

(10-2002)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollect@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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 MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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 19408-1415

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

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

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.

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA,
OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR
WYOMING, SEND APPLICATIONS TO:

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

MS 16
L-4
03037043

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

☐

A. NEW LICENSE

☒B. AMENDMENT TO LICENSE NUMBER 52-31094-01☐

C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

PET Imaging Corp.
Centro Médico San Pablo
Edificio Arturo Cadilla
Primer Piso
Bayamón, Puerto Rico 00961

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

The PET/CT Laboratory is located within the
Premises of the Advanced Interventional
Imaging Center (AIIC)
Centro Médico San Pablo
Primer Piso Edificio Arturo Cadilla
Bayamón, Puerto Rico

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

María Margarita Palacios, M.S.

TELEPHONE NUMBER

(787) 615-9271

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 EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

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

FEE CATEGORY 7C

AMOUNT
ENCLOSED \$

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

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, 36, 39, 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Lcdo. Juan V. Bernal / Executive Director

SIGNATURE

Juan V. Bernal

DATE

Feb 14 / 08

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

141439
NMSS/RCM MATERIALS-002

ITEM 5 Radioactive material

- a. Any byproduct material authorized under 10 CFR 35.200
- b. Any
- c. As needed

ITEM 6 Purpose for which licensed material will be use

Diagnostic medical use in humans

ITEM 7 Individual(s) responsible for radiation safety program and their training and experience

The radiation safety program responsibilities have been delegated to our consultant medical physicist, Mrs. Maria M. Palacios, M.S. Mrs. Palacios' credentials are on file at NRC since 1962.

Enclosed please find a copy of letter delegating the authority for the oversight of the radiation protection program to the RSO, as well as the RSO's written acceptance of such responsibilities.

Authorized users:

Rene Dietrich Ormachea, M.D. – his credentials are on file at NRC under license # 52-14931-01

José T. Medina, M.D. – his credentials are on file at NRC under license # 52-14931-01

ITEM 9 Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

Description of the survey meter: Ludlum 14-C GM survey meter with Model 44-9 "pancake" probe

We reserve the right to upgrade our survey instruments as necessary as they are adequate to measure the type and level of radiation for which they are used.

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions. Attached is a description, identified as Attachment 9.4, of additional facilities and equipment.

ITEM 10 We will provide dosimetry that meets the requirements listed under

"Criteria" in NUREG – 1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program- Specific Guidance About Medical Use Licenses."

We have developed and will implement and maintain written procedures for area surveys in accordance with 10CFR 20,1101 that meet the requirements of 10CFR 20.1501 and 10CFR 35.70.

We have developed and will document and implement written procedures for a radiation protection program that will ensure compliance with all applicable NRC regulations and the security and safe use of unsealed byproduct material in diagnostic nuclear medicine.

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10CFR 20.1101.

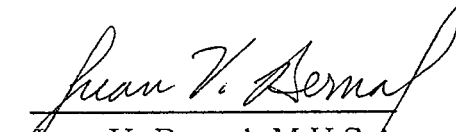
PET IMAGING CORP.

LETTER OF AGREEMENT

As per 10 CFR, Pat § 35.24, Maria M. Palacios is hereby appointed as Radiation Safety Officer to be responsible for implementing the radiation protection program.

The radiation Safety Officer is provided sufficient authority, organizational freedom, time, resources, and management prerogative to:

1. Identify radiation safety problems
2. Initiate, recommend or provide corrective actions
3. Stop unsafe operations; and
4. Verify implementation of corrective actions


Juan V. Bernal, M.H.S.A.
Executive Director

I accept the responsibilities described above.



María M. Palacios, M.S.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Radiation Safety Officer Name: <u>Maria M. Palacios, M.S.</u> 52-14931-01 52-21325-01 52-15139-01 52-30886-01 52-24937-01 ETC.</p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience specified in 10 CFR 35.900(b).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Authorized Users Names and Requested Uses for Each Individual _____</p> <p>Jose T. Medina, M.D. ✓ Rene Dietrich Ormanachea, M.D. 52-14931-01</p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested.</p> <p style="text-align: center;">OR</p> <p>A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested;</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 7: Authorized Nuclear Pharmacists</p> <p>Names: _____</p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named ANP.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the radiopharmacy board(s) recognized by NRC under 10 CFR 35.55(a) or 10 CFR 35.980(a).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.</p> <p style="text-align: center;">AND</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

APPENDIX C

Table C.3 (continued)

[illegible]

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Authorized Medical Physicists</p> <p>Names: _____</p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an AMP for the units requested.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC in 10 CFR 35.51(a) or 10 CFR 35.961(a) or (b).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.961(c) for the units requested.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b) for the units requested.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 9: Facility Diagram</p>	<p>A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:</p> <ul style="list-style-type: none"> • Drawings should be to scale, and indicate the scale used. • Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, as provided above under the heading "Discussion"; • Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and • Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.). 	<p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

