

MATERIALS LICENSE

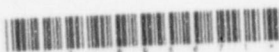
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, 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		3. License Number
1. Mirview Incorporated		21-26775-01
2. 237 Dino Drive, Suite A Ann Arbor, MI 48103		4. Expiration Date
		March 31, 2002
		5. Docket or Reference No.
		030-34321
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. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding xenon and generators)	B. As needed
9. Authorized Use:		
A. Medical use described in 10 CFR 35.100.		
B. Medical use described in 10 CFR 35.200 (excluding xenon and generators).		

CONDITIONS

10. Licensed material listed in Item 6., excluding xenon and generators, may be used at medical facilities anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.
11. Radiation Safety Officer: Frank M. Fayz

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

21-26775-01

Docket or Reference Number

030-34321

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

Material and Use

Frank M. Fayz

10 CFR 35.100 and 35.200 (excluding xenon and generators).

13. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:
1. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and
 2. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Branch, 801 Warrenville Road, Lisle, IL 60532-4351 has been notified that activities authorized by the license will be initiated.
14. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.
15. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."
16. Licensed material (excluding xenon and generators) may be delivered to vans that are located at temporary sites occupied by Mirview personnel in accordance with application dated July 12, 1996 and letter dated February 20, 1997.
17. Radioactive waste generated by the licensee, may be picked up by a nuclear pharmacy from vans located at temporary job sites and occupied by Mirview personnel in accordance with application dated July 12, 1996.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

21-26775-01

Docket or Reference Number

030-34321

18. 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 July 12, 1996; and
- B. Letter dated February 20, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 12 MARCH 1997

By

William P. Keulholz

Nuclear Materials Licensing Branch, Region III

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

21-26775-01

Docket or Reference Number

030-34321

18. 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 July 12, 1996; and

B. Letter dated February 20, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 12 March 1997

By William P. Kuhlholdt
Nuclear Materials Licensing Branch, Region III

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License Fee Management Branch, ARM
and
Regional Licensing Sections

S9
ms-15

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: Program Code:
: Status Code: 3-----
: Fee Category: -----
: Exp. Date: 0 -----
: Fee Comments:
: Decom Fin Assur Reqdt: -----

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A. REGION

Applicant/Licensee: MIRVIEW INCORPORATED
Received Date: 961230
Docket No: 3034321
Control No.: 302175
License No.:
Action Type: New Licensee

Amount: 1400
Check No.: 0777

Signed D. Hersey
Date 1-3-97

1. Fee Category and Amount: 7C \$1400

Amendment	Rate	Applies
Renewal	---	---
License	---	---

Signed _____
Date 1/6/97

Log Jan 3 III
Remitter Jean Tangalakis
Check No. 111
Amount \$1400
Fee Category 7C
Type of Fee APP
Date Check Rec'd 1/6/97
Date Completed 1/6/97
By: SC

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 9 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. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, 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 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 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 LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GA 30323-0190

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 SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137-5927

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, 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

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

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

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

☒ XX

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER _____

C. RENEWAL OF LICENSE NUMBER _____

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

Mirview, Inc.
237 Dino Drive, Suite A
Ann Arbor, MI 48103

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

Mobile Nuclear Medicine Service

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dawn Edwards, Medical Physics
Consultants, Inc.

TELEPHONE NUMBER

313-662-3197

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. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7C AMOUNT ENCLOSED \$ 1400
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, 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

Dean Tangalakakis, President

SIGNATURE

DATE

7/12/96

FOR NRC USE ONLY

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

DATE

Pm: 12-26-96

DEC 30 1996

REGION III 302125



November 27, 1996

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351

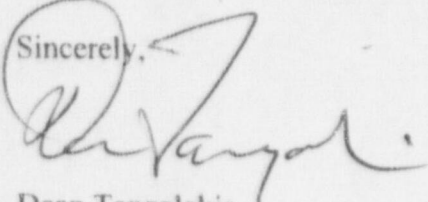
Re: New license application, Mirview, Inc.

Enclosed, please file our new license application for a mobile SPECT imaging service.

Also enclosed is the \$1400 application fee.

If you have any questions regarding the application please contact Dawn Edwards, our consultant, at 313-662-3197.

Thank you for your cooperation in this matter.

Sincerely, 

Dean Tangalakis
President
Mirview, Inc.

RECEIVED
DEC 30 1996
REGION III

DEC 30 1996

Mirview, Inc.
New License Request
July 1996

APPLICABILITY TABLE

Item	Topic	
8.1	Training Program	Enclosed
8.2	Other Training Program	N/A
9.1	Facility Diagram & Equipment List	Enclosed
9.2	Survey Instrument Calibration	Per 10CFR35.51
9.3	Dose Calibrator Calibration	Enclosed
9.4	Personnel Monitoring Program	Enclosed
9.5	Mobile Imaging Equipment QA	Enclosed
9.6	Other Equipment and Facilities	N/A
10.1	Radiation Safety Committee	Enclosed
10.2	ALARA Program	Enclosed
10.3	Leak Test	Per Appendix H Reg Guide 10.8
10.4	Safe Use of Radiopharmaceuticals	Enclosed
10.5	Spill Procedures	Enclosed
10.6	Ordering and Receiving	Enclosed
10.7	Opening Packages	Enclosed
10.8	Unit Dose Records	Enclosed
10.9	Multidose Vial Records	Enclosed
10.10	Mo-99 Concentration Records	N/A
10.11	Implant Source Use Records	Per Appendix M.4 Reg Guide 10.8
10.12	Area Survey Procedures	Enclosed
10.13	Air Concentration Control	Enclosed
10.14	Radiopharmaceutical Therapy	N/A
10.15	Implant Therapy	N/A
10.16	Other Safety Procedures	N/A
11.1	Waste Disposal	Enclosed
11.2	Other Waste Disposal	N/A
12.1	Quality Management Plan	Enclosed

Mirview, Inc.
New License Request
July 1996

RADIOACTIVE MATERIAL AND USE

Byproduct Material	<i>Item 5</i> Amount	<i>Item 6</i> Purpose
Material in 35.100	As Needed	Uptake, dilution, and excretion studies
Material in 35.200	As Needed	Imaging and localization studies

RADIATION SAFETY PROGRAM RESPONSIBILITY

Item 7.1

Authorized Users

Materials

*Frank M. Fayz, M.D.

35.100 and 35.200 excluding Xenon
and Radionuclide Generators

Item 7.3

Radiation Safety Officer

Frank M. Fayz, M.D.

