

2/14/83

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ADMINISTRATIVE LAW JUDGE

In the Matter of

ISOTOPE MEASUREMENTS LABORATORIES,
INC.
3304 Commercial Avenue
Northbrook, Illinois 60062

)
) Docket No. 30-4291
) License No. 12-13568-01
) (EA 81-32)
)

STAFF COMMENTS ON DRAFT MEMORANDUM AND
ORDER TERMINATING CIVIL PENALTY PROCEEDING

On January 27, 1983, the Administrative Law Judge distributed a draft "Memorandum and Order Terminating Civil Penalty Proceeding" for the parties' comments. The memorandum and order would approve, subject to an additional condition, the settlement agreement submitted jointly by the Staff and Isotope Measurements Laboratories, Inc. (IML) on November 29, 1982. The Staff's proposed revisions are attached to this pleading. Although most of the revisions are self-explanatory, the Staff wishes to note its reasons for the following two suggested revisions.

Page 6, change "transferee" to "transferor":

This change is made to conform this sentence to the other portions of the condition. In the absence of this conforming change, the condition would merely restate IML's existing obligation under 10 C.F.R. 30.41(c) to verify that the recipient of byproduct material is authorized to receive it, rather than stating the new condition. See also 10 C.F.R. 30.41(d)(3).

Page 7, substitute "Both parties agree that the practice in dispute did not endanger health under these particular circumstances" for deleted language:

The Staff would delete the reference to IML's averment that it carried out the unlawful transfers for altruistic and not financial reasons. The Staff does not have sufficient information to either agree or disagree with IML's averment. While it is worth noting in general terms that the transfers at issue here did not endanger public health and safety under these particular circumstances, a reference to IML's averred motivation for the transfers is unnecessary for proper disposition of this proceeding.

The settlement agreement, and the Administrative Law Judge's proposed additional condition, should provide strong assurance that IML will not lightly disregard the terms of its license and the Commission's regulations in the future, and the Staff urges that the Administrative Law Judge adopt the draft memorandum and order as revised by the Staff.

Respectfully submitted,



Stephen G. Burns
Counsel for NRC Staff

Attachment:
Marked draft

Dated at Bethesda, Maryland
this 14th day of February, 1983.

UNITED STATES OF AMERICA

DRAFT FOR COMMENT

NUCLEAR REGULATORY COMMISSION

Before Administrative Law Judge
Ivan W. Smith

In the Matter of)	
)	
ISOTOPE MEASUREMENTS LABORATORIES, INC.))	License No. 12-13568-01
3304 Commercial Avenue)	(EA-8 2 -32)
Northbrook, Illinois 60062)	<u>1</u>

MEMORANDUM AND ORDER TERMINATING CIVIL PENALTY PROCEEDING

Isotope Measurements Laboratories, Inc. (IML), Northbrook, Illinois is the holder of an NRC byproduct material license which authorizes it to receive packaged radiopharmaceuticals from licensed suppliers and deliver them to licensed recipients.

Pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2282), and 10 CFR 2.205, on May 28, 1981, the Director of the Office of Inspection and Enforcement served on the Licensee a Notice of Violation and Proposed Imposition of Civil Penalty, which alleged that the Licensee was receiving and distributing radiopharmaceuticals without specific authorization. After considering the Licensee's response, the Director issued an Order Imposing a Civil Penalty on October 22, 1981 in the total amount of \$5700.00. 46 Fed. Reg. 53548 (October 29, 1981). On November 2, 1981, the Licensee

requested a hearing which was authorized by the Commission's Notice of Hearing dated January 5, 1982.

No hearing was conducted, however, because counsel for IML and the NRC Staff submitted a joint motion to terminate the proceeding on November 29, 1982. The motion is founded upon an agreement in which IML admits certain facts, the parties agree to settle the matter in the compromised amount of \$4000, and IML agrees to cease and desist from receiving radioactive material from any supplier not authorized to distribute it in accordance with 10 CFR 32.72. The agreement recites that IML neither admits nor denies that its activities did not comply with NRC "requirements". Pursuant to 10 CFR 2.203 the compromise of a civil penalty is subject to the approval of the designated presiding officer who, under the express provision of that section, must accord due weight to the position of the Staff.

I approve the settlement but several aspects of the Notice of Violation, the Licensee's answer, and the compromise agreement present unusual issues relating to the integrity of the NRC enforcement process. Therefore, the material aspects of the alleged violation and the reasons for approving the compromised settlement should be set out on the public record of this proceeding.

The facts of the controversy are not in dispute. ^{Technetium} ~~Technetium~~-99m (Tc99m) is a byproduct material with a six-hour half life used in a diagnostic radiopharmaceutical. Because of the short half life some

hospitals, in this case Mason District and Pana Community, are permitted to possess and to use a molybdenum/^{technetium}~~technetium~~-99m (Mo/Tc99m) generator which will permit the eluting or "milking" of Tc99m as needed. NRC regulations, 10 CFR 32.72, require a license to manufacture and distribute radiopharmaceuticals containing byproduct material for use by persons such as physicians licensed for that purpose. Generally hospitals such as Mason District and Pana Community do not possess licenses to manufacture and distribute radioactive material, i.e., they are not licensed radiopharmaceutical suppliers. Mason District and Pana Community did not, in fact, possess such licenses during the time relevant to this proceeding. As noted, IML's license, as pertinent, is limited to receiving radiopharmaceuticals from licensed suppliers.

