

FINAL OMB SUPPORTING STATEMENT  
FOR  
NRC FORM 313, "APPLICATION FOR MATERIALS LICENSE,"  
AND NRC FORMS 313A (RSO), 313A (AMP), 313A (ANP), 313A (AUD), 313A (AUT),  
AND 313A (AUS)

(3150-0120)

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EXTENSION WITH BURDEN REVISION

Description of the Information Collection

In order for a person to be licensed to possess, use, or distribute licensed material, the person must submit an application that will permit the U.S. Nuclear Regulatory Commission (NRC) to determine whether the applicant has training, experience, equipment, facilities, and procedures for the use of radioactive material that are adequate to protect the public health and safety. NRC Form 313, "Application for Materials License" is used to provide the information required.

For medical use and commercial nuclear pharmacy applicants, the NRC Form 313 may include the following NRC Form 313A series of forms:

- NRC Form 313A (RSO), "Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR 35.50]"
- NRC Form 313A (AMP), "Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR 35.51]"
- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]"
- NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]"
- NRC Form 313A (AUT), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]"
- NRC Form 313A (AUS), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]"

If the information in the NRC Form 313 (which includes the NRC Form 313A series of forms) in the application fulfills the substantive requirements stated elsewhere in the regulations, the NRC issues a license.

On November 30, 2007, the NRC's final rule "10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171, Requirements for Expanded Definition of Byproduct Material," (the "NARM Rule") took effect. As part of the OMB package for this rule, there was a three year annualized burden associated with one new NRC Positron Emission Tomography (PET) radionuclide production license and four new PET licenses for Agreement States. These burdens are included in this package.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

10 CFR Sections 30.15, 30.19, 30.20, 30.21, 30.32, 30.37, 30.38, 32.18, 32.11, 33.12, 34.11, 35.12, 36.11, 39.11, 40.31, 40.43, and 40.44 provide for the filing of an application for a specific license for possession, use, and distribution of byproduct or source material on NRC Form 313, "Application for Materials License," for a specific license. 10 CFR Section 35.12 also provides for the filing of training and experience information on NRC Form 313 of which NRC Form 313A series of forms is a part. The information required under training and experience for the medical use and commercial nuclear pharmacy applicant or licensee is found in 10 CFR Sections 32.72, 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, and 35.690.

The information submitted on NRC Form 313 (which may include the NRC Form 313A series of forms) is reviewed by the NRC staff to determine whether the applicant is qualified by training and experience, as well as to assess whether the applicant has equipment, facilities, and procedures which are adequate to protect the health and safety of the public and minimize danger to life or property.

2. Agency Use of Information

NRC reviews the information submitted in order to determine whether the applicant's training, personnel experience, equipment, facilities, and procedures for the use of byproduct or source material are adequate to protect the public health and safety as required by the Atomic Energy Act, as amended, the Energy Reorganization Act of 1974, as amended, and the Energy Policy Act of 2005 so that the Commission may determine whether to issue, amend, or renew a license.

3. Reduction of Burden through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. The current percentage of electronic submission is about 5 percent.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

While a number of licensees are considered small businesses, the health and safety consequences of improper use of radioactive material are the same for large and small entities. There is a minimum amount of information that must be provided in order for the Commission to determine if an applicant's facilities, equipment, and procedures are adequate to protect the public health and safety. Therefore, it is not possible to reduce the burden on small businesses by less frequent submission or less complete applications.

6. Consequences to Federal Program or Policy Activities if the Collection is not Conducted or is Conducted Less Frequently

Applications for a new license are submitted only once, while applications for renewal of a license are submitted every ten years. Amendments are submitted as needed by the licensee. This is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of the public health and safety. If the information is not collected, the NRC will have no way to determine the adequacy of licensees' programs to protect the public health and safety.

7. Circumstances which Justify Variation from OMB Guidelines

There are no variations from OMB guidelines.

8. Consultations Outside the NRC

The opportunity for public comment on the information collection requirements for this clearance package was published in the Federal Register on May 30, 2008 (73 FR 31151). No comments were received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

11. Justification for Sensitive Questions

Sensitive information is not requested under these regulations.

12. Estimated Burden and Burden Hour Cost

A. NRC Licensees

The burden associated with the use of NRC Form 313 and NRC Form 313A series of forms for new licenses, amendments and renewals is based on (1) the

estimated number of licensing actions processed during fiscal year (FY) 2007, and (2) the NARM Rule burden already described.

The estimated number of NRC licenses for 2008 through 2011 is based on the number of NRC materials licenses and Master Materials License permits at the end of FY 2007 adjusted for Pennsylvania becoming an Agreement State on March 31, 2008. This results in a total estimated number of NRC licensees of 4,005.

The number of new NRC licenses and amendments per year for 2008 through 2011 is estimated from the number of these NRC licensing actions in FY 2007 (excluding licensing actions for licensees in Pennsylvania) and the addition of NRC Master Materials License permit amendments. This resulted in an estimated 147 new license and 1,831 amendment applications per year for the possession, use, and initial distribution of byproduct and source material for 2008 through 2011. The burden associated with the use of NRC Forms 313 and 313A for license renewals per year is based on the estimated number of NRC licenses averaged over the 10 year license renewal period. Because NRC did not redistribute these renewals over the entire 10 year period, almost all licenses are renewed during the first 5 years of this period. This results in an estimated 386 renewal applications per year for the same period. Therefore, the total estimated number of NRC licensing actions per year from 2008 through 2011 is 2,364.

In addition, the NARM rule includes 40 hours of annual burden for 1 PET license application. The total NARM burden included is 40 hours.

