

2018
RATIONALE FOR REVISIONS
PART C
LICENSING OF RADIOACTIVE MATERIAL

Introduction

The proposed revisions to Part C were made to make Part C compatible with federal regulations. Since Part C was last revised in 2008 a number of amendments to federal regulations have been made. A summary of these amendments can be found at https://scp.nrc.gov/rss_regamendments.html. The federal regulations amendments are specified in U.S. Nuclear Regulatory Commission Regulation Amendment Tracking System Identification Numbers (RATS ID) 2011-1, 2011-2, 2012-3, 2012-4, 2013-1 and 2013-2. Other federal regulation amendment that were made since 2008 (see RATS ID 2012-1, 2012-2, 2015-1, 2015-2, 2015-3, 2015-4 and 2015-5) did not affect Part C.

Specific Provisions

C.2 - Carriers.

C.2. Reference was added to Part V to be consistent with 10 CFR 30.13 (RATS 2013-1).

C.3 - Source Material.

C.3 was changed as follows to be consistent with 10 CFR 40.13 (RATS 2013-2).

C.3c. Part D added to regulations that a person is exempt from. Spelling of thorium corrected in c.i.(6).

C.3c.ii. Manufacture before date of August 27, 2013 added to (1) and (2). Percentage by weight of source material added to (2).

C.3c.v. Paragraph (1) deleted and remaining paragraphs renumbered. Footnote revised.

C.3c.vii. Uranium added to thorium and mirror added to lens. Manufacture before date of August 27, 2013 added. Percentage by weight of source material added.

C.3c.viii. Deleted paragraph and renumbered remaining paragraphs.

C.3c.ix. Added new paragraph concerning transfer or distribution of source material to persons exempt.

C.4 - Radioactive Material Other Than Source Material.

C.4c. was changed as follows to be consistent with 10 CFR 30.15, 30.19, 30.20, 30.22 (RATS 2012-4).

C.4c.i(b). Added paragraph concerning static elimination devices and ion generating tubes.

C.4c.ii.(2) Deleted Ra-226 exemption.

C.4c.ii.(3) Renumbered to C.4.ii.(2). Added “initial transfer for sale or distribution” and added requirement for a certificate of registration.

C.4c.iii.(1) Reworded to change “life” to “health , safety” and deleted fires and airborne hazards phrase.

C.4c.iii.(3) Changed “byproduct material” to “radioactive material” and added requirement for a certificate of registration.

C.4c.v. Added new paragraph “Certain Industrial Devices”.

C.21 General Licenses - Source Material.

C.21. was changed as follows to be consistent with 10 CFR 40.22 (RATS 2013-2).

C.21a. Reworded to specify isotopes and forms of source material. Added C.21.a.i, ii., iii., iv. which sets the amount of source material allowed under the general license.

C.21b. Reworded to specify the other regulations that a person must comply with under the general license.

C.21c. Reworded and added C.21.c.i., ii. To state prohibitions on the general license.

C.21f. Added paragraph concerning minimizing contamination.

C.21g. Added paragraph concerning the required license to initially transfer or distribute source material to persons generally licensed.

C.22 General Licenses - Radioactive Material Other Than Source Material.

C.22. was changed as follows to be consistent with 10 CFR 31.3 (RATS 2012-4).

C.22.a. Paragraph was removed and reserved.

Footnote 4 was removed.

C.24 Filing Application for Specific Licenses.

C.24. was changed as follows to be consistent with 10 CFR 30.32 (RATS 2012-4).

C.24g.iii. Removed “containing naturally occurring or accelerator produced radioactive material” and changed manufactured prior to date to October 23, 2012. Added new paragraphs C.24.g.iii.(3) and (4).

C.25 General Requirements for the Issuance of Specific Licenses.

C.25e. Added to term “commencement of construction”.

C.28 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material.

C.28. was changed as follows to be consistent with 10 CFR 32.51, 32.53, 32.55, 32.56, 32.57, 32.59, 32.61, 32.62, 32.74, 32.101, 32.102, 32.103, 32.110, 32.210 (RATS 2012-4) and 10 CFR 40.54 and 40.55 (RATS 2013-2).

C.28d.i.(6) The new language was added.

C.28e.i.(2)(e) The paragraph was reworded.

C.28e.i.(4)(d) The paragraph was reworded.

C.28e.i.(4)(e) The paragraph was added.

C.28e.i.(4)(f) The paragraph was added.

C.28e.iii.(2), (3), (4) were completely rewritten.

C.28e.iv. The section was deleted.

C.28.e.v. The section was renumbered to C.28.e.iv. Statement concerning transfer reports added to paragraph (1). New paragraph (2) added.

C.28f.i.(4) Reference to the deleted Schedule C of this Part was deleted.

C.28f.ii. Schedule C prototype tests were deleted, paragraph was reworded to be consistent with federal regulations.

C.28i.ii.(3), (4), (5) Paragraphs was reworded to be consistent with federal regulations.

C.28i.iii. Information on prototype tests deleted. Paragraph was reworded to be consistent with federal regulations.

C.28k.vii. Added to require SSD registration.

C.28m. Paragraph concerning acceptance sampling procedures and Lot Tolerance Percent Defectives were deleted.

C.28m. New paragraph concerning registration of product information added.

C.28n. New paragraph added.

C.28o. New paragraph added.

C.29 Inactivation of Certificates of Registration of Sealed Sources and Devices.

C.29 was changed as follows to be consistent with 10 CFR 32.211 (RATS 2012-4).

C.29 New paragraph added.

C.31 Specific Terms and Conditions of Licenses.

C.31 was changed as follows to be consistent with 10 CFR 30.34 and 10 CFR 40.46 (RATS 2011-1) and 10 CFR 30.34 (RATS 2012-3).

C.31b.ii. New paragraph added concerning information needed to transfer a license.

C.31e.ii. US Code reference updated.

Matters for Future Consideration

1. Part C will need to be amended to reflect changes to federal regulations outlined in RATS ID 2018-1 “Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments” which take effect on January 14, 2019. The required amendments to Part C will need to be made in conjunction with amendments to Part G “Use of Radionuclides in the Healing Arts”.
2. In the “Matters for Future Consideration” following the 2008 revision to Part C it was suggested that Part C be restructured to “make it more user friendly and easier to read.” This revision does not reflect this needed restructuring. A restructuring of Part C would be a major and resource intensive effort that would also affect other SSR Parts.