

OFFICIAL RECORD COPY MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. Bernardo A. Puebla, M.D.	3. License Number	52-23097-02
2. P.O. Box 117 Guayama, P.R. 00785	4. Expiration Date	March 31, 2002
	5. Docket or Reference No.	030-34051
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Strontium 90	A. Sealed source in an applicator device registered pursuant to 10 CFR 32.210 or an equivalent Agreement State regulation	A. 125 millicuries (4.63 GBq)
9. Authorized Use:		
A. Medical treatment of superficial eye conditions as identified in 10 CFR 35.400(e).		

CONDITIONS

10. Licensed material shall be used and stored at the licensee's facilities located at 27 Enrique González St. (corner with San Antonio St.), Guayama, Puerto Rico, and in addition shall be used at Hospital Santa Rosa, Los Veteranos Ave., Guayama, Puerto Rico, and Hospital de Area Dr. Alejandro Buitrago, Pedro Albizu Campos Ave., Guayama, Puerto Rico.
11. The Radiation Safety Officer for this license is Bernardo A. Puebla, M.D.
12. Licensed material shall be used only by Bernardo A. Puebla, M.D.
13. Sealed sources containing licensed material shall not be opened or removed from the source holder by the licensee.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 52-23097-02

Docket or Reference Number 030-34051

(cont.)

CONDITIONS

14. The eye applicator device shall have a locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The eye applicator must be locked in its storage container when in transport, storage or when not under the direct surveillance of an authorized user.
15. The licensee shall maintain records of information important to safe and effective decommissioning at 27 Enrique González St. (corner with San Antonio St.), Guayama, Puerto Rico, pursuant to the provision of 10 CFR 30.35(g) until this license is terminated by the Commission.
16. For compliance with 10 CFR 35.59(h), the licensee is authorized to use thermoluminescent dosimeters (TLD's) exchanged quarterly, to measure the ambient dose rates in all areas where eye applicator sources are stored.
17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated January 21, 1996.

B. Letters dated:

- April 21, 1996 (Additional information)
- June 30, 1996 (Additional information)

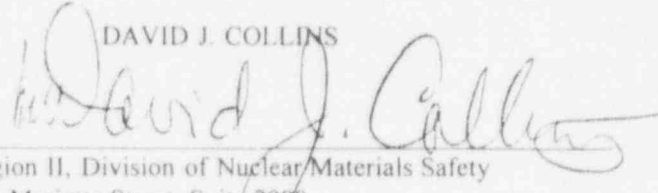
FOR THE U. S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS


Date

MAR 28 1997

By


Region II, Division of Nuclear Materials Safety
101 Marietta Street, Suite 2900
Atlanta, GA 30323

N/MLICENSE/52-23097-N01

 3/28/97

[illegible]

We note that a 2/6/97 TAR for Wills Eye Hospital extended weekly surveys under 35.70 to quarterly surveys. Perhaps a quarterly TLD would suffice for eye applicator surveys. Let me know if you need more...

From: Torre Taylor
To: ATD1.ATP1.J/P
Date: 2/6/97 10:19am
Subject: TAR for Sr-90 issue

John,

I received your fax yesterday (Wed, 2/5/97) providing one of the letters for the exemption request. I am emailing you, with a cc to Hector, since Hector is out of the office this week.

There are a couple of things we will need:

1. We will need the letter from the other licensee also - it is needed for legal reasons - we must have the request from each licensee with their signature. I confirmed this with OGC.
2. The letter did not include a justification as to the need for the exemption. I presumed that the cost burden information provided in the cover TAR summary was from the licensee, but there is no reference to cost needs in the licensee's letter. Therefore, the licensees should submit specific reasons as to why they need the exemption.
3. The licensee indicated that they will do environmental monitoring with Landauer X-9 dosimeter maintained for a year to confirm the dose limits. The licensee did not specify an exchange frequency for the dosimeters. While the use of dosimeters is not an absolute necessity, though nice, to get approval of the exemption, if the licensee is going to use them, a frequency of exchange needs to be specified. I'm not sure as to the technical specs. on the dosimeters, but understand from a co-worker that aluminum oxide TLDs don't fade excessively. We agree that it is a good idea to exchange them on a set frequency through the year - I would recommend quarterly.

Please contact me if you wish to discuss this in more detail. I will be leaving on a rotation to Commissioner Dicus' office on 2/10/97, so this TAR will be transferred. I do not have the new contact as of yet. However, I have all of these notes and previous discussion information with the file, so the new contact will be able to pick it right up.

I will leave this ticket open pending receipt of the above information.

Thanks for your help - Torre Taylor

CC: ATD1.ATP1.HXB1, slm2



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

2/5/97
of pages 12

To	Torre Taylor	From	John Patten
Dept./Agency	NMSS/IMNS/IMAB	Phone	RII
Fax #	301/415-5369	Fax #	
NSN 7540-01-317-7368	5099-101	GENERAL SERVICES ADMINISTRATION	

Headquarter Reviewer:

Regional Reviewer: Jose Diaz Velez

Reviewer Code: G-6

Reviewer Phone No.: (404) 331-7438

Request Needed by: As soon as possible.

