



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAR 26 1985

PDR-016

Dr. Martin A. Welt, President
Radiation Technology, Inc.
P.O. Box 185
108 Lake Denmark Road
Rockaway, NJ 07866

IN RESPONSE REFER
TO FOIA-85-119

Dear Dr. Welt:

This is in response to your letter dated February 13, 1985, in which you requested, pursuant to the Freedom of Information Act (FOIA), copies of license applications submitted by Isomedix, and Precision Materials Corp., of New Jersey.

Enclosed are documents 6, 9, and 10 listed on the enclosed Appendix A. The other listed documents which are indicated by asterisks were previously placed in the NRC Public Document Room (PDR), 1717 H Street NW, Washington, DC, where they are available for public inspection and copying. The NRC accession numbers indicated beside the document description will assist you in obtaining access to these documents.

In response to a previous FOIA request, other documents concerning the subject of your request were placed in the PDR and are filed in PDR folder FOIA-85-71 (SCUIK). Copies of the NRC's response letters dated February 12 and March 15, 1985, are enclosed for your assistance in obtaining access to those documents.

A copy of a notice which explains the charges and procedures for obtaining copies of records from the PDR is enclosed.

Sincerely,

J. M. Felton, Director
Division of Rules and Records
Office of Administration

Enclosures: As stated

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PDR FOIA
WELT85-119 PDR

APPENDIX A

CATEGORY 1-ISOMEDIX

- *1. 02/21/83 Letter to NMSS from Dietz with application for a Byproduct Material License (156 pages) Accession No. 8411060289 NMS LIC30 29-19769-03 PDR
- *2. 05/25/83 Letter to Dietz from Wang-requests additional information (2 pages) Accession No. 8411060284 841022 NMS LIC30 29-19769-03 PDR
- *3. 06/23/83 Letter to Wang from Dietz-provides additional information (2 pages) Accession No. 8411060271 841022 NMS LIC30 29-19769-03 PDR
- *4. 12/22/83 Letter to Wang from Dietz re: change in RSO (3 pages) Accession No. 8411060263 841022 NMS LIC30 29-19769-03 PDR
- *5. 08/27/84 Letter to NRC Region I from Dietz Re: License No. 29-19769-03 w/encl. (2 pages) Accession No. 8411060227 NMS LIC30 29-19769-03 PDR
- 6. 09/14/84 NRC Form 218 Telephone or Verbal Conversation Record (1 page)
- *7. 09/21/84 Letter to Thompson from Dietz Re: License No. 29-19769-03 (1 page) Accession No. 8411060236 NMS LIC30 29-19769-03 PDR
- *8. 10/22/84 Letter to Dietz from Glenn (2 pages) Accession No. 8411060222 NMS LIC30 29-19769-03

CATEGORY 2-Precision Materials Corp.

- 9. 02/20/85 Letter to Nestor from Glenn, requests additional information (5 pages)
- 10. 02/25/85 Letter to Glenn from Nestor w/encl. (9 pages)

*This document can be located in the NRC Public Document Room by the Accession Number indicated.

"SECTION COPY"

FEB 20 1985

DOCKET NO. 030-22063
CONTROL NO. 03115

Precision Materials Corporation
ATTN: Eugene R. Nestor
Compliance Officer
Replogle Avenue
Mine Hill, New Jersey 07801

Gentlemen:

This is in reference to your application, dated November 5, 1984, for a Byproduct Material License and to your additional submission dated January 16, 1985. In order to complete our review, we need the following additional information:

1. Please confirm that you will not irradiate flammable or corrosive materials. For this purpose, flammable will mean any material with a flash point at a temperature below the temperature you expect irradiated products to reach during irradiation. However, in no case should any material with a flash point below 145 degrees Fahrenheit be irradiated. For this purpose, corrosive will mean any material with a pH less than 4.0 or greater than 10.0. You may propose different definitions if justification is provided.
2. It is now the policy of the NRC that a responsible user be physically present at an irradiation facility any time that the sources are in the exposed position. It appears that Martin Stein and Russell Stein have the training and experience to qualify as responsible users and we will condition the license to require that one of them be in the facility at all times when the source is exposed. Eugene Nestor does not have the required three months experience, including one month with an operating irradiator, to qualify as a responsible user at this time.

