

NOTICE OF VIOLITION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

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License No. 34-02867-01
EA 83-28

As a result of a routine safety inspection conducted on February 16, 1983, it appears that violations of NRC requirements have occurred in that iodine-131 diagnostic capsules were mailed to patients' homes in violation of NRC and U.S. Postal regulations. In addition, in violation of the license, the patients self-administered the capsules in their homes - locations not authorized by the license. These violations are of concern because they could have resulted in unnecessary radiation exposure to members of the general public.

In order to emphasize the importance of this matter and the need to ensure effective control over the licensed program, NRC proposes to impose a civil penalty in the amount of Five Hundred Dollars. In accordance with the NRC Enforcement Policy (10 CFR Part 2, Appendix C) 47 FR 9987 (March 9, 1982), and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended ("Act"), 42 U.S.C. 2282, PL 96-295, and 10 CFR 2.205, the particular violations and associated civil penalty are set forth below:

I. CIVIL PENALTY VIOLATION:

10 CFR 71.5 "Transportation of Licensed Material" requires licensees to comply with the applicable requirements of the Department of Transportation regulations, and with the U.S. Postal Service regulations in the Postal Service Manual (Domestic Mail Manual), section 124.3.

Section 124.3 of the Domestic Mail Manual states, in paragraph .37, that any package of radioactive materials which is required to bear the Department of Transportation's Radioactive White-I, Radioactive Yellow-II, or Radioactive Yellow-III label is nonmailable.

License Condition No. 10 requires that licensed material be used only at two locations in Toledo, Ohio.

Contrary to the above requirements, in 1982, diagnostic iodine-131 capsules (averaging 51 microcuries per capsule) were mailed to about 22 patients and on February 16, 1983, two capsules containing approximately 150 microcuries each of iodine-131 were mailed to patients resulting in licensed material being used at unauthorized locations. In addition, a survey on the surface of a mailing envelope containing a similar capsule showed an average radiation level of 18.5 mR/hr. Such an envelope would require a Radioactive Yellow-II warning label due to the radiation level and would not be mailable.

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This is a Severity Level III violation (Supplements V and VI).
(Civil Penalty - \$500)

II. VIOLATION NOT ASSESSED CIVIL PENALTY

License Condition No. 14 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in applications dated May 22, 1978 and August 26, 1978, and letter dated September 29, 1978.

In the letter dated September 29, 1978, the licensee stated that he will have his survey instruments tested and recalibrated once a year.

Contrary to the above requirement, the licensee's Nuclear Chicago, Model 2610A, Serial No. 1791 survey instrument has not been calibrated since June 1979, a period exceeding one year.

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

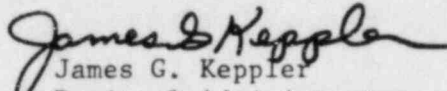
Pursuant to the provisions of 10 CFR 2.201, John R. Sinkey, M.D. is hereby required to submit to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, IL 60137, within 30 days of the date of this Notice a written statement or explanation, including for each alleged violation: (1) admission or denial of the alleged violation; (2) the reasons for the violation, if admitted; (3) the corrective steps which have been taken and the results achieved; (4) the corrective steps which will be taken to avoid further violations; and (5) the date when full compliance will be achieved. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, John R. Sinkey, M.D. may pay the civil penalty in the amount of \$500 or may protest imposition of the civil penalty, in whole or in part, by a written answer. Should John R. Sinkey, M.D. fail to answer within the time specified, the Director, Office of Inspection and Enforcement will issue an Order imposing the civil penalty proposed above. Should John R. Sinkey, M.D. elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, such answer may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty. In requesting mitigation of the proposed penalty, the five factors contained in Section IV(B) of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation

in reply pursuant to 10 CFR 2.201, but may incorporate statements or explanations by specific reference (e. g., citing page and paragraph numbers) to avoid repetition. John R. Sinkey's attention is directed to the other provisions of 10 CFR 2.205, regarding the procedures for imposing a civil penalty.

Upon failure to pay any civil penalty due, which has been subsequently determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C 2282.

FOR THE NUCLEAR REGULATORY COMMISSION


James G. Keppler
Regional Administrator

Dated at Glen Ellyn, Illinois
this 20 day of April 1983