



MARYLAND DEPARTMENT OF THE ENVIRONMENT

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APR 30 2007

Scott W. Moore, Deputy Director
Division-Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Moore:

Enclosed is a copy of the proposed revisions to the Maryland Radiological Health Rules COMAR 26.12.01.01 "Regulations For the Control of Ionizing Radiation (1994)." It is our intent to propose these regulations in the Maryland Register and allow for public comment around summer of 2007. We request NRC's comments prior to that submittal. The proposed regulations are identified by line-in/line-out text and correspond to the following equivalent amendments to NRC's regulations:

| <u>Rats ID</u> | <u>Title</u> | <u>State Section(s)</u> |
|----------------|--|-------------------------|
| 2002-2 | Medical Use of Byproduct Materials-Parts 20, 32, and 35 | A, C, D, E, and G |
| 2005-1 | Security Requirements for Portable Gauges Containing Byproduct Material -Part 30 | D.803 |
| 2005-2 | Medical Use of Byproduct Material-Recognition of Specialty Boards-Part 35 | G |

We believe that adoption of these revisions satisfy the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Programs (FSME) Procedure SA-200. If you have any questions, please feel free to contact Ray Manley of my staff at 410-537-3300.

Sincerely,

Roland G. Fletcher, Manager
Radiological Health Program
Air and Radiation Management Administration

RGF
RGF/REM

Enclosures:
As stated.

PART A
GENERAL PROVISIONS

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5 Sec. A.1 Scope. Except as otherwise specifically provided, these regulations apply to all persons who
6 receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in
7 these regulations shall apply to any person to the extent such person is subject to regulation by the U.S.
8 Nuclear Regulatory Commission.¹ This part also gives notice to all persons who knowingly provide to
9 any licensee, applicant, certificate of registration holder, contractor, or subcontractor, components,
10 equipment, materials, or other goods or services, that relate to a licensee's, applicant's or certificate of
11 registration holder's activities subject to these regulations, that they may be individually subject to
12 Maryland Department of the Environment enforcement actions for violation of A.16.

13
14 Sec. A.2 Definitions. As used in these regulations, these terms have the definitions set forth below.
15 Additional definitions used only in a certain part will be found in that part.

16
17 "A1" means the maximum activity of special form radioactive material permitted in a Type A package.

18 "A2" means the maximum activity of radioactive material, other than special form radioactive material,
19 permitted in a Type A package. These values are either listed in Appendix A of Part T of these
20 regulations, Table I, or may be derived in accordance with the procedure prescribed in Appendix A of
21 Part T of these regulations.

22
23 "Absorbed dose" [See "Dose"]

24
25 "Accelerator-produced material" means any material made radioactive by a particle accelerator.

26
27 "Act" means the Annotated Code of Maryland, Environment Article, Title 8 "Radiation."

28
29 "Activity" means the rate of disintegration (or transformation) or decay of radioactive material. The units
30 of activity are the becquerel (Bq) and the curie (Ci).

31
32 "Adult" means an individual 18 or more years of age.

33
34 "Agency" means the Maryland Department of Environment, Radiological Health Program.

35
36 "Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the U.S.
37 Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the
38 Atomic Energy Act of 1954, as amended (73 Stat. 689).

39
40 "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts,
41 fumes, particulates, mists, vapors, or gases.

42
43 "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material
44 exists in concentrations:

45
46 (1) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of Part D of
47 these regulations, or

48
49 (2) To such a degree that an individual present in the area without respirator protective equipment could
50 exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on
51 intake (ALI) or 12 DAC hours.

52 -----
53 1/ Attention is directed to the fact that regulation by the State of source material, byproduct material, and
54 special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the
55 agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the
56 Commission's regulations.

- 59 "Annually" means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time
60 per year (plus or minus 1 month).
61
- 62 "As low as reasonably achievable (ALARA)" means making every reasonable effort to maintain
63 exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the
64 purpose for which the licensed or registered activity is undertaken, taking into account the state of
65 technology, the economics of improvements in relation to state of technology, the economics of
66 improvements in relation to benefits to the public health and safety, and other societal and socioeconomic
67 considerations, and in relation to utilization of nuclear energy and licensed or registered sources of
68 radiation in the public interest.
69
- 70 "Authorized nuclear pharmacist" means a pharmacist who is:
- 71
- 72 (1) ~~Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties~~ Meets the
73 requirements in Sections G.55 and G.59; or
74
- 75 (2) ~~Is identified as an authorized nuclear pharmacist on:~~ a license issued by the Agency, the NRC, or any
76 other Agreement State that authorizes the use of radioactive material in the practice of nuclear pharmacy;
77 or
- 78 (i) A specific license issued by the Agreement State or NRC that authorizes medical use or the
79 practice of nuclear pharmacy;
80
- 81 (ii) A permit issued by an NRC master material licensee that authorizes medical use or the
82 practice of nuclear pharmacy;
83
- 84 (iii) An authorization issued by an Agreement State or NRC broad scope medical use licensee
85 that authorizes medical use or the practice of nuclear pharmacy; or
86
- 87 (iv) A permit issued by an NRC master material license broad scope medical use permittee that
88 authorizes medical use or the practice of nuclear pharmacy; or
89
- 90 (3) ~~Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been~~
91 ~~authorized to identify authorized nuclear pharmacists on a permit issued by the Agency, NRC, or any~~
92 ~~other Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive~~
93 ~~material in the practice of nuclear pharmacy; or~~
94
- 95 (4) Is designated as an authorized nuclear pharmacist in accordance with Sec. C.28(j)(2)(iv).
96
- 97 "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials,
98 including radon, except as a decay product of source or special nuclear material, and including global
99 fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear
100 accidents such as Chernobyl that contribute to background radiation and are not under the control of the
101 licensee. "Background radiation" does not include sources of radiation from radioactive materials or
102 radiation producing machines regulated by the Agency.
103
- 104 "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or
105 transformation per second (S-1).
106
- 107 "Bioassay" means the determination of kinds, quantities or concentrations and, in some cases, the
108 locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or
109 by analysis and evaluation of materials excreted or removed from the human body. For purposes of these
110 regulations, "radiobioassay" is an equivalent term.

111
112 "Byproduct material" means:
113
114 (1) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure
115 to the radiation incident to the process of producing or utilizing special nuclear material; and
116
117 (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore
118 processed primarily for its source material content, including discrete surface wastes resulting from
119 uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution
120 extraction operations do not constitute "byproduct material" within this definition.

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123 "Interlock" means a device arranged or connected such that the occurrence of an event or
124 condition is required before a second event or condition can occur or continue to occur.
125

126 "Internal dose" means that portion of the dose equivalent received from radioactive material
127 taken into the body.
128

129 "License" means a license to possess or use radioactive material, including a license amendment,
130 issued by the Agency.
131

132 "Licensed material" means radioactive material received, possessed, used, transferred or
133 disposed of under a general or specific license issued by the Agency.
134

135 "Licensee" means any person who is licensed by the Agency in accordance with these
136 regulations.
137

138 "Licensing State" means any State with regulations equivalent to the Suggested State
139 Regulations for Control of Radiation relating to, and an effective program for, the regulatory
140 control of NARM and which has been granted final designation by the Conference of Radiation
141 Control Program Directors, Inc.
142

143 "Limits" [See "Dose Limits"]
144

145 "Lost or missing licensed material" means licensed material whose location is unknown. This
146 definition includes licensed material that has been shipped but has not reached its planned
147 destination and whose location cannot be readily traced in the transportation system.
148

149 "Major processor" means a user processing, handling, or manufacturing radioactive material
150 exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B
151 quantities as sealed sources, but does not include nuclear medicine programs, universities,
152 industrial radiographers, or small industrial programs. Type A and B quantities are defined in
153 Section 71.4 of 10 CFR Part 71.
154

155 "Medical use" means the intentional internal or external administration of radioactive material,
156 or the radiation therefrom, to patients or human research subjects in the practice of the healing
157 arts.
158

159 "Member of the public" means any individual except when that individual is receiving an
160 occupational dose.
161

162 "Minor" means an individual less than 18 years of age.
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- 176 "Monitoring" means the measurement of radiation, radioactive material concentrations, surface
177 area activities or quantities of radioactive material and the use of the results of these
178 measurements to evaluate potential exposures and doses. For purposes of these regulations,
179 "radiation monitoring" and "radiation protection monitoring" are equivalent terms.
180
- 181 "NARM" means any naturally occurring or accelerator-produced radioactive material. It does
182 not include byproduct, source, or special nuclear material.
183
- 184 "Natural radioactivity" means radioactivity of naturally occurring nuclides.
185
- 186 "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its
187 duly authorized representatives.
188
- 189 "Occupational dose" means the dose received by an individual in the course of employment in
190 which the individual's assigned duties involved exposure to sources of radiation, whether in the
191 possession of the licensee, registrant, or other person. This includes exposure to radiation from
192 registered and unregistered radiation machines or exposure to radioactive material from licensed
193 and unlicensed sources of radiation. Occupational dose does not include dose received from
194 background radiation, from any medical administration the individual has received, from
195 exposure to individuals administered radioactive material and released in accordance with Sec.
196 G.725, from voluntary participation in medical research programs, or as a member of the public.
197
- 198 "Package" means the packaging together with its radioactive contents as presented for transport.
199
- 200 "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons,
201 or other charged particles in a vacuum and of discharging the resultant particulate or other
202 radiation into a medium at energies usually in excess of 1 MeV.
203
- 204 "Person" means an individual, receiver, trustee, guardian, personal representative, fiduciary, or
205 representative of any kind and any partnership, firm, association, corporation, or other entity.
206 "Person" includes any public or municipal corporation and any agency, bureau, department, or
207 instrumentality of state or local government and, to the extent authorized by federal law, federal
208 government.
209
- 210 "Personnel monitoring equipment" [See "Individual monitoring devices"]
211
- 212 "Pharmacist" means an individual licensed by a State or Territory of the United States, the
213 District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.
214
- 215 "Physician" means an individual who is authorized under the Maryland Medical Practice Act to
216 practice medicine in this State.
217
- 218 "Prescribed dose" means:
219
- 220 (1) For gamma stereotactic radiosurgery, the total dose as documented in the written
221 directive;
 - 222
 - 223 (2) For teletherapy, the total dose and dose per fraction as documented in the written
224 directive; or
 - 225
 - 226 (3) For manual brachytherapy, either the total source strength and exposure time or the
227 total dose, as documented in the written directive; or
 - 228
 - 229 (4) For remote brachytherapy afterloaders, the total dose and dose per fraction as
230 documented in the written directive.

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234 "Public dose" means the dose received by a member of the public from exposure to radiation and/or to
 235 radioactive material released by a licensee or registrant, or to any other source of radiation under the control of
 236 the licensee or registrant. Public dose does not include occupational dose ~~or~~ doses received from background
 237 radiation, ~~dose~~ from any medical administration the individual has received, ~~dose~~ from exposure to individuals
 238 administered radioactive material and released in accordance with Sec. G.275, or dose from voluntary
 239 participation in medical research programs.

240
 241 "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130 F (54.4 C).
 242 A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal
 243 conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which
 244 can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious
 245 transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive
 246 materials.

247
 248 "Quality factor" (Q) means the modifying factor, listed in Tables 1 and 2 of A.13, that is used to derive dose
 249 equivalent from absorbed dose.

250
 251 "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg/gram or 0.01
 252 joule/kilogram (0.01 gray).

253
 254 "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-
 255 speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing
 256 radiation is an equivalent term. Radiation, as used in these regulations, does not include non-ionizing radiation,
 257 such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

258
 259 "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an
 260 individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the
 261 source of radiation or from any surface that the radiation penetrates.

262
 263 "Radiation machine" means any assemblage of components capable of producing radiation except those
 264 devices with radioactive material as the only source of radiation. This assemblage may include, as determined
 265 by the Agency:

- 266
 267 (1) Not more than one control panel;
 268
 269 (2) The necessary supporting structures; and
 270
 271 (3) Any additional components or auxiliary equipment that function with the assemblage to produce the
 272 result desired by using the machine.

273
 274 "Radiation safety officer" means an individual, ~~authorized by the agency under a specific license or a~~
 275 ~~registration~~, who:

- 276
 277 (1) Meets the requirements in Secs. G.50(a) and G.59; or
 278
 279 (2) Is identified as a Radiation Safety Officer on:
 280 (i) A specific medical use license issued by an Agreement State or the NRC; or
 281 (ii) A medical use permit issued by a NRC master material licensee; or
 282
 283 (3) Has been determined by a registrant as an individual who has the knowledge and responsibility to
 284 apply appropriate radiation protection regulations.
 285
 286

287
288 "Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.
289

290 "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.
291

292 "Registrant" means any person who is registered with the Agency or is legally obligated to register with the
293 Agency pursuant to these regulations and Act.
294

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298 "Registration" means registration with the Agency in accordance with the regulations adopted by the Agency.
299
300 "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.
301
302 "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem
303 is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).
304
305 "Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the
306 extension of investigative findings and theories of a scientific or technical nature into practical application for
307 experimental and demonstration purposes, including the experimental production and testing of models,
308 devices, equipment, materials, and processes. Research and development does not include the internal or
309 external administration of radiation or radioactive
310 material to human beings.
311
312 "Residual Radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a
313 site resulting from activities under the licensee's control. This includes radioactivity from all licensed and
314 unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive
315 materials remaining at the site as a result of
316 routine or accidental releases of radioactive material at the site, and previous burials at the site, even if those
317 burials were made in accordance with the provisions of Part D.
318
319 "Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of
320 protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not
321 include areas used as residential quarters, but separate rooms in a residential building may be set apart as a
322 restricted area.
323
324 "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air
325 (see "Exposure").
326
327 "Sealed source" means any radioactive material that is ~~permanently bonded or fixed~~ encased in a capsule or
328 ~~matrix~~ designed to prevent release and dispersal ~~leakage or escape~~ of the radioactive material ~~under the most~~
329 ~~severe conditions which are likely to be encountered in normal use and handling.~~
330
331 "Shallow dose equivalent" [See "Dose"]
332
333 "SI" means the abbreviation for the International System of Units.
334
335 "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in
336 sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).
337
338 "Site Boundary" means that line beyond which the land or property is not owned, leased, or otherwise
339 controlled by the licensee or registrant.
340
341 "Source material" means:
342
343 (1) Uranium or thorium, or any combination thereof, in any physical or chemical form; or
344
345 (2) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium,
346 thorium, or any combination of uranium and thorium. Source material does not include special
347 nuclear material.
348
349
350

351 byproduct material as defined in Section 11(e)(2) of the Atomic Energy Act (uranium or thorium
352 tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law
353 and in accordance with 10 CFR §62.1(a) by the U.S. Nuclear Regulatory Commission.

354

355 "Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior
356 to disposal and/or persons licensed to dispose of radioactive waste.

357

358 "Week" means 7 consecutive days starting on Sunday.

359

360 "Weighting factor" (W_T) for an organ or tissue (T) means the proportion of the risk of stochastic
361 effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when
362 the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values
363 of W_T are:

364

ORGAN DOSE WEIGHTING FACTORS

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| Organ or Tissue | W_T |
|--------------------|-------------------|
| Gonads | 0.25 |
| Breast | 0.15 |
| Red Bone Marrow | 0.12 |
| Lung | 0.12 |
| Thyroid | 0.03 |
| Bone Surfaces | 0.03 |
| Remainder | 0.30 ^a |
| Whole Body | 1.00 ^b |

^a 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest dose.

^b For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $W_T=1.0$ has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specified guidance is issued.

388 "Whole body" means, for purposes of external exposure, head, trunk including male gonads,
389 arms above the elbow, or legs above the knee.

391 "Worker" means an individual engaged in work under a license or registration issued by the
392 Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

398 "Working level" means any combination of short-lived radon daughters in 1 liter of air that will
 399 result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy. The short-
 400 lived radon daughters are--for radon-222: polonium-218, lead-214, bismuth-214, and polonium-
 401 214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.
 402

403 "Working level month" (WLM) means an exposure to 1 working level for 170 hours--2,000
 404 working hours per year divided by 12 months per year is approximately equal to 170 hours per
 405 month.
 406

407 "Written directive" means: ~~an order in writing for a specific patient or human research subject,~~
 408 ~~dated and signed by an authorized user prior to the administration of a radiopharmaceutical or~~
 409 ~~radiation, or in the case of radiation from a radiation machine, by a physician, except as specified~~
 410 ~~in paragraph (6) of this definition, containing the following information:~~
 411

412 ~~(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-~~
 413 ~~125 or I-131: the dosage;~~
 414

415 ~~(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide~~
 416 ~~I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;~~
 417

418 ~~(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern,~~
 419 ~~and total dose;~~
 420

421 ~~(4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment~~
 422 ~~period;~~
 423

424 ~~(5) For high dose rate remote afterloading brachytherapy: the radioisotope, treatment~~
 425 ~~site, and total dose; or~~
 426

427 ~~(6) For all other brachytherapy:~~
 428

429 ~~(i) Prior to implantation: the radioisotope, number of sources, and source~~
 430 ~~strengths; and~~
 431

432 ~~(ii) After implantation but prior to completion of the procedure: the radioisotope,~~
 433 ~~treatment site, and total source strength and exposure time (or, equivalently, the~~
 434 ~~total dose).~~
 435

436 (1) For radioactive material, an authorized user's written order for the administration of
 437 radioactive material or radiation from radioactive material to a specific patient or human
 438 research subject, as specified in Sec. G.40.
 439

440 (2) For registrants, for teletherapy, an order in writing for a specific patient or human
 441 research subject, dated and signed by a physician containing the total dose, dose per
 442 fraction, treatment site and overall treatment period.
 443

444 "Year" means the period of time beginning in January used to determine compliance with the
 445 provisions of these regulations. The licensee or registrant may change the starting date of the
 446 year used to determine compliance by the licensee or registrant provided that the change is made
 447 at the beginning of the year and that no day is omitted or duplicated in consecutive years.
 448

449 Exemptions from the Regulatory Requirements

450

451 Sec. A.3 Exemptions.

452
453 (a) General Provision. The Agency may, upon application or upon its own initiative, grant such
454 exemptions or exceptions from the requirements of these regulations as it determines are
455 authorized by law and will not result in undue hazard to public health and safety or property.

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1 (viii) Ionizing radiation measuring instruments containing, for purposes of internal
2 calibration or standardization, one or more sources of radioactive material, provided
3 that:

4
5 (a) Each source contains no more than one exempt quantity set forth in
6 Appendix B of this part, and

7
8 (b) Each instrument contains no more than 10 exempt quantities. For
9 purposes of this requirement, an instrument's source(s) may contain either one
10 or different types of radionuclides and an individual exempt quantity may be
11 composed of fractional parts of one or more of the exempt quantities in
12 Appendix B of this part, provided that the sum of such fractions shall not
13 exceed unity.

14
15 (c) For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt
16 quantity under C.4(c)(1)(viii).

17
18 (ix) Spark gap irradiators containing not more than 1 microcurie (37 kBq) of cobalt-
19 60 per spark gap irradiator for use in electrically ignited fuel oil burners having a
20 firing rate of at least 3 gallons (11.4 l) per hour.

21
22 (2) Self-Luminous Products Containing Radioactive Material.

23
24 (i) Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture,
25 process, or produce self-luminous products containing tritium, krypton-85, or
26 promethium-147, any person is exempt from these regulations to the extent that such
27 person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or
28 promethium-147 in self-luminous products manufactured, processed, produced,
29 imported, or transferred in accordance with a specific license issued by the U.S.
30 Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32,
31 which license authorizes the transfer of the product to persons who are exempt from
32 regulatory requirements. The exemption in C.4(c)(2) does not apply to tritium,
33 krypton-85, or promethium-147 used in products primarily for frivolous purposes or
34 in toys or adornments.

35
36 (ii) Radium-226. Any person is exempt from these regulations to the extent that
37 such person receives, possesses, uses, transfers, or owns articles containing less than
38 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to December 6,
39 1982.

40
41 (3) Gas and Aerosol Detectors Containing Radioactive Material.

42
43 (i) Except for persons who manufacture, process, or produce gas and aerosol
44 detectors containing radioactive material, any person is exempt from these
45 regulations to the extent that such person receives, possesses, uses, transfers, owns,
46 or acquires radioactive material in gas and aerosol detectors designed to protect life
47 or property from fires and airborne hazards provided that detectors containing
48 radioactive material shall have been manufactured, imported, or transferred in
49 accordance with a specific license issued by the U.S. Nuclear Regulatory
50 Commission pursuant to Section 32.26 of 10 CFR Part 32; or a Licensing State
51 pursuant to C.28(c), which authorizes the transfer of the detectors to persons who are
52 exempt from regulatory requirements.

55
56 (ii) Gas and aerosol detectors previously manufactured and distributed to general
57 licensees in accordance with a specific license issued by an Agreement State shall be
58 considered exempt under C.4(c)(3)(i), provided that the device is labeled in
59 accordance with the specific license authorizing distribution of the generally
60 licensed device, and provided further that they meet the requirements of C.28(c).

61
62 (iii) Gas and aerosol detectors containing NARM previously manufactured and
63 distributed in accordance with a specific license issued by a Licensing State shall be
64 considered exempt under C.4(c)(3)(i), provided that the device is labeled in
65 accordance with the specific license authorizing distribution, and provided further
66 that they meet the requirements of C.28(c).

67
68 (4) Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells.

69 Any person is exempt from these regulations to the extent that such person receives,
70 possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46
71 which are designed for sand consolidation in oil wells. Such resins shall have been
72 manufactured or imported in accordance with a specific license issued by the U.S. Nuclear
73 Regulatory Commission, or shall have been manufactured in accordance with the
74 specifications contained in a specific license issued by the Agency or any Agreement State
75 to the manufacturer of such resins pursuant to licensing requirements equivalent to those in
76 Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear
77 Regulatory Commission. This exemption does not authorize the manufacture of any resins
78 containing scandium-46.

79
80 (5) Radioactive Drug: Capsules Containing Carbon-14 Urea for "In vivo" Diagnostic Use
81 for Humans.

82
83 (i) Except as provided in paragraphs (b) and (c) of this section, any person is
84 exempt from the requirements for a license and from these regulations provided that
85 such person receives, possesses, uses, transfers, owns, or acquires capsules
86 containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may
87 occur during the manufacturing process) each, for "in vivo" diagnostic use for
88 humans.

89
90 (ii) Any person who desires to use the capsules for research involving human
91 subjects shall apply for and receive a specific license pursuant to Section C.

92
93 (iii) Any person who desires to manufacture, prepare, process, produce, package,
94 repackage, or transfer for commercial distribution such capsules shall apply for and
95 receive a specific license pursuant to 10 CFR §32.21.

96
97 (iv) Nothing in this section relieves persons from complying with applicable FDA,
98 Federal, and State requirements governing receipt, administration, and use of drugs.

99
100 Sec. C.5 - C.19 Reserved.

101
102
103
104
105 -----
106 2/ Authority to transfer possession or control by the manufacturer, processor or producer of any
107 equipment, device, commodity, or other product containing byproduct material whose
108 subsequent possession, use, transfer, and disposal by all other persons are exempted from
109 regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission,
110 Washington, D.C. 20555.

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113 (iv) within 30 days of any transfer, shall report in writing to the Agency the name
114 and address of the person receiving the depleted uranium pursuant to such transfer;
115 and

116
117 (v) shall not export such depleted uranium except in accordance with a license
118 issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.
119

120 (5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium
121 pursuant to the general license established by C.21(e)(1) is exempt from the requirements
122 of Parts D and J of these regulations with respect to the depleted uranium covered by that
123 general license.
124

125 Sec. C.22 General Licenses* - Radioactive Material Other Than Source Material.
126

127 (a) Certain Devices and Equipment. A general license is hereby issued to transfer, receive,
128 acquire, own, possess, and use radioactive material incorporated in the following devices or
129 equipment which have been manufactured, tested and labeled by the manufacturer in accordance
130 with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission
131 for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the
132 provisions of A.4 through A.9, C.4(a)(2), C.31, C.40, C.50 and Parts D^{4/}, J, and T of these
133 regulations.
134

135 (1) Static Elimination Device. Devices designed for use as static eliminators which
136 contain, as a sealed source or sources, radioactive material consisting of a total of not more
137 than 500 microcuries (18.5 MBq) of polonium-210 per device.
138

139 (2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed
140 source or sources, radioactive material consisting of a total of not more than 500
141 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50
142 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.
143

144 (b) General License to Install Devices Generally Licensed in Sec. C.22
145

146 Any person who holds a specific license issued by an Agreement State or the U.S. Nuclear
147 Regulatory Commission authorizing the holder to manufacture, install, or service a device
148 described in C.22 within such Agreement State is hereby granted a general license to install and
149 service such device in the State of Maryland as defined in C.90 provided that:
150

151 (1) [Reserved]
152

153 (2) The device has been manufactured, labeled, installed, and serviced in accordance with
154 applicable provisions of the specific license issued to such person by the U.S. Nuclear
155 Regulatory Commission or Agreement State.
156

157 (3) Such person assures that any labels required to be affixed to the device under
158 regulations of the U.S. Nuclear Regulatory Commission or Agreement State that licensed
159 manufacture of the device bear a statement that removal of the label is prohibited.
160

161 (c) Reserved.
162

163 *Note: Different general licenses are issued in this section, each of which has its own specific conditions
164 and requirements.
165

166 ^{4/} Attention is directed particularly to the provisions of Part D of these regulations which relate to the
167 labeling of containers.
168

171 (d) Certain Measuring, Gauging or Controlling Devices.
172

173 (1) A general license is hereby issued to commercial and industrial firms and to research,
174 educational and medical institutions, individuals in the conduct of their business, and State
175 or local government agencies to own, receive, acquire, possess, use or transfer in
176 accordance with the provisions of C.22(d)(2), (3), and (4), radioactive material, excluding
177 special nuclear material, contained in devices designed and manufactured for the purpose
178 of detecting, measuring, gauging or controlling thickness, density, level, interface location,
179 radiation, leakage, or qualitative or quantitative chemical composition, or for producing
180 light or an ionized atmosphere.

181
182 (2) The general license in C.22(d)(1) applies only to radioactive material contained in
183 devices which have been manufactured or initially transferred and labeled in accordance
184 with the specifications contained in a specific license issued by the Agency pursuant to
185 C.28(d) or in accordance with the specifications contained in a specific license issued by
186 the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, which
187 authorizes distribution of devices to persons generally licensed by the U.S. Nuclear
188 Regulatory Commission, an Agreement State or a Licensing State and the device has been
189 manufactured and installed so that:

190
191 (i) The dose rate in the radiation beam of the device at 18 inches (0.46 meters) from
192 the radiation source with the device shutter in the open position does not exceed 125
193 millirem (1.25 mSv) per hour; and

194
195 (ii) There is not an accessible airgap of 18 inches (0.46 meters) or greater between
196 the radiation source and detector which would allow insertion of a 12 inch (0.30
197 meters) diameter sphere into the radiation beam^{5/}.

198
199 (3) The devices must have been received from one of the specific licensees described in
200 C.22(d)(2)(i) or through a transfer made under C.22(d)(34)(viii).

201
202 (4) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive
203 material in a device pursuant to the general license in C.22(d)(1):

204
205 (i) shall assure that all labels affixed to the device at the time of receipt, and
206 bearing a statement that removal of the label is prohibited, are maintained thereon
207 and shall comply with all instructions and precautions provided by such labels;

208
209 (ii) shall assure that the device is tested for leakage of radioactive material and
210 proper operation of the "on-off" mechanism and indicator, if any, at no longer than
211 6-month intervals or at such other intervals as are specified in the label, however,

212
213 (a) devices containing only krypton need not be tested for leakage of
214 radioactive material, and
215
216

217 ^{5/} Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control
218 devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.
219

222 (b) devices containing only tritium or not more than 100 microcuries (3.7
223 MBq) of other beta- and/or gamma-emitting material or 10 microcuries (0.37
224 MBq) of alpha-emitting material and devices held in storage in the original
225 shipping container prior to initial installation need not be tested for any
226 purpose;

227
228 (iii) shall assure that the tests required by C.22(d)(34)(ii) and other testing,
229 installation, servicing, and removal from installation involving the radioactive
230 material, its shielding or containment, are performed:

231
232 (a) in accordance with the instructions provided by the labels, or

233
234 (b) by a person holding an applicable specific license from the Agency, the
235 U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing
236 State to perform such activities;

237
238 (iv) shall maintain records showing compliance with the requirements of
239 C.22(d)(34)(ii) and (iii). The records shall show the results of tests. The records
240 also shall show the dates of performance of, and the names of persons performing,
241 testing, installation, servicing, and removal from installation concerning the
242 radioactive material, its shielding or containment. Records of tests for leakage of
243 radioactive material required by C.22(d)(34)(ii) shall be maintained for 2 years after
244 the next required leak test is performed or until the sealed source is transferred or
245 disposed of. Records of tests of the "on-off" mechanism and indicator required by
246 C.22(d)(34)(ii) shall be maintained for 2 years after the next required test of the "on-
247 off" mechanism and indicator is performed or until the sealed source is transferred
248 or disposed of. Records which are required by C.22(d)(34)(iii) shall be maintained
249 for a period of 2 years from the date of the recorded event or until the device is
250 transferred or disposed of;

251
252 (v) shall immediately suspend operation of the device if there is a failure of, or
253 damage to, or any indication of a possible failure of or damage to, the shielding of
254 the radioactive material or the on-off mechanism or indicator, or upon the detection
255 of 185 becquerel (0.005 microcurie) or more removable radioactive material. The
256 device may not be operated until it has been repaired by the manufacturer or other
257 person holding a specific license to repair such devices that was issued under
258 Section C or by the U.S. Nuclear Regulatory Commission, an Agreement State or a
259 Licensing State. The device and any radioactive material from the device may only
260 be disposed of by transfer to a person authorized by a specific license to receive the
261 byproduct material in the device or as otherwise approved by the U.S. Nuclear
262 Regulatory Commission, an Agreement State or a Licensing State. A report
263 containing a brief description of the event and the remedial action taken; and, in the
264 case of detection of 0.005 microcurie or more removable radioactive material or
265 failure of or damage to a source likely to result in contamination of the premises or
266 the environs, a plan for ensuring that the premises and environs are acceptable for
267 unrestricted use; must be furnished to the Manager, Radiological Health Program,
268 1800 Washington Boulevard, Baltimore, Maryland 21230 within 30 days. Under
269 these circumstances, the criteria set out in Section D.1402, "Radiological Criteria for
270 Unrestricted Use", may be applicable, as determined by the Agency on a case-by-
271 case basis;

272
273 (vi) shall not abandon the device containing radioactive material;

274
275 (vii) shall transfer or dispose of the device containing radioactive material by
276 transfer to another general licensee as authorized in C.22(d)(34)(x), or to a person
277 authorized to receive the device by a specific license issued under Section C that
278 authorizes waste collection, or equivalent regulations of the U.S. Nuclear Regulatory
279 Commission, an Agreement State, or as otherwise approved under C.22(d)(34)(ix);

282 (viii) shall within 30 days after the transfer of a device to a specific licensee or
283 export, furnish a report to: Manager, Radiological Health Program, 1800
284 Washington Boulevard, Baltimore, Maryland 21230. The report shall contain:

285
286 (a) the identification of the device by manufacturer's (or initial transferor's)
287 name, model number, and serial number,

288
289 (b) the name, address, and license number of the person receiving the device
290 (license number not applicable if exported), and

291
292 (c) the date of the transfer;

293
294 (ix) shall obtain written Agency approval before transferring the device to any other
295 specific licensee not specifically identified in C.22(d)(34)(vii);

296
297 (x) shall transfer the device to another general licensee only if:

298
299 (a) the device remains in use at a particular location. In this case, the
300 transferor shall give the transferee a copy of Sections C.20(a), C.22(d), C.38,
301 D.1201, and D.1202 and any safety documents identified in the label of the
302 device. Within 30 days of the transfer, the transferor shall report to the
303 Manager, Radiological Health Program, 1800 Washington Boulevard,
304 Baltimore, Maryland 21230:

305
306 (1) the manufacturer's (or initial transferor's) name,

307
308 (2) the model number and the serial number of the device transferred,

309
310 (3) the transferee's name and mailing address for the location of use, and

311
312 (4) the name, title, and phone number of the responsible individual
313 identified by the transferee in accordance with C.22(d)(34)(xii) to have
314 knowledge of and authority to take actions to ensure compliance with the
315 appropriate regulations and requirements; or

316
317 (b) the device is held in storage by an intermediate person in the original
318 shipping container at its intended location of use prior to initial use by a
319 general licensee;

320
321 (xi) shall comply with the provisions of Sections D.1201 and D.1202 for reporting
322 radiation incidents, theft, or loss of licensed material, but shall be exempt from the
323 other requirements of Parts D and J;

324
325 (xii) shall appoint an individual responsible for having knowledge of the appropriate
326 regulations and requirements and the authority for taking required actions to comply
327 with appropriate regulations and requirements. The general licensee, through this
328 individual, shall ensure the day-to-day compliance with appropriate regulations and
329 requirements. This appointment does not relieve the general licensee of any of its
330 responsibility in this regard;

336 (xiii) shall report changes to the mailing address for the location of use (including
337 change in name of general licensee) to the Manager, Radiological Health Program,
338 1800 Washington Boulevard, Baltimore, Maryland 21230 within 30 days of the
339 effective date of the change. For a portable device, a report of address change is
340 only required for a change in the device's primary place of storage;
341

342 (xiv) may not hold devices that are not in use for longer than 2 years. If devices
343 with shutters are not being used, the shutter must be locked in the closed position.
344 The testing required by C.22(d)(34)(iii) need not be performed during the period of
345 storage only. However, when devices are put back into service or transferred to
346 another person, and have not been tested within the required test interval, they must
347 be tested for leakage before use or transfer and the shutter tested before use. Devices
348 kept in standby for future use are excluded from the two-year time limit if the
349 general licensee performs quarterly physical inventories of these devices while they
350 are in standby;
351

352 (xv) shall not export the device containing byproduct material except in accordance
353 with 10 CFR Part 110; and
354

355 (xvi) shall respond to written requests from the Agency to provide information
356 relating to the general license within 30 calendar days of the date of the request, or
357 other time specified in the request. If the general licensee cannot provide the
358 requested information within the allotted time, it shall, within that same time period,
359 request a longer period to supply the information by providing the Agency a written
360 justification for the request.
361

362 (5) The general license in C.22(d)(1) does not authorize the manufacture of devices
363 containing radioactive material.
364

365 (6) The general license provided in C.22(d)(1) is subject to the provisions of A.4 through
366 A.9, C.31, C.40, C.50, and Part T of these regulations.
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392 (e) Luminous Safety Devices for Aircraft.

