

MARYLAND DEPARTMENT OF THE ENVIRONMENT

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Martin O'Malley Governor Robert M. Summers, Ph.D. Secretary

Anthony G. Brown Lieutenant Governor

DEC 5 2013

Bran Holian, Deputy Director Division Materials Safety and State Agreements Office of Federal and State Materials and Environmental Management Programs U.S. Nuclear Regulatory Commission T8-E24 Washington, D.C. 20555-0001

Dear Mr. Holian:

Enclosed is a copy of proposed revisions (Supplement 24) to the Maryland Radiological Health Program Rules COMAR 26.12.01.01 titled, "Regulations for the Control of lionizing Radiation (1994)." The proposed regulations are identified by the attached line-in/line-out text and correspond to the following equivalent amendment(s) to NRC's regulations. We anticipate that we will be publishing this proposed supplement in the Maryland Register on or about April 18, 2014 with comments due prior to May 19, 2014.

RATS	Title	State Section(s)	
2012-3	Technical Corrections	C.31(e)(2)	
	Part 30, 34, 40 and 70	E.20(a)(1)	
	77 FR 39899	T Table A1	
	General License record retention.	C.22(d)(4)(iv)	
	Correction NRC comment final		
	Maryland license renewal schedule	C.33(b)	
	Clarification of calibration frequency	G.61(a)	



TTY Users 1-800-735-2258

Deputy Director Holian Page Two

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) procedure SA-200. If you have any questions, please feel free to contact Ray Manley of my staff at 410-537-3191 or at raymond.manley@maryland.gov.

Sincerely, Roland & . Fletch

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

Enclosure(s):

As stated

Code of Maryland Regulations 26.12.01.01

Adopted: September 9, 1995 Effective: October 9, 1995

Supplement 1	Effective: December 16, 1996
Supplement 2	Effective: November 3, 1997
Supplement 3	Effective: June 29, 1998
Supplement 4	Effective: December 28, 1998
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	
Supplement 24	

REGULATIONS FOR THE CONTROL OF IONIZING RADIATION (1994)



RADIOLOGICAL HEALTH PROGRAM AIR AND RADIATION MANAGEMENT ADMINISTRATION MARYLAND DEPARTMENT OF THE ENVIRONMENT 1800 WASHINGTON BOULEVARD BALTIMORE, MARYLAND 21230 (b) devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- and/or gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) shall assure that the tests required by C.22(d)(4)(ii) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

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

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

(iv) shall maintain records showing compliance with the requirements of C.22(d)(4)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by C.22(d)(4)(ii) shall be maintained for $\frac{23}{2}$ years after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by C.22(d)(4)(ii) shall be maintained for 2 years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by C.22(d)(4)(iii) shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed of.

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

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

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(vii) shall transfer or dispose of the device containing radioactive material by transfer to another general licensee as authorized in C.22(d)(4)(x), or to a person authorized to receive the device by a specific license issued under Section C that authorizes waste collection, or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or as otherwise approved under C.22(d)(4)(x);

Comment [mdk1]: Correction requested by NRC 3/28/13

Supp. 1524

Sec. C.30 Issuance of Specific Licenses.

(a) Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to this part.

Sec. C.31 Specific Terms and Conditions of Licenses.

(a) Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

- (b) (1) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.
 - (2) An application for transfer of license must include:
 - (i) The identity, technical and financial qualifications of the proposed transferee; and
 - (ii) Financial assurance for decommissioning information required by Section C.29.

(c) Each person licensed by the Agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(e) Each specific licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

- (1) the licensee;
- (2) an entity (as that term is defined in 11 U.S.C. 101(1415)) controlling the licensee or listing the license or licensee as property of the estate; or

Comment [mdk2]: RATS 2012-3

Supp. 2324

(i) As the final step in decommissioning, the licensee shall—

(1) Certify to the Agency in writing the disposition of all licensed material, including accumulated wastes; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406. The licensee shall, as appropriate—

(i) Report levels of gamma radiation in units of millisieverts (microroentgens) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters—removable and fixed—for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instruments(s) used and certify that each instrument is properly calibrated and tested.

