

DRAFT SUPPORTING STATEMENT FOR  
10 CFR PART 30  
"RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT  
MATERIAL"

(3150-0017)

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EXTENSION

Description of Information Collection

The regulatory requirements in 10 CFR Part 30 identify the information required by the U.S. Nuclear Regulatory Commission (NRC) in order for an individual or other entity to be licensed to possess, use, or distribute byproduct material. These requirements specify that the individual or other entity must submit an application that contains the information that will permit the NRC to determine whether the applicant has training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect public health and safety. There is no required template for applying for a license, however the NRC published a series of technical reports (NUREG-1556 series, "Consolidated Guidance About Materials Licenses")<sup>1</sup>, that may assist applicants in developing their submissions. An applicant may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in 10 CFR 30.6, "Communications."<sup>2</sup> The information collections related to NRC Form 313 are captured under OMB No. 3150-0120.

10 CFR Part 30 also includes reporting and record keeping requirements for current byproduct material licensees. An example of a reporting requirement for an event involving licensed material would be 1) an unplanned contamination or 2) a failure of equipment that is required by regulation or license condition to prevent releases exceeding regulatory limits. Licensees are also required to maintain certain records related to the receipt, transfer, and disposal of byproduct material for specific periods of time.

A. Justification

1. Need for the Collection of Information

The commitments made by the applicant in the application, as well as the information provided as part of the application package, are reviewed by the NRC staff to determine if the applicant has training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect public health and safety. In addition, the information is needed by NRC staff to prepare the license. The license will include the quantity and type of byproduct material that will be used, the form of the byproduct material, and will

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<sup>1</sup> NUREG-1556 is available on the NRC website at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>

<sup>2</sup> NRC Form 313 is available on the NRC website at <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf> and is approved by OMB under clearance number 3150-0120

identify the types of activities that the licensee will be authorized to perform. When issued, the licenses for possession, use, and distribution will include conditions in the license or "license conditions." License conditions are specific to the particular licensee as dictated by that licensee's particular facilities, equipment, or type of use of material. Some license conditions are applied to most licensees, and some to certain types of licensees based on the category of use of byproduct material (e.g., radiography, medical use for humans, etc.). These are known as "established standard license conditions." Established standard license conditions are utilized by NRC and the Agreement States to ensure that provisions for protection of public health and safety are imposed consistently among licensees. They are used in conjunction with the requirements in 10 CFR that the licensee commits to when applying for a license. A selection of commonly used standard license conditions which contain reporting or recordkeeping requirements are described in detail under the description of Section 30.34(e)(4).

The new technology/uses standard license conditions are imposed on individual licensees and groups of licensees engaged in new materials uses or the use of new technologies in established materials uses. New technology/uses standard license conditions will be utilized by all NRC regions to ensure that provisions for protection of public health and safety are imposed consistently among licensees. They are used in conjunction with the requirements in Title 10 of the Code of Federal Regulations (10 CFR) that the licensee commits to when applying for a license. New technology/uses standard license conditions which contain reporting or recordkeeping requirements similar to those in the regulations and established license conditions are described in greater detail in Section 30.34(e)(4).

After the NRC issues a license, the NRC will ensure that licensees are following their commitments by performing health and safety inspections. Inspections include review of the licensee records related to byproduct material. These records are needed to ensure that the licensee is using the byproduct material safely and in accordance with applicable NRC regulations. It is the licensee's responsibility to ensure it continues to maintain the commitments it made in its application to ensure it fulfills the regulatory requirements in 10 CFR Part 30.

A description of each information collection requirement contained in 10 CFR Part 30 is located in Supplement 1, at the end of this supporting statement.

## 2. Agency Use and Practical Utility of the Information

The records that 10 CFR Part 30 requires the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC radiation safety requirements for possession and use of byproduct material.

The records of receipt, transfer, and disposal of byproduct material are reviewed by the NRC inspectors to determine that licensees have confined their possession and

use of byproduct material to the locations, purposes, receipt, and quantities authorized in their licenses.

Reports of significant safety events and theft of radioactive material are used by the agency in evaluating the protective actions required to avoid exposures to radiation or releases of radioactive materials that could exceed regulatory limits and, therefore, impact public health and safety, the common defense and security, and the environment.

Bankruptcy reports, decommissioning plans, decommissioning funding plans, and certifications of financial assurance for decommissioning are reviewed by the NRC to ensure that a licensee has adequate procedures and funds for any necessary clean-up efforts before a licensee's responsibility for byproduct materials is terminated and the site is released for unrestricted use.

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. The NRC has issued [\*Guidance for Electronic Submissions to the NRC\*](#) which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by facsimile or by e-mail. It is estimated that approximately 5% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. The 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

The majority of licensees who use byproduct material are small businesses. Since the health and safety consequences of improper handling or use of radioactive byproduct material are the same for large and small entities, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

If the information is not collected, the NRC will have no way to assess whether this category of licensee is operating within the radiation safety requirements applicable to the possession, use, or transfer of byproduct material.

The required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments are submitted only once. Applications for renewal of licenses are usually submitted every 15 years. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of public health and safety.

## 7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the Office of Management and Budget Guidelines (OMB) in 5 CFR 1320.6(b), the NRC requires some information to be submitted in less than 30 days:

- Section 30.9(b) requires that licensees submit a notification to NRC in less than 30 days from the date of identifying information having significant implications for the public health and safety or the common defense and security and which is not covered by other reporting requirements. The requirement to provide notification within two working days following the identification of the information is necessary to ensure that NRC is made aware of the significant safety information so as to take prompt action to protect the public health and safety.
- Section 30.34(h) requires that licensees submit a notification to NRC in less than 30 days from the date of filing of a petition for bankruptcy. The requirement to provide notification promptly following the filing of the petition is necessary to ensure that the NRC is made aware of the bankruptcy so as to take effective action to protect the public health and safety. Allowing a period of 30 or more days to elapse might preclude the NRC from becoming aware of the licensee's distressed financial circumstances in time to prevent the development or aggravation of a potential hazard to the public. Moreover, the United States Code contains requirements regarding notification of creditors in bankruptcy. Section 30.34(h) would require one additional notification. Notifying the NRC promptly after the filing of the petition would in fact be less of a burden on the bankrupt licensee than a separate notification later in the proceedings.
- Section 30.50(a) requires licensees to notify the NRC immediately (i.e., within 4 hours) by telephone of events or conditions that threaten the health and safety of individuals using licensed material or that prevent the performance of surveys or other safety-related duties necessary to maintain control over licensed material. It is important that the NRC be notified in such cases because accidental contamination events increase radiation exposure and the risk of ingesting radioactive material. Immediate notification is needed so that such events may be promptly evaluated, and measures taken to minimize any spread of contamination and determine the performance of features designed to control licensed material.
- Section 30.50(b) requires licensees to notify the NRC within 24 hours after the discovery of specific events involving licensed material in the following situations: 1) in unplanned contamination events, 2) events in which equipment

is disabled or fails to function as designed, 3) events requiring unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body, or 4) an unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material. Prompt notification is necessary so that NRC can ensure that an evaluation is performed and that measures are taken to prevent recurrence. Licensees are also required to report all fires and explosions damaging any licensed material or any device, container, or equipment containing licensed material, so that such events may be promptly evaluated and measures taken to minimize any spread of contamination and determine the performance of features designed to control licensed material.

