K & K Diagnostic and Imaging, LLC
Iftekhar Kadri, M.D.
81 Northfield Ave, Suite 102
West Orange, NJ 07052
Telephone: 973-926-7894

J-9

December 4, 2006

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Licensing Assistance Section
Nuclear Materials Safety Branch
United States Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

03036783

Re: NRC License Number: 29-30982-01 – License Amendment
Mobile Nuclear Medicine Services

Dear Sir/Madam:

Since we are planning provide mobile nuclear medicine services an amendment application is attached herein for your approval and appropriate action(s). Presently we are operating under the authorization/conditions of the following license:

NRC License Number: 29-30982-01

The section on mobile nuclear medical service starts on page 42-48 of the attached application. Please make appropriate changes to our existing license NRC License Number: 29-30982-01.

In addition, please amend to include my name, Iftekhar Kadri as Radiation Safety Officer instead of Sang O. Lee, M.D. Sang O. Lee will still remain as an authorized user.

We request that you execute an expedited review of this amendment.

Should you have any questions regarding this application, please contact me. If I am unavailable you may contact Mr. Venkata K. Lanka, our consulting physicist at (973) 972-6019 for any additional information.

Sincerely,

Iftekhar Kadri, M.D.

139823
NMSS/RGN1 MATERIALS-002

ITEM 1: LICENSE ACTION TYPE

THIS IS AN APPLICATION FOR:

Type of Action	License No.
☐ A. New License	Not Applicable
☒ B. Amendment to License No.	29-30982-01
☐ C. Renewal of License No.	Not applicable

ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

K & K Diagnostic and Imaging, LLC
Iftekhar Kadri, M.D. F.A.C.C.
81 Northfield Avenue, Suite 102
West Orange, New Jersey, NJ 07052

Telephone: 973-736-2600

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

Address 1:	81 Northfield Ave, Suite 102 West Orange, NJ 07052
Adress2:	Amjad Najeer. M.D., P.C. 22 Howard Blvd., Suite 103 Mt. Arlington, NJ 07856

A mobile van is used to transport radioactive materials to the Address 2. Radioactive materials used for .

ITEM 4: PERSON TO BE CONTACTED ABOUT THISAPPLICATION

Iftekhar Kadri, M.D. F.A.C.C.
81 Northfield Avenue, Suite 102
West Orange, New Jersey, NJ 07052

Telephone: 973-736-2600

ITEM 5: RADIOACTIVE MATERIAL

Byproduct, Source, Special Nuclear Material	Chemical and/or Physical Form	Maximum Amount Licensee Possesses
A. ^{99m}Tc	A. Any (no generators)	A. As needed

ITEM 5: RECORDKEEPING FOR DECOMMISSIONING AND FINANCIAL ASSURANCE

We restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35 (d) for establishing decommissioning financial assurance. No Financial assurance is needed.

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

Radioactive Material specified in Item 5 will be used as follows:

A. For use in medical diagnosis. Specifically used for cardiac stress test only.

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

Responsible Individual for Radiation Safety Program:	Iftekhar Kadri, M.D. F.A.C.C.
	Telephone: 973-736-2600
Training and Experience:	Previously is on the license.

ITEM 7: RADIATION SAFETY OFFICER (RSO)

Radiation Safety Officer: Iftekhar Kadri, M.D. F.A.C.C.

RSO Responsibilities: Some of the typical duties and responsibilities of RSO include ensuring the following:

- ☐ Unsafe activities involving licensed materials are stopped;
- ☐ Radiation exposures are ALARA;
- ☐ Material accountability and disposal;
- ☐ Interaction with NRC;
- ☐ Timely and accurate reporting and maintenance of appropriate records;
- ☐ Annual program audits;
- ☐ Proper use and routine maintenance;
- ☐ Personnel training; and
- ☐ Investigation of incidents involving byproduct material (e.g., medical events).

ITEM 8: TRADINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

The following individuals may be working in/frequenting restricted areas:

1. The Nuclear Medicine Technologist
2. EKG Technologist/Nurse
3. Housekeeping

We provide both initial training on annual training for Nuclear Medicine Technologist (if hired) and/or EKG technologist/Nurse with reference to their specific tasks and film badges, ALARA program, patient handling, personal protection, ambient surveys, general safety rules. The records of training will be maintained as required.

The house keeping individual (if applicable) will be trained on what the radiation symbol represents and which waste can to empty and which waste can was held for decay, etc.

ITEM 9: FACILITY DIAGRAM

The facilities shown in Item 3 are already on license. Now we are applying for mobile license.

See original application.

Security of Radioactive materials:

a. After hours our lab containing radioactive materials is locked and staff is required to secure the rooms when they leave during breaks and lunch. The storage areas are secured when staff is not present.

b. We will secure from unauthorized removal or access those radioactive materials that are stored in controlled or unrestricted areas.

c. All cabinets that store radioactive materials are fitted with lock.