TAR-10

FAX No.: (404) 331-5559

Form

FAX TO: Torre Taylor (301) 415 5369

9/93

Per your discussion with Jose Diaz on 2/4/97, we enclose the 4/21/96 and 6/30/96 letters from Dr. Puebla requesting the exemption for quarterly surveys of Sr-90 eye applicators. The Dr. Colon-Vaguer letter is essentially the same, since it was prepared by the same consultant for the same reasons. PLS advise if you need more.

Thanks,

John Patten RII

2/5/97

From: Jose Diaz-Velez
To: HXB1
Date: 2/4/97 4:31pm
Subject: TAR for Colon-Vaquer/Puebla

I spoke today with Torre Taylor re: TAR for Sr-90 eye applicators. NMSS is going to consider this as an independent request (not generic), to be reviewed on a case by case.

Ms. Taylor needs the original documentation that came in with the license applications, please forward a copy to her ASAP.

CC: JPP, TMT



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: October 22, 1996

Mail or E-Mail to: Donald A. Cool (DAC), Mail Stop: T-8 F5, **If E-mail, cc:** CLE
Division of Industrial and Medical Nuclear Safety, NMSS

From: John P. Potter (JPP) *[Signature]* (Name and E-mail initials) Region II
Chief, Materials Licensing/Inspection, Branch 2

Licensee: Jose Colon-Vaquero M.D. and Bernardo A. Puebla M.D.
License No.: 52-25113-02 and 52-23097-01

☐ **Control No.** 256921 and 256908 (if applicable)

☐ **Letters dated:** January 31, 1996 and January 21, 1995 (if applicable)

☐ **Suggested change in licensing procedure (enclosed):** n/a

☐ **Problem/Issue:** 10 CFR 35.400 identifies the SR-90 applicator as a brachytherapy device. 10 CFR 35.59 (h) requires the licensee to measure the ambient dose rates quarterly in all areas where such sources are stored. Most of the licensees with eye applicators are small licensees, with the applicator being the only source possessed. To require them to purchase a survey meter and to keep it calibrated or to pay a consultant to come into the office to perform a quarterly survey places an undue financial burden on them when compared to the additional safety factor. The applicator is unlikely to be misplaced or lost. The applicator is quite large in comparison to brachytherapy seeds and kept in its case in a secure area when not in use. The dose rate is known by decay from the manufacturer's calibration certificate. The rate will not change due to addition and removal of additional sources. The licensee typically uses the same applicator for many years.

☐ **Action Required:** Allow for a license condition to exempt licensees who possess only an eye applicator such that they would not be required to perform a quarterly survey.

Recommended Action (with revisions): ☐ Approve or ☐ Reject

We recommend that a license condition such as the following be allowed:

"Notwithstanding 10 CFR 35.59 (h), the sealed source applicator shall be maintained, used, and leak tested in accordance with the provisions of 10 CFR 35.59; except that, after performance of an initial survey to measure ambient dose rates, this procedure need not be repeated."



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0190

Remarks: n/a

Headquarter Reviewer:

Regional Reviewer: Jose Diaz Velez

Reviewer Code: G-6

Reviewer Phone No.: (404) 331-7438

Request Needed by: As soon as possible.

TAR-10

FAX No.: (404) 331-5559

Form

9/93

Dr. Bernardo A. Puebla

Guayama, Puerto Rico

June 30, 1996

Mr. José M. Diaz
Material License Reviewer
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission Region II
101 Marietta St. NW, Suite 290
Atlanta, GA 30323-0199

Dear Mr. Diaz:

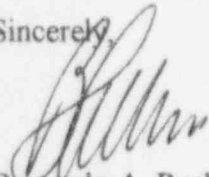
With regards to our telephone conversation, I want to state for the completion of my license application (reference: control no. 256908; docket no. 030-34051) that the Sr-90 Eye Applicator will be stored locked in a solid wood compartment at the storage room shown in the floor plan presented with this application.

Included are the letters from two area hospitals that state that they have no objections for the use in their institutions of the Sr-90 Eye Applicator in my surgical patients.

With regards to the quarterly surveys of ambient dose rates required in 10 CFR 35.59(h), I will like to request exemption of this requirement since the ambient radiation dose determination included with my application clearly determines that ambient radiation dose is way below accepted levels and no danger of exposure will exist for the general public nor employees in my office. This will furthermore be proven if the X-9 Dosimeters maintained for a year confirm the findings of the office radiation levels survey included in the application.

I hope this information will finally complete the requirements for the issuing of my license and I also want to thank you for your great assistance in helping me complete this application.