- Section 30.55(c) requires that each person who is authorized to possess tritium shall report promptly to the appropriate NRC regional office, by telephone and telegraph, mailgram, or facsimile, any incident in which any attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or 100 curies of such material in any one calendar year. The initial report must be followed within 15 days by a written report setting forth the details of the incident and its consequences. Receipt of these reports in less than 30 days is necessary to permit the regional office to determine whether there has been a diversion or other loss of material and to initiate prompt action in the event of such diversion or loss. The written reports submitted to NRC regional offices which set forth the details of the incident, its consequences, and any substantive additional information are duplicate copies of reports filed with the Federal Bureau of Investigation on the theft or unlawful diversion of tritium.
- Appendix C requires licensees to notify the NRC immediately if the company no longer meets the financial test requirements, of its intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days. It is important that the NRC be notified immediately in such cases to permit the NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site so that the decommissioning will be carried out in a manner which protects public health and safety.
- Appendix C requires licensees to notify the NRC within 20 days if at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A-" or above by Standard and Poor's or in any category of "A3" and above by Moody's. It is important that the NRC be notified promptly in such cases to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site so that the decommissioning will be carried out in a manner which protects public health and safety.
- Appendix C requires guarantors to notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph H of Appendix C. The notification must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be

transferred to the standby trust as soon as possible. It is important that the NRC be notified promptly in such cases to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site so that the decommissioning will be carried out in a manner which protects public health and safety.

- Appendix E requires licensees to notify NRC within 20 days if at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's. It is important that the NRC be notified promptly in such cases to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site so that the decommissioning will be carried out in a manner which protects public health and safety.
- Appendix E requires guarantors to notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph G of Appendix E. The notification must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible. It is important that the NRC be notified promptly in such cases to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site so that the decommissioning will be carried out in a manner which protects public health and safety.

Contrary to the Office of Management and Budget Guidelines (OMB) in 5 CFR 1320.5(d)(2), the NRC requires some records to be maintained for longer than 3 years:

- Section 30.35(g) requires that licensees keep records important to the safe and effective decommissioning of the facility until the site is released for unrestricted use. It is necessary that the records be retained longer than 3 years so that the Commission may determine whether an applicant will be able to carry out the requirements of Section 30.36 which specify that licensed premises must be decontaminated to a level "suitable for release for unrestricted use" before the license may be terminated. The NRC reviews the information to ensure that adequate funds will be available to ensure that the applicant will conduct decontamination efforts in a timely manner and minimize exposure of workers to radioactive materials. The information is also used to ensure that the decontamination efforts will reduce the residual radioactive contamination sufficiently to protect the public health and safety after the site is released for unrestricted use.

- Section 30.51(a) requires retention of records of receipt of byproduct material as long as the material is possessed and for three years following transfer or disposal, provides a three-year retention period for records of transfer of byproduct material, and provides that records of disposal of licensed material must be maintained until the Commission terminates the license. Section 30.51(b) requires licensees to retain records that are required by the regulations in 10 CFR Parts 30-36 and 39, or by license conditions, must be maintained for the period specified by the appropriate regulation or license condition. In any case in which a retention period is not specified, the records must be maintained until the Commission authorizes their disposition.

These records are necessary as a primary source for determination that licensees have confined their possession and use of byproduct material to the locations and purposes authorized in the licenses and have not violated or failed to observe any of the terms and provisions of the Atomic Energy Act or any regulation or order of the Commission. Records of receipt can demonstrate that the licensee has received byproduct material of the element and mass number and in the chemical and/or physical form specified in the license. Records of transfer can demonstrate that the licensee has transferred byproduct material of the type, form, and quantity that transferees are authorized to receive. Records of disposal can demonstrate that the licensee has obtained approval of disposal procedures and/or has disposed of byproduct material in accordance with NRC regulations. Records of receipt, transfer, and disposal, taken together, can demonstrate that the licensee has possessed at any one time, no more than the maximum quantity of byproduct material authorized in the license. Retention for longer than three years, where required, is necessary to provide reasonable assurance that records will be available for Commission inspection after the recorded event.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the Federal Register.

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). However, no information normally considered confidential or proprietary is requested.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

## 12. Estimated Burden and Burden Hour Cost

The \$275 hourly rate used in the burden estimates is based on the Nuclear Regulatory Commission's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the basis of this rate, see the Revision of Fee Schedules; Fee Recovery for Fiscal Year 2018 (83 FR 29622, June 25, 2018).

The number of NRC licensees is based on the number of NRC Materials Licenses in the Web-Based Licensing System database. This results in a total estimated number of NRC licensees of approximately 2,800. The number of NRC licensees is expected to remain constant over the next clearance period; therefore, burden estimates assume 2,800 licensees.

The estimated number of Agreement State licensees (16,500) is based on information contained in NRC's 2018-2019 Information Digest (NUREG-1350, Volume 30). The NRC establishes a ratio based on the total number of similarly licensed NRC licensees to the total number of estimated Agreement State licensees. The NRC uses this ratio of the total of NRC licensees (subject to Part 30) to the total number Agreement State licensees to estimate the Agreement State burden for each section.

The NRC estimates that there is approximately 5.9 times the number of Agreement State licensees as there are NRC licensees. The change from the previous estimate of 6.9 to 5.9 (Agreement States burdens is  $16,500/2,800$ , approximately 5.9) is based on (1) the most recent estimate of 2,800 similar NRC licensees and (2) the estimated 16,500 Agreement State licenses.

### NRC Licensees:

The total annual burden is estimated to be about 35,291 hours per year for the approximately 2,800 licensees covered by 10 CFR Part 30. The details are shown in Tables 1, 2, and 3. All 2,800 NRC licensees are record-keepers; however, only a portion of these respondents are annually reporting under Part 30.

The total burden for NRC licensees is 35,291 hours (16,792 hours for recordkeeping + 16,439 reporting hours + 2,060 hours for third-party disclosures) multiplied by \$275/hour at a cost of \$9,705,025.

### Agreement State Licensees:

Section 274 of the Atomic Energy Act of 1954 provides a statutory basis under which NRC relinquishes to the States portions of its regulatory authority to license and regulate byproduct materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials. The mechanism for the transfer of NRC's authority to a State is an agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with section 274b of the Act. Licensees operating in these "Agreement States" are referred to in this supporting statement as "Agreement State Licensees."



The NRC has established compatibility requirements for Agreement states to implement their own regulations in a manner consistent with NRC regulations. The number of NRC licensees is known, whereas the total number of Agreement State licensees is an estimate based on NRC's best information available from the Agreement States. NRC uses the ratio of the total of NRC licensees (subject to Part 30) to the total number Agreement State licensees to estimate the number of Agreement State respondents for each section. NRC uses this ratio approach as the total number of Agreement State licensees subject to various Part 30 Sections is not known exactly and, therefore, must be estimated. The current ratio, based on the number and size of NRC regulated states to Agreement states as discussed in detail above, is approximately 1:5.9 (NRC licensees: Agreement State licensees).

Based on ratios discussed above, the total annual burden is estimated to be about 5.9 times that of NRC licensees (with exceptions for burden regarding Orders) or 192,988 hours per year for the approximately 16,500 Agreement State licensees. The details are shown in Tables 4, 5, and 6.