Shielding:

We purchased leaded shielding (L-blocks, leaded waste containers, syringe shields, leaded syringe shield boxes, etc.) which will have sufficient thickness to maintain the exposure rate below 2 mR/hr at 3 feet from the surface of the shield.

Stress Lab:

i. Walls – The walls have a low flame spread characteristic.

ii. Floors – The floor covering is sealed with waxed floor tiles so that spills are contained and they are easily decontaminated.

iii. Surfaces – Surfaces on benches are non-porous and smooth to facilitate cleanup should a spill occur.

a. Stress Lab Equipment for Radiation Safety

i. The storage cabinet is lockable. Entrances to lab and storage areas are posted with radioactive signs.

ii. Protective Clothing – We insure that there are lab coats and an adequate supply of disposable rubber or plastic gloves available for individuals under my supervision.

iii. Bench Top Covering – we will have adequate supplies of absorbent plastic backed paper to cover bench tops where radioactive materials are handled.

iv. We purchased radiation detection and counting equipment for use in evaluating contamination levels.

Description of Mobile Van:

Mobile van is under purchase.

This van will be parked at 81 Northfield Ave, West Orange, NJ 07052 facility, when no patients are treated or overnight.

ITEM 9: RADIATION MONITORING INSTRUMENTS

Survey Meter:

Radiation Monitoring Instrument (Survey Instruments): Radiation detecting instrument (GM Counter) which is capable of detecting gamma radiation will be purchased as soon as possible. This will be used to conduct daily contamination surveys, and personal monitoring surveys, etc.

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

Survey Instruments are calibrated annually, before first use and after servicing and repairs which effect calibration. Battery changes are not considered "servicing."

Before use, perform daily check (with a dedicated check source) and battery checks.

Instrument readings should be within ± 10% of known radiation values at calibration points; however, readings within ± 20% are acceptable if a calibration chart or graph is prepared and made available with the instrument.

A record must be made of each survey meter calibration and retained for 3 years after each record is made (10 CFR 20.2103(a) and 10 CFR 35.2061)

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

Well/Gamma Counter:

We have purchased a well counter to conduct wipe test surveys.

Calculating the Gamma Well Efficiency of Counting Equipment

Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed byproduct material is prepared, administered, or stored. Converting cpm to dpm using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. Calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and/or after repair, using the following procedure:

□ Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.

- Calculate efficiency of the instrument.

$$\text{Eff} = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{(\text{activity of std in microcurie})}$$

where:

Eff = efficiency, in cpm / microcurie,
cpm = counts per minute,
std = standard, and
bkg = background.

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test should be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due and
- Results of efficiency calculation(s).

ITEM 9: DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED BYPRODUCT MATERIAL

Equipment used to measure dosages is calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. We use attenuators to perform linearity test.

At the mobile facility, we use the decay method for injecting radionuclides.

ITEM 9: OTHER EQUIPMENT AND FACILITIES

Mobile van is used for carrying unit doses and patient injections.

ITEM 10: RADIATION PROTECTION PROGRAM

1. Licensee Commitment:

   We 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 will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our office.

   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, and consultations with the outside consultants.

   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.

   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.

2. Review of ALARA Program:

   a. The RSO will encourage users under my authorization to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

   b. We will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels (described in the Occupational Dose section) 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.

   c. We will evaluate our office's overall efforts for maintaining doses ALARA on an annual basis.

   d. Education Responsibilities for ALARA Program:

      1. We will schedule briefings and educational sessions to inform workers of ALARA program efforts.
      2. We will ensure that Nuclear Medicine Technologists, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy.

   c. Cooperative Efforts for Development of ALARA Procedures:

Nuclear Medicine Technologists will be given opportunities to participate in formulating the procedures that they will be required to follow:

1. I will be in close contact with workers in order to develop ALARA procedures for working with radioactive materials.
2. I establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

3. 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.

ITEM 10: SAFETY PROCEDURES AND INSTRUCTIONS

Model Spill Procedures

We will establish and implement the following model procedures published in Appendix N of NUREG-1556, Vol.9, Consolidated Guidance About Materials Licenses.

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a "caution radioactive material" labeled bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
5. Report the incident to the RSO.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with "caution radioactive material" labeled absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated and radiotoxicity of the spilled material. For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest ALI, an alternative spill procedure may be restricted

access pending complete decay.

Note: A report to NRC may be required pursuant to 10 CFR 30.50.

Use Table P.1 as general guidance to determine whether a major spill procedure or a minor spill procedure will be implemented.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure, based on the following information. Spills above these mCi amounts are considered major, and below these levels are considered minor.