Sincerely,



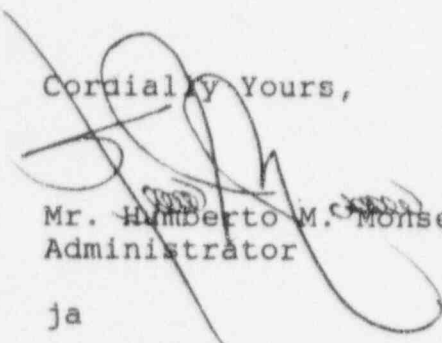
Bernardo A. Puebla, MD

June 14, 1996

TO WHOM IT MIGHT CONCERN

This is to certify that Santa Rosa Hospital has no objection to the use in our institution of Beta radiation source property of Dr. Bernardo Puebla for the application of radiation therapy to his surgical patients.

Cordially Yours,



Mr. Humberto M. Monserrate, MHSA
Administrator

ja

Hospital Dr. Alejandro Buitrago

Apartado 10006

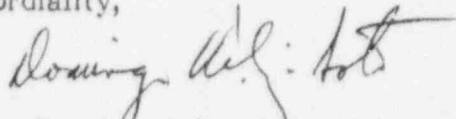
Guayama, Puerto Rico 00785 - 10006

June 21, 1996

To whom it might concern

This is to certify that **Guayama Area Hospital** has no objection to the use in our institution of the **Beta** radiation source property of Dr. Bernardo Puebla for the application of radiation therapy to his surgical patients.

Cordially,



Lic. Domingo Vélez Soto, M.H.S.A.
Executive Director

csr .

Dr. Bernardo A. Puebla

Guayama, Puerto Rico

April 21, 1996

Mr. José M. Diaz
Material License Reviewer
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission Region II
101 Marietta St. NW, Suite 290
Atlanta, GA 30323-0199

Dear Mr. Diaz :

In response to your request for additional information with regards to my license application (reference: control no. 256908, docket no. 030-34051), I have been working to gather and complete the solicited material to the best of my capacity.

Items 1,2, and 3.

In order to comply with 10 CFR 35.59(h) , I had a survey done to measure the radiation levels produced by the Sr-90 Eye Applicator at its storage location and at the surroundings of the treatment area when the applicator is in use that clearly demonstrate that the total radiation exposure to the general public will not be significant enough to make it a necessity to perform quarterly surveys of ambient dose rates. To comply with this requirement I am ordering from Landauer two X-9 Dosimeters for environmental monitoring of the Sr-90 sealed source storage and treatment areas that if satisfactory (an average radiation exposure below 100 mRems and average radiation levels below 0.5 mR/hr) should confirm the safety to the general public, my employees, and myself of the storage and use of my Sr-90 eye applicator.

Item 4.

A radiation protection program to warranty doses ALARA is enclosed.

Item 5.

I will follow and incorporate the instructions in the RULES FOR HANDLING Sr-90 EYE APPLICATORS to our radiation protection program.

Item 7.

With regards to Personnel External Exposure Monitoring Program, since no office nor hospital employees will handle directly nor indirectly the Sr-90 eye applicator we feel that a Exposure Monitoring Program is not necessary at this moment. I will establish and implement a personnel external exposure monitoring program if the situation requires that any office or hospital personnel is required to handle the applicator or be exposed to radiation during its use.

The low frequency of applications (less than 8 applications / mo.) make it unnecessary to assign dosimetry to the authorized user.

Item 8.

Leak tests will be done at intervals not greater than 6 month following the procedure published in Appendix H to Regulatory Guide 10.8, Revision 2 and using a cotton swab wipe method that will then be sent to an institution authorized by the NCR to perform such services. The source will immediately be removed from service if leak test results indicate any increase in detectable activity from that of previous tests. The authorized user will be the person in charge of performing the leak tests.

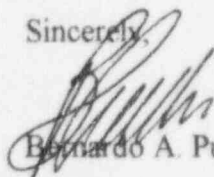
Removable contamination activity should be much less than 0.005 uCi.

Item 9.

The same Quality Management Program (QMP) presented for my previous license (docket file 52-23097-01) will be transferred and maintained for this license without changes.

I hope this information will complete the requirements to continue the review of my application and I would also like to thank you for your assistance and orientation for the completion of this application.

Sincerely,



Bernardo A. Puebla, MD

RADIATION SAFETY INSPECTION REPORT.-

Place : Bernardo A. Puebla, M.D. Office - Guayama, P.R.

Radiation Source: Sr-90 Eye Applicator (NER-8090) Serial No.0231
Activity : 100 mCi (07- 1977)

Instrument used: G.M. Survey Meter - Eberline Model 520 - Calibrated
on Nov.30,1995

Main objective : To measure radiation levels produced by a Sr-90 Eye
Applicator at the storage location and at the surroundings of
the treatment area when applicator is in use.

Surveyor : Santiago Gomez-Figueroa, M.S.