The total burden for Agreement State licensees is 192,988 hours (91,627 hours for recordkeeping + 90,343 reporting hours + 11,018 hours for third-party disclosures) at a cost of \$53,071,700.

*Total:*

The total Part 30 annual burden is 228,279 hours [108,419 recordkeeping hours + 106,782 reporting hours + 13,078 third-party disclosure hours] for a total cost of \$62,776,725.

13. Estimate of Other Additional Costs

NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the records storage cost has been determined to be equal to 0.0004 times of the recordkeeping burden cost. Therefore, the records storage cost for this clearance is \$11,926 (108,419 recordkeeping hours x \$275/hr x 0.0004).

14. Estimated Annualized Cost to the Federal Government

The staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses. The annual cost for the NRC to review the records and reports required by 10 CFR Part 30 is estimated to be 5,678 hours x \$275/hour, or \$1,561,450. This cost can be broken down into: 4,394 hours, or \$1,208,350, for review of the reports submitted to NRC; and 1,284 hours, or \$353,100, for review of the records during inspections. Additionally, the cost for review of reports associated with review of the decommissioning funding plans and decommissioning plans account for 3,198 hours, or \$879,450. In addition, technical assistance contracts for review of these plans are estimated at \$131,133. Therefore, the total

estimated annualized cost to the Federal government for the 10 CFR Part 30 information collection requirements is approximately \$2,572,033. Application review activities for 10 CFR Part 30 licensees are attributed to and reported under OMB Clearance No. 3150-0120 for NRC Form 313. The burden of certifying the disposition of all licensed material, including accumulated wastes, required for termination of 10 CFR Part 30 licenses is reported under OMB Clearance No. 3150-0028 for NRC Form 314. These costs are fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Changes in Burden or Cost

The overall burden has decreased by 48,680 hours from 276,959 hours to 228,279 hours. This includes an increase of 2,059 hours of NRC licensee overall burden (from 33,233 hours to 35,291 hours) and a decrease of 50,738 hours of Agreement State licensee overall burden (from 243,726 hours to 192,988 hours). Based on the NRC's estimates, the total number of licensees has decreased by approximately 1,288 from 20,588 to 19,300. There was an increase in the number of NRC licensees, which increased from 2,600 to approximately 2,800. The increase in NRC license numbers may be attributed to natural fluctuations in the needs of businesses and other entities in NRC jurisdiction.

The ratio used to estimate Agreement State respondents changed from 6.9 to 5.9 and the estimated number of Agreement State licensees decreased from 17,988 to 16,500. The ratio changed because the difference in the number of NRC licensees versus Agreement States licensees has decreased.

The overall decrease in the number of licensees is tied to a corresponding decrease in the number of expected responses for various sections, resulting in an overall decrease in the burden hour estimate. Additionally, the remaining security-related orders were rescinded for NRC licensees in 2017 due to the implementation of 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material" resulting in a decrease in burden accounted for under 10 CFR 30.34(e) for NRC licensees. The security-related orders were also rescinded for Agreement State Licensees in 2016 and 2017, resulting in a significant reduction in burden for Agreement State Licensees.

The reporting burden decreased from 126,527 hours to 106,782 hours. The burden attributed to third-party disclosures decreased by 1,680 hours (from 14,758 hours to 13,078 hours). The burden for recordkeeping decreased from 132,706 hours to 108,419, a decrease of 24,287 hours. The decrease in burden due to reporting, third-party disclosures, and recordkeeping is attributed to a decrease in the estimated number of licensees and the significant reduction in burden from security-related orders being rescinded as discussed above.

There was a change in the overall cost because the hourly rate decreased from \$279 to \$275.

16. Publication for Statistical Use

There is no application to statistics in the information collected. There are no plans for publication of this information.

17. Reason for Not Displaying the Expiration Date

The requirements are contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

Table 1. Part 30 Reporting Burden for NRC Licensees<sup>1</sup>

Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Burden Hour per Response	Total Annual Reporting Burden (Hours)	Cost @ \$275/Hour
30.9(b)	6	1	6	1	6	1,650
30.11	12	1	12	5	60	16,500
30.32(h)	Burden included in Section 30.35(a)&(b)					
30.32(i)	1	1	1	10	10	2,750
30.32(j)(3)	10	1	10	0.5	5	1,375
30.34(b)	162	1	162	2	324	89,100
<b><u>30.34(e)(4)</u></b>	See lines below counted under this regulation					
New technology/uses standard conditions	2	1	2	4	8	2,200
Other Standard License Conditions	215	1	215	1	215	59,125
Orders	0	3	30	1	0	0
30.34(f)	1	1	1	10	10	2,750
30.34(h)	6	1	6	0.5	3	825
<b><u>30.35(a)&amp;(b)</u></b>	See lines below counted under these regulations					
Certification	32	1	32	100	3,200	880,000
Funding Plan	12	1	12	300	3,600	990,000
30.35(e), (f), and (h)	Burden included in Section 30.35(a)&(b)					
30.36(d)	179	1	179	1	179	49,225
30.36(e)	Burden included in Section 30.35(a)&(b)					
30.36(e)(2)	6	1	6	6	36	9,900
30.36(g)	15	1	15	360	5,400	1,485,000
30.36(j)	29	1	29	100	2,900	797,500
30.50(a),(b), and (c)	41	1	41	4	164	45,100
30.51(d)	162	1	162	0.5	81	22,275
30.51(f)	323	1	323	0.5	162	44,550
30.55(c)	2	1	2	10	20	5,500
Appendix A	Burden included in Section 30.35(a)&(b)					
Appendix C	Burden included in Section 30.35(a)&(b)					
Appendix D	3	1	3	1	3	825
Appendix E	53	1	53	1	53	14,575

<sup>1</sup> Reporting burden for sections 30.3(b)&(c), 30.15(b), 30.18(d), 30.19(b), 30.20(b), 30.21(b), 30.21(c), 30.32(a), 30.32(b), 30.32(f), 30.32(g), 30.36(h), 30.37(a), and 30.38 is covered under OMB clearance number 3150-0120 (Form 313 and 313A series of forms). Reporting burden for section 30.34(k) is covered under OMB clearance number 3150-0055. Reporting burden for sections 30.19(b), 30.20(b), 30.22(b) is also covered under OMB clearance number 3150-0001 (10 CFR Part 32).