* see NRC license No. 21-26306-01 , Fairview Radiology

PERSONNEL TRAINING PROGRAM

Item 8.1

Page 1 of 2

Personnel

All radiation workers and ancillary personnel whose duties will require them to work in the vicinity of radioactive materials will receive instruction. Ancillary personnel may include housekeeping, nursing, maintenance, and ECG technologists.

Training Frequency

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or in the terms of the license.

Instruction Topics

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. The licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. The worker's right to be informed of occupational radiation exposure and bioassay results.

Mirview, Inc.
New License Request
July 1996
Item 8.1

Page 2 of 2

9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of the license and license conditions, as required by 10 CFR Part 19.

Documentation will be kept on hand for review of the list of topics covered, the date of the instruction, and the names of those attending.

Mirview, Inc.
New License Request
July 1996

EQUIPMENT LIST

Item 9.1 (cont.)

Imaging Equipment

Gamma Camera

Dose Calibrator

Capintec

Survey Meter

GM meter

Range (0-2000 mR/hr)

Other

Lead Glass Face Shield

Leaded Syringe Shields

Remote Handling Tools

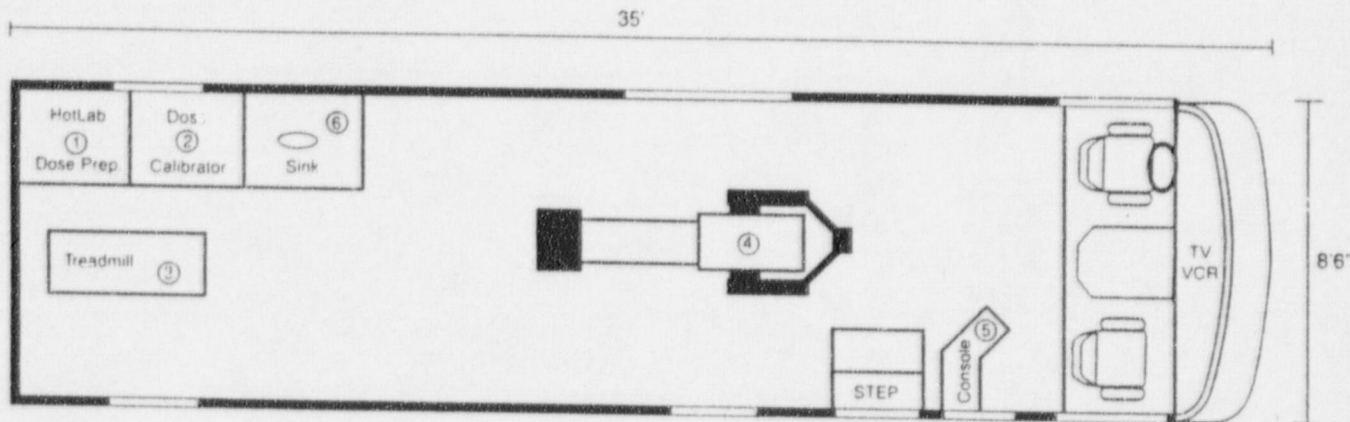
Leadlined receptacles for storage of radioactive material

RadiacWash

Mirview, Inc.
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FACILITY DIAGRAM

Item 9.1



- | | |
|---------------------------------|--------------|
| 1. "L" shield / dose prep. area | 3. treadmill |
| 1a.(below) waste storage | 4. camera |
| 2. dose calibrator | 5. console |
| 2a.(below) package transit area | 6. hand sink |

This license is for a mobile SPECT imaging service. Imaging will be performed in a truck which has been modified to accommodate a SPECT camera. Radioactive material and radioactive waste will be kept in the truck.

All radiopharmaceuticals will be delivered to the nuclear medicine service truck. Radioactive material will be packaged in accordance with DOT regulations during transport to each location. A GM survey meter will be present in the truck at all times.

Radioactive will remain in the truck except for those rare instances when a patient will be administered a dose in a waiting area or exam room at the mobile site. In these cases, care will be taken to remove all materials possibly contaminated during the administration and a GM survey of the area will be performed. The results of this survey will be documented and retained for three years. The records will be in accordance with Item 10.12 of this application.

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July 1996

All radioactive materials will be shielded using lead to insure that no member of the general public will receive greater than 100 mrem exposure.

The truck (including cab) will be locked whenever it is unattended by an employee. Unauthorized entrance to the truck will be prohibited by the use of an electronic security system.

The imaging truck will generally be parked at the following address when not in use: 5245 Schaefer, Dearborn, MI 48126. This is a clinic parking lot and is the location in which the Radiation Safety Officer, Frank M. Fayz, M.D., will be most often be located during the day.

The door to the truck will be posted with a Caution Radioactive Materials sign.

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CALIBRATION OF SURVEY INSTRUMENTS

Item 9.2

All survey Instruments will be calibrated and checked in accordance with 10 CFR 35.51. Survey instruments will be calibrated by :

1. The manufacturer:
2. Medical Physics Consultants: (NRC License # 21-20153-01)
3. Any authorized user licensed to perform survey meter calibrations as a service.

CALIBRATION OF DOSE CALIBRATOR

Item 9.3

Page 1 of 2

Test	Frequency	Tolerance
Constancy	Each day at each job site prior to patient dose assays	+/- 10%
Linearity	Installation, following repair, and quarterly	+/- 10%
Accuracy	Installation, following repair, and annually	+/- 10%
Geometry Dependence	Installation and following repair	+/- 10%

CONSTANCY testing will be performed using a long-lived reference source (e.g., Cesium-137) with activity greater than 50 microcuries. Zero or record the background reading on the appropriate setting. Assay the source for both the reference source setting and the most commonly used radiopharmaceutical settings. Record the readings and compare to the calculated values. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the constancy error exceeds 10 percent.

LINEARITY testing will be performed using a Technetium-99m source having activity at least as great as the maximum activity administered to patients. Testing will be conducted with the decay or the leaded-sleeve method over the entire range of administered activity.

Decay method: Assay the source at approximately 0, 6, 24, 30, 48, etc. hours over the entire range of use (between the highest activity administered to patients and 30 uCi). Record the net activities, time, and date. Using a measured activity for reference which is closest to that which is commonly administered to patients, calculate the expected readings and compare to the measured readings. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of activity.

Sleeve method: The sleeves will be calibrated at the time of an initial reading of a decay-method linearity test. Either the "Calicheck" or "Lineator" product will be used and the testing procedure will be performed according to the manufacturer's instructions. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of use.

ACCURACY testing will be performed using Cesium-137 and Cobalt-57 or Barium-133 reference sources having NBS-traceable activities greater than 50 microcuries. The net measured activities will be compared to the calculated activities based on radioactive decay. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the accuracy error exceeds 10 percent.