393
394 (1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or
395 promethium-147 contained in luminous safety devices for use in aircraft, provided:

396
397 (i) each device contains not more than 10 curies (370 GBq) of tritium or 300
398 millicuries (11.1 GBq) of promethium-147; and

399
400 (ii) each device has been manufactured, assembled or imported in accordance with a
401 specific license issued by the U.S. Nuclear Regulatory Commission, or each device
402 has been manufactured or assembled in accordance with the specifications contained
403 in a specific license issued by the Agency or any Agreement State to the
404 manufacturer or assembler of such device pursuant to licensing requirements
405 equivalent to those in Section 32.53 of 10 CFR Part 32.

406
407 (2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant
408 to the general license in C.22(e)(1) are exempt from the requirements of Parts D and J of
409 these regulations except that they shall comply with the provisions of D.1001, D.1201,
410 D.1202 and D.1207.

411
412 (3) This general license does not authorize the manufacture, assembly, or repair of
413 luminous safety devices containing tritium or promethium-147.

414
415 (4) This general license does not authorize the ownership, receipt, acquisition, possession
416 or use of promethium-147 contained in instrument dials.

417
418 (5) This general license is subject to the provisions of A.4 through A.9, C.31, C.40, C.50,
419 and Part T of these regulations.

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laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.

Name of manufacturer

(5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in D.1001 of these regulations.

(i) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under C.22(j) will be approved if:

- (1) the applicant satisfies the general requirements of C.25; and
- (2) the criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

(j) Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Part G.

(1) An application for a specific license to manufacture, prepare or transfer for commercial distribution radioactive drugs containing radioactive material for persons authorized pursuant to Part G of this regulation will be approved if:

- (i) The applicant satisfies the general requirements specified in C.25;
- (ii) The applicant submits evidence that the applicant is at least one of the following:
 - (a) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;
 - (b) Registered or licensed with a state agency as a drug manufacturer;
 - (c) Licensed as a pharmacy by a State Board of Pharmacy; or
 - (d) Operating as a nuclear pharmacy within a Federal medical institution.
- (iii) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and
- (iv) The applicant satisfies the following labeling requirements:
 - (a) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

505 (b) A label is affixed to each syringe, vial, or other container used to hold a
506 radioactive drug to be transferred for commercial distribution. The label must
507 include the radiation symbol and the words "CAUTION, RADIOACTIVE
508 MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier
509 that ensures that the syringe, vial, or other container can be correlated with the
510 information on the transport radiation shield label.

511
512 (2) A licensee described by ~~Paragraph (j)(1)(ii)(e) or (d) of this Section in C.28(j)(1)(ii)(c)~~
513 ~~or (d)~~:

514
515 (i) May prepare radioactive drugs for medical use, as defined in ~~§A.2~~ Sec. G.2,
516 provided that the radioactive drug is prepared by either an authorized nuclear
517 pharmacist, as specified in ~~paragraph (j)(2)(ii) and (iii)~~ C.28(j)(2)(ii) and (iv) of this
518 section, or an individual under the supervision of an authorized nuclear pharmacist
519 as specified in Sec. G.4027.

520
521 (ii) May allow a pharmacist to work as an authorized nuclear pharmacist if:

522
523 (a) This individual qualifies as an authorized nuclear pharmacist as defined in
524 Sec. A.2;

525
526 (b) This individual meets the requirements specified in Secs. G.755(b) and
527 G.7659 and the licensee has received an approved license amendment
528 identifying this individual as an authorized nuclear pharmacist; or

529
530 (c) This individual is designated as an authorized nuclear pharmacist in
531 accordance with ~~paragraph C.28(j)(2)(iii)(iv) of this section.~~

532
533 (iii) The actions authorized in ~~paragraphs C.28(j)(2)(i) and (ii) of this section~~ are
534 permitted in spite of more restrictive language in license conditions.

535
536 (iv) May designate a pharmacist (as defined in Sec. A.2) as an authorized nuclear
537 pharmacist, as defined in §A.2, if the individual is identified as of ~~[the effective date~~
538 ~~of this regulation]~~ December 2, 1994, as an "authorized user" on a nuclear pharmacy
539 license issued by the Agency under this Part.

540
541 (v) Shall provide to the Agency a copy of each individual's certification by the
542 Board of Pharmaceutical Specialties, the ~~NRC~~ Agency or ~~other~~ Agreement State
543 license, or the permit issued by a licensee of broad scope, and a copy of the state
544 pharmacy licensure or registration, no later than 30 days after the date that the
545 licensee allows, pursuant to ~~paragraphs C.28(j)(2)(ii)(a)(a) and (e)(c) of this section,~~
546 the individual to work as an authorized nuclear pharmacist.

547
548 (3) A licensee shall possess and use instrumentation to measure the radioactivity of
549 radioactive drugs. The licensee shall have procedures for use of the instrumentation. The
550 licensee shall measure, by direct measurement or by combination of measurements and
551 calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting
552 radioactive drugs prior to transfer for commercial distribution. In addition, the licensee
553 shall:

554
555 (i) Perform tests before initial use, periodically, and following repair, on each
556 instrument for accuracy, linearity, and geometry dependence, as appropriate for the
557 use of the instrument; and make adjustments when necessary; and

558
559 (ii) Check each instrument for constancy and proper operation at the beginning of
560 each day of use.

561
562 (4) Nothing in this section relieves the licensee from complying with applicable FDA,
563 other Federal, and State requirements governing radioactive drugs.

567 (k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of
568 Radiopharmaceuticals Containing Radioactive Material.^{10/} An application for a specific license
569 to manufacture and distribute generators or reagent kits containing radioactive material for
570 preparation of radiopharmaceuticals by persons licensed pursuant to this part for the uses listed
571 in G.31 of these regulations will be approved if:

572
573 (1) the applicant satisfies the general requirements specified in C.25;

574
575 (2) the applicant submits evidence that:

576
577 (i) the generator or reagent kit is to be manufactured, labeled and packaged in
578 accordance with the Federal Food, Drug and Cosmetic Act or the Public Health
579 Service Act, such as a new drug application (NDA) approved by the Food and Drug
580 Administration (FDA), or a "Notice of Claimed Investigational Exemption for a
581 New Drug" (IND) that has been accepted by the FDA, or

582
583 (ii) the manufacture and distribution of the generator or reagent kit are not subject to
584 the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

585
586 (3) the applicant submits information on the radionuclide, chemical and physical form,
587 packaging including maximum activity per package, and shielding provided by the
588 packaging of the radioactive material contained in the generator or reagent kit;

589
590 (4) the label affixed to the generator or reagent kit contains information on the
591 radionuclide, quantity, and date of assay; and

592
593 (5) the label affixed to the generator or reagent kit, or the leaflet or brochure which
594 accompanies the generator or reagent kit, contains:

595
596 (i) adequate information, from a radiation safety standpoint, on the procedures to be
597 followed and the equipment and shielding to be used in eluting the generator or
598 processing radioactive material with the reagent kit, and

599
600 (ii) a statement that this generator or reagent kit, as appropriate, is approved for use
601 by persons licensed by the Agency pursuant to G.31 of these regulations or under
602 equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement
603 State, or a Licensing State. The labels, leaflets, or brochures required by C.28(k) are
604 in addition to the labeling required by the Food and Drug Administration (FDA) and
605 they may be separate from or, with the approval of FDA, may be combined with the
606 labeling required by FDA.

607
608 (l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for
609 Medical Use or Irradiation of Materials. An application for a specific license to manufacture and
610 distribute sources and devices containing radioactive material to persons licensed pursuant to
611 Part G for use as a calibration or reference source, or for diagnostic, brachytherapy or teletherapy
612 sources for the uses listed in G.39400, G.44500, and G.47600 of these regulations, or for use to
613 irradiate materials will be approved if:

614
615 (1) the applicant satisfies the general requirements in C.25 of this part;

616
617 (2) the applicant submits sufficient information regarding each type of source or device
618 pertinent to an evaluation of its radiation safety, including:

619
620 ^{10/} Although the Agency does not regulate the manufacture and distribution of reagent kits that do not
621 contain radioactive material, it does regulate the use of such reagent kits for the preparation of
622 radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of
623 radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who
624 desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to G.31 of
625 these regulations may submit the pertinent information specified in C.28(k).
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628

629 to an evaluation of its radiation safety, including:

- 630 (i) the radioactive material contained, its chemical and physical form, and amount,
- 631
- 632 (ii) details of design and construction of the source or device,
- 633
- 634 (iii) procedures for, and results of, prototype tests to demonstrate that the source or
- 635 device will maintain its integrity under stresses likely to be encountered in normal
- 636 use and accidents,
- 637
- 638 (iv) for devices containing radioactive material, the radiation profile of a prototype
- 639 device,
- 640
- 641 (v) details of quality control procedures to assure that production sources and
- 642 devices meet the standards of the design and prototype tests,
- 643
- 644 (vi) procedures and standards for calibrating sources and devices,
- 645
- 646 (vii) legend and methods for labeling sources and devices as to their radioactive
- 647 content, and
- 648
- 649 (viii) instructions for handling and storing the source or device from the radiation
- 650 safety standpoint; these instructions are to be included on a durable label attached to
- 651 the source or device or attached to a permanent storage container for the source or
- 652 device; provided, that instructions which are too lengthy for such label may be
- 653 summarized on the label and printed in detail on a brochure which is referenced on
- 654 the label;
- 655
- 656

657 (3) the label affixed to the source or device, or to the permanent storage container for the
658 source or device, contains information on the radionuclide, quantity, and date of assay, and
659 a statement that the source or device is licensed by the Agency for distribution to persons
660 licensed pursuant to Part G and G.39400, and G.41500 and G.47600 and for use to
661 irradiate materials of these regulations or under equivalent licenses of the U.S. Nuclear
662 Regulatory Commission, an Agreement State, or a Licensing State, provided that such
663 labeling for sources which do not require long term storage may be on a leaflet or brochure
664 which accompanies the source;

665 (4) in the event the applicant desires that the source or device be required to be tested for
666 leakage of radioactive material at intervals longer than 6 months, he shall include in his
667 application sufficient information to demonstrate that such longer interval is justified by
668 performance characteristics of the source or device or similar sources or devices and by
669 design features that have a significant bearing on the probability or consequences of
670 leakage of radioactive material from the source; and

671 (5) in determining the acceptable interval for test of leakage of radioactive material, the
672 Agency will consider information that includes, but is not limited to:

- 673 (i) primary containment or source capsule,
- 674
- 675 (ii) protection of primary containment,
- 676
- 677 (iii) method of sealing containment,
- 678
- 679 (iv) containment construction materials,
- 680
- 681 (v) form of contained radioactive material,
- 682
- 683 (vi) maximum temperature withstood during prototype tests,
- 684
- 685 (vii) maximum pressure withstood during prototype tests,
- 686
- 687
- 688
- 689

47 e. The Agency may impose additional restrictions on radiation levels in unrestricted areas and
48 on the total quantity of radionuclides that a licensee may release in effluents in order to
49 restrict the collective dose.

50 Sec. D.302 Compliance with Dose Limits for Individual Members of the Public.

51
52 a. The licensee or registrant shall make or cause to be made surveys of radiation levels in
53 unrestricted areas and radioactive materials in effluents released to unrestricted areas to
54 demonstrate compliance with the dose limits for individual members of the public in D.301.
55

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- 58 b. A licensee or registrant shall show compliance with the annual dose limit in D.301a-i. by:
59
60 i. Demonstrating compliance with D.101a.; and
61
62 ii. (1) Demonstrating by measurement, or calculation, or appropriate simulation model
63 that the total effective dose equivalent to the individual likely to receive the
64 highest dose from the licensed or registered source of radiation does not exceed
65 the annual dose limit of D.301; or
66
67 (2) Demonstrating that:
68
69 (a) The annual average concentrations of radioactive material released in
70 gaseous and liquid effluents at the boundary of the unrestricted area do not
71 exceed the values specified in Table II of Appendix B; and
72
73 (b) If an individual were continually present in an unrestricted area, at the
74 point of highest potential exposure from the licensed or registered source
75 of radiation, the dose to that individual would not exceed 0.02 mSv (0.002
76 rem) in an hour and 0.5 mSv (0.05 rem) in any year.
77
78
79

80 TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

81 Sec. D.401 Testing for Leakage or Contamination of Sealed Sources.

- 82
83
84
85
86 a. Each sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any
87 form other than gas, shall be tested for leakage or contamination prior to initial use and,
88 unless otherwise authorized by the Agency, at intervals not to exceed 6 months. If, at any
89 other time, there is reason to suspect that a sealed source might have been damaged or might
90 be leaking, it shall be tested for leakage before further use. In the absence of a certificate
91 from a transferor indicating that a test for leakage has been made within 6 months prior to the
92 transfer, the sealed source shall not be put into use until tested and the results received.
93
94 i. Tests for leakage for all sealed sources, except those manufactured to contain radium,
95 shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of radioactive
96 material on a test sample. Test samples shall be taken from the sealed source or from
97 the surfaces of the container in which the sealed source is stored or mounted on which
98 one might expect contamination to accumulate.
99

105 **STORAGE AND CONTROL OF LICENSED OR REGISTERED**
106 **SOURCES OF RADIATION**

107
108 Sec. D.801 Security of Stored Sources of Radiation. Sources of radiation shall be secured against
109 unauthorized removal or access from the place of storage.

110
111 Sec. D.802 Control of Sources of Radiation Not in Storage.

- 112
113 a. The licensee shall control and maintain constant surveillance of licensed radioactive material
114 that is in an unrestricted area and that is not in storage or in a patient.
115
116 b. The registrant shall maintain control of radiation machines that are in an unrestricted area and
117 that are not in storage.
118

119 Section D.803 Security Requirements for Portable Gauges.

- 120
121 a. Each portable gauge licensee shall use a minimum of two independent physical controls that
122 form tangible barriers to secure portable gauges from unauthorized removal, whenever
123 portable gauges are not under the control and constant surveillance of the licensee.
124
125 b. The licensee shall ensure that the source locking mechanism for each device is engaged in
126 the secured and fully shielded position during storage and transport.
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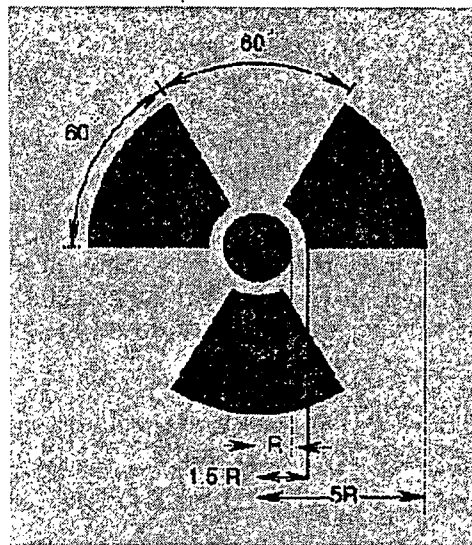
PRECAUTIONARY PROCEDURES

Sec. D.901 Caution Signs.

- a. Standard Radiation Symbol. Unless otherwise authorized by the Agency, the symbol prescribed by D.901 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

- i. Cross-hatched area is to be magenta, or purple, or black, and
- ii. The background is to be yellow.



- b. Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of D.901a., licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.
- c. Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in Part D, the licensee or registrant shall provide, on or near the required signs and labels, additional information as appropriate to make individuals aware of potential radiation exposures and to minimize the exposures.

189 **WASTE DISPOSAL**

190
191 Sec. D.1001 General Requirement. No licensee shall dispose of any radioactive material except:

- 192
193 a. By transfer to an authorized recipient as provided in D.1007 and C.40 of these regulations, or
194
195 b. As authorized pursuant to D.301, D.302, D.1002, D.1003, D.1005, or D.1006.
196
197 c. Notwithstanding the provisions of D.1001a and b, the Agency may prohibit by rule,
198 regulation or order any transfer or disposal of radioactive material.
199
200 d. For materials that will be managed as biomedical waste after they have been released from
201 the licensee, a licensee must remove or obliterate all radiation labels, except for radiation
202 labels on materials that are within containers, before release from the licensee's control.
203

204 Sec. D.1002 Method of Obtaining Approval of Proposed Disposal Procedures.

205
206 Any person may apply to the Agency for approval of proposed procedures to dispose of
207 radioactive material in a manner not otherwise authorized in this Part. Each application shall
208 include a description of the radioactive material, including the quantities and kinds of radioactive
209 material and levels of radioactivity involved, and the proposed manner and conditions of
210 disposal. The application, where appropriate, should also include an analysis and evaluation of
211 pertinent information as to the nature of the environment, including topographical, geological,
212 meteorological, and hydrological characteristics; usage of ground and surface waters in the
213 general area; the nature and location of other potentially affected facilities; and procedures to be
214 observed to minimize the risk of unexpected or hazardous exposures.
215

216 Sec. D.1003 Disposal by Release into Sanitary Sewerage.

- 217
218 a. No licensee shall discharge licensed material into sanitary sewerage unless each of the
219 following conditions is satisfied.
220
221 i. The material is readily soluble, or is a readily dispersible biological material, in water;
222 and
223
224 ii. The quantity of licensed or other radioactive material that the licensee releases into the
225 sewer in 1 month divided by the average monthly volume of water released into the
226 sewer by the licensee does not exceed the concentration listed in Table III of Appendix
227 B; and
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- 243 iii. If more than one radionuclide is released, the following conditions must also be
244 satisfied.
245
246 (1) The licensee shall determine the fraction of the limit in Table III of Appendix B
247 represented by discharges into sanitary sewerage by dividing the actual monthly
248 average concentration of each radionuclide released by the licensee into the
249 sewer by the concentration of that radionuclide listed in Table III of Appendix B;
250 and
251
252 (2) The sum of the fractions for each radionuclide required by D.1002a.iii.(1) does
253 not exceed unity; and
254
255 iv. The total quantity of licensed and other radioactive material that the licensee releases
256 into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37
257 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials
258 combined.
259
260 b. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material
261 are not subject to the limitations contained in D.1003a.
262

263 Sec. D.1004 RESERVED.
264

265 Sec. D.1005 Treatment or Disposal by Incineration. No licensee shall treat or dispose of licensed
266 material by incineration except for materials listed under Sec. D.1006 or as specifically approved
267 by the Agency pursuant to Sec. D.1002.
268

269 Sec. D.1006 Disposal of Specific Wastes.
270

- 271 a. Any licensee may dispose of the following radioactive material without regard to its radioactivity:
272
273 i. 0.05 microcurie (1.85 kBq) or less of hydrogen-3, or carbon-14 per gram of medium
274 used for liquid scintillation counting, and
275
276 ii. 0.05 microcurie (1.85 kBq) or less of hydrogen-3, or carbon-14 per gram of animal
277 tissue averaged over the weight of the entire animal; provided, however, tissue may not
278 be disposed of under D.1006 in a manner that would permit its use either as food for
279 humans or as animal feed.
280
281 b. Nothing in D.1006(a), however, relieves the licensee of maintaining records showing the
282 receipt, transfer and disposal of such radioactive material as specified in A.4 of these
283 regulations.
284
285 c. Nothing in D.1006(a) relieves the licensee from complying with other applicable federal, state, and local
286 regulations governing any other toxic or hazardous property of these materials.
287
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295 If the test for leakage or contamination required pursuant to D.401 indicates a sealed source is
296 leaking or contaminated, a written report of the test shall be filed within 5 days with the Agency
297 describing the equipment involved, the test results and the corrective action taken.

298
299
300

Sec. D.1207 Annual Reports from General Licensees.

- 301 a. A licensee granted a general license under Section C.22(e), (g), (i), or (j) shall report
302 annually, the following information on a form provided by the Agency:
303
304 i. The amount and kind of radioactive material received during the previous year;
305
306 ii. The form of the radioactive material;
307
308 iii. The amount possessed by the licensee at the time of the report; and
309
310 iv. The pathways and amounts of radioactive material disposed of by that person during
311 the previous year.
312
313 b. The information required by D.1207a.iv. shall be estimated using a technique that is
314 acceptable to the Department.
315
316 c. The report required by D.1207a. shall cover the calendar year from January 1 to December
317 31 and shall be forwarded to the Department not later than March 1 of the following year.

318 **NOTE: D.1208 HAS BEEN DELETED AND REPLACED.**

319 Sec. D.1208 Misadministration. Misadministration means:

- 320
321 ~~a. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-~~
322 ~~131:~~
323
324 ~~i. Involving the wrong individual or wrong radiopharmaceutical, or~~
325
326 ~~ii. When both the administered dosage differs from the prescribed dosage by more than~~
327 ~~20 percent of the prescribed dosage and the difference between the administered~~
328 ~~dosage and prescribed dosage exceeds 30 microcuries.~~
329
330 ~~b. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:~~
331
332 ~~i. Involving the wrong individual, wrong radiopharmaceutical, or wrong route of~~
333 ~~administration; or~~
334
335 ~~ii. When the administered dosage differs from the prescribed dosage by more than 20~~
336 ~~percent of the prescribed dosage.~~
337
338 ~~c. A gamma stereotactic radiosurgery radiation dose:~~
339
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341
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343

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346

- 346 — i. — Involving the wrong individual or wrong treatment site; or
347
348 — ii. — When the calculated total administered dose differs from the total prescribed dose by
349 more than 10 percent of the total prescribed dose.
350
351 d. — A teletherapy radiation dose or dose from a radiation machine:
352
353 — i. — Involving the wrong individual, wrong mode of treatment, or wrong treatment site, or
354 of a type other than the one intended;
355
356 — ii. — When the treatment consists of three or fewer fractions and the calculated total
357 administered dose differs from the total prescribed dose by more than 10 percent of the
358 total prescribed dose;
359
360 — iii. — When the calculated weekly administered dose is 30 percent greater than the weekly
361 prescribed dose; or
362
363 — iv. — When the calculated total administered dose differs from the total prescribed dose by
364 more than 20 percent of the total prescribed dose.
365
366 e. — A brachytherapy radiation dose:
367
368 — i. — Involving the wrong individual, wrong radioisotope, or wrong treatment site
369 (excluding for permanent implants, seeds that were implanted in the correct site but
370 migrated outside the treatment site);
371
372 — ii. — Involving a sealed source that is leaking;
373
374 — iii. — When, for a temporary implant, one or more sealed sources are not removed upon
375 completion of the procedure; or
376
377 — iv. — When the calculated administered dose differs from the prescribed dose by more than
378 20 percent of the prescribed dose.
379
380 f. — A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of
381 either sodium iodide I-125 or I-131, both:
382
383 — i. — Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or
384 when the administered dosage differs from the prescribed dosage; and
385
386 — ii. — When the dose of the individual exceeds 5 rems effective dose equivalent or 50 rems
387 dose equivalent to any individual organ.
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398 Sec. D.1208 Report and Notification of a Misadministration.
399

400 a. Licensees and registrants shall establish appropriate procedures, through compliance with the
401 written directive, to prevent the occurrence of a misadministration.
402

403 b. A licensee or registrant shall report any misadministration in which the administration of
404 radioactive material, or radiation from radioactive material or a radiation machine results in:
405

406 i. A dose from radioactive material that differs from the prescribed dose or dose that
407 would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv)
408 effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv)
409 shallow dose equivalent to the skin; and

410
411 (1) The total dose delivered differs from the prescribed dose by 20 percent or more;
412

413 (2) The total dosage delivered differs from the prescribed dosage by 20 percent or
414 more or falls outside the prescribed dosage range; or
415

416 (3) The fractionated dose delivered differs from the prescribed dose, for a single
417 fraction, by 50 percent or more.
418

419 ii. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an
420 organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the
421 following:
422

423 (1) An administration of a wrong radioactive drug containing radioactive material;
424

425 (2) An administration of a radioactive drug containing radioactive material by the
426 wrong route of administration;
427

428 (3) An administration of a radioactive material dose or dosage to the wrong
429 individual or human research subject;
430

431 (4) An administration of a radioactive material dose or dosage delivered by the
432 wrong mode of treatment; or
433

434 (5) A leaking sealed source.
435

436 iii. A radioactive material dose to the skin or an organ or tissue other than the treatment
437 site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the
438 dose expected from the administration defined in the written directive (excluding, for
439 permanent implants, seeds that were implanted in the correct site but migrated outside
440 the treatment site).
441

442 iv. A teletherapy radiation dose or dose from a radiation machine:
443

444 (1) Involving the wrong individual, wrong mode of treatment, or wrong treatment
445 site, or of a type other than the one intended; or
446

447 (2) When the treatment consists of three or fewer fractions, a difference of the
448 calculated total administered dose from the total prescribed dose by more than
449 10 percent of the total prescribed dose; or
450

- 451 (3) A calculated weekly administered dose that is 30 percent greater than the weekly
452 prescribed dose; or
453
- 454 (4) A calculated total administered dose that differs from the total prescribed dose
455 by more than 20 percent of the total prescribed dose.
456
- 457 c. The licensee or registrant shall notify by telephone the Agency no later than the next calendar
458 day after discovery of the misadministration.
459
- 460 d. The licensee or registrant shall submit a written report to the Agency within 15 days after
461 discovery of the misadministration.
462
- 463 i. The written report must include:
464
- 465 (1) The licensee's or registrant's name;
466
- 467 (2) The name of the prescribing physician;
468
- 469 (3) A brief description of the misadministration;
470
- 471 (4) Why the misadministration occurred;
472
- 473 (5) The effect, if any, on the individual(s) who received the administration;
474
- 475 (6) What actions, if any, have been taken or are planned to prevent recurrence; and
476
- 477 (7) A verification signed by the appropriate authorized user or registrant that the
478 licensee or registrant notified the individual (or the individual's responsible
479 relative or guardian), and if not, why not.
480
- 481 ii. The report may not contain the individual's name or any other information that could
482 lead to identification of the individual.
483
- 484 e. The licensee or registrant shall provide notification of the misadministration to the referring
485 physician and also notify the individual who is the subject of the misadministration no later
486 than 24 hours after its discovery, unless the referring physician personally informs the
487 licensee or registrant either that he or she will inform the individual or that, based on medical
488 judgment, telling the individual would be harmful. The licensee or registrant is not required
489 to notify the individual without first consulting the referring physician. If the referring
490 physician or the affected individual cannot be reached within 24 hours, the licensee or
491 registrant shall notify the individual as soon as possible thereafter. The licensee or registrant
492 may not delay any appropriate medical care for the individual, including any necessary
493 remedial care as a result of the misadministration, because of any delay in notification. To
494 meet the requirements of this paragraph, the notification of the individual who is the subject
495 of the misadministration may be made instead to that individual's responsible relative or
496 guardian. If a verbal notification is made, the licensee or registrant shall inform the
497 individual, or appropriate responsible relative or guardian, that a written description of the
498 misadministration can be obtained from the licensee or registrant upon request. The licensee
499 or registrant shall provide such a written description if requested.
500
- 501 f. Aside from the notification requirement, nothing in this section affects any rights or duties of
502 licensees, registrants or physicians in relation to each other, to individuals affected by the
503 misadministration, or to that individual's responsible relatives or guardians.

- 504
505 g. A licensee or registrant shall:
506
507 i. Include with a copy of the report provided to the Agency:
508
509 1. The name of the individual who is the subject of the misadministration; and
510
511 2. The social security number or other identification number, if one has been
512 assigned, of the individual who is the subject of the misadministration; and
513
514 ii. For licensees, provide a copy of the report in Sec. D.1208(g)(i) to the referring
515 physician, if other than the licensee, no later than 15 days after the discovery of the
516 misadministration.
517
518 h. Each licensee or registrant shall retain a record of each misadministration for five years. The
519 record must contain the names of all individuals involved (including the prescribing
520 physician, allied health personnel, the individual who received the misadministration, and
521 that individual's referring physician, if applicable), the individual's social security number or
522 identification number if one has been assigned, a brief description of the misadministration,
523 why it occurred, the effect on the individual, what improvements are needed to prevent
524 recurrence, and the actions taken to prevent recurrence.

525 **NOTE: D.1209 HAS BEEN DELETED.**

526 Sec. D.1209 Notifications, Records and Reports of Misadministrations.

- 527
528 a. For a misadministration:
529
530 i. The licensee or registrant shall notify by telephone the Agency⁴ no later than the next calendar
531 day after the discovery of the misadministration.
532
533 ii. The licensee or registrant shall submit a written report to the Agency within 15 days after
534 discovery of the misadministration. The written report must include the licensee's or
535 registrant's name; the prescribing physician's name; a brief description of the event; why the
536 event occurred; the effect on the individual; what improvements are needed to prevent
537 recurrence; whether the licensee or registrant notified the individual, or the individual's
538 responsible relative or guardian (this person will be subsequently referred to as "the
539 individual" in this section), and if not, why not, and if the individual was notified, what
540 information was provided to the individual; and actions taken to prevent recurrence. The
541 report must not include the individual's name or other information that could lead to
542 identification of the individual. To meet the requirements of this section, the notification of
543 the individual receiving the misadministration may be made instead to that individual's
544 responsible relative or guardian, when appropriate.
545
546 iii. The licensee or registrant shall notify the referring physician and also notify the individual of
547 the misadministration no later than 24 hours after its discovery, unless the referring physician
548 personally informs the licensee or registrant either that he will inform the individual or that,
549 based on medical judgement, telling the individual would be harmful. The licensee or
550 registrant is not required to notify the individual without first consulting the referring
551 physician. If the referring physician or individual cannot be reached within 24 hours, the
552 licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or
553 registrant may not delay appropriate medical care for the individual, including any necessary
554 remedial care as a result of the misadministration, because of any delay in notification.
555

556 ~~iv. If the individual was notified, the licensee or registrant shall also furnish, within 15 days after~~
557 ~~discovery of the misadministration, a written report to the individual by sending either:~~

558
559 ~~1. A copy of the report that was submitted to the Agency; or~~
560

561 ~~2. A brief description of both the event and the consequence as they may affect the~~
562 ~~individual, provided a statement is included that the report submitted to the Agency can~~
563 ~~be obtained from~~
564

565 ~~⁴The after hours telephone number of the Agency Emergency Operations Unit is (410) 243-8700.~~

566
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569

569 the licensee or registrant.

570
571 ~~b. Each licensee or registrant shall retain a record of each misadministration for five years. The record~~
572 ~~must contain the names of all individuals involved (including the prescribing physician, allied health~~
573 ~~personnel, the individual who received the misadministration, and that individual's referring~~
574 ~~physician, if applicable), the individual's social security number or identification number if one has~~
575 ~~been assigned, a brief description of the misadministration, why it occurred, the effect on the~~
576 ~~individual, what improvements are needed to prevent recurrence, and the actions taken to prevent~~
577 ~~recurrence.~~

578
579 ~~c. Aside from the notification requirement, nothing in this section affects any rights or duties of~~
580 ~~licensees or registrants and physicians in relation to each other, to individuals receiving~~
581 ~~misadministrations, or to that individual's responsible relatives or guardians.~~

582
583 Sec. D.1210 Report and Notification of a Dose to an Embryo/fetus or a Nursing Child.

584
585 a. A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose
586 equivalent that is a result of an administration of radioactive material or radiation from radioactive
587 material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in
588 advance, by the authorized user.

589
590 b. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive
591 material to a breast-feeding individual that:

592
593 i. Is greater than 5 rem (50 mSv) total effective dose equivalent; or

594
595 ii. Has resulted in unintended permanent functional damage to an organ or a physiological system
596 of the child, as determined by a physician.

597
598 c. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery
599 of a dose to the embryo/fetus or nursing child that requires a report in D.1210a. or b.

600
601 d. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to
602 the embryo/fetus or nursing child that requires a report in D.1210(a) or (b).

603
604 i. The written report must include:

605
606 (1) The licensee's name;

607
608 (2) The name of the prescribing physician;

609
610 (3) A brief description of the misadministration;

611
612 (4) Why the misadministration occurred;

613
614 (5) The effect, if any, on the embryo/fetus or the nursing child;

615
616 (6) What actions, if any, have been taken or are planned to prevent recurrence; and

617
618 (7) Certification that the licensee notified the pregnant individual or mother (or the
619 mother's or child's responsible relative or guardian), and if not, why not.