<b>Section</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Total Annual Responses</b>	<b>Burden Hour per Response</b>	<b>Total Annual Reporting Burden (Hours)</b>	<b>Cost @ \$275/Hour</b>
Totals	323		1,272		16,439	4,520,725

Table 2. Part 30 Recordkeeping Burden for NRC Licensees

Section	No. of Recordkeepers	Annual Hours Per Recordkeeper	Total Annual Recordkeeping Hours	Cost @ \$275/Hour
30.32(i)	3	1	3	825
<b><u>30.34(e)(4)</u></b>	See lines below counted under this regulation			
Conditions "RSC" & "RSO"	127	0.5	64	17,600
Condition "UBTI"	262	0.5	131	36,025
Condition "DIS"	145	0.5	73	20,075
Condition "PI"	1,615	0.08	129	35,475
Condition "SSLT"	1,615	0.08	129	35,475
New technology/uses standard conditions	86	0.2	17	4,675
Standard License Conditions	262	0.5	131	36,025
Orders	0	8	0	0
30.34(g)	43	17	731	201,025
30.34(j)(2)(ii)	10	200	2,000	550,000
30.35(f)	3	1	3	825
30.35(g)	332	10	3,320	913,000
30.41(c)&(d)	144	4	576	158,400
30.51	2,710	3.5	9,485	2,608,375
Totals	2,800		16,792	4,617,800

Table 3. Part 30 Third-Party Disclosure Burden for NRC Licensees

<b>Section</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Total Annual Responses</b>	<b>Burden Hour per Response</b>	<b>Total Annual Reporting Burden (Hours)</b>	<b>Cost @ \$275/Hour</b>
30.34(e) – Other Standard License Conditions	54	1	54	1	54	14,850
30.34(f)	1	2	2	2.5	5	1,375
30.34(j)(2)(i)	10	2,000	20,000	0.08	1,600	440,000
30.35(g)	32	1	32	10	320	88,000
30.51(e)	162	1	162	0.5	81	22,275
Totals	162		20,250		2,060	566,500

Total NRC Licensee Burden (Tables 1, 2 and 3): 35,291 hours.

Table 4. Part 30 Equivalency Reporting Burden for Agreement State Licensees<sup>2</sup>

Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Burden Hour per Response	Total Annual Reporting Burden (Hours)	Cost @ \$275/Hour
30.9(b)	35	1	35	1	35	9,625
30.11	65	1	65	5	325	89,375
30.32(h)	Burden included in Section 30.35(a)&(b)					
30.32(i)	6	1	6	10	60	16,500
30.32(j)(3)	53	1	53	0.5	53	7,425
30.34(b)	885	1	885	2	1,770	486,750
<b><u>30.34(e)(4)</u></b>	See lines below counted under this regulation					
New technology/uses standard conditions	12	1	12	4	48	13,200
Other Standard License Conditions	1,180	1	1,180	1	1,180	324,500
Orders	0	3	0	1	5,592	1,560,168
30.34(f)	6	1	6	10	60	16,500
30.34(h)	35	1	35	0.5	18	4,950
<b><u>30.35(a)&amp;(b)</u></b>	See lines below counted under these regulations					
Certification	177	1	177	100	17,700	4,867,500
Funding Plan	65	1	65	300	19,500	5,362,500
30.35(e), (f), and (h)	Burden included in Section 30.35(a)&(b)					
30.36(d)	979	1	979	1	979	269,225
30.36(e)	Burden included in Section 30.35(a)&(b)					
30.36(e)(2)	35	1	35	6	210	57,750
30.36(g)	83	1	83	360	29,880	8,217,000
30.36(j)	159	1	159	100	15,900	4,372,500
30.50(a),(b), and (c)	224	1	224	4	896	246,400
30.51(d)	885	1	885	0.5	443	121,825
30.51(f)	1,770	1	1,770	0.5	885	243,375
30.55(c)	12	1	12	10	120	33,000
Appendix A	Burden included in Section 30.35(a)&(b)					
Appendix C	Burden included in Section 30.35(a)&(b)					
Appendix D	18	1	18	1	18	4,950
Appendix E	289	1	289	1	289	79,475
Totals	1,770		6,973		90,343	24,844,325

<sup>2</sup> Reporting burden sections 30.3(b)&(c), 30.15(b), 30.18(d), 30.19(b), 30.20(b), 30.21(b), 30.21(c), 30.32(a), 30.32(b), 30.32(f), 30.32(g), 30.36(h), 30.37(a), and 30.38 is covered under OMB clearance number 3150-0120 (Form 313 and 313A series of forms). Reporting burden for section 30.34(k) is covered under OMB clearance number 3150-0055. Reporting burden for sections 30.19(b), 30.20(b), 30.22(b) is also covered under OMB clearance number 3150-0001 (10 CFR Part 32).



Table 5. Part 30 Equivalency Recordkeeping Burden for Agreement State Licensees

Section	No. of Recordkeepers	Annual Hours Per Recordkeeper	Total Annual Recordkeeping Hours	Cost @ \$275/Hour
30.32(i)	18	1	18	4,950
<b><u>30.34(e)(4)</u></b>	See lines below counted under this regulation			
Conditions "RSC" & "RSO"	696	0.5	348	95,700
Condition "UBTI"	1434	0.5	717	197,175
Condition "DIS"	797	0.5	399	109,725
Condition "PI"	8,850	0.08	708	194,700
Condition "SSLT"	8,850	0.08	708	194,700
New technology/uses standard conditions	472	0.2	94	25,850
Other Standard License Conditions	1,434	0.5	717	197,175
Orders	0	8	0	0
30.34(g)	236	17	4012	1,103,300
30.34(j)(2)(ii)	53	200	10,600	2,915,000
30.35(f)	18	1	18	4,950
30.35(g)	1,817	10	18,170	4,996,750
30.41(c)&(d)	791	4	3,164	870,100
30.51	14,844	3.5	51,954	14,287,350
Totals	16,500		91,627	25,197,425

Table 6. Part 30 Equivalency Third-Party Disclosure Burden for Agreement State Licensees

Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Burden Hour per Response	Total Annual Reporting Burden (Hours)	Cost @ \$275/Hour
30.34(e) – Other Standard License Conditions	295	1	295	1	295	81,125
30.34(f)	6	2	12	2.5	30	8,250
30.34(j)(2)(i)	53	2000	106,000	0.08	8,480	2,232,000
30.35(g)	177	1	177	10	1,770	468,750
30.51(e)	885	1	885	0.5	443	121,825
Totals	885		107,369		11,018	3,029,950

Total Agreement State Licensee Burden (Tables 4, 5 and 6): 192,988 hours.

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Total Annual Burden for NRC Licensees: 35,291 hours (16,439 reporting hours + 16,792 recordkeeping hours + 2,060 third-party disclosure hours)

Total Annual Burden for Agreement State Licensees: 192,988 hours (90,343 reporting hours + 91,627 recordkeeping hours + 11,018 third-party disclosure hours)

Total Part 30 Annual Burden: 228,279 hours (106,782 reporting hours + 108,419 recordkeeping hours + 13,078 third-party disclosure hours)

Total Number of Annual Respondents: 19,300 (2,800 NRC Licensees and 16,500 Agreement State Licensees)

Total Number of Annual Responses: 155,164 (24,322 NRC Licensee responses [1,272 reporting responses + 2,800 for recordkeepers + 20,250 third-party disclosures] and (130,842 Agreement State Licensee responses [6,973 reporting responses + 16,500 for recordkeepers + 107,369 third-party disclosures])

Total Number of Annual Recordkeepers: 19,300 (2,800 NRC Licensees and 16,500 Agreement State Licensees)

## **SUPPLEMENT 1**

### **DESCRIPTION OF INFORMATION COLLECTION REQUIREMENTS CONTAINED IN 10 CFR PART 30**

Section 30.9(b) requires that an applicant or licensee notify the Commission of information which the applicant or licensee recognizes as having significant implications for public health and safety or the common defense and security. This requirement applies only to information which is not already required to be provided to the Commission by other reporting or updating requirements. The information must be provided within two working days to the administrator of the appropriate NRC regional office.

