

**RADIOLOGICAL HEALTH PROGRAM
LIMITED MEDICAL SPECIFIC LICENSE APPLICATION CHECKLIST
Modified July, 2018**

LICENSEE NAME: _____ **APPLICATION DATE:** _____

LICENSE #: _____

**All referenced Appendices refer to those in USNRC NUREG 1556, Vol. 9, Rev. 2
“Section” references refer to COMAR 26.12.01.01, primarily Sections D, G, J, and T**

Item # Required Information

2. Licensee name and mailing address 1556 Section 8.2
Full name of legal entity (e.g., corporation, not division)
If a change in licensee name indicates possible change in ownership –require information for transfer and control or name change (7 points). License cannot be in the name of one physician unless he/she is the owner of the facility/practice and the name of the practice is the physician’s name.
Check ownership carefully.

Street address _____
City _____
State, Zip, County _____
Telephone Number _____
E-mail Address _____
FID Number _____

3. Location of use (cannot be a P.O. Box) 1556 Section 8.3
If a mobile nuclear medicine service is requested see G.80. and section 9.5 of this checklist

4. Contact Person 1556 Section 8.4
Name _____
Telephone Number _____
E-mail Address _____

5. & 6. Authorized Materials 1556 Section 8.5

| <u>Material</u> | <u>Possession Limits</u> |
|--------------------------------|--------------------------|
| G.100 | As needed |
| G.200 | As needed |
| except Xenon and/or Generators | |

G.300

Limit activity ___ mCi

If licensee does not request or qualify for full G.300 authorization, use line items on license (i.e. I-131, Sr-89)

G.400

Limit activity

If licensee does not request or qualify for full G.400 authorization, use line items on license (i.e. I-125, Pd-103)

G. 500**C.22(i)** (prepackaged kits)

Limit activity to 200 microcuries

Eye Applicator (line item if no other G.400 uses)

Limit activity

Cesium 137 (SS for instrument calibration) Limit per source and total activity G.65

Add SS conditions to license if SS is not included in Part G uses (G.65)

If HDR is requested, review HDR program using the HDR checklist.

If license contains an HDR, the HDR program code becomes the primary program code or is separate license.

If R&D isotopes (CHIPS, etc.) are requested, review R&D program using Laboratory checklist. Normally must be separate license

- 7.1 Authorized Users 1556 Appx. D, 1556 Section 8.12
For renewal, if there is no change for a user or his/her authorized uses, no additional information is needed for that user. For new or additional authorized users, see below.
- 7.1 Physician Qualifications (G.190, G.290, G.390, G.392, G.394, G.396, G.490, G.491, G.590)
Authorized users identified as an authorized user on a Commission or Agreement State license that authorizes the use of byproduct material in medical use; or identified as an authorized user on a permit issued by a Commission or Agreement State licensee of broad scope that is authorized to permit the use of byproduct material in medical use can be authorized by the licensee. However, at renewal the licensee must provide a complete list of users. If the authorized user does not meet the criteria specified in this paragraph, SEE INDIVIDUAL SECTION G REFERENCES. MUST MEET THESE, i.e. PRECEPTOR ATTESTATION, etc.

Preceptor statement if dated w/in 7 years

1. G.100 Procedures, G.190
2. G.200 Procedures, G.290
3. G.300 Procedures Check G. 390, 392, 394, 396 for specific requirements
4. G.400 Procedures G.490
5. G.500 Procedures G.590
6. *G.600 Procedures G.690 – use separate checklist for HDR, Gamma Knife, Gamma Pod*
7. Preceptor statement signed by an authorized user (the preceptor) currently authorized for requested groups.
8. “Recentness of training” must be within 7 years of current request to be AU. G.59

- 7.2 Users Non-Medical Use (e.g. instrument calibration, for evaluation of users of R&D isotopes refer to laboratory checklist) *Separate license required.*
- 7.3 Medical Physicists for new physicists. G.51, G.57, G.59, 1556Appx. D, 1556 Section 8.14
Requested for HDR, Gamma Knife Gamma Pod licenses
If not on current license (either Agreement State or NRC) or appearing on license greater than 7 years ago, request NRC 313 preceptor statement.
- 7.4 Radiation Safety Officer G.50, G.57, G.59, 1556 Appx. D, 1556 Section 8.11
A. Use G.50 if RSO is not current RSO or on another Agreement State or NRC license.
B. Request completed NRC Form 313 (Preceptor Statement).
C. If requesting that consultant be named RSO, consultant must conform to G.50
- 8.1 Training J.12, 1556 Section 8.32
A. Technologists
B. Ancillary personnel (housekeeping, security, nursing, secretarial as applicable)
C. Initial (before beginning duties) and whenever there is significant change in duties, regulations or terms of the license
D. Annual refresher training
E. **1556 Vol. 9, Rev 2 Appendix J Procedures**
F. List of those groups receiving training, the method(s) and frequency
G. Records of training - date, duration, place, instructor, subjects covered, names of attendees
- 9.1 Facility Diagram 1556 Sections 8.15, 8.16
A. Generator storage
B. Radiopharmaceutical storage
C. Radioactive waste storage including area for decay-in-storage
D. Shielding for kit preparation and dispensing (including syringe shields)
E. Adjacent areas identified
F. Fume hood for storage of multi-dose volatiles and gases D.701
G. Submit room clearance rates for gases D.701
H. If authorized for brachytherapy, describe sealed source storage
I. Require commitment to security, i.e. lock on hot lab door and commitment to surveillance and control at all times. D.801, 802
- Instruments G.60A, G.60B, 1556 Section 8.17
A. Identify survey meter(s).
B. Identify instrument used for wipe tests
C. Sufficient sensitivity to detect and measure energy of isotope used .
- 9.2 Survey Meter Calibration G.61
A. 1. Outside provider (company/consultant) - must specify done by persons authorized by the NRC or Agreement State to perform and check that any named entity is licensed.
2. Frequency must be at least annually

- B. In-house calibration
 - 1. Frequency (annually)
 - 2. Calibration source identity (energy, activity & calibration accuracy)
 - 3. Two points each scale
 - 4. Plus or minus 20%
 - 5. Apparent exposure rate from dedicated check source at calibration
 - 6. Records meet G.61. No need to request additional information if application is silent on this requirement. Ask about these records only if application provides recordkeeping information that contradicts G.61
 - 7. **NUREG 1556, Vol 9, Rev 2, Appendix K Procedures**
 - 8. Identity and experience of person performing calibration
- C. Back-up instrument shall be required during absence of primary instruments for calibration
- D. May not perform calibrations for other licensees unless obtains license for survey meter calibration.

9.3 Dose Calibrator Calibration G.60B, 1556 Section 8.18

- A. Constancy (Daily) - **beginning** of each day
 - 1. Calibration standard (at least one)
 - not < 10 uCi Ra-226, not < 50 uCi others with half-life greater than 90 days.
 - 2. On one frequently used setting
 - 3. Plus or minus 10% or replace or repair
- B. Linearity (Quarterly)
 - 1. Between maximum patient dosage and down to 30 microcuries
 - 2. For shield method: manufacturer's instructions
- C. Accuracy Upon installation and annually.
 - 1. Two standard sources, one between 100 and 500 keV
 - a. Calibration accuracy of standard - 5%
 - b. not < 10 uCi Ra-226, not < 50 uCi others
 - 2. Plus or minus 10% or replace or repair
- D. Geometry (Installation and after repair, adjustment or relocation)
 - Over range of volumes and geometries (volume configurations) which will be used
- E. Dose Calibrator Recordkeeping G.60(e)
 - No need to request additional information if application is silent on this requirement. Ask about these records only if application provides recordkeeping information that contradicts or specifically omits portions of G.60(e) requirements
- F. **Make licensee submit procedures. If the calibrator is used to measure alpha or beta emitters, verify procedures are in accordance with nationally recognized standards.**

- 9.4 Personnel Monitoring Program D.501, D.502, D.1107, 1556 Section 8.23, 1556 Appx M
- A. Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
adults who **potentially** may receive, in 1 year, from sources external to the body, a dose in excess of 10 percent of the limits in D.201(a) and minors and declared pregnant women who potentially may receive, in 1 year from sources external to the body, as dose in excess of 10 percent of any of the applicable limits in D.207 or D.208. and individuals entering a high or very high radiation area.
 - B. Supply extremity monitors for: occupationally exposed adults with the potential to receive 10% of D.201(a)(2)(ii) limits; occupationally exposed minors likely to receive 10% of D.207 limits
 - C. Frequency of exchange must be monthly for all medical licensees
 - D. NVLAP accredited dosimetry processor
 - E. **NUREG 1556 Vol.9 Appendix M Procedures**
 - F. Must use ring badges and not wrist badges for extremity monitoring.
 - G. Maintaining records
- 9.5 Mobile Nuclear Medicine Service G.80, 1556 section 8.37 and appendix V-1
- A. Must have base office
 - B. Signed agreement with clients
 - C. Commit to send monthly schedule in advance to RHP (via e-mail)
 - D. Conform to all other requirements
 - E. Submit signed agreements with authorized users
 - F. **NUREG 1556 Vol. 9 Appendix V Procedures**
- 10.1 Radiation Safety Committee G.26
Committee required if licensee is authorized for one or more therapeutic uses for both medical institution and private medical office.
- A. Membership
 1. Administrator (Management)
 2. Representative from each department
 3. Radiation Safety Officer
 4. Nursing
 - B. Duties, Responsibilities and Authority
 - C. Quarterly Meeting Frequency
 - D. Quorum Requirements
 - E. Commitment to maintain records
 - F. **Must commit to and describe as above.**

- 10.2 ALARA Program G.24(h)
- A. Develop and implement a written radiation protection program that includes provisions for keeping doses ALARA
Management, RSO and all authorized users must participate in the program as requested by the RSO and/or RSC
 - B. Worker notification of program and required participation
 - C. Worker training to ensure individual and collective doses are ALARA
 - D. **Must submit their entire ALARA program**
 - E. Quarterly or annual limits must be as in D.201
- 10.21 Radiation Safety Officer Duties G.25,
- A. List duties of the RSO
 - B. Perform annual audit 1556 Appx. L, Section 8.38
 - C. Delegation of authority as in **NUREG 1556, Vol 9, Rev.2, Appendix I**
- 10.3 Leak Test G.67, D.401, 1556 Section 8.46
- A. Must test every six months or intervals stated on SSD sheet.
 - B. Report if ≥ 0.005 uCi
 - C. Licensed individual to conduct D.401 (b)
 - D. **NUREG 1556 Vol. 9, Rev.2, Appendix Q Procedures**
- 10.31 Sealed Source Inventory 1556 Section 8.42
- A. Every six (6) months.
- 10.4 Laboratory Instructions 1556 Section 8.25
- A. Lab coats
 - B. Gloves
 - C. Labelling G.69, D.904
 - D. Monitor hands
 - E. Syringe shields
 - F. Eating, drinking and smoking (or storage)
 - G. Wear personnel monitors (whole body and extremity rings)
 - H. Disposal of waste
 - I. Pipetting
 - J. Assay dose
 - K. Secure RAM at all times D.801, 802
 - K. **NUREG 1556, Vol. 9, Rev. 2, Appendix T Procedures**
- 10.5 Emergency Instructions 1556 Section 8.39, 1556 Section 8.26
- A. Immediate actions
 - B. Notification of RSO
 - C. Decontamination and surveys
 - D. Notification of RHP with phone numbers.
 - E. **NUREG 1556, Vol. 9, Rev 2, Appendix N Procedures**

- 10.6 Ordering and Receiving D.906, 1556 Sections 8.40, 8.41
- A. Working hours
 - B. Storage location for off-duty hours - if location indicates that exposure levels do not exceed D.301(a) dose limits for individual members of public
 - C. Instructions for personnel receiving RAM during off-duty hours
 - D. RSO telephone number
 - E. **NUREG 1556, Vol. 9, Rev. 2, Appendix O Procedures**
- 10.7 Opening Packages D.906, 1556 Section 8.34
- A. Monitor outside of package for radiation levels
 - B. Wear gloves while opening package
 - C. Check packing material for contamination
 - D. Report leakage
 - E. **NUREG 1556, Vol. 9, Rev. 2, Appendix P Procedures**

Byproduct Material Recordkeeping

No need to request additional information if application is silent on these recordkeeping requirements. Ask about these records only if application provides recordkeeping information that contradicts or specifically omits portions of Section G requirements specified below:

- 10.8 A. Unit dosage records
- 10.9 B. Multi-dosage records
- 10.10 C. Molybdenum concentration records
- 10.11 D. Implant source use records
- E. **NUREG 1556 Vol. 9, Rev.2, Appendix X Procedures**
- 10.12 Area Surveys D.301, D.302, G.70, D.501, 1556 Section 8.24
- A. Daily ambient - Elution and Preparation Areas END of Day
 - B. Weekly ambient- All Areas
 - C. Weekly contamination - Wipe Tests to 200 dpm or below
 - D. Records millirem per hour, dpm
 - E. **NUREG 1556, Vol. 9, Rev. 2, Appendix R Procedures**
 - F. Notification if action levels exceeded
If licensee requests an unrestricted area action level that is greater than 0.5 mR/hr, ask about compliance with D.301(a)(1) - (public dose limit - 100 mRem/year)
- 10.13 Xenon and Aerosols D.203, D.501, D.502 (b)
- Negative pressure is required in Xenon use areas. No need to request additional information if application is silent on this since it is a regulation. Ask about negative pressure only if application differs or provides ambiguous/questionable information about it.
- 10.13.1 A. Worker Dose From Noble Gases (Xe-133)
1. Collect spent gas in shielded trap and monitor with an air contamination monitor, **or**
 2. Collect spent gas in shielded trap and monitor trap **or**
 3. Vent to atmosphere in closed system
- 10.13.2 B. Worker Dose from Aerosols (Tc-99m)
- Collect spent aerosol in single use shielded trap or monitor for reusable traps
- 10.13.3 C. Public Dose From Airborne Effluent (Xe-133 and Tc-99m)
1. If not venting spent aerosols and gases to the atmosphere this is not necessary

