STATE OF MAINE

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE FOR MEDICAL USE

INSTRUCTIONS: This application complies with the license requirements of Section C of the State of Maine Rules Relating to Radiation Protection (SMRRRP). Complete items 1 through 12. Supplemental sheets may be needed for items 5 through 11. Mail the completed application to: Radiation Control Program, 11 State House Station, Augusta, Maine, 04333. Telephone: (207) 287-5676. Facsimile: (207) 287-3059. E-Mail: radiation.dhhs@maine.gov

The Department of Health and Human Services (DHHS) does not discriminate on the basis of disability, race, color, creed, gender, age, or national origin, in admission to, access to or operations of its programs, services, or activities or its hiring or employment practices. This notice is provided as required by Title II of the Americans with Disabilities Act of 1990 and in accordance with the Civil Rights Acts of 1964 as amended, Section 504 of the Rehabilitation Act of 1973 as amended, the Age Discrimination Act of 1975, Title IX of the Education Amendments of 1972 and the Maine Human Rights Act. Questions, concerns, complaints, or requests for additional information regarding the ADA may be forwarded to the DHHS' ADA Compliance/EEO Coordinator, State House Station #11, Augusta, Maine 04333, 207-287-4289 (V) or 207-287 3488 (V), TTY: 800-606-0215. Individuals who need auxiliary aids for effective communication in programs and services of DHHS are invited to make their needs and preferences known to the ADA Compliance/EEO Coordinator. This notice is available in alternate formats, upon request.

1. THIS IS AN APPLICATION FOR (check one)

| NEW LICENSE | Office Use Only |
|-------------------------------|-----------------|
| RENEWAL of license number > | |
| AMENDMENT of license number > | |

This application includes security-related sensitive information which is marked "Security-related information – withhold under 10 CFR 2.390" (see Section 5.2 of NUREG-1556 Vol. 9, Rev 2., January 2008)

2. NAME AND MAILING ADDRESS OF APPLICANT

3. ADDRESS(ES) WHERE MATERIAL BE WILL **USED AND/OR STORED.**

PHONE:

PHONE:

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

| NAME: | PHONE |
|-------|-------|
| | |

ADDRESS: (If different from #2.)

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E-Mail:

For items 5 through 11, the requested information may be submitted on standard size paper. Answer all items. For any that do not apply, answer by giving the item number with "not applicable" after it.

5. RADIOACTIVE MATERIAL and

6. PURPOSE AND USE

A: Radioactive Material for medical use: Please place an "X" next to all the disciplines you wish to be licensed for.

| X | Radioisotope | Form or Manufacturer /Model No. | Maximum Quantity | Purpose of Use |
|---|--|---|---------------------|---|
| | Any radioactive material permitted by G.100 | Any | As needed | Any uptake, dilution, and excretion study permitted by G.100. |
| | Any radioactive material permitted by G.200 | Any | As needed | Any imaging and localization study permitted by G.200. |
| | Fluorine-18 | Any | Ci Bq | Production of PET radioactive drugs under C.7.H. |
| | Oxygen-15 | Any | Ci Bq | Production of PET radioactive drugs under C.7.H. |
| | Carbon-11 | Any | Ci Bq | Production of PET radioactive drugs under C.7.H. |
| | Any radioactive material permitted by G.300 | Any | Ci Bq | Any radiopharmaceutical therapy procedure permitted by G.300. |
| | lodine-131 | Any | Ci Bq | Administration of I-131 sodium iodide. |
| | Radioactive material permitted by G.400 (Radionuclide) | Sealed source or device Manufacturer/Model | Ci Bq | Any brachytherapy procedure permitted by G.400. |
| | Radioactive material permitted by G.400 (Radionuclide) | Sealed source or device Manufacturer/Model | Ci Bq | Any brachytherapy procedure permitted by G.400. |