(3) Forward all records required by Sec. C.38 to the Agency.

(j) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

(1) Radioactive material has been properly disposed of;

(2) Reasonable effort (as determined by the Agency) has been made to eliminate residual radioactive contamination if present; and

(3) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in Sections D.1401-1406.

Sec. C.33 Application for Renewal of Licenses.

(a) Subject to C.32(a), an application for renewal of a specific license must be filed on a form prescribed by the Agency, in accordance with C.24.

(b) All applications for the renewal of a specific license shall be submitted to the Agency for review and approval seven (7) months prior to the expiration date of the license.

<u>Sec. C.34 Amendment of Licenses at Request of Licensee</u>. Applications for amendment of a license shall be filed in accordance with C.24 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Sec. C.35 Agency Action on Applications to Renew or Amend. In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in C.25, C.26, C.27, and C.28 and in Parts E, G, or W of these regulations, as applicable.

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Supp. <u>924</u>

(2) No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the Agency until disposition is authorized by the Agency.

(3) The registrant shall perform an evaluation, at intervals not to exceed 1 year, to determine conformance with D.301 of these regulations. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed 1 year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Agency for a period of 3 years after the evaluation.

(c) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Agency pursuant to Part A.3(a) of these regulations.

Subpart C - Equipment

Sec. E.20 Performance Requirements for Industrial Radiography Equipment Using Sealed Sources of Radiation.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) (1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone: (212) 642-4900.

(2) Notwithstanding the provisions of paragraph E.308(a)(1), engineering analyses may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography components. Upon review, the Agency may find this an acceptable alternative to actual testing of the component pursuant to the referenced standard.

(b) In addition to the requirements specified in paragraph (a) of this section, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

(1) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the--

(i) Chemical symbol and mass number of the radionuclide in the device;

Comment [mdk3]: RATS 2012-3

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(d)A licensee shall also perform checks and tests required by G.60.B(b) following adjustment or repair of the dose calibrator.

(e) A licensee shall retain a record of each check and test required by G.60.B(b) for 3 years. The records required by G.60.B(b) shall include:

(1) For G.60.B(b)(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For G.60.B(b)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the identity of the individual performing the test;

(3) For G.60.B(b)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test; and

(4) For G.60.B(b)(4), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the identity of the individual performing the test.

Sec. G.61 Calibration and Check of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with this part have been calibrated before first use, annually at intervals not to exceed 12 months, and following repair.

(b) To satisfy the requirements of G.61(a), the licensee shall:

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

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

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

(c) To satisfy the requirements of G.61(b), the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

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

(e) The licensee shall retain a record of each calibration required in G.61(a) for 3 years. The record shall include:

(1) A description of the calibration procedure; and

Supp. 2024

Table A-1-A₁ and A₂ VALUES FOR RADIONUCLIDES

Comment [mdk4]: RATS 2012-3

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) <u>b</u>	A ₂ (TBq)	A ₂ (Ci) <u>b</u>	Specific activity	
						(TBq/g)	(Ci/g)
Tc-95m (<u>a</u>)	Technetium (43)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	8.3X10 ²	2.2X10 ⁴
Tc-96		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.2X10 ⁴	3.2X10 ⁵
Tc-96m (<u>a</u>)		4.0X10 ⁻¹	1.1X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.4X10 ⁶	3.8X10 ⁷
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	5.2X10 ⁻⁵	1.4X10 ⁻³
Tc-97m		4.0X10 ¹	1.1X10 ³	1.0	2.7X10 ¹	5.6X10 ²	1.5X10 ⁴
Tc-98		8.0X10 ⁻¹	2.2X10 ¹	7.0X10 ⁻¹	1.9X10 ¹	3.2X10 ⁻⁵	8.7X10 ⁻⁴
Tc-99		4.0X10 ¹	1.1X10 ³	9.0X10 ⁻¹	2.4X10 ¹	6.3X10 ⁻⁴	1.7X10 ⁻²
Tc-99m		1.0X10 ¹	2.7X10 ²	4.0	1.1X10 ²	1.9X10 ⁵	5.3X10 ⁶
Te-121	Tellurium (52)	2.0	5.4X10 ¹	2.0	5.4X10 ¹	2.4X10 ³	6.4X10 ⁴
Te-121m		5.0	1.4X10 ²	3.0	8.1X10 ¹	2.6X10 ²	7.0X10 ³
Te-123m		8.0	2.2X10 ²	1.0	2.7X10 ¹	3.3X10 ²	8.9X10 ³
Te-125m		2.0X10 ¹	5.4X10 ²	9.0X10 ⁻¹	2.4X10 ¹	6.7X10 ²	1.8X10 ⁴
Te-127		2.0X10 ¹	5.4X10 ²	7.0X10 ⁻¹	1.9X10 ¹	9.8X10 ⁴	2.6X10 ⁶
Te-127m (<u>a</u>)		2.0X10 ¹	5.4X10 ²	5.0X10 ⁻¹	1.4X10 ¹	3.5X10 ²	9.4X10 ³
Te-129		7.0X10 ⁻¹	1.9X10 ¹	6.0X10 ⁻¹	1.6X10 ¹	7.7X10 ⁵	2.1X10 ⁷
Te-129m (<u>a</u>)		8.0X10 ⁻¹	2.2X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	1.1X10 ³	3.0X10 ⁴
Te-131m (<u>a</u>)		7.0X10 ⁻¹	1.9X10 ¹	5.0X10 ⁻¹	1.4X10 ¹	3.0X10 ⁴	8.0X10 ⁵
Te-132 (<u>a</u>)		5.0X10 ⁻¹	1.4X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	3.1X10 ⁴ 1 .1X10 ⁴	3.0X10 ⁵
Th-227	Thorium (90)	1.0X10 ¹	2.7X10 ²	5.0X10 ⁻³	1.4X10 ⁻¹	1.1X10 ³	3.1X10 ⁴
Th-228 (<u>a</u>)		5.0X10 ⁻¹	1.4X10 ¹	1.0X10 ⁻³	2.7X10 ⁻²	3.0X10 ¹	8.2X10 ²
Th-229		5.0	1.4X10 ²	5.0X10 ⁻⁴	1.4X10 ⁻²	7.9X10 ⁻³	2.1X10 ⁻¹
Th-230		1.0X10 ¹	2.7X10 ²	1.0X10 ⁻³	2.7X10 ⁻²	7.6X10 ⁻⁴	2.1X10 ⁻²
Th-231		4.0X10 ¹	1.1X10 ³	2.0X10 ⁻²	5.4X10 ⁻¹	2.0X10 ⁴	5.3X10 ⁵
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	4.0X10 ⁻⁹	1.1X10 ⁻⁷
Th-234 (<u>a</u>)		3.0X10 ⁻¹	8.1	3.0X10 ⁻¹	8.1	8.6X10 ²	2.3X10 ⁴
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	8.1X10 ⁻⁹	2.2X10 ⁻⁷
Ti-44 (<u>a</u>)	Titanium (22)	5.0X10 ⁻¹	1.4X10 ¹	4.0X10 ⁻¹	1.1X10 ¹	6.4	1.7X10 ²
TI-200	Thallium (81)	9.0X10 ⁻¹	2.4X10 ¹	9.0X10 ⁻¹	2.4X10 ¹	2.2X10 ⁴	6.0X10 ⁵
TI-201		1.0X10 ¹	2.7X10 ²	4.0	1.1X10 ²	7.9X10 ³	2.1X10 ⁵
TI-202		2.0	5.4X10 ¹	2.0	5.4X10 ¹	2.0X10 ³	5.3X10 ⁴

Supp. <u>1624</u>