



May 7, 1984

Mr. Bernard Singer, Chief
Material Certification & Procedure Branch
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY NMSS
7915 Eastern Avenue
Silver Springs, Maryland 20910

Dear Mr. Singer:

This letter will refer to our discussion during my May 2, 1984, visit to your office. As you will recall, this visit was stimulated by Mr. Richard Cunningham's Nuclear Regulatory Commission (NRC) memorandum of April 3, 1984 (copy attached) to Mr. John Jicha of the Department of Energy (DOE) on the subject of the requested certification of sealed rods containing cesium-137 chloride extracted and encapsulated at the Hanford Reservation Waste Encapsulation and Storage Facility (WESF). The intent of the DOE requested certification is to expedite the licensing process for irradiators using these cesium-137 containing capsules as the radiation source elements for treating a variety of materials.

During my visit, I advised you that our company is in the advanced stages of design and construction of a cesium-137 based medical products irradiator to be located in Northglenn, Colorado. It will serve the sterilization needs of American Precision Plastics, a Division of American Hospital Supply Corporation, and other Denver area medical products manufacturers. This project was undertaken in full knowledge of the Colorado Department of Health, Radiation Safety Division. We have been working closely with their representatives in the matter of licensing of the facility since Colorado is an NRC Agreement State.

I further advised you that a valid order for 12.0 MCi of cesium-137 chloride has been placed with the DOE Isotope Sales Office, National Laboratories (ORNL), to provide the radiation source for our Northglenn facility. In spite of your surprise, or lack of understanding, as to how such an order might be placed and our project advanced without your knowledge, I can assure you that we have fully complied with all applicable law and regulations in this respect. It is our plan to complete the licensing process for the Northglenn irradiation facility (as we have been advised this is a reasonable expectation) by the end of 1984 so that loading of the source material may begin in January, 1985. A copy of the project schedule developed by our engineers, CH2M HILL, was provided during my visit.

It is important for you to understand that at present we have expended or made firm commitments for engineering services, construction services, and equipment exceeding a value of \$1,000,000 and will soon be making additional financial commitments of about \$2,000,000. During this

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process we have received no notification or other indication from the State of Colorado or the Nuclear Regulatory Commission that use of the WESF capsule containing cesium chloride would present a problem in obtaining irradiator licensing approval. As I related to you during our meeting, ~~personnel from the Colorado Department of Health, Radiation Safety Division~~, even participated in public hearings concerning the financing and siting of our irradiator.

We have been aware for some time that extensive testing of the WESF capsule by Sandia National Laboratories and others has provided the substantial data submitted to NRC supporting its certification as a sealed source for cesium-137 chloride and that this data complies with certification requirements. We are also aware of the nearly 25 years wherein stainless steel capsules containing cesium-137 chloride (produced at ORNL) have been used as radioactive sources in commercially supplied irradiators, teletherapy units, and radiography units. This information and the seven year history of demonstration of the use of the WESF capsule as a wet load - dry operate irradiator by Sandia National Laboratories has been compelling, leading to our design concept, which includes the wet load - dry operate mode. It is difficult to understand how your memo to Mr. Jicha could state, "we believe that an in-depth analysis of the use of WESF capsules in irradiators is needed", in view of the existing experience history for both cesium-137 chloride and the WESF capsule form.

A FEW SMALL SELF-CONTAINED IRRADIATORS.
WET LOADS USES POC FOR SOURCE MANAGEMENT?
INCLUDES? - LIMITED TO?

It was with some delay that the ~~April 30, 1988 Communication~~ to Mr. Jicha (which you state you authored) bearing Mr. Cunningham's signature, came to our attention. Having now reviewed the copy you provided on my visit, I characterize it as extremely subjective and an avoidance of the entire issue of what, if any, objections are raised to the registration of the WESF capsule or licensing of irradiation facilities using cesium-137 sources in this form. The only quasi-technical reference relates to water solubility and dispersibility of cesium-137 chloride, but without regard for test data on the WESF capsule or measures incorporated in the design of irradiation facilities to mitigate the the circumstances resulting in the event the integrity of each of the double capsules is breached. I can understand your statement that "There is a close coupling between the safety provided by the capsule and the safety provided by the facility or equipment in which it is used." It is, for example, well known that the combined interaction of water and heat with cobalt metal, when the integrity of cobalt-60 containing rods is breached, results in easily dispersed, soluble, radioactive salts of cobalt. Yet, encapsulated cobalt-60 forms have been used for over 20 years without incident. The key is in the safety considerations made a part of the irradiator design. I, therefore, find inconsistent your statement that you would not consider licenses for commercial irradiators using cesium chloride in the WESF form, even though you admit never reviewing such designs and/or associated Safety Analysis Reports.

LOCKED IN HAS A LARGE COST CUTLY TO CLEAN UP AFTER A CO. LEAKAGE.

The above referenced memo to Mr. Jicha appears an attempt to meet at least three diverse objectives and interests. First, it attempts to satisfy DOE's need to explore applications of irradiation using nuclear by-products in the wholly new area of food products and commodities by

ENOUGH TO FILL 4
ORDERS OF THE
SECTION SIZE!!

WHAT IS THE ANNUAL DEMAND FOR ISOTOPES FOR IRRADIATORS?

THERE'S NOT
ENOUGH MATERIAL
TO BRING ABOUT
WIDE SPREAD
USE IN THE
FOREIGN
FUTURE.

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~~CONFIDENTIAL - based upon anything other than TALL~~
~~CONFIDENTIAL~~

Sincerely,

E. Kent Robinson

E. Kent Robinson, Ph.D.
President
IOTECH, INC.

CC: Mr. John J. Jicha, Jr.
Director, R&D and Byproducts Division

Richard E. Cunningham
Director, Division of Fuel Cycle and Material Safety, NMSS

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Telephone conversation on May 4, 1984, between Nathan Bassin, NMSS and C. Mattson, State of Colorado.

- ° Colorado has not received an application from Iotech
- ° Colorado had discussed licensing requirements for an irradiator with personnel of CH2M Hill, parent company of Iotech
- ° Colorado had the impression from discussion with CH2M Hill that the irradiator would be a pool-storage type.
- ° There was no discussion of the capsules other than Colorado informing CH2M Hill that the capsules would have to be "approved" by NRC ~~on~~ a Agreement State.
- ° The "public hearing" was an appearance before the Northglenn City Council in an effort to get municipal bond financing to aid in construction of the facility.
- ° There has been no public hearings by the Colorado Department of Public Health relating to proposed construction of an irradiator in Northglenn.
- ° Colorado had not heard from CH2M Hill or Iotech in approximately 1 1/2 months.
- ° Colorado did not inform CH2M Hill or Iotech that NRC "clearance" was needed.

CHUCK MATTSO
STATE OF COLORADO
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