GEOMETRY DEPENDENCE testing will be performed using a solution of Technetium-99m having an activity concentration of 1-10 mCi/ml. If generators and/or radiopharmaceutical kits are normally used, both of the following tests will be performed:

Unit dose users will assay 0.5 cc of the solution in a 3 cc plastic syringe. The solution in the syringe will then be diluted with water and assayed at incremental volumes of 1.0, 1.5, and 2.0 cc. Record all readings. Select a standard volume closest to that normally used for injections and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

Kit users will assay 1.0 cc of the solution in a 30 cc glass vial. The solution in the vial will then be diluted with water and assayed at incremental volumes of 3, 5, 7, 9, 11, 13, 15, 17, and 19 cc. The assays should take place within 10 minutes. Record all readings. Select a standard volume closest to that normally used for mixing kits and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

PERSONNEL MONITORING PROGRAM

Item 9.4

1. The RSO or delegate will promptly review all film or TLD exposure reports to look for workers or groups of workers whose reported exposures are unusual.
2. All individuals who are occupationally exposed to radiation on a regular basis will be issued a film or TLD whole body monitor.
3. All individuals who handle radioactive material on a regular basis will be issued a film or TLD finger monitor.
4. All individuals who are occupationally exposed to significant radiation levels on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for those patients.
5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.
6. All film and TLD badges will be changed on a monthly basis.

PROCEDURE FOR CHECKING EQUIPMENT USED IN MOBILE NUCLEAR MEDICINE SERVICE

Item 9.5

Page 1 of 2

Survey Meter

The survey meter shall be checked for proper operation with a dedicated check source upon arrival at the imaging location. The dedicated check source reading shall be compared to the reading noted on the side of the meter. If the meter is not functioning properly, radioactive material will not be used.

Camera

Prior to use of radioactive material at each location, the following checks will be performed.

1. Peak the camera according to manufacturer's instructions.
2. Perform a uniformity test either intrinsically or extrinsically. Acquire at least 1000K counts for a small field of view camera or 3000K counts for a large field of view camera.
3. The imaging technologist shall verify that the uniformity is acceptable before administering any radioactive material.

Weekly Checks

1. Acquire a bar pattern/resolution image with the most frequently used collimator in place.
2. The smallest quadrant of the bar pattern will be imaged in each of the four quadrants of the camera face.
3. Display these images to verify that the storage and display devices are functional.

These images will be retained for three years.

Checks Following Repair and Quarterly

1. Check the motion interlocks by activating the emergency-off switch(es) while the camera is in motion. If the off switch does not stop the motion, the camera

Mirview, Inc.

New License Request

July 1996

must be repaired before it is used with patients. This test is not required if its performance jeopardizes the components of the system.

2. Check all motion switches by beginning movement of the camera and then releasing the motion enable switches. If the camera continues movement after the enabling switches have been released, do not use the camera until it has been repaired.

A record of all of these checks shall be kept for three years.

**RADIATION SAFETY COMMITTEE CHARTER
AND
RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY**

Item 10.1

Page 1 of 4

This license is for an out-patient mobile diagnostic clinic and, therefore, is not required to have a Radiation Safety Committee. The following statements which refer to the Radiation Safety Committee will actually mean Radiation Safety Officer for this license. All pertinent responsibilities of the Radiation Safety Committee will be met by the Radiation Safety Officer with the assistance of the radiological physics consultants.

RESPONSIBILITIES

The Radiation Safety Committee (RSC) shall:

1. Ensure that ionizing radiation will be used safely, to includes the review as necessary of training programs, equipment, facility design, supplies and procedures.
2. Ensure that ionizing radiation is used in compliance with all state and federal regulations and all licenses and registrations granted for usage.
3. Ensure that the usage of ionizing radiation is consistent with the As Low As Reasonably Achievable (ALARA) philosophy and program.
4. Establish investigation levels for individual occupational radiation exposures, consistent with the ALARA philosophy and program.
5. Entrust to the Radiation Safety Officer (RSO), the day to day responsibility of management of the radiation safety program, reportable to the committee as noted below.

DUTIES

The RSC shall:

1. Be familiar with all pertinent regulations, all license applications, all licenses their conditions and amendments.

2. Review the training and experience of the proposed authorized users and the RSO to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and all licenses issued to the facility.
3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the facility.
4. Review recommendations on ways to maintain individual and collective doses ALARA.
5. Prescribe special conditions that will be required during a proposed method of use of ionizing radiation such as requirements for bioassays, physical examinations of users, and special monitoring procedures.
6. Review on the basis of safety, and approve with the advice and consent of the RSO and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted within the regulations.
7. Review quarterly with the assistance of the RSO a summary of the occupational radiation dose records, consistent with the ALARA program.
8. Review quarterly with the assistance of the RSO, all incidents or unusual occurrences, such as misadministrations of ionizing radiation, spills, etc. which involved ionizing radiation.
9. Identify radiation safety problems, as well as initiate, recommend, provide and verify corrective actions.
10. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used are appropriately instructed as required in 10CFR19.12.
11. Review at least annually the radiation safety program to insure compliance with all regulations, conditions of licensure and the ALARA program to include records, reports from the RSO, inspection results and adequacy of the management control system.
12. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

RADIATION SAFETY OFFICER

The Radiation Safety Officer (RSO) shall:

1. Investigate overexposures, accidents spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, Misadministrations, and other deviations from the radiation safety practices approved by facility management, if applicable.
2. Establish, implement, and collect in a centralized location policies and procedures as follows:
 - a. Authorization for the purchase of radioactive material.
 - b. Receipt and opening of packages containing radioactive material.
 - c. Storage of radioactive material.
 - d. Inventory control of radioactive material
 - e. Safe use of radioactive material.
 - f. Emergency procedures in the event of loss, theft, etc.
 - g. Periodic radiation surveys
 - h. Checks of radiation survey and other radiation safety instruments.
 - i. Disposal of radioactive material.
 - j. Personnel training of those who work in or frequent areas of radiation
3. Maintain a record systems to include at least the following:
 - a. All records, reports, written policies and procedures required by regulatory agencies concerning radioactive material.
 - b. A copy of the regulations governing the possession, use and disposal of licensed material, such as Title 10 Code of Federal Regulations.
4. Review and sign the following radiation safety program records, if applicable:
 - a. Sealed Source Inventories
 - b. Sealed Source Leak Tests
 - c. Dose Calibrator Linearity Tests
 - d. Dose Calibrator Accuracy Tests
 - e. Dose Calibrator Geometrical Variation Tests
 - f. Misadministration documentation
 - g. Changes in the radiation safety program
 - h. Radiation surveys of sealed source storage.