Prior to August 8, 1980 IML received radiopharmaceuticals from hospitals not licensed under 10 CFR 32.72 and transferred them to other hospitals. On August 8, 1980, Mr. Keppler, Director of NRC Region III sent a letter to IML stating:

With regard to the matters discussed, we understand that you have undertaken or will undertake the following action by August 9, 1980: Discontinue all transfers and deliveries of byproduct material from facilities that are not licensed by the Nuclear Regulatory Commission for distribution under 10 CFR 32.72.

In a telephone conference with the parties on January 24, 1983, I confirmed that Mr. Keppler's letter was a reference to the same practice which has given rise to this civil penalty proceeding.

Nevertheless beginning on August 11, 1980, IML began a series of 21 pickups (on 19 penalty days) of radiopharmaceuticals containing Tc99m from Mason District and Pana Community Hospitals and delivered them to other hospitals. This activity resulted in the imposition of the civil penalty by the Director of I&E.

IML defended on several bases. First it states: "Milking the generator does not constitute 'manufacture' of the eluate. Therefore, a hospital may ship eluate without first obtaining a 10 CFR 32.72 license."¹ This answer did not convince the Staff, nor does it convince me, because it does not address the fact that 10 CFR 32.72 specifically covers the distribution as well as the manufacture of radiopharmaceuticals.

IML also states that Mr. Keppler's letter referring to the distribution of byproduct materials under 10 CFR 32.72 could not mean what it seems to say because that interpretation would prevent the transport of standard sources for calibration purposes. The better reasoning, according to IML, is that IML was ordered to "[n]ot distribute radiopharmaceuticals which contain byproduct material unless the radio-

¹ Answers to Order to Show Cause and to Notice of Imposition of Civil Penalty, June 24, 1981.

pharmaceutical was manufactured by a person licensed under 10 CFR 32.72."²

Apparently IML's logic is that the license to manufacture the Mo/Tc99m generator carried with it the license to distribute the eluate since eluting the generator is not a separate manufacturing step. But the logic fails because IML received the Tc99m from an unlicensed hospital, not from the licensed manufacturer/distributor of the generator/eluate. In any event, by advancing this argument IML ignores the central concern that it had entered into an understanding with the Region III office that accepting radiopharmaceuticals from hospitals not licensed under 10 CFR 32.72 was a violation of the terms of IML's license and that the practice would stop. There was no basis to read Mr. Keppler's letter differently because it was that very practice which was involved.

Because of IML's apparent difficulty in interpreting and complying with the terms of its license and complying with its understanding with Region III and because of its continued unwillingness to acknowledge that its activities were not in compliance with the regulations, the cease-and-desist terms of the settlement agreement seemed insufficiently specific to provide assurance that the practice would end.

² Answer to Show Cause Order.

IML's commitment was:

3. IML agrees that it will cease and desist from any future receipt of radioactive material from persons who are not authorized as radiopharmaceutical suppliers to distribute material in accordance with 10 CFR 32.72, and from making further distribution of such material without a license under 10 CFR 32.72. In this regard, IML further acknowledges that hospitals such as Mason District Hospital and Pana Community Hospital are generally not authorized to distribute radioactive material as licensed radiopharmaceutical suppliers in the absence of an express license condition permitting such distribution.

Under IML's theory that the manufacturer of the Mo/Tc99m generator was the respective licensed distributor, the very practice now penalized would be permissible under the cease-and-desist agreement. Therefore I requested and received a further commitment from IML as a condition of approving the compromised settlement. Added to paragraph 3 will be:

Upon receiving radiopharmaceuticals containing byproduct material, IML shall make an affirmative inquiry and receive a definite demonstration that the person supplying the material is authorized to do so by a license issued under 10 CFR 32.72, or, in the case of a hospital, that the hospital has the functional equivalent of a Section 32.72 license. The methods set out under 10 CFR 30.41 to verify the authority of a recipient, when applied to a supplier, would be an appropriate demonstration. Provided however, IML may continue to act upon emergency requests for the transfer of radiopharmaceuticals under a temporary authority granted by the NRC to a person authorized to receive radiopharmaceuticals pursuant to 10 CFR 35.14. When IML relies upon an oral certification from a ~~transferee~~ *transferor* under emergency authority from the NRC, that oral certification must be confirmed in writing within ten days.

Both parties agree that the practice in dispute did not endanger health
The amount of the penalty as compromised appears reasonable. ^{under these circumstances,} The

Staff reports that its belief that IML's activities were in knowing violation of its understanding with Region III was considered in calculating the penalty. The penalty is in accordance with the Staff guidelines in effect during the time of the relevant activities, and approximately the same result would be achieved under the Commission's General Statement of Policy and Procedure for Enforcement Actions, 47 Fed. Reg. 9987, March 9, 1982. ~~Also, I have accepted as true IML's statement that the practice did not endanger health and that the challenged transfers were carried out for altruistic, not financial reasons.~~

Accordingly in consideration of the settlement agreement as modified I approve the imposition of the compromised civil penalty and terminate the proceeding.

Ivan W. Smith
ADMINISTRATIVE LAW JUDGE

Bethesda, Maryland

/ DATE /