Date: March 27, 1996

RESULTS (mR/hr) (See Office Layout Diagram)

<u>A. When source in storage inside a Cabinet</u>		<u>B. When source in current use at the treatment area(Ex.Room 1</u>	
1.(Contact to cabinet) :	1.0	4.-	0.4
2.(one foot away) :	0.2	5.	0.1
3.(three feet away) :	0.08	6.	0.1
		7.	0.08

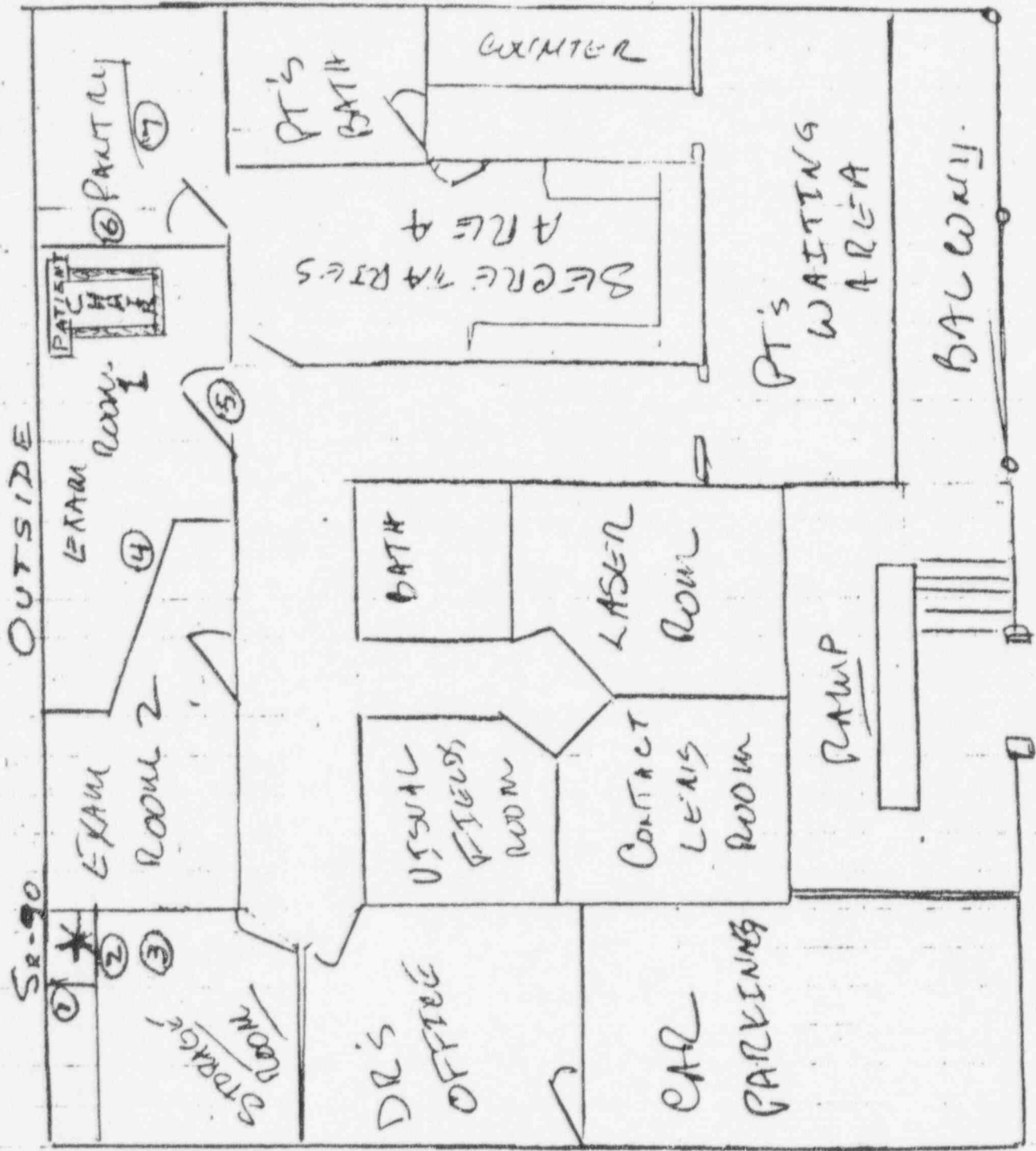
CONCLUSION : Considering an average radiation level less than 0.3
mR/hr, it is expected that the total radiation exposure dose to the general
public will not be greater than the standard, i.e. 100 mRem/year.

Signed :

Santiago Gomez-Figueroa, MS

Date :

04/10/96



Dr Pucuba's Office Floor Plan

CERTIFICATE OF SEALED SOURCE TEST

ISSUED TO: Nuclear Associates, Inc.
100 Voice Road
Carle Place, New York 11514

NEN ORDER NO.: 855860

Radionuclide: ^{90}Sr Nominal Radioactivity: 100 mCi
 Source Model: NER-8090 Serial No.: 0231
 Capsule No.: NB-1 Date of Mfr.: July, 1977
 ANSI N5.10-1968 Performance Classification C43311 "Special Form"

* * * * *

Radioassay

The source radioactivity was measured on 7/22 1977 and determined to be 100 \pm _____ %
 millicuries. The measurement value is based on ☐ Gamma Dose Rate _____ R/Hr/Cm/mCi ☒ Special measure-
 ment technique. Surface Dose Rate = 57 Rads/Sec

Seal Integrity Test

The source capsule was tested for seal integrity on 7/22 1977 pursuant to the specifications of
 ANSI N5.10-1968 Procedure No. B2.4 and/or special Procedure No. _____ as prescribed. Test
 indicated seal integrity.

