

NUCLEAR REGULATORY COMMISSION

REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

AUG 3 0 1988

Veterans Administration Edward Hines, Jr. Hospital ATTN: John R. Fears Director Hines, IL 60°

License No. 12-01087-07 EA 88-42

Gentlemen:

This refers to your June 6, 1988 letter in which you requested modification of the February 25, 1988 Order to Show Cause (Order). This also refers to our June 29, 1988 letter requesting additional information concerning training and qualifications of nuclear medicine residents and your response to that request dated July 29, 1988.

The basis of your request is to ensure adequate and prompt medical attention to patients needing emergency nuclear medicine scans. After discussions with my staff, our review of recent audit reports and our evaluation of your justification for the modification, I have determined, in accordance with Section IV.D. of the Order, that good cause exists to modify Section IV.A. of the Order to relax the verification requirements for emergency call-in nuclear medicine procedures performed by Mr. Mark Niemiro during non-regular hours.

Pursuant to the Order, the NRC hereby modifies the required condition of Section IV.A. as follows. The remainder of the Order remains unchanged.

- "IV.A. Mark Niemiro may only engage in activities involving the administration of NRC licensed material to humans so long as, prior to the administration, another nuclear medicine technologist or authorized user verifies in writing:
 - that the patient is the individual for whom the dosage is prescribed;
 - 2. that it is the prescribed pharmaceutical; and
 - that the dosage of the pharmaceutical is properly measured and complies with the prescription within hospital measurement error limits.

In the event of emergency (call-in) nuclear medicine procedures during non-regular hours, the requirements are hereby modified to require that the above-referenced verifications be performed by another nuclear medicine technologist, an authorized user, or the Nuclear Medicine resident on-call, provided that the resident on-call has met the training and review commitments referenced in the licensee's letters dated June 6, 1988 and July 29, 1988.

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The documentation of the verification shall include the date of each item that was verified and the signature of the person making the verification. If the verification is not contained on the standard hospital forms associated with the administration, the documentation of the verifications shall be retained as long as this requirement remains in effect."

Should you have any questions, please contact us.

Sincerely.

Enclosure: Ltrs dtd 6/6/88: 6/29/88 and 7/29/88

cc w/enclosure:

PDR SECY

CA

J. Taylor, DEDRO

A. B. Davis, RIII

J. Lieberman, OE L. Chandler, OGC

G. Cant, OE

Enforcement Coordinators

RI, RII, RIII, RIV, RV

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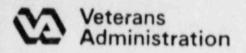
OE File

EA File

DCS

J. Fletcher, M.D.,

Veterans Administration



June 6, 1988

In Reply Refer to 578 001A- .

Mr. A. Bert Davis Regional Administrator Region 3 USNRC 799 Roosevelt Road Glen Ellyn, IL 60137

Dear Mr. Davis:

Dr. Bushnell, Acting Chief, Nuclear Medicine Service, has asked me to request that the Order to Show Cause of February 25, 1988, pertaining to Mark Niemiro, a technologist in the Nuclear Medicine Service at Hines VA Hospital be amended.

As written, that order requires verification of all radiotracer administrations given by Mr. Niemiro by either another technologist, or an authorized user. This presents the Muclear Medicine Service with a problem when scintigraphic studies are required on an emergency basis in the late evening. Under such circumstances, the technologist on call would come to the hospital and perform the radiotracer preparation and imaging study. As you may know, we have an ACOME approved residency training program in Nuclear Medicine. As part of that program residents are required to provide consultation to the referring service and review the images for emergency late night procedures. The residents are not allowed to participate in "On-call" work for approximately 2-3 months after beginning their training or until the program director decides they are reasonably and adequately prepared. Consequently, I would like to request that for emergency procedures, when Mr. Niemiro is the technologist, the Muclear Medicine resident on-call be allowed to verify and document the appropriate information regarding the radiotracer and the patient. While Muclear Medicine residents are trained in radiopharmacy and radiochemistry, Dr. Bushnell will have them review dose calibrations and the use of the dose calibrator prior to participating in any verification procedure.

I strongly urge you to consider this request in a positive manner as I believe it is responsible and will help us to avoid a significant potential problem relating to performance of on-call studies in the Nuclear Medicine Service.

Please advise us as soon as possible of your decision on this issue.

Sincerely,

JOHN R, FEARS

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"America is #1 - Thanks to our Vererans"

Veterans Administration Edward Hines, Jr. Hospital ATTN: Mr. John R. Fears, Director Hines, IL 60141

License No. 12-01087-07 EA 88-42

Gentlemen:

This refers to your June 6, 1988 letter in which you requested modification of the February 25, 1988 Order to Show Cause (Order) to allow nuclear medicine residents to verify Mr. Niemiro's measurements of the amount of radiopharmaceuticals to be delivered to patients. As stated in a prior telephone conversation between Dr. David Bushnell, Acting Chief, Muclear Medicine Service, Hines Hospital, and Dr. Bruce S. Mallett of this office on May 25, 1988, this modification could not be granted until we determine that the residents have training equivalent to that obtained by a nuclear medicine technologist or an authorized user. The training program described in your June 6, 1988 letter was too general for us to make a decision.

In order to consider your request further, please provide us with the following information:

- 1. Specific training to be received by the residents prior to their participation in the verification procedure. Your submittal should include, in addition to the areas of review, a specific number of hours involved and the number of procedures (e.g., dose preparation and dose calibrator use) performed by the resident to assure the competency of his/her verification and documentation of the required procedures specified in Section IV.A.1-3 of the Order.
- The name and qualifications of the individual(s) performing the training.

Should you have any questions in regard to the above request for additional information, please contact Mr. Robert E. Burgin (312/790-5622) of this office.

Sincerely.

A. Bert Davis Regional Administrator

cc w/ltr dtd 6/6/88: DCD/DCB (RIDS) Dr. J. W. Fletcher, Veterans Administration

bcc w/ltr dtd 6/6/88: H. L. Thompson, NMSS J. Lieberman, OE L. J. Chandler, OGC RIII ¢ Burgin/bt 06/27/88