5. Inform facility management at least annually of the status of the licensed material program.
6. Establish personnel exposure investigational levels as a part of the ALARA program and philosophy.
7. Approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management, if applicable.

MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

Item 10.2

Page 1 of 6

1. Management Commitment

a. We, the management of this medical facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our facility. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposures ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(1) Management will delegate authority to the RSO for the enforcement of the ALARA concept.

(2) Management will support the RSO when it is necessary for the RSO to assert authority.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table I are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

Table I: Investigational Levels

Body Part Exposed	Level I (mrems per calendar quarter)	Level II
1. Whole body; head and trunk; active blood forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1250	3750
3. Skin of the whole body	1250	3750
4. Eye (lens)	375	1125

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform or cause to be performed an annual review of the radiation safety program for adherence to ALARA concepts. Review of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review or cause to be reviewed at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report.

(3) Quarterly review of records of radiation surveys. The RSO will review or cause to be reviewed radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report.

b. Education Responsibilities for the ALARA Program

- (1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
- (2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to followed.

- (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish or cause to be established procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

- (1) The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

- (1) The authorized user will consult with the RSO during the planning stage before using radioactive materials for new uses.
- (2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

b. Authorized User's Responsibility to Supervised Individuals

- (1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
- (2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

- a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
- b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

6. Establishment of Investigational levels in Order to Monitor Individual Occupational External Radiation Doses

This facility hereby establishes investigational levels for occupational external radiation doses which, when exceeded will initiate review or investigation by the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 20.401 of 10 CFR Part 20. The following actions will be taken at the investigational levels as stated in Table 1.

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

- b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The RSO will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

- c. Personnel dose equal to or greater than Investigational Level II.

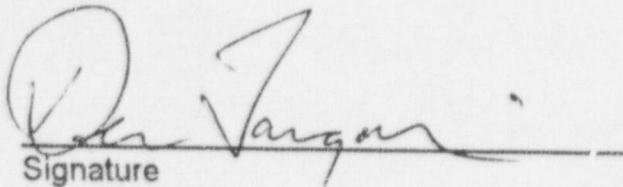
The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's NRC Form-5 or its equivalent will be generated.

- d. Re-establishment of investigational Levels to levels above those listed in Table 1.

In cases where a worker or group of worker's doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented. The RSC will review the justification for and must approve or disapprove all revisions of investigational levels

7. Signature of Certifying Official

I hereby certify that this institution has implemented the ALARA Program set forth above.


Signature

DEAN TANGALAKIS
Name (Print or Type)

PRESIDENT
Title

Mirview, Inc.
New License Request
July 1996

PROCEDURE FOR LEAK-TESTING SEALED SOURCES

Item 10.3

1. Medical Physics Consultants, Inc. (NRC License No. 21-20153-01), or anyone licensed by the NRC to perform leak testing as a service. Sources will be leak tested on a bi-annual basis that is not to exceed 6 months.

RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

Item 10.4

Page 1 of 2

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low background area.
4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindicated. In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose.
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.
6. Do not store food, drink, or personal effects in areas where radioactive material is used or stored.
7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility in a designated low-background area.
8. Wear a finger exposure monitor during the elution of generators, during the preparation, assay, and injection of radiopharmaceuticals, and when holding patients during procedures.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for contamination.
11. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

Item 10.4

Page 2 of 2

12. Confine radioactive solutions in shielded containers that are clearly labeled with the isotope, compound name, and the date and time of receipt or preparation. Syringes and/or syringe shields shall be labeled with the radiopharmaceutical name or abbreviation contained within, type of study, or patient's name.
13. Assay each patient dose in the dose calibrator before administration. Do not use a dose if it differs from the prescribed dose by more than ten percent, except prescriptions of less than 30 uCi. Check the patient's name and I.D. number and the prescribed radionuclide, chemical form, and dosage before administering.
14. Always keep radioactive materials in shielded locations or containers.
15. When practical, use a cart or wheelchair to move flood sources, syringes, waste, and other radioactive material.
16. Do not pipette by mouth.

EMERGENCY PROCEDURES

Item 10.5

Page 1 of 2

Minor Spills

1. **NOTIFY:** Notify persons nearby that a spill has occurred.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent paper.
3. **CLEAN UP:** Use disposable gloves and remote handling tools. Carefully fold the absorbent paper with the clean side out and insert in a plastic bag for transfer to a radioactive waste container. Also place the contaminated gloves and any other contaminated disposable material in the bag.
4. **SURVEY:** Survey the area with a low-range, GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.
5. **REPORT:** Report the incident to the RSO who will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to ensure that the Report and Survey are completed properly.

Major Spills

1. **CLEAR THE AREA:** Notify all persons not involved in the spill to vacate the room.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent paper, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. **SHIELD THE SOURCE:** This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. **CLOSE THE ROOM:** Leave the room and lock the door(s) to prevent entry.
5. **NOTIFY:** Notify the RSO immediately.

Mirview, Inc.
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Item 10.5 (cont)

Page 2 of 2

6. PERSONNEL DECONTAMINATION: Decontaminate personnel by removing contaminated clothing and flushing the contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.

REPORT: The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to see that the report and the survey are completed properly.

PACKAGE ORDER AND RECEIPT PROCEDURES

Item 10.6

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
 - a. **For routinely used materials**
 - (1) Written records that identify the authorized user or department, isotope, chemical form, activity, supplier will be made.
 - (2) The above records will be checked to confirm that material received was ordered through proper channels.
 - b. **For occasionally used materials (e.g., therapeutic dosages)**
 - (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.
 - (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.
3. Packages will be delivered directly to the Nuclear Medicine Truck.
4. Deliveries will only be made when a member of our staff is present in the trailer. Please see the memorandum which will be issued to the radiopharmacy.

Mirview, Inc.
New License Request
July 1996

Delivery Memorandum

TO: Delivery Personnel

FROM: Dean Tangelakis, President, Mirview, Inc.

SUBJECT: Delivery of Packages Containing Radioactive Material

Please deliver all radioactive material packages directly to our Nuclear Medicine Trailer. The address will be provided when the order is placed. You may only deliver to an employee who is in attendance at the trailer. Under no circumstances are you to leave the container of radiopharmaceuticals if the trailer is unattended.

If the package appears to be damaged, immediately contact one of the individuals identified below. Remain at the hospital until it can be determined that neither you, the driver, nor the delivery vehicle is contaminated.