Radioactivity Leakage/Contamination Test

The source was tested for capsule contamination and radioactivity leakage immediately after manufacture,
 pursuant to ANSI standard N5.10-1968 Procedure ☐ B2.1 Smear Test or ☒ B2.2 Immersion Test. Less than
 $< 1 \times 10^{-3}$ microcurie was detected.

The source was again tested on 7/29 1977 per Procedure ☐ B2.1 ☒ B2.2. Less than
 $< 1 \times 10^{-4}$ microcurie was detected.

The source was determined to be free of leakage or contamination as specified by applicable regulations and
 specifications.

New England Nuclear Corporation certifies that the herein described sealed source has been manufactured
 in conformance with approved specifications and/or specification No. 313-132 Rev D issued by
New England Nuclear Corporation; that the source has been tested as described herein; as well as
 in accordance with the requirements of the above specification.

DATE: August 4, 1977



For NEW ENGLAND NUCLEAR CORPORATION

By: R.W. Karm, Supervisor

Research and Industrial Sources
Nuclides and Sources Division

environmental/low level dosimetry service



Landauer's environmental/low level dosimetry service is designed to meet ANSI standards and provides accurate reporting to 0.1 mrem. For years, many organizations have measured in environmental and low level exposure conditions with badges known to be better suited for the needs of personnel monitoring. Now Landauer provides a significantly improved dosimeter designed specifically for use in environmental and other low level applications - the Landauer "X9" aluminum oxide TLD dosimeter.

Landauer has developed a truly unique dosimeter that is rugged enough to withstand the rigors of outdoor usage and environmental extremes, but sensitive enough to measure to tenths of a millirem. Laboratory and field testing validated the efficacy of highly sensitive aluminum oxide TLDs and found them superior for this purpose, with distinct advantages over other available materials. Participation in international environmental dosimetry intercomparisons has resulted in exemplary performance. The bottom line: the X9 is a rugged, easy-to-use dosimeter, highly sensitive and accurate, for measuring very low levels of radiation exposure.

APPLICATIONS

- Environmental Monitoring - site characterization, site boundaries, offsite, compliance with administrative and regulatory requirements
- Low Level Exposure Studies - area monitoring, shielding studies, special studies
- Determining Exposure to Members of the Public - ensure compliance with current guidelines and the revisions to the Code of Federal Regulations (10CFR20) which limit dose for non-occupationally exposed persons to 100 mrem annually (or less), a factor of five lower than previously required

BY
Landauer

RADIATION PROTECTION PROGRAM

In order to ensure that radiation exposure to employees and staff members will be as low as reasonably achievable (ALARA), in the use and handling of the Sr-90 sealed source, the authorized user, Dr. Bernardo A. Puebla, will enforce the following actions:

1. The only person to work with and be allowed to perform the radiation applications will be the authorized user, Dr. Bernardo A. Puebla. No other staff members, office personnel nor hospital personnel will be allowed at or near the treatment site at the time of the application.
2. As soon as new staff members (e.g. physicians or other personnel who may assist with patient treatments) report for duty and at least annually thereafter, a refresher training will be organized to review the rules for the safely handling of the Sr-90 Applicator.
3. At least once a year the radiation safety officer will review the need for personnel monitoring procedures or its results, and consider possible ways of reducing radiation exposures and implement needed changes in procedures and equipment to make sure exposures to radiation is kept as low as reasonably achievable.



Dr. Bernardo A. Puebla
Radiation Safety Officer

OFFICIAL RECORD COPY

MAR 12 1996

Bernardo A. Puebla, M.D.
P.O.Box 117
Guayama, P.R. 00785

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION CONCERNING LICENSE APPLICATION
DATED JANUARY 21, 1996 (REFERENCE: CONTROL NO. 256908;
DOCKET NO. 030-34051)

Dear Dr. Puebla:

This letter is in reference to your radioactive materials application dated January 21, 1996. The following information is needed to continue our review of your amendment application:

1. 10 CFR 35.59(h) requires that licensees in possession of brachytherapy sources perform quarterly surveys of ambient dose rates in all areas where such sources are stored. In your application, you indicated that a properly calibrated survey meter will be available from a radiation consultant under emergency circumstances only. Please describe how you plan to comply with the requirement specified in 10 CFR 35.59(h).
2. Please describe the survey instrument that will be used to perform the quarterly surveys referenced in the paragraph above.
3. If for your response to item 1 of this letter you decide to possess a survey meter to perform the required surveys pursuant to 10 CFR 35.59(h), please (1) provide the name and NRC or Agreement State license number of at least one instrument calibration service that you may utilize to ensure that your instrument complies with the requirements of 10 CFR 35.51, and (2) submit your procedures for calibrating survey instruments. See appendix B to Regulatory Guide 10.8, Revision 2, 1987. (Enclosure 1)
4. The regulations in 10 CFR 35.20(a) (Enclosure 2) require each licensee to develop and implement a written radiation protection program that includes provisions for keeping doses ALARA. For your information, the NRC's Model ALARA Program is enclosed (Appendix G to Regulatory Guide 10.8, Revision 2). Since your license is not for a medical institution, the enclosed program is not 100% applicable, therefore it needs to be reviewed to ensure that it is commensurate with the scope and extent of your licensed activities. Please submit a signed copy of your ALARA program with your response to this letter.
5. 10 CFR 20.1101 requires that each NRC licensee develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions in Part 20. For your information, we are enclosing a model of instructions for the safe handling of the strontium 90 eye

applicator (see enclosure 3). Please confirm that you will follow and incorporate these instructions into your radiation protection program or you may develop an alternative set of instructions. If you elect to develop an alternative program, please submit a copy of your radiation protection program pursuant to 10 CFR 20.1101.

7. Please submit a description of your personnel monitoring program which addresses the following:

- a. the criteria you will use to determine which groups of workers will be assigned dosimetry.
- b. types of devices which will be used (e.g., film badges, TLD, body, wrist, ring).
- c. frequency of exchange, and
- d. the NVLAP accredited dosimetry processor you will use.

Appendix D of the enclosed regulatory guide (Enclosure 1) may be helpful in preparing your response and provides a program that is acceptable to the NRC.

8. Please provide the following information regarding the leak testing of your sealed sources:

- a. A description of the procedure for leak testing the source.
- b. The instrumentation used to measure activity on the wipe and the lower limit of detectability for this instrumentation.
- c. A commitment that leak tests will be conducted at intervals not greater than 6 months.

If you elect to have another person perform the leak test, please submit the name of the person and the applicable NRC or Agreement State license number. Appendix H of the enclosed regulatory guide (Enclosure 1) may be helpful in preparing your response and provides an acceptable procedure to the NRC.

9. You are requesting authorization for 10 CFR 35.400 materials, which address the use of sealed sources for brachytherapy. 10 CFR 35.32(a) states, in part, that a licensee must establish and maintain a written Quality Management Program (QMP) for all 10 CFR Part 35 uses applicable to their program. Your previous License docket file (52-23097-01) includes a copy of a QMP with a transmittal letter dated June 28, 1994. Please submit a new QMP addressing 10 CFR 35.400 uses as required by 10 CFR 35.32(a) (include a written certification indicating that you will establish and maintain it), or alternatively confirm that you will establish and maintain the previous QMP referenced in the June 28, 1994 letter.

Bernardo A. Puebla, M.D.

3

If you wish to pursue your license application, please either contact me by phone or provide your reply within 20 days of receipt of this letter. If additional time to respond to this letter is needed, please request it in writing and state the reason for requesting the extension. When responding, please refer to Mail Control No. 256908 and provide two copies of your reply.




If you have questions about this letter, please call me at 404-331-7438 (FAX: 404-331-7437).

Sincerely,

José M. Díaz Vélez
Materials License Reviewer
Division of Nuclear Materials Safety

Enclosures:

1. Regulatory Guide 10.8
2. 10 CFR 35
3. Rules for Safe Handling
of Sr-90 Eye Applicators

SEND TO PUBLIC DOCUMENT ROOM? <input checked="" type="radio"/> YES <input type="radio"/> NO						
OFFICE	RII:DNMS	RII:DNMS	RII:DNMS	RII:DNMS	RII:DNMS	RII:DNMS
SIGNATURE						
NAME	J. Díaz Vélez	J. Henson	P. Potter			
DATE	03 / 12 / 95	03 / 14 / 96	03 / 12 / 96	03 / / 96	03 / / 96	03 / / 96
COPY?	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	YES NO	YES NO	YES NO	YES NO

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Last saved: March 12, 1996



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

February 12, 1996

Mail Control No. 256908

Docket No. 030-34051

Bernardo A. Puebla, M.D.
P.O. Box 117
Guayama, Puerto Rico 00785

SUBJECT: ACKNOWLEDGEMENT OF REQUEST FOR A LICENSING ACTION

(Your: ☐ Letter ☒ Application ☐ Dated ☐ Received 1/21/96.)

Dear Dr. Puebla:

1. In response to your request, we have performed a preliminary review of your application for a: ☒ new ☐ amendment ☐ renewal ☐ termination licensing action.
2. It appears that your request is complete and:
☒ routine (see 3-5 below);
☐ non-routine, and if necessary, can be completed within ____ - ____ days, following fee approval and response to any telephone or telefax deficiency requests from our license reviewer.
3. New and amendment actions are normally processed in 20 - 30 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
4. Renewal actions are normally processed in 60 - 90 days, however under timely filing (before expiration) you may continue to operate under your existing license.
5. Termination actions are normally processed in 20 - 30 days, unless confirmatory surveys following decontamination are involved.
6. A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6067) for approval of the fee category and amount.
7. If you have a compelling safety or business-related reason for requesting expedited review, please contact me or our Licensing Assistant at 404/331-4673 [voice/ans] or 404/331-7437 [fax] or Internet: ddh@nrc.gov. We will try to complete your request, as stated in 2. above.

