

June 14, 2012

SUMMARY OF INFORMATION COLLECTION REQUEST

Title: 10 CFR Parts 30, 40, 70, and 170: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of the General License and Exemptions

Current and New Hours and Responses:

	Current		New		Total	
	Hours	Responses	Hours	Responses	Hours	Responses
Part 19	640,521	43,505	112.8	28	640,776	43,530
Part 20	65,418	894	255	25	65,699.40	1031
Part 40	31,795	3,967	281.4	137	31,907.80	3,995
NRC Form 313	83,558	15,127	218.4	18.7	83,675.20	15,139.70
			867.6	208.7		

Total for rule: 867.6 hours/ 208.7 responses or 4.2 hours per response

Frequency of Response: One time for licensing applications and amendments for new initial distribution licenses or for certain general licensees ceasing activities; annual for reports on initial distribution of source material; occasional for responses to direct NRC requests for information.

Number of Respondents: TOTAL 75 (40 NRC licensees, 35 AS licensees)

- 10 CFR Part 19 = 3 respondents
- 10 CFR Part 20 = 18 respondents
- 10 CFR Part 40 = 75 respondents
- NRC Form 313 = 16.3 respondents)

75 (10 CFR Part 19 = 3 respondents, 10 CFR Part 20 = 18 respondents, 10 CFR Part 40 = 75 respondents, NRC Form 313 = 16.3 respondents). Because some licensees may report under multiple parts, the total number of respondents for the final rule is 75 (40 NRC licensees plus 35 Agreement State licensees). Some of these licensees are already reporting to the NRC. It is estimated that 68 licensees will be subject to new reporting and recordkeeping requirements in Part 40 (38 due to the new requirement in 40.22(b)(4) and 30 due to new requirements in 40.53(c)). In addition, 3 Part 19 licensees and 18 Part 20 licensees will be newly subject to reporting and recordkeeping requirements under those parts, as well as 16 licensees reporting on NRC Form 313.

Reasons for Changes in Burden/Responses: The rule results in a total increase in burden of 867.6 hours and 208.7 responses annually:

- The burden for Part 19 increased by 112.8 hours, from 31,795 to 31,907.8 hours.
- The burden for Part 20 increased by 255 hours, from 640,521 hours to 640,776 hours.
- The burden for Part 40 increased by 281.4 hours, from 65,418 to 65,669.4 hours.

- The burden for NRC Form 313 increased by 218.4 hours, from 83,558 hours to 83,776.4 hours.

Currently, Part 40 does not include any requirement to report information about source material being distributed for use under the general license in Section 40.22 or under any exemption from licensing in Section 40.13. Because the NRC does not require the reporting of products and materials distributed for use under the general license or exemptions, the NRC cannot readily determine if the source material is being maintained in accordance with the regulatory requirements for those uses, or how or in what quantities the source material is being used. As a result, the NRC cannot fully assess the resultant risks to public health and safety. Because of the difficulty of collecting such information and its limited reliability, the NRC has concluded that new reporting requirements on the distribution of source material to Section 40.22 general licensees and persons exempt from licensing would significantly increase the NRC's ability to evaluate impacts and more efficiently and effectively protect public health and safety from the use of source material.

The final rule adds a requirement in 10 CFR 40.13(c)(10) that requires persons who initially transfer products for use under a product exemption in 10 CFR 40.13(c) to obtain a specific license to be issued under 10 CFR 40.52. This means that those persons who previously operated as general licensees (and therefore did not have to submit an application to the NRC) and manufacture and initially distribute products for use under 10 CFR 40.13(c) must now be licensed as specific licensees. To become specific licensees, they must submit an application (NRC Form 313, "Application for Materials License") to the NRC. An estimated 30 licensees would be required to submit NRC Form 313 as an application to become specific licensees in order to distribute source material products to persons for use under exemption.

As specific licensees, these licensees are also subject to Parts 19 and 20. Previously, as general licensees, they were not subject to the requirements of these Parts. However, an estimated 18 of these new specific licensees would meet thresholds for reporting and recordkeeping requirements under Part 20 and 3 would meet the thresholds for Part 19.

Recordkeeping Requirements in Accordance with the Retention Periods for Records/Rule:

There is no variation from OMB guidelines in terms of records retention.

Abstract: The NRC is proposing to amend its regulations in 10 CFR Part 40 to establish new requirements for distributors of source material to persons exempt from the regulations or for use under a general license in § 40.22. In addition, the Commission is also proposing to modify the existing possession and use requirements for § 40.22 general licensees to align the requirements with current health and safety standards. Finally, the Commission is proposing to revise, clarify, or delete certain exemptions in § 40.13(c) to make the exemptions more risk informed. Conforming changes would be made to 10 CFR Parts 30, 70, 170 and 171. These changes would affect manufacturers and distributors of products and materials containing source material and future users of some products used under exemptions from licensing and under the § 40.22 general license.

Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements contained in Parts 19, 20, 40 and NRC Form 313 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval numbers 3150-0014, -0020, -0044, and -0120. The final rule changes to 10 CFR parts 30, 70, 170, and 171 do not contain new or amended information collection requirements.

The burden to the public for these information collections is estimated to average 4.2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov; and to the Desk Officer, Chad Whiteman, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0014, -0020, -0044, and -0120), Office of Management and Budget, Washington, DC 20503. You may also e-mail comments to [Chad S Whiteman@omb.eop.gov](mailto:Chad_S_Whiteman@omb.eop.gov) or comment by telephone at (202) 395-4718.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.