Dean Tangelakis, President _____ Phone _____

Technologist _____ Phone _____

PROCEDURE FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Item 10.7

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO.
3. Measure the exposure rate from the package at 1 meter and at the package surface. If the rate is higher than expected, stop and notify the RSO. The surface dose rate should not exceed 200 millirem per hour. Packages with the "White I" labels should be less than 0.5 millirem per hour at the package surface.
4. Wipe the external surface of the source container and analyze the sample for activity in (dpm's). If the value is above the established trigger level, and there is contamination, notify the RSO.
5. Follow the steps listed below when opening the package.
 - a.) Remove the packing slip.
 - b.) Open the outer package following the supplier's instructions, if available.
 - c.) Open the inner package and verify that the contents agree with the packing slip.
 - d.) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
 - e.) If anything unusual is noticed, stop and notify the RSO.
6. Verify that the material received is the material ordered.
7. Monitor the packing material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.
8. Record the receipt and all readings taken.

BYPRODUCT MATERIAL USE

Item 10.8

Unit Dose Records shall contain:

1. Technical Data
 - a. Radionuclide
 - b. Chemical form or abbreviation
 - c. Date of receipt, administration or disposal
 - d. Activity as recorded on the packing slip
 - e. Supplier
 - f. Lot or control number
2. Administrative Data
 - a. Time and date of administration or disposal
 - b. Measured activity
 - c. Patient name and ID number
 - d. Method of disposal
 - e. Initials of person recording the information
 - f. Prescribed Dosage

Item 10.9

Multidose Vial Records shall contain:

1. Technical Data
 - a. Radionuclide
 - b. Chemical form or abbreviation
 - c. Date of receipt or preparation
 - d. Date, time, and activity of initial assay
 - e. Supplier of kit manufacturer
2. Administrative Data
 - a. Date and time dosage was drawn and measured
 - b. Prescribed dosage
 - c. Calculated volume needed for prescribed dose
 - d. Measured activity
 - e. Patient name and ID number
 - f. Method of disposal and date
 - h. Initials of person recording information

AREA SURVEY PROCEDURES

Item 10.12

Page 1 of 2

Surveys for contamination and ambient exposure rates will be performed in accordance with 10 CFR 35.70.

1. All areas where radiopharmaceuticals are eluted, prepared, and administered will be surveyed each day following use at each temporary job site for ambient radiation exposure rates and weekly for removable contamination. Special care will be taken to remove all paraphernalia from patients rooms where diagnostic administrations are occasionally made; and these rooms will not be surveyed.
2. All areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and for removable contamination.
3. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/h.
4. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm.
5. The trigger level for exposure rate surveys will be rates twice the normal background reading for that area.
6. The trigger level for removable contamination surveys will be the detection of values equal to or less than the recommended levels in Table N-1 of the Regulatory Guide 10.8. For example, the action level for Tc-99m contamination will be 2000 dpm or lower.
7. Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to background on repeat surveys.

8. A record shall be kept of all survey results. The record will include:
- a. Location, date, and type of equipment used.
 - b. Initials of the person conducting the survey.
 - c. Drawing of the area surveyed.
 - d. Trigger levels keyed to the location on the drawing.
 - e. Results keyed to the location on the drawing.
 - f. Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.
9. The RSO or his designate will review the survey results on a quarterly basis for conformance to certain action levels.
10. The method for determining the efficiency factor of each counting instrument used to detect contamination for wipe testing is as follows:

A= Calculated source activity of sample isotope in dpm

B= Measured source counts of sample isotope in cpm

C= Measured background counts in cpm

D= B-C (Net Counts in cpm)

Efficiency Factor = $\frac{\text{Calculated activity in dpm (A)}}{\text{Net counts in cpm (D)}}$

Wipe sample in dpm = Net counts of wipe sample x Efficiency factor

11. The RSO will be notified of all positive wipe test and ambient survey results.

Mirview, Inc.
New License Request
July 1996

AIR CONCENTRATION CONTROL

Item 10.13.1

We will not use radioactive gases at this facility.

WORKER DOSE FROM AEROSOLS

Item 10.13.2

We will collect spent aerosol in a single-use shielded trap device, therefore no effluent monitoring is needed.

PUBLIC DOSE FROM AIRBORNE EFFLUENT

Item 10.13.3

We will not directly vent spent aerosols and gases to the atmosphere, therefore no effluent estimation is necessary.

WASTE DISPOSAL

Item 11.1

Page 1 of 2

Liquids and Gases

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere.

1. Disposal to the sanitary sewer system will be made in accordance with 10 CFR 20. A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.
2. Permissible concentrations in effluents will be kept within the limits numerated in Table II of Appendix B of 10 CFR 20. A record will be kept of the date, radionuclide, estimated activity released, estimated concentration, and vent site at which the material was released.

Decay in Storage

1. Only material with a physical half-life of less than 65 days may be decayed in storage at the facility.
2. Each container will be tagged to include:
 - a. the date sealed or set into storage
 - b. the longest-lived isotope in the container
 - c. the initials of the person setting the waste for decay.
3. Material will be decayed for at least 10 half-lives.
4. Prior to disposal as in-house waste, each container will be monitored as follows:
 - a. Low-range GM survey meter will be checked for proper operation.
 - b. Waste will be monitored in a low level area.
 - c. Any shielding around the container will be removed.
 - d. All surfaces of each individual container will be monitored.
 - e. Only those containers which cannot be distinguished from background levels will be disposed of after all radioactive labels have been defaced.
 - f. The date on which the container was placed in storage will be recorded.
 - g. The date of disposal will be recorded.
 - h. The type of material will be recorded.

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July 1996

Item 11.1

Page 2 of 2

Unit Dose Waste

If a unit dose pharmacy is used, the materials supplied by them (e.g., syringes, needles, etc.) may be returned to the unit dose pharmacy in the original shipping container. Pertinent DOT regulations will be followed as specified by the unit dose pharmacy.

MAR 12 1997

Dean Tangalakis, President
Mirview, Inc.
237 Dino Drive, Suite A
Ann Arbor, MI 48103

Dear Mr. Tangalakis:

Enclosed is your NRC Material License Number 21-26775-01 in accordance with your request.

Your letter dated February 20, 1997, states you have not purchased a survey meter yet. Please be advised that you may not possess and use licensed materials authorized in your license until you have obtained the equipment described in the application and supporting documentation.

Please note that the revised Part 20 (10 CFR 20.1906) modifies the package receipt/opening procedures. You may need to revise your current receipt/opening procedures to comply with the changes in the revised Part 20. Enclosed is Appendix X which provides guidance on complying with the new Part 20 requirements.

Also note, it appears your shipping procedures contain older terms for hazardous material descriptions and proper shipping names, etc. You may need to revise your shipping procedures to comply with current changes in the Department of Transportation (DOT) regulations. Enclosed are copies of the Federal Register and other documentation which provide guidance on complying with the DOT regulations.