| х | Radioisotope | Form or Manufacturer /Model No. | Maximum Quantity | Purpose of Use |
|---|---|---|---|--|
| | Radioactive material permitted by G.400 (Radionuclide) | Sealed source or device Manufacturer/Model | Ci Bq | Any brachytherapy procedure permitted by G.400. |
| | Radioactive material permitted by G.400 (Radionuclide) | Sealed source or device Manufacturer/Model | Ci Bq | Any brachytherapy procedure permitted by G.400. |
| | Strontium-90 | Sealed source or device Manufacturer/Model | Ci Bq | Treatment of superficial eye conditions using an applicator distributed pursuant to C.11.K. and permitted by G.400. |
| | Cesium-137 | Sealed source or device Manufacturer/Model | Ci Bq | Brachytherapy radionuclide permitted by G.400. |
| | Palladium-103 | Sealed source or device Manufacturer/Model | Ci Bq | Manual brachytherapy source permitted by G.400 |
| | Radioactive material permitted by G.500 Check all that apply: Gd-153 I-125 Ra-226 Other, describe | Sealed source or device Manufacturer/Model | Per source: Ci Bq Total: Ci Bq | Diagnostic medical use of sealed sources permitted by G.500 in compatible devices registered pursuant to C.7. |
| | Iridium-192 | Sealed source or device Manufacturer/Model | Per source: Ci Bq Total: Ci Bq | For medical use permitted by G.600, in a Manufacturer/Model remote afterloader brachytherapy device One source in its shipping container as necessary for replacement of the source in the remote afterloader device. |

| x | Radioisotope | Form or Manufacturer /Model No. | Maximum Quantity | Purpose of Use |
|---|---|---|---|--|
| | | Sealed source or device Manufacturer/Model | Per source: Ci | For medical use permitted by G.600, in a Manufacturer/ Model |
| | Cobalt-60 | | Bq Total: Ci Bq | teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy device. |
| | | Sealed source or device Manufacturer/Model | Per source: Ci | For medical use permitted by G.600, in a Manufacturer /Model |
| | Cobalt 60 | | Bq Total: Ci Bq | Gamma stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the source in the stereotactic radiosurgery device. |
| | Radioactive material permitted by G.1000 Check all that apply: Y-90 I-125 Ra-226 Other, describe | Source Manufacturer/Model | Per source: Ci Bq Total: Ci Bq | For medical use as permitted by G.1000. |
| | Any radioactive material under C.6.F. | Prepackaged kits | Ci Bq | In-vitro studies. |
| | Depleted uranium | Metal | kilograms | Shielding in a teletherapy unit. |
| | Depleted uranium | Metal | kilograms | Shielding in a linear accelerator. |
| | Any radionuclide in excess of 1.11 GBq (30 millicuries) for use in calibration, transmission, and reference sources. (List Radionuclide) | Sealed source or device Manufacturer/Model | Ci Bq | For use in a Manufacturer/Model device for calibration and |
| | | | J JY | checking of licensee's survey instruments. |

| x | Radioisotope | Form or Manufacturer /Model No. | Maximum Quantity | Purpose of Use |
|---|---------------|---|---|------------------------------|
| | Americium-241 | Sealed source or device Manufacturer/Model | Per source: Ci Bq Total: Ci | Use as an anatomical marker. |
| | Other | Form or Manufacturer/Model No. | Вq Сі Вq | Purpose of use: |

If Financial Assurance is required then Evidence of Financial Assurance must be provided

7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

7.1 RADIATION SAFETY OFFICER (RSO): Complete Form HHE-853 (RSO)

| Name: | Telephone: |
|----------|------------|
| Address: | Fax: |
| | E-mail: |
| | |
| | |

For an individual previously identified as an RSO on an Agency, NRC or Agreement State license or permit provide:

Previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO; **OR**

For an individual qualifying under G.57.A(3) provide the following:

Documentation that this individual functioned as an RSO for only accelerator-produced radioactive materials, discrete sources of Ra-226, or both; **AND**

Documentation that the individual performed as the RSO for the same medical uses requested; **OR**

For an individual qualifying under G.50.A. provide the following:

Copy of the certification by a specialty board whose certification process has been recognized by the Agency, NRC or Agreement State under G.50.A.; **AND**

Description of the training and experience specified in G.50.E. demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO; AND
 Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and

experience specified for this certification, as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge to function independently as an RSO; AND

If applicable, a description of recent related continuing education and experience as required by G.59; OR