Bernardo A. Puebla, M.D.

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8. Please call or write with any questions. I can be reached directly at 404/331-5571 [voice/ans/fax] or via Internet: jpp@nrc.gov.

Sincerely,

Jose M. Diaz Velez for

John Potter, Chief
Material/Licensing Inspection Branch 2

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: (FOR LFMS USE)
: INFORMATION FROM LTS
:
:
: Program Code: _____
: Status Code: 3
: Fee Category: _____
: Exp. Date: 0
: Fee Comments: _____
: Decom Fin Assur Req'd: _____
:

1996 JAN 29 AM 11: 27

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED

Applicant/licensee: BERNARDO A. PUEBLA, MD
Received Date: 960125
Docket No: 3034051
Control No.: 256908
License No.:
Action Type: New License

2. FEE ATTACHED

Amount: 1300⁰⁰
Check No.: 1224

3. COMMENTS

Signed
Date

[Signature]
1/25/96

8. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered 1/1)

1. Fee Category and Amount: 7C \$1300

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License ✓

3. OTHER _____

Signed
Date

[Signature]
1/30/96

Log	<u>Jan 6 II</u>
Remitter	_____
Check No.	<u>1224</u>
Amount	<u>\$1300</u>
Fee Category	<u>7C</u>
Type of Fee	<u>Appl</u>
Date Check Rec'd.	_____
Date Completed	<u>1/30/96</u>
By:	<u>[Signature]</u>

Dr. Bernardo A. Puebla

Guayama, Puerto Rico

Jan 21, 1995

Nuclear Materials Safety Section
U. S. Nuclear Regulatory Commission
Region II
101 Marietta Street, NW, Suite 2900
Atlanta, GA 30323

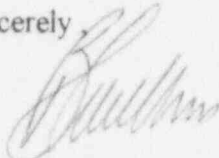
Sirs:

Due to medical problems in my house, I was unable to return my renewal application papers in time, therefore I am now requesting the issue of a new license for the use and storage of the Sr-90 eye applicator.

To support this request , please find enclosed a complete License Application form and a check for \$1300.00 for the proper fee as informed by phone from your office.

I will be glad to provide any further information needed or necessary for the issuing of the license requested.

Sincerely



Bernardo A. Puebla, MD

Enclosure: License Application, Fee Check.

256908

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 3.25 HOURS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

MATERIALS RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☒ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER 52-23097-01

2. NAME AND MAILING ADDRESS OF APPLICANT (Includes Zip Code)

Bernardo A. Puebla, MD
P.O. Box 117
Guayama, PR 00785

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Office: 27 W B. Gonzalez St.
Guayama, Puerto Rico

Also use at local area
hospitals.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Bernardo A. Puebla, MD

TELEPHONE NUMBER

(809) 864-2010

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 7C AMOUNT ENCLOSED \$ 1,300.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

Bernardo A. Puebla, MD

Ophthalmologist

1-21-

1996

FOR NRC USE ONLY

TYPE OF FEE FEE LOG FEE CATEGORY COMMENTS

AMOUNT RECEIVED CHECK NUMBER

APPROVED BY

256908
DATE

Attachments

Items 5 and 6: Radioactive material and purpose

Element: Sr-90/Y-90

Physical form: Sealed source in an eye applicator
New England Nuclear Model NB-1

Maximum Amount: 100 mCi

Purpose: Beta radiation therapy treatment of superficial eye conditions

Item 7: Authorized user and radiation safety officer.

Bernardo A. Puebla, MD is the only authorized user and the Radiation Safety Officer in charge of the radiation safety on the day-by-day basis. If any problems arise a Radiation Physics Consultant will be immediately consulted by the user to advise and help manage the emergency.

Item 8: Personnel Training

The Beta eye applicator will only be handled by the authorized user when the treatments are performed or leak test are being performed. Bernardo A. Puebla, MD is a trained ophthalmologist experienced with the use and management of ophthalmic beta radiation applicators.

During treatments, paramedical personnel stay away from the source in such a manner that the total dose received, if any, will not exceed the maximum permissible for the general public.

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Item 9. Facility and equipment

Office facility's floor plan is included with this application. Location for storage of radiation source is marked in floor plan and key-locked arrangements are available for the safe storage of the radiation source.

Transportation from storage site to and from hospitals, where treatment to surgical patients could be applied, will be only by Dr. Puebla and following the methods that will ensure proper handling and transportation of the source, securing it and following emergency procedures in the case of an automobile accident during transportation of the source.

In case of emergency during leak tests leakage identification or any other case requiring radiation levels determinations, arrangements will be made with a Radiation Safety Consultant to ensure access to a recently calibrated GM Survey Meter.

Item 10. Radiation Safety Program

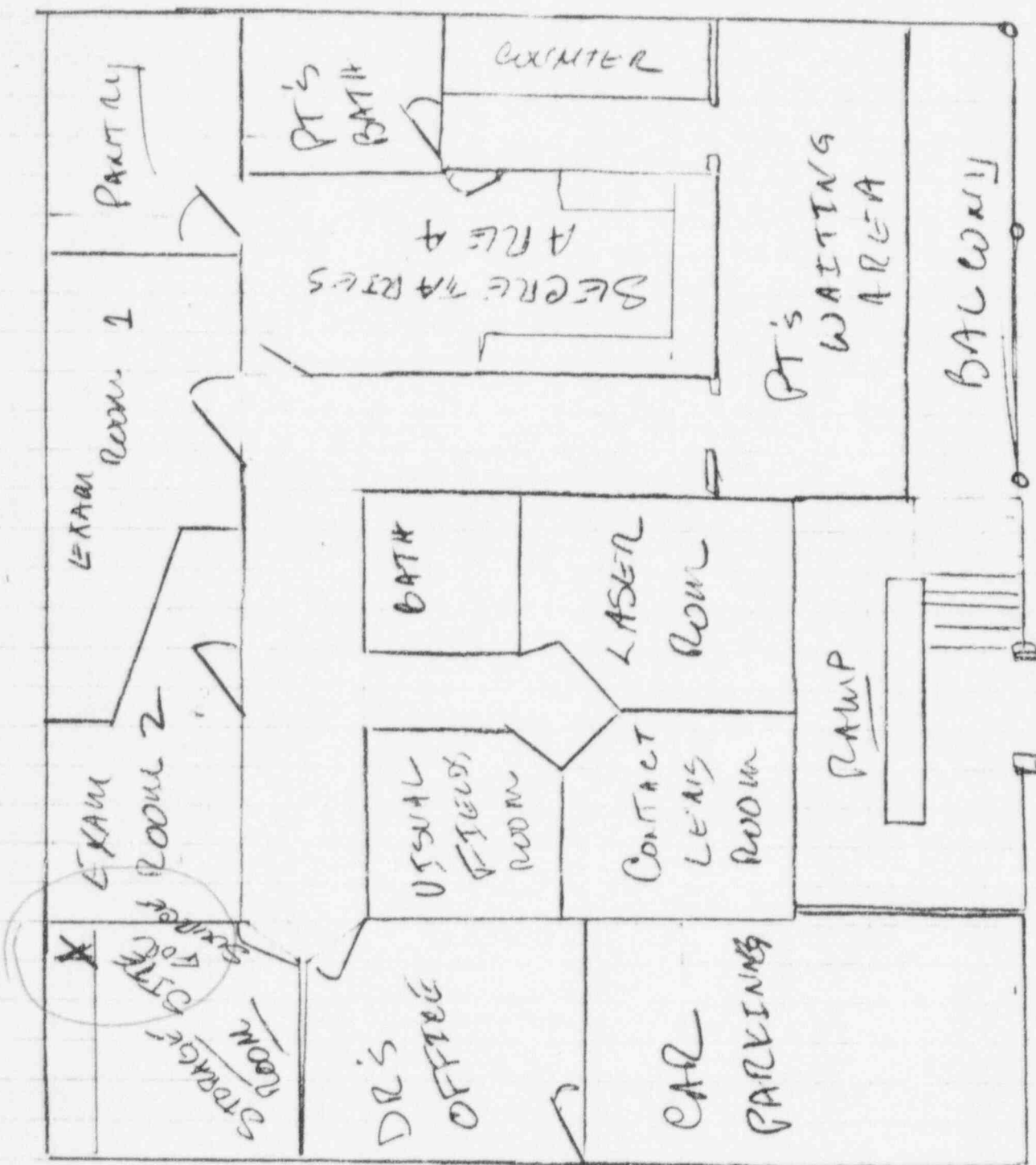
Leak test will be performed routinely at approximately 6 month intervals and records maintained. The source will be withdrawn from service if leak test results indicate any increase in detectable activity from that of previous tests.

Safety rules for handling a Sr-90 eye applicators will be followed at all times and according to necessity. In the event of apparent or probable damage to the source, it will immediately be removed from service and placed into its storage container, placed into a plastic bag and secured. A Radiation Safety Consultant, a Radiation Protection Officer and the Nuclear Regulatory Agency will be contacted immediately for consultation and action. To make sure that radiation exposure will be as low as reasonably achievable (ALARA) in the use and handling of the Sr-90 sealed source, Dr. Puebla will enforce all possible actions to educate, train and protect office personnel in avoidance of radiation exposure. Since they will not participate in the application of radiation directly to patients, radiation exposure should probably be negligible.

Item 11. Waste management

There is no waste generation foreseen and no waste disposal expected from the proposed use and handling of the Sr-90 sealed source eye applicator.

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Dr. Pucuba's Office Floor Plan

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