Based on your declaration in letter dated February 20, 1997, we agree that a "Quality Management Program" need not be implemented at this time. However, in the future, should you wish to institute procedures in accordance with the provisions of Section 35.32(a)(1), it will be necessary to submit a QMP to our office for review and approval prior to its implementation.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

302175

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license; or
 - b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.
4. Request and obtain a license amendment before you:
 - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
 - b. Permit anyone, except individuals described in 10 CFR 35.13(b) to work as an authorized user under the license;
 - c. Change Radiation Safety Officers;
 - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - f. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
William P. Reichhold
Nuclear Materials Licensing Branch

License No. 21-26775-01
Docket No. 030-34321

Enclosures:

1. New License Package
2. Appendix X
3. Copies of Federal Register DOT

DOCUMENT NAME: M:\03034321.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII <i>WPR</i>								
NAME	WPreichhold:ort								
DATE	03/12/97								

OFFICIAL RECORD COPY



February 20, 1997

Mr. Bill Reichhold
United States Nuclear Regulatory Commission
Region III, Materials Licensing
801 Warrenville Road
Lisle, IL 60532

RE: Additional information for new license request for Mirview, Inc., Control
Number 302175

Dear Mr. Reichhold:

Enclosed is the additional information you requested regarding our new license
request.

If you have any additional questions please contact Dawn Edwards, our
consulting physicist, at 313-662-3197.

Thank you for your cooperation in this matter.

Sincerely,

Dean Tangalakis
President
Mirview, Inc.

RECEIVED
MAR 03 1997
REGION III

FAIRVIEW RADIOLOGY

ACCREDITED BY AMERICAN COLLEGE OF RADIOLOGY IN MAMMOGRAPHY

AFFILIATED PHYSICIAN OF THE CLEVELAND CLINIC FOUNDATION

FRANK M. FAYZ, M.D.

Diplomate American Board of Radiology

- CT Scan
- Nuclear Medicine
- Nuclear Cardiology
- Stress Lab

- General Radiology
- Fluoroscopy
- Mammography
- MRI/MRA

- Ultrasound
- Transrectal Ultrasound
- Echo Cardiography
- Color Flow Doppler

February 20, 1997

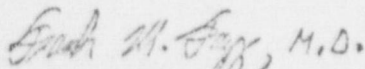
Dean Tangelakis, President
MIRVIEW, INC.
237 Dino Drive, Suite A
Ann Arbor, MI 48103

Dear Mr. Tangelakis:

This letter is to inform you that you may park the mobile Nuclear Medicine imaging truck owned by Mirview, Inc. in the parking lot at our facility. It is our understanding that our parking lot will become the general parking area for the truck and that it will be parked in our lot on a daily basis. Please be aware that the truck must be parked adjacent to our building and must not be in any public right of way.

Access to our parking lot is granted to Mirview personnel at all times to park the truck or enter the truck when needed. In the event of any disharmony between Mirview and Fairview Radiology, you will be granted full access to the parking lot and the truck for decontamination and removal of radioactive material.

Sincerely,



Frank M. Fayz
Owner
Fairview Radiology

Fairview Medical Center

5245 Schaefer Road Dearborn, Michigan 48126
313/581-3000 FAX 313/581-6464

Oaklane Medical

17000 Hubbard Drive, Suite 600 Dearborn, Michigan 48126
313/336-5300 FAX 313/336-5353

Radiation Safety Officer:

1. Dr. Fayz will be located on a daily basis at Fairview radiology which is where the Mirview truck will be parked at the end of each day. This location will enable him to be available daily and perform his duties as RSO. Dr. Fayz or his delegate will be available by either phone and / or beeper at all times whenever services are being provided.
2. Dr. Fayz will spend approximately 15 hours per week performing his duties as RSO.
3. The maximum response time is approximately 30 minutes to any client location.
4. Dr. Fayz has given up a portion of his duties at Fairview Radiology so that he will be able to spend 50% of his time performing his duties at each facility.

Training:

We will use both lecture and written documents to train personnel. The lecture will be given by either the Radiation Safety Officer or our consulting physicist. In addition, quizzes will be periodically given to personnel to assure comprehension of the covered materials.

Survey Meter:

We have not yet purchased a survey meter for the facility but will most likely purchase a Ludlum 14C GM survey meter.

Facility:

1. The radiopharmaceutical storage and waste storage is located in a locked cabinet below the dose prep area and dose calibrator.
2. The exact location of the trailer will vary from site to site. However, we will position the trailer in a location agreed upon by the client. It will not be parked in public right-of-ways such as streets, public parking areas or alleys.
3. All radioactive materials will be kept in shielded containers until immediately prior to its use. The worst case scenario for exposure rate outside the trailer would be an unshielded syringe prior to insertion into a syringe shield. This activity would most likely be 30 mCi of Tc99m. Therefore the maximum

possible exposure rate at a very conservative distance of one meter would be 1.8 mR/hr. Additionally, the attenuation from the walls of the truck would substantially reduce this even further. Since this is not a constant source of exposure and emanates from a mobile truck, it is not conceivable that any member of the public would receive exposures that would exceed the limits as required in 10 CFR part 20.

4. We will obtain a letter signed by the management of each client's for services which are rendered that authorizes the use of radioactive material at the client's address of use. We anticipate that most of client's will not be authorized to provide nuclear medicine services. However, when we provide service to a client who is authorized to provide these services, we will request a copy of their license and the conditions which are pertinent to our use. We will then meet the most restrictive of either of our license conditions. We will make available for the client's review the required NRC documents and records kept under this license. In addition, we will allow the client to observe the our licensed activities at any time.
5. All areas of the van will be surveyed following use at each temporary job site for ambient exposure rates. In addition, surveys for removable will be performed in the area where radiopharmaceuticals are located during transport at each site prior to opening the packages. Complete surveys of the van for removable contamination will be performed weekly.
6. The general parking area for the van at Fairview Radiology is adjacent to the building which is not in a public right of way. The parking area is owned by Fairview Radiology. Enclosed is an agreement between Mirview, Inc. and Fairview Radiology allowing the van to be parked in the Fairview Radiology parking lot.

