INSTRUCTION SHEET

COMAR 26.12.01.01

Title: Regulations for the Control of Ionizing Radiation (1994)

SUPPLEMENT No. 34

Instructions: Supplement 34 to the document "Regulations for the Control of Ionizing Radiation (1994)" includes the following pages (all pages are inclusive):

Remove Pages	Insert Pages (future)
Cover Sheet	Cover Sheet
C53-3 through C53-4	C53-3 through C53-4
G15 through G15-1	G15 through G15-1
G17 through G19-1	G17 through G19-1

Verify to make certain that you have the pages listed above.

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Supplement 5 – Effective: June 14, 1999
Supplement 6 – Effective: February 7, 2000
Supplement 7 – Effective: April 1, 2002
Supplement 8 – Effective: October 13, 2003
Supplement 9 – Effective: October 27, 2003
Supplement 10 – Effective: March 29, 2004
Supplement 11 – Effective: June 7, 2004
Supplement 12 – Effective: June 20, 2005
Supplement 13 – Effective: December 8, 2005
Supplement 14 – Effective: October 9, 2006
Supplement 15 – Effective: December 17, 2007
Supplement 16 – Effective: June 15, 2009
Supplement 17 – Effective: June 15, 2009
Supplement 18 – Effective: November 15, 2010
Supplement 19 – Effective: November 15, 2010
Supplement 20 – Effective: September 19, 2011
Supplement 21 – Effective: August 6, 2012
Supplement 22 – Effective: October 29, 2012
Supplement 23 – Effective: January 6, 2014
Supplement 24 – Effective: September 15, 2014
Supplement 25 – Effective: June 22, 2015
Supplement 26 – Effective: September 14, 2015
Supplement 27 – Effective: October 26, 2015
Supplement 28 – Effective: November 24, 2016
Supplement 29 – Effective May 21, 2018
Supplement 30 – Effective February 22, 2021
Supplement 31 – Effective December 27, 2021
Supplement 32 – Effective December 12, 2022
Supplement 33 – Effective August 7, 2023
Supplement 34 – Effective pending

REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)

RADIOLOGICAL HEALTH PROGRAM
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(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by C.43(a) through (e). By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

~~(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 1, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 1, 2009. The information may be submitted by using any of the methods identified by C.43(f)(1) through (f)(4). The initial inventory report must include the following information:~~

~~(1) The name, address, and license number of the reporting licensee;~~

~~(2) The name of the individual preparing the report;~~

~~(3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;~~

~~(4) The radioactive material in the sealed source;~~

~~(5) The initial or current source strength in becquerels (curies); and~~

~~(6) The date for which the source strength is reported.~~

Secs.C.44–C.49 Reserved.

Modification and Revocation of Licenses

Sec. C.50 Modification and Revocation of Licenses.

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Agency.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Agency.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination or as otherwise provided by Agency order.

Sec. C.51 - C.89 Reserved.

(a) Has completed a structured educational program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(v) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an NRC or Agreement State license or permit issued by an NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a NRC or an Agreement State license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve the following:

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(iii) Securing and controlling radioactive material;

(iv) Using administrative controls to avoid mistakes in the administration of radioactive material;

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(vi) Using emergency procedures to control radioactive material; and

(vii) Disposing of radioactive material; and:

(3) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in G.50(b)(1) and G.50(d), and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(b) (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by an Agreement State or the NRC under G.51(a) and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and who meets the requirements in G.50(d); or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an NRC or an Agreement State license, a permit issued by an NRC master material licensee, a permit issued by an NRC or an Agreement State licensee of broad scope, or a permit issued by an NRC master material licensee broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer responsibilities; and meets the requirements in G.50(d) of this section; or

(3) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by an NRC master material licensee ~~master material license~~. The individual must also meet the requirements G.50 (d).

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

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in G.51(b)(1) and G.51(c), and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in G.51, G.57, or equivalent Agreement State or NRC requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(a) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Secs. G.52 – G.54 Reserved.

Sec. G.55 Training for an Authorized Nuclear Pharmacist.

Except as provided in G.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in G.55(b)(2). 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. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) (previously named American Council on Pharmaceutical Education) ~~American Council on Pharmaceutical Education~~ or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

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

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

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

(b) Has completed:

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

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

(e) Radiation biology; and

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

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

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

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

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

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

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

Sec. G.56 Reserved.

Sec. G.57 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.

(a) (1) An individual identified as a Radiation Safety Officer, a teletherapy physicist or authorized medical physicist, or an authorized nuclear pharmacist on an NRC or Agreement State license or a permit issued by an NRC or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of these regulations need not comply with the training requirements of G.50, G.51, or G.55, respectively except the Radiation Safety Officers and authorized medical physicists identified in G.57(a) must meet the training requirements in G.50(d) or G.51(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of G.50 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an NRC or an Agreement State license or an NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in G51, for those materials and uses that these individuals performed on or before October 24, 2005.

(4) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of G.50, G.51 or G.55, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

(b) (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized before the effective date of these regulations need not comply with the training requirements of G.100 through G.690.

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued in accordance with an NRC master material broad scope license on or before October 24, 2005 need not comply with the training requirements of G.100 through G.690 for those materials and uses that these individuals performed on or before October 24, 2005 as follows:.

(i) For uses authorized under G.100 or G.200, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under G.300, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under G.400 orG.600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under G.500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of G.100 through G.690 when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on a specific license for the same uses for which these individuals are authorized.

Sec. G.58 Reserved.