

In August of 2007, The Nuclear Regulatory Commission (NRC) amended its regulations to include jurisdiction over discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. This provided a regulatory framework by which to license and regulate byproduct material in accordance with the new, expanded definition. The amended regulations impacted numerous existing NRC information collections. The NRC packaged all the impacted information collections under the amended regulations and submitted it to OMB as a new information collection, which OMB approved and assigned control number 3150-0203. NRC is submitting this “no material or nonsubstantive change to a currently approved collection” to move the approved information collection burden covered under 3150-0203 to the NRC existing approved collections for Parts 31, 32, and Form 313. The specifics for each “no material or nonsubstantive change is outlined below.

One of the areas of existing Nuclear Regulatory Commission (NRC) regulations revised was Part 32 of which the information collection is covered by the currently approved information collection 3150-0001. The amended sections of Part 32 covered in 3150-0203 are outlined below.

Section 32.72(a)(4) requires that an applicant for a license pursuant to Section 32.72 satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The universe of licensees affected by this regulation is increased by an estimated 22 NRC licensees and 88 new Agreement State licensees.

Section 32.72(b)(5) applies to licensees that are licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution. These licensees are required to provide the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the State pharmacy licensure or registration. The universe of licensees affected by this regulation is increased by an estimated 22 NRC licensees and 88 new Agreement State licensees.

Section 32.72(c) requires that a licensee that possesses and uses instrumentation to measure radioactivity of radioactive drugs, pursuant to Section 32.72, shall have procedures for use of the instrumentation. The licensees may use procedures provided by the manufacturer of the instrumentation. There is an annualized one-time implementation burden for an estimated 22 NRC licensees and 88 new Agreement State licensees.

Section 32.74(a)(2)(viii) requires that persons licensed pursuant to Section 32.74 label the source or device with instructions for handling and storing the source or device from the radiation safety standpoint. The universe of licensees affected by this regulation is increased by an estimated 3 NRC licensees and 12 new Agreement State licensees.

One of the areas of existing Nuclear Regulatory Commission (NRC) regulations revised was Part 31.

One of the areas of existing Nuclear Regulatory Commission (NRC) regulations revised was Part 31. The following sections impacted the existing information collections cleared under OMB number 3150-0016:

Section 31.5(c)(4) requires general licensees to maintain records showing that tests for leakage of radioactive materials, proper operation of on-off mechanism, and/or other specified tests have been performed. The universe of NRC licensees affected by this regulation is increased by an estimated 100 licensees and 400 new Agreement State licensees.

Section 31.5(c)(5) requires the general licensee to report to NRC within 30 days in the case of failure or damage to a device, or evidence of damage or contamination. The report must include a brief description of the event and remedial actions undertaken. This is to ensure that any significant contamination from incidents involving these devices is adequately cleaned up. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. However, the circumstances for reporting have a low probability of occurring, and no overall change in the number of reports is expected.

Section 31.5(c)(8) requires general licensees to transfer or dispose of devices containing byproduct material by one of five different methods and report the transfer to NRC. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. A small fraction of these new licensees, about 5 NRC general licensees and 20 new Agreement State licensees would transfer a device in any year.

Section 31.5(c)(9) requires a general licensee wishing to transfer a device to another general licensee to provide certain information to the transferee and report the transfer to the NRC. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. Such transfers occur infrequently. One additional NRC licensee and 4 additional Agreement State licensees are expected to be affected by this provision.

Section 31.5(c)(11) is revised to require general licensees to respond to written requests from NRC to provide information relating to the general license. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. The universe of NRC licensees affected by this regulation is increased by an estimated 10 licensees and 40 new Agreement State licensees.

Section 31.5(c)(13) is revised to require general licensees to register devices containing 3.7 megabecquerels (0.1 millicurie) of radium-226. The reporting burden for this is done under NRC Form 664, "General License Registration," cleared under OMB Clearance No. 3150-0198. No overall change in the number of reports is expected.