For an individual qualifying under G.50.B. provide the following:

| Description of the training and experience specified in G.50.B. demonstrating that the proposed RSO is qualified | |
|---|---|
| by training and experience as applicable to the types of use for which the applicant seeks approval of an individua | |
| to serve as RSO; AND | |
| Description of the training and experience specified in G.50.E. demonstrating that the proposed RSO is qualified | ł |
| by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use | |
| for which the applicant seeks approval of an individual to serve as RSO; AND | |
| Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and | ł |
| experience in G.50.B, as well as the required training and experience in radiation safety, regulatory issues, and | ł |
| emergency procedures for the types of use for which the licensee seeks approval and has achieved a level o | |
| radiation safety knowledge to function independently as an RSO; AND | |
| | |
| If applicable, a description of recent related continuing education and experience as required by G.59; OR | |
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For an individual qualifying under G.50.C(1) provide the following

| Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized by the Agency, NRC or Agreement State under G.51.A and description of the experience specified in G.50.C(1) demonstrating that the proposed RSO is qualified by training and experience applicable to the types of use for which the applicant seeks approval or an individual to serve as RSO; AND |
|--|
| Description of the training and experience specified in G.50.E. demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO; AND |
| Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and experience in G.50.C(1), as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge to function independently as an RSO; AND |
| If applicable, a description of recent related continuing education and experience as required by G.59; OR |

For an individual qualifying under G.50.C.(2) provide the following:

| Copy of the licensee's license indicating that the individual is an AU, AMP, or ANP identified on the licensee's license and has experience with the radiation safety aspects of similar types of radioactive material for which the | | |
|--|--|--|
| applicant seeks approval or an individual to serve as RSO; AND | | |
| | | |
| Description of the training and experience specified in G.50.E. demonstrating that the proposed RSO is qualified | | |
| by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use | | |
| for which the applicant seeks approval of an individual to serve as RSO; AND | | |
| Written attestation, signed by a preceptor RSO, that the individual satisfactorily completed the requirements in | | |
| G.50.C(2), as well as the required training and experience in radiation safety, regulatory issues, and emergency | | |
| procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety | | |
| knowledge to function independently as an RSO; AND | | |
| If applicable, a description of recent related continuing education and experience as required by G.59. | | |
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We have established, in writing, the authority, duties, and responsibilities of the RSO.

We will ensure that the RSO is authorized to stop unsafe operation; and has sufficient time to perform radiation safety duties and responsibilities.

7.2 AUTHORIZED USERS (AUs) NAMES AND REQUESTED USES FOR EACH INDIVIDUAL: Complete the applicable Form (HHE-853) for each individual.

| Name: | Telephone: |
|------------------|-----------------|
| Address: | Fax: |
| | E-mail: |
| Uses requested: | |
| License number : | Issuing entity: |

For an individual identified as an AU on an Agency, NRC or Agreement State license or permit, provide the following:

Previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) or copy of a permit issued by an NRC master materials licensee, a permit issued by an Agency, NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist or podiatrist was specifically named as an Authorized User for the uses requested; AND
 For an AU requesting a medical use not currently authorized on a license or permit, a description of the additional

For an AU requesting a medical use not currently authorized on a license or permit, a description of the additional training and experience is needed to demonstrate the AU is also qualified for the new medical uses requested. A preceptor attestation may also be required; **OR**

For an individual qualifying under G.57.B(3), provide the following:

Documentation that this individual used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both; **AND**

Documentation that this individual used these materials for the same medical uses requested; AND

For an AU requesting a medical use not currently authorized on a license or permit, a description of the additional training and experience is needed to demonstrate the AU is also qualified for the new medical uses requested. A preceptor attestation may also be required; **OR**

For an individual qualifying under Part G, Subparts D, E, F, G, and/or H, who is board-certified, provide the following:

| Copy of the certification(s) by a specialty board whose certification process has been recognized by the Agency, | |
|---|-----|
| NRC or Agreement State under Part G, Subparts D, E, F, G, and/or H, as applicable to the used requested; AND | |
| For a physician with board certification recognized under G.390, a description of the supervised work experience | |
| administering dosages of radioactive drugs required in G.390.B.(1)(b)(vii) demonstrating that the proposed AU is | S |
| qualified for the types of administrations for which authorization is sought; AND | |
| For a physician with board certification recognized under G.390 for medical uses described in G.200, a description | |
| of the supervised work experience eluting generator systems required in G.290.C(1)(b)(vii) demonstrating that the | e |
| proposed AU is also qualified imaging and localization medical uses; AND | |
| For a physician with board certification recognized under G.490 or G.690 for medical uses described in G.396, a | |
| description of the training and supervised work experience and a copy of the attestation required in G.396.D to | |
| demonstrate qualifications for administering parenteral administrations of unsealed radioactive material requiring a | а |
| written directive; AND | |
| For an individual seeking authorization under Part G, Subpart H, a description of the training specified in G.690.0 | С (|
| demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought; AND | |
| Written attestation, signed by a preceptor physician AU, that the training and experience specified for certification | |
| have been satisfactorily completed a that a level of competency sufficient to function independently as an AU fo | |
| the medical uses authorized has been achieved. For individuals seeking authorization under G.390, G.396, and | |
| G.690, the attestation must also include successful completion of the clinical case work in G396.B(1)(b)(vii), o | or |
| training and experience required by G396.D, or training for G.600 types of use, as appropriate; AND | |
| If applicable, a description of recent related continuing education and experience as required by G.59; OR | |
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For an individual qualifying under Part G, Subparts D, E, F, G, and/or H, who is not board-certified, provide the following:

| A description of the training and experience identified in Part G, Subpart D, E, F. G, and H, demo | onstrating that the |
|--|---------------------|
| proposed AU is qualified by training and experience for use(s) requested; AND | |
| For an individual seeking authorization under Part G, Subpart H, a description of the training spe | cified in G.690.C |
| demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is so | ought; AND |
| Written attestation, signed by a preceptor physician AU, that the above training and experi satisfactorily completed a that a level of competency sufficient to function independently as an A | |
| uses authorized has been achieved; AND | |
| If applicable, a description of recent related continuing education and experience as required by G | 3.59. |
| | |

For an AU for nonmedical uses, provide the following:

| Ν | lame: | Telephone: | | | | | |
|--|--|------------|--------------------------------|------------|-----------------|--|--|
| Address: | | | Fax: | | | | |
| | | | E-mail: | | | | |
| R | adionucl | ide(s) | Form or Manufacturer/Model No. | Quantities | Purpose of use: | | |
| A description of the individual's educational and radiation safety training and experience with the typ materials and uses requested, this may include: A copy of the Agency, NRC or Agreement State License listing the individual as an AU for the types, quantities, and uses requested. | | | | | | | |
| | A permit issued by a Master Materials License licensee or broad-scope licensee or broad-scope permittee identifying the individual as an AU for the types, quantities, and uses requested. | | | | | | |
| | | Other: | | | | | |

7.3 AUTHORIZED NUCLEAR PHARMACIST (ANP): Complete the Form (HHE-853 ANP) for each individual.

| Name: | Telephone: |
|------------------|-----------------|
| Address: | Fax: |
| | E-mail: |
| Uses requested: | |
| License number : | Issuing entity: |

For an individual identified as an ANP on an Agency, NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANP, provide the following:

Previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) or copy of a permit issued by an NRC master materials licensee, a permit issued by an Agency, NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs; **OR**

For an individual qualifying under G.57.A(3), provide the following:

Documentation that the nuclear pharmacist used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both; **AND**

Documentation that this nuclear pharmacist used these materials for the same medical uses requested; OR

For an individual qualifying under G.55.A, provide the following:

Copy of the certification of the specialty board whose certification process has been recognized under G.55.A; AND

Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed a that a level of competency sufficient to function independently as an ANP has been achieved; AND

If applicable, a description of recent related continuing education and experience as required by G.59; OR

For an individual qualifying under G.55.B, provide the following:

Description of the training and experience specified in G.55.B. demonstrating that the proposed ANP is qualified by training and experience; and copy of the certification of the specialty board whose certification process has been recognized under G.55.A; **AND**

Written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed a that a level of competency sufficient to function independently as an ANP has been achieved; **AND** If applicable, a description of recent related continuing education and experience as required by G.59.