620
621 ii. The report must not contain the individual's or child's name or any other information that
622 could lead to identification of the individual or child.
623
624 e. The licensee shall provide notification of the misadministration to the referring physician and also
625 notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24
626 hours after discovery of a misadministration that would require reporting under D.1210a. or b., unless
627 the referring physician personally informs the licensee either that he or she will inform the mother or
628 that, based on medical judgment, telling the mother would be harmful. The licensee is not required to
629 notify the mother without first consulting with the referring physician. If the referring physician or
630 mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as
631 soon as possible thereafter. The licensee may not delay any appropriate medical care for the
632 embryo/fetus or for the nursing child, including any necessary remedial care as a result of the
633 misadministration, because of any delay in notification. To meet the requirements of D.1210e., the
634 notification may be made to the mother's or child's responsible relative or guardian instead of the
635 mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or
636 child's responsible relative or guardian, that a written description of the misadministration can be
637 obtained from the licensee upon request. The licensee shall provide such a written description if
638 requested.
639

640 f. A licensee shall:

641 i. Include with a copy of the report provided to the Agency:

642 1. The name of the pregnant individual or the nursing child who is the subject of the
643 misadministration; and

644 2. The social security number or other identification number, if one has been assigned, of
645 the pregnant individual or the nursing child who is the subject of the misadministration;
646 and

647 ii. Provide a copy of the annotated report to the referring physician, if other than the licensee, no
648 later than 15 days after the discovery of the misadministration.
649

650
651 Sec. D.121011 Additional Reporting Requirements for Radioactive Materials.
652

653
654 a. Immediate report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours
655 after the discovery of an event that prevents immediate protective actions necessary to avoid
656 exposures to radiation or radioactive materials that could exceed regulatory limits or release of
657 licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas
658 releases, etc.).
659

660
661 b. Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of
662 any of the following events involving licensed material:
663

664
665 1. An unplanned contamination event that:

666
667 i. Requires access to the contaminated area, by workers or the public, to be restricted for
668 more than 24 hours by imposing additional radiological controls or by prohibiting entry
669 into the area;
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- ii. Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Part D; and
 - iii. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
2. An event in which equipment is disabled or fails to function as designed when:
- i. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
 - ii. The equipment is required to be available and operable when it is disabled

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- 686 or fails to function; and
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688 iii. No redundant equipment is available and operable to perform the required safety
689 function.
690
691 3. An event that requires unplanned medical treatment at a medical facility of an individual
692 with spreadable radioactive contamination on the individual's clothing or body.
693
694 4. An unplanned fire or explosion damaging any licensed material or any device, container,
695 or equipment containing licensed material when:
696
697 i. The quantity of material involved is greater than five times the lowest annual
698 limit on intake specified in Appendix B of Part D; and
699
700 ii. The damage affects the integrity of the licensed material or its container.
701
702 c. Preparation and submission of reports. Reports made by licensees in response to the
703 requirements of this section must be made as follows:
704
705 1. Licensees shall make reports required by paragraphs (a) and (b) of this section by
706 telephone to the Agency. To the extent that the information is available at the time of
707 notification, the information provided in these reports must include:
708
709 i. The caller's name and call back number;
710
711 ii. A description of the event, including date and time;
712
713 iii. The exact location of the event;
714
715 iv. The isotopes, quantities, and chemical and physical form of the licensed material
716 involved; and
717
718 v. Any personnel radiation exposure data available.
719
720 2. Written report. Each licensee who makes a report required by paragraph (a) or (b) of this
721 section shall submit a written follow-up report within 30 days of the initial report. Written
722 reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the
723 reports contain all of the necessary information and the appropriate distribution is made. These
724 reports must be sent to the Agency. The reports must include the following:
725
726 i. A description of the event, including the probable cause and the manufacturer
727 and model number (if applicable) of any equipment that failed or malfunctioned;
728
729 ii. The exact location of the event;
730
731 iii. The isotopes, quantities, and chemical and physical form of the licensed material
732 involved;
733
734 iv. Date and time of event;
735
736 v. Corrective actions taken or planned and the results of any evaluations or assessments;
737 and
738
739 vi. The extent of exposure of individuals to radiation or to radioactive materials without
740 identification of individuals by name.
741
742

744 d. Each specific licensee, or general licensee possessing radioactive material as defined in
 745 C.22(k)(5)(i), shall notify the Agency in writing immediately following the filing of a voluntary or
 746 involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code
 747 by or against:

- 748
- 749 1. The licensee;
 - 750
 - 751 2. An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing
 752 the license or licensee as property of the estate; or
 - 753
 - 754 3. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.
 - 755

756 e. The notification specified in D.12101(d) shall indicate the bankruptcy court in which the petition
 757 for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.
 758

759 Sec. D.1220 Notification of Failure To Comply or Existence of a Defect and Its Evaluation.
 760

761 a. Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations
 762 in this part shall adopt appropriate procedures to--
 763

- 764 1. Evaluate deviations and failures to comply to identify defects and failures to comply
 765 associated with substantial safety hazards as soon as practicable, and, except as provided in
 766 paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a
 767 reportable defect or failure to comply that could create a substantial safety hazard, were it to remain
 768 uncorrected;
 769
- 770 2. Ensure that if an evaluation of an identified deviation or failure to comply potentially
 771 associated with a substantial safety hazard cannot be completed within 60 days from discovery of the
 772 deviation or failure to comply, an interim report is prepared and submitted to the Department through
 773 a director or responsible officer or designated person as discussed in Sec. D.1220(c)(5). The interim
 774 report should describe the deviation or failure to comply that is being evaluated and should also state
 775 when the evaluation will be completed. This interim report must be submitted in writing within 60
 776 days of discovery of the deviation or failure to comply; and
 777
- 778 3. Ensure that a director or responsible officer subject to the regulations of this part is informed
 779 as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation
 780 described in Sec. D.1220(a)(1) or Sec. D.1220(a)(2) if the construction or operation of a facility or
 781 activity, or a basic component supplied for such facility or activity--
 782

- 783 i. Fails to comply with COMAR 26.12.01.01 Regulations for the Control of Ionizing
 784 Radiation (1994), or any applicable rule, order, or license of the Department relating to a
 785 substantial safety hazard, or
 786

- 787 ii. Contains a defect.
 788

789 b. If the deviation or failure to comply is discovered by a supplier of basic components, or services
 790 associated with basic components, and the supplier determines that it does not have the capability to perform
 791 the evaluation to determine if a defect exists, then the supplier must inform the purchasers
 792

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1 Each licensee shall maintain a copy of current operating and emergency procedures until the
2 Department terminates the license. Superseded material must be retained for 3 years after the change is
3 made.
4

5 Sec. E.82 Records of Personnel Monitoring Procedures.
6

7 Each licensee shall maintain the following exposure records specified in Sec. E.47:
8

9 (a) Direct reading dosimeter readings and yearly operability checks required by Sec. E.47(b) and (c)
10 for 3 years after the record is made.
11

12 (b) Records of alarm ratemeter calibrations for 3 years after the record is made.
13

14 (c) Personnel dosimeter results received from the accredited NVLAP processor until the
15 Department terminates the license.
16

17 (d) Records of estimates of exposures as a result of: off-scale personnel direct reading
18 dosimeters, or lost or damaged personnel dosimeters, until the Department terminates the license.
19

20 Sec. E.85 Records of Radiation Surveys.
21

22 Each licensee shall maintain a record of each exposure device survey conducted before the device is
23 placed in storage as specified in Sec. E.49(c), if that survey is the last one performed in the workday. Each
24 record must be maintained for 3 years after it is made.
25

26 Sec. E.87 Form of Records.
27

28 Each record required by this part must be legible throughout the specified retention period. The
29 record may be the original or a reproduced copy or a microform provided that the copy or microform is
30 authenticated by authorized personnel and that the microform is capable of reproducing a clear copy
31 throughout the required retention period. The record may also be stored in electronic media with the
32 capability for producing legible, accurate, and complete records during the required retention period.
33 Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps,
34 initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of
35 records.
36

37 Sec. E.89 Location of Documents and Records.
38

39 (a) Each licensee or registrant subject to Part E shall maintain copies of records required by this part
40 and other applicable parts of this chapter at the location specified in the person's license or
41 registration.
42
43
44
45
46
47
48
49
50
51

52 (b) Each licensee or registrant subject to Part E shall also maintain copies of the following
53 documents and records sufficient to demonstrate compliance at each applicable field station and
54 each temporary job site:
55

- 56 (1) The license or registration authorizing the use of sources of radiation;
57
58 (2) A copy of COMAR 26.12.01.01 Regulations for Control of Ionizing Radiation (1994);
59
60 (3) Utilization records for each radiation machine or radiographic exposure device
61 dispatched from that location as required by Sec. E.71;
62
63 (4) Records of equipment problems identified in daily checks of equipment as required by
64 Sec. E.73(a);
65
66 (5) Records of alarm system and entrance control checks required by Sec. E.75, if
67 applicable;
68
69 (6) Records of direct reading dosimeters such as pocket dosimeter and/or electronic
70 personal dosimeter readings as required by Sec. E.82;
71
72 (7) Operating and emergency procedures required by Sec. E.81;
73
74 (8) Evidence of the latest calibration of the radiation survey instruments in use at the site, as
75 required by Sec. E.65;
76
77 (9) Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket
78 dosimeters and/or electronic personal dosimeters as required by Sec. E.82;
79
80 (10) Latest survey records required by Sec. E.85;
81
82 (11) The shipping papers for the transportation of radioactive materials required by Sec. T.5
83 of this chapter; and
84
85 (12) When operating under reciprocity pursuant to Sec. C.90, a copy of the NRC or
86 Agreement State license authorizing the use of licensed materials.
87

88 **Subpart F - Notifications**

89 Sec. E.101 Notifications.

- 90
91
92 (a) In addition to the reporting requirements specified in Sec. D.1201 through D.1206, D.1210¹, and
93 D.1220 of these regulations, each licensee or registrant shall immediately notify the Department
94 and shall provide a written report to the Maryland Department of the Environment, Radiological
95 Health Program, 1800 Washington Boulevard,
96
97
98
99

Part G**USE OF RADIONUCLIDES IN THE HEALING ARTS****General Regulatory Information**

Sec. G.1 Purpose and Scope. This part establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

Sec. G.2 Definitions. As used in this part, the following definitions apply:

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

"Authorized medical physicist" means an individual who:

- (1) Meets the requirements in G.51(a) and G.59, or
- (2) Is identified as an authorized medical physicist or teletherapy physicist on:
 - (i) A specific medical use license issued by the NRC or Agreement State;
 - (ii) A medical use permit issued by an NRC master material licensee;
 - (iii) A permit issued by an NRC or Agreement State broad scope medical use licensee; or
 - (iv) A permit issued by an NRC master material license broad scope medical use permittee.

"Authorized user" means a physician, dentist, or podiatrist who is:

- ~~(1) Board certified by at least one of the boards listed in Paragraph (a) of §§G.65, G.66, G.67, G.68, G.70, or G.71;~~
- ~~(2) Identified as an authorized user on a license issued by the Agency, the NRC, or any other Agreement State that authorizes the medical use of radioactive material; or~~
- ~~(3) Identified as an authorized user on a permit issued by the Agency, NRC, or any other Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material.~~

47 (1) Meets the requirements in G.59 and G.190(a), G.290(a), G.390(a), G.392(a),
48 G.394(a), G.490(a), G.590(a), or G.690(a); or

49
50 (2) Is identified as an authorized user on:

51
52 (i) An Agreement State or NRC license that authorizes the medical use of
53 radioactive material;

54
55 (ii) A permit issued by an NRC master material licensee that is authorized to
56 permit the medical use of radioactive material;

57
58 (iii) A permit issued by an NRC or Agreement State specific licensee of broad
59 scope that is authorized to permit the medical use of radioactive material; or

60
61 (iv) A permit issued by an NRC master material license broad scope permittee
62 that is authorized to permit the medical use of radioactive material.

63
64 "Brachytherapy" means a method of radiation therapy in which ~~sealed sources are utilized~~ sources
65 are used to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary,
66 intraluminal, or interstitial application.

67
68 "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or
69 a combination of these sources that is designed to deliver a therapeutic dose within a distance of
70 a few centimeters.

71
72 "Dedicated check source" means a radioactive source that is used to assure the constant operation of
73 a radiation detection or measurement device over several months or years. This source may also be
74 used for other purposes.

75
76 "High dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose
77 rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

78
79 "Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose
80 rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is
81 prescribed.

82
83 "Management" means the chief executive officer or that individual's designee.

84
85 "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources
86 (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities
87 that are in close proximity to a treatment site or directly into the tissue volume.

88
89 "Medical institution" means an organization in which several medical disciplines are practiced.
90

91 "Medical use" means the intentional internal or external administration of radioactive material, or
92 the radiation ~~therefrom~~ radioactive material, to patients or human research subjects ~~in the practice of~~
93 ~~the healing arts~~ under the supervision of an authorized user.

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97 ~~"Mobile nuclear medicine service" means the transportation and medical use of radioactive material~~
98 ~~medical service" means the transportation of radioactive material to and its medical use at the~~
99 ~~client's address.~~

100
101 "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates
102 from a teletherapy unit for a specified set of exposure conditions.

103
104 "Preceptor" means an individual who provides, directs, or verifies the training and experience
105 required for an individual to become an authorized user, an authorized medical physicist, an
106 authorized nuclear pharmacist, or a Radiation Safety Officer.

107
108 ~~"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:~~

109
110 ~~—— (1) —— In a written directive; or~~

111
112 ~~—— (2) —— Either in the diagnostic clinical procedures manual or in any appropriate record in~~
113 ~~accordance with the directions of the authorized user for diagnostic procedures.~~

114
115 "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive
116 material as documented:

117
118 (1) In a written directive; or

119
120 (2) In accordance with the directions of the authorized user for procedures performed
121 pursuant to G.100 and G.200.

122
123 ~~"Prescribed dose" means~~ _____

124
125 ~~—— (1) —— For gamma stereotactic radiosurgery, the total dose as documented in the written~~
126 ~~directive;~~

127
128 ~~—— (2) —— For teletherapy, the total dose and dose per fraction as documented in the written~~
129 ~~directive; or~~

130
131 ~~(3) —— For brachytherapy, either the total source strength and exposure time or the total~~
132 ~~dose, as documented in the written directive.~~

133
134 "Recordable event" means the administration of:

135
136 (1) A radiopharmaceutical or radiation without a written directive where a written
137 directive is required;

138
139 (2) A radiopharmaceutical or radiation where a written directive is required without
140 daily recording of each administered radiopharmaceutical dosage or radiation dose in the
141 appropriate record;

142

143 (3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-
144 125 or I-131 when both:

145
146 (i) The administered dosage differs from the prescribed dosage by more than 10
147 percent of the prescribed dosage, and

148
149 (ii) The difference between the administered dosage and the prescribed dosage
150 exceeds 15 microcuries;

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154

- 154 (4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131,
155 when the administered dosage differs from the prescribed dosage by more than 10 percent of
156 the prescribed dosage;
157
- 158 (5) A teletherapy radiation dose when the calculated weekly administered dose exceeds
159 the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or
160
- 161 (6) A brachytherapy radiation dose when the calculated administered dose differs by
162 more than 10 percent of the prescribed dose.
163

164 "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an
165 Agency license.
166

167 "Treatment site" means the anatomical description of the tissue intended to receive a radiation
168 dose, as described in a written directive.
169

170 "Visiting authorized user" means an authorized user who is not identified on the license of the
171 licensee being visited.
172

173

174

175

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General Regulatory Requirements

NOTE: Existing G.6 has been entirely replaced by new G.6 below, which is a rewrite of old G.7.7.]

Sec. G.6 Provisions for the Protection of Human Research Subjects.

(a) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its Agency medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

200
201 (1) Obtain review and approval of the research from an "Institutional Review
202 Board," as defined and described in the Federal Policy; and

203
204 (2) Obtain "informed consent," as defined and described in the Federal Policy, from
205 the human research subject.

206
207 (d) Nothing in this section relieves licensees from complying with the other requirements in
208 this part.

209
210 Sec. G.311 License Required.

211
212 (a) A person shall not manufacture, produce, acquire, receive, possess, prepare, use, or transfer
213 radioactive material for medical use except in accordance with a specific license issued by the
214 Agency, the NRC, or any other Agreement State, or as allowed in G.11 Paragraph (b) or G.11(c) of
215 this section.

216
217 (b) Unless prohibited by license condition, an individual may receive, possess, use, or transfer
218 radioactive material in accordance with the regulations in this part under the supervision of an
219 authorized user as provided in G.4027.

220
221 (c) An individual may prepare unsealed byproduct radioactive material for medical use in
222 accordance with the regulations in this part under the supervision of an authorized nuclear
223 pharmacist or authorized user as provided in G.4027, unless prohibited by license condition.

224
225 (d) Exemptions. A licensee possessing a Type A specific license of broad scope for medical
226 use is exempt from the following:

227
228 (1) The provisions of §G.412(b)(2);

229
230 (2) The provisions of §G.412(b)(5) regarding additions to or changes in the areas of use

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235 only at the addresses specified in the license;

236

237 (3) The provisions of §G.145(a); and

238

239 (4) The provisions of §G.514(b)(1) for an authorized user or an authorized nuclear
240 pharmacist; and

241

242 (5) Amendments requesting sealed sources and devices manufactured and distributed
243 in accordance with Sec. C.28(1).

244

245 Sec. G.412 License Applications and Amendments.

246

247 (a) Applications.

248

249 (1) If the application is for medical use sited in a medical institution, only the
250 institution's management may apply. If the application is for medical use not sited in a
251 medical institution, any person may apply.

252

253 (2) An application for a license, or license amendment, or license renewal under this
254 pPart must be made by filing the application on a form prescribed by the Agency.

255

256 (3) An applicant that satisfies the requirements specified in Sec. C.27(b) may apply for a
257 Type A specific license of broad scope.

258

259 (b) Amendments. A licensee shall apply for and must receive a license amendment:

260

261 (1) Before it receives, prepares, or uses radioactive material for a clinical procedure
262 permitted under this pPart but not permitted by the license issued pursuant to this pPart;

263

264 (2) Before it permits anyone to work as an authorized user, ~~or~~ authorized nuclear
265 pharmacist, or authorized medical physicist under the license except an individual who is:

266

267 (i) An authorized user in each category of use certified by the organizations
268 specified in paragraph (a) of §G.65, G.66, G.67, G.68, G.70, or G.71 G.51(a),
269 G.57(a), G.390(a), G.392(a), G.394(a), G.396(a), G.490(a), G.491(a) and
270 G.590(a);

271

272 (ii) An authorized nuclear pharmacist certified by the organization specified in
273 paragraph (a) of G.7555(a);

274

275 (iii) Identified as an authorized user or an authorized nuclear pharmacist on a
276 license issued by the Agency, the NRC or any other Agreement State that authorizes
277 the use of radioactive material in medical use or in the practice of nuclear pharmacy,
278 respectively; or

279

280 (iv) Identified as an authorized user or an authorized nuclear pharmacist on a
281 permit issued by the Agency, the NRC or any other Agreement State licensee of

282

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285 broad scope that is authorized to permit the use of radioactive material in medical
286 use or in the practice of nuclear pharmacy, respectively;

- 287
288 (3) Before it changes Radiation Safety Officers or tTeletherapy physicists;
289
290 (4) Before it orders radioactive material in excess of the amount, or radionuclide or form
291 different than authorized on the license; and
292
293 (5) Before it adds to or changes the areas of use or addresses of use identified in the
294 application or on the license.
295

296 Sec. G.514 Notifications.

297
298 (a) A licensee shall provide to the Agency a copy of the board certification, the Agency or
299 Agreement State license, or the permit issued by the licensee of broad scope for each individual no
300 later than 30 days after the date that the licensee permits the individual to work as an authorized user
301 or an authorized nuclear pharmacist pursuant to §G4.12(b)(2)(i) through G.12(b)(2)(iv).
302

303 (b) A licensee shall notify the Agency by letter no later than 30 days after:

304
305 (1) An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or
306 teletherapy physicist permanently discontinues performance of duties under the license or
307 has a name change; or
308

309 (2) The licensee's -mailing address changes.
310

311 (c) The licensee shall mail the documents required in this section to the appropriate address
312 identified in §Sec. A.12.
313
314
315

316 **Additional Requirements**

317
318
319
320 Sec. G.6 Additional Programs Required.

321
322 (a) ~~ALARA Program.~~ [NOTE: See G.24(h) for ALARA.]
323

324 ~~(1) Each licensee shall develop and implement a written program to maintain radiation~~
325 ~~doses and releases of radioactive material in effluents to unrestricted areas as low as~~
326 ~~reasonably achievable in accordance with D.1 of these regulations.~~
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329

329 (2) ~~To satisfy the requirement of G.6(a)(1):~~

330
331 (i) ~~The management, Radiation Safety Officer, and all authorized users shall~~
332 ~~participate in the establishment, implementation, and operation of the program as~~
333 ~~required by these regulations or the Radiation Safety Committee; or~~

334
335 ~~(ii) For licensees that are not medical institutions, management and all~~
336 ~~authorized users shall participate in the program as required by the Radiation Safety~~
337 ~~Officer.~~

338
339 ~~(3) The ALARA program shall include an annual review by the Radiation Safety~~
340 ~~Committee for licensees that are medical institutions, or management and the Radiation~~
341 ~~Safety Officer for licensees that are not medical institutions, of summaries of the types and~~
342 ~~amounts of radioactive material used, occupational dose reports, and continuing education~~
343 ~~and training for all personnel who work with or in the vicinity of radioactive material. The~~
344 ~~purpose of the review is to ensure that individuals make every reasonable effort to maintain~~
345 ~~occupational doses, doses to the general public, and releases of radioactive material as low~~
346 ~~as reasonably achievable.~~

347
348 ~~(4) The licensee shall retain a current written description of the ALARA program for the~~
349 ~~duration of the license. The written description shall include:~~

350
351 ~~(i) A commitment by management to keep occupational doses as low as~~
352 ~~reasonably achievable;~~

353
354 ~~(ii) A requirement that the Radiation Safety Officer brief management once each~~
355 ~~year on the radiation safety program;~~

356
357 ~~(iii) Personnel exposure investigational levels as established in accordance with~~
358 ~~G.8(b)(8) that, when exceeded, will initiate an investigation by the Radiation Safety~~
359 ~~Officer of the cause of the exposure; and~~

360
361 ~~(iv) Personnel exposure investigational levels that, when exceeded, will initiate a~~
362 ~~prompt investigation by the Radiation Safety Officer of the cause of the exposure~~
363 ~~and a consideration of actions that might be taken to reduce the probability of~~
364 ~~recurrence.~~

365 [NOTE: (b) and (c) deleted.]

366 ~~(b) Quality Control Program for Imaging Equipment. Each licensee shall establish written~~
367 ~~quality control procedures for all equipment used to obtain images from radionuclide studies. As a~~
368 ~~minimum, the procedures shall include quality control procedures recommended by equipment~~
369 ~~manufacturers or procedures which have been approved by the Agency. The licensee shall conduct~~
370 ~~quality control procedures in accordance with written procedures.~~

371
372 ~~(c) Quality Management Program~~

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375

375 (1) Each applicant or licensee under this part, as applicable, shall establish and maintain
 376 a written quality management program to provide high confidence that byproduct material
 377 or radiation from byproduct material will be administered as directed by the authorized user.
 378 The quality management program must have written policies and procedures to meet the
 379 following specific objectives:

380
 381 ~~————— (i) That, prior to administration, a written[†] directive is prepared for:~~

382
 383 ~~————— (a) Any teletherapy radiation dose;~~

384
 385 ~~————— (b) Any gamma stereotactic radiosurgery radiation dose;~~

386
 387 ~~————— (c) Any brachytherapy radiation dose;~~

388
 389 ~~————— (d) Any administration of quantities greater than 30 microcuries of either~~
 390 ~~sodium iodide I 125 or I 131; or~~

391
 392 ~~————— (e) Any therapeutic administration of a radiopharmaceutical, other than~~
 393 ~~sodium iodide I 125 or I 131;~~

394
 395 ~~————— (ii) That, prior to each administration, the patient's or human research subject's~~
 396 ~~identity is verified by more than one method as the individual named in the written~~
 397 ~~directive;~~

398
 399 ~~(iii) That final plans of treatment and related calculations for brachytherapy,~~
 400 ~~teletherapy, and gamma stereotactic radiosurgery are in accordance with the~~
 401 ~~respective written directives;~~

402
 403
 404
 405
 406
 407 [†] ~~————— If, because of the patient's condition, a delay in order to provide a written revision to an existing written~~
 408 ~~directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable,~~
 409 ~~provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed~~
 410 ~~by the authorized user within 48 hours of the oral revision.~~

411 ~~————— Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic~~
 412 ~~procedure provided that the revision is dated and signed by an authorized user prior to the administration of the~~
 413 ~~radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or~~
 414 ~~the next teletherapy fractional dose.~~

415 ~~————— If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive~~
 416 ~~would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the~~
 417 ~~oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the~~
 418 ~~oral directive.~~

419
 420
 421

- 421 (iv) That each administration is in accordance with the written directive; and
422
423 ~~(v) That any unintended deviation from the written directive is identified and~~
424 ~~evaluated, and appropriate action is taken.~~
425
426 (2) ~~The licensee shall:~~
427
428 ~~(i) Develop procedures for and conduct a review, at intervals no greater than 12~~
429 ~~months, of the quality management program including, since the last review, an~~
430 ~~evaluation of:~~
431
432 ~~(a) A representative sample of patient and human research subject~~
433 ~~administrations;~~
434
435 ~~(b) All recordable events, and~~
436
437 ~~(c) All misadministrations.~~
438
439 ~~(ii) Evaluate each of these reviews to determine the effectiveness of the quality~~
440 ~~management program and, if required, make modifications to meet the objectives of~~
441 ~~paragraph (a) of this section; and~~
442
443 ~~(iii) Retain records of each review, including the evaluations and findings of the~~
444 ~~review, in an auditable form for three years.~~
445
446 (3) ~~The licensee shall evaluate and respond, within 30 days after discovery of the~~
447 ~~recordable event by:~~
448
449 ~~(i) Assembling the relevant facts including the cause;~~
450
451 ~~(ii) Identifying what, if any, corrective action is required to prevent~~
452 ~~reoccurrence; and~~
453
454 ~~(iii) Retain a record, in an auditable form, for three years, of the relevant facts~~
455 ~~and what corrective action, if any, was taken.~~
456
457 (4) ~~The licensee shall retain:~~
458
459 ~~(i) Each written directive; and~~
460
461 ~~(ii) A record of each administered radiation dose or radiopharmaceutical dosage~~
462 ~~where a written directive is required in paragraph (a)(1) above, in an auditable form,~~
463 ~~for three years after the date of administration.~~
464
465
466
467

467 (5) — The licensee may make modifications to the quality management program to
468 increase the program's efficiency provided the program's effectiveness is not decreased. The
469 licensee shall furnish any modification to the Agency for approval prior to the modification
470 having been made.

471
472 ~~(6) (i) — Each applicant for a new license, as applicable, shall submit to the Agency a~~
473 ~~written certification that the quality management program has been implemented~~
474 ~~along with a copy of the program.~~

475
476 ~~(ii) — Each existing licensee, as applicable, shall submit to the Agency a written~~
477 ~~certification that the quality management program has been implemented along with~~
478 ~~a copy of the program.~~

479

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481

482

General Administrative Requirements

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486

Sec. G.24 Authority and Responsibilities for the Radiation Protection Program. [NOTE: Old G.9
487 rewritten.]

488

489

(a) In addition to the radiation protection program requirements of Sec. D.101, a licensee's
490 management shall approve in writing:

491

492

(1) Requests for a license application, renewal, or amendment before submittal to the
493 Agency; and

494

495

(2) Any individual before allowing that individual to work as an authorized user,
496 authorized nuclear pharmacist, or authorized medical physicist.

497

498

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing,
499 to be responsible for implementing the radiation protection program. The licensee, through the
500 Radiation Safety Officer, shall ensure that radiation safety activities are being performed in
501 accordance with licensee-approved procedures and regulatory requirements.

502

503

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual
504 qualified to be a Radiation Safety Officer, under G.50 and G.59, to function as a temporary
505 Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided
506 in G.24(g), if the licensee takes the actions required in G.24(b), G.24(e), G.24(g), and G.24(h)
507 and notifies the Agency in accordance with G.14.

508

509

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety
510 Officer in accordance with G.24(c) if needed to ensure that the licensee has a temporary
511 Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each
512 of the different types of uses of radioactive material permitted by the license.

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(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) Reserved.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

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

(h) ALARA Program. [NOTE: Was G.6(a)]

(1) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with Sec. D.1 of these regulations.

(2) To satisfy the requirement of G.24(h)(1):

(i) The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the Radiation Safety Committee; or

(ii) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.

(3) The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or management and the Radiation Safety Officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable.

(4) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

- 558 (i) A commitment by management to keep occupational doses as low as
559 reasonably achievable;
- 560
- 561 (ii) A requirement that the Radiation Safety Officer brief management once
562 each year on the radiation safety program;
- 563
- 564 (iii) Personnel exposure investigational levels as established in accordance
565 with G.26(b)(9) that, when exceeded, will initiate an investigation by the
566 Radiation Safety Officer of the cause of the exposure; and
- 567
- 568 (iv) Personnel exposure investigational levels that, when exceeded, will initiate
569 a prompt investigation by the Radiation Safety Officer of the cause of the
570 exposure and a consideration of actions that might be taken to reduce the
571 probability of recurrence.
- 572
- 573 (i) A licensee shall retain a record of actions taken under G.14(a), G.14(b), and G.14(e) in
574 accordance with G.2024.

575

576 Sec. G.725 Radiation Safety Officer.

577

578 (a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the
579 radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that
580 radiation safety activities are being performed in accordance with approved procedures and
581 regulatory requirements in the daily operation of the licensee's radioactive material program.

582

583 (b) The Radiation Safety Officer shall:

584

585 (1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts,
586 uses, transfers, and disposals, and other deviations from approved radiation safety practice
587 and implement corrective actions as necessary;

588

589 (2) Implement written policy and procedures for:

590

591 (i) Authorizing the purchase of radioactive material;

592

593 (ii) Receiving and opening packages of radioactive material;

594

595 (iii) Storing radioactive material;

596

597 (iv) Keeping an inventory record of radioactive material;

598

599 (v) Using radioactive material safely;

600

601 (vi) Taking emergency action if control of radioactive material is lost;

602

603 (vii) Performing periodic radiation surveys;

- 606 (viii) Performing checks and calibrations of survey instruments and other safety
607 equipment;
- 608
609 (ix) Disposing of radioactive material;
- 610
611 (x) Training personnel who work in or frequent areas where radioactive material
612 is used or stored; and
- 613
614 (xi) Keeping a copy of all records and reports required by the Agency
615 regulations, a copy of these regulations, a copy of each licensing request and license
616 and amendments, and the written policy and procedures required by the regulations;
617 and
- 618
619 (3) For medical use not sited at a medical institution, approve or disapprove radiation
620 safety program changes with the advice and consent of management prior to submittal to the
621 Agency for licensing action; or
- 622
623 (4) For medical use sited at a medical institution or private medical licensee that is
624 authorized for one or more therapeutic use, assist the Radiation Safety Committee in the
625 performance of its duties.

626
627 Sec. G.826 Radiation Safety Committee. Each medical institution licensee shall establish a
628 Radiation Safety Committee to oversee the use of radioactive material. Each private medical
629 licensee that is authorized for one or more therapeutic use shall also establish a Radiation Safety
630 Committee.

631
632 (a) The Committee shall meet the following administrative requirements:

633
634 (1) Membership must consist of at least 3 individuals and shall include an authorized
635 user of each type of use permitted by the license, the Radiation Safety Officer, a
636 representative of the nursing service (if applicable), and a representative of management
637 who is neither an authorized user nor a Radiation Safety Officer. Other members may be
638 included as the licensee deems appropriate.

639
640 (2) The Committee shall meet at least once each calendar quarter.

641
642 (3) The minutes of each Radiation Safety Committee meeting shall include:

643
644 (i) The date of the meeting;

645
646 (ii) Members present;

647
648 (iii) Members absent;

649
650 (iv) Summary of deliberations and discussions;

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- 653 (v) Recommended actions and the numerical results of all ballots; and
654
655 (vi) Documentation of any reviews required in Sec. D.101(c)G.6(e) and
656 G.826(b).
657
658 (4) The Committee shall provide each member with a copy of the meeting minutes, and
659 retain one copy until the Agency authorizes its disposition.
660
661 (b) To oversee the use of licensed material, the Committee shall:
662
663 (1) Be responsible for monitoring the institutional program to maintain occupational
664 doses as low as reasonably achievable;
665
666 (2) Review, on the basis of safety and with regard to the training and experience
667 standards of this part, and approve or disapprove any individual who is to be listed as an
668 authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or
669 ~~t~~Teletherapy pPhysicist before submitting a license application or request for amendment or
670 renewal; or
671
672 (3) Review, pursuant to Sections G.124(b)(2)(i) through (iv), on the basis of the board
673 certification, the license, or the permit identifying an individual, and approve or disapprove
674 any individual prior to allowing that individual to work as an authorized user or authorized
675 nuclear pharmacist;
676
677 (4) Review on the basis of safety and approve or disapprove each proposed method of
678 use of radioactive material;
679
680 (5) Review on the basis of safety, and approve with the advice and consent of the
681 Radiation Safety Officer and the management representative, or disapprove procedures and
682 radiation safety program changes prior to submittal to the Agency for licensing action;
683
684 (6) Review quarterly, with the assistance of the Radiation Safety Officer, occupational
685 radiation exposure records of all personnel working with radioactive material;
686
687 (7) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents
688 and misadministrations involving radioactive material with respect to cause and subsequent
689 actions taken;
690
691 (8) Review annually, with the assistance of the Radiation Safety Officer, the radioactive
692 material program; and
693
694 (9) Establish a table of investigational levels for occupational dose that, when exceeded,
695 will initiate investigations and considerations of action by the Radiation Safety Officer.
696
697
698
699

- 1230 (a) A medical use licensee authorized to administer radiopharmaceuticals shall possess a
1231 dose calibrator and use it to measure the amount of activity administered to each patient
1232 or human research subject.
1233
- 1234 (b) A licensee shall:
1235
- 1236 (1) Check each dose calibrator for constancy with a dedicated check source at the
1237 beginning of each day of use. To satisfy the requirement of this section, the check shall
1238 be done on a frequently used setting with a sealed source of not less than 10 microcuries
1239 (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting
1240 radionuclide with a half-life greater than 90 days;
1241
- 1242 (2) Test each dose calibrator for accuracy upon installation and at intervals not to
1243 exceed 12 months thereafter by assaying at least 2 sealed sources containing different
1244 radionuclides, the activity of which the manufacturer has determined within 5 percent of
1245 the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226
1246 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least
1247 one of which has a principal photon energy between 100 keV and 500 keV;
1248
- 1249 (3) Test each dose calibrator for linearity upon installation and at least quarterly
1250 thereafter over a range from the highest dosage that will be administered to a patient or
1251 human research subject to 1.1 megabecquerels (30 microcuries); and
1252
- 1253 (4) Test each dose calibrator for geometry dependence upon installation over the
1254 range of volumes and volume configurations for which it will be used. The licensee shall
1255 keep a record of this test for the duration of the use of the dose calibrator.
1256
- 1257 (c) A licensee shall mathematically correct dosage readings for any geometry or linearity
1258 error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall
1259 repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
1260
- 1261 (d) A licensee shall also perform checks and tests required by G.4560.B(b) following
1262 adjustment or repair of the dose calibrator.
1263
- 1264 (e) A licensee shall retain a record of each check and test required by G.4560.B(b) for 23
1265 years. The records required by G.4560.B(b) shall include:
1266
- 1267 (1) For G.4560.B(b)(1), the model and serial number of the dose calibrator, the
1268 identity and calibrated activity of the radionuclide contained in the check source, the date
1269 of the check, the activity measured, the instrument settings, and the initials of the
1270 individual who performed the check;
1271
- 1272 (2) For G.4560.B(b)(2), the model and serial number of the dose calibrator, the model
1273 and
1274
1275

1190 ~~Sec. G.60 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.~~
1191 ~~If the survey required by G.58 indicates that an individual in an unrestricted area may be exposed~~
1192 ~~to levels of radiation greater than those permitted by D.301(a) of these regulations, before~~
1193 ~~beginning the treatment program the licensee shall:~~

1194

1195 (a) ~~Either equip the unit with stops or add additional radiation shielding to ensure~~
1196 ~~compliance with D.301(a) of these regulations;~~

1197

1198 (b) ~~Perform the survey required by G.58 again; and~~

1199

1200 (c) ~~Include in the report required by G.61 the results of the initial survey, a description of the~~
1201 ~~modification made to comply with G.60(a), and the results of the second survey.~~

1202

1203 [NOTE: G.60.A is old G.14.]

1204 Sec. G.1460.A Possession, Use, Calibration, and Check of Instruments to Measure Dosages of
1205 Alpha- or Beta-emitting Radionuclides.

1206

1207 (a) This section does not apply to unit dosages of alpha- and beta-emitting radionuclides that
1208 are obtained from a manufacturer or preparer licensed by the Agency pursuant to Sec. C.28(j), or
1209 licensed by the NRC or any other Agreement State pursuant to provisions equivalent to Sec.
1210 C.28(j).

1211

1212 (b) For other than unit dosages obtained pursuant to paragraph (a) of this section, a licensee
1213 shall possess and use instrumentation to measure the radioactivity of alpha- and beta-emitting
1214 radionuclides. The licensee shall have procedures for the use of the instrumentation. The
1215 licensee shall measure, by direct measurement or by combination of measurements and
1216 calculations, the amount of radioactivity in dosages of alpha- and beta-emitting radionuclides
1217 prior to administration to each patient or human research subject. In addition, the licensee shall:

1218

1219 (1) Perform tests before initial use, periodically, and following repair, on each
1220 instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of
1221 the instrument; and make adjustments when necessary; and

1222

1223 (2) Check each instrument for constancy and proper operation at the beginning of
1224 each day of use.