Table N.1 Relative Hazards of Common Radionuclides

Radionuclide	Millicurie	Radionuclide	Millicurie
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Spill Kit

Assemble a spill kit that may contain the following items:

- ☐ Disposable gloves and housekeeping gloves;
- ☐ Disposable lab coats;
- ☐ Disposable head coverings;
- ☐ Disposable shoe covers;
- ☐ Roll of absorbent paper with plastic backing;
- ☐ Masking tape;
- ☐ Plastic trash bags with twist ties;
- ☐ "Radioactive Material" labeling tape;
- ☐ Marking pen;
- ☐ Pre-strung "Radioactive Material" labeling tags;
- ☐ Contamination wipes;

- ☐ Instructions for "Emergency Procedures";
- ☐ Clipboard with copy of Radioactive Spill Report Form;
- ☐ Pencil; and
- ☐ Appropriate survey instruments, including batteries.

ITEM 10: OCCUPATIONAL DOSE

Either we will perform 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 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials License: Program-Specific Guidance About Medical Use Licensees," dated October 2002.

We will establish and implement the Model Procedures for an Occupational Dose Program published in NUREG-1556, Vol.9 (attached for your reference).

Model Procedures for an Occupational Dose Program

The As Low As Reasonably Achievable "ALARA" Program

10 CFR 20.1101 states that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities" and, "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Additionally, 10 CFR 20.1101 requires that licensees periodically review the content of the radiation protection program and its implementation.

External Exposure

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits on radiation dose and to help demonstrate that doses are maintained at ALARA levels. Providing for the safe use of radioactive materials and radiation is a management responsibility. It is important that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in 10 CFR 20.1201 that apply to external exposure: deep dose to the whole body (5 rem or 0.05 Sv), shallow dose to the skin or extremities (50 rem or 0.5 Sv), and dose to the lens of the eye (15 rem or 0.15 Sv). According to the definitions in 10 CFR 20.1003, the (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm^2), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm^2), and eye dose equivalent at 0.3 cm (300 mg/cm^2). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

10 CFR 20.1502(a) requires the use of individual monitoring devices for the following:

□ Adults likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits in 10 CFR 20.1201(a). Monitoring devices are accordingly required for adults with an annual dose in excess of

- 0.5 rem (0.005 Sv) DDE
- 1.5 rem (0.015 Sv) eye dose equivalent
- 5 rem (0.05 Sv) shallow-dose equivalent to the skin
- 5 rem (0.05 Sv) shallow-dose equivalent to any extremity.

☐ Minors who are likely to receive an annual dose in excess of

- 0.1 rem (1.0 mSv) DDE
- 0.15 rem (1.5 mSv) eye dose equivalent
- 0.5 rem (5 mSv) shallow-dose equivalent to the skin
- 0.5 rem (5 mSv) shallow-dose equivalent to any extremity.

☐ Declared pregnant women likely to receive an annual dose in excess of 0.1 rem (1.0 mSv) DDE during the entire pregnancy.

☐ Individuals entering a high or a very high radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, NRC does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate that doses are expected to be within 10% of regulatory limits:

☐ Prior Experience: Review of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits;

☐ Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys (e.g., using a survey meter or area thermoluminescent dosimeters (TLDs)) in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable 'accident' scenarios should also be evaluated);

☐ The licensee performs a reasonable calculation based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters (OSLs), or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP)-approved, as required by 10 CFR 20.1501.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year (10 CFR 20.1201(c)). When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly non-uniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

10 CFR 20.2106 requires that the recording for individual monitoring be done on NRC Form 5 or equivalent. NRC Form 5 is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees should be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

In order to demonstrate compliance with occupational dose limits of 10 CFR 20.1201, the licensee needs to perform and document an evaluation of the dose the individual received and to add it to the employee's dose record, if an individual's dosimeter is lost. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

Investigational Levels – External Dose Monitoring

NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," investigational levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker's or a group of workers' 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 should be documented.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table M.1 (i.e., 10% of the annual limit for occupational exposure), the RSO or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds Investigational Level II in Table M.1 (i.e., 30% of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

Table M.1 Investigational Levels

Part of Body	**Investigational Level I (mrem per year)**	**Investigational Level II (mrem per year)**
whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee	500 (5 mSv)	1500 (15 mSv)
hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
lens of the eye	1500 (15 mSv)	4500 (45 mSv)

Review and record on NRC Form 5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring. Take the actions listed below when the investigation levels listed in Table M.1 are reached:

☐ Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken if an individual's dose is less than Table M.1 values for the Investigational Level I.

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

When the dose of an individual whose dose equals or exceeds Investigational Level I, the RSO or the RSO's designee should conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. 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 or the RSO's designee. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks to determine if improvements additional safety measures are needed to reduce exposures. Evaluate in the context of ALARA program quality and record the results of investigations and evaluations.