Delivery of Radiopharmaceuticals:

1. The van will most often be located at Fairview Radiology when radiopharmaceuticals are delivered. The doses will be transported via the mobile Imaging truck to the client. On occasion, the radiopharmaceuticals will be delivered to the truck while we are parked at a clients facility. All doses will only be delivered when our personnel are in the trailer either on location at a client's site or in the general parking area. Upon approval of this application we will notify the unit dose supplier in writing of this requirement. No radioactive material will be shipped to and / or delivered directly to the clients address of use.
2. Access to the truck (including the cab) will be controlled by locking the entrance doors and by a electronic security system at any time when not attended. All areas of use that require posting will be posted as required in

10 CFR part 19. These conditions will apply at the general parking area as well as at the client's facility.

Dose Calibrator:

1. When using the shield method for the linearity check, we will measure over the entire range of use (between the highest activity administered to patients and 30 uCi).
2. The source used for the accuracy test will be within +/- 5% of the true activity of the source.

Transportation:

1. All radioactive material will be shipped in accordance with DOT regulations during transport to each imaging location. We have enclosed a copy of our radioactive material shipping paper and the policies associated with the above procedures.
2. Unit dose syringes are packaged inside the lead syringe holders (either 1/8" or 1/4" lead thickness) and packaged inside U.S. Government approved metal ammunition boxes. The ammunition boxes were tested by Albuquerque Testing Laboratories, 532 Jefferson St., N.E., P.O. Box 4101, Albuquerque, New Mexico, 87105 and surpassed all Type A packaging tests including drop, compression and penetration. Documentation of these tests and further description of the ammunition boxes are on file.
3. All personnel responsible for the packaging and transport of radioactive material will be trained prior to assuming duties and at least annually thereafter. The in-service shall consist of the proper procedures to follow for: emergency response, recognizing unsafe conditions, response to unsafe conditions and transport conditions pertinent to the transport of these materials. This training will also cover the requirements for HAZMAT 10 CFR part 41. We will document the instructors name, the individuals attending, the topics discussed and the dates.
4. Management and / or it's representative will perform quarterly audits of the transportation documentation and temporary job site activities.
5. All packages will be secured within the transport vehicle through tie-downs or braces in such a manner to prevent movement of the containers during normal transportation.

6. We have enclosed a copy of the emergency procedures for your review. We will have a copy of these procedures clearly visible in the truck at all times when radioactive material is being transported.
7. Prior to transport and at the end of the day, radioactive waste will be packaged in sealed containers or plastic bags and placed in a locked storage area under the countertop. Most radioactive waste will be transported back to the unit dose supplier for storage and disposal. Any waste that the unit dose supplier will not take will be decayed on site in the locked storage area.

Supervision:

1. The RSO and / or his delegate will review all of the required records and procedures on a quarterly basis. The RSO or delegate will be on-site to review the supervised individual's use of byproduct material during this review. A written report will be generated as the result of this visit. In addition the RSO will review and sign these reports and selected documents and records in a timely fashion. Reports will be kept and maintained for NRC review. If the use of byproduct material is found to be not acceptable, on-site visits will be conducted on a more frequent basis such as monthly or weekly.
2. The RSO can be physically present at temporary job sites in response to incidents such as accidents, spills and misadministrations. Maximum response time is approximately 30 minutes.

Area Surveys:

The trigger levels for exposure rate surveys will not exceed 5 mR/hr. in restricted areas and 0.5 mR/hr. in unrestricted areas.

Quality Management Program:

We confirm that all radioactive material covered under the QMP (i.e., ^{131}I or ^{125}I >30 uCi, therapeutic use of radiopharmaceuticals, brachytherapy, teletherapy, or gamma stereotatic radiosurgery) will not be used at this facility. Therefore, we are not submitting a QMP.

TRANSPORTATION POLICIES

1. Summary of Radioactive Materials Transportation Regulations:
The Department of Transportation (DOT) has regulatory responsibility for safety in the transportation of radioactive materials by all modes of transport in interstate commerce. The Nuclear Regulatory Commission (NRC) also has responsibility for safety in the transport of license byproduct materials. Copies of applicable DOT and NRC regulations (10 CFR 71) are available upon request in the radiopharmacy.

2. Transportation Classifications:
The radiopharmaceuticals transported are categorized as (a) Normal Form Radioactive Materials - n.o.s., (b) Type A Quantity - less than 20 Curies, and (c) Transport Group IV.

3. Shipper's Requirements in the Preparation and Transport of Radioactive Material Packages (R.A.M.):
 - a. Maximum Radiation Levels at any point on the external surface of any package may not exceed 200 millirems per hour and 10 millirems per hour at 3 feet (i.e. Transportation Index may not exceed 10 mR/hr).

 - b. Each package must be labeled on two opposite sides with the proper Radioactive Package Label:

LABEL	DOSE RATE (surface)	DOSE RATE (at 3 feet)
"Radioactive - White I"	0.5 mR/hr	background
"Radioactive - Yellow II"	50 mR/hr	1.0 mR/hr
"Radioactive - Yellow III"	200 mR/hr	10 mR/hr

*requires vehicle placarding

- c. The applicable information as required in the blank spaces on the Radioactive Package Label must be inserted by legible printing as follows:
 1. **CONTENTS:** Name of the Radionuclide

 2. **NUMBER OF CURIES:** Units must be expressed in curies (Ci), millicuries (mCi), or microcuries (uCi)

 3. **TRANSPORTATION INDEX (TI):** Dose rate at 3 feet from the external surface of the package must be measured using the GM survey meter and entered on the label.

- d. The radioactive packages will be stored at the greatest possible distance from the driver, and at no less than 3 feet from any occupants.
- e. When transporting Yellow III packages, drivers will be assigned film badges to be worn during transportation.
- f. The outside of each R.A.M. package must be labeled with the proper shipping name: "TYPE A".
- g. Shipping papers must be included that specify the following information:

Proper shipping name: Radioactive Material, n.o.s. Salt/Liquid

Transport group: IV

TYPE A QUANTITY

This is to certify that the above mentioned materials are properly classified, described, packages, marked and in proper condition for transportation according to applicable regulations of DOT and NRC.

- h. If not in direct view of Mirview personnel during the entire transport, the outside of each radioactive packages must incorporate a security seal which is not readily breakable and which, while intact, is evidence that the package has not been illicitly opened.
- i. The vehicle must remain locked and alarm set whenever it is left unattended.

4. Contamination Control:

- a. After transporting DOT specified activities of radioactive materials, the transport vehicle will be wipe tested in the location of the radioactive packages. The vehicle wipe test shall be counted and recorded. If wipe counts are greater than $2000 \text{ dpm}/100 \text{ cm}^2$, the vehicle shall be decontaminated before being returned to service. In this case, results will be recorded in $\text{dpm}/100 \text{ cm}^2$ or uCi/cm^2 .
- b. Prior to transporting DOT specified activities of radioactive materials, the surface of the packages will be wipe tested and counted. The results will be recorded. If wipe counts are greater than $2000 \text{ dpm}/100 \text{ cm}^2$, the dose case, or syringe holder may not be returned to service until being properly decontaminated. In this case, results will be recorded in $\text{dpm}/100 \text{ cm}^2$ or $\text{uCi}/100 \text{ cm}^2$.