APPENDIX C

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.	<input type="checkbox"/>

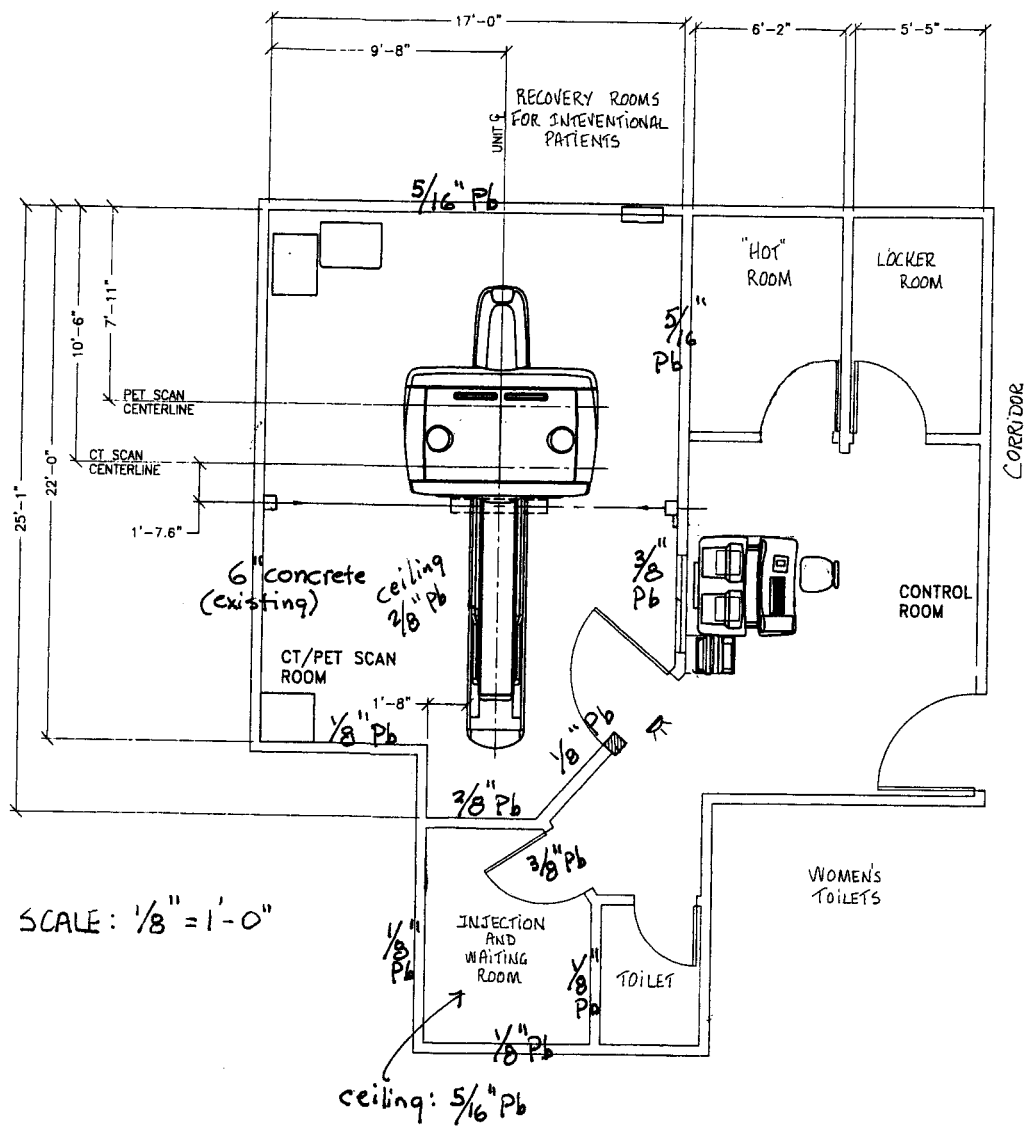
Table C.3 (continued)[illegible]

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Safety Procedures and Instructions	Attached procedures required by 10 CFR 35.610	<input type="checkbox"/>
Item 10: Occupational Dose	A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2002." OR A description of an alternative method for demonstrating compliance with the referenced regulations.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Item 10: Area Surveys	A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."	<input checked="" type="checkbox"/>
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."	<input checked="" type="checkbox"/>
Item 10: Spill Procedures	A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."	<input checked="" type="checkbox"/>
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: AND Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. AND Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	N/A

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 11: Waste Management	A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92."	<input type="checkbox"/>



ATTACHMENT 9.4
Additional Facilities and Equipment

General Electric Discovery ST PET/CT scanner

Atomlab 100 dose calibrator, including vial/syringe dipper and well insert

Ludlum 14-C GM survey meter with probe Model 44-9 ("pancake") and mounted Cs-137, 1.0 uCi check source

Sun Nuclear wipe test counter, including 5" diameter test smears and a Cs-137, 0.5 uCi check source

Vial calibration sources: Co-57, 10 mCi; Cs-137, 250 uCi; Ba-133, 250 uCi

Lead-lined PET unit dose cabinet

L-block shield with built-in dose calibrator shield

Sharps container shield, PET, 1" lead

Sharps container, round, monoject 12/pg

Pro-Tec PET syringe shields – 3cc, 5cc, and 10cc

Shielded syringe carrier, small, 0.25" lead

Forceps, 9.5," curved, locking

Radiation signs

Radiacwash, spray or gal.

Absorbent paper, plus dispenser