☐ Personnel dose equal to or greater than Investigational Level II.

The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. A consideration of actions should be taken by the RSO to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

☐ Re-establishment of Investigational Level II to a level above that listed in Table M.1.

Declared Pregnancy and Dose to Embryo/Fetus

10 CFR 20.1208 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo/fetus shall be taken as the sum of:

☐ The deep-dose equivalent to the declared pregnant woman; and

☐ The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

Internal Exposure

With respect to internal exposure, licensees are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the annual limit on intake (ALI) from intakes in 1 year (10 CFR 20.1502). 10 CFR Part 20 provides terms for radionuclide intakes by means of inhalation and ingestion, i.e., derived air concentration (DAC) and ALI.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in □Ci/ml that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in 10 CFR Part 20, Appendix B.

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, again, with no consideration for the contribution of external dose.

The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The 10 CFR Part 20 ALI and DAC numbers reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (W_T), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." Per 10 CFR Part 20, Appendix B, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established.

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include:

i. adequate equipment to perform bioassay measurements,

ii. procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units,

iii. the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),

iv. the interval between bioassays,

v. action levels, and

vi. the actions to be taken at those levels.

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program" dated July 1993, Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, dated July 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 10 CFR 20.2106. For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data."

Summation of External and Internal Doses

Pursuant to 10 CFR 20.1202, the external and internal doses shall be summed if required to monitor both under 10 CFR 20.1502.

ITEM 10: AREA SURVEYS

We will develop and 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. We will perform all areas located in the van everyday and for contamination and record surveys.

ITEM 10: SAFE USE OF UNSEALED LICENSED MATERIAL

We will develop and implement and maintain procedures for safe use of unsealed byproduct material in accordance with 10 CFR 20.1101, that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

Posting Requirements

(a) All signs and labels used to caution individuals of the presence of radiation or radioactive materials shall have a standard three-bladed radiation symbol in black or purple on a yellow background.

(b) The Nuclear Medicine suite/room shall be posted with a conspicuous sign bearing a radiation symbol and the words "Caution, Radioactive Materials."

(c) If there is a location in our nuclear medicine van where an individual may receive a whole body dose equivalent of 5 millirem in one hour at a distance of 30 centimeters from a source or a surface through which the radiation penetrates shall be posted with a conspicuous sign bearing a radiation symbol and the words "Caution, Radiation Area".

(d) Each cabinet or other device or appliance that contains radioactive material shall have a conspicuous sign bearing a radiation symbol and the words "Caution, Radioactive Materials."

(e) Each container of radioactive material shall have a durable label bearing a radiation symbol and the words "Caution, Radioactive Material." In addition, the label will also specify the radionuclide present, the date, and the activity present on that date.

(f) Each container used for temporary storage of radioactive waste shall be conspicuously posted with a label bearing a radiation symbol.

(g) The bench area routinely used for handling radioactive material shall be posted with a conspicuous sign having a label bearing a radiation symbol and which reads "Caution Radiation Work Area." Each sink used for decontamination shall be posted with a sign bearing a radiation symbol and the words "Caution, Radioactive Material."

(h) In addition to posting signs and labels to caution individuals of the presence of radiation and/or radioactive materials, we will post the following documents and ensure that each individual under my supervision knows of their presence.

i Copies of forms NRC-3 "Notice to Employees", and NJDEP (8/89) "Notice to Employees: Standards for Protection Against Radiation."

ii Copies of the emergency procedures and a list of individuals, with telephone number, who should be contacted in the event of a radiation incident.

(i) We will, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.

Labeling Syringes:

Each syringe that contains unsealed radioactive material, we will ensure that we label to identify that radioactive drug.

Each syringe shield will be labeled when the label on the syringe is not visible or shielded.

Radiation Safety Surveys

(a) All areas where unsealed radioactive material is used will be surveyed with radiation detection survey instrument at the end of each day of use.

(b) We will retain the records of each survey in accordance with 10 CFR 35.2070

(c) Wipe tests shall be made of all surfaces where radioactive materials are handled, and in other locations which have a risk of becoming contaminated.

(d) Each wipe test shall cover an area no greater than 100 square centimeters, and the number of wipe tests taken per survey shall be sufficient to ensure that any contamination within the work area is detected.

(e) Wipe tests for contamination shall be counted using a well type sodium iodide scintillation counting system for which the counting efficiency is known for radionuclide being sampled and the counting source geometry used.

(f) The results of wipe test surveys will be recorded and maintained as required.

(g) Wipe test samples, which give a count rate in excess of three times the background level, shall indicate the presence of contamination and will be decontaminated.