This requirement is necessary because there may be some circumstances in which a licensee possesses some information which could be important to the protection of public health and safety or the common defense and security, but which is not otherwise required to be reported. The full disclosure requirement should not result in significant additional burdens on applicants or licensees. No formal program is required. It is expected that licensees will maintain a professional attitude toward safety and that, if some potential safety information is identified by the licensee, the information will be provided freely and promptly to the NRC so that the agency can evaluate it and act on it, if necessary.

Section 30.11 provides that the Commission may, upon the application of any interested person or on its own initiative, grant exemptions from the requirements of 10 CFR Parts 30-36 and 39 under specified conditions.

The information submitted under this section is examined by the NRC to determine whether the requested exemption is authorized by law, and will not endanger life or property or the common defense and security, and is otherwise in the public interest.

Section 30.14(d) requires that any person who desires to introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Section 30.14, apply for a specific license pursuant to Section 32.11. Such a license indicates that the product or material may be distributed by the licensee to persons exempt from the regulations (hereinafter "exempt persons").

Section 30.15(b) states that any person who desires to apply byproduct material to, or to incorporate it into, the products exempted in Section 30.15(a), or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to Section 32.14. Such a license indicates that the product may be distributed by the licensee to persons exempt from the regulations.

Section 30.18(d) indicates that no person may, for purposes of commercial distribution, transfer byproduct material in the quantities set forth in Section 30.71, Schedule B, to exempt persons, except in accordance with a license issued under Section 32.18.

Section 30.19(b) indicates that any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products to exempt persons for use, should apply for a license pursuant to Section 32.22, with a license provision that the product may be transferred to exempt persons and a certificate of registration in accordance with Section 32.210 of this chapter.

Section 30.20(b) requires that any person, who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products to exempt persons for use, apply for a license pursuant to Section 32.26, with a license provision that the product may be initially transferred to exempt persons and a certificate of registration in accordance with Section 32.210 of this chapter.

Section 30.21(b) requires that any person who desires to use capsules containing carbon-14 urea for "in vivo" diagnostic use for research involving human subjects shall apply for and receive a specific license pursuant to part 35 of this chapter. The NRC review of the information and the findings therefrom form the basis for NRC licensing decisions. NRC Form 313, "Application for Material License," which is used to collect this information, is cleared under OMB Clearance No. 3150-0120.

Section 30.21(c) requires that any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing carbon-14 urea for "in vivo" diagnostic use, shall apply for a license pursuant to Section 32.21, with a license provision that the product may be transferred to exempt persons.

Section 30.22(b) states that any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under Section 30.22(a), should apply for a license under Section 32.30 of this chapter and for a certificate of registration in accordance with Section 32.210 of this chapter.

For Sections 30.14(d) through 30.22(b) above, the information supplied on the application is necessary to permit the NRC to determine whether the proposed use of byproduct material provides adequate protection of public health and safety. The NRC review of the information and the findings therefrom form the basis for NRC licensing decisions. NRC Form 313, "Application for Material License," is used to collect this information and is cleared under OMB Clearance No. 3150-0120.

Section 30.32(a) requires that applications for specific licenses for byproduct material may be submitted on NRC Form 313, "Application for Material License."

The NRC reviews the information submitted on the NRC Form 313 "Application for Material License," to determine whether an applicant for a license has the training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect the public health and safety. NRC Form 313 is cleared under OMB Clearance No. 3150-0120.

Section 30.32(b) provides that NRC may require further statements after the filing of the application, and before the expiration of the license, to enable NRC to determine whether the application should be granted or denied or whether a license should be modified or revoked. Such additional information is sometimes needed to clarify information submitted in the application, or to rectify deficiencies in proposed or existing programs for protection of the public health and safety, the common defense and security, or the environment.

The additional information is reviewed by various NRC organizational units to assess the adequacy of the applicant's physical plant, procedures, and plans for protection of the public health and safety, common defense and security, and the environment. The NRC review of the information and the findings therefrom form the basis for NRC decisions concerning the issuance, modification, or revocation of licenses for byproduct material.

The burden and cost associated with further statements is included in the burden and cost data for submittal of applications on NRC Form 313, "Application for Material License," which is cleared under OMB Clearance No. 3150-0120.

Section 30.32(f) requires that an application for a license to receive and possess byproduct material for the conduct of any activity which the Commission determines will significantly affect the quality of the environment must be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by an environmental report required pursuant to 10 CFR Part 51, Subpart A.

Facilities for commercial waste disposal, or other activities covered by this section, are generally large and complex and have the potential to significantly affect the quality of the human environment. NRC's consideration of environmental effects and balancing of alternatives for the project, as mandated by the "National Environmental Policy Act of 1969," which applies only to Federal Government actions, requires the applicant to submit a comprehensive and detailed environmental report. The NRC licensing staff reviews the environmental report to assure that it is complete and that it considers and balances alternatives for the project in order to best protect the environment.

This section refers to and requires the submission of information pursuant to 10 CFR Part 51. The collection of information, the burden imposed on respondents, and the cost to the Government is contained in the supporting statement for 10 CFR Part 51, which is cleared under OMB Clearance No. 3150-0021.

Section 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number, as registered with the NRC under Section 32.210 or with an Agreement State, or contain the radiation safety related information that is identified in Section 32.210(c). The section also includes the requirement that the application identify the manufacturer and model number for sources and devices containing radium-226 as registered with a State, and describes information that can be submitted for legacy sources that are not registered. Section 30.32(g)(3) states that the applicant may supply only the manufacturer, model number, and radionuclide and quantity for sealed sources or devices allowed to be distributed without registration of safety information in accordance with Section 32.210(g)(1) of this chapter. Section 30.32(g)(4) states that the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source if it is not feasible to identify each sealed source and device individually. This information is used to establish that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. The NRC review of the information and the findings therefrom form the basis for NRC licensing decisions. NRC Form 313, which is used to collect this information, is cleared under OMB Clearance No. 3150-0120.

Section 30.32(h) requires that, as provided by Section 30.35, certain applications for specific licenses must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. Section 30.35 sets forth the requirements for financial assurance and recordkeeping for decommissioning.

The burden and cost data for the information provided in these applications is included under Section 30.35.

Section 30.32(i) requires applicants that will possess radioactive materials in unsealed form on foils or plated source or sealed in a glass in excess of the quantities in Section 30.72 must either submit an evaluation demonstrating an emergency plan is not needed or to provide an emergency plan. Those requiring an emergency plan must also commit to providing prompt notification to offsite response organizations and NRC in the event of an event triggering the emergency plan. The evaluation or emergency plans are submitted in the new license application, amendment, or renewal process. NRC Form 313, "Application for Material License," is used to collect this information and is cleared under OMB Clearance No. 3150-0120.

The records and reports required in Section 30.32(i) are necessary for the Commission to determine whether the applicant will be able to respond

adequately to an accident and to provide the proper notifications to NRC and off site response organizations to adequately protect the public health and safety in the event of an accident.

Section 30.32(j) requires that an application from a medical facility, educational institution, or Federal facility for authorization to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use include evidence of an existing license for a PET radionuclide production facility within the consortium, the applicant's and authorized user's qualifications, and confirmation that the PET drugs are to be non-commercially transferred. The NRC review of the information and the findings therefrom form the basis for NRC licensing decisions. NRC Form 313, which is used to collect this information, is cleared under OMB Clearance No. 3150-0120.