Certain events that are alleged to have occurred at RSA Corporation and its successor, International Nutronics, Inc., have created doubts about the judgement demonstrated by their managements in determining what events should have been reported to the NRC. Since both individuals qualified to be responsible users were employed at these companies, we conclude that you must provide for an independent evaluation of your radiation safety program on a periodic basis.

8505150231 5pp.

Please confirm that you will have independent audits of your program performed at least annually by an organization knowledgeable in the hazards at an irradiation facility. The first audit should be performed within the first three months of operation. Submit detailed procedures for these audits which describe how you will select the auditors and assure their independence. All reports of audit findings, including drafts, should be submitted to the NRC at the same time that they are sent to you.

3. You need to clarify certain of the answers submitted to the fifty question quiz given to operators.

a. The answer numbered 13. is actually the answer to question 12. Please supply an answer for question 13.

b. The answers to questions 7., 35.b., and 36. do not mention that the NRC expects all exposures to be ALARA and that each licensee is required to evaluate all aspects of the program to reduce exposures whenever it is reasonable to do so. Also, the answers seem to indicate that there is no risk so long as exposures are maintained below the absolute limits required by the NRC. Please submit answers that reflect that training will be given in the ALARA principle at your facility and that training includes instruction that all exposure may carry some risk (low probability but with a possible high consequence).

c. The answer to question 19. should be changed to reflect your new commitment to consider an increase of 1 mR/hr at the PRM to be an indication of a leaking source and that MODE "C" should be initiated.

d. Should not the answer to question 21. include the initiation of MODE "C"?

e. The answer to question 49. should be modified by adding: "provided that a responsible user listed on our NRC license is physically present in the facility."

4. Because your primary radiation barriers (shielding walls) are constructed of loose, stacked block, it is not clear that your facility meets the requirements of Section 20.203(c)(6)(iii) of Part 20 (enclosed). Therefore, you should either:

- a. Provide a more substantive analysis for the qualification of the irradiator shield during a seismic event of the magnitude that may be expected in your area. The analysis should demonstrate that the type of construction employed is capable of withstanding sliding of the concrete block between layers and that the structure can resist overturning due to a coupled horizontal and vertical excitation. The analysis should also address the qualification of the ceiling blocks supported by the structural steel I-beam and channel shapes to resist sliding and overturning effects during such events. A minimum factor of safety against sliding and overturning should be established. A factor of safety of 1.1 would be acceptable. Or
 - b. You may provide an evaluation that the destruction of the irradiator shield from a seismic event or from a horizontal impact would not result in exposure levels in excess of 100 mR/hr outside the restricted area. Or
 - c. You may provide a description of the control devices which will reduce the exposure levels by lowering the sources into the storage pool in any circumstance which would result in the removal of the primary radiation barrier.
5. Please confirm that entry control devices will be tested for proper functioning prior to initial operation on any day that operations are not uninterruptedly continued from the previous day or before resuming operations after any unintended interruption as required by Section 20.203(c)(6)(vii) of Part 20. Please submit detailed procedures for the conduct of these tests.
 6. Please provide the ranges of conductivity and pH you will consider acceptable for pool water. In addition, describe those actions you will take when sample results fall outside the acceptable range. Conductivity should not exceed 10 microsiemens per centimeter.
 7. Please confirm that your pool water supply system is not connected to a municipal water supply system or that means have been provided to prevent migration of pool water into the water supply system.

8. We understand your reluctance to install an automatic fire extinguishing system. However, fires have occurred at irradiator facilities and we believe that it is in the interest of safety to provide a means to extinguish fires. Since an alarm system will alert the operator, we would find a manually operated system acceptable. However, the system must provide adequate coverage for the entire cell. Please describe the fire extinguishing system you will provide. Alternatively, you may submit an analysis which conclusively demonstrates that the shielding and safety systems would not be rendered ineffective given the heat loading from the maximum credible fire inside the irradiator structure.
9. Please submit confirmation of or a description of your program radiation measuring survey instruments.
- a. Confirm that instruments will be calibrated so that readings are within 20% of actual values over the range of the instrument.
 - b. Confirm that a chart or graph showing the results of the calibration, the date of the last calibration, and the due date of the next calibration will be affixed to the instrument.
 - c. Identify each person or firm who will perform calibrations by name and NRC or Agreement State license number.