(h) Spot checks for personal and area contamination should be performed between routine contamination surveys. Spot checks may be performed using a GM survey meter having a probe with a window sufficiently thin to allow detection of the radionuclide(s) being surveyed.

(i) Decontamination procedures shall be initiated immediately whenever a contamination survey or spot check yields positive results. The trigger levels for removable contamination surveys in research laboratories are 200 dpm per 100 cm^2.

General Rules of Safety

(a) Each individual under the supervision of the licensee, who handles radioactive material is responsible for minimizing the radiation exposure to themselves and other individuals within the work area, and to take appropriate steps to prevent personal contamination and contamination of the environment. To satisfy this requirement, we will ensure that, as a minimum, the following rules are observed, where unsealed sources of radioactive material are handled:

i Eating and drinking, or the presence of food or beverages, is be forbidden.
ii The presence of reusable cups or eating implements in the suite is forbidden.
iii Smoking, or the presence of tobacco products and smoking paraphernalia, shall be forbidden.
iv Pipetting by mouth shall be forbidden.
v Radioactive materials shall not be handled by individuals with exposed cuts or abrasions.
vi No individual shall handle unsealed radioactivity unless he/she is wearing protective gloves and a lab coat. Protective gloves and lab coats shall be removed immediately when contamination is suspected.
vii Handling of radioactive material shall be limited to the smallest area possible. To the extent practical, radioactive work areas shall be delineated using warning tape or warning signs. Each worker is responsible for informing others in the laboratory of the locations where he/she is using radioactive material.
viii All items used during procedures involving unsealed radioactivity shall be labeled with radioactive material warning tape.
ix All surfaces on which work with unsealed radioactivity is conducted shall be covered with waterproof backed absorbent paper. This covering shall be changed when contaminated.
x Sources of penetrating radiation shall be maintained in a suitable shield to the extent practical.
xi Unshielded sources of radioactivity shall only be handled using forceps or other device to maintain an adequate distance from the fingers.
xii When personal or area contamination is suspected, work with unsealed radioactivity shall be stopped as soon as possible so that decontamination procedures may be undertaken.

(b) Immediate notification to the licensee shall be required in the event of any of the following incidents:

i A known or suspected whole body radiation exposure which may result in an absorbed dose equivalent of 25 millirem in one hour;
ii Any known or suspected internalization of radioactive material by an individual;
iii Any known or suspected presence of airborne radioactivity;
iv Any known or suspected unauthorized release of radioactive material to an unrestricted area, or exposure of a member of the general public; and
v Any theft or otherwise unauthorized removal of radioactive material.

Also, we will implement the following Model Procedure published in the NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses":

Model Procedures for Safe Use of Unsealed Licensed Material

This model provides acceptable procedures for safe use of unsealed licensed material. You may either adopt this model procedure or develop your own procedure. (Some of the health physics practices listed below may also apply to sealed sources.)

- ☐ Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

- ☐ Wear disposable gloves at all times while handling radioactive materials.

- ☐ Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area using an appropriate survey instrument.

- ☐ Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle.)

- ☐ Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.

- ☐ Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.

- ☐ Wear extremity dosimeters, if required, when handling radioactive material.

- ☐ Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

- ☐ Never pipette by mouth.

- ☐ Wipe-test unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.

- ☐ Survey with a radiation detection survey meter all areas of licensed material use, including the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with 10 CFR 35.70 (except when administering therapy dosages in patients' rooms when patients are confined).

- ☐ Store radioactive solutions in shielded containers that are clearly labeled.

- ☐ Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904.

- ☐ Syringes and unit dosages must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in Appendix C to Part 20, the syringe or vial need only be labeled to identify the radioactive drug (10 CFR 35.69). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.

- ☐ For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (10 CFR 35.63).

- ☐ Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an authorized user.

- ☐ When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.

- ☐ Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive (10 CFR 35.41).

- ☐ Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

- ☐ Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the NRC license (or such individual's designee).

ITEM 10: SPILL PROCEDURES

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.

Emergency Procedures for Radioactive Contamination:

I Small Spills of non-volatile radioactive liquids

1. Obtain protective shoe covers. Don two pairs of protective gloves.

2. Avoid personal contamination and spreading of the spill. Use a Geiger counter or make wipe tests to determine the extent of the effected area. Mark the perimeter of the spill and cover with absorbent paper.

3. Place saturated paper in double plastic trash bags. Continue covering the spill with absorbent paper until all free liquid has been absorbed.

4. Remove residual radioactivity with detergent and water (use commercial decontaminant when available). Clean a small area at a time using a minimum amount of liquid. Work your way toward the center of the spill. Use Geiger counter or liquid scintillation counter to check paper towels used. Place contaminated towels directly into the plastic waste bags.

5. The spill is considered clean when radioactivity can no longer be detected in the effected area and when the measurements made of the paper towels reveal that there is no longer any removable activity.