5. Shipping Container Description:

Unit dose syringes are packaged inside the lead syringe holders (either 1/8" or 1/4" lead thickness) and packaged inside U.S. Government approved metal ammunition boxes. The ammunition boxes were tested by Albuquerque Testing Laboratories, 532 Jefferson St., N.E., P.O. Box 4101, Albuquerque, New Mexico, 87105 and surpassed all Type A packaging tests including drop, compression and penetration. Documentation of these tests and further description of the ammunition boxes are on file in the radiopharmacy.

6. In addition, the packing slips and wipe test results are checked routinely by the RSO and / or his delegate as part of our established inspection program.
7. Drivers will be employed by Mirview, Inc. These individuals shall be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

EMERGENCY POLICY:

Procedures to be Followed in the Event of a Serious Traffic Accident

1. Generally, the radioactive material carried in this vehicle consists of diagnostic nuclear medicine and presents a minimal radiation hazard. See D.O.T. – Emergency Response Information.
2. A complete list of materials contained in the delivery cases can be found in the envelope attached to the outside of each case.
3. The following individuals should be contacted immediately for instructions if a traffic accident has occurred involving this vehicle such that the vehicle is damaged and/or the driver is injured to the extent that the cases cannot be delivered:

Frank M. Fayz, M.D. (RSO) 313-581-3000

4. Delivery cases are not to be removed from the vehicle.
5. In the event, a delivery case has been thrown from the vehicle, it should not be moved until instructions have been received from the RSO or his delegate.

D.O.T. -- EMERGENCY RESPONSE INFORMATION

as per 49 CFR 172.602

Description & Technical Name of the Hazardous Material

Radioactive Material in the following forms are possibly transported by this vehicle.
(Refer to Shipper's Bill of Lading for this specific shipment.)

Physical Form:	Liquid	Solid/Salt	Gas	Sealed Sources
Contained In:	Vials and/or Syringes	Radionuclide Generators	Sealed Vials	Lead Lined Containers
Radionuclides	Tc-99m, Tl-201 Ga-67, In-111 I-131, I-123	Mo-99/Tc-99m	Xe-133	Co-57, Ba-133 Cs-137

Immediate Health Hazard

If emergency involves a **FIRE** to include the radioactive material in transport, note the following:

LIQUIDS

Evaporation of aqueous based radioactive material encased in lead could lead to internal radiation exposure due to inhalation. - **Minimal to Moderate Risk**

SOLID/SALT

Melting of solid radioactive material encased in lead could lead to internal radiation exposure due to inhalation. - **Moderate to High Risk**

GAS

Rupture of glass vial encased in lead would allow gas to escape and be diluted in air. - **NO RISK**

SEALED SOURCES

Melting of solid radioactive material encased in lead could lead to internal radiation exposure due to inhalation. - **Moderate to High Risk**

If **NO FIRE** the only hazard could be from liquid leakage or external exposure due to source/lead shield displacement.

Risk of Fire and Explosion

Due to the radioactive material in transport - **NONE**

Immediate Precautions

If **FIRE** involves radioactive material suppress fire with as little liquid as possible to prevent possible spread.

If **NO FIRE** check radioactive material shipping container for liquid leaks and contain with absorbent material to prevent spread.

Immediate Method of Handling Fire

Suppress fire as quickly as possible with as little or no liquid as possible to prevent spread of contamination.

Handling Spills

Containment with absorbent material, i.e. sheets, cloth, etc.

First Aid

Evaluate if victim has been externally exposed and/or contaminated or internally contaminated to radioactive material by evaluating accident, spills, fire, victim proximity to radioactive material, etc.

Life saving measures are to be taken without regards to radiation exposure for the victim, once removed from the accident.

If victim has been externally contaminated with radioactive material, contain exposed area in non-absorbent material to prevent spread of contamination and transport to hospital.

If only internally contaminated and/or externally exposed to radioactive material transport to hospital.

SHIPPER'S BILL OF LADING

SHIPPER: _____

COSIGNEE: _____

Emerg Ph # _____

CARRIER: Same as Shipper

NAME/CLASSIFICATION: Radioactive Material N.O.S. UN 2982
TYPE A Radioactive

Number of Packages: _____

Date / Time of Shipment: ____ / ____ / 19 ____

# PIECES	RADIONUCLIDE	CHEM / PHYS FORM	ACTIVITY (mCi)
_____	Mo - 99 / Tc - 99m	Inorganic Salt Solid	_____
_____	Tc - 99m	Inorganic Salt Liquid	_____
_____	In - 111	Blood (WBC) Liquid	_____
_____	I - 123	Inorganic Salt Solid	_____
_____	Xe - 133	Inert Gas Gas	_____
_____	_____	_____	_____
_____	_____	_____	_____

Background: _____ dpm Source Container: _____ dpm Package: _____ dpm

Action Level = 6600 dpm/ 300 cm² Above Background

Pkg. Survey - Surface: _____ mR/hr

SURFACE	ONE METER (Transport Index)	Proper Label
0.5 mR/hr or less	NONE	Radioactive White I
0.51 mR/hr to 50 mR/hr	0.1 mR/hr to 1.0 mR/hr	Radioactive Yellow II
50.1 mR/hr to 200 mR/hr	1.1 mR/hr to 10 mR/hr	Radioactive Yellow III

Pkg. Label: Radioactive White - I Transport Index: _____
Radioactive Yellow II Transport Index: _____
Radioactive Yellow III Transport Index: _____

(Vehicle Placard Required !!)

Wipe Test Instrument: _____

Survey Meter Used: _____

Shipper: _____

Courier: _____

Cosignee: _____

Date: _____ Time: _____

Date: _____ Time: _____

Date: _____ Time: _____

CERTIFICATION

The materials named above are properly classified, described, packaged, marked & labeled for transportation per D.O.T. regulations

The radioactive contents of each package are within the limits of A2 Normal Form per 49 CFR 173.435

The radioactive material within this shipment is intended for research, medical diagnosis or treatment.



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

January 3, 1997

Frank M. Fayz, M.D.
Radiation Safety Officer
Mirview Incorporated
237 Dino Drive, Suite A
Ann Arbor, MI 48103

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter & Application Dated 11/27/96 & 07/12/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☒ New License ☐ Amendment ☐ Renewal
☐ Termination ☐ Auth User (Amendment not required)
☐ Other _____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302175
License No. 21-26775-01