We will continue our review of your application upon receipt of this information. If satisfactory responses are received, we will be able to issue a license authorizing the requested activities. Please reply in duplicate and refer to Control No. 03115.

Precision Materials Corpor

Sincerely,

Final Signed By
E. Glenn
on E. Glenn, P. O. Chief
Nuclear Materials Safety
Section B
Division of Radiation Safety
and Safeguards

Enclosure:
10 CFR Part 20

cc:
Jeffrey E. Michelson, Esq.
Wiley, Malehorn and Sirote
250 Madison Avenue
P. O. Drawer 210C
Morristown, New Jersey 07960



PRECISION MATERIALS CORPORATION

REPLOGLE AVENUE

MINE HILL, N.J. 07801

(201) 989-0100

MS-12
PI

February 25, 1985

Dr. John Glenn, Chief
Nuclear Material Section B
U.S. Nuclear Regulatory Commission
631 Park Avenue
King of Prussia, PA 19406

Dear Sir:

This is in reference to your letter dated February 18, 1985 containing your request for additional information or clarification on nine separate areas of consideration. Also, please allow this letter to confirm the resolution of these points as discussed with you at our meeting held on February 22, 1985, at your office.

1. Contained as Attachment I is our change to Page 3 Item 6 of our license applications. We understand that the verbal authorization pertains to experimental quantities of the materials under consideration and that if we desire to go into full production of any of these materials, we will need written authorization from the Nuclear Regulatory Commission.
- 2a. We understand that, at the present time, only Martin Stein and Russell Stein qualify as responsible user of the irradiator under the guidelines of the Nuclear Regulatory Commission and that one of them must be present in the facility whenever the source is exposed. We also understand that we may, in the future, submit the names of any other personnel we feel qualify as a responsible user and that this submission will be as a license amendment.
- 2b. Precision Materials Corporation commits to having an independent audit performed annually by an organization or person knowledgeable in the hazards of irradiator operations. The first of these audits is to be performed within three months of commencing operations. Precision Materials Corporation also commits to submitting, to the NRC, detailed

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PRECISION MATERIALS CORPORATION

Dr. John Glenn, Chief
February 25, 1985
Page 2

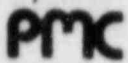
procedure for the selection of the auditor and the performance of the audits prior to the time of the first required audit.

3. Contained as Attachment II are our changes to the answers as we discussed at our meeting on February 22, 1985.
4. Precision Materials Corporation commits to installing a Seismic Sensor that will be designed to drive the source rack into the pool if a seismic event of 0.05g is detected. The maximum time to drive the source rack to below the deck plates is 15 seconds. Given the time delay from detection of the 0.05g force until the integrity of the Inner Chamber is breached the source rack will have ample time to reach a point below the deck plates.
5. Section 20.203 (c)(6)(vii) of Part 20 requires the testing of the Omega's "entry control devices". The Omega's "entry control devices" center around the doors being interlocked with the source lowering mechanism. According to our license application, whenever either door is open, the source will be driven down. Due to the "wraparound" safety systems of the Omega, normal interlock testing would be contrary to all safety procedures.

The best form of testing would be a continuous (many times a second) check to make sure that when either door is open that the source is being driven down. This is accomplished by having the monitor computer constantly perform this check. If the Omega fails such a check, the monitor computer would go to alert status, sound the operator alert, print out that there is an "interlock alert" on hard copy and put the irradiator in "MODE C" automatically.