Based on 2,364 licensing actions per year and the described NARM burden, the industry burden for licensing is estimated to be 10,205 hours (4.3 hrs/licensing action x 2,364 licensing actions plus 40 NARM burden hours for 1 licensing action). The annual cost to all affected NRC licensees is estimated to be \$2,428,790 (10,205 x \$238/hr).

#### B. Agreement State Licensees

NRC estimates that there is approximately 4.6 times the number of Agreement State licensees as there are NRC licensees now that Pennsylvania has become an Agreement State. The change from the previous estimate of 3.6 to 4.6 is based on (1) the most recent estimate of 4,005 NRC byproduct material licensees (including NRC Master Material License permittees and reduced by the number of Pennsylvania licenses that became Agreement State licensees on March 31, 2008) and (2) the estimated 18,293 Agreement State licenses (including the Pennsylvania licenses that became Agreement State licenses).

The numbers of Agreement State new license (676 new licenses) and amendment applications (8,423 amendment applications) are estimated from the number of these NRC licensing actions times the 4.6 ratio of Agreement State licenses to NRC licenses. The Agreement States retained an average 5-year license renewal period for its byproduct, source, and special nuclear materials licenses. The estimated number of Agreement State renewals is 3,659. Therefore, it is estimated that there are a total of 12,758 Agreement State licensing actions annually. Additionally, NRC estimates that the amount of time

to prepare an application and the associated costs will be the same as for NRC licensees.

Since the Agreement States already regulated NARM materials, only the burden for the 4 new PET licenses was needed to correct for the use of NARM material (4 PET licensing actions X 40 hours per licensing action = 160 hours).

The total burden for Agreement State licensees is estimated to be 55,019 hours (4.3 hrs/licensing action X 12,758 licensing actions plus 160 NARM burden hours for 4 PET licensing actions).

The estimated annual cost to the Agreement State licensees to prepare applications and submit required information on forms equivalent to NRC Form 313 (which may include the NRC Form 313A series of forms) is estimated to be \$13,094,522 (\$238 per hr X 55,019 hrs).

#### C. Total

The total burden for NRC licensees and Agreement State licensees combined is 65,224 hours (NRC licensees: 10,205 hours + Agreement State licensees: 55,019 hours). The estimated total cost is \$15,523,312 (65,224 hours x \$238/hr).

#### 13. Estimate of Other Additional Costs

There is no additional cost.

#### 14. Estimated Annualized Cost to the Federal Government

It is estimated that the review of the information on NRC Forms 313 (which for medical use and commercial nuclear pharmacy applicants and licensees may include the NRC Form 313A series of forms) will take an average of approximately 4.3 hours per application. Based on an anticipated 2,365 licensing actions (2,364 licensing actions plus the estimated 1 NARM licensing action), at a cost of \$238 per hour, the cost to perform the licensing review would be \$2,420,341 (2,365 licensing actions x 4.3 hrs/licensing action x \$238/hr). This cost is fully recovered through license fees charged to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

#### 15. Reasons for Changes in Burden or Cost

##### NRC Licensees

The previous burden for NRC licensees was 12,759 hours which included 12,719 hours to complete the NRC Form 313 (which may include NRC Form 313A series of forms) and 40 hours of burden attributed to the NARM Rule. The burden for NRC licensees is expected to decrease from 12,759 to 10,205 hours because of the reduction in licensing actions by an estimated 594, from 2,958 to 2,364 licensing actions. At 4.3 hours per licensing action, this is a reduction of 2,554 hours (594 actions x 4.3 hours = 2,554). This reduction in licensing actions is because there are fewer NRC licensees as a result of Pennsylvania becoming an Agreement State and a trend of a slight decrease in overall licensing actions.

### Agreement State Licensees

The previous burden for Agreement State licensees was 57,307 hours, which included 57,147 hours to complete the NRC Form 313 and NRC Form 313A series of forms and 160 hours of burden attributed to the NARM rule. There are fewer estimated licensing actions for Agreement States based on our calculations even though there is an increase in the number of Agreement State licensees now that Pennsylvania is an Agreement State. The estimated number of licensing actions decreased by 532 from 13,290 to 12,758 licensing actions. At 4.3 hours per licensing action, this is a reduction of 2,288 hours (532 actions x 4.3 hours = 2,288), a change from 57,307 to 55,019 hours.

### Total Burden

The total estimated burden for completing NRC Form 313 (which includes the NRC 313A series of forms) will decrease by 4,842 hours, from 70,066 hours (12,759 for NRC licensees and 57,307 for Agreement State licensees) to 65,224 hours (10,205 for NRC licensees and 55,019 for Agreement States).

In addition, the fee rate increased from \$156 to \$238 per hour.

#### 16. Publication for Statistical Use

This information will not be published for statistical use.

#### 17. Reason for Not Displaying the Expiration Date

The expiration date is displayed on NRC Forms 313 and NRC Form 313A series of forms.

#### 18. Exceptions to the Certification Statement

There are no exceptions.

### B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

TABLE 1

## Annualized Reporting Burden for NRC Licensees

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours
NRC Form 313 and 313A Series Licensing Actions	2,364	1	2,364	4.3	10,165
PET new licensees	1	1	1	40	40
<b>TOTAL</b>			2,365		10,205

TABLE 2

## Annualized Reporting Burden for Agreement States

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours
NRC Form 313 and 313A Series Licensing Actions	12,758	1	12,758	4.3	54,859
PET new licensees	4	1	4	40	160
<b>TOTAL</b>			12,762		55,019