

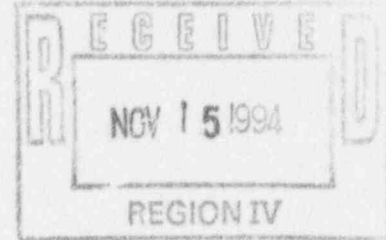


West Park  
Hospital

NOVEMBER 8 1994

FROM: WEST PARK HOSPITAL  
LICENSE 49-18P30-01  
DOCKET 030-14895

TO: NRC



NOTICE OF CORRECTIVE ACTION

DURING AN NRC INSPECTION CONDUCTED ON AUGUST 3 TWO VIOLATIONS OF NRC REQUIREMENTS WERE IDENTIFIED. FOLLOWING IS A PLAN OF CORRECTIVE ACTION AND ITS IMPLEMENTATION.

A. 10 CFR 35.32(a) STATES EACH LICENSEE MUST ESTABLISH AND MAINTAIN A WRITTEN QUALITY MANAGEMENT PROGRAM TO PROVIDE HIGH CONFIDENCE THAT BYPRODUCT MATERIAL OR RADIATION FROM BYPRODUCT MATERIAL WILL BE ADMINISTERED AS DIRECTED BY THE AUTHORIZED USER. OUR QMP DID NOT INCLUDE OUR STRONTIUM-90 EYE APPLICATOR. IT IS INCLUDED IN THE NEW QMP PROGRAM WHICH HAS ALSO BEEN FORWARDED TO OUR DISTRICT.

THE EYE APPLICATOR WAS OVERLOOKED ONLY DUE TO CARELESSNESS ON OUR PART. THE PHYSICIAN AND OPERATING ROOM WERE INFORMED OF NEW REGULATIONS, HOWEVER, THIS WAS NOT INCLUDED IN OUR QMP. THE CORRECTIVE STEPS INCLUDE REWRITING THE QMP, NOTIFICATION OF PHYSICIAN AND OPERATING ROOM. IN THE FUTURE UPON ITS USE, WE WILL ALSO BE CONTACTED TO ASSURE THE PROPER SEQUENCE OF EVENTS ARE BEING FOLLOWED. THE DATE OF COMPLETE COMPLIANCE WAS AUGUST 31, 1994.

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## West Park Hospital

B. 10 CFR 35.70 THIS REQUIRES THAT A LICENSEE CONDUCT THE WEEKLY SURVEYS FOR REMOVABLE CONTAMINATION OF ALL AREAS WHERE RADIOPHARMACEUTICALS ARE ROUTINELY PREPARED FOR USE , ADMINISTERED, OR STORED. OUR FACILITY WAS USING AN ALTERNATE METHOD OUTLINED TO US BY OUR CONSULTANT. WE WERE USING THIS METHOD BECAUSE OF THE RELATIVELY SMALL QUANTITIES OF RADIOACTIVE MATERIALS USED AT OUR HOSPITAL. THE FOLLOWING IS THE PROCEDURE:

- a. WIPE TEST SAMPLES WILL BE ASSAYED BY HOLDING THE SMEAR IMMEDIATELY ADJACENT TO THE OPEN WINDOW OF OUR LOW LEVEL SURVEY METER. CARE WILL BE TAKEN TO AVOID CONTAMINATION OF THE PROBE.
- b. THE SMEAR WILL BE HELD ADJACENT TO THE PROBE FOR APPROXIMATELY 30 SECONDS TO ENSURE THAT ANY CONTAMINATION OVER NORMAL BACKGROUND LEVELS WILL BE DETECTABLE.
- c. NORMAL BACKGROUND LEVELS AT OUR HOSPITAL ARE APPROXIMATELY .05 MR/HR. ANY WIPE TEST READING OVER THAT LEVEL WILL INDICATE THE NEED TO DECONTAMINATE THE TESTED AREA.

BECAUSE OF THIS VIOLATION, IF THIS PROCEDURE IS FOUND TO BE UNACCEPTABLE WE WILL HAVE TO PURCHASE A NEW PIECE OF EQUIPMENT. THIS WILL NEED TO BE BUDGETED FOR AND THESE FUNDS WOULD BE AVAILABLE TO US IN JULY 1995, OR SOONER IF DEEMED NECESSARY BY THIS REGULATING BODY.

THANK YOU FOR YOUR TIME.

SINCERELY,

GARY BISHOP, CEO  
707 SHERIDAN AVENUE  
WEST PARK HOSPITAL  
CODY, WY 82414

QUALITY ASSURANCE FORM FOR THERAPEUTIC ADMINISTRATIONS AND  
SODIUM IODIDE I-125 OR I-131 DOSES ABOVE 30 MICROCURIES  
(INCLUDES STRONTIUM 90)

This survey is to ensure that all requirements of the Nuclear  
Medicine Quality Management Program are followed and to evaluate  
the Quality Management Program.

PATIENT NAME: \_\_\_\_\_

NAME OF THERAPY OR RADIOIODINE PROCEDURE ORDERED:

\_\_\_\_\_ DATE: \_\_\_\_\_

- A. Written Directive Present: Circle One YES NO
- B. Patient Identification By Name: Circle One YES NO
- C. Comparison Identification: Circle One
- |                   |                     |                           |
|-------------------|---------------------|---------------------------|
| 1. Birth Date     | 2. Address          | 3. Social Security Number |
| 4. Signature      | 5. Bracelet         | 6. Hospital ID Card       |
| 7. Insurance Card | 8. Driver's License |                           |
- D. Dosage Within 20% of Written Directive: Circle One  
YES NO If No Explain \_\_\_\_\_
- E. Dose Administered \_\_\_\_\_ I-125 \_\_\_\_\_ I-131  
\_\_\_\_\_ Other \_\_\_\_\_
- F. Route of Administration \_\_\_\_\_
- G. Was There Any Deviation From the Written Directive. Circle One  
YES NO If Yes Explain \_\_\_\_\_

Form Completed BY: \_\_\_\_\_ Date: \_\_\_\_\_  
Sign and Print Last Name

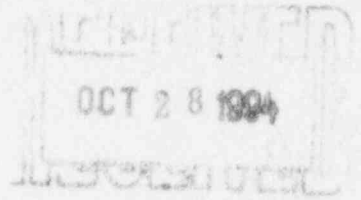


UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-8064

OCT 24 1994



West Park Hospital  
ATTN: Gary Bishop, Administrator  
707 Sheridan Avenue  
Cody, Wyoming 82414

SUBJECT: NRC INSPECTION REPORT 030-14695/94-01 (NOTICE OF VIOLATION)

Gentlemen:

This refers to the routine, unannounced inspection conducted by Mr. Robert A. Brown of this office on August 3 through September 12, 1994. The inspection included a review of activities authorized by Byproduct Materials License 49-18230-01. At the conclusion of the inspection, the findings were discussed with members of your staff.

The inspection was an examination of activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observation of activities in progress.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice).

As discussed during the telephonic exit interview conducted by Mr. Robert A. Brown of this office with Mr. Gary Bishop of your staff on September 12, 1994, 10 CFR Part 35 was revised in January 1992 to require that NRC medical licensees establish and maintain a written Quality Management Program (QMP) to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by an authorized user. Although West Park Hospital developed and submitted a QMP to the NRC in January 1992, it did not include provisions for the use of a strontium-90 eye applicator used to administer therapeutic treatments to patients. Thus, West Park Hospital's QMP failed to meet the primary objective of providing high confidence that these treatments would be administered as directed by an authorized user.

While the NRC considers this violation a significant regulatory concern, we acknowledge that in no case did it appear that this violation affected, or resulted in errors in, the treatment of patients. It was noted that:

- (1) since January 1992, only one treatment using the strontium-90 eye applicator had occurred,
- (2) the dose was recorded on the patient chart, and
- (3) there were surgery protocols in place to verify the identify of the patient prior to treatment.

Therefore, although the failure to establish a QMP for each medical use of byproduct material specified in 10 CFR 35.32 may be considered for escalated enforcement in accordance with NRC's Enforcement

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Policy (10 CFR Part 2, Appendix C), given the specific circumstances described above, the NRC has categorized this issue as a Severity Level IV violation.

A second violation was identified involving a failure to conduct weekly removable contamination surveys in a manner which ensured that the limits of 10 CFR 35.70(f) were met. This violation is described in the enclosed Notice.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Also reviewed were the actions you had taken with respect to the violations observed during our previous inspection conducted on November 20, 1991. The inspection verified that the corrective actions for these violations had been implemented as stated in your report, dated January 15 and February 16 and 24, 1992, and that these actions were effective.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

Should you have any questions concerning this letter, please contact Ms. Linda L. Kasner at (817) 860-8213.

Sincerely,



Samuel J. Collins, Director  
Division of Radiation Safety  
and Safeguards

Docket: 030-14695  
License: 49-18230-01

Enclosure:  
Appendix - Notice of Violation

cc:  
Wyoming Radiation Control Program Director

APPENDIX

NOTICE OF VIOLATION

West Park Hospital  
Cody, Wyoming 82414

Docket: 030-14695  
License: 49-18230-01

During an NRC inspection conducted on August 3 through September 12, 1994, two violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. 10 CFR 35.32(a), which became effective January 27, 1992, states, in part, that each licensee must establish and maintain a written Quality Management Program (QMP) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The QMP must include written policies and procedures to meet specific objectives for, among other things, any brachytherapy radiation dose.

Contrary to the above, between January 27, 1992, and August 3, 1994, the licensee administered a brachytherapy radiation dose, using a strontium-90 eye applicator, to a patient and as of August 31, 1994, the licensee had not established and maintained a written QMP to provide high confidence that radiation from the byproduct material noted above would be administered as directed by the authorized user.

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 35.70(f) requires that a licensee conduct the weekly surveys for removable contamination of all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored, required by 10 CFR 35.70(e), so as to be able to detect contamination on each wipe sample of 2,000 disintegrations per minute.

Contrary to the above, as of August 3, 1994, the licensee did not conduct weekly surveys for contamination in areas where radiopharmaceuticals were routinely prepared for use, administered, or stored in such a manner so as to be able to detect contamination on each wipe sample of 2,000 disintegrations per minute.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, West Park Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the

results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas  
this *24<sup>th</sup>* day of October 1994