There are two situations which would trigger an "Interlock Alert". They are as follows:

1. If for any reason the source is down, either door is open and the source is not being driven down.
EXAMPLE: Interlock Failure
2. If for any reason, the source is up and either door is opened.
EXAMPLE: Unauthorized Entry Attempt



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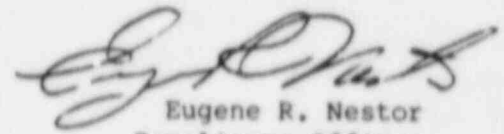
Dr. John Glenn, Chief
February 25, 1985
Page 3

6. Contained as Attachment III is the change to the application reflecting your concerns.
7. Precision Materials Corporation confirms that our pool water supply system is not connected to a municipal water supply system. At the present time, the facility is equipped with its own well for water supply. If in the future we are connected to a municipal water supply system, we will install check valves to assure that no pool water can migrate to the municipal system.
8. As per our discussion, we are installing a manual fire suppression system. The system will consist of sufficient bottles of Nitrogen to fill the inner chamber. These bottles will be located just outside the Pump Room. The Nitrogen bottles will be connected to one of the spare serpentine pipes and equipped with a manually operated valve.
9. As per your request, all our instruments will be calibrated by Teledyne Isotopes, 50 Van Buren Avenue, Westwood, New Jersey 07675, NRC License #29-00055-06. Should Teledyne Isotopes not be able to calibrate any of our instruments, we will use the manufacture of the instrument for calibration purposes. Each of our instruments will also have a sticker affixed to it showing its last calibration date and its calibration due date signed by the compliance officer of PMC.

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Once again, we would like to thank you for your time; and if you have any further questions, please call me.

Sincerely,


Eugene R. Nestor
Compliance Officer

ERN:tmc

Enclosures

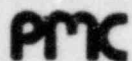


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ITEM 6 - PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

The Precision Materials Corporation "OMEGA" Irradiator will be employed as a service unit for the irradiator of a wide range of materials, excluding explosives. However, in no case will any material with a flashpoint below 145 degrees Fahrenheit or any material with a PH of less than 4.0 or greater than 10.0 be irradiated without prior verbal authorization from the Nuclear Regulatory Commission. Most materials to be irradiated will be products or components from the Cosmetics, Pharmaceutical and Medical Device industries. It is anticipated that food for human consumption will be irradiated in accordance with, and under the jurisdiction of, the regulations of the U.S. Food and Drug Administration and any other pertinent regulatory body.

- 37) What are the emergency limits for exposure and when may they be used?
- 38) Describe the various survey instruments available at Precision Materials Corporation and what each is used for.
- 39) What is the purpose of the SAFETY COMMITTEE? Who are the members?
- 40) Where is radioactive material stored at PMC?
- 41) Define "Radiation Control Area". What are the requirements for entering a "Radiation Control Area"?
- 42) Give the effects of the following doses to a customer's product:
a) 100 RAD b) 100 KRAD c) 1 MRAD.
- 43) Describe the Source Hoist System. What interlocks are associated with this system?
- 44) Who can authorize maintenance work on a safety system?
- 45) What is the function of the Radiation Safety Officer? Who, at PMC, is qualified to be an RSO?
- 46) In general, describe the procedure to be followed if a source is suspected of leaking.
- 47) What would the consequences be if any person is found violating a safety procedure?
- 48) What is the primary safety feature of the Irradiator?
- 49) Who is allowed to operate the Irradiator?
- 50) What was the primary purpose of the training you have just completed?
- 51) What is ALARA?

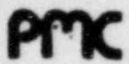


PRECISION MATERIALS CORPORATION

12. A one line diagram showing the major components and the normal flowpath is sufficient.
14. The main purpose of the DIDO INTERLOCK SYSTEM is to make sure that no one is in the Irradiator with the source in the Up position. The DIDO prohibits a person from ever being left in the Irradiator when both doors are closed. The source cannot be raised unless both doors are closed. Therefore, no one can be in the Irradiator when the source is in the Up position.

The system consists of two doors, the Door-In and the Door-Out. The logic is controlled by proximity switches mounted on each door and the Operations Computer System. This equipment interacts with the Radiation Check procedure and the Personnel Check procedure. Through various electrical and computer interlocks, personnel are prohibited from entering the Irradiator undetected by the operator prior to the doors closing. Thus, no one can be in the Irradiator when the source is raised.