Section 31.5(c)(14) requires general licensees to notify NRC within 30 days of changes of address for the location of use of devices. For portable devices, the change of address reporting applies only to the device's primary place of storage. This requirement will apply to the general licensees added under Section 31.5 as a result of this action. Such moves occur infrequently. About 5 NRC general licensees and 20 Agreement State licensees would notify of a change of address in any year.

Sections 31.11(b) and (e) add cobalt-57 used for in vitro clinical or laboratory testing to the currently required byproduct material to be reported on NRC Form 483, "Registration Certificate - In vitro testing with Byproduct Material under General License" because the general license in Section 31.11 now also apply to certain quantities of cobalt-57. It is believed there will be no overall change in the number of reports due to this new reporting requirement.

Section 31.12(c)(1) is new and requires that the new category of general licensee report to NRC any indication of possible damage to the product such that it appears a loss of the radioactive material could result. It is estimated that 3 reports annually will be made to NRC under this new requirement and 12 reports annually will be made to Agreement States.

Section 31.12(c)(4) indicates acceptable means of disposal of the products covered by this new general license and requires NRC approval for means not listed. No requests for alternate means are expected.

Section 31.12(c)(5) is new and requires that the new category of general licensee respond to written requests from NRC to provide information relating to the general license. Licensees to be covered by the new general license are not currently known to the NRC. This provision will provide a means of obtaining needed information if situations presenting potential health and safety impacts become known to NRC in the future. No requests for information are expected to be made in the immediate future.

The previously approved burden for Part 31:

Number of Responses: 51,205 responses (NRC licensees = 1,977 responses + 6,600 recordkeepers plus Agreement States = 16,228 responses + 26,400 recordkeepers)
Respondents: 33,000 (6,600 NRC licensees + 26,400 Agreement State licensees)
Burden Hours: 15,118 hours (NRC licensees = 2,474 hrs plus Agreement States = 12,644 hrs)

Burden Hour increase for Part 31 as a result of the final rule (see Tables 1-4):

Number of Responses: 620 (124 NRC + 496 Agreement State)
Respondents: 500 (NRC licensees = 100 plus Agreement State licensees = 400)
Burden Hours: 225 hours (45 NRC + 180 Agreement State)

TOTAL REQUESTED BURDEN HOURS (Previously approved burden plus final rule)

Number of Responses: 51,825 responses (NRC licensees = 2,001 responses + 6,700 recordkeepers plus Agreement States = 16,324 responses + 26,800 recordkeepers)
Respondents: 33,500 (6,700 NRC licensees + 26,800 Agreement State licensees)
Burden Hours: 15,343 hours (NRC licensees = 2,519 hrs plus Agreement States = 12,824 hrs)

Table 1
Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours
31.5(c)(5)	0	1	0	0.6	0
31.5(c)(8)	5	1	5	0.6	3
31.5(c)(9)	1	1	1	1	1
31.5(c)(11)	10	1	10	0.34	3.4
31.5(c)(13)	0	1	0	0.6	0
31.5(c)(14)	5	1	5	0.1	.5
31.11(b)&(e)	0	1	0	0.6	0
31.12(c)(1)	3	1	3	4	12
31.12(c)(4)	0	1	0	4	0
31.12(c)(5)	0	1	0	4	0
Total Part 31 Reporting		Not Applicable	24		20

Table 2
Recordkeeping Requirements for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours
31.5(c)(4)	100	0.25	25
Total Part 31 Recordkeeping			25

PART 31 NRC Licensee Totals:

Number of Responses: 124 (24 responses + 100 additional recordkeepers)

Number of Respondents: 100

Total Burden Hours: 45 hours (20 hours reporting + 25 hours recordkeeping)

Table 3**Part 31 Equivalency Reporting Burden for Agreement State Licensees**

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours
31.5(c)(5)	0	1	0	0.6	0
31.5(c)(8)	20	1	20	0.6	12
31.5(c)(9)	4	1	4	1	4
31.5(c)(11)	40	1	40	0.34	13.6
31.5(c)(13)	0	1	0	0.6	0
31.5(c)(14)	20	1	20	0.1	2
31.11(b)&(e)	0	1	0	0.6	0
31.12(c)(1)	12	1	12	4	48
31.12(c)(4)	0	1	0	4	0
31.12(c)(5)	0	1	0	4	0
Total Part 31 Reporting		Not Applicable	96		80

Table 4**Part 31 Equivalency Recordkeeping Burden for Agreement State Licensees**

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours
31.5(c)(4)	400	0.25	100
Total Part 31 Recordkeeping			100

PART 31 Agreement State Licensee Totals:

Number of Responses: 496 (96 responses + 400 additional recordkeepers)

Number of Respondents: 400

Total Burden Hours: 180 hours (80 hours reporting + 100 hours recordkeeping)

PART 31 Totals

Number of Responses: 620 (124 NRC + 496 Agreement State)

Number of Respondents: 500 (100 NRC + 400 Agreement State)

Total Burden Hours: 225 hours (45 NRC + 180 Agreement State)

One of the areas of existing Nuclear Regulatory Commission (NRC) regulations revised was Form 313 and the 313A series of forms, OMB control number 3150-0120.

NRC Form 313 is used to apply to the NRC for a materials license. The universe of licensees that use this form will increase as a result of the final rule. The increase is estimated to be a total of 1 NRC licensee on an annual basis and 4 Agreement State licensees on an annual basis (total of 5 licensees). The additional burden associated with NRC licensees' effort to complete NRC Form 313 on an annual basis is a total of 40 hours as shown in the NRC Form 313 table at the end of this section. The estimated equivalent additional burden for Agreement State licensees is a total of 160 hours as shown in the table at the end of this section. The total increase in hours for NRC Form 313 on an annual basis is 200 hours.

The currently approved burden for Form 313 is as follows:

Responses:	16,248 responses (2,958 for NRC Licensees plus 13,290 for Agreement State Licensees).
Respondents:	16,248 respondents (2,958 for NRC Licensees plus 13,290 for Agreement State Licensees).
Burden Hours	69,866 hours (12,719 hours for NRC Licensees plus 57,147 hours for Agreement State Licensees)

Burden Hour increase as a result of the final rule (see Tables 1-4):

Responses:	5 (1 NRC + 4 Agreement State)
Respondents:	5 (1 NRC + 4 Agreement State)
Burden Hours:	200 hours (40 NRC + 160 Agreement State)

TOTAL REQUESTED BURDEN HOURS (Currently approved burden plus final rule)

Responses:	16,253 responses (2,959 for NRC Licensees plus 13,294 for Agreement State Licensees).
Respondents:	16,253 respondents (2,959 for NRC Licensees plus 13,294 for Agreement State Licensees).
Burden Hours	70,066 hours (12,759 hours for NRC Licensees plus 57,307 hours for Agreement State Licensees)

NRC Form 313 (includes the Form 313A series of forms) Reporting Burden (3150-0120)

Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours
PET-new lic	1	1	1	40	40
NRC Form 313 Reporting			1		40

NRC Form 313 NRC Licensee Totals:

Number of Responses: 1
 Number of Respondents: 1
 Total Burden Hours: 40 hours

Annual Reporting Requirements for Agreement State Licensees

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours
PET-new lic	4	1	4	40	160
NRC Form 313 Reporting			4		160

NRC Form 313 Agreement State Licensee Totals:

Number of Responses: 4
 Number of Respondents: 4
 Total Burden Hours: 160 hours

NRC Form 313 Totals

Number of Responses: 5 (1 NRC + 4 Agreement State)
 Number of Respondents: 5 (1 NRC + 4 Agreement State)
 Total Burden Hours: 200 hours (40 NRC + 160 Agreement State)