1225

1226 Sec. G.1560.B Possession, Use, Calibration, and Check of Dose Calibrators.

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1144 (c) Calculating, assaying, and safely preparing dosages for patients or
1145 human research subjects;

1146
1147 (d) Using administrative controls to avoid misadministrations in the
1148 administration of radioactive material; and

1149
1150 (e) Using procedures to prevent or minimize radioactive
1151 contamination and using proper decontamination procedures; and

1152
1153 (2) Has obtained written attestation, signed by a preceptor authorized nuclear
1154 pharmacist, that the individual has satisfactorily completed the requirements in G.
1155 55(a)(1), (a)(2), and (a)(3) or G.55(b)(1) and has achieved a level of competency
1156 sufficient to function independently as an authorized nuclear pharmacist.

1157 [NOTE: OLD G.57 rewritten at G.642. New G.57 is old G.64, G.73, and G.75.1 rewritten.]
1158 Sec. G.57 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist,
1159 Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear
1160 Pharmacist.

1161
1162 (a) An individual identified as a Radiation Safety Officer, a teletherapy physicist or
1163 authorized medical physicist, or an authorized nuclear pharmacist on an NRC or Agreement
1164 State license or a permit issued by an NRC or Agreement State broad scope licensee or master
1165 material license permit or by a master material license permittee of broad scope before the
1166 effective date of these regulations need not comply with the training requirements of G.50, G.51,
1167 or G.55, respectively.

1168
1169 (b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of
1170 radioactive material on a license issued by the NRC or Agreement State, a permit issued by an
1171 NRC master material licensee, a permit issued by an NRC or Agreement State broad scope
1172 licensee, or a permit issued by an NRC master material license broad scope permittee who
1173 perform only those medical uses for which they were authorized before the effective date of
1174 these regulations need not comply with the training requirements of G.100 through G.690.

1175
1176 [NOTE: OLD G.59 deleted. New G.59 is old G.76 slightly revised.]
1177 Sec. G.59 Recentness of Training.

1178
1179 The training and experience specified in Sec. G must have been obtained within the 7 years
1180 preceding the date of application or the individual must have had related continuing education
1181 and experience since the required training and experience was completed.

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General Technical Requirements

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[NOTE: Old G.60 deleted.]

1099 the NRC's Web page. To have its certification process recognized, a specialty board shall
1100 require all candidates for certification to:

1101
1102 (1) Have graduated from a pharmacy program accredited by the American Council on
1103 Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate
1104 Examination Committee (FPGEC) examination;

1105
1106 (2) Hold a current, active license to practice pharmacy;

1107
1108 (3) Provide evidence of having acquired at least 4000 hours of training/experience in
1109 nuclear pharmacy practice. Academic training may be substituted for no more than 2000
1110 hours of the required training and experience; and

1111
1112 (4) Pass an examination in nuclear pharmacy administered by diplomates of the
1113 specialty board, that assesses knowledge and competency in procurement, compounding,
1114 quality assurance, dispensing, distribution, health and safety, radiation safety, provision
1115 of information and consultation, monitoring patient outcomes, research and development;
1116 or

1117
1118 (b) Has completed:

1119
1120 (1) 700 hours in a structured educational program consisting of both:

1121
1122 (i) 200 hours of classroom and laboratory training in the following areas:

1123
1124 (a) Radiation physics and instrumentation;

1125
1126 (b) Radiation protection;

1127
1128 (c) Mathematics pertaining to the use and measurement of
1129 radioactivity;

1130
1131 (d) Chemistry of radioactive material for medical use; and

1132
1133 (e) Radiation biology; and

1134
1135 (ii) Supervised practical experience in a nuclear pharmacy involving:

1136
1137 (a) Shipping, receiving, and performing related radiation surveys;

1138
1139 (b) Using and performing checks for proper operation of instruments
1140 used to determine the activity of dosages, survey meters, and, if
1141 appropriate, instruments used to measure alpha- or beta-emitting
1142 radionuclides;

1143

- 1053
1054 (b) (1) Holds a master's or doctor's degree in physics, medical physics, other physical
1055 science, engineering, or applied mathematics from an accredited college or university;
1056 and has completed 1 year of full-time training in medical physics and an additional year
1057 of full-time work experience under the supervision of an individual who meets the
1058 requirements for an authorized medical physicist for the type(s) of use for which the
1059 individual is seeking authorization. This training and work experience must be
1060 conducted in clinical radiation facilities that provide high-energy, external beam therapy
1061 (photons and electrons with energies greater than or equal to 1 million electron volts) and
1062 brachytherapy services and must include:
1063
1064 (i) Performing sealed source leak tests and inventories;
1065
1066 (ii) Performing decay corrections;
1067
1068 (iii) Performing full calibration and periodic spot checks of external beam
1069 treatment units, stereotactic radiosurgery units, and remote afterloading units as
1070 applicable; and
1071
1072 (iv) Conducting radiation surveys around external beam treatment units,
1073 stereotactic radiosurgery units, and remote afterloading units as applicable; and
1074
1075 (2) Has obtained written attestation that the individual has satisfactorily completed
1076 the requirements in G.51(c) and G.51(a)(1) and (2), or G.51(b)(1) and G.51(c), and has
1077 achieved a level of competency sufficient to function independently as an authorized
1078 medical physicist for each type of therapeutic medical unit for which the individual is
1079 requesting authorized medical physicist status. The written attestation must be signed by
1080 a preceptor authorized medical physicist who meets the requirements in G.51, or
1081 equivalent Agreement State or NRC requirements for an authorized medical physicist for
1082 each type of therapeutic medical unit for which the individual is requesting authorized
1083 medical physicist status; and
1084
1085 (c) Has training for the type(s) of use for which authorization is sought that includes hands-
1086 on device operation, safety procedures, clinical use, and the operation of a treatment planning
1087 system. This training requirement may be satisfied by satisfactorily completing either a training
1088 program provided by the vendor or by training supervised by an authorized medical physicist
1089 authorized for the type(s) of use for which the individual is seeking authorization.
1090 [NOTE: OLD G.55 rewritten as G.630. New G.55 is old G.75 rewritten.]
1091 Sec. G.55 Training for an Authorized Nuclear Pharmacist.
1092
1093 Except as provided in G.57, the licensee shall require the authorized nuclear pharmacist to be a
1094 pharmacist who:
1095
1096 (a) Is certified by a specialty board whose certification process has been recognized by the
1097 NRC or an Agreement State and who meets the requirements in G.55(b)(2). The names of board
1098 certifications which have been recognized by the NRC or an Agreement State will be posted on

1007
1008 (2) Is an authorized user, authorized medical physicist, or authorized nuclear
1009 pharmacist identified on the licensee's license and has experience with the radiation
1010 safety aspects of similar types of use of radioactive material for which the individual has
1011 Radiation Safety Officer responsibilities; and

1012
1013 (d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the
1014 individual has satisfactorily completed the requirements in G.50 and has achieved a level of
1015 radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for
1016 a medical use licensee; and

1017
1018 (e) Has training in the radiation safety, regulatory issues, and emergency procedures for the
1019 types of use for which a licensee seeks approval. This training requirement may be satisfied by
1020 completing training that is supervised by a Radiation Safety Officer, authorized medical
1021 physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for
1022 the type(s) of use for which the licensee is seeking approval.

1023 [NOTE: OLD G.51 rewritten as G.615.]

1024 Sec. G.51 Training for an Authorized Medical Physicist.

1025
1026 Except as provided in G.57, the licensee shall require the authorized medical physicist to be an
1027 individual who:

1028
1029 (a) Is certified by a specialty board whose certification process has been approved by the
1030 NRC or an Agreement State and who meets the requirements in G.51(b)(2) and G.51(c). The
1031 names of board certifications which have been approved by the NRC or an Agreement State will
1032 be posted on the NRC's Web page. To have its certification process recognized, a specialty
1033 board shall require all candidates for certification to:

1034
1035 (1) Hold a master's or doctor's degree in physics, medical physics, other physical
1036 science, engineering, or applied mathematics from an accredited college or university;

1037
1038 (2) Have 2 years of full-time practical training and/or supervised experience in
1039 medical physics:

1040
1041 (i) Under the supervision of a medical physicist who is certified in medical
1042 physics by a specialty board recognized by the NRC or an Agreement State; or

1043
1044 (ii) In clinical radiation facilities providing high-energy, external beam
1045 therapy (photons and electrons with energies greater than or equal to 1 million
1046 electron volts) and brachytherapy services under the direction of physicians who
1047 meet the requirements for authorized users in G.490 or G.690; and

1048
1049 (3) Pass an examination, administered by diplomates of the specialty board, that
1050 assesses knowledge and competence in clinical radiation therapy, radiation safety,
1051 calibration, quality assurance, and treatment planning for external beam therapy,
1052 brachytherapy, and stereotactic radiosurgery; or

- 961 (iii) Pass an examination, administered by diplomates of the specialty board,
962 that assesses knowledge and competence in clinical diagnostic radiological or
963 nuclear medicine physics and in radiation safety; or
964
- 965 (b) Has completed a structured educational program consisting of both:
966
- 967 (1) 200 hours of classroom and laboratory training in the following areas:
968
- 969 (i) Radiation physics and instrumentation;
970
- 971 (ii) Radiation protection;
972
- 973 (iii) Mathematics pertaining to the use and measurement of radioactivity;
974
- 975 (iv) Radiation biology; and
976
- 977 (v) Radiation dosimetry; and
978
- 979 (2) One year of full-time radiation safety experience under the supervision of the
980 individual identified as the Radiation Safety Officer on an NRC or Agreement State
981 license or permit issued by an NRC master material licensee that authorizes similar
982 type(s) of use(s) of radioactive material involving the following:
983
- 984 (i) Shipping, receiving, and performing related radiation surveys;
985
- 986 (ii) Using and performing checks for proper operation of instruments used to
987 determine the activity of dosages, survey meters, and instruments used to measure
988 radionuclides;
989
- 990 (iii) Securing and controlling radioactive material;
991
- 992 (iv) Using administrative controls to avoid mistakes in the administration of
993 radioactive material;
994
- 995 (v) Using procedures to prevent or minimize radioactive contamination and
996 using proper decontamination procedures;
997
- 998 (vi) Using emergency procedures to control radioactive material; and
999
- 1000 (vii) Disposing of radioactive material; or
1001
- 1002 (c) (1) Is a medical physicist who has been certified by a specialty board whose
1003 certification process has been recognized by an Agreement State or the NRC under
1004 G.51(a) and has experience in radiation safety for similar types of use of radioactive
1005 material for which the licensee is seeking the approval of the individual as Radiation
1006 Safety Officer and who meets the requirements in G.50(d) and G.50(e); or

917 ~~(2) Check each instrument for constancy and proper operation at the beginning of each~~
918 ~~day of use.~~

919 [New G.50 was G.63 (rewritten). Old language in G.50 deleted.]

920 Sec. G.50 Training For Radiation Safety Officer.

921

922 Except as provided in G.57, the licensee shall require an individual fulfilling the responsibilities
923 of the Radiation Safety Officer as provided in G.24 to be an individual who:

924

925 (a) Is certified by a specialty board whose certification process has been recognized by the
926 NRC or an Agreement State and who meets the requirements in G.50(d) and G.50(e) (The names
927 of board certifications which have been recognized by the NRC or an Agreement State will be
928 posted on the NRC's Web page.):

929

930 (1) To have its certification process recognized, a specialty board shall require all
931 candidates for certification to:

932

933 (i) Hold a bachelor's or graduate degree from an accredited college or
934 university in physical science or engineering or biological science with a
935 minimum of 20 college credits in physical science;

936

937 (ii) Have 5 or more years of professional experience in health physics
938 (graduate training may be substituted for no more than 2 years of the required
939 experience) including at least 3 years in applied health physics; and

940

941 (iii) Pass an examination administered by diplomates of the specialty board,
942 which evaluates knowledge and competence in radiation physics and
943 instrumentation, radiation protection, mathematics pertaining to the use and
944 measurement of radioactivity, radiation biology, and radiation dosimetry; or

945

946 (2) (i) Hold a master's or doctor's degree in physics, medical physics, other
947 physical science, engineering, or applied mathematics from an accredited college
948 or university;

949

950 (ii) Have 2 years of full-time practical training and/or supervised experience
951 in medical physics:

952

953 (a) Under the supervision of a medical physicist who is certified in
954 medical physics by a specialty board recognized by the NRC or an
955 Agreement State; or

956

957 (b) In clinical nuclear medicine facilities providing diagnostic and/or
958 therapeutic services under the direction of physicians who meet the
959 requirements for authorized users in G.290, G.390; and

960

872 a license issued pursuant to these regulations or the equivalent regulations of another Agreement
873 State, a Licensing State or the U.S. Nuclear Regulatory Commission;

874
875 (b) ~~Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance~~
876 ~~with an approval issued by the U.S. Food and Drug Administration;~~

877
878 (c) ~~Teletherapy sources manufactured and distributed in accordance with a license issued~~
879 ~~pursuant to these regulations, or the equivalent regulations of another Agreement State, a Licensing~~
880 ~~State, or the U.S. Nuclear Regulatory Commission; and~~

881
882 (da) ~~Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance~~
883 ~~with a license issued pursuant to these regulations under Sec. C., 10 CFR Part 30 and 10 CFR~~
884 ~~32.74, or the equivalent regulations requirements of another Agreement State, a Licensing State, or~~
885 ~~the U.S. Nuclear Regulatory Commission.;~~

886
887 (b) ~~Sealed sources or devices noncommercially transferred from a 10 CFR Part 35 licensee~~
888 ~~or an Agreement State medical use licensee; or~~

889
890 (c) ~~Teletherapy sources manufactured and distributed in accordance with a license issued~~
891 ~~under 10 CFR Part 30 or the equivalent requirements of an Agreement State.~~

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Specific Requirements

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897

898 [NOTE: For G.14, see G.60.A.]

899 Sec. G.14 Possession, use, calibration, and check of instruments to measure dosages of alpha or
900 beta emitting radionuclides.

901

902 (a) ~~This section does not apply to unit dosages of alpha and beta emitting radionuclides that~~
903 ~~are obtained from a manufacturer or preparer licensed by the Agency pursuant to C.28(j), or~~
904 ~~licensed by the NRC or any other Agreement State pursuant to provisions equivalent to C.28(j).~~

905

906 (b) ~~For other than unit dosages obtained pursuant to paragraph (a) of this section, a licensee~~
907 ~~shall possess and use instrumentation to measure the radioactivity of alpha and beta emitting~~
908 ~~radionuclides. The licensee shall have procedures for the use of the instrumentation. The licensee~~
909 ~~shall measure, by direct measurement or by combination of measurements and calculations, the~~
910 ~~amount of radioactivity in dosages of alpha and beta emitting radionuclides prior to administration~~
911 ~~to each patient or human research subject. In addition, the licensee shall:~~

912

913 ~~(1) Perform tests before initial use, periodically, and following repair, on each~~
914 ~~instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of~~
915 ~~the instrument; and make adjustments when necessary; and~~

916

839 Sec. G.41 Procedures for Administrations Requiring a Written Directive.

840

841 (a) For any administration requiring a written directive, the licensee shall develop,
842 implement, and maintain written procedures to provide high confidence that:

843

844 (1) Prior to each administration, the patient's or human research subject's identity is
845 verified by more than one method as the individual named in the written directive; and

846

847 (2) Each administration is in accordance with the written directive.

848

849 (b) At a minimum, the procedures required by G.41(a) must address the following items that
850 are applicable to the licensee's use of radioactive material:

851

852 (1) Verifying the identity of the patient or human research subject;

853

854 (2) Verifying that the administration is in accordance with the treatment plan, if
855 applicable, and the written directive;

856

857 (3) Checking both manual and computer-generated dose calculations; and

858

859 (4) Verifying that any computer-generated dose calculations are correctly transferred
860 into the consoles of therapeutic medical units authorized by G.600.

861

862 (c) A licensee shall retain a copy of the procedures required in G.41 in accordance with
863 G.2041.

864

865 Sec. G.1349 Suppliers for Sealed Sources or Devices for Medical Use. For medical use, a
866 licensee may shall only use for medical use only:

867

868 (a) Radioactive material manufactured, labeled, packaged, and distributed in accordance with

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(b) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(c) The written directive must contain the patient or human research subject's name and the following information:

(1) For any administration of quantities greater than 1.11 MBq (30 μ Ci) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically-distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(d) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(e) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(f) The licensee shall retain a copy of the written directive in accordance with G.2040.

747 (b) A licensee that permits the preparation of radioactive material for medical use by an
748 individual under the supervision of an authorized nuclear pharmacist or physician who is an
749 authorized user, as allowed by G.311(c), shall:

750
751 (1) Instruct the supervised individual in the preparation of radioactive material for
752 medical use, as appropriate to that individual's involvement with radioactive material; and
753 and the principles of and the procedures for radiation safety and in the licensee's written
754 quality management program, as appropriate to that individual's use of radioactive material;
755

756 ~~(2) Require the supervised individual to follow the instructions given pursuant to~~
757 ~~paragraph (1) of this section and to comply with the regulations of this chapter and license~~
758 ~~conditions; and~~

759 (2) Require the supervised individual to follow the instructions of the supervising
760 authorized user or authorized nuclear pharmacist regarding the preparation of radioactive
761 material for medical use, written radiation protection procedures established by the
762 licensee, the regulations of this chapter, and license conditions.
763

764 ~~(3) Require the supervising authorized nuclear pharmacist or physician who is an~~
765 ~~authorized user to periodically review the work of the supervised individual as it pertains to~~
766 ~~preparing radioactive material for medical use and the records kept to reflect that work.~~
767

768 (c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section
769 supervises an individual is responsible for the acts and omissions of the supervised individual.

770 [NOTE: G.11 deleted.]

771 Sec. G.11 Reserved.

772 [NOTE: G.12 deleted but some provisions in new G.80]

773 Sec. G.12 Mobile Nuclear Medicine Service Administrative Requirements.
774

775 ~~(a) The Agency will only license mobile nuclear medicine services in accordance with this part~~
776 ~~and other applicable requirements of these regulations to serve clients who do not have an Agency~~
777 ~~license.~~
778

779 ~~(b) Mobile nuclear medicine service licensees shall retain for the duration of service a letter~~
780 ~~signed by the management of each location where services are rendered that authorizes use of~~
781 ~~radioactive material.~~
782

783 ~~(e) A mobile nuclear medicine service shall not have radioactive material delivered directly~~
784 ~~from the manufacturer or the distributor to the client's address of use.~~
785

786 [NOTE: Old G.40 deleted. New section.]

787 Sec. G.40 Written Directives.
788

789 (a) A written directive must be dated and signed by an authorized user before the
790 administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries
791 (μ Ci)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of
792 radiation from radioactive material.

699 [NOTE: G.9 rewritten as G.24.]

700 Sec. G.9 Statement of Authorities and Responsibilities.

701

702 ~~(a) A licensee shall provide sufficient authority and organizational freedom to the Radiation~~
703 ~~Safety Officer and the Radiation Safety Committee to:~~

704

705 ~~———— (1) Identify radiation safety problems;~~

706

707 ~~———— (2) Initiate, recommend, or provide solutions; and~~

708

709 ~~———— (3) Verify implementation of corrective actions.~~

710

711 ~~(b) A licensee shall establish in writing the authorities, duties, responsibilities, and radiation~~
712 ~~safety activities of the Radiation Safety Officer and the Radiation Safety Committee.~~

713

714 ~~(e) Each applicant or licensee shall establish a quality management program as specified in~~
715 ~~Section G.76.~~

716

717 Sec. G.1027 Supervision.

718

719 (a) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an
720 individual under the supervision of an authorized user as allowed by G.311(b) shall:

721

722 (1) Instruct the supervised individual in the licensee's written radiation protection
723 procedures, written directive procedures, regulations of this chapter, and license
724 conditions with respect to the use of radioactive material; and principles of radiation safety
725 appropriate to that individual's use of radioactive material;

726

727 ~~———— (2) Review the supervised individual's use of radioactive material, provide reinstruction~~
728 ~~as needed and review records kept to reflect this use;~~

729 (2) Require the supervised individual to follow the instructions of the supervising
730 authorized user for medical uses of radioactive material, written radiation protection
731 procedures established by the licensee, written directive procedures, regulations of this
732 chapter, and license conditions with respect to the medical use of radioactive material.

733

734 ~~———— (3) Require the authorized user to be immediately available to communicate with the~~
735 ~~supervised individual;~~

736

737 ~~———— (4) Require the authorized user to be able to be physically present and available to the~~
738 ~~supervised individual on 1 hours notice;² and~~

739

740 (5) Require that only those individuals specifically trained, and designated by the
741 authorized user, shall be permitted to administer radionuclides or radiation to patients.

742

743 ²/The supervising authorized user need not be present for each use of radioactive material.

744

745

1276 serial number of each source used and the identity of the radionuclide contained in the
1277 source and its activity, the date of the test, the results of the test, the instrument settings,
1278 and the identity of the individual performing the test;

1279

1280 (3) For G.4560.B(b)(3), the model and serial number of the dose calibrator, the
1281 calculated activities, the measured activities, the date of the test, and the identity of the
1282 individual performing the test; and

1283

1284 (4) For G.4560.B(b)(4), the model and serial number of the dose calibrator, the
1285 configuration and calibrated activity of the source measured, the activity of the source,
1286 the activity measured and the instrument setting for each volume measured, the date of
1287 the test, and the identity of the individual performing the test.

1288

1289 Sec. G.4661 Calibration and Check of Survey Instruments.

1290

1291 (a) A licensee shall ensure that the survey instruments used to show compliance with this
1292 part have been calibrated before first use, annually, and following repair.

1293

1294 (b) To satisfy the requirements of G.4661(a), the licensee shall:

1295

1296 (1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with
1297 a radiation source;

1298

1299 (2) For each scale that shall be calibrated, calibrate two readings separated by at least
1300 50 percent of scale rating; and

1301

1302 (3) Conspicuously note on the instrument the apparent dose rate from a dedicated
1303 check source as determined at the time of calibration, and the date of calibration.

1304

1305 (c) To satisfy the requirements of G.4661(b), the licensee shall consider a point as calibrated
1306 if the indicated exposure rate differs from the calculated exposure rate by not more than 20
1307 percent, and shall conspicuously attach a correction chart or graph to the instrument.

1308

1309 (d) A licensee shall check each survey instrument for proper operation with a dedicated
1310 check source before each use. The licensee is not required to keep records of these checks.

1311

1312 (e) The licensee shall retain a record of each calibration required in G.4661(a) for 23 years.
1313 The record shall include:

1314

1315 (1) A description of the calibration procedure; and

1316

1317 (2) A description of the source used and the certified dose rates from the source, and

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1322 the rates indicated by the instrument being calibrated, the correction factors deduced from
1323 the calibration data, the signature of the individual who performed the calibration, and the
1324 date of calibration.

1325

1326 (f) To meet the requirements of G.1661(a), G.1661(b), and G.1661(c), the licensee may
1327 obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory
1328 Commission, an Agreement State, or a Licensing State to perform calibrations of survey
1329 instruments. Records of calibrations which contain information required by G.1661(e) shall be
1330 maintained by the licensee.

1331

1332 Sec. G.1763 Measurement Determination of Ddosages of Uunsealed Rradioactive Mmaterial for
1333 Mmedical Uuse. A licensee shall:

1334

1335 (a) A licensee shall Measure determine and record the activity of each dosage of a photon-
1336 emitting radionuclide prior to before medical use;

1337

1338 (b) ~~Measure, by direct measurement or by combination of measurements and calculations, the~~
1339 ~~activity of each dosage of an alpha or beta emitting radionuclide prior to medical use, except for~~
1340 ~~unit dosages obtained from a manufacturer or preparer licensed by the Agency pursuant to C.28(j);~~
1341 ~~or licensed by the NRC or any other Agreement State pursuant to provisions equivalent to C.28(j);~~
1342 ~~and~~

1343 (b) For a unit dosage, this determination must be made by:

1344

(1) Direct measurement of radioactivity; or

1345

(2) A decay correction, based on the activity or activity concentration determined by:

1346

(i) A manufacturer or preparer licensed under Sec. C.28, or equivalent NRC
1347 or Agreement State requirements; or

1348

(ii) An NRC or Agreement State licensee for use in research in accordance
1349 with a Radioactive Drug Research Committee-approved protocol or an
1350 Investigational New Drug (IND) protocol accepted by FDA.

1351

(c) For other than unit dosages, this determination must be made by:

1352

(1) Direct measurement of radioactivity;

1353

(2) Combination of measurement of radioactivity and mathematical calculations; or

1354

(3) Combination of volumetric measurements and mathematical calculations, based
1355 on the measurement made by a manufacturer or preparer licensed under Sec. C.28, or
1356 equivalent NRC or Agreement State requirements.

1357 (d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the
1358 dosage does not fall within the prescribed dosage range or if the dosage differs from the
1359 prescribed dosage by more than 20 percent.

1360 (e) A licensee shall retain a record of the measurements required by this section dosage
1361 determination required by G.2063 for three years. To satisfy this requirement, the record must
1362 contain the:

1363
1364 (1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot
1365 number, and expiration dates, and the radionuclide;

1366
1367 (2) Patient's or human research subject's name, and identification number if one has
1368 been assigned;

1369
1370 (3) Prescribed dosage and activity of the dosage at the time of measurement, or a
1371 notation that the total activity is less than 1.1 megabecquerels (30 microcuries);

1372
1373 (4) Date and time of the measurement; and

1374
1375 (5) Initials of the individual who made the record.

1376

1377 Sec. G.1865 Authorization for Calibration, Transmission, and Reference Sources. Any person
1378 authorized by G.311 for medical use of radioactive material may receive, possess, and use any of
1379 the following radioactive material for check, calibration, transmission, and reference use:

1380

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1383
 1384 (a) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by
 1385 a persons specifically licensed pursuant to Part C of these regulations under Sec. C.28, or
 1386 equivalent NRC provisions of the U.S. Nuclear Regulatory Commission, or Agreement State
 1387 requirements, or Licensing State and that do not exceed 15 millicuries (555 MBq) each;
 1388

1389 (b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee
 1390 authorized to redistribute the sealed sources manufactured and distributed by a person licensed
 1391 under Sec. C.28 or equivalent NRC or Agreement State regulations, providing the redistributed
 1392 sealed sources are in the original packaging and shielding and are accompanied by the
 1393 manufacturer's approved instructions.
 1394

1395 (c) Any radioactive material listed in G.29 or G.31 with a half-life of not longer than 100 120
 1396 days or less in individual amounts not to exceed 15 millicuries (555 MBq) 0.56 GBq (15 mCi).
 1397

1398 (ed) Any radioactive material listed in G.29 or G.31 with a half life greater longer than 100 120
 1399 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and the smaller of 7.4
 1400 MBq (200 μ Ci) or 1000 times the quantities in Sec. D Appendix C.
 1401

1402 (de) Technetium-99m in individual amounts as needed, not to exceed 50 millicuries (1.85
 1403 GBq).
 1404

1405 Sec. G.1967 Requirements for Possession of Sealed Sources and Brachytherapy Sources.
 1406

1407 (a) A licensee in possession of any sealed source or brachytherapy source shall follow the
 1408 radiation safety and handling instructions supplied by the manufacturer. ~~or equivalent instructions~~
 1409 ~~approved by the Agency and shall maintain the instructions for the duration of source use in a legible~~
 1410 ~~form convenient to users.~~

1411 (b) A licensee in possession of a sealed source shall: ~~assure that:~~

1412 ~~———— (1) ——— The source is tested~~

1413 (1) Test the source for leakage before its first use unless the licensee has a certificate
 1414 from the supplier indicating that the source was tested within 6 months before transfer to
 1415 the licensee; and
 1416

1417 (2) ~~———— The source is tested for leakage at intervals not to exceed 6 months or at intervals~~
 1418 ~~approved by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear~~
 1419 ~~Regulatory Commission.~~

1420 (2) Test the source for leakage at intervals not to exceed 6 months or at other
 1421 intervals approved by the NRC or an Agreement State in the Sealed Source and Device
 1422 Registry.
 1423

1424 (e) ~~———— To satisfy the leak test requirements of G.19(b), the licensee shall assure that:~~

1425 (1) ~~———— Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of~~
 1426 ~~radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of~~
 1427 ~~0.001 microcurie (37 Bq) per 24 hours;~~
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~~(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and~~

~~(3) Test samples are taken when the source is in the "off" position.~~

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 µCi) of radioactive material in the sample.

~~(d) A licensee shall retain leak test records for 5 years. The records shall~~

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1446 contain the model number, and serial number, if assigned, of each source tested, the identity of each
1447 source radionuclide and its estimated activity, the measured activity of each test sample expressed in
1448 microcuries (becquerels), a description of the method used to measure each test sample, the date of
1449 the test, and the signature of the Radiation Safety Officer.

1450

1451 (d) A licensee shall retain leak test records in accordance with G.2067(a).

1452

1453 ~~(e) If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable~~
1454 ~~contamination, the licensee shall:~~

1455

1456 ~~(1) Immediately withdraw the sealed source from use and store it in accordance with the~~
1457 ~~requirements of these regulations; and~~

1458

1459 ~~(2) File a report with the Agency within 5 days of receiving the leak test results~~
1460 ~~describing the equipment involved, the test results, and the action taken.~~

1461

1462 (e) If the leak test reveals the presence of 185 Bq (0.005 μ Ci) or more of removable
1463 contamination, the licensee shall:

1464

1465 (1) Immediately withdraw the sealed source from use and store, dispose, or cause it to
1466 be repaired in accordance with the requirements in Sec D.401; and

1467

1468 (2) File a report within 5 days of the leak test in accordance with Sec. D.1206.

1469

1470 (f) A licensee need not perform a leak test on the following sources:

1471

1472 (1) Sources containing only radioactive material with a half-life of less than 30 days;

1473

1474 (2) Sources containing only radioactive material as a gas;

1475

1476 ~~(3) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting~~
1477 ~~material or 10 microcuries (370 kBq) or less of alpha-emitting material; and~~

1478 (3) Sources containing 3.7 MBq (100 μ Ci) or less of beta or gamma-emitting material
1479 or 0.37 MBq (10 μ Ci) or less of alpha-emitting material;

1480

1481 (4) Seeds of iridium-192 encased in nylon ribbon; and

1482

1483 (5) Sources stored and not being used. ~~The licensee shall, however, test each such~~
1484 ~~source for leakage before any use or transfer unless it has been tested for leakage within 6~~
1485 ~~months before the date of use or transfer. However, the licensee shall test each such source~~
1486 for leakage before any use or transfer unless it has been leak tested within 6 months
1487 before the date of use or transfer.

1488

1489 ~~(g) A licensee in possession of a sealed source or brachytherapy source shall conduct a physical~~
1490 ~~inventory of all such sources at intervals not to exceed 3 months. The licensee shall retain each~~
1491 ~~inventory record for 5 years. The inventory records shall contain the model number of each source,~~

1492 ~~and serial number if one has been assigned, the identity of each source radionuclide and its~~
1493 ~~estimated activity, the location of each source, date of the inventory, and the signature of the~~
1494 ~~Radiation Safety Officer.~~

1495 (g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma
1496 stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such
1497 sources in its possession. The licensee shall retain each inventory record in accordance with
1498 G.2067(b).

1499
1500 ~~(h) A licensee in possession of a sealed source or brachytherapy source shall survey with a~~
1501 ~~radiation survey instrument at intervals not to exceed 3 months all areas where such sources are~~
1502 ~~stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in~~
1503 ~~diagnostic devices.~~

1504
1505 ~~(i) A licensee shall retain a record of each survey required in G.19(h) for 2 years. The record~~
1506 ~~shall include the date of the survey, a sketch of each area that is surveyed, the measured dose rate at~~
1507 ~~several points in each area expressed in millirems (microsieverts) per~~

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1511 hour, the model number and serial number of the survey instrument used to make the survey, and
1512 the signature of the Radiation Safety Officer.

1513 [NOTE: Old G.20, G.21, G.22, and G.23 rewritten as G.69.]

1514 Sec. G.20 Syringe Shields.

1515

1516 (a) ~~A licensee shall keep syringes that contain radioactive material to be administered in a~~
1517 ~~radiation shield.~~

1518

1519 (b) ~~A licensee shall require each individual who prepares or administers radiopharmaceuticals~~
1520 ~~to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or~~
1521 ~~human research subject.~~

1522

1523 Sec. G.21 Syringe Labels. ~~Unless utilized immediately, a licensee shall conspicuously label each~~
1524 ~~syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the~~
1525 ~~radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to~~
1526 ~~be performed, or the patient's or human research subject's name.~~

1527

1528 Sec. G.69 Labeling of Vials and Syringes.

1529 Each syringe and vial that contains unsealed radioactive material must be labeled to identify the
1530 radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the
1531 syringe or vial is visible when shielded.

1532 ~~Sec. G.22 Vial Shields.~~ ~~A licensee shall require each individual preparing or handling a vial that~~
1533 ~~contains a radiopharmaceutical to keep the vial in a vial radiation shield.~~

1534

1535 ~~Sec. G.23 Vial Shield Labels.~~ ~~A licensee shall conspicuously label each vial radiation shield that~~
1536 ~~contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.~~

1537

1538 Sec. G.2470. Surveys for Contamination and Ambient Radiation Dose Rate.

1539

1540 (a) A licensee shall survey with a radiation detection survey instrument at the end of each day
1541 of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

1542

1543 (b) A licensee shall survey with a radiation detection survey instrument at least once each week
1544 all areas where radiopharmaceuticals or radioactive wastes are stored.

1545

1546 (c) A licensee shall conduct the surveys required by G.2470(a) and G.70(b) so as to be able to
1547 measure dose rates as low as 0.1 millirem (1 μ Sv) per hour.

1548

1549 (d) A licensee shall establish dose rate action levels for the surveys required by G.2470(a) and
1550 G.70(b) and shall require that the individual performing the survey immediately notify the Radiation

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1554 Safety Officer if a dose rate exceeds an action level.

1555

1556 (e) A licensee shall survey for removable contamination once each week all areas where
1557 radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive
1558 materials are stored.

1559

1560 (f) A licensee shall conduct the surveys required by G.2470(e) so as to be able to detect
1561 contamination on each wipe sample of 200 disintegrations per minute (33.3 Bq).

1562

1563 (g) A licensee shall establish removable contamination action levels for the surveys required by
1564 G.2470(e) and shall require that the individual performing the survey immediately notify the Radiation
1565 Safety Officer if contamination exceeds action levels.

1566

1567 (h) A licensee shall retain a record of each survey required by G.2470(a), (b), and (e) for 23 years.
1568 The record must include the date of the survey, a sketch of each area surveyed, action levels established
1569 for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts)
1570 per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels)
1571 per 100 square centimeters, the serial number and the model number of the instrument used to make the
1572 survey or analyze the samples, and the initials of the individual who performed the survey.

1573

1574 Sec. G.2575 Release of Individuals Containing Radiopharmaceuticals-Unsealed Radioactive Material or
1575 Permanent Implants Containing Radioactive Material.

1576

1577 (a) ~~The licensee may authorize release from its control of any individual who has been administered~~
1578 ~~radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose~~
1579 ~~equivalent to any other individual from exposure to the released individual is not likely to exceed 5~~
1580 ~~millisieverts (0.5 rem).³~~

1581

1582 (a) A licensee may authorize the release from its control of any individual who has been
1583 administered unsealed radioactive material or implants containing radioactive material if the total
1584 effective dose equivalent to any other individual from exposure to the released individual is not
1585 likely to exceed 5 mSv (0.5 rem).¹

1586

1587 (b) ~~The licensee shall provide the released individual with written instructions, on actions~~
1588 ~~recommended to maintain doses to other individuals as low as is reasonably achievable if the total~~
1589 ~~effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to~~
1590 ~~a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption~~
1591 ~~of breast-feeding, the instructions shall also include:~~

1592

1593 (b) A licensee shall provide the released individual, or the individual's parent or guardian,
1594 with instructions, including written instructions, on actions recommended to maintain doses to
1595 other individuals as low as is reasonably achievable if the total effective dose equivalent to any
1596 other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a
1597 nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of
1598 breast-feeding, the instructions must also include:

1599

(1) Guidance on the interruption or discontinuation of breast-feeding; and

1600

1601 ³ ~~NRC Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials,"~~
1602 ~~describes methods for calculating doses to other individuals and contains tables of activities not likely to~~
1603 ~~cause doses exceeding 5 millisieverts (0.5 rem).~~

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1607 (2) Information on the potential consequences, if any, of failure to follow the guidance.

1608 (c) ~~A~~The licensee shall maintain a record of the basis for authorizing the release of an individual in
1609 accordance with G.2075(a), for 3 years after the date of release, if the total effective dose equivalent is
1610 calculated by:

1611 (1) ~~Using the retained activity rather than the activity administered;~~

1612 (2) ~~Using an occupancy factor less than 0.25 at one meter;~~

1613 (3) ~~Using the biological or effective half life; or~~

1614 (4) ~~Considering the shielding by tissue.~~

1615 (d) ~~The licensee shall maintain a record, for 3 years after the date of release, that instructions were~~
1616 ~~provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-~~
1617 ~~feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).~~

1618 (d) The licensee shall maintain a record of instructions provided to a breast-feeding female in
1619 accordance with G.2075(b).

1620 ¹ NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical
1621 Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses
1622 exceeding 5 mSv (0.5 rem).

1623 Sec. G.2680 Mobile Nuclear Medicine Service Technical Requirements Provision of Mobile Medical
1624 Service.

1625 A licensee providing mobile nuclear medicine service shall:

1626 (a) ~~Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals~~
1627 ~~or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;~~

1628 (b) ~~Bring into each location of use all radioactive material to be used and, before leaving, remove all~~
1629 ~~unused radioactive material and associated radioactive waste;~~

1630 (c) ~~Secure or keep under constant surveillance and immediate control all radioactive material when~~
1631 ~~in transit or at a location of use;~~

1632 (d) ~~Check survey instruments and dose calibrators as required in G.15(b)(1), G.15(d), G.15(e) and~~
1633 ~~G.16(d), and check all other transported equipment for proper function before medical use at each~~
1634 ~~location of use;~~

1635 (e) ~~Carry two calibrated survey meters in each vehicle that is being used to transport radioactive~~
1636 ~~material, and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a~~
1637 ~~radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated~~
1638 ~~radioactive waste have been removed; and~~

1639 (f) ~~Retain a record of each survey required by G.26(e) for 2 years. The record must include the date~~
1640 ~~of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area~~
1641 ~~of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument~~
1642 ~~used to make the survey, and the initials of the individual who performed the survey.~~

1643 (a) A licensee providing mobile medical service shall--

1644

- 1660 (1) Obtain a letter signed by the management of each client for which services are
1661 rendered that permits the use of radioactive material at the client's address and clearly
1662 delineates the authority and responsibility of the licensee and the client;
1663
1664 (2) Check instruments used to measure the activity of unsealed radioactive material
1665 for proper function before medical use at each client's address or on each day of use,
1666 whichever is more frequent. At a minimum, the check for proper function required by this
1667 paragraph must include a constancy check;
1668
1669 (3) Check survey instruments for proper operation with a dedicated check source
1670 before use at each client's address; and
1671
1672 (4) Before leaving a client's address, survey all areas of use to ensure compliance
1673 with the requirements in COMAR 26.12.01.01 Part D.
1674
1675 (b) A mobile medical service may not have radioactive material delivered from the
1676 manufacturer or the distributor to the client unless the client has a license allowing possession of
1677 the radioactive material. Radioactive material delivered to the client must be received and
1678 handled in conformance with the client's license.
1679
1680 (c) A licensee providing mobile medical services shall retain the letter required in
1681 G.80(a)(1) and the record of each survey required in paragraph G.80(a)(4) in accordance with
1682 G.2080(a) and (b), respectively.

1683 [NOTE: G.27 deleted.]

1684 ~~Sec. G.27 Storage of Volatiles and Gases.~~

1685 (a) ~~A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's~~
1686 ~~radiation shield and container.~~

1687 (b) ~~A licensee shall store and use a multidose container in a properly functioning fume hood.~~

1688 [NOTE: G.28 deleted.]

1689 ~~Sect. G.28 Reserved.~~

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1697 **Specific Requirements for the Use of Radiopharmaceuticals for**
1698 **Uptake, Dilution, or Excretion Studies**
1699 **Unsealed Radioactive Material--Written Directive Not Required**

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1702
1703 Sec. G.29100 Use of Radiopharmaceuticals--Unsealed Radioactive Material for Uptake, Dilution, or
1704 and Excretion Studies for which a Written Directive is Not Required.

1705
1706 Except for quantities that require a written directive under G.40(b), a licensee may use any
1707 unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies
1708 that is— A licensee may use for uptake, dilution, or excretion studies any unsealed radioactive
1709 material prepared for medical use that is either:

1710
1711 (a) Obtained from a manufacturer or preparer licensed by the Agency pursuant to C.28(j), or
1712 licensed by the NRC or any other Agreement State pursuant to provisions equivalent to C.28(j); or

1713
1714 (b) Prepared by an authorized nuclear pharmacist; a physician who is an authorized user and
1715 who meets the requirements specified in G.65G.290, or G.390 and G.290(c)(1)(ii)(g); or an
1716 individual under the supervision of either as specified in G.1027; or

1717
1718 (c) Obtained from and prepared by an NRC or Agreement State licensee for use in research
1719 in accordance with a Radioactive Drug Research Committee-approved protocol or an
1720 Investigational New Drug (IND) protocol accepted by FDA; or

1721
1722 (d) Prepared by the licensee for use in research in accordance with a Radioactive Drug
1723 Research Committee-approved application or an Investigational New Drug (IND) protocol
1724 accepted by FDA.

1725
1726 [NOTE: G.30 deleted.]

1727 Sec. G.30 Possession of Survey Instrument. A licensee authorized to use radioactive material for
1728 uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument
1729 capable of detecting dose rates over the range 0.1 millirem (1.0 μ Sv) per hour to 100 millirems
1730 (1000 μ Sv) per hour. The instrument shall be operable and calibrated in accordance with G.17.

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1734 **Specific Requirements for the Use of Radiopharmaceuticals, Generators,**
1735 **and Reagent Kits for Imaging and Localization Studies**

1736
1737
1738 [NOTE: G.190 replaces old G.65.]

1739 Sec. G.190 Training for Uptake, Dilution, and Excretion Studies.

1740
1741 Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive
1742 material for the uses authorized under G.100 to be a physician who:

1743 (a) Is certified by a medical specialty board whose certification process has been recognized
1744 by the NRC or an Agreement State and who meets the requirements in G.190(c)(2). (The names
1745 of board certifications which have been recognized by the NRC or an Agreement State will be
1746 posted on the NRC's Web page.) To have its certification process recognized, a specialty board
1747 shall require all candidates for certification to:

1748 (1) Complete 60 hours of training and experience in basic radionuclide handling
1749 techniques and radiation safety applicable to the medical use of unsealed radioactive
1750 material for uptake, dilution, and excretion studies that includes the topics listed in
1751 G.190(c)(1)(i) and G.190(c)(1)(ii); and

1752 (2) Pass an examination, administered by diplomates of the specialty board, that
1753 assesses knowledge and competence in radiation safety, radionuclide handling, and
1754 quality control; or

1755 (b) Is an authorized user under G.290, G.390, or equivalent NRC requirements; or

1756 (c) Has completed the following:

1757
1758 (1) 60 hours of training and experience, including a minimum of 8 hours of classroom
1759 and laboratory training, in basic radionuclide handling techniques applicable to
1760 the medical use of unsealed radioactive material for uptake, dilution, and
1761 excretion studies. The training and experience must include:

1762
1763 (i) Classroom and laboratory training in the following areas:

1764
1765 (a) Radiation physics and instrumentation;

1766
1767 (b) Radiation protection;

1768
1769 (c) Mathematics pertaining to the use and measurement of
1770 radioactivity;

1771
1772 (d) Chemistry of radioactive material for medical use; and

1773
1774 (e) Radiation biology; and

1775
1776 (ii) Work experience, under the supervision of an authorized user who meets
1777 the requirements in G.190, G.290, G.390, or equivalent NRC or Agreement State
1778 requirements, involving:

1779
1780 (a) Ordering, receiving, and unpacking radioactive materials safely
1781 and performing the related radiation surveys;

1782
1783 (b) Performing quality control procedures on instruments used to
1784 determine the activity of dosages and performing checks for proper
1785 operation of survey meters;

- 1786
1787 (c) Calculating, measuring, and safely preparing patient or human
1788 research subject dosages;
1789
1790 (d) Using administrative controls to prevent a misadministration
1791 involving the use of unsealed radioactive material;
1792
1793 (e) Using procedures to contain spilled radioactive material safely and
1794 using proper decontamination procedures; and
1795
1796 (f) Administering dosages of radioactive drugs to patients or human
1797 research subjects; and
1798
1799 (2) Has obtained written attestation, signed by a preceptor authorized user who meets
1800 the requirements in G.190, G.290, G.390, or equivalent NRC or Agreement State
1801 requirements, that the individual has satisfactorily completed the requirements in
1802 G.190(a)(1) or G.190(c)(1) and has achieved a level of competency sufficient to function
1803 independently as an authorized user for the medical uses authorized under G.100.
1804

1805 Sec. G.34200 Use of Unsealed Radioactive Material for Imaging and Localization Studies for
1806 Which a Written Directive is Not Required.
1807

1808 Except for quantities that require a written directive under G.40(b), Aa licensee may use any
1809 unsealed radioactive material prepared for medical use for imaging and localization studies any
1810 unsealed radioactive material prepared for medical use that is either:
1811

- 1812 (a) Obtained from a manufacturer or preparer licensed pursuant to under Sec. C.28(j) or
1813 equivalent Agreement State or NRC requirements; or
1814
1815 (b) Prepared by:
1816
1817 (1) Aan authorized nuclear pharmacist;
1818
1819 (2) Aa physician who is an authorized user and who meets the requirements specified in
1820 G.66290, or G.390 and G.290(c)(1)(ii)(g); or
1821
1822 (3) or Aan individual under the supervision, as specified in G.27, of either as specified
1823 in G.10 of the authorized nuclear pharmacist in G.200(b)(1) or the physician who is an
1824 authorized user in G.200(b)(2);
1825
1826 (c) Obtained from and prepared by an Agreement State licensee or NRC for use in research
1827 in accordance with a Radioactive Drug Research Committee-approved protocol or an
1828 Investigational New Drug (IND) protocol accepted by FDA; or
1829

1830 (d) Prepared by the licensee for use in research in accordance with a Radioactive Drug
1831 Research Committee-approved application or an Investigational New Drug (IND) protocol
1832 accepted by FDA.

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1836 [NOTE: G.204 is a rewrite of old G.32.]

1837 Sec. G.204 Permissible Molybdenum-99 Concentration.

1838

1839 (a) A licensee may not administer to humans a radiopharmaceutical that contains more than
1840 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie
1841 of molybdenum-99 per millicurie of technetium-99m).

1842

1843 (b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a
1844 technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the
1845 first eluate after receipt of a generator to demonstrate compliance with G.204(a).

1846

1847 (c) If a licensee is required to measure the molybdenum-99 concentration, the licensee shall
1848 retain a record of each measurement in accordance with G.2204.

1849 [NOTE: G.33 and G.34 deleted.]

1850 [NOTE: New G. 290 is a revision of old G.66.]

1851 Sec. G.290 Training for Imaging and Localization Studies.

1852

1853 Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive
1854 material for the uses authorized under G.200 to be a physician who:

1855

1856 (a) Is certified by a medical specialty board whose certification process has been recognized
1857 by an Agreement State or the NRC and who meets the requirements in G.290(c)(2). (The names
1858 of board certifications which have been recognized by the NRC or an Agreement State will be
1859 posted on the NRC's Web page.) To have its certification process recognized, a specialty board
1860 shall require all candidates for certification to:

1861

1862 (1) Complete 700 hours of training and experience in basic radionuclide handling
1863 techniques and radiation safety applicable to the medical use of unsealed radioactive
1864 material for imaging and localization studies that includes the topics listed in
1865 G.290(c)(1)(i) and G.290(c)(1)(ii); and

1866

1867 (2) Pass an examination, administered by diplomates of the specialty board, which
1868 assesses knowledge and competence in radiation safety, radionuclide handling, and
1869 quality control; or

1870

1871 (b) Is an authorized user under G.390 and meets the requirements in G.290(c)(1)(ii)(g), or
1872 equivalent Agreement State or NRC requirements; or

1873

1874 (c) Has completed the following:

1875

1876 (1) 700 hours of training and experience, including a minimum of 80 hours of
1877 classroom and laboratory training, in basic radionuclide handling techniques applicable to
1878 the medical use of unsealed radioactive material for imaging and localization studies. The
1879 training and experience must include, at a minimum:

1880

1881 (i) Classroom and laboratory training in the following areas:

1929 Sec. G.32 Permissible Molybdenum 99 Concentration. [See G.204.]

1930

1931 (a) ~~A licensee shall not administer a radiopharmaceutical containing more than 0.15 microcurie~~
1932 ~~of molybdenum 99 per millicurie of technetium 99m (0.15 kilobecquerel of molybdenum 99 per~~
1933 ~~megabecquerel of technetium 99m).~~

1934

1935 (b) ~~A licensee preparing technetium 99m radiopharmaceuticals from molybdenum-~~
1936 ~~99/technetium 99m generators shall measure the molybdenum 99 concentration in each eluate or~~
1937 ~~extract.~~

1938

1939 (c) ~~A licensee who must measure molybdenum concentration shall retain a record of each~~
1940 ~~measurement for 2 years. The record shall include, for each elution or extraction of technetium-~~
1941 ~~99m, the measured activity of the technetium expressed in millicuries (megabecquerels), the~~
1942 ~~measured activity of molybdenum expressed in microcuries (kilobecquerels), the ratio of the~~
1943 ~~measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of~~
1944 ~~molybdenum per megabecquerel of technetium), the date of the test, and the initials of the~~
1945 ~~individual who performed the test.~~

1946

1947 (d) ~~A licensee shall report immediately to the Agency each occurrence of molybdenum 99~~
1948 ~~concentration exceeding the limits specified in G.32(a).~~

1949

1950 Sec. G.33 Control of Aerosols and Gases:

1951

1952 (a) ~~A licensee who administers radioactive aerosols or gases shall do so with a system that will~~
1953 ~~keep airborne concentrations within the limits prescribed by D.701, D.702, D.703 and D.302 of~~
1954 ~~these regulations.~~

1955

1956 (b) ~~The system shall either be directly vented to the atmosphere through an air exhaust or~~
1957 ~~provide for collection and decay or disposal of the aerosol or gas in a shielded container.~~

1958

1959 (c) ~~A licensee shall only administer radioactive gases in rooms that are at negative pressure~~
1960 ~~compared to surrounding rooms.~~

1961

1962 (d) ~~Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount~~
1963 ~~of time needed after a release to reduce the concentration in the area of use to the occupational limit~~
1964 ~~listed in Appendix B Table I of Part D of these regulations. The calculation shall be based on the~~
1965 ~~highest activity of gas handled in a single container and the measured available air exhaust rate.~~

1966

1967 (e) ~~A licensee shall post the time calculated in G.33(d) at the area of use and require that, in~~
1968 ~~case of a gas spill, individuals evacuate the room until the posted time has elapsed.~~

1969

1970

1971

1972

1972 ~~(f) — A licensee shall check the operation of collection systems monthly and measure the~~
 1973 ~~ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and~~
 1974 ~~measurements shall be maintained for 2 years.~~

1975
 1976 ~~(g) — A copy of the calculations required in G.33(d) shall be recorded and retained for the~~
 1977 ~~duration of the license.~~

1978
 1979 ~~Sec. G.34 Possession of Survey Instruments. A licensee authorized to use radioactive material for~~
 1980 ~~imaging and localization studies shall possess a portable radiation detection survey instrument~~
 1981 ~~capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 100 millirems~~
 1982 ~~(1000 μ Sv) per hour, and a portable radiation measurement survey instrument capable of measuring~~
 1983 ~~dose rates over the range 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The~~
 1984 ~~instruments shall be operable and calibrated in accordance with G.16.~~

1985
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 1988 **Specific Requirements for the Use of Radiopharmaceuticals for Therapy**
 1989 **Unsealed Radioactive Material--Written Directive Required**
 1990

1991
 1992
 1993 ~~Sec. G.35300 Use of Unsealed Radioactive Material for Therapeutic Administration Which a~~
 1994 ~~Written Directive is Required.~~

1995
 1996 A licensee may use for therapeutic administration any unsealed radioactive material prepared for
 1997 medical use and for which a written directive is required that is either:

1998
 1999 (a) ~~Obtained from a manufacturer or preparer licensed pursuant to~~ under Sec. C.28(j) or
 2000 equivalent NRC or Agreement State or NRC requirements; or

2001
 2002 (b) Prepared by:

2003
 2004 (1) Aan authorized nuclear pharmacist;

2005
 2006 (2) Aa physician who is an authorized user and who meets the requirements specified in
 2007 G.67290 and G.390; or

2008
 2009 (3) Aan individual under the supervision, of either as specified in G.10, as specified in
 2010 G.27, of the authorized nuclear pharmacist in G.300(b)(1) or the physician who is an
 2011 authorized user in G.300(b)(2); or

2012 (c) Obtained from and prepared by an Agreement State or NRC licensee for use in research
 2013 in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

2014 (d) Prepared by the licensee for use in research in accordance with an Investigational New
 2015 Drug (IND) protocol accepted by FDA.

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Sec. G.36310 Safety Instruction.

In addition to the requirements of Sec. J.12:

(a) ~~A licensee shall provide oral and written radiation safety instruction, for all personnel caring for patients undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed 1 year, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under G.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:~~

(b) ~~To satisfy G.36(a), the instruction shall describe the licensee's procedures for:~~

- (1) Patient or human research subject control;

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2033 (2) Visitor control, including;

2034

2035 (i) Routine visitation to hospitalized individuals in accordance with Sec.
2036 D.301(a)(1); and

2037

2038 (ii) Visitation authorized in accordance with Sec. D.301(d);

2039

2040 (3) Contamination control;

2041

2042 (4) Waste control; and

2043

2044 (5) Notification of the Radiation Safety Officer, or his or her designee, and an or
2045 authorized user if the patient or the human research subject has a medical emergency or
2046 dies, in case of the patient's death or medical emergency; and

2047

2048 (6) ~~Part J training requirements.~~

2049

2050 (eb) ~~A licensee shall keep retain a record of individuals receiving instruction required by G.36(a),~~
2051 ~~a description of the instruction, the date of instruction, and the name of the individual who gave the~~
2052 ~~instruction in accordance with G.2310.—Such record shall be maintained for inspection by the~~
2053 ~~Agency for 2 years.~~

2054

2055 Sec. G.37315 Safety Precautions.

2056

2057 (a) ~~For each patient or human research subject who cannot be released under G.75, receiving~~
2058 ~~radiopharmaceutical therapy and hospitalized for compliance with G.25, a licensee shall:~~

2059

2060 (1) ~~Provide a private room with a private sanitary facility;~~

2061

2062 (1) Quarter the patient or the human research subject either in:

2063

2064 (i) A private room with a private sanitary facility; or

2065

2066 (ii) A room, with a private sanitary facility, with another individual who also
2067 has received therapy with unsealed radioactive material and who also cannot be
2068 released under G.75;

2069

2070 (2) ~~Post the patient's or the human research subject's door with a "Caution: Radioactive~~
2071 ~~Material" sign and note on the door or on the patient's chart where and how long visitors~~
2072 ~~may stay in the patient's or human research subject's room;~~

2073

2074 (2) Visibly post the patient's or the human research subject's room with a
2075 "Radioactive Materials" sign.

2076

2077 (3) ~~Authorize visits by individuals under 18 years of age only on a case-by-case basis~~
2078 ~~with the approval of the authorized user after consultation with the Radiation Safety Officer;~~

2079

2080 (3) Note on the door or in the patient's or human research subject's chart where and
2081 how long visitors may stay in the patient's or the human research subject's room; and

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~~(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of D.301 of these regulations and retain for 2 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey;~~

(54) Either monitor material and items removed from the patient's or the human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items

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2096 as radioactive waste;

2097

2098 ~~(6) Provide the patient or human research subject with radiation safety guidance that~~
2099 ~~will help to keep radiation dose to household members and the public as low as reasonably~~
2100 ~~achievable before authorizing release of the patient or human research subject;~~

2101

2102 ~~(7) Survey the patient's or human research subject's room and private sanitary facility~~
2103 ~~for removable contamination with a radiation detection survey instrument before assigning~~
2104 ~~another patient or human research subject to the room. The room must not be reassigned~~
2105 ~~until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100~~
2106 ~~square centimeters; and~~

2107

2108 ~~(8) Measure the thyroid burden of each individual who helped prepare or administer a~~
2109 ~~dosage of iodine-131 within 3 days after administering the dosage, and retain for the period~~
2110 ~~required by D.1107 of these regulations a record of each thyroid burden measurement, date~~
2111 ~~of measurement, the name of the individual whose thyroid burden was measured, and the~~
2112 ~~initials of the individual who made the measurements.~~

2113

2114 (b) A licensee shall notify the Radiation Safety Officer, or his or her designee, or the and the
2115 authorized user immediately as soon as possible if the patient or human research subject dies or has
2116 a medical emergency or dies.

2117 [NOTE: G.38 deleted.]

2118 Sec. G.38 Possession of Survey Instruments. A licensee authorized to use radioactive material for
2119 radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable
2120 of detecting dose rates over the range 0.1 millirem (1 μ Sv) per hour to 100 millirems (1000 μ Sv) per
2121 hour, and a portable radiation measurement survey instrument capable of measuring dose rates over
2122 the range 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall
2123 be operable and calibrated in accordance with G.16.

2124 [NOTE: Old G.67 rewritten as G.390.]

2125 Sec. G.390 Training for Use of Unsealed Radioactive Material for Which a Written Directive is
2126 Required.

2127

2128 Except as provided in G.57, the licensee shall require an authorized user of unsealed radioactive
2129 material for the uses authorized under G.300 to be a physician who:

2130 (a) Is certified by a medical specialty board whose certification process has been recognized
2131 by the NRC or an Agreement State and who meets the requirements in G.390(b)(1)(ii)(g) and
2132 G.390(b)(2). (Specialty boards whose certification processes have been recognized by the NRC
2133 or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty
2134 board shall require all candidates for certification to:

2135 (1) Successfully complete residency training in a radiation therapy or nuclear
2136 medicine training program or a program in a related medical specialty. These residency
2137 training programs must include 700 hours of training and experience as described in
2138 G.390(b)(1)(i) through G.390(b)(1)(ii)(c). Eligible training programs must be approved
2139 by the Residency Review Committee of the Accreditation Council for Graduate Medical

- 2140 Education, the Royal College of Physicians and Surgeons of Canada, or the Committee
2141 on Post-Graduate Training of the American Osteopathic Association; and
- 2142 (2) Pass an examination, administered by diplomates of the specialty board, which
2143 tests knowledge and competence in radiation safety, radionuclide handling, quality
2144 assurance, and clinical use of unsealed radioactive material for which a written directive
2145 is required; or
- 2146 (b) (1) Has completed 700 hours of training and experience, including a minimum of 200
2147 hours of classroom and laboratory training, in basic radionuclide handling techniques
2148 applicable to the medical use of unsealed radioactive material requiring a written
2149 directive. The training and experience must include:
- 2150 (i) Classroom and laboratory training in the following areas:
- 2151 (a) Radiation physics and instrumentation;
- 2152 (b) Radiation protection;
- 2153 (c) Mathematics pertaining to the use and measurement of
2154 radioactivity;
- 2155 (d) Chemistry of radioactive material for medical use; and
- 2156 (e) Radiation biology; and
- 2157 (ii) Work experience, under the supervision of an authorized user who meets
2158 the requirements in G.390, or equivalent Agreement State or NRC requirements.
2159 A supervising authorized user, who meets the requirements in G.390(b), must also
2160 have experience in administering dosages in the same dosage category or
2161 categories (i.e., G.390(b)(1)(ii)(g)) as the individual requesting authorized user
2162 status. The work experience must involve:
- 2163 (a) Ordering, receiving, and unpacking radioactive materials safely
2164 and performing the related radiation surveys;
- 2165 (b) Performing quality control procedures on instruments used to
2166 determine the activity of dosages, and performing checks for proper
2167 operation of survey meters;
- 2168 (c) Calculating, measuring, and safely preparing patient or human
2169 research subject dosages;
- 2170 (d) Using administrative controls to prevent a misadministration
2171 involving the use of unsealed radioactive material;

2172 (e) Using procedures to contain spilled radioactive material safely and
2173 using proper decontamination procedures;

2174 (f) [Reserved]

2175 (g) Administering dosages of radioactive drugs to patients or human
2176 research subjects involving a minimum of three cases in each of the
2177 following categories for which the individual is requesting authorized user
2178 status:

2179 (1) Oral administration of less than or equal to 1.22
2180 gigabecquerels (33 millicuries) of sodium iodide I-131, for which
2181 a written directive is required;

2182 (2) Oral administration of greater than 1.22 gigabecquerels (33
2183 millicuries) of sodium iodide I-131;²

2184 (3) Parenteral administration of any beta emitter, or a photon-
2185 emitting radionuclide with a photon energy less than 150 keV, for
2186 which a written directive is required; and/or

2187 (4) Parenteral administration of any other radionuclide, for
2188 which a written directive is required; and

2189 (2) Has obtained written attestation that the individual has satisfactorily completed
2190 the requirements in G.390(a)(1) and G.390(b)(1)(ii)(g) or G.390(b)(1), and has achieved
2191 a level of competency sufficient to function independently as an authorized user for the
2192 medical uses authorized under G.300. The written attestation must be signed by a
2193 preceptor authorized user who meets the requirements in G.390 or equivalent Agreement
2194 State or NRC requirements. The preceptor authorized user, who meets the requirements
2195 in G.390(b), must have experience in administering dosages in the same dosage category
2196 or categories (i.e., G.390(b)(1)(ii)(g)) as the individual requesting authorized user status.

2197

2198 ² Experience with at least 3 cases in G.390(b)(1)(ii)(g)(2) also satisfies the requirement in Category
2199 G.390(b)(1)(ii)(g)(1)

2200

2201 Sec. G.392 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written
2202 Directive in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicuries).

2203

2204 Except as provided in G.57, the licensee shall require an authorized user for the oral
2205 administration of sodium iodide I-131 requiring a written directive in quantities less than or
2206 equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

2207 (a) Is certified by a medical specialty board whose certification process includes all of the
2208 requirements in G.392(c)(1) and G.392(c)(2) and whose certification process has been
2209 recognized by the NRC or an Agreement State and who meets the requirements in G.392(c)(3).
2210 (The names of board certifications which have been recognized by the NRC or an Agreement
2211 State will be posted on the NRC's Web page.); or

2212 (b) Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(1) or (2), G.394, or
2213 equivalent Agreement State or NRC requirements; or

2214

2215 (c) (1) Has successfully completed 80 hours of classroom and laboratory training,
2216 applicable to the medical use of sodium iodide I-131 for procedures requiring a written
2217 directive. The training must include:

2218 (i) Radiation physics and instrumentation;

2219 (ii) Radiation protection;

2220 (iii) Mathematics pertaining to the use and measurement of radioactivity;

2221 (iv) Chemistry of radioactive material for medical use; and

2222 (v) Radiation biology; and

2223 (2) Has work experience, under the supervision of an authorized user who meets the
2224 requirements in G.390, G.392, G.394, or equivalent Agreement State or NRC
2225 requirements. A supervising authorized user who meets the requirements in G.390(b)
2226 must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(1)
2227 or (2). The work experience must involve:

2228 (i) Ordering, receiving, and unpacking radioactive materials safely and
2229 performing the related radiation surveys;

2230

2231 (ii) Performing quality control procedures on instruments used to determine
2232 the activity of dosages and performing checks for proper operation of survey
2233 meters;

2234 (iii) Calculating, measuring, and safely preparing patient or human research
2235 subject dosages;

- 2236 (iv) Using administrative controls to prevent a misadministration involving the
2237 use of radioactive material;
- 2238 (v) Using procedures to contain spilled radioactive material safely and using
2239 proper decontamination procedures; and
- 2240 (vi) Administering dosages to patients or human research subjects, that
2241 includes at least 3 cases involving the oral administration of less than or equal to
2242 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and
- 2243 (3) Has obtained written attestation that the individual has satisfactorily completed
2244 the requirements in G.392(c)(1) and G.392(c)(2), and has achieved a level of competency
2245 sufficient to function independently as an authorized user for medical uses authorized
2246 under G.300. The written attestation must be signed by a preceptor authorized user who
2247 meets the requirements in G.390, G.392, or G.394, or equivalent Agreement State or
2248 NRC requirements. A preceptor authorized user, who meets the requirement in G.390(b),
2249 must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(1)
2250 or (2).
- 2251 Sec. G.394 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written
2252 Directive in Quantities Greater than 1.22 Gigabecquerels (33 millicuries).
2253
- 2254 Except as provided in G.57, the licensee shall require an authorized user for the oral
2255 administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22
2256 Gigabecquerels (33 millicuries), to be a physician who:
- 2257 (a) Is certified by a medical specialty board whose certification process includes all of the
2258 requirements in G.394(c)(1) and G.394(c)(2), and whose certification has been recognized by the
2259 NRC or an Agreement State, and who meets the requirements in paragraph G.394(c)(3). (The
2260 names of board certifications which have been recognized by the NRC or an Agreement State
2261 will be posted on the NRC's Web page.); or
- 2262 (b) Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(2) or equivalent
2263 Agreement State or NRC requirements; or
- 2264 (c) (1) Has successfully completed 80 hours of classroom and laboratory training,
2265 applicable to the medical use of sodium iodide I-131 for procedures requiring a written
2266 directive. The training must include:
- 2267 (i) Radiation physics and instrumentation;
- 2268 (ii) Radiation protection;
- 2269 (iii) Mathematics pertaining to the use and measurement of radioactivity;
- 2270 (iv) Chemistry of radioactive material for medical use; and

- 2271 (v) Radiation biology; and
- 2272 (2) Has work experience, under the supervision of an authorized user who meets the
2273 requirements in G.390, G.394, or equivalent Agreement State or NRC requirements. A
2274 supervising authorized user, who meets the requirements in G.390(b), must also have
2275 experience in administering dosages as specified in G.390(b)(1)(ii)(g)(2). The work
2276 experience must involve:
- 2277 (i) Ordering, receiving, and unpacking radioactive materials safely and
2278 performing the related radiation surveys;
- 2279 (ii) Performing quality control procedures on instruments used to determine
2280 the activity of dosages and performing checks for proper operation of survey
2281 meters;
- 2282 (iii) Calculating, measuring, and safely preparing patient or human research
2283 subject dosages;
- 2284 (iv) Using administrative controls to prevent a misadministration involving the
2285 use of radioactive material;
- 2286 (v) Using procedures to contain spilled radioactive material safely and using
2287 proper decontamination procedures; and
- 2288 (vi) Administering dosages to patients or human research subjects, that
2289 includes at least 3 cases involving the oral administration of greater than 1.22
2290 gigabecquerels (33 millicuries) of sodium iodide I-131; and
- 2291 (3) Has obtained written attestation that the individual has satisfactorily completed
2292 the requirements in G.394(c)(1) and G.394(c)(2), and has achieved a level of competency
2293 sufficient to function independently as an authorized user for medical uses authorized
2294 under G.300. The written attestation must be signed by a preceptor authorized user who
2295 meets the requirements in G.390 or G.394, or equivalent Agreement State or NRC
2296 requirements. A preceptor authorized user, who meets the requirements in G.390(b),
2297 must also have experience in administering dosages as specified in G.390(b)(1)(ii)(g)(2).
- 2298 Sec. G.396 Training for the Parenteral Administration of Unsealed Radioactive Material
2299 Requiring a Written Directive.
- 2300
- 2301 Except as provided in G.57, the licensee shall require an authorized user for the parenteral
2302 administration requiring a written directive, to be a physician who:
- 2303 (a) Is an authorized user under G.390 for uses listed in G.390(b)(1)(ii)(g)(3) or
2304 G.390(b)(1)(ii)(g)(4), or equivalent Agreement State or NRC requirements; or

- 2305 (b) Is an authorized user under G.490 or G.690, or equivalent Agreement State or NRC
2306 requirements and who meets the requirements in G.396(d); or
- 2307 (c) Is certified by a medical specialty board whose certification process has been recognized
2308 by the NRC or an Agreement State under G.490 or G.690, and who meets the requirements in
2309 G.396(d).
- 2310 (d) (1) Has successfully completed 80 hours of classroom and laboratory training,
2311 applicable to parenteral administrations, for which a written directive is required, of any
2312 beta emitter, or any photon-emitting radionuclide with a photon energy less than 150
2313 keV, and/or parenteral administration of any other radionuclide for which a written
2314 directive is required. The training must include:
- 2315 (i) Radiation physics and instrumentation;
- 2316 (ii) Radiation protection;
- 2317 (iii) Mathematics pertaining to the use and measurement of radioactivity;
- 2318 (iv) Chemistry of radioactive material for medical use; and
- 2319 (v) Radiation biology; and
- 2320 (2) Has work experience, under the supervision of an authorized user who meets the
2321 requirements in G.390 or G.396, or equivalent Agreement State or NRC requirements, in
2322 the parenteral administration, for which a written directive is required, of any beta
2323 emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV,
2324 and/or parenteral administration of any other radionuclide for which a written directive is
2325 required. A supervising authorized user who meets the requirements in G.390 must have
2326 experience in administering dosages as specified in G.390(b)(1)(ii)(g)(3) and/or
2327 G.390(b)(1)(ii)(g)(4). The work experience must involve:
- 2328 (i) Ordering, receiving, and unpacking radioactive materials safely, and
2329 performing the related radiation surveys;
- 2330 (ii) Performing quality control procedures on instruments used to determine
2331 the activity of dosages, and performing checks for proper operation of survey
2332 meters;
- 2333 (iii) Calculating, measuring, and safely preparing patient or human research
2334 subject dosages;
- 2335 (iv) Using administrative controls to prevent a misadministration involving the
2336 use of unsealed radioactive material;

2337 (v) Using procedures to contain spilled radioactive material safely, and using
 2338 proper decontamination procedures; and

2339 (vi) Administering dosages to patients or human research subjects, that include
 2340 at least 3 cases involving the parenteral administration, for which a written
 2341 directive is required, of any beta emitter, or any photon-emitting radionuclide
 2342 with a photon energy less than 150 keV and/or at least 3 cases involving the
 2343 parenteral administration of any other radionuclide, for which a written directive
 2344 is required; and

2345 (3) Has obtained written attestation that the individual has satisfactorily completed
 2346 the requirements in G.396(b) or (c), and has achieved a level of competency sufficient to
 2347 function independently as an authorized user for the parenteral administration of unsealed
 2348 radioactive material requiring a written directive. The written attestation must be signed
 2349 by a preceptor authorized user who meets the requirements in G.390, G.396, or
 2350 equivalent Agreement State or NRC requirements. A preceptor authorized user, who
 2351 meets the requirements in G.390, must have experience in administering dosages as
 2352 specified in G.390(b)(1)(ii)(g)(3) and/or G.390(b)(1)(ii)(g)(4).

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2357

Manual Brachytherapy

Specific Requirements for the Use of Sealed Sources for Diagnosis

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2361

2362 **[NOTE: G.39 rewritten as G.500.]**

2363 **Sec. G.39 Use of Sealed Sources for Diagnosis.** A licensee shall use the following sealed sources
 2364 in accordance with the manufacturer's radiation safety and handling instructions:

2365

2366 (a) ~~Iodine 125 as a sealed source in a device for bone mineral analysis;~~

2367

2368 (b) ~~Americium 241 as a sealed source in a device for bone mineral analysis;~~

2369

2370 (c) ~~Gadolinium 153 as a sealed source in a device for bone mineral analysis; and~~

2371

2372 (d) ~~Iodine 125 as a sealed source in a portable device for imaging.~~

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2376 [NOTE: Old G.40 wording deleted.]

2377 Sec. G.40 Availability of Survey Instrument. A licensee authorized to use radioactive material
2378 as a sealed source for diagnostic purposes shall have available for use a portable radiation
2379 detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 μ Sv)
2380 per hour to 100 millirems (1000 μ Sv) per hour or a portable radiation measurement survey
2381 instrument capable of measuring dose rates over the range 1 millirem (10 μ Sv) per hour to 1000
2382 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with
2383 G.17.

2384

2385

2386

2387 Specific Requirements for the Use of Sources for Brachytherapy

2388

2389

2390

2391 Sec. G.41400 Use of Sources for Manual Brachytherapy. A licensee shall use only brachytherapy
2392 sources for therapeutic medical uses:

2393 (a) As approved in the Sealed Source and Device Registry; or

2394 (b) In research in accordance with an active Investigational Device Exemption (IDE)
2395 application accepted by the FDA provided the requirements of G.49(a) are met.

2396 the following sources in accordance with the manufacturer's radiation safety and handling
2397 instructions:

2398

2399 (a) Cesium 137 as a sealed source in needles and applicator cells for topical, interstitial, and
2400 intracavitary treatment of cancer;

2401

2402 (b) Cobalt 60 as a sealed source in needles and applicator cells for topical, interstitial, and
2403 intracavitary treatment of cancer;

2404

2405 (c) Gold 198 as a sealed source in seeds for interstitial treatment of cancer;

2406

2407 (d) Iodine 125 as a sealed source in seeds for interstitial treatment of cancer;

2408

2409 (e) Iridium 192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

2410

2411 (f) Radium 226 as a sealed source in needles or applicator cells for topical, interstitial, and
2412 intracavitary treatment of cancer;

2413

2414 (g) Radon 222 as seeds for interstitial treatment of cancer;

2415

2416 (h) Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions;
2417 and

2418

2419 ~~(i) Palladium 103 as a sealed source in seeds for the interstitial treatment of cancer.~~

2420 [NOTE: New G.404 has some of the language in old G.44.]

2421 Sec. G.404 Surveys after Source Implant and Removal.

2422 (a) Immediately after implanting sources in a patient or a human research subject, the
2423 licensee shall make a survey to locate and account for all sources that have not been implanted.

2424 (b) Immediately after removing the last temporary implant source from a patient or a human
2425 research subject, the licensee shall make a survey of the patient or the human research subject
2426 with a radiation detection survey instrument to confirm that all sources have been removed.

2427 (c) A licensee shall retain a record of the surveys required by G.404(a) and G.404(b) in
2428 accordance with G.2404.

2429 Sec. G.406 Brachytherapy Sources Accountability.

2430 (a) A licensee shall maintain accountability at all times for all brachytherapy sources in
2431 storage or use.

2432 (b) As soon as possible after removing sources from a patient or a human research subject, a
2433 licensee shall return brachytherapy sources to a secure storage area.

2434 (c) A licensee shall maintain a record of the brachytherapy source accountability in
2435 accordance with G.2406.

2436 Sec. G.42410 Safety Instruction. In addition to the requirements of Sec. J.12,

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2441 (a) The licensee shall provide ~~oral and written~~ radiation safety instruction, initially and at least
 2442 annually, to all personnel caring for a patient or human research subjects who are receiving ~~implant~~
 2443 therapy. ~~Refresher training shall be provided at intervals not to exceed 1 year.~~ brachytherapy and
 2444 cannot be released under G.75. To satisfy this requirement, the instruction must be
 2445 commensurate with the duties of the personnel and include the:

2446
 2447 (b) ~~To satisfy G.42(a), the instruction shall describe:~~

- 2448
- 2449 (1) Size and appearance of the brachytherapy sources;
 - 2450
 - 2451 (2) Safe handling and shielding instructions ~~in case of a dislodged source;~~
 - 2452
 - 2453 (3) ~~Procedures for patient or human research subject control;~~
 - 2454
 - 2455 (4) ~~Procedures for v~~Visitor control, including both;
 - 2456
 - 2457 (i) Routine visitation of hospitalized individuals in accordance with Sec.
 2458 D.301(a)(1); and
 - 2459
 - 2460 (ii) Visitation authorized in accordance with Sec. D.301(d); and
 - 2461
 - 2462 (5) ~~Procedures for n~~Notification of the Radiation Safety Officer, or his or her designee,
 2463 and or an authorized user if the patient or the human research subject dies or has a medical
 2464 emergency or dies.; and
 - 2465
 - 2466 ~~(6) Part J training requirements.~~

2467
 2468 (eb) A licensee shall ~~maintain~~retain a record of individuals receiving instruction in accordance
 2469 with G.2310, required by G.42(a), a description of the instruction, the date of instruction, and the
 2470 name of the individual who gave the instruction for 2 years.

2471
 2472 Sec. G.43415 Safety Precautions.

2473
 2474 (a) For each patient or human research subject who is receiving brachytherapy and cannot be
 2475 released under G.75, a licensee shall: ~~receiving implant therapy a licensee shall:~~

- 2476
- 2477 (1) ~~Not place the patient or human research subject in the same room with a patient or~~
 2478 ~~human research subject who is not receiving radiation therapy unless the licensee can~~
 2479 ~~demonstrate compliance with the requirement of D.301 of these regulations at a distance of~~
 2480 ~~1 meter from the implant;~~
 - 2481
 - 2482 (2) ~~Post the patient's or human research subject's door with a "Caution: Radioactive~~
 2483 ~~Materials" sign and note on the door or the patient's or human research subject's chart where~~
 2484 ~~and how long visitors may stay in the patient's or human research subject's room;~~
- 2485

2486 ~~(3) Authorize visits by individuals under 18 years of age only on a case by case basis~~
2487 ~~with the approval of the authorized user after consultation with the Radiation Safety Officer;~~

2488

2489 (1) Not quarter the patient or the human research subject in the same room as an
2490 individual who is not receiving brachytherapy;

2491

2492 (2) Visibly post the patient's or human research subject's room with a "Radioactive
2493 Materials" sign; and

2494

2495 (3) Note on the door or in the patient's or human research subject's chart where and
2496 how long visitors may stay in the patient's or human research subject's room.

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2500 ~~(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted~~
2501 ~~and unrestricted areas with a radiation measurement survey instrument to demonstrate~~
2502 ~~compliance with D.301 of these regulations and retain for 3 years a record of each survey~~
2503 ~~that includes the time and date of the survey, a sketch of the area or list of points surveyed,~~
2504 ~~the measured dose rate at several points expressed in millirems (μ Sv) per hour, the~~
2505 ~~instrument used to make the survey, and the initials of the individual who made the survey;~~
2506 ~~and~~

2507
2508 ~~(5) Provide the patient or human research subject with radiation safety guidance that~~
2509 ~~will help keep the radiation dose to household members and the public as low as reasonably~~
2510 ~~achievable before releasing the patient or human research subject if the patient or human~~
2511 ~~research subject was administered a permanent implant.~~

2512 (b) A licensee shall have applicable emergency response equipment available near each
2513 treatment room to respond to a source:

2514
2515 (1) Dislodged from the patient; and

2516
2517 (2) Lodged within the patient following removal of the source applicators.

2518
2519 ~~(b) A licensee shall notify the Radiation Safety Officer or authorized user immediately if the~~
2520 ~~patient or human research subject dies or has a medical emergency.~~

2521 (c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an
2522 authorized user as soon as possible if the patient or human research subject has a medical
2523 emergency or dies.

2524 Sec. G.432 Calibration Measurements of Brachytherapy Sources.

2525 (a) Before the first medical use of a brachytherapy source on or after the date of these
2526 regulations, a licensee shall have:

2527 (1) Determined the source output or activity using a dosimetry system that meets the
2528 requirements of G.630(a);

2529 (2) Determined source positioning accuracy within applicators; and

2530 (3) Used published protocols currently accepted by nationally recognized bodies to
2531 meet the requirements of G.432(a)(1) and G.432(a)(2).

2532 (b) Instead of a licensee making its own measurements as required in G.432(a), the licensee
2533 may use measurements provided by the source manufacturer or by a calibration laboratory
2534 accredited by the American Association of Physicists in Medicine that are made in accordance
2535 with G.432(a).

2536 (c) A licensee shall mathematically correct the outputs or activities determined in G.432(a)
2537 for physical decay at intervals consistent with 1 percent physical decay.

2538 (d) A licensee shall retain a record of each calibration in accordance with G.2432.

2539 Sec. G.433 Decay of Strontium-90 Sources for Ophthalmic Treatments.

2540 (a) Only an authorized medical physicist shall calculate the activity of each strontium-90
2541 source that is used to determine the treatment times for ophthalmic treatments. The decay must
2542 be based on the activity determined under G.432.

2543 (b) A licensee shall retain a record of the activity of each strontium-90 source in accordance
2544 with G.2433.

2545 Sec. G.457 Therapy-related Computer Systems.

2546 The licensee shall perform acceptance testing on the treatment planning system of therapy-
2547 related computer systems in accordance with published protocols accepted by nationally
2548 recognized bodies. At a minimum, the acceptance testing must include, as applicable,
2549 verification of:

2550 (a) The source-specific input parameters required by the dose calculation algorithm;

2551 (b) The accuracy of dose, dwell time, and treatment time calculations at representative
2552 points;

2553 (c) The accuracy of isodose plots and graphic displays; and

2554 (d) The accuracy of the software used to determine sealed source positions from radiographic
2555 images.

2556 [NOTE: G.44 deleted, but some language now in G.404.]

2557 Sec. G.44 Brachytherapy Sources Inventory.

2558

2559 ~~(a) Each time brachytherapy sources are returned to an area of storage from an area of use, the~~
2560 ~~licensee shall immediately count or otherwise verify the number returned to ensure that all sources~~
2561 ~~taken from the storage area have been returned.~~

2562

2563 ~~(b) A licensee shall make a record of brachytherapy source utilization which includes:~~

2564

2565 ~~— (1) The names of the individuals permitted to handle the sources;~~

2566

2567 ~~— (2) The number and activity of sources removed from storage, the room number of use~~
2568 ~~and patient's or the human research subject's name, the time and date they were removed~~
2569 ~~from storage, the number and activity of sources in storage after the removal, and the initials~~
2570 ~~of the individual who removed the sources from storage; and~~

2571

2572 ~~— (3) The number and activity of sources returned to storage, the room number of use and~~
2573 ~~patient's or human research subject's name, the time and date they were returned to storage;~~

2574 ~~the number and activity of sources in storage after the return, and the initials of the~~
2575 ~~individual who returned the sources to storage.~~

2576
2577 (e) ~~Immediately after implanting sources in a patient or human research subject and~~
2578 ~~immediately after removal of sources from a patient or human research subject, the licensee~~
2579 ~~shall make a radiation survey of the patient or human research subject and the area of use,~~
2580 ~~using an appropriate hand held survey instrument, to confirm that no sources have been~~
2581 ~~misplaced. The licensee shall make a record of each survey.~~

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2585 (d) A licensee shall maintain the records required in G.44(b) and (c) for 3 years.

2586 [NOTE: G.45 deleted.]

2587 Sec. G.45 Release of Patients or Human Research Subjects Treated With Temporary Implants.

2588

2589 (a) ~~Immediately after removing the last temporary implant source from a patient or human~~
2590 ~~research subject, the licensee shall perform a radiation survey of the patient or human research~~
2591 ~~subject with a hand held radiation detection survey instrument to confirm that all sources have been~~
2592 ~~removed. The licensee shall not release from confinement for medical care a patient or human~~
2593 ~~research subject treated by temporary implant until all sources have been removed.~~

2594

2595 (b) ~~A licensee shall maintain a record of patient or human research subject surveys which~~
2596 ~~demonstrate compliance with G.45(a) for 2 years. Each record shall include the date of the survey,~~
2597 ~~the name of the patient or human research subject, the dose rate from the patient or human research~~
2598 ~~subject expressed as millirems (microsieverts) per hour and measured within 1 meter from the~~
2599 ~~patient or human research subject, and the initials of the individual who made the survey.~~

2600 [NOTE: G.46 deleted.]

2601 Sec. G.46 Possession of Survey Instruments. ~~A licensee authorized to use radioactive material for~~
2602 ~~implant therapy shall possess a portable radiation detection survey instrument capable of detecting~~
2603 ~~dose rates over the range 0.1 millirem (1 μ Sv) per hour to 100 millirems (1000 μ Sv) per hour, and a~~
2604 ~~portable radiation measurement survey instrument capable of measuring dose rates over the range 1~~
2605 ~~millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable~~
2606 ~~and calibrated in accordance with G.16.~~

2607 [NOTE: Old G.68 replaced by G.490.]

2608 Sec. G.490 Training for Use of Manual Brachytherapy Sources.

2609

2610 Except as provided in G.57, the licensee shall require an authorized user of a manual
2611 brachytherapy source for the uses authorized under G.400 to be a physician who:

2612 (a) Is certified by a medical specialty board whose certification process has been recognized
2613 by the NRC or an Agreement State, and who meets the requirements in G.490(b)(3). (The names
2614 of board certifications which have been recognized by the NRC or an Agreement State will be
2615 posted on the NRC's Web page.) To have its certification process recognized, a specialty board
2616 shall require all candidates for certification to:

2617 (1) Successfully complete a minimum of 3 years of residency training in a radiation
2618 oncology program approved by the Residency Review Committee of the Accreditation
2619 Council for Graduate Medical Education or the Royal College of Physicians and
2620 Surgeons of Canada or the Committee on Post-Graduate Training of the American
2621 Osteopathic Association; and

2622 (2) Pass an examination, administered by diplomates of the specialty board, that tests
2623 knowledge and competence in radiation safety, radionuclide handling, treatment
2624 planning, quality assurance, and clinical use of manual brachytherapy; or

2625 (b) (1) Has completed a structured educational program in basic radionuclide handling
2626 techniques applicable to the use of manual brachytherapy sources that includes:

- 2627 (i) 200 hours of classroom and laboratory training in the following areas:
- 2628 (a) Radiation physics and instrumentation;
- 2629 (b) Radiation protection;
- 2630 (c) Mathematics pertaining to the use and measurement of
2631 radioactivity; and
- 2632
- 2633 (d) Radiation biology; and
- 2634 (ii) 500 hours of work experience, under the supervision of an authorized user
2635 who meets the requirements in G.490 or equivalent Agreement State or NRC
2636 requirements at a medical institution, involving:
- 2637 (a) Ordering, receiving, and unpacking radioactive materials safely
2638 and performing the related radiation surveys;
- 2639 (b) Checking survey meters for proper operation;
- 2640 (c) Preparing, implanting, and removing brachytherapy sources;
- 2641 (d) Maintaining running inventories of material on hand;
- 2642 (e) Using administrative controls to prevent a misadministration
2643 involving the use of radioactive material;
- 2644 (f) Using emergency procedures to control radioactive material; and
- 2645 (2) Has completed 3 years of supervised clinical experience in radiation oncology,
2646 under an authorized user who meets the requirements in G.490 or equivalent Agreement
2647 State or NRC requirements, as part of a formal training program approved by the
2648 Residency Review Committee for Radiation Oncology of the Accreditation Council for
2649 Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada
2650 or the Committee on Postdoctoral Training of the American Osteopathic Association.
2651 This experience may be obtained concurrently with the supervised work experience
2652 required by G.490(b)(1)(ii); and
- 2653 (3) Has obtained written attestation, signed by a preceptor authorized user who meets
2654 the requirements in G.490 or equivalent Agreement State or NRC requirements, that the
2655 individual has satisfactorily completed the requirements in G.490(a)(1), or G.490(b)(1)
2656 and G.490(b)(2) and has achieved a level of competency sufficient to function
2657 independently as an authorized user of manual brachytherapy sources for the medical
2658 uses authorized under G.400.

2659 [NOTE: G.491 replaces old G.69.]

2660 Sec. G.491 Training for Ophthalmic Use of Strontium-90.

2661

2662 Except as provided in G.57, the licensee shall require the authorized user of strontium-90 for
2663 ophthalmic radiotherapy to be a physician who:

2664 (a) Is an authorized user under G.490 or equivalent Agreement State requirements; or

2665 (b) (1) Has completed 24 hours of classroom and laboratory training applicable to the
2666 medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

2667 (i) Radiation physics and instrumentation;

2668 (ii) Radiation protection;

2669 (iii) Mathematics pertaining to the use and measurement of radioactivity; and

2670 (iv) Radiation biology; and

2671 (2) Supervised clinical training in ophthalmic radiotherapy under the supervision of
2672 an authorized user at a medical institution, clinic, or private practice that includes the use
2673 of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical
2674 training must involve:

2675 (i) Examination of each individual to be treated;

2676 (ii) Calculation of the dose to be administered;

2677 (iii) Administration of the dose; and

2678 (iv) Follow up and review of each individual's case history; and

2679 (3) Has obtained written attestation, signed by a preceptor authorized user who meets
2680 the requirements in G.490 or G.491, or equivalent Agreement State or NRC
2681 requirements, that the individual has satisfactorily completed the requirements in
2682 G.491(a) and G.491(b) and has achieved a level of competency sufficient to function
2683 independently as an authorized user of strontium-90 for ophthalmic use.

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Sealed Sources for Diagnosis

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[NOTE: Old G.39 rewritten as G.500.]

Sec. G.500 Use of Sealed Sources for Diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

[NOTE: G.590 replaces old G.70.]

Sec. G.590 Training for Use of Sealed Sources for Diagnosis.

Except as provided in G.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under G.500 to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in G.590(b) and G.590(c) and whose certification has been recognized by the NRC or an Agreement State. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.); or

(b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(c) Has completed training in the use of the device for the uses requested.

**Specific Requirements for the Use of a Sealed Source in Teletherapy
Photon Emitting Remote Afterloader Units, Teletherapy Units,
and Gamma Stereotactic Radiosurgery Units**

Sec. G.47600 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions. sealed sources in

2726 photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery
2727 units for therapeutic medical uses:

2728

2729 (a) As approved in the Sealed Source and Device Registry; or

2730

2731 (b) In research in accordance with an active Investigational Device Exemption (IDE)

2732 application accepted by the FDA provided the requirements of G.49(a) are met.

2733

2734 Sec. G.604 Surveys of Patients and Human Research Subjects Treated with a Remote
2735 Afterloader Unit.

2736 (a) Before releasing a patient or a human research subject from licensee control, a licensee

2737 shall survey the patient or the human research subject and the remote afterloader unit with a

2738 portable radiation detection survey instrument to confirm that the source(s) has been removed

2739 from the patient or human research subject and returned to the safe shielded position.

2740 (b) A licensee shall retain a record of these surveys in accordance with G.2404.

2741 [NOTE: Old G.48 replaced by G.605.]

2742 Sec. G.48605 Installation, Maintenance, Adjustment and Repair-Restrictions.

2743

2744 (a) Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory

2745 Commission, or an Agreement State to perform teletherapy unit maintenance and repair NRC or an

2746 Agreement State shall install, maintain, adjust, or repair/relocate, or remove a remote afterloader

2747 unit, teletherapy unit, sealed source or a teletherapy gamma stereotactic radiosurgery unit that

2748 contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other

2749 mechanism of a teletherapy unit that involves work on the source(s) shielding, the source(s)

2750 driving unit, or other electronic or mechanical component that could expose the source(s), reduce

2751 the shielding around the source(s), or result in increased radiation levels compromise the radiation

2752 safety of the unit or the source(s).

2753 (b) Except for low dose-rate remote afterloader units, only a person specifically licensed by

2754 the NRC or an Agreement State shall install, replace, relocate, or remove a sealed source or

2755 source contained in other remote afterloader units, teletherapy units, or gamma stereotactic

2756 radiosurgery units.

2757 (c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the

2758 NRC or an Agreement State or an authorized medical physicist shall install, replace, relocate, or

2759 remove a sealed source(s) contained in the unit.

2760 (d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of

2761 remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in

2762 accordance with G.2605.

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2765 ~~[NOTE: G.49 deleted.]~~

2766 ~~Sec. G.49 Amendments.~~ In addition to the requirements specified in G.4, a licensee shall apply for
2767 and receive a license amendment before:

2768

2769 (a) ~~— Making any change in the treatment room shielding;~~

2770

2771 (b) ~~— Making any change in the location of the teletherapy unit within the treatment room;~~

2772

2773 (c) ~~— Using the teletherapy unit in a manner that could result in increased radiation levels in areas~~
2774 ~~outside the teletherapy treatment room;~~

2775

2776 (d) ~~— Relocating the teletherapy unit; or~~

2777

2778 (e) ~~— Allowing an individual not listed on the licensee's license to perform the duties of the~~
2779 ~~teletherapy physicist.~~

2780 ~~[NOTE: G.50 language deleted.]~~

2781 ~~Sec. G.50 Safety Instruction.~~

2782

2783 (a) ~~— A licensee shall conspicuously post written instructions at the teletherapy unit console.~~
2784 ~~These instructions shall inform the operator of:~~

2785

2786 ~~— (1) — The procedure to be followed to ensure that only the patient or human research~~
2787 ~~subject is in the treatment room before turning the primary beam of radiation "on" to begin a~~
2788 ~~treatment or after a door interlock interruption;~~

2789

2790 ~~— (2) — The procedure to be followed if the operator is unable to turn the primary beam of~~
2791 ~~radiation "off" with controls outside the treatment room or any other abnormal operation~~
2792 ~~occurs; and~~

2793

2794 ~~— (3) — The names and telephone numbers of the authorized users and Radiation Safety~~
2795 ~~Officer to be immediately contacted if the teletherapy unit or console operates abnormally.~~

2796

2797 (b) ~~— A licensee shall provide instruction in the topics identified in G.50(a) to all individuals who~~
2798 ~~operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals~~
2799 ~~not to exceed 1 year.~~

2800

2801 (c) ~~— A licensee shall maintain a record of individuals receiving instruction required by G.50(b), a~~
2802 ~~description of the instruction, the date of instruction, and the name of the individual who gave the~~
2803 ~~instruction for 2 years.~~

2804

2805 Sec. G.610 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units,
2806 and Gamma Stereotactic Radiosurgery Units.

2807 (a) A licensee shall:

- 2808 (1) Secure the unit, the console, the console keys, and the treatment room when not in
2809 use or unattended;
- 2810 (2) Permit only individuals approved by the authorized user, Radiation Safety
2811 Officer, or authorized medical physicist to be present in the treatment room during
2812 treatment with the source(s);
- 2813 (3) Prevent dual operation of more than one radiation producing device in a treatment
2814 room if applicable; and
- 2815 (4) Develop, implement, and maintain written procedures for responding to an
2816 abnormal situation when the operator is unable to place the source(s) in the shielded
2817 position, or remove the patient or human research subject from the radiation field with
2818 controls from outside the treatment room. These procedures must include:
- 2819 (i) Instructions for responding to equipment failures and the names of the
2820 individuals responsible for implementing corrective actions;
- 2821 (ii) The process for restricting access to and posting of the treatment area to
2822 minimize the risk of inadvertent exposure; and
- 2823 (iii) The names and telephone numbers of the authorized users, the authorized
2824 medical physicist, and the Radiation Safety Officer to be contacted if the unit or
2825 console operates abnormally.
- 2826 (b) A copy of the procedures required by G.610(a)(4) must be physically located at the unit
2827 console.
- 2828 (c) A licensee shall post instructions at the unit console to inform the operator of:
- 2829 (1) The location of the procedures required by G.610(a)(4); and
- 2830 (2) The names and telephone numbers of the authorized users, the authorized medical
2831 physicist, and the Radiation Safety Officer to be contacted if the unit or console operates
2832 abnormally.
- 2833 (d) A licensee shall provide instruction, initially and at least annually, to all individuals who
2834 operate the unit, as appropriate to the individual's assigned duties, in:
- 2835 (1) The procedures identified in G.610(a)(4); and
- 2836 (2) The operating procedures for the unit.
- 2837 (e) A licensee shall ensure that operators, authorized medical physicists, and authorized users
2838 participate in drills of the emergency procedures, initially and at least annually.

2839 (f) A licensee shall retain a record of individuals receiving instruction required by G.610(d)
2840 in accordance with G.2310.

2841 (g) A licensee shall retain a copy of the procedures required by G.610(a)(4) and G.610(d)(2)
2842 in accordance with G.2610.

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2845 Sec. G.51615 Doors, Interlocks, and Warning Systems Safety Precautions for Remote Afterloader
2846 Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

- 2847.
- 2848 (a) A licensee shall control access to the ~~teletherapy~~ treatment room by a door at each entrance.
- 2849
- 2850 (b) A licensee shall equip each entrance to the ~~teletherapy~~ treatment room with an electrical
2851 interlock system that shall will:
- 2852
- 2853 (1) Prevent the operator from ~~turning the primary beam of radiation "on" initiating the~~
2854 treatment cycle unless each treatment room entrance door is closed;
- 2855
- 2856 (2) ~~Turn the beam of radiation "off" immediately when an entrance door is opened~~
2857 Cause the source(s) to be shielded when an entrance door is opened; and
- 2858
- 2859 (3) Prevent the ~~primary beam of radiation from being turned "on" source(s) from being~~
2860 exposed following an interlock interruption until all treatment room entrance doors are
2861 closed and the beam source(s) on-off control is reset at the console.
- 2862
- 2863 (c) ~~A licensee shall equip each entrance to the teletherapy room with a conspicuously visible~~
2864 warning light, that is activated only by the physical detection of radiation. Such light shall activate
2865 when radiation levels exist at one meter from the source of radiation equal to or exceeding 500 R/hr.
- 2866 (c) A licensee shall require any individual entering the treatment room to assure, through the
2867 use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
- 2868
- 2869 (d) Except for low-dose remote afterloader units, a licensee shall construct or equip each
2870 treatment room with viewing and intercom systems to permit continuous observation of the
2871 patient or the human research subject from the treatment console during irradiation.
- 2871 (e) For licensed activities where sources are placed within the patient's or human research
2872 subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a
2873 decoupled or jammed source.
- 2874 (f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a
2875 licensee shall:
- 2876 (1) For medium dose-rate and pulsed dose-rate remote afterloader units, require:
- 2877 (i) An authorized medical physicist and either an authorized user or a
2878 physician, under the supervision of an authorized user, who has been trained in
2879 the operation and emergency response for the unit to be physically present during
2880 the initiation of all patient treatments involving the unit; and
- 2881 (ii) An authorized medical physicist and either an authorized user or an
2882 individual, under the supervision of an authorized user, who has been trained to
2883 remove the source applicator(s) in the event of an emergency involving the unit.

2884 to be immediately available during continuation of all patient treatments involving
2885 the unit.

2886 (2) For high dose-rate remote afterloader units, require:

2887 (i) An authorized user and an authorized medical physicist to be physically
2888 present during the initiation of all patient treatments involving the unit; and

2889 (ii) An authorized medical physicist and either an authorized user or a
2890 physician, under the supervision of an authorized user, who has been trained in
2891 the operation and emergency response for the unit, to be physically present during
2892 continuation of all patient treatments involving the unit.

2893 (3) For gamma stereotactic radiosurgery units, require an authorized user and an
2894 authorized medical physicist to be physically present throughout all patient treatments
2895 involving the unit.

2896 (4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as
2897 soon as possible if the patient or human research subject has a medical emergency or
2898 dies.

2899 (g) A licensee shall have applicable emergency response equipment available near each
2900 treatment room to respond to a source:

2901 (1) Remaining in the unshielded position; or

2902 (2) Lodged within the patient following completion of the treatment.

2903

2904 [NOTE: G.52, G.53, & G.54 deleted.]

2905 Sec. G.52 Possession of Survey Instrument. A licensee authorized to use radioactive material in a
2906 teletherapy unit shall possess either a portable radiation detection survey instrument capable of
2907 detecting dose rates over the range 0.1 millirem (1 μ Sv) per hour to 100 millirems (1000 μ Sv) per
2908 hour or a portable radiation measurement survey instrument capable of measuring dose rates over
2909 the range 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall
2910 be operable and calibrated in accordance with G.16.

2911

2912 Sec. G.53 Radiation Monitoring Device.

2913

2914 (a) A licensee shall have in each teletherapy room a permanent radiation monitor capable of
2915 continuously monitoring beam status.

2916

2917 (b) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit
2918 malfunction that results in an exposed or partially exposed source. The visible indicator of high
2919 radiation levels shall be observable by an individual entering the teletherapy room.

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2922 ~~(c) — Each radiation monitor shall be equipped with a backup power supply separate from the~~
2923 ~~power supply to the teletherapy unit. This backup power supply may be a battery system.~~

2924
2925 ~~(d) — A radiation monitor shall be checked with a dedicated check source for proper operation~~
2926 ~~each day before the teletherapy unit is used for treatment of patients or human research subjects.~~

2927
2928 ~~(e) — A licensee shall maintain a record of the check required by G.53(d) for 2 years. The record~~
2929 ~~shall include the date of the check, notation that the monitor indicates when the source is exposed,~~
2930 ~~and the initials of the individual who performed the check.~~

2931
2932 ~~(f) — If a radiation monitor is inoperable, the licensee shall require any individual entering the~~
2933 ~~teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any~~
2934 ~~malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with~~
2935 ~~a dedicated check source for proper operation at the beginning of each day of use. The licensee~~
2936 ~~shall keep a record as described in G.53(e).~~

2937
2938 ~~(g) — A licensee shall promptly repair or replace the radiation monitor if it is inoperable.~~

2939
2940 ~~Sec. G.54 Viewing System. A licensee shall construct, equip and maintain each teletherapy room~~
2941 ~~to permit continuous observation of the patient or human research subject from the teletherapy unit~~
2942 ~~console during irradiation.~~

2943 ~~[NOTE: OLD G.55 rewritten as G.630 (there is a new G.55).]~~

2944 ~~Sec. G.55 Dosimetry Equipment.~~

2945
2946 ~~(a) — A licensee shall have a calibrated dosimetry system available for use. To satisfy this~~
2947 ~~requirement, one of the following two conditions shall be met:~~

2948
2949 ~~—— (1) — The system shall have been calibrated by the National Institute of Standards and~~
2950 ~~Technology or by a calibration laboratory accredited by the American Association of~~
2951 ~~Physicists in Medicine. The calibration shall have been performed within the previous 2~~
2952 ~~years and after any servicing that may have affected system calibration; or~~

2953
2954 ~~(2) The system shall have been calibrated within the previous 4 years; 18 to 30 months after~~
2955 ~~that calibration, the system shall have been intercompared at an intercomparison meeting~~
2956 ~~with another dosimetry system that was calibrated within the past 24 months by the National~~
2957 ~~Institute of Standards and Technology or by a calibration laboratory accredited by the~~
2958 ~~American Association of Physicists in Medicine. The intercomparison meeting shall be~~
2959 ~~sanctioned by a calibration laboratory or radiologic physics center accredited by the~~
2960 ~~American Association of Physicists in Medicine. The results of the intercomparison~~
2961 ~~meeting must have indicated that the calibration factor of the licensee's system had not~~
2962 ~~changed by more than 2 percent. The licensee shall not~~

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2966 ~~use the intercomparison result to change the calibration factor. When intercomparing~~
2967 ~~dosimetry systems to be used for calibrating cobalt 60 teletherapy units, the licensee shall~~
2968 ~~use a teletherapy unit with a cobalt 60 source. When intercomparing dosimetry systems to~~
2969 ~~be used for calibrating cesium 137 teletherapy units, the licensee shall use a teletherapy unit~~
2970 ~~with a cesium 137 source.~~

2971
2972 (b) ~~The licensee shall have available for use a dosimetry system for spot check measurements.~~
2973 ~~To meet this requirement, the system may be compared with a system that has been calibrated in~~
2974 ~~accordance with G.55(a). This comparison shall have been performed within the previous year and~~
2975 ~~after each servicing that may have affected system calibration. The spot check system shall be the~~
2976 ~~same system used to meet the requirement in G.55(a).~~

2977
2978 (e) ~~The licensee shall maintain a record of each calibration, intercomparison, and comparison~~
2979 ~~for the duration of the license. For each calibration, intercomparison, or comparison, the record~~
2980 ~~shall include the date, the model numbers and serial numbers of the instruments that were~~
2981 ~~calibrated, intercompared, or compared as required by G.55(a) and (b), the correction factors that~~
2982 ~~were determined, the names of the individuals who performed the calibration, intercomparison, or~~
2983 ~~comparison, and evidence that the intercomparison meeting was sanctioned by a calibration~~
2984 ~~laboratory or radiologic physics center accredited by the American Association of Physicists in~~
2985 ~~Medicine.~~

2986
2987 Sec. G.630 Dosimetry Equipment.

2988 (a) Except for low dose-rate remote afterloader sources where the source output or activity is
2989 determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for
2990 use. To satisfy this requirement, one of the following two conditions must be met:

2991 (1) The system must have been calibrated using a system or source traceable to the
2992 National Institute of Standards and Technology (NIST) and published protocols accepted
2993 by nationally recognized bodies; or by a calibration laboratory accredited by the
2994 American Association of Physicists in Medicine (AAPM). The calibration must have
2995 been performed within the previous 2 years and after any servicing that may have
2996 affected system calibration; or

2997 (2) The system must have been calibrated within the previous 4 years. Eighteen to
2998 thirty months after that calibration, the system must have been intercompared with
2999 another dosimetry system that was calibrated within the past 24 months by NIST or by a
3000 calibration laboratory accredited by the AAPM. The results of the intercomparison must
3001 indicate that the calibration factor of the licensee's system had not changed by more than
3002 2 percent. The licensee may not use the intercomparison result to change the calibration
3003 factor. When intercomparing dosimetry systems to be used for calibrating sealed sources
3004 for therapeutic units, the licensee shall use a comparable unit with beam attenuators or
3005 collimators, as applicable, and sources of the same radionuclide as the source used at the
3006 licensee's facility.

3007 (b) The licensee shall have a dosimetry system available for use for spot-check output
3008 measurements, if applicable. To satisfy this requirement, the system may be compared with a
3009 system that has been calibrated in accordance with G.630(a). This comparison must have been
3010 performed within the previous year and after each servicing that may have affected system
3011 calibration. The spot-check system may be the same system used to meet the requirement in
3012 G.630(a).

3013 (c) The licensee shall retain a record of each calibration, intercomparison, and comparison in
3014 accordance with G.2630.

3015 Sec. G.56632 Full Calibration Measurements on Teletherapy Units.

3016

3017 (a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration
3018 measurements on each teletherapy unit:

3019

3020 (1) Before the first medical use of the unit; and

3021

3022 (2) Before medical use under the following conditions:

3023

3024 (i) Whenever spot-check measurements indicate that the output differs by more
3025 than 5 percent from the output obtained at the last full calibration corrected
3026 mathematically for radioactive decay;

3027

3028 (ii) Following replacement of the source or following reinstallation of the
3029 teletherapy unit in a new location; and

3030

3031 (iii) Following any repair of the teletherapy unit that includes removal of the
3032 source or major repair of the components associated with the source exposure
3033 assembly; and

3034

3035 (3) At intervals not exceeding 1 year.

3036

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3039 (b) To satisfy the requirement of G.56632(a), full calibration measurements shall must include
3040 determination of:

3041
3042 (1) The output within ± 3 percent for the range of field sizes and for the distance or
3043 range of distances used for medical use;

3044
3045 (2) The coincidence of the radiation field and the field indicated by the light beam
3046 localizing device;

3047
3048 (3) The uniformity of the radiation field and its dependence on the orientation of the
3049 useful beam;

3050
3051 (4) Timer accuracy, ~~constancy,~~ and linearity over the range of use;

3052
3053 (5) "On-off" error; and

3054
3055 (6) The accuracy of all distance measuring and localization devices in medical use.

3056
3057 (c) A licensee shall use the dosimetry system described in G.55630(a) to measure the output for
3058 one set of exposure conditions. The remaining radiation measurements required in G.56632(b)(1)
3059 may ~~then~~ be made using a dosimetry system that indicates relative dose rates.

3060
3061 (d) A licensee shall make full calibration measurements required by G.56632(a) in accordance
3062 with published protocols accepted by nationally recognized bodies ~~either the procedures~~
3063 ~~recommended by the Scientific Committee on Radiation Dosimetry of the American Association of~~
3064 ~~Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971,~~
3065 ~~pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American~~
3066 ~~Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983,~~
3067 ~~pp. 741-771, and Vol. 11, No. 2, 1984, p.213.~~

3068
3069 (e) A licensee shall ~~correct~~ mathematically correct the outputs determined in G.56632(b)(1) for
3070 physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at
3071 intervals consistent with 1 percent decay for all other nuclides.
3072 ~~and intervals not exceeding 6 months for cesium-137.~~

3073
3074 ~~(f)(f)~~ (f) Full calibration measurements required by G.56632(a) and physical decay corrections
3075 required by G.56632(e) must shall be performed by the authorized medical physicist, ~~a teletherapy~~
3076 ~~physicist named on the licensee's license or authorized by a license issued by the U.S. Nuclear~~
3077 ~~Regulatory Commission or an Agreement State to perform such services.~~

3078
3079 ~~(g)(g)~~ (g) A licensee shall maintain a record of each calibration in accordance with G.2632 ~~for the~~
3080 ~~duration of the license. The record shall include the date of the calibration, the manufacturer's~~
3081 ~~name, model number, and serial number for both the teletherapy unit and the source, the model~~
3082 ~~numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that~~
3083 ~~describe the output of the unit over the range of field sizes and for the range of distances used in~~

3084 radiation therapy, a determination of the coincidence of the radiation field and the field indicated by
3085 the light beam
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3088 ~~localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-~~
3089 ~~off" error, the estimated accuracy of each distance measuring or localization device, and the~~
3090 ~~signature of the teletherapy physicist.~~

3091

3092 Sec. G.633 Full Calibration Measurements on Remote Afterloader Units.

3093 (a) A licensee authorized to use a remote afterloader unit for medical use shall perform full
3094 calibration measurements on each unit:

3095 (1) Before the first medical use of the unit;

3096 (2) Before medical use under the following conditions:

3097 (i) Following replacement of the source or following reinstallation of the unit
3098 in a new location outside the facility; and

3099 (ii) Following any repair of the unit that includes removal of the source or
3100 major repair of the components associated with the source exposure assembly;
3101 and

3102 (3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and
3103 pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days;
3104 and

3105 (4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

3106 (b) To satisfy the requirement G.633(a), full calibration measurements must include, as
3107 applicable, determination of:

3108 (1) The output within ± 5 percent;

3109 (2) Source positioning accuracy to within ± 1 millimeter;

3110 (3) Source retraction with backup battery upon power failure;

3111 (4) Length of the source transfer tubes;

3112 (5) Timer accuracy and linearity over the typical range of use;

3113 (6) Length of the applicators; and

3114 (7) Function of the source transfer tubes, applicators, and transfer tube-applicator
3115 interfaces.

3116 (c) A licensee shall use the dosimetry system described in G.630(a) to measure the output.

- 3117 (d) A licensee shall make full calibration measurements required by G.633(a) in accordance
3118 with published protocols accepted by nationally recognized bodies.
- 3119 (e) In addition to the requirements for full calibrations for low dose-rate remote afterloader
3120 units in G.633(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory
3121 and source(s) arrangement at intervals not exceeding 1 quarter.
- 3122 (f) For low dose-rate remote afterloader units, a licensee may use measurements provided by
3123 the source manufacturer that are made in accordance with G.633(a) through G.633(e).
- 3124 (g) A licensee shall mathematically correct the outputs determined in G.633(b)(1) for
3125 physical decay at intervals consistent with 1 percent physical decay.
- 3126 (h) Full calibration measurements required by G.633(a) and physical decay corrections
3127 required by paragraph G.633(g) must be performed by the authorized medical physicist.
- 3128 (i) A licensee shall retain a record of each calibration in accordance with G.2632.
- 3129 Sec. G.635 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.
- 3130 (a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall
3131 perform full calibration measurements on each unit:
- 3132 (1) Before the first medical use of the unit;
- 3133 (2) Before medical use under the following conditions:
- 3134 (i) Whenever spot-check measurements indicate that the output differs by
3135 more than 5 percent from the output obtained at the last full calibration corrected
3136 mathematically for radioactive decay;
- 3137 (ii) Following replacement of the sources or following reinstallation of the
3138 gamma stereotactic radiosurgery unit in a new location; and
- 3139 (iii) Following any repair of the gamma stereotactic radiosurgery unit that
3140 includes removal of the sources or major repair of the components associated with
3141 the source assembly; and
- 3142 (3) At intervals not exceeding 1 year, with the exception that relative helmet factors
3143 need only be determined before the first medical use of a helmet and following any
3144 damage to a helmet.
- 3145 (b) To satisfy the requirement of G.635(a), full calibration measurements must include
3146 determination of:
- 3147 (1) The output within ± 3 percent;

- 3148 (2) Relative helmet factors;
- 3149 (3) Isocenter coincidence;
- 3150 (4) Timer accuracy and linearity over the range of use;
- 3151 (5) On-off error;
- 3152 (6) Trunnion centricity;
- 3153 (7) Treatment table retraction mechanism, using backup battery power or hydraulic
3154 backups with the unit off;
- 3155 (8) Helmet microswitches;
- 3156 (9) Emergency timing circuits; and
- 3157 (10) Stereotactic frames and localizing devices (trunnions).
- 3158 (c) A licensee shall use the dosimetry system described in G.630(a) to measure the output for
3159 one set of exposure conditions. The remaining radiation measurements required in G.635(b)(1)
3160 may be made using a dosimetry system that indicates relative dose rates.
- 3161 (d) A licensee shall make full calibration measurements required by G.635(a) in accordance
3162 with published protocols accepted by nationally recognized bodies.
- 3163 (e) A licensee shall mathematically correct the outputs determined in G.635(b)(1) at intervals
3164 not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for
3165 all other radionuclides.
- 3166 (f) Full calibration measurements required by G.635(a) and physical decay corrections
3167 required by G.635(e) must be performed by the authorized medical physicist.
- 3168 (g) A licensee shall retain a record of each calibration in accordance with G.2632.
- 3169 Sec. G.57642 Periodic Spot-checks for Teletherapy Units.
- 3170
- 3171 (a) A licensee authorized to use teletherapy units for medical use shall perform output spot
3172 checks on each teletherapy unit at intervals not to exceed 1 month, once in each calendar month
3173 that include determination of:
- 3174
- 3175 (b) To satisfy the requirement of G.57(a), spot checks shall include determination of:
- 3176
- 3177 (1) Timer constancy accuracy, and timer linearity over the range of use;
- 3178
- 3179 (2) "On-off" error;

- 3180
3181 (3) The coincidence of the radiation field and the field indicated by the light beam
3182 localizing device;
3183
3184 (4) The accuracy of all distance measuring and localization devices used for medical
3185 use;
3186
3187 (5) The output for one typical set of operating conditions measured with the dosimetry
3188 system described in G.630(b); and
3189
3190 (6) The difference between the measurement made in G.57(b)(5)642(a)(5) and the
3191 anticipated output, expressed as a percentage of the anticipated output (i.e., the value
3192 obtained at last full calibration corrected mathematically for physical decay).
3193
3194 (c) ~~A licensee shall use the dosimetry system described in G.55 to make the spot check required~~
3195 ~~in G.57(b)(5).~~
3196
3197 (db) A licensee shall perform ~~spot checks~~ measurements required by G.57642(a) in accordance
3198 with written procedures established by the teletherapy authorized medical physicist. The
3199 ~~teletherapy physicist does not need to actually perform the output spot check measurements.~~ That
3200 individual need not actually perform the spot-check measurements.
3201
3202 (ec) A licensee shall have the teletherapy-authorized medical physicist review the results of each
3203 ~~output spot check~~ within 15 days. The teletherapy-authorized medical physicist shall promptly
3204 notify the licensee as soon as possible in writing of the results of each ~~output spot check.~~ The
3205 ~~licensee shall keep a copy of each written notification for 2 years.~~
3206
3207 (fd) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot
3208 checks of each teletherapy facility at intervals not to exceed 1 month, once in each calendar month
3209 and after each source installation to assure proper operation of:
3210

3213 ~~(g) To satisfy the requirement of G.57(f), safety spot checks shall assure proper operation of:~~

- 3214
- 3215 (1) Electrical interlocks at each teletherapy room entrance;
- 3216
- 3217 (2) Electrical or mechanical stops installed for the purpose of limiting use of the primary
- 3218 beam of radiation (restriction of source housing angulation or elevation, carriage or stand
- 3219 travel, and operation of the beam "on-off" mechanism);
- 3220
- 3221 ~~(3) Beam condition Source exposure indicator lights on the teletherapy unit, on the~~
- 3222 ~~control console, and in the facility;~~
- 3223
- 3224 (4) Viewing and intercom systems;
- 3225
- 3226 (5) Treatment room doors from inside and outside the treatment room; and
- 3227
- 3228 (6) Electrically assisted treatment room doors with the teletherapy unit electrical power
- 3229 turned "off".
- 3230

3231 ~~(he) If the results of the checks required in G.642(d) indicate the malfunction of any system,~~

3232 ~~a licensee shall lock the control console in the "off" position if any door interlock malfunctions.~~

3233 ~~No licensee shall and not use the unit until the interlock system is repaired unless specifically~~

3234 ~~authorized by the Agency except as may be necessary to repair, replace, or check the~~

3235 ~~malfunctioning system.~~

3236

3237 ~~(i) A licensee shall promptly repair any system identified in G.57(g) that is not operating~~

3238 ~~properly. The teletherapy unit shall not be used until all repairs are completed.~~

3239

3240 ~~(j) A licensee shall maintain retain a record of each spot check required by G.57642(a) and~~

3241 ~~(f)G.642(d), for 2 years. The record shall include the date of the spot check, the manufacturer's~~

3242 ~~name, model number, and serial number for both the teletherapy unit and source, the manufacturer's~~

3243 ~~name, model number and serial number of the instrument used to measure the output of the telether-~~

3244 ~~apy unit, the timer constancy and linearity, the calculated "on-off" error, a determination of the~~

3245 ~~coincidence of the radiation field and the field indicated by the light beam localizing device, the~~

3246 ~~timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the~~

3247 ~~estimated accuracy of each distance measuring or localization device, the difference between the~~

3248 ~~anticipated output and the measured output, notations indicating the operability of each entrance~~

3249 ~~door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the~~

3250 ~~viewing system and doors, and the signature of the individual who performed the periodic spot~~

3251 ~~check, and a copy of the procedures required by paragraph G.642(b), in accordance with G.2642.~~

3252

3253 Sec. G.643 Periodic Spot-checks for Remote Afterloader Units.

3254 (a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-

3255 checks of each remote afterloader facility and on each unit:

- 3256 (1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate
3257 remote afterloader unit on a given day;
- 3258 (2) Before each patient treatment with a low dose-rate remote afterloader unit; and
- 3259 (3) After each source installation.
- 3260 (b) A licensee shall perform the measurements required by G.643(a) in accordance with
3261 written procedures established by the authorized medical physicist. That individual need not
3262 actually perform the spot check measurements.
- 3263 (c) A licensee shall have the authorized medical physicist review the results of each spot-
3264 check within 15 days. The authorized medical physicist shall notify the licensee as soon as
3265 possible in writing of the results of each spot-check.
- 3266 (d) To satisfy the requirements of G.643(a), spot-checks must, at a minimum, assure proper
3267 operation of:
- 3268 (1) Electrical interlocks at each remote afterloader unit room entrance;
- 3269 (2) Source exposure indicator lights on the remote afterloader unit, on the control
3270 console, and in the facility;
- 3271 (3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and
3272 pulsed dose-rate remote afterloader facility;
- 3273 (4) Emergency response equipment;
- 3274 (5) Radiation monitors used to indicate the source position;
- 3275 (6) Timer accuracy;
- 3276 (7) Clock (date and time) in the unit's computer; and
- 3277 (8) Decayed source(s) activity in the unit's computer.
- 3278 (e) If the results of the checks required in G.643(d) indicate the malfunction of any system, a
3279 licensee shall lock the control console in the off position and not use the unit except as may be
3280 necessary to repair, replace, or check the malfunctioning system.
- 3281 (f) A licensee shall retain a record of each check required by G.643(d) and a copy of the
3282 procedures required by G.643(b) in accordance with G.2643.

3283 Sec. G.645 Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

3284 (a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall
3285 perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

3286 (1) Monthly;

3287 (2) Before the first use of the unit on a given day; and

3288 (3) After each source installation.

3289 (b) A licensee shall:

3290 (1) Perform the measurements required by G.645(a) in accordance with written
3291 procedures established by the authorized medical physicist. That individual need not
3292 actually perform the spot check measurements.

3293 (2) Have the authorized medical physicist review the results of each spot-check
3294 within 15 days. The authorized medical physicist shall notify the licensee as soon as
3295 possible in writing of the results of each spot-check.

3296 (c) To satisfy the requirements of G.645(a)(1), spot-checks must, at a minimum:

3297 (1) Assure proper operation of:

3298 (i) Treatment table retraction mechanism, using backup battery power or
3299 hydraulic backups with the unit off;

3300 (ii) Helmet microswitches;

3301 (iii) Emergency timing circuits; and

3302 (iv) Stereotactic frames and localizing devices (trunnions).

3303 (2) Determine:

3304 (i) The output for one typical set of operating conditions measured with the
3305 dosimetry system described in G.630(b);

3306 (ii) The difference between the measurement made in G.645(c)(2)(i) and the
3307 anticipated output, expressed as a percentage of the anticipated output (i.e., the
3308 value obtained at last full calibration corrected mathematically for physical
3309 decay);

3310 (iii) Source output against computer calculation;

- 3311 (iv) Timer accuracy and linearity over the range of use;
- 3312 (v) On-off error; and
- 3313 (vi) Trunnion centricity.
- 3314 (d) To satisfy the requirements of G.645(a)(2) and G.645(a)(3), spot-checks must assure
3315 proper operation of:
- 3316 (1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
- 3317 (2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on
3318 the control console, and in the facility;
- 3319 (3) Viewing and intercom systems;
- 3320 (4) Timer termination;
- 3321 (5) Radiation monitors used to indicate room exposures; and
- 3322 (6) Emergency off buttons.
- 3323 (e) A licensee shall arrange for the repair of any system identified in G.645(c) that is not
3324 operating properly as soon as possible.
- 3325 (f) If the results of the checks required in G.645(d) indicate the malfunction of any system, a
3326 licensee shall lock the control console in the off position and not use the unit except as may be
3327 necessary to repair, replace, or check the malfunctioning system.
- 3328 (g) A licensee shall retain a record of each check required by G.645(c) and G.645(d) and a
3329 copy of the procedures required by G.645(b) in accordance with G.2645.
- 3330 Sec. G.647 Additional Technical Requirements for Mobile Remote Afterloader Units.
- 3331 (a) A licensee providing mobile remote afterloader service shall:
- 3332 (1) Check survey instruments before medical use at each address of use or on each
3333 day of use, whichever is more frequent; and
- 3334 (2) Account for all sources before departure from a client's address of use.
- 3335 (b) In addition to the periodic spot-checks required by G.643, a licensee authorized to use
3336 mobile afterloaders for medical use shall perform checks on each remote afterloader unit before
3337 use at each address of use. At a minimum, checks must be made to verify the operation of:
- 3338 (1) Electrical interlocks on treatment area access points;

3339 (2) Source exposure indicator lights on the remote afterloader unit, on the control
3340 console, and in the facility;

3341 (3) Viewing and intercom systems;

3342 (4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

3343 (5) Radiation monitors used to indicate room exposures;

3344 (6) Source positioning (accuracy); and

3345 (7) Radiation monitors used to indicate whether the source has returned to a safe
3346 shielded position.

3347 (c) In addition to the requirements for checks in G.647(b), a licensee shall ensure overall
3348 proper operation of the remote afterloader unit by conducting a simulated cycle of treatment
3349 before use at each address of use.

3350 (d) If the results of the checks required in G.647(b) indicate the malfunction of any system, a
3351 licensee shall lock the control console in the off position and not use the unit except as may be
3352 necessary to repair, replace, or check the malfunctioning system.

3353 (e) A licensee shall retain a record of each check required by G.647(b) in accordance with
3354 G.2647.

3355

3356 Sec. G.40651 Availability of Survey Instrument. A licensee authorized to use radioactive
3357 material as a sealed source for diagnostic purposes shall have available for use a portable
3358 radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem
3359 (1 μ Sv) per hour to 100 millirems (1000 μ Sv) per hour or a portable radiation measurement
3360 survey instrument capable of measuring dose rates over the range 1 millirem (10 μ Sv) per hour
3361 to 1000 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in
3362 accordance with G.4761.

3363

3364 Sec. G.58652 Radiation Surveys for Teletherapy Facilities.

3365

3366 (a) In addition to the survey requirement in Sec. D.501, a person licensed under this part
3367 shall make surveys to ensure that the maximum radiation levels and average radiation levels
3368 from the surface of the main source safe with the source(s) in the shielded position do not exceed
3369 the levels stated in the Sealed Source and Device Registry.

3370 (b) The licensee shall make the survey required by G.652(a) at installation of a new source
3371 and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or
3372 mechanical component that could expose the source, reduce the shielding around the source(s),
3373 or compromise the radiation safety of the unit or the source(s).

3374 (c) A licensee shall retain a record of the radiation surveys required by G.652(a) in
3375 accordance with G.2652.

3376 (a) ~~Before medical use, after each installation of a teletherapy source, and after making any~~

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3380 change for which an amendment is required by G.49, the licensee shall perform radiation surveys
3381 with an operable radiation measurement survey instrument calibrated in accordance with G.16 to
3382 verify that:

3383
3384 ~~———— (1) ——— The maximum and average radiation dose rates at 1 meter from the teletherapy~~
3385 ~~source with the source in the "off" position and the collimators set for a normal treatment~~
3386 ~~field do not exceed 10 millirems (100 μ Sv) per hour and 2 millirems (20 μ Sv) per hour,~~
3387 ~~respectively; and~~

3388
3389 ~~———— (2) ——— With the teletherapy source in the "on" position with the largest clinically available~~
3390 ~~treatment field and with a scattering phantom in the primary beam of radiation, that:~~

3391
3392 ~~———— (i) ——— Radiation dose rates in restricted areas are not likely to cause personnel~~
3393 ~~exposures in excess of the limits specified in D.201 of these regulations; and~~

3394
3395 ~~———— (ii) ——— Radiation dose rates in unrestricted areas do not exceed the limits specified~~
3396 ~~in D.301(a) of these regulations.~~

3397
3398 ~~(b) ——— If the results of the surveys required in G.58(a) indicate any radiation dose rates in excess of~~
3399 ~~the respective limit specified in that paragraph, the licensee shall lock the control in the "off"~~
3400 ~~position and not use the unit:~~

3401
3402 ~~———— (1) ——— Except as may be necessary to repair, replace, or test the teletherapy unit, the~~
3403 ~~teletherapy unit shielding, or the treatment room shielding; or~~

3404
3405 ~~———— (2) ——— Until the licensee has received a specific exemption from the Agency.~~

3406
3407 ~~(c) ——— A licensee shall maintain a record of the radiation measurements made following~~
3408 ~~installation of a source for the duration of the license. The record shall include the date of the~~
3409 ~~measurements, the reason the survey is required, the manufacturer's name, model number and serial~~
3410 ~~number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each~~
3411 ~~dose rate measured around the teletherapy source while in the "off" position and the average of all~~
3412 ~~measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured~~
3413 ~~dose rate at several points in each area expressed in millirems (microsieverts) per hour, the~~
3414 ~~calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted~~
3415 ~~area, and the signature of the Radiation Safety Officer.~~

3416 ~~[NOTE: G.59 deleted.]~~

3417 ~~Sec. G.59 Safety Spot Checks for Teletherapy Facilities.~~

3418
3419 ~~(a) ——— A licensee shall promptly check all systems listed in G.57(g) for proper function after~~
3420 ~~each installation of a teletherapy source and after making any change for which an amendment is~~
3421 ~~required by G.49(a) through (d).~~

3422
3423
3424
3425

3425 (b) If the results of the safety spot checks required in G.59(a) indicate the malfunction of any
3426 system specified in G.57, the licensee shall lock the control console in the "off" position and not
3427 use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
3428

3429 (c) A licensee shall maintain a record of the safety spot checks following installation of a source
3430 for 2 years. The record shall include notations indicating the operability of each entrance door
3431 interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing
3432 system, doors, and the signature of the Radiation Safety Officer.

3433 [NOTE: G.60 deleted.]

3434 Sec. G.60 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program. If
3435 the survey required by G.58 indicates that an individual member of the public may be exposed to a
3436 dose greater than those permitted by D.301(a) of these regulations, before beginning the treatment
3437 program the licensee shall:

3438
3439 (a) Either equip the unit with stops or add additional radiation shielding to ensure compliance
3440 with D.301(a) of these regulations;

3441
3442 (b) Perform the survey required by G.58 again; and

3443
3444 (c) Include in the report required by G.61 the results of the initial survey, a description of the
3445 modification made to comply with G.60(a), and the results of the second survey; or

3446 [NOTE: G.61 deleted.]

3447 Sec. G.61 Reports of Teletherapy Surveys, Checks, Tests, and Measurements. A licensee shall
3448 furnish a copy of the records required in G.58, G.59, G.60 and the output from the teletherapy
3449 source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full
3450 calibration required in G.56 to the Agency within 30 days following completion of the action that
3451 initiated the record requirement.

3452
3453 Sec. G.62655 Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

3454
3455 (a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully
3456 inspected and serviced during teletherapy source replacement or at intervals not to exceed 5 years,
3457 whichever comes first, to assure proper functioning of the source exposure mechanism.

3458
3459 (b) This inspection and servicing shall only be performed by persons specifically licensed to do
3460 so by the Agency, an Agreement State, or the U.S. Nuclear Regulatory Commission.

3461
3462 (c) A licensee shall keep a record of the inspection and servicing in accordance with G.2655.

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3466 (e) ~~A licensee shall maintain a record of the inspection and servicing for the duration of the~~
 3467 ~~license. The record shall contain the inspector's name, the inspector's license number, the date of~~
 3468 ~~inspection, the manufacturer's name and model number and serial number for both the teletherapy~~
 3469 ~~unit and source, a list of components inspected, a list of components serviced and the type of~~
 3470 ~~service, a list of components replaced, and the signature of the inspector.~~

3471

3472 Sec. G.657 Therapy-Related Computer Systems.

3473

3474 The licensee shall perform acceptance testing on the treatment planning system of therapy-
 3475 related computer systems in accordance with published protocols accepted by nationally
 3476 recognized bodies. At a minimum, the acceptance testing must include, as applicable,
 3477 verification of:

3478

3479 (a) The source-specific input parameters required by the dose calculation algorithm;

3480

3481 (b) The accuracy of dose, dwell time, and treatment time calculations at representative
 3482 points;

3483

3484 (c) The accuracy of isodose plots and graphic displays;

3485

3486 (d) The accuracy of the software used to determine sealed source positions from radiographic
 3487 images; and

3488

3489 (e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment
 3490 delivery unit from the treatment planning system.

3491

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3494

Specific Requirements for Training

3495

3496

3497

[NOTE: For Training for Radiation Safety Officer, see G.50.]

3498

Sec. G.63 Radiation Safety Officer. Except as provided in G.64, an individual fulfilling the
 3499 responsibilities of the Radiation Safety Officer as provided in G.7 shall:

3500

3501

(a) Be certified by the:

3502

3503

———— (1) American Board of Health Physics in Comprehensive Health Physics;

3504

———— (2) American Board of Radiology in Radiological Physics, Therapeutic Radiological
Physics, or Medical Nuclear Physics;

3505

3506

———— (3) American Board of Nuclear Medicine;

3507

———— (4) American Board of Science in Nuclear Medicine;

3508

———— (5) Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science;

3509

———— (6) American Board of Medical Physics in Radiation Oncology Physics;

3510

———— (7) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine;

3511

———— (8) American Osteopathic Board of Radiology; or

- 3512 ~~(9) American Osteopathic Board of Nuclear Medicine; or~~
3513
3514 ~~(b) Have had 200 hours of classroom and laboratory training as follows:~~
3515
3516 ~~(1) Radiation physics and instrumentation;~~
3517
3518 ~~(2) Radiation protection;~~
3519
3520 ~~(3) Mathematics pertaining to the use and measurement of radioactivity;~~
3521
3522 ~~(4) Radiation biology;~~
3523
3524 ~~(5) Radiopharmaceutical chemistry; and~~
3525
3526 ~~(6) 1 year of full time experience in radiation safety at a medical institution under the~~
3527 ~~supervision of the individual identified as the Radiation Safety Officer on an Agency,~~
3528 ~~Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that~~
3529
3530
3531
3532

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3532 authorizes the medical use of radioactive material;

3533

3534 (c) ~~Be an authorized user for those radioactive material uses that come within the Radiation~~
3535 ~~Safety Officer's responsibilities.~~

3536

3537 ~~Sec. G.64 Training for Existing Radiation Safety Officers. An individual identified as a Radiation~~
3538 ~~Safety Officer on an Agency, Agreement State, Licensing State, or U.S. Nuclear Regulatory~~
3539 ~~Commission license on October 9, 1995 who oversees only the use of radioactive material for~~
3540 ~~which the licensee was authorized on that date need not comply with the training requirements of~~
3541 ~~G.63.~~

3542

3543 [NOTE: Old G.65 rewritten as G.190.]

3544 ~~Sec. G.65 Training for Uptake, Dilution, or Excretion Studies. Except as provided in G.73 and~~
3545 ~~G.74, the licensee shall require the authorized user of a radiopharmaceutical listed in G.29 to be a~~
3546 ~~physician who:~~

3547

3548 (a) ~~Is certified in:~~

3549

3550 ~~———— (1) Nuclear medicine by the American Board of Nuclear Medicine;~~

3551

3552 ~~———— (2) Diagnostic radiology by the American Board of Radiology;~~

3553

3554 ~~———— (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;~~

3555

3556 ~~———— (4) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine; or~~

3557

3558 ~~———— (5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~

3559

3560 (b) ~~Has completed 40 hours of instruction in basic radionuclide handling techniques applicable~~
3561 ~~to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.~~

3562

3563 ~~———— (1) To satisfy the basic instruction requirement, 40 hours of classroom and laboratory~~
3564 ~~instruction shall include:~~

3565

3566 ~~———— (i) Radiation physics and instrumentation;~~

3567

3568 ~~———— (ii) Radiation protection;~~

3569

3570 ~~———— (iii) Mathematics pertaining to the use and measurement of radioactivity;~~

3571

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3574

- 3574 (iv) ~~Radiation biology; and~~
 3575
 3576 ~~(v) Radiopharmaceutical chemistry.~~
 3577
 3578 ~~(2) To satisfy the requirement for 20 hours of supervised clinical experience, training~~
 3579 ~~must be under the supervision of an authorized user at a medical institution and shall~~
 3580 ~~include:~~
 3581
 3582 ~~(i) Examining patients or human research subjects and reviewing their case~~
 3583 ~~histories to determine their suitability for radionuclide diagnosis, limitations, or~~
 3584 ~~contraindications;~~
 3585
 3586 ~~(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring~~
 3587 ~~the dosages;~~
 3588
 3589 ~~(iii) Administering dosages to patients or human research subjects and using~~
 3590 ~~syringe radiation shields;~~
 3591
 3592 ~~(iv) Collaborating with the authorized user in the interpretation of radionuclide~~
 3593 ~~test results; and~~
 3594
 3595 ~~(v) Patient or human research subject followup; or~~
 3596
 3597 ~~(e) Has successfully completed a 6 month training program in nuclear medicine as part of a~~
 3598 ~~training program that has been approved by the Accreditation Council for Graduate Medical~~
 3599 ~~Education and that included classroom and laboratory training, work experience, and supervised~~
 3600 ~~clinical experience in all the topics identified in G.65(b).~~

3601
 3602 [NOTE: Old G.66 rewritten as G.290.]

3603 Sec. G.66 Training for Imaging and Localization Studies. Except as provided in G.73 or G.74, the
 3604 licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit
 3605 specified in G.31 to be a physician who:

- 3606
 3607 (a) Is certified in:
 3608
 3609 ~~(1) Nuclear medicine by the American Board of Nuclear Medicine;~~
 3610
 3611 ~~(2) Diagnostic radiology by the American Board of Radiology;~~
 3612
 3613 ~~(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;~~
 3614
 3615 ~~(4) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine; or~~

- 3619 (5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
3620
- 3621 (b) Has completed 200 hours of instruction in basic radionuclide handling techniques applicable
3622 to the use of prepared radiopharmaceuticals, generators, and reagent kits, and 500 hours of
3623 supervised clinical experience.
- 3624
- 3625 (1) To satisfy the basic instruction requirement, 200 hours of classroom and laboratory
3626 training shall include:
- 3627
- 3628 (i) Radiation physics and instrumentation;
- 3629
- 3630 (ii) Radiation protection;
- 3631
- 3632 (iii) Mathematics pertaining to the use and measurement of radioactivity;
- 3633
- 3634 (iv) Radiopharmaceutical chemistry;
- 3635
- 3636 (v) Radiation biology;
- 3637
- 3638 (vi) Ordering, receiving, and unpacking radioactive materials safely and
3639 performing the related radiation surveys;
- 3640
- 3641 (vii) Calibrating dose calibrators and diagnostic instruments and performing
3642 checks for proper operation of survey meters;
- 3643
- 3644 (viii) Calculating and safely preparing patient or human research subject dosages;
- 3645
- 3646 (ix) Using administrative controls to prevent the misadministration of radioactive
3647 material;
- 3648
- 3649 (x) Using emergency procedures to contain spilled radioactive material safely
3650 and using proper decontamination procedures; and
- 3651
- 3652 (xi) Eluting technetium-99m from generator systems, assaying and testing the
3653 eluate for molybdenum-99 and alumina contamination, and processing the eluate
3654 with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.
- 3655
- 3656 (2) To satisfy the requirement for 500 hours of supervised clinical experience, training
3657 shall be under the supervision of an authorized user at a medical institution and shall
3658 include:
- 3659
- 3660 (i) Examining patients or human research subjects and reviewing their case
- 3661

- 3664 histories to determine their suitability for radionuclide diagnosis, limitations, or
 3665 contraindications;
- 3666
- 3667 ~~(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring~~
 3668 ~~the dosages;~~
- 3669
- 3670 ~~(iii) Administering dosages to patients or human research subjects and using~~
 3671 ~~syringe radiation shields;~~
- 3672
- 3673 ~~(iv) Collaborating with the authorized user in the interpretation of radionuclide~~
 3674 ~~test results; and~~
- 3675
- 3676 ~~(v) Patient or human research subject followup; or~~
- 3677
- 3678 ~~(c) Has successfully completed a 6-month training program in nuclear medicine that has been~~
 3679 ~~approved by the Accreditation Council for Graduate Medical Education and that included classroom~~
 3680 ~~and laboratory training, work experience, and supervised clinical experience in all the topics~~
 3681 ~~identified in G.66(b).~~

3682

3683 [NOTE: Old G.67 rewritten as G.390.]

3684 ~~Sec. G.67 Training for Therapeutic Use of Radiopharmaceuticals. Except as provided in G.73, the~~
 3685 ~~licensee shall require the authorized user of a radiopharmaceutical listed in G.35 for therapy to be a~~
 3686 ~~physician who:~~

3687

3688 ~~(a) Is certified by:~~

- 3689
- 3690 ~~(1) The American Board of Nuclear Medicine;~~
- 3691
- 3692 ~~(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation~~
 3693 ~~oncology;~~
- 3694
- 3695 ~~(3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or~~
- 3696
- 3697 ~~(4) The American Osteopathic Board of Radiology after 1984; or~~

3698

3699 ~~(b) Has completed 80 hours of instruction in basic radionuclide handling techniques applicable~~
 3700 ~~to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.~~

3701

3702 ~~(1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory~~
 3703 ~~training shall include:~~

- 3707 (i) ~~— Radiation physics and instrumentation;~~
 3708
 3709 ~~— (ii) — Radiation protection;~~
 3710
 3711 ~~— (iii) — Mathematics pertaining to the use and measurement of radioactivity; and~~
 3712
 3713 ~~— (iv) — Radiation biology;~~
 3714
 3715 ~~— (2) — To satisfy the requirement for supervised clinical experience, training shall be under~~
 3716 ~~the supervision of an authorized user at a medical institution and shall include:~~
 3717
 3718 ~~— (i) — Use of iodine-131 for diagnosis of thyroid function and the treatment of~~
 3719 ~~hyperthyroidism or cardiac dysfunction in ten individuals;~~
 3720
 3721 ~~— (ii) — Use of soluble phosphorus-32 for the treatment of ascites, polycythemia~~
 3722 ~~vera, leukemia, or bone metastases in three individuals;~~
 3723
 3724 ~~— (iii) — Use of iodine-131 for treatment of thyroid carcinoma in three individuals;~~
 3725
 3726 ~~— (iv) — Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for~~
 3727 ~~intra-cavitary treatment of malignant effusions in three individuals; and~~
 3728
 3729 ~~— (v) — Use of Strontium-89 chloride for pain palliation therapy in three patients.~~
 3730 [NOTE: Old G.68 replaced by G.490.]
 3731 Sec. G.68 Training for Therapeutic Use of Brachytherapy Sources. Except as provided in G.73, the
 3732 licensee shall require the authorized user using a brachytherapy source specified in G.41 for therapy
 3733 to be a physician who:
 3734
 3735 (a) ~~— Is certified in:~~
 3736
 3737 ~~— (1) — Radiology, therapeutic radiology, or radiation oncology by the American Board of~~
 3738 ~~Radiology;~~
 3739
 3740 ~~— (2) — Radiation oncology by the American Osteopathic Board of Radiology;~~
 3741
 3742 ~~— (3) — Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty~~
 3743 ~~of Radiology" or "Fellow of the Royal College of Radiology"; or~~
 3744
 3745 ~~— (4) — Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or~~
 3746
 3747
 3748
 3749

3749 (b) ~~Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in~~
3750 ~~basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources,~~
3751 ~~and a minimum of 3 years of supervised clinical experience.~~

3752
3753 ~~(1) To satisfy the requirement for instruction, 200 hours of classroom and laboratory~~
3754 ~~training shall include:~~

3755
3756 ~~(i) Radiation physics and instrumentation;~~

3757
3758 ~~(ii) Radiation protection;~~

3759
3760 ~~(iii) Mathematics pertaining to the use and measurement of radioactivity;~~

3761
3762 ~~(iv) Radiation biology;~~

3763
3764 ~~(v) Ordering, receiving, and unpacking radioactive materials safely and~~
3765 ~~performing the related radiation surveys;~~

3766
3767 ~~(vi) Checking survey meters for proper operation;~~

3768
3769 ~~(vii) Preparing, implanting, and removing sealed sources;~~

3770
3771 ~~(viii) Using administrative controls to prevent the misadministration of radioactive~~
3772 ~~material; and~~

3773
3774 ~~(ix) Using emergency procedures to control radioactive material.~~

3775
3776 ~~(2) To satisfy the requirement for a period of supervised clinical experience, training~~
3777 ~~shall include 1 year in a formal training program approved by the Residency Review~~
3778 ~~Committee for Radiology of the Accreditation Council for Graduate Medical Education or~~
3779 ~~the Committee on Postdoctoral Training of the American Osteopathic Association, and an~~
3780 ~~additional 2 years of clinical experience in therapeutic radiology under the supervision of an~~
3781 ~~authorized user at a medical institution. The supervised clinical experience shall include:~~

3782
3783 ~~(i) Examining individuals and reviewing their case histories to determine their~~
3784 ~~suitability for brachytherapy treatment, and any limitations or contraindications;~~

3785
3786 ~~(ii) Selecting the proper brachytherapy sources, dose, and method of~~
3787 ~~administration;~~

3788
3789 ~~(iii) Calculating the dose; and~~

3790
3791 ~~(iv) Post-administration followup and review of case histories in collaboration~~

3792

3793

3795 with the authorized user.

3796 [NOTE: Old G.69 replaced by G.491.]

3797 ~~Sec. G.69 Training for Ophthalmic Use of Strontium 90. Except as provided in G.73, the licensee~~
3798 ~~shall require the authorized user using only strontium 90 for ophthalmic radiotherapy to be a~~
3799 ~~physician who:~~

3800
3801 (a) ~~Is certified in radiology, therapeutic radiology, or radiation oncology by the American Board~~
3802 ~~of Radiology; or~~

3803
3804 (b) ~~Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24~~
3805 ~~hours of instruction in basic radionuclide handling techniques applicable to the use of strontium 90~~
3806 ~~for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.~~

3807
3808 ~~(1) To satisfy the requirement for instruction, the classroom and laboratory training shall~~
3809 ~~include:~~

3810
3811 ~~(i) Radiation physics and instrumentation;~~

3812
3813 ~~(ii) Radiation protection;~~

3814
3815 ~~(iii) Mathematics pertaining to the use and measurement of radioactivity; and~~

3816
3817 ~~(iv) Radiation biology.~~

3818
3819 ~~(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic~~
3820 ~~radiotherapy, training shall be under the supervision of an authorized user at a medical~~
3821 ~~institution and shall include the use of strontium 90 for the ophthalmic treatment of five~~
3822 ~~individuals that includes:~~

3823
3824 ~~(i) Examination of each individual to be treated;~~

3825
3826 ~~(ii) Calculation of the dose to be administered;~~

3827
3828 ~~(iii) Administration of the dose; and~~

3829
3830 ~~(iv) Followup and review of each individual's case history.~~

3831 [NOTE: Old G.70 replaced by G.590.]

3832 ~~Sec. G.70 Training for Use of Sealed Sources for Diagnosis. Except as provided in G.73, the~~
3833 ~~licensee shall require the authorized user using a sealed source in a device specified in G.39 to be a~~
3834 ~~physician, dentist, or podiatrist who:~~

3835

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3838

- 3838 ~~(a) Is certified in:~~
- 3839
- 3840 ~~———— (1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the~~
- 3841 ~~American Board of Radiology;~~
- 3842
- 3843 ~~———— (2) Nuclear medicine by the American Board of Nuclear Medicine;~~
- 3844
- 3845 ~~———— (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;~~
- 3846 ~~or~~
- 3847
- 3848 ~~———— (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or~~
- 3849
- 3850 ~~(b) Has completed 8 hours of classroom and laboratory instruction in basic radionuclide~~
- 3851 ~~handling techniques specifically applicable to the use of the device that includes:~~
- 3852
- 3853 ~~———— (1) Radiation physics, mathematics pertaining to the use and measurement of~~
- 3854 ~~radioactivity, and instrumentation;~~
- 3855
- 3856 ~~———— (2) Radiation biology;~~
- 3857
- 3858 ~~———— (3) Radiation protection; and~~
- 3859
- 3860 ~~———— (4) Training in the use of the device for the purposes authorized by the license.~~
- 3861 ~~[NOTE: For old G.71, see G.690.]~~
- 3862 ~~Sec. G.71 Training for Teletherapy. Except as provided in G.73, the licensee shall require the~~
- 3863 ~~authorized user of a sealed source specified in G.47 in a teletherapy unit to be a physician who:~~
- 3864
- 3865 ~~(a) Is certified in:~~
- 3866
- 3867 ~~———— (1) Radiology, therapeutic radiology, or radiation oncology by the American Board of~~
- 3868 ~~Radiology;~~
- 3869
- 3870 ~~———— (2) Radiation oncology by the American Osteopathic Board of Radiology;~~
- 3871
- 3872 ~~———— (3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of~~
- 3873 ~~Radiology" or "Fellow of the Royal College of Radiology"; or~~
- 3874
- 3875 ~~———— (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;~~
- 3876 ~~or~~
- 3877

3880 ~~(b) — Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction~~
3881 ~~in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, and a~~
3882 ~~minimum of 3 years of supervised clinical experience.~~

3883
3884 ~~————— (1) — To satisfy the requirement for instruction, the classroom and laboratory training shall~~
3885 ~~include:~~

3886
3887 ~~————— (i) — Radiation physics and instrumentation;~~

3888
3889 ~~————— (ii) — Radiation protection;~~

3890
3891 ~~————— (iii) — Mathematics pertaining to the use and measurement of radioactivity;~~

3892
3893 ~~————— (iv) — Radiation biology;~~

3894
3895 ~~————— (v) — Review of the full calibration measurements and periodic spot checks;~~

3896
3897 ~~————— (vi) — Preparing treatment plans and calculating treatment times;~~

3898
3899 ~~————— (vii) — Using administrative controls to prevent misadministrations;~~

3900
3901 ~~————— (viii) — Implementing emergency procedures to be followed in the event of the~~
3902 ~~abnormal operation of a teletherapy unit or console; and~~

3903
3904 ~~————— (ix) — Checking and using survey meters.~~

3905
3906 ~~(2) — To satisfy the requirement for a period of supervised clinical experience, training~~
3907 ~~shall include 1 year in a formal training program approved by the Residency Review~~
3908 ~~Committee for Radiology of the Accreditation Council for Graduate Medical Education or~~
3909 ~~the Committee on Postdoctoral Training of the American Osteopathic Association and an~~
3910 ~~additional 2 years of clinical experience in therapeutic radiology under the supervision of an~~
3911 ~~authorized user at a medical institution. The supervised clinical experience shall include:~~

3912
3913 ~~————— (i) — Examining individuals and reviewing their case histories to determine their~~
3914 ~~suitability for teletherapy treatment, and any limitations or contraindications;~~

3915
3916 ~~————— (ii) — Selecting the proper dose and how it is to be administered;~~

3917
3918 ~~————— (iii) — Calculating the teletherapy doses and collaborating with the authorized user~~
3919 ~~in the review of patients' progress and consideration of the need to modify originally~~
3920 ~~prescribed doses as warranted by patient's or human research subject's reaction to~~
3921 ~~radiation; and~~

3922

3923

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3925

(iv) ~~Post administration followup and review of case histories.~~

[NOTE: For old G.72, see G.57.]

~~Sec. G.72 Training for Teletherapy Physicist. The licensee shall require the teletherapy physicist to:~~

(a) ~~Be certified by the American Board of Radiology in:~~

~~———— (1) Therapeutic radiological physics;~~

~~———— (2) Roentgen-ray and gamma-ray physics;~~

~~———— (3) X-ray and radium physics; or~~

~~———— (4) Radiological physics; or~~

(b) ~~Be certified by the American Board of Medical Physics in radiation oncology physics; or~~

(c) ~~Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full time training in therapeutic radiological physics and also 1 year of full time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in G.19, G.56, G.57, and G.58 under the supervision of a teletherapy physicist during the year of work experience.~~

[For old G.73, see G.57.]

~~Sec. G.73 Training for Existing Authorized Users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an Agency, NRC or Agreement State or Licensing State license on October 9, 1995 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of G.63 through G.75.~~

~~Sec. G.74 Physician Training in a Three-Month Program. A physician who, before July 1, 1984, began a 3-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of G.65 or G.66.~~

[For old G.75, see G.55.]

~~Sec. G.75 Training for an Authorized Nuclear Pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:~~

- 3965
 3966 (a) ~~Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical~~
 3967 ~~Specialties, or~~
 3968
 3969 (b) (1) ~~Has completed 700 hours in a structured educational program consisting of both:~~
 3970
 3971 ~~(i) Didactic training in the following areas:~~
 3972
 3973 ~~(a) Radiation physics and instrumentation;~~
 3974
 3975 ~~(b) Radiation protection;~~
 3976
 3977 ~~(c) Mathematics pertaining to the use and measurement of radioactivity;~~
 3978
 3979 ~~(d) Chemistry of radioactive material for medical use; and~~
 3980
 3981 ~~(e) Radiation biology; and~~
 3982
 3983 ~~(ii) Supervised experience in a nuclear pharmacy involving the following:~~
 3984
 3985 ~~(a) Shipping, receiving, and performing related radiation surveys;~~
 3986
 3987 ~~(b) Using and performing checks for proper operation of dose~~
 3988 ~~calibrators, survey meters, and, if appropriate, instruments used to measure~~
 3989 ~~alpha or beta emitting radionuclides;~~
 3990
 3991 ~~(c) Calculating, assaying, and safely preparing dosages for patients or~~
 3992 ~~human research subjects;~~
 3993
 3994 ~~(d) Using administrative controls to avoid mistakes in the administration~~
 3995 ~~of radioactive material; and~~
 3996
 3997 ~~(e) Using procedures to prevent or minimize contamination and using~~
 3998 ~~proper decontamination procedures; and~~
 3999
 4000 ~~(2) Has obtained written certification, signed by a preceptor authorized nuclear~~
 4001 ~~pharmacist, that the above training has been satisfactorily completed and that the individual~~
 4002 ~~has achieved a level of competency sufficient to independently operate a nuclear pharmacy.~~

4003 [NOTE: For old G.75.1, see G.57.]

4004 Sec. G.75.1 Training for Existing Nuclear Pharmacists. A licensee may apply for and must receive
 4005 a license amendment identifying an existing nuclear pharmacist as an authorized nuclear pharmacist
 4006 before it allows this individual to work as an authorized nuclear pharmacist. A

4011 ~~pharmacist who has completed a structured educational program as specified in G.75 before [the~~
4012 ~~effective date of this regulation], and who is working in a nuclear pharmacy would qualify as an~~
4013 ~~existing nuclear pharmacist. An existing nuclear pharmacist need not comply with the requirements~~
4014 ~~on preceptor statement (G.75(b)(2)) and recency of training (G.76) to qualify as an authorized~~
4015 ~~nuclear pharmacist.~~

4016 [For old G.76, see G.59.]

4017 ~~Sec. G.76 Recency of Training. The training and experience specified in this Part shall have~~
4018 ~~been obtained within the 7 years preceding the date of application or the individual shall have had~~
4019 ~~continuing applicable experience since the required training and experience was completed.~~

4020 [Old G.77 rewritten as G.6.]

4021 ~~Sec. G.77 Provisions for Research Involving Human Subjects Using Radioactive Material. A~~
4022 ~~licensee may conduct research using radioactive material provided that the research is conducted,~~
4023 ~~funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for~~
4024 ~~the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a~~
4025 ~~specific amendment to its license before conducting such research. Both types of licensees shall, at~~
4026 ~~a minimum, obtain informed consent from the human subjects and obtain prior review and approval~~
4027 ~~of the research activities by an "Institutional Review Board" in accordance with the meaning of~~
4028 ~~these terms as defined and described in the Federal Policy for the Protection of Human Subjects.~~

4029 [New G.690 is old G.71.]

4030 Sec. G.690 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma
4031 Stereotactic Radiosurgery Units.

4032

4033 Except as provided in G.57, the licensee shall require an authorized user of a sealed source for a
4034 use authorized under G.600 to be a physician who:

4035

4036 (a) Is certified by a medical specialty board whose certification process has been recognized
4037 by the NRC or an Agreement State and who meets the requirements in G.690(b)(3) and
4038 G.690(c). (The names of board certifications which have been recognized by the NRC or an
4039 Agreement State will be posted on the NRC's Web page.) To have its certification process
4040 recognized, a specialty board shall require all candidates for certification to:

4041

4042 (1) Successfully complete a minimum of 3 years of residency training in a radiation
4043 therapy program approved by the Residency Review Committee of the Accreditation
4044 Council for Graduate Medical Education or the Royal College of Physicians and
4045 Surgeons of Canada or the Committee on Post-Graduate Training of the American
4046 Osteopathic Association; and

4047

4048 (2) Pass an examination, administered by diplomates of the specialty board, which
4049 tests knowledge and competence in radiation safety, radionuclide handling, treatment
4050 planning, quality assurance, and clinical use of stereotactic radiosurgery, remote
4051 afterloaders and external beam therapy; or

4052

4053 (b) (1) Has completed a structured educational program in basic radionuclide techniques
4054 applicable to the use of a sealed source in a therapeutic medical unit that includes:

4055

4056 (i) 200 hours of classroom and laboratory training in the following areas:

- 4057
- 4058 (a) Radiation physics and instrumentation;
- 4059
- 4060 (b) Radiation protection;
- 4061
- 4062 (c) Mathematics pertaining to the use and measurement of
- 4063 radioactivity; and
- 4064
- 4065 (d) Radiation biology; and
- 4066
- 4067 (ii) 500 hours of work experience, under the supervision of an authorized user
- 4068 who meets the requirements in G.690, or NRC or equivalent Agreement State
- 4069 requirements at a medical institution, involving:
- 4070
- 4071 (a) Reviewing full calibration measurements and periodic spot-checks;
- 4072
- 4073 (b) Preparing treatment plans and calculating treatment doses and
- 4074 times;
- 4075
- 4076 (c) Using administrative controls to prevent a misadministration
- 4077 involving the use of radioactive material;
- 4078
- 4079 (d) Implementing emergency procedures to be followed in the event of
- 4080 the abnormal operation of the medical unit or console;
- 4081
- 4082 (e) Checking and using survey meters; and
- 4083
- 4084 (f) Selecting the proper dose and how it is to be administered; and
- 4085
- 4086 (2) Has completed 3 years of supervised clinical experience in radiation therapy,
- 4087 under an authorized user who meets the requirements in G.690, or NRC or equivalent
- 4088 Agreement State requirements, as part of a formal training program approved by the
- 4089 Residency Review Committee for Radiation Oncology of the Accreditation Council for
- 4090 Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada
- 4091 or the Committee on Postdoctoral Training of the American Osteopathic Association.
- 4092 This experience may be obtained concurrently with the supervised work experience
- 4093 required by G.690(b)(1)(ii); and
- 4094
- 4095 (3) Has obtained written attestation that the individual has satisfactorily completed
- 4096 the requirements in G.690(a)(1) or G.690(b)(1) and G.690(b)(2), and G.690(c), and has
- 4097 achieved a level of competency sufficient to function independently as an authorized user
- 4098 of each type of therapeutic medical unit for which the individual is requesting authorized
- 4099 user status. The written attestation must be signed by a preceptor authorized user who
- 4100 meets the requirements in G.690, or NRC or equivalent Agreement State requirements for
- 4101 an authorized user for each type of therapeutic medical unit for which the individual is
- 4102 requesting authorized user status; and

4103
4104 (c) Has received training in device operation, safety procedures, and clinical use for the
4105 type(s) of use for which authorization is sought. This training requirement may be satisfied by
4106 satisfactory completion of a training program provided by the vendor for new users or by
4107 receiving training supervised by an authorized user or authorized medical physicist, as
4108 appropriate, who is authorized for the type(s) of use for which the individual is seeking
4109 authorization.

4110
4111
4112
4113 **Other Medical Uses of Radioactive Material or Radiation From Radioactive Material**

4114
4115
4116
4117 **Sec. G.1000 Other Medical Uses of Radioactive Material or Radiation from Radioactive**
4118 **Material.**

4119
4120 A licensee may use radioactive material or a radiation source approved for medical use which is
4121 not specifically addressed in G.100 through G.690 if:

4122
4123 (a) The applicant or licensee has submitted the information required by G.12(a)(2) through
4124 G.12(b); and

4125
4126 (b) The applicant or licensee has received written approval from the Agency in a license or
4127 license amendment and uses the material in accordance with the regulations and specific
4128 conditions the Agency considers necessary for the medical use of the material.

4129
4130
4131
4132 **Records**

4133
4134
4135
4136 **Sec. G.2024 Records of Authority and Responsibilities for Radiation Protection Programs.**

4137
4138 (a) A licensee shall retain a record of actions taken by the licensee's management in
4139 accordance with G.24(a) for 5 years. The record must include a summary of the actions taken
4140 and a signature of licensee management.

4141
4142 (b) The licensee shall retain a copy of both authority, duties, and responsibilities of the
4143 Radiation Safety Officer as required by G.24(e), and a signed copy of each Radiation Safety
4144 Officer's agreement to be responsible for implementing the radiation safety program, as required
4145 by G.24(b), for the duration of the license. The records must include the signature of the
4146 Radiation Safety Officer and licensee management.

4147
4148 **Sec. G.2040 Records of Written Directives.**

4149

4150 A licensee shall retain a copy of each written directive as required by G.40 for 3 years.

4151

4152 Sec. G.2041 Records for Procedures for Administrations Requiring a Written Directive.

4153

4154 A licensee shall retain a copy of the procedures required by G.41(a) for the duration of the
4155 license.

4156

4157 Sec. G.2060 Records of Calibrations of Instruments Used to Measure the Activity of Unsealed
4158 Radioactive Material.

4159

4160 A licensee shall maintain a record of instrument calibrations required by G.60.A and G.60.B for
4161 3 years. The records must include the model and serial number of the instrument, the date of the
4162 calibration, the results of the calibration, and the name of the individual who performed the
4163 calibration.

4164

4165 Sec. G.2061 Records of Radiation Survey Instrument Calibrations.

4166

4167 A licensee shall maintain a record of radiation survey instrument calibrations required by G.61
4168 for 3 years. The record must include the model and serial number of the instrument, the date of
4169 the calibration, the results of the calibration, and the name of the individual who performed the
4170 calibration.

4171

4172 Sec. G.2063 Records of Dosages of Unsealed Radioactive Material for Medical Use.

4173

4174 (a) A licensee shall maintain a record of dosage determinations required by G.63 for 3 years.

4175

4176 (b) The record must contain:

4177

4178 (1) The radiopharmaceutical;

4179

4180 (2) The patient's or human research subject's name, or identification number if one
4181 has been assigned;

4182

4183 (3) The prescribed dosage, the determined dosage, or a notation that the total activity
4184 is less than 1.1 MBq (30 μ Ci);

4185

4186 (4) The date and time of the dosage determination; and

4187

4188 (5) The name of the individual who determined the dosage.

4189

4190 Sec. G.2067 Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy
4191 Sources.

4192

4193 (a) A licensee shall retain records of leak tests required by G.67(b) for 3 years. The records
4194 must include the model number, and serial number if one has been assigned, of each source
4195 tested; the identity of each source by radionuclide and its estimated activity; the results of the
4196 test; the date of the test; and the name of the individual who performed the test.

4197
4198 (b) A licensee shall retain records of the semi-annual physical inventory of sealed sources
4199 and brachytherapy sources required by G.67(g) for 3 years. The inventory records must contain
4200 the model number of each source, and serial number if one has been assigned, the identity of
4201 each source by radionuclide and its nominal activity, the location of each source, and the name of
4202 the individual who performed the inventory.

4203
4204 Sec. G.2070 Records of Surveys for Ambient Radiation Exposure Rate.
4205
4206 A licensee shall retain a record of each survey required by G.70 for 3 years. The record must
4207 include the date of the survey, the results of the survey, the instrument used to make the survey,
4208 and the name of the individual who performed the survey.

4209
4210 Sec. G.2075 Records of the Release of Individuals Containing Unsealed Radioactive Material or
4211 Implants Containing Radioactive Material.

4212
4213 (a) A licensee shall retain a record of the basis for authorizing the release of an individual in
4214 accordance with G.75, if the total effective dose equivalent is calculated by:
4215
4216 (1) Using the retained activity rather than the activity administered;
4217
4218 (2) Using an occupancy factor less than 0.25 at 1 meter;
4219
4220 (3) Using the biological or effective half-life; or
4221
4222 (4) Considering the shielding by tissue.

4223
4224 (b) A licensee shall retain a record that the instructions required by G.75(b) were provided to
4225 a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding
4226 could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).
4227
4228 (c) The records required by G.2075(a) and G.2075(b) must be retained for 3 years after the
4229 date of release of the individual.

4230
4231 Sec. G.2080 Records of Mobile Medical Services.
4232
4233 (a) A licensee shall retain a copy of each letter that permits the use of radioactive material at
4234 a client's address, as required by G.80(a)(1). Each letter must clearly delineate the authority and
4235 responsibility of the licensee and the client and must be retained for 3 years after the last
4236 provision of service.

4237
4238 (b) A licensee shall retain the record of each survey required by G.80(a)(4) for 3 years. The
4239 record must include the date of the survey, the results of the survey, the instrument used to make
4240 the survey, and the name of the individual who performed the survey.

4241
4242 Sec. G.2204 Records of Molybdenum-99 Concentrations.
4243

4244 A licensee shall maintain a record of the molybdenum-99 concentration tests required by
4245 G.204(b) for 3 years. The record must include, for each measured elution of technetium-99m,
4246 the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of
4247 technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date
4248 of the measurement, and the name of the individual who made the measurement.

4249

4250 Sec. G.2310 Records of Safety Instruction.

4251

4252 A licensee shall maintain a record of safety instructions required by G.310, G.410, and G.610 for
4253 3 years. The record must include a list of the topics covered, the date of the instruction, the
4254 name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

4255

4256 Sec. G.2404 Records of Surveys after Source Implant and Removal.

4257

4258 A licensee shall maintain a record of the surveys required by G.404 and G.604 for 3 years. Each
4259 record must include the date and results of the survey, the survey instrument used, and the name
4260 of the individual who made the survey.

4261

4262 Sec. G.2406 Records of Brachytherapy Source Accountability.

4263

4264 (a) A licensee shall maintain a record of brachytherapy source accountability required by
4265 G.406 for 3 years.

4266

4267 (b) For temporary implants, the record must include:

4268

4269 (1) The number and activity of sources removed from storage, the time and date they
4270 were removed from storage, the name of the individual who removed them from storage,
4271 and the location of use; and

4272

4273 (2) The number and activity of sources returned to storage, the time and date they
4274 were returned to storage, and the name of the individual who returned them to storage.

4275

4276 (c) For permanent implants, the record must include:

4277

4278 (1) The number and activity of sources removed from storage, the date they were
4279 removed from storage, and the name of the individual who removed them from storage;

4280

4281 (2) The number and activity of sources not implanted, the date they were returned to
4282 storage, and the name of the individual who returned them to storage; and

4283

4284 (3) The number and activity of sources permanently implanted in the patient or
4285 human research subject.

4286

4287 Sec. G.2432 Records of Calibration Measurements of Brachytherapy Sources.

4288

4289 (a) A licensee shall maintain a record of the calibrations of brachytherapy sources required
4290 by G.432 for 3 years after the last use of the source.

- 4291
4292 (b) The record must include:
4293
4294 (1) The date of the calibration;
4295
4296 (2) The manufacturer's name, model number, and serial number for the source and
4297 the instruments used to calibrate the source;
4298
4299 (3) The source output or activity;
4300
4301 (4) The source positioning accuracy within the applicators; and
4302
4303 (5) The name of the individual, the source manufacturer, or the calibration laboratory
4304 that performed the calibration.
4305

4306 Sec. G.2433 Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.
4307

4308 (a) A licensee shall maintain a record of the activity of a strontium-90 source required by
4309 G.433 for the life of the source.
4310

4311 (b) The record must include:
4312

- 4313 (1) The date and initial activity of the source as determined under G.432; and
4314
4315 (2) For each decay calculation, the date and the source activity as determined under
4316 G.433.
4317

4318 Sec. G.2605 Records of Installation, Maintenance, Adjustment, and Repair of Remote
4319 Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.
4320

4321 A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote
4322 afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by
4323 G.605 for 3 years. For each installation, maintenance, adjustment and repair, the record must
4324 include the date, description of the service, and name(s) of the individual(s) who performed the
4325 work.
4326

4327 Sec. G.2610 Records of Safety Procedures.
4328

4329 A licensee shall retain a copy of the procedures required by G.610(a)(4) and G.610(d)(2) until
4330 the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic
4331 radiosurgery unit.
4332

4333 Sec. G.2630 Records of Dosimetry Equipment used with Remote Afterloader Units, Teletherapy
4334 Units, and Gamma Stereotactic Radiosurgery Units.
4335

4336 (a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its
4337 dosimetry equipment done in accordance with G.630 for the duration of the license.

4338

4339 (b) For each calibration, intercomparison, or comparison, the record must include:

4340

(1) The date;

4341

4342 (2) The manufacturer's name, model numbers and serial numbers of the instruments
4344 that were calibrated, intercompared, or compared as required by G.630(a) and G.630(b);

4345

4346 (3) The correction factor that was determined from the calibration or comparison or
4347 the apparent correction factor that was determined from an intercomparison; and

4348

4349 (4) The names of the individuals who performed the calibration, intercomparison, or
4350 comparison.

4351

4352 Sec. G.2632 Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic
4353 Radiosurgery full Calibrations.

4354

4355 (a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and
4356 gamma stereotactic radiosurgery unit full calibrations required by G.632, G.633, and G.635 for 3
4357 years.

4358

4359 (b) The record must include:

4360

(1) The date of the calibration;

4361

4362 (2) The manufacturer's name, model number, and serial number of the teletherapy,
4364 remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the
4365 instruments used to calibrate the unit(s);

4366

4367 (3) The results and an assessment of the full calibrations;

4368

4369 (4) The results of the autoradiograph required for low dose-rate remote afterloader
4370 units; and

4371

4372 (5) The signature of the authorized medical physicist who performed the full
4373 calibration.

4374

4375 Sec. G.2642 Records of Periodic Spot-checks for Teletherapy Units.

4376

4377 (a) A licensee shall retain a record of each periodic spot-check for teletherapy units required
4378 by G.642 for 3 years.

4379

4380 (b) The record must include:

4381

(1) The date of the spot-check;

4382

- 4383
4384 (2) The manufacturer's name, model number, and serial number of the teletherapy
4385 unit, source and instrument used to measure the output of the teletherapy unit;
4386
4387 (3) An assessment of timer linearity and constancy;
4388
4389 (4) The calculated on-off error;
4390
4391 (5) A determination of the coincidence of the radiation field and the field indicated by
4392 the light beam localizing device;
4393
4394 (6) The determined accuracy of each distance measuring and localization device;
4395
4396 (7) The difference between the anticipated output and the measured output;
4397
4398 (8) Notations indicating the operability of each entrance door electrical interlock,
4399 each electrical or mechanical stop, each source exposure indicator light, and the viewing
4400 and intercom system and doors; and
4401
4402 (9) The name of the individual who performed the periodic spot-check and the
4403 signature of the authorized medical physicist who reviewed the record of the spot-check.
4404
4405 (c) A licensee shall retain a copy of the procedures required by G.642(b) until the licensee no
4406 longer possesses the teletherapy unit.

4407
4408 Sec. G.2643 Records of Periodic Spot-checks for Remote Afterloader Units.
4409

- 4410 (a) A licensee shall retain a record of each spot-check for remote afterloader units required
4411 by G.643 for 3 years.
4412
4413 (b) The record must include, as applicable:
4414
4415 (1) The date of the spot-check;
4416
4417 (2) The manufacturer's name, model number, and serial number for the remote
4418 afterloader unit and source;
4419
4420 (3) An assessment of timer accuracy;
4421
4422 (4) Notations indicating the operability of each entrance door electrical interlock,
4423 radiation monitors, source exposure indicator lights, viewing and intercom systems, and
4424 clock and decayed source activity in the unit's computer; and
4425
4426 (5) The name of the individual who performed the periodic spot-check and the
4427 signature of the authorized medical physicist who reviewed the record of the spot-check.
4428

4429 (c) A licensee shall retain a copy of the procedures required by G.643(b) until the licensee no
4430 longer possesses the remote afterloader unit.

4431

4432 Sec. G.2645 Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

4433

4434 (a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery
4435 units required by G.645 for 3 years.

4436

4437 (b) The record must include:

4438

4439 (1) The date of the spot-check;

4440

4441 (2) The manufacturer's name, model number, and serial number for the gamma
4442 stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

4443

4444 (3) An assessment of timer linearity and accuracy;

4445

4446 (4) The calculated on-off error;

4447

4448 (5) A determination of trunnion centricity;

4449

4450 (6) The difference between the anticipated output and the measured output;

4451

4452 (7) An assessment of source output against computer calculations;

4453

4454 (8) Notations indicating the operability of radiation monitors, helmet microswitches,
4455 emergency timing circuits, emergency off buttons, electrical interlocks, source exposure
4456 indicator lights, viewing and intercom systems, timer termination, treatment table
4457 retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

4458

4459 (9) The name of the individual who performed the periodic spot-check and the
4460 signature of the authorized medical physicist who reviewed the record of the spot-check.

4461

4462 (c) A licensee shall retain a copy of the procedures required by G.645(b) until the licensee no
4463 longer possesses the gamma stereotactic radiosurgery unit.

4464

4465 Sec. G.2647 Records of Additional Technical Requirements for Mobile Remote Afterloader
4466 Units.

4467

4468 (a) A licensee shall retain a record of each check for mobile remote afterloader units required
4469 by G.647 for 3 years.

4470

4471 (b) The record must include:

4472

4473 (1) The date of the check;

4474

- 4475 (2) The manufacturer's name, model number, and serial number of the remote
4476 afterloader unit;
4477
4478 (3) Notations accounting for all sources before the licensee departs from a facility;
4479
4480 (4) Notations indicating the operability of each entrance door electrical interlock,
4481 radiation monitors, source exposure indicator lights, viewing and intercom system,
4482 applicators, source transfer tubes, and transfer tube applicator interfaces, and source
4483 positioning accuracy; and
4484
4485 (5) The signature of the individual who performed the check.
4486

4487 Sec. G.2652 Records of Surveys of Therapeutic Treatment Units.
4488

- 4489 (a) A licensee shall maintain a record of radiation surveys of treatment units made in
4490 accordance with G.652 for the duration of use of the unit.
4491
4492 (b) The record must include:
4493
4494 (1) The date of the measurements;
4495
4496 (2) The manufacturer's name, model number and serial number of the treatment unit,
4497 source, and instrument used to measure radiation levels;
4498
4499 (3) Each dose rate measured around the source while the unit is in the off position
4500 and the average of all measurements; and
4501
4502 (4) The signature of the individual who performed the test.
4503

4504 Sec. G.2655 Records of 5-year Inspection for Teletherapy and Gamma Stereotactic
4505 Radiosurgery Units.
4506

- 4507 (a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma
4508 stereotactic radiosurgery units required by G.655 for the duration of use of the unit.
4509
4510 (b) The record must contain:
4511
4512 (1) The inspector's radioactive materials license number;
4513
4514 (2) The date of inspection;
4515
4516 (3) The manufacturer's name and model number and serial number of both the
4517 treatment unit and source;
4518
4519 (4) A list of components inspected and serviced, and the type of service; and
4520
4521 (5) The signature of the inspector.

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4523

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