Section 30.32(j)(3) requires that licensees must notify the NRC when an existing authorized nuclear pharmacist (ANP) begins working at the pharmacy that produces PET drugs as provided under 10 CFR 32.72(b)(2).

Section 30.34(b) requires that the licensee provide full information before transferring, assigning, or in any manner disposing of any license through transfer of control to any person. No action is required of a licensee unless and until a transfer of control is initiated.

The information required by Section 30.34(b) is used only to verify that the licensing information that was previously submitted on Form 313, "Application for Material License," is still correct, and to permit the NRC to determine whether the proposed licensee provides adequate resources to protect public health and safety. The NRC review of the information and the findings therefore form the basis for NRC licensing decisions.

Section 30.34(e) permits the Commission to incorporate in any license issued pursuant to the regulations in 10 CFR Parts 30-36 and 39, by appropriate rule, regulation or order, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of byproduct material. In addition, reports and maintaining the records may be required, as necessary, to fulfill the purposes of the Atomic Energy Act and regulations of the Commission.

#### Established Standard License Conditions:

These conditions are developed based on the licensee's particular facilities, equipment, or type of use of material or based on the category of use of radioactive material (e.g., radiography, medical human use, etc.). These conditions are used by all NRC regions to ensure that provisions for protection of public health and safety are imposed consistently among licensees. A selection of commonly used established standard license conditions which contain reporting or recordkeeping requirements are described in detail below.

Conditions "Radiation Safety Committee" ("RSC") and "Use Under Supervision of Radiation Safety Officer" ("RSO"). Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee (condition "RSC"). The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material. Licensed material shall be used by or under the supervision of individuals designated, in writing, by the Radiation Safety Officer (condition "RSO"). The

licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.

Condition "Use By or Under Supervision of Trained Individuals" ("UBTI"). Licensed material shall only be used by, or under the supervision of, individuals who have received the training described in an application, and have been designated in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.

Condition "Decay In-Storage" ("DIS"). Certain licensees may be authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash, provided it is determined that its radioactivity cannot be distinguished from background, and all radiation labels are removed or obliterated. The licensee shall maintain a record of each such disposal permitted under this license condition for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Condition "Physical Inventory" ("PI"). The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the NRC, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

Condition "Sealed Source Leak Test (I)" ("SSLT"). The licensee must maintain records of leak test results in units of microcuries for 3 years.

The new technology/uses standard license conditions:

These conditions are imposed on individual licensees and groups of licensees engaged in new materials uses or the use of new technologies in established materials uses. These conditions are developed to account for the unique properties of the new uses or new technologies and used to ensure the same degree of public health and safety is applied uniformly for similar established and developing materials uses. In most cases, the new technology/uses standard recordkeeping conditions are used to modify the specific information required in recordkeeping requirements for a similar established use. These are also used to document alternative procedures needed to meet the objective of a procedure specifically included in the regulations or established standard license conditions (such as leak test that cannot be performed as described in either the regulations or the established standard leak test license condition). In a few cases, the recordkeeping requirement will be needed to assure unique safety significant information is retained. The new technology/uses standard license conditions may also be used to ensure reporting of events involving the new materials uses and new technologies that are substantially the same as existing reportable events contained in the regulations but are not technically described in the regulation (e.g., reporting an error in the medical use of an emerging medical technology when the unique characteristics of the technology are not specifically addressed in the medical event reporting regulation).

Orders



This regulation is also cited as the authority, when necessary, for the issuance of orders for the modification of licenses. The Commission may issue an order when licensees are not in compliance with the existing regulations, or in cases where a new safety issue is identified and the existing regulations are not adequate. In addition, orders may be issued when a new threat to the common defense and security has occurred. Typically the Commission may issue 2 to 3 orders per year. However, in light of the events on September 11, 2001, certain licensees were required to take compensatory actions against terrorist threats.

These compensatory actions were issued as orders. However, recently, the remaining security-related orders were rescinded for NRC licensees due to the implementation of 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." These security-related orders were also rescinded for Agreement State Licensees in the last three years.

When the issuance of such orders involves the imposition of reporting or recordkeeping requirements, requests for OMB clearance of the specific information collection requirements are submitted, as necessary.

The information is used by the NRC staff to verify that the licensee has performed required actions in a complete and timely manner.

Section 30.34(f) requires that licensees that must submit emergency plans in accordance with Section 30.32(i) shall follow the emergency plan approved by the NRC. The licensee may change the approved without NRC approval only if the changes do not decrease effectiveness of the plan. It also requires the licensee to furnish the change to the NRC and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the NRC.

The reports required in Section 30.34(f) are necessary for the NRC to determine whether the applicant will be able to respond adequately to an accident and to provide the proper notifications to NRC and offsite response organizations to adequately protect the public health and safety in the event of an accident.

Section 30.34(g) requires each licensee preparing technetium-99m radio-pharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators to test the generator elute for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Section 35.204. The licensee is required to record the results of each test and maintain records of the test results for three years.

The requirement to maintain the records of test results is necessary to permit the NRC inspection staff to determine that nuclear pharmacy licensees and broad medical licensees have conducted the tests to determine the amount of molybdenum-99 in technetium-99 or strontium-82 and strontium-85 in rubidium-82 radioactive drugs before administration to patients. If excessive molybdenum-99, strontium-82, or strontium-85 is present, it would result in unnecessary radiation doses to patients.

Section 30.34(h) requires that each specific licensee and certain general licensees immediately notify the appropriate NRC regional administrator, in writing, following the filing of a bankruptcy petition by or against the licensee or a controlling or affiliate entity. No action is required of a licensee unless and until a petition for bankruptcy is filed.

This information is needed because a licensee who is experiencing severe economic hardship may not be capable of carrying out licensed activities in a manner that protects public health and safety. In particular, a licensee involved in bankruptcy proceedings can have problems affecting payment for proper handling of licensed radioactive material and for decontamination and decommissioning of the licensed facility in a safe manner. Improper materials handling or decontamination activities can lead to spread of contamination throughout a licensee's facility and the potential for dispersion of contaminated material offsite. Financial difficulties can also result in problems affecting the licensee's waste disposal activities.

The information provided by the notification is used by the NRC regional inspection and licensing staff, in consultation with headquarters legal and program staff, to determine the need for prompt NRC response or regulatory action in the event of a potential hazard to public health and safety posed by a licensee that does not have the resources to properly secure the licensed material or clean up possible contamination. In addition, prompt notification would allow the Commission to take timely and appropriate action in a bankruptcy proceeding to seek to have available assets of the licensee applied to cover costs of cleanup before funds are disbursed and become unavailable for cleanup.

Section 30.34(j)(2)(i) requires that each licensee authorized to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must satisfy the labeling requirements in 10 CFR 32.72(a)(4) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

Section 30.34(j)(2)(ii) requires that each licensee authorized to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter.

Section 30.34(k) requires licensees, if required by the Additional Protocol, to file with the Commission location information described in 10 CFR 75.11 of this chapter. The burden for 10 CFR Part 75 is cleared under OMB Clearance No 3150-0055.

