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SACRED HEART Hospital

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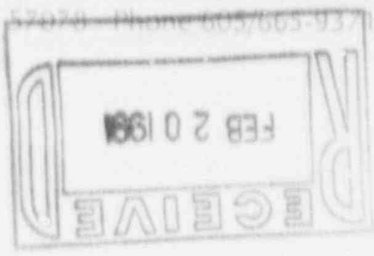

February 15, 1991

In Reference To:
License: 4 -01683-01

A. Bill Beach, Director
Division of Radiation Safety
and Safeguards
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76011

Dear Sir:

In reference to your letter of 2/1/91 the Department of Nuclear Medicine at Sacred Heart Hospital was asked to identify the reasons for the violations.

I hope the following explanation will provide the information you need:

In regards to violations #1, #3, and #4. The Department of Nuclear Medicine, in reviewing the new changes, in the NRC guidelines did address most of the new regulations. The department did update and change those policies and procedures to become in compliance. Items #1, #3 and #4 were, however, over looked.

In previous inspections by the NRC those areas were reviewe but never brought to our attention as not being within compliance with NRC standards. Since we are now aware of those standards I believe our actions taken will remedy any problems with noncompliance.

In the future the Department will review the new NRC guidelines with much more scrutiny so we will not miss any new regulations or changes in regulations. The department will also contact the NRC or an outside consultant if we do not totally understand a new regulation.

In regards to violation #2. The physicist who has been caliberating our survey instruments for the past eight years assured us that he was doing it in accordance with NRC standards. Until the survey, we did not realize he was not meeting NRC regulations. I am certain that this problem will be rectified since we are now sending our insturments to the manufacturer for caliberation. The manufacturer is sending us written proof that their caliberations will meet NRC specifications.

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In response to violation #5. In researching with the manufacturer of the Microaggregated Albumin Kits that we use we could not find anywhere, even in the package inserts, information that addressed our specific problem. The problem being on rare occasions we do not have enough activity to reconstitute the kit according to manufacturer's instructions. The department has contacted the manufacturer and they believe the new procedure is acceptable and safe to follow. Both the Medical Director of Nuclear Medicine and the R.S.O. have documented their approval of this procedure.

I am enclosing a copy of our response with this letter. I hope that we have satisfactorily responded to all of your concern. Thank you for your consideration in these matters.

Sincerely,

Kevin Fistulka, RT(R)

Kevin Fistulka, RT(R)
Director of Radiology

REPLY TO NOTICE OF N.R.C. VIOLATIONS - LICENSE #40-01683-01

In regards to violation #1 - 10 CFR 35.50 (b) (3) - Sacred Heart Hospital Department of Nuclear Medicine neglected to test the dose calibrator for linearity to below a level of 10 microcuries.

CORRECTIVE ACTIONS TAKEN: Enclosed is an amendment request to N.R.C. for license #40-01683-01 to begin the use of an Attenuator Kit. This will enable the Department of Nuclear Medicine to conduct the test over a range of activity as low as 10 microcuries. (See attached amendment request Exhibit A)

With implementation of new procedure, the Linearity testing will be scheduled on a quarterly basis.

Compliance will be achieved by February 1, 1991.

In regards to #2 - 10 CFR 35.51 (a) (2) - Sacred Heart Hospital Department of Nuclear Medicine did not calibrate the Victoreen Model 592B and Nuclear Chicago 2612 survey instruments using two separate readings on each scale of use during calibrations in October, 1988, and November, 1989, for Victoreen instruments and July, 1989, for Nuclear Chicago instruments.

Department of Nuclear Medicine failed to calibrate the Nuclear Chicago instruments such that the indicated exposure rate differed from the calculated exposure rate by less than 20% or to attach a correction chart or graph to the instrument when indicated exposure rates varied as much as 10% from the calculated value for calibrations done in June, 1988, and July, 1989.

CORRECTIVE ACTION TAKEN: The Nuclear Chicago survey instrument Model 2612 has been replaced with a Victoreen Survey and Count Meter Model 190 (See enclosed Exhibit B). Department of Nuclear Medicine has also signed an agreement to have Victoreen calibrate both the Victoreen Model 592B and Survey and Count Meter Model 190. This new agreement will assure compliance with N.R.C. Regulations.

Compliance will be achieved by February, 1, 1991.

In regards to violation #3 - 10 CFR 35.70 (h) - Sacred Heart Hospital Department of Nuclear Medicine did not retain a record of each radiation survey which included a plan of each area surveyed, the Trigger level established for each area, the detected dose rate at several points in each area expressed in mr/hr, and the instrument used to make the survey.

CORRECTIVE ACTION TAKEN: Department of Nuclear Medicine has implemented new records that include a plan of each area surveyed and trigger levels for each area have been established. Detected dose rates are now being expressed in mr/hr and we are documenting the survey instrument used. (See Exhibit C)

Compliance has bee achieved as of January 2, 1991.

In regardss to violation #4 - 10 CFR 35.92 (b) - Sacred Heart Hospital Department of Nuclear Medicine did not include the following: 1. Notation of the survey instrument used for disposal surveys. 2. Background or waste container surface dose rate at the time of disposal. The Department of Nuclear Medicine had instead recorded "Background".

CORRECTIVE ACTION TAKEN: Procedure for recording disposals has been established that includes the notation of what survey instrument is used, the background dose rate, and the container surface dose rate will be recorded in mr/hr. (See Exhibit D1 and)

Compliance has been achieved as of January 2, 1991.

In regards to violation #5 - 10 CFR 35.200 (b) - Sacred Heart Hospital Department of Nuclear Medicine failed to prepare reagent kits in accordance with the manufacturer's instructions. Section 35.200 (c) (1) specifies, in part, that a licensee may depart from the manufacturer's instructions in preparing reagent kits provided that the licensee has a written directive made by an authorized user physician that directs a specific departure for a particular patient or for a radiopharmaceutical.

The manufacturer's instructions for the macroaggregated albumin reagent (MAA) used by the licensee specifies that each vial be reconstituted with 20-50 millicuries of technetium-99m and that the recommended number of particles per single injection be 200,000-700,000.

During the period August through October, 1990, the Sacred Heart Hospital Department of Nuclear Medicine had reconstituted the reagent kit using less than 20 millicuries of technetium-99m and had injected as many as 2 million particles per single injection.

CORRECTIVE ACTION TAKEN: A new procedure has been implemented to insure patients receive a maximum of 700,000 particles per injection. Each vial contains from 3.6-6.5 million particles. Prior to use, in uses where our total activity available is below 20 mCi, the vial will be reconstituted with 5 ml of normal saline. Then, depending on the amount of activity available, a fraction of the 5 ml will be withdrawn and discarded to match the fraction of activity we have that is below 20 mCi. For example, if we only have 15 mCi of activity which is 25% below the 20 mCi minimum then 25% (or 1.25 ml) of the reconstituted 5 ml solution will be withdrawn and discarded. The available activity will be injected into the remaining solution and the total volume calculated. A fraction of this will be used to give a dose of 3-5 mCi and the range of particles should be 200,000-500,000 per injection. For purposes of calculation, the vial will be assumed to have 5 million particles initially. (A chart will be available to guide the technologist in this procedure. See Exhibit E.)

Compliance has been achieved as of January 2, 1991.