6. When decontamination is finished, place shoe covers and gloves into the plastic waste bag, seal it, and label with a radioactive material warning sticker.

7. The Radiation Safety Officer shall confirm that decontamination is complete, monitor individuals for personal contamination.

II Large spills of non-volatile radioactive liquids

1. Alert the nearest person (s) that spill has occurred.

2. Don two pairs of protective gloves. While avoiding personal contamination, prolonged exposure, or spreading of the spill, cover the effective area and a two foot perimeter with absorbent paper.

3. Follow the procedure above as in I

III Skin Contamination

1. Alert the nearest person(s).

2. Immediately begin decontamination. Use mild soap and water - wash the effected area two or three times, but no more. Be careful not to spread localized contamination. Strenuous scrubbing will defat and abrade the skin, leading to increased penetration of the contaminant. Do not use strong alkaline detergents or organic solvents. Simple washing should be adequate to remove most of the contamination. If residual radioactivity remains on the hands, donning protective gloves to induce sweating will help flush out skin pores; however, the gloves must be removed and the hands washed immediately after profuse sweating begins or else contamination will penetrate the dilated pores.

3. If hair becomes contaminated, immediately begin washing with soap and water. Avoid spreading contamination to other parts of the head.

4. If contamination of the eyes occurs, flush with copious amounts of isotonic solution (if available), otherwise, use water. Be sure to roll back the eyelid as far as possible. If residual contamination remains, further decontamination shall require medical supervision.

5. If contamination of nose or mouth occurs, immediately flush with copious amounts of water: be careful not to ingest the rinse.

6. If contamination of a small wound occurs, stimulate bleeding and flush with sterile water, then follow standard first aid procedures. If contamination of a large wound occurs, control the bleeding and seek medical attention. Decontamination may be undertaken when the situation is medically under control.

IV Contamination of Clothing

1. Obtain disposable paper surgical scrubs. Change out of effected clothing being careful not to contaminate your skin. Place effected clothing in plastic bag, label with a radioactive material warning sticker, and hold for decay.

2. If the soles of the shoes become contaminated, remove shoes and wear surgical booties. Do not cause the spread of contamination by moving around in contaminated shoes. Shoe soles are typically decontaminated easily using soap and water. Perform this procedure over a sink normally used for radioactive materials. Use a Geiger counter or make wipe tests to determine when decontamination is complete. Initiate a survey of your work area to determine the source of the contamination. If not possible to decontaminate, we hold for decay.

ITEM 11: WASTE MANAGEMENT

We have developed and 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.

We will hold by product material with physical half-life less than 120 days for decay-in-storage prior to disposal with out regard to radioactivity. We will perform the following prior to disposal:

(1) Monitors material at surface with an appropriate radiation detection survey meter set on its sensitive scale with no interposed shielding before disposal and determines that its radioactivity cannot be distinguished from the background radiation levels; and
(2) Removes or obliterates all radiation labels, except for radiation labels on material that are within the containers and that will be managed as biomedical waste after they have been released from the license.

We maintain and retain a record of each permitted disposal in accordance with 35.2092.

ITEM 12: FEES

Not Applicable, since it is an amendment for a mobile license.

ITEM 13: CERTIFICATION

We certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, and that all information contained herein is true and correct to the best of their knowledge and belief.

8.31 SAFETY INSTRUCTION FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

We will establish and implement the model program that was published in Appendix J to the NUREG-1556, Vol. 9, "Consolidated Guidance About Materials License."

8.32 PUBLIC DOSE

We will:

a. Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour from licensed operations.

b. Ensure air emissions of radioactive materials to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from these emissions.

c. Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

8.36 MOBILE MEDICAL SERVICE

Type and Location of Use:

Class 2 mobile Service: We will transportation of byproduct material to a client's facility and use within a client's facility by the mobile service's employees (i.e., transport and use).

All radioactive materials will be received at the following licensed facility:

Address 1: 81 Northfield Avenue, Suite 102
West Orange, New Jersey, NJ 07052

Type of Mobile Service:

Mobile Medical services: We will transport byproduct material, trained personnel, and gamma camera to a client's facility (in van use) and administer radioactive materials for diagnostic purposes at the client's facility. We are responsible for all aspects of by product material use and authorized patient administrations. All scans will be performed in the van using the gamma camera located in the van.

When providing services, the van will be located on the client's property that is under client's control.

Client's Site(s) and Address:

Amjad Najeer, M.D., P.C.

22 Howard Blvd.
Mt. Arlington, NJ 07856

Licensed Activities:

Licensed activities will be conducted in accordance with the regulations for compliance with 10 CFR 35.80(a).