Section 30.35 sets forth the requirements for financial assurance and recordkeeping for decommissioning. Sections 30.35(a) and (b) specify which licensees are required to submit a decommissioning funding plan or a certification that financial assurance for decommissioning has been provided. Sections 30.35(c) and (d) specify the criteria for and required amounts of financial

assurance for decommissioning. Section 30.35(e) specifies the content of the decommissioning funding plan and requires that decommissioning cost estimates be updated and submitted at the time of license renewal and at intervals not to exceed three years. Section 30.35(f) requires that the financial instrument used for decommissioning funding assurance include the licensee's name, license number, and docket number, and the name, address, and other contact information of the issuer, and if a trust is used, the trustee. If there are any changes to this information, the licensee must submit financial instruments reflecting these changes to the NRC within 30 days. Section 30.35(f) also specifies acceptable methods for providing for financial assurance for decommissioning: either through prepayment; a surety method, insurance or other guarantee method; or, in the case of Government licensees, a statement of intent containing a cost estimate for decommissioning.

Section 30.35(g) requires that each person licensed under 10 CFR Parts 30, 32-36, and 39 keep records of information important to the safe and effective decommissioning of the facility until the license is terminated by the Commission. Licensees are required to list in a single document (to be held by the licensee and updated once every two years) identification of all restricted areas where licensed materials were used or stored, all areas outside of restricted areas where documentation is required for unusual occurrences or spills, and all areas outside of restricted areas where waste has been buried or which contain material such that, if the license expired, the licensee would be required to either decontaminate the area or seek special approval for disposal. This information is needed by the NRC to ensure that no future users of the site will be inadvertently exposed to radiation.

Section 30.35(h) specifies that each licensee must use its financial assurance funds only for decommissioning activities. It also requires monitoring by the licensee of its investment balance in the decommissioning trust account. If the investment balance in the trust account is below the estimated cost of decommissioning, but is not below 75 percent of the cost, then the licensee must, within 30 days after the end of the calendar quarter, deposit funds into the trust account to fully cover the estimated cost. If at any time the loss results in a balance that is below 75 percent of the amount necessary to cover the decommissioning cost, the licensee must, within 30 days of such occurrence, deposit funds into the trust account to fully cover the estimated cost. The licensee must report taking such actions to the NRC within 30 days of the occurrence.

The records and reports required by Section 30.35 are necessary for the Commission to determine whether an applicant will be able to carry out the requirements of Section 30.36 which specify that licensed premises must be decontaminated to a level "suitable for release for unrestricted use" before the license may be terminated. NRC will review the information to ensure that adequate funds will be available to ensure that the applicant will conduct decontamination efforts in a timely manner and minimize exposure of workers to radioactive materials. The information will also be used to ensure that the decontamination efforts will reduce the residual radioactive contamination sufficiently to protect the public health and safety after the site is released for unrestricted use.

Section 30.36 specifies procedures for terminating licensee responsibility for nuclear materials and clarifies that a license will continue in effect, with respect to possession of byproduct material, until the Commission notifies the licensee in writing that the license is terminated. Section 30.36(d) requires each licensee to

notify the Commission in writing of its decision not to renew its license and to either begin decommissioning its site or submit within 12 months of notification a decommissioning plan. Section 30.36(e) requires that coincident with the notification required by Section 30.36(d), licensees maintain all decommissioning financial assurances established by the licensee pursuant to Section 30.35. Section 30.36(e)(2) allows, following approval of the decommissioning plan, that a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Commission. Section 30.36(g) requires that a decommissioning plan be submitted, if required by license condition or if the proposed procedures and activities necessary to carry out the decommissioning have not been previously approved by the Commission, and these procedures could increase potential health and safety impacts to workers or to the public.

Section 30.36(h) requires licensees in certain circumstances to request license termination (a license amendment process whose burden and cost is included in the supporting statement for NRC Form 313, which is cleared under OMB Clearance No. 3150-0120).

All of the above information required by Section 30.36 is reviewed by the NRC to determine that there is no significant risk to public health and safety before a licensee's responsibility for nuclear materials is terminated and a facility is released for unrestricted use.

Section 30.36(j) requires, as a final step in decommissioning, that a licensee certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314, "Certificate of Disposition of Materials." In addition, this section requires that the licensee conduct a radiation survey of the site where the licensed activities were carried out and note on NRC Form 314

whether or not the survey was conducted and, if so, attach the results, if not separately forwarded to NRC. The radiation survey, similar to those generated during operations, is required to confirm the absence of radioactive materials or to establish the level of residual radioactive contamination. The information on disposal of nuclear materials and the survey are considered the minimum information necessary to establish a record to support a finding that a license can be safely terminated. NRC Form 314 is cleared under OMB Clearance No. 3150-0028.

Section 30.37 requires that an application for renewal of a specific license be filed in accordance with Section 30.32. The NRC reviews the information submitted to determine whether an applicant for a license renewal has the training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect the public health and safety.

The burden and cost data for these applications for renewal of specific licenses have been included in the supporting statement for NRC Form 313, which is cleared under OMB Clearance No. 3150-0120.

Section 30.38 requires that an application for amendment of a license be filed in accordance with Section 30.32. The NRC reviews the information submitted to determine whether the licensee has the training, experience, equipment, facilities, and procedures for the use of byproduct material that are adequate to protect the public health and safety. It also requires that applications for amendment of sealed source and device registration certificates must be files in accordance with Section 32.210 and any other applicable provisions.

The burden and cost data for these applications for license amendments have been included in the supporting statements for NRC Form 313 (see OMB Clearance No. 3150-0120) and 10 CFR Part 32 (see OMB Clearance No. 3150-0001).

Sections 30.41(c) and (d). Section 30.41(c) requires that, before transferring byproduct material to a specific licensee or a general licensee who is required to register prior to receipt of byproduct material, the transferor must verify that the transferee's license authorizes receipt of the type, form, and quantity of byproduct material to be transferred. Section 30.41(d) specifies methods acceptable to the Commission for accomplishing the required verification, including:

- (1) The transferor may have in his possession, and read, a copy of the transferee's specific license or registration certificate;
- (2) The transferor may have a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration number, issuing agency, and expiration date;
- (3) For emergency shipments, the transferor may accept oral certification from the transferee, provided it is confirmed in writing within 10 days;

- (4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or Agreement State licensing agency; or
- (5) When the above methods of verification are not readily available or when a transferor desires to verify that information received by one of the above methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or Agreement State licensing agency.

The information required by Sections 30.41(c) and (d) is used by transferring licensees to provide assurance that the licensed byproduct material is being transferred to a person who is authorized to receive it. This verification serves as an additional check to prevent transfer of byproduct material to persons who may not have the facilities, training, experience, equipment, or procedures necessary for the safe handling of the material. Records of these certifications will be reviewed by NRC inspectors during periodic inspections to ensure that licensees have been complying with verification requirements.

Section 30.50 requires licensees to notify NRC of events or conditions that threaten the health and safety of individuals either using or potentially exposed to licensed material.

Section 30.50(a) requires licensees to notify the NRC as soon as possible, but no later than 4 hours after discovery, of events that prevent immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed the regulatory limits.

Section 30.50(b) requires licensees to notify the NRC within 24 hours after the discovery of any of the following events involving licensed material. Licensees must report unplanned contamination events, such as those in which access to an area must be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area. It is important that the NRC be notified in such cases because accidental contamination events increase radiation exposure and the risk of ingesting radioactive material. Licensees are required to report events in which equipment necessary to prevent releases of radioactive material exceeding regulatory limits, to prevent overexposure to radiation, or to mitigate the consequences of an accident is disabled or fails to function as designed. This includes procedural errors, equipment failure, and equipment damage among other unplanned situations. This notification is necessary in situations in which there are no backup systems available to perform the required safety function. Notification is not required for an individual component failure if redundant systems are operable and available to automatically perform the required function. Licensees are required to report events that require medical treatment of a radioactively contaminated individual at a medical facility. Such events are significant because they may: (1) indicate safety problems in a licensed operation, (2) risk internal contamination through

open wounds, and (3) expose medical personnel to radiation and contamination. Prompt notification is necessary so that NRC can ensure that an evaluation is performed and that measures are taken to prevent recurrence. Licensees are also required to report all fires and explosions damaging any licensed material or any device, container, or equipment containing licensed material, so that such events may be promptly evaluated and measures taken to minimize any spread of contamination and determine the performance of features designed to control licensed material.

Licensees are required to make the reports required by Sections 30.50(a) and (b) by telephone to the NRC Operations Center.

Section 30.50(c)(2) requires that, in addition to the telephone report, licensees must submit a written follow-up report within 30 days which includes, in addition to descriptive information, an evaluation of the probable cause, a description of corrective actions taken or planned, and the results of any evaluations or assessments.

Section 30.51 establishes overall record retention requirements applicable to byproduct material licensees for cases in which retention periods are not otherwise specified in the regulations.

Section 30.51(a) requires that each licensee who receives byproduct material must keep records showing the receipt, transfer, and disposal of the byproduct material. It provides for retention of records of receipt of byproduct material as long as the material is possessed by the licensee and for three years following transfer or disposal of the material, provides a three-year retention period for records of transfer of byproduct material for the transferor (unless a specific requirement in another part of the regulations in this chapter dictates otherwise), and provides that records of disposal of licensed material must be maintained until the Commission terminates the license that authorizes the disposal of the material.

Section 30.51(b) requires licensees to retain records that are required by the regulations in 10 CFR Parts 30-36 and 39 or by license conditions must be maintained for the period specified by the appropriate regulation or license condition. In any case in which a retention period is not specified, the records must be maintained until the Commission terminates the license that authorizes the subject activity.

Sections 30.51(d) and (f) requires that the licensee transfer disposal records, survey records and other records important to decommissioning to the NRC prior to license termination.

Section 30.51(e) requires the licensee transfer disposal records and other assorted records important to decommissioning to the new licensee.

Records are necessary as a primary source for determination that licensees have confined their possession and use of byproduct material to the locations and purposes authorized in the licenses and have not violated or failed to observe any of the terms and provisions of the Atomic Energy Act or any regulation or order of the Commission. Records of receipt can demonstrate that the licensee has received byproduct material of the element and mass number and in the chemical and/or physical form specified in the license. Records of transfer can demonstrate that the licensee has transferred byproduct material of the type, form, and quantity that transferees are authorized to receive. Records of disposal can demonstrate that the licensee has obtained approval of disposal procedures and/or has disposed of byproduct material in accordance with NRC regulations. Records of receipt, transfer, and disposal, taken together, can demonstrate that the licensee has possessed at any one time no more than the maximum quantity of byproduct material authorized in the license. The retention periods provide reasonable assurance that records will be available for Commission inspection after the recorded event.

Section 30.55(c) requires that each person who is authorized to possess tritium shall report promptly to the appropriate NRC regional office any incident in which any attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or 100 curies of such material in any one calendar year. The initial report shall be followed within 15 days by a written report which contains the details of the incident, its consequences, and any substantive additional information.

The information submitted by licensees under this requirement is used by the regional office to determine whether there has been a diversion or other loss of material and to initiate prompt action in the event of such diversion or loss. The written reports submitted to NRC regional offices are duplicate copies of reports filed with the Federal Bureau of Investigation on the theft or unlawful diversion of tritium.

Appendix A establishes criteria for parent companies to pass the financial test and to obtain a parent company financial guarantee. It specifies various financial ratios, including net worth and asset/liability ratios, and bond ratings. It requires that the licensee notify the NRC within 90 days of any matters coming to the attention of the independent auditor which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test. Also, after the initial financial test, the parent company must annually pass the test and provide documentation of its continued eligibility to use the parent company guarantee, to the NRC within 90 days after the close of each succeeding fiscal year. If the parent company no longer meets the financial test requirements, the licensee must send notice to the NRC of intent to establish alternate financial assurance as specified in the NRC's regulations. The notice must be sent within 90 days after the end of the fiscal year for which year-end financial data show that the company no longer meets the financial test requirements. These notices are necessary to either permit the NRC to take action to ensure that alternative means of financial assurance are available for

decommissioning the licensee's site or confirm that the parent company still meets the applicable criteria.



Appendix C establishes criteria for companies to pass the financial test and to obtain a self-guarantee for financial assurance. It specifies various financial ratios, including net worth ratios, and bond ratings. It requires that the licensee notify the NRC within 90 days of any matters coming to the attention of the independent auditor which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test. Also, after the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee, to the NRC within 90 days after the close of each succeeding fiscal year. If the company no longer meets the financial test requirements, the licensee must send immediate notice to NRC of intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days of such notice. The licensee will promptly forward to the NRC and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission in accordance with the Securities and Exchange Act of 1934. If at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A-" or above by both Standard and Poors or in any category of "A3" and above by Moody's, the licensee must notify NRC within 20 days. Appendix C requires guarantors to notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph H of Appendix C. The notification must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible. These notices are necessary to permit the NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site or confirm that the company still meets the applicable criteria.

Appendix D establishes criteria for companies with no outstanding rated bonds to pass the financial test when they furnish their own guarantee that funds will be available for decommissioning cost. It specifies net tangible worth, assets, ratios of cash flow and ratios of these to the total current decommissioning cost estimates. It requires that the licensee notify the NRC within 90 days of any matters coming to the attention of the independent auditor which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test. Also, after the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee, to the NRC within 90 days after the close of each succeeding fiscal year. If the company no longer meets the financial test requirements, the licensee must notify the NRC within 90 days of intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days. These notices are necessary to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site or confirm that the company still meets the applicable criteria.

Appendix E establishes the criteria for nonprofit colleges, universities and hospitals to pass the financial test when they furnish their own guarantee that funds will be available to cover the decommissioning cost. It specifies bonds, unrestricted endowment, total revenue ratios, current assets, operating revenues and various other financial ratios. It requires that the licensee notify the NRC within 90 days of any matters coming to the attention of the independent auditor which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test. Also, after the initial financial test, the licensee must repeat passage of the test and provide documentation of its continued eligibility to use the self-guarantee, to the NRC within 90 days after the close of each succeeding fiscal year. If the company no longer meets the financial test requirements, the licensee must send notice within 90 days to NRC of intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days. If at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moody's, the licensee must notify NRC within 20 days. Appendix E requires guarantors to notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph G of Appendix E. The notification must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible. These notices are necessary to permit NRC to take action to ensure that alternative means of financial assurance are available for decommissioning the licensee's site or confirm that the company still meets the applicable criteria.