7.4 AUTHORIZED MEDICAL PHYSICIST (AMP): Complete the Form (HHE-853 AMP) for each individual.

| Name: | Telephone: | |
|----------|------------|--|
| Address: | Fax: | |
| | E-mail: | |
| | | |

For an individual identified as an AMP on an Agency, NRC or Agreement State license or permit, provide the following:

Previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) or copy of a permit issued by an NRC master materials licensee, a permit issued by an Agency, NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AMP for the uses requested, **OR**

For an individual qualifying under G.57.A(3), provide the following:

Documentation that the medical physicist used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both for medical uses; **AND**

Documentation that the medical physicist used these materials for the same medical uses requested; OR

For an individual qualifying under G.51.A, provide the following:

Copy of the certification(s) for the specialty board(s) whose certification process has been recognized under G.51; **AND**

Description of the training and experience specified in G.51.C demonstrating the proposed AMP is qualified by training in the types of use for which the individual is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system; **AND**

Written attestation, signed by a preceptor AMP, that the training and experience required for certification, as well as the required training in G.51.C for the types of uses specified, have been satisfactorily completed a that a level of competency sufficient to function independently as an AMP has been achieved; AND

If applicable, a description of recent related continuing education and experience as required by G.59; OR

For an individual qualifying under G.51.B, provide the following:

Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in G.51.B(1) for the uses requested; **AND**

Description of the training and experience specified in G.51.C demonstrating the proposed AMP is qualified by training in the types of use for which the individual is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system; AND

Written attestation, signed by a preceptor AMP, that the training and experience required in G.51.B.(1), as well as the required training in G.51.C for the types of uses specified, have been satisfactorily completed a that a level of competency sufficient to function independently as an AMP has been achieved; **AND**

If applicable, a description of recent related continuing education and experience as required by G.59.

8. SAFETY INSTRUCTION FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

We will provide adequate safety instruction for individuals working with or in the vicinity of licensed material in accordance with Parts G and J. (Appendix J to NUREG 1556, Vol. 9 or equivalent)

9. FACILITIES AND EQUIPMENT:

9.1 Facility Diagram: Provide the following on the facility diagrams. (Drawings will be to scale and indicate scale) :

Location, room number(s), and principal use of each room or area where radioactive material is prepared, used or stored and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms. Indicate whether the room is a restricted or an unrestricted area as defined in A.2; AND

Description and of the rooms where patients will be housed if they cannot be released under G.30. (This should include room number(s) and a description of the shielding, if applicable); **AND**

Shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used; **AND**

The directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.

9.2 Radiation Monitoring Instruments

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations; AND/OR

We have developed and will implement and maintain the written survey meter calibration procedures in accordance with the requirements of D.1501 and that meet the requirements of G.61. (Appendix K to NUREG 1556, Vol. 9 or equivalent).

Provide a description of the instrumentation (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.

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.

9.3 Dose Calibrator And Other Dosage Measuring Equipment

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

9.4 Therapy Unit – Calibration And Use

Provide the procedures required by G.642, G.643, and G.645, if applicable to the license application.

9.5 Other Equipment And Facilities

Provide a description of additional facilities and equipment.

For manual brachytherapy facilities

Provide a description of emergency response equipment.

For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:

Warning systems and restricted area controls for each therapy treatment room;

Area radiation monitoring equipment;

Viewing and intercom systems (except LDR units);

Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiationproducing equipment are in the treatment room;

Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and

Emergency response equipment.

10. RADIATION PROTECTION PROGRAM:

10.1 Safety Procedures And Instructions

Provide the procedures required by G.657.

10.2. Occupational Dose

We will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive , in one year, a radiation dose in excess of 10% of the allowable limits in Part D; **OR** We will provide dosimetry that meets the requirements listed under "Criteria" in article 8.22 of NUREG 1556, Vol.

9; **OR**

Provide a description of an alternative method for demonstrating compliance with the regulations.

10.3. Area Surveys

We have developed and will implement and maintain written procedures for area surveys in accordance with D.1101. that meet the requirements of D.1501 and G.70. (Appendix R to NUREG 1556, Vol. 9. or equivalent)

10.4. Safe Use Of Unsealed Licensed Material

We have developed and will implement and maintain procedures for safe use of unsealed radioactive material that meets the requirements of D.1101. and D.1301. (Appendix T to NUREG 1556, Vol. 9. or equivalent)

10.5. Spill Procedures

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with D.1101. (Appendix N to NUREG 1556, Vol. 9. or equivalent)

10.6. Installation, Maintenance, Adjustment, Repair, Inspection Of Therapy Devices Containing Sealed Sources

We will contract with personnel who are licensed by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State to install, maintain, adjust, repair, and inspect the specific therapy device possessed by the licensee; **OR**

Name of proposed employee and types of activities requested:

Provide a description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested; **AND**

Provide a copy of the manufacturer's training certification and an outline of the training in procedures to be followed.