We will obtain a letter signed by the management (i.e., chief executive officer or delegate) of each of our clients for which services are rendered. The letter will permit the use of byproduct material at the client's address and clearly delineate the authority and responsibility of each entity. This agreement shall be applicable for the entire period of time over which the service is to be provided. The letter will be retained for three years after the last provision of service.

we will develop and implement survey procedures to ensure that all byproduct material, including radiopharmaceuticals, sealed sources, and all associated wastes have been removed before leaving each location of use as required by 10 CFR 35.80(d).

Applicants who will provide transportable services to the client's site and use within the client's facility (i.e., Class 2) must provide the following facility information and commitment:

1. Building Construction

   This building is constructed of noncombustible materials, with exterior walls designed to withstand the effects of fire and prevent its spread. Early detection and warning of fire is provided by automatic fire detection systems designed to detect the incipient stages of a fire. There are fire extinguishers through out the building.

   The lab is utilized as patient imaging area and store the transported radioactive material

in a secured area. Leaded shielded storage containers will be brought to the lab to potect personnel. The room has a single access which is locked whenever the room is unoccupied.

i. All generated waste will be brought to one of the base locations and will be decayed for 10 half lives and disposed as non-radioactive waste after surveying with the calibrated GM counters to ensure that it is at background levels.
ii. The lab door is lockable.
iii. A treadmill for stress testing is located in the room.

2. Fire Protection

a. The building described in this application is constructed of noncombustible materials with exterior walls designed to withstand the effects of fire and prevent its spread.

b. There are fire extinguishers throughout the building.

3. Security

a. All patients come through front of the building. Unless the employee opens the door no one can enter into the suite without any authorization.

b. The lab is secured when staff is not present.

c. We will secure from unauthorized removal or access those radioactive materials that are stored in controlled or unrestricted areas.

Shielding:

We purchased leaded shielding (L-blocks, leaded waste containers, syringe shields, leaded syringe shield boxes, etc.) which will have sufficient thickness to maintain the exposure rate below 2 mR/hr at 3 feet from the surface of the shield.

Lab:

i. Walls – The walls have a low flame spread characteristic.

ii. Floors – The floor covering is sealed with waxed floor tiles so that spills are contained and they are easily decontaminated.

iii. Surfaces – Surfaces on benches are non-porous and smooth to facilitate cleanup should a spill occur.

iv. Entrances to lab and storage areas are posted with radioactive signs whenntreating patients.

v. Protective Clothing – We insure that there are lab coats and an adequate supply of disposable rubber or plastic gloves available for individuals under my supervision.

vi. Bench Top Covering – we will have adequate supplies of absorbent plastic backed paper to cover bench tops where radioactive materials are handled.

vii. We use radiation detection and counting equipment for use in evaluating contamination levels.

- We will retain a record establishing that the mobile service licensee has full control of the treatment room during byproduct material use for each client. We will obtain in either the form of a signed agreement or a lease agreement with the client, establishing full control of the treatment room by the applicant during all periods of use.

Base Location(s):

Address: 81 Northfield Avenue, Suite 102
West Orange, New Jersey, NJ 07052

Byproduct material will be delivered (if necessary) directly to the van only if the van is occupied by licensee personnel at the time of delivery.

Training And Experience

We will require the supervised individual to:

- follow the instructions of the supervising authorized user for medical uses of byproduct material;
- follow the written radiation established by the licensee; and
- comply with the regulations of 10 CFR 35.80, 10 CFR 35.647 (if applicable) and the license conditions with respect to the mobile use of byproduct material.

Training for Individuals Working in or Frequenting Restricted Areas

In addition to the training requirements of 10 CFR 19.12, 10 CFR 35.27, 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610 (as applicable), drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures. The training records for these individuals will include (at a minimum) dates, topics discussed (e.g., DOT regulations, shielding, ALARA, basic radiation protection), attendees, and the instructor's name, and shall be maintained for 3 years for NRC review.

Survey Instrument & Dose Measurement Instrument Checks

We will check survey instruments for proper operation with a dedicated check source before use at each address of use. We will check dose measurement instruments (e.g., dose calibrator) as described in 10 CFR 35.60 or 10 CFR 35.62, as applicable, before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported

equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Byproduct Material

Byproduct material will be delivered by a supplier to the base location. Delivery of byproduct material to a van that is not occupied by the mobile service personnel will not be permitted.

