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RECORD #182

TITLE: License Requirements Which Stipulate Specific Individuals

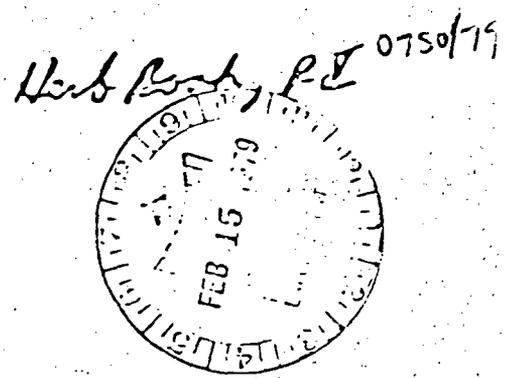
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 7 1979



MEMORANDUM FOR: A. B. Davis, Chief, FFMS Branch, Region III

FROM: L. B. Higginbotham, AD, Division of FFMSI

SUBJECT: LICENSE REQUIREMENTS WHICH STIPULATE SPECIFIC INDIVIDUALS
(F30466H3)

Your memorandum of January 17, 1979 distinguishes the RSO from the users of radioactive materials named on university, hospital and radiography licenses. While the RSO function of health and safety is important, our primary concern should be with the actual users of the material.

We have no problem with university and radiography licensees ceasing operations until they recruit and are authorized by NMSS to permit work with new users and RSOs. However, it is not the fault of NMSS if licensees fail to request amendments for new users and RSOs, and IE should not request NMSS to expedite approvals because the licensee did not submit a timely request. Any request for expediting NMSS actions should come from the licensee, and it is up to NMSS to decide whether it will expedite action on the request. With respect to what IE should do in these situations, an IAL is appropriate as an initial step.

In theory, hospitals should be handled the same way; however, we all realize that an immediate action to shut down a hospital could have an effect on patient treatment by not allowing a physician the use of certain nuclear medical tools. On the other hand, as you have indicated, if we are aware that a licensee is operating in noncompliance and something adverse happens to a patient or a worker we could be held accountable for taking no enforcement action. Consequently, in situations involving nuclear medicine programs, the decision on a course of action must be tempered with reasoned judgement. The following guidance is provided:

Cases involving unauthorized users in a nuclear medicine program should be brought to the attention of Headquarters. Each case will probably be different, so they should be handled on a case-by-case basis.

During inspections we should be primarily concerned with users of the material, and secondarily with the RSOs.

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We should try to determine if the "unauthorized user" appears to have the requisite qualifications to be named as an authorized user; if not, it would be appropriate to take action to require immediate shut down of the operation--considering carefully the impact on patient care.

If the "unauthorized user" appears qualified and the program otherwise appears to be operating within regulatory requirements, the hospital should be told to send in an application to NMSS with a request to expedite approval.

If there are no patients undergoing treatment, an immediate requirement should be imposed to cease the operation.

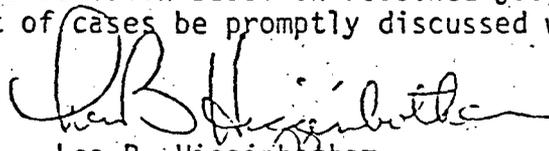
If patients are in the middle of a series of treatments, this should not be stopped (see some alternative considerations below).

New patients should not be accepted for the program; they should be referred to another hospital with a similar program.

Again, the use of an Immediate Action Letter would be appropriate for an initial action.

Further considerations should include transfer of patients undergoing treatment to another hospital, provided that the hospital is nearby, consultation between the two hospitals can be accomplished, and the patient can be moved. Another consideration should be to ascertain whether only diagnostic procedures are performed (less hazardous than therapeutic treatment) and to ascertain the probability of improper diagnoses (by an inexperienced user) and the use of improper drugs. These considerations and others that may come to mind in handling a case are important, and some of them should be discussed with the licensee.

In summary, we (1) emphasize that the cases involving a critical service to the public will require a decision based on reasoned judgement, and (2) request that these sort of cases be promptly discussed with Headquarters.



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