- 10.13.4 D. Spilled Gas Clearance Time (Xe-133)
- 10.14 Radiopharmaceutical Therapy G.75, G.300, 1556 Section 8.47
- A. Assurance that patient is not pregnant or breast feeding. Instructions on cessation of breast feeding and resuming, if applicable.
 - B. Written directive required and 2 methods of patient identification G.40
 - C. Instructions to applicable personnel G.310
 - D. Personnel dosimetry - nurses
 - E. Room assignment, private with bathroom required G.315
 - F. Posting CRAM sign on door G.315
 - G. Contamination control -Disposable items, etc. G.315
 - H. Patient trash held to decay G.315
 - I. Linens held to decay G.315
 - J. Surveys of patient room and all contiguous areas G.315
 - K. Posted visiting time and safe line or equivalent position
 - L. Room release contamination survey (<200 dpm/100 cm²)
 - M. Patient dismissal if survey shows that no member of the general public will receive a dose of 5mSv (0.5 rem)
 - N. Bioassay for volatile iodine (liquid) D.202
 - O. Instructions to patients prior to release must address precautions to protect the general public
 - P. Will patients be permitted to stay alone in hotel immediately after dosing?
 - Q. **NUREG 1556, Vol. 9, Rev.2, Appendix S Procedures for Written Directives, and G.40**
 - R. **NUREG 1556, Vol. 9, Rev.2, Appendix U Procedures for Release of Patients**
- 10.15 Manual Brachytherapy G.67, G.75, G.400, 404, 406, 410, 415, 432, 1556 Section 8.47
- A. Instructions to applicable personnel
 - B. Personnel dosimetry - nurses
 - C. Source accountability log/records
 - D. Room assignment, private room
 - E. Posting CRAM sign on door
 - F. Post allowed visiting time
 - G. Emergency response equipment for retrieving dislodged source or source lodged within patient following removal of applicators.
 - E. Surveys of patient room and all contiguous areas
 - F. Posted visiting time and safe line or equivalent position
 - G. Patient dismissal survey background for temporary implants
 - H. Patient dismissal for permanent implant if survey shows that no member of the general public will receive a dose of 5mSv (0.5 rem)
 - I. Instructions to patient prior to release for permanent implants. Review instructions.
 - I. **NUREG 1556, Vol. 9, Rev. 2, Appendices S and Q Written directive & Release Criteria, Appx. U.**
 - J. Save linen for survey
 - K. Precautions for handling sources (shielding, remote handling)
 - L. Transportation of sources in-house
 - M. Measurement of extremity dose
 - N. Survey for I-125 seeds

11. Waste Disposal
 - A. Methods used D.1001-D.1008, D.1109, 1556 Section 8.29
 1. Decay-in-storage (DIS), isotopes with $t_{1/2} < 90$ days, stored for 10 half lives and surveyed prior to disposal; remove or obliterate labels; records. *There are no MD regs covering this, so we are just tying down what they commit to.*
 2. Release to environment (sanitary sewer, unrestricted areas). Patient excreta is exempt. Limits of other than patient are in Appendix B of Section D of COMAR.
 3. Transfer to manufacturer or disposal facility
 - B. **NUREG 1556, Vol. 9, Rev.2, Appendix W Procedures (covers all the above)**

12. Certifying Signature 1556, Section 8.31
Application must be signed by licensee or certifying official for licensee (senior management) not RSO or consultant.

Additional Issues:

Quality Management Program G.40, G.2040, 1556 Section 8.35, 8.36

See SRP for QM program reviews and associated checklist.

Check to ensure that all pertinent modalities of use requested in an application have been addressed by the licensee's QM program.

If the licensee has had its QM program previously reviewed and commented upon, no review of the QM program is necessary. These QM programs will be reviewed at the time of the next inspection.

QM programs for new licenses and amendments with new modalities must be reviewed. Control the QM program review as separate action (type 6) from the licensing review. The license cannot be issued until questions associated with the QM programs have been resolved.

Decommissioning/Financial Assurance (D/FA) Part C, Appendix E, F, G and C.29, 1556 Section 8.8
Specific Medical Licensees with R&D programs and Broad Scope Medical Licensees may require decommissioning/financial assurance. Isotopes with $t_{1/2} < 120$ days are not a concern. Any isotopes with $t > 120$ days must be considered.

Control D/FA as separate action from licensing review. If D/FA is submitted with application, separate it out from application and control as separate action. Follow D/FA procedure in D/FA manual.

Emergency Contingency Planning

Specific Medical Licensees with R&D programs and Broad Scope Medical Licensees may require emergency contingency planning.