Emergency Procedures

We will develop and implement emergency procedures, in accordance with 10 CFR 20.1101, that, in part, will indicate that the RSO, AU, or a responsible designee, can be physically present at the client's address in response to incidents (e.g., accidents, spills, medical events) that occur at client facilities. We will indicate typical response times of the RSO and AU in the event of an incident. We will develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other events, such as, wind, water or fire damage that results in damage to exterior or interior portions of the vehicle or the byproduct material used in the mobile service. The transportation emergency response plan will cover both the actions to be taken by the mobile service provider's headquarters emergency response personnel and the "on scene" hazmat trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency response contacts. At a minimum, this plan will include:

- A 24-hour emergency contact telephone number for the mobile service provider's emergency response personnel.
- Emergency contact number for NRC's Operation Center and all appropriate state radiological protection agencies.
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist.
- Preplanned decontamination procedures including ready access to all necessary materials.
- A copy of the report, generated in accordance with 10 CFR 30.50, will be provided to any Class 2 clients following any accident in which there is actual or possible damage to the facility or device.
- A calibrated, operational survey meter should be maintained in the cab of the transporting vehicle. Such a survey meter may be used at an accident scene for conducting surveys.

Note: The type of response is consistent with the level of the incident. The response is ranging from phone contact for minor spills, to prompt on-site response (less than 3 hours) to events such as a medical event or lost radioactive material.

In summary we will perform the following:

(1) We will obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) We will check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) We will check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) We will before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter.

(5) We will retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with § 35.2080(a) and (b), respectively.

8.33 OPENING PACKAGES

We will ensure that packages are opened safely and that the requirements of 10 CFR 20.1906 are met. We will retain records of package surveys in accordance with 10 CFR 20.2103.

Model Procedure for Safely Opening Packages Containing Radioactive Material

This model provides acceptable procedures for opening packages containing radioactive material. Applicants may either adopt this model procedure or develop an alternative procedure to meet the requirements of 10 CFR 20.1906.

For which monitoring is required, we will check for external radiation levels and surface contamination within 3 hours of receipt (if received during working hours) or no later than 3 hours from the beginning of the next working day (if received after working hours), in accordance with the requirements of 10 CFR 20.1906(c). NRC Regional Office and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i); and
- External radiation levels exceed the limits of 10 CFR 71.47.

Model Procedure

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 the procedure and notify the RSO.
3. Monitor the external surfaces of a labeled[1] package for radioactive contamination.
4. Monitor the external surfaces of a labeled[1] package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Table A to 10 CFR Part 71.
5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
6. Remove the packing slip.
7. Open the outer package, following any instructions that may be provided by the supplier.
8. Open the inner package and verify that the contents agree with the packing slip.
9. Check the integrity of the final source container. Notify the RSO (or the RSO's designee) of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
10. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI (T1)

[1]Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations.

crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. *Note: a dose calibrator is not sufficiently sensitive for this measurement.* Take precautions against the potential spread of contamination.

11. Check the user request to ensure that the material received is the material that was ordered.
12. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
13. Make a record of the receipt.

8.37 AUDIT PROGRAM

We develop and implement procedures for the required review or audit of the radiation protection program's content and implementation. We implement the model guidance for Audit Program that was published in Appendix L to the NUREG-156, Vol. 9, Consolidated Guidance About Materials Licenses.

8.39 MATERIAL RECEIPT AND ACCOUNTABILITY

To maintain the accountability of licensed material, we will do the following:

1. Secure licensed material;
2. Maintain records of receipt, transfer, and disposal of licensed material; and
3. Conduct physical inventories at required frequencies to account for licensed materials.

8.40 ORDERING AND RECEIVING

We will establish and implement the following model guidance for ordering and receiving radioactive material that was published in Appendix O to the NUREG-156, Vol. 9, Consolidated Guidance About Materials Licenses.

8.41 SEALED SOURCE INVENTORY

According to 10 CFR 35.67, we will conduct a semi-annual physical inventory of all sealed sources in possession. Also, we maintain the list of receipt, transfer, and disposal of equipment such as liquid scintillation those contain generally licensed radioactive sources.

8.42 RECORDS OF DOSAGES

We will make and maintain records of each dosage and administration prior to medical use. The records will include:

- ☐ Radiopharmaceutical;
- ☐ Patient's name;
- ☐ Determined dosage; and
- ☐ Date and time of dosage determination.

8.43 RECORDKEEPING

We will establish and implement the recordkeeping requirements appears in Appendix X to the NUREG-156, Vol.9, Consolidated Guidance About Materials Licenses.

8.44 REPORTING

We will establish and implement the reporting requirements appears in Appendix Y to the NUREG-156, Vol.9, Consolidated Guidance About Materials Licenses.

8.45 LEAK TESTS

Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six (6) months.

8.47 TRANSPORTATION

We will establish and implement and maintain safety programs for the transport of radioactive material (prepare shipment, ship, or transport radioactive materials, including radioactive waste) to ensure compliance with NRC and DOT regulations. All ^{99m}Tc waste will be decayed on site.

This is to acknowledge the receipt of your letter/application dated

12/4/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 29-30982-01

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 139823.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader