclosure has a high likelihood of causing serious and irreversible harm to the patient." However, the American College of Physicians offers the following caution: "On balance, this privilege should be interpreted narrowly: invoking it too broadly can undermine the entire concept of informed consent."

There are many potential benefits of disclosing *harmful* mistakes to the patient. There is widespread agreement among physicians that this is necessary. Regrettably, even current requirements for notification have not ensured patient notification of harmful mistakes.

I believe that current NRC requirements for notification would not increase such disclosures sufficiently to offset the harm noted above, particularly since the majority of "medical events" are harmless.

Enclosure: As stated