15. The purpose of the ARM's is to detect radiation in the Irradiator and provide a signal to the safety & interlock system.
16.
 - a - Immediately leave the area (DON'T PANIC).
 - b - Call Dover General Hospital
 - c - Secure the Irradiator
 - d - Go to MODE "C"
 - e - Call an RSO
 - f - Log Event
 - g - Return Film Badge to Rack
 - h - Wait outside the building for the ambulance.



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49. Any person trained and qualified under Section 8 of the license provided that a responsible user listed on our NRC license is physically present in the facility.
50. Due to the fact that each operator is a different individual with their own reasoning, PMC training has prepared them to expect the unexpected. This is done by not overstressing overreliance on any one safety or interlock system. They are trained to check that all systems are working "safely" prior to entering the Irradiator. Even then, they enter the Irradiator with caution and with a hand held survey meter, which is also tested prior to each use.
51. ALARA is the requirement that all exposures be as low as is reasonably achievable. This means that each licensee is required to take those steps that are within reason to reduce personnel exposure to a minimum.
13. The safe operation of the Irradiator, at any given time, is the responsibility of the responsible user, listed in the License, who is on shift at that time.

Filter PRM. The detector probe is located on the side of the filter housing and the meter readout is on the control console in the Control Room. If the reading on the PRM rises to 1 mr/hr above normal, the Monitor Computer will sound an alert and automatically initiate a MODE "C" condition.

The pH of the pool water will be maintained between 6.0 and 8.0. Should the pH fall outside of this range, secure the pool recirculation system and change out the resin bed. If this does not correct the problem an investigation will be considered and the NRC will be notified prior to any other corrective action being taken.

The pool water conductivity limit is ¹⁰ ~~5~~ microseimens per square centimeter. Should the conductivity exceed this limit check the conductivity of the demineralizer discharge. If this reading is >10 microseimens per square centimeter, secure the pool recirculation system and change out the resin bed. If this reading is <10 microseimens per square centimeter, continue recirculating the pool water and check the reading every four hours to insure it remains below 10 microseimens per square centimeter.



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- .1 OBJECTIVE: To list the initiating events and response required for a MODE "C".

NOTE: MODE "C" is defined as any condition that warrants the immediate securing of normal operations and the placing of the Irradiator in a safe condition.

- .2 INITIATING EVENTS:

.2.1 Automatic Initiation

- .2.1.1 Smoke in the Irradiator
- .2.1.2 High Radiation Level on Filter PRM
- .2.1.3 Either ARM reads Radiation Positive and either door is not fully closed.
- .2.1.4 Either door is open and the source is not being driven down.

.2.2 Manual Initiation

- .2.2.1 Loss of either the Operations Control or the Monitor Control Computers
- .2.2.2 Loss of a second ARM.
- .2.2.3 Anytime an ARM reads $>10\text{mr/hr}$ and the source is down.
- .2.2.4 Anytime $>10\text{mr/hr}$ is detected while doing a radiation check.
- .2.2.5 Anytime any malfunction prevents the dropping of the source.
- .2.2.6 Anytime either the DI or DO are not fully closed and the source is not down.
- .2.2.7 During the loading or unloading of the source plaque or source cask.

DATE 9/14/84

TIME ~~8:00~~ ☐ A.M. ☒ P.M.

TELEPHONE OR VERBAL CONVERSATION RECORD

☒ INCOMING CALL

☐ OUTGOING CALL

☐ VISIT

PERSON CALLING

George Dietz

OFFICE/ADDRESS

IsomediX, Inc.

PHONE NUMBER

EXTENSION

(201) 887-4700

PERSON CALLED

Thompson

OFFICE/ADDRESS

Region I

PHONE NUMBER

EXTENSION

5303

CONVERSATION

SUBJECT

Return call

SUMMARY

I pointed out a 10 ml/hr reading on survey submitted 8/27/84. George said he will send a letter to us describing how this area is a small inaccessible crack ~ 10' from the floor.

REFERRED TO:

ACTION REQUESTED

ACTION TAKEN

☐ ADVISE ME OF ACTION TAKEN.

INITIALS

DATE

INITIALS

DATE

"OFFICIAL RECORD COPY"

MLIO

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