10.7 Public Dose

We will 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 nor exceed 0.02 mSv (2mrem) in any one hour from licensed operations.

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

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

10.8. Opening Packages

We have established and will maintain and retain written procedures for safely opening packages to ensure that the monitoring requirements of D.1906. are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA. (Appendix P to NUREG 1556, Vol. 9 or equivalent)

10.9. Procedures For Administrations When A Written Directive Is Required

We have developed and will implement and maintain written procedures to provide high confidence that licensed material is administered as directed by authorized users in accordance with G.41. (Appendix S to NUREG 1556, Vol. 9 or equivalent)

10.10. Release of Patients Or Human Research Subjects

We will provide radiation written safety instructions to patients or human research subjects (or their parent, guardian or caregiver) released in accordance with G.75. (Appendix U to NUREG 1556, Vol. 9 or equivalent)

10.11. Mobile Nuclear Medicine Services

We will comply with the requirements of G.80 and G.647, as applicable, as well as all other applicable regulations. (Appendix V to NUREG 1556, Vol. 9. or equivalent)

10.12 Audit Program

We will annually review the content and implementation of the radiation protection program to ensure compliance with Agency and applicable DOT regulations; the terms and conditions of the license; occupational doses; and doses to members of the general public are ALARA. (Appendix L to NUREG 1556, Vol. 9 or equivalent)

10.13 Operating And Emergency Procedures

We have developed and will implement, and maintain specific operating and emergency procedures. (Appendix N to NUREG 1556, Vol. 9. or equivalent)

10.14. Material Receipt And Accountability

We will secure licensed material.

We will maintain records of receipt, transfer, and disposal of licensed material.

We will conduct physical inventories at required frequencies to account for licensed material.

10.15 Ordering And Receiving

We will ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, we will ensure that packages are secured and radiation exposure from packages is minimized. (Appendix O to NUREG 1556, Vol. 9. or equivalent)

10.16. Sealed Source Inventory

We will conduct a semi-annual physical inventory of all sealed sources and brachytherapy sources (individual GSR sources are exempt) in our possession.

We will maintain records of GSR source receipt, transfer, and disposal to indicate the current inventory of sources at our facility.

10.17. Records Of Dosages And Use Of Brachytherapy Source

We will make and maintain the records of each dosage and administration prior to medical use.

We will make and maintain the appropriate records for molybdenum concentrations.

We will make and maintain the appropriate records for the manual use of brachytherapy sources.

10.18. Record keeping

We will maintain records as provided in Subpart L to Part D, and Subpart L to Part G. (Appendix X to NUREG 1556, Vol. 9.)

10.19 Reporting

We will report to the Agency incidents that might compromise the health and safety of patients, health care providers, or the public as required in Subpart M to Part D. and Subpart M to Part G. (Appendix Y to NUREG 1556, Vol. 9.)

We will report to the Agency by telephone immediately and followed by a written report within 30 days any event tin which the security of radioactive material is compromised.

10.20 Leak Tests

We will perform leak testing of sealed sources, e.g., calibration, transmission, and reference sources, or brachytherapy sources in accordance with G.67. (Appendix Q to NUREG 1556, Vol. 9 or equivalent)

10.21 Safety Procedures For Treatments When Patients Are Hospitalized

We have developed and will implement procedures to ensure that access to therapy treatment rooms, and exposure rates from therapy treatments, are limited to maintain doses to occupational workers and members of the general public within regulatory limits. (G.75, G.315, G.415, G.615)

10.22 Transportation

We have developed and will implement and maintain a safety program for the transport of radioactive materials to ensure compliance with State and Federal regulations. (Appendix Z to NUREG 1556, Vol. 9)

11. WASTE MANAGEMENT: Waste Disposal

We have developed and will implement and maintain written disposal procedures for licensed material in accordance with Part D.1101 that also meet the requirements of the applicable section of Subpart K to Part D. and G.92. (Appendix W to NUREG 1556, Vol. 9. or equivalent)

12. CERTIFICATION: The applicant and any official executing this certificate on behalf of the applicant named in item 2, certify that this application is prepared in conformity with the State of Maine Rules Relating to Radiation Protection and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

DATE: SIGNATURE OF APPLICANT:

TITLE: TYPED/PRINTED NAME: