NOTICE OF VIOLATION

Tri-State Medical Center
Huntington, West Virginia

Docket No. 999-90002
EA 98-506

During an Office of Investigations investigation conducted on November 18, 1997, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

> 10 CFR 35.11 requires, in part, that a person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.
>
> Contrary to the above, between approximately January 15, 1996, and August 29, 1997, Tri-State Medical Center acquired, received, possessed, and used byproduct material for medical use without and thus, not in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of 10 CFR 35.11.

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

Pursuant to the provisions of 10 CFR 2.201, Tri-State Medical Center 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 II, 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. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to 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.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001, and the Director, Enforcement and Investigations Coordination Staff, Region II, Atlanta, GA 30303-3415.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must

specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated at Atlanta, Georgia
this 30 day of December 1998

SYNOPSIS

The Office of Investigations (OI), U.S. Nuclear Regulatory Commission (NRC), Region II, initiated this investigation on October 16, 1997, to determine whether Now Care, Inc. (NCI), without authorization, transferred control of its license to another business entity.

Based upon evidence developed during this investigation, OI determined NCI willfully transferred control of its NRC license, without authorization, to Tri-State Medical Center (TSMC), Huntington, West Virginia. Further, NCI willfully failed to notify the NRC of its March 1996 bankruptcy.

Additionally, OI determined TSMC willfully received, possessed, and used byproduct material without a specific or general license issued by the NRC.

~~NOT FOR PUBLIC DISCLOSURE WITHOUT APPROVAL OF FIELD OFFICE DIRECTOR, OFFICE OF INVESTIGATIONS, REGION II~~ Approved for Release on December 18, 1998

EA 98-506

Tri-State Medical Center
ATTN: Kirti K. Jain, M.D.
Administrator
2628 5th Avenue
Huntington, WV 25704

SUBJECT: NOTICE OF VIOLATION (OFFICE OF INVESTIGATIONS (OI) REPORT NO. 2-1997-026 - NOW CARE INC.)

Dear Dr. Jain:

This refers to the OI investigation conducted on November 18, 1997, at your former facility at 611 Seventh Avenue, Huntington, West Virginia. The purpose of the investigation was to determine the circumstances associated with the apparent transfer of control of NRC License No. 47-25152-01 from Now Care, Inc. to Tri-State Medical Center (TSMC) on or about January 15, 1996. A copy of the Synopsis from the OI report is enclosed.

Based on the results of the investigation, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notices of Violation (Notice). The violation cited against TSMC deals with the possession and use of byproduct material for medical use without a specific license issued by the Commission. This is a matter of concern because the possession and use of byproduct material for medical use by unlicensed entities could result in the improper administration of this material to patients and result in undue, and potentially serious personnel exposures and subsequent harm to the exposed individuals. This violation was considered for escalated enforcement action as described in the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) NUREG-1600, but after review of the circumstances regarding this violation, we determined that escalated enforcement was not warranted due to the safety significance of the violation. Safety significance involves the consideration of the actual safety consequence, the regulatory significance, and the potential safety consequence. In this case we determined that the actual and potential safety consequences of this unlicensed use of byproduct material were low because the medical use of byproduct material was performed by qualified individuals and the materials were otherwise appropriately controlled. However, in the future, if a similar violation is identified, we may take escalated enforcement action.

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 also address the actions you will take to ensure that you are adequately informed of the regulatory requirements associated with the medical use of licensed material and that you will take the appropriate actions to ensure compliance with these requirements. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," is