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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

APR 21 1983

30-2710

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

John R. Sinkey, M.D.
4346 Secor Road
Suite 102
Toledo, OH 43623

Dear Dr. Sinkey:

This refers to the routine safety inspection conducted by S. R. Lasuk of our staff on February 16, 1983, of activities authorized by NRC Byproduct Material License No. 34-02867-01. The results of the inspection were discussed on March 24, 1983, during an enforcement conference in your office between you and Messrs. J. R. Miller and S. R. Lasuk of the NRC staff.

The inspection showed, among other things, that you mailed licensed material (iodine-131 diagnostic capsules) to patients in violation of NRC and U.S. Postal Service regulations. In addition, in violation of your license, the patients self-administered the capsules in their homes - locations not authorized by your license. We are especially concerned that such transfers, which were made in envelopes without labels or markings to indicate the radioactive contents, may have resulted in unnecessary radiation exposure to mail handlers and to members of the patients' households.

To emphasize the importance of this matter and the need to ensure effective control of your licensed program, we propose to impose a civil penalty for the item set forth in Section I of the Notice of Violation which is enclosed with this letter. The violations in the Notice have been categorized at the severity levels in accordance with the NRC Enforcement Policy published in the Federal Register, 47 FR 9987 (March 9, 1982). In assessing this civil penalty, we gave consideration not only to the circumstances of the violations described above, but also to the matters that were discussed during the March 24, 1983 enforcement conference. After consultation with the Director of the Office of Inspection and Enforcement, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the of amount Five Hundred Dollars.

You are required to respond to this letter and should follow the instructions in the Notice when preparing your response. You should give particular attention to those actions that you will take to ensure compliance with NRC requirements. Your reply to this letter and the results of future inspections will be considered in determining whether further enforcement action is appropriate.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

8304260159 830421
NMS LIC30
34-02867-01 PDR

John R. Sinkey, M.D.

APR 21 1983

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the 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, PL 96-511.

Sincerely,

Original signed by
James G. Keppler

James G. Keppler
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

RIII
Miller/jp
4/19/83

RIII
Hind
4/19/83

RIII
Lewis
4/19

RIII
Schultz
A-20-83

RIII
Davis
4/20

RIII
Keppler
4/20/83

APR 21 1983

John R. Sinkey, M.D.

Distribution

PDR

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JCrooks, AEOD

BHayes, OI

JCummings, OIA

DNussbaumer, OSP

JKeppler, RIII

Enforcement Coordinators

RI, RII, RIII, RIV, RV

EDO Rdg File

IE/ES Chron

IE/EA File

DCS

Department of Health

ATTN: Robert M. Quillen

Radiological Health Program

246 North High Street

P. O. Box 118

Columbus, OH 43216