

FINAL OMB SUPPORTING STATEMENT
FOR
10 CFR PART 32
SPECIFIC DOMESTIC LICENSES TO
MANUFACTURE OR TRANSFER CERTAIN
ITEMS CONTAINING BYPRODUCT MATERIAL
AND NRC FORM 653, 653A AND 653B,
"TRANSFERS OF INDUSTRIAL DEVICES REPORT"
(3150-0001)

EXTENSION

Description of the Information Collection

The Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 32 provide requirements for the manufacture and distribution of a wide range of materials and products containing radioactive material. Part 32 also provides requirements governing holders of certificates of registration for certain products and materials. The requirements in Part 32 specify: information that must be submitted in an application for a license to manufacture and distribute materials and products; records that must be kept; reports that must be submitted; labeling and marking products; and information that must be forwarded to users of these products and materials.

Note: The regulations in the following sections of 10 CFR Part 32 require certain information to be submitted as part of a license applications for a materials license: 32.11, 32.14(b), 32.18(d), 32.21(a), 32.22(a)(2), 32.26(b), 32.30(b), 32.51(a)(2), 32.51(b), 32.51(c), 32.53(b), 32.57(b), 32.61(b), 32.72(a)(2), 32.72(a)(3), 32.74(a)(2), and 32.74(b). License applications are submitted on NRC Form 313, which is approved under OMB clearance number 3150-0120. Because the burden for materials license applications is included in the clearance for NRC Form 313, these sections are not included in this Part 32 clearance package.

A. Justification

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

This information is necessary to determine the kind of products and materials into which byproduct material will be incorporated and provides NRC with information concerning those persons who would produce and transfer the products or materials. The information is also needed so that the NRC may determine that the product has an adequate margin of safety. The NRC determines that use of the product or materials, and performance of any operations associated with the product or materials, can be safely performed by individuals untrained in radiological protection or can be distributed for medical uses by medical use licensees. Specific requirements for exempt license distribution, general license distribution, medical license distribution, and for obtaining certificates of registration for sealed sources and devices can be found in Part 32.

The records and reports described in this information collection are necessary for products distributed to general licensees and persons exempt from licensing so that the NRC will be aware of what types and quantities of byproduct materials are introduced into materials which could enter the environment and/or be used by persons not subject to any regulatory requirements. The NRC must be aware of the location of devices and products in the

possession of general licensees and distribution trends of exempt products. These reports are the only means the Commission has to keep track of the location of the generally licensed radioactive devices and perform trend analysis of exempt distribution products. Also, information in reports allows NRC to contact the general licensees and to provide information to those actually knowledgeable of the device and the regulations for possession, to ensure compliance with the terms and conditions of the general license in Section 31.5 by these general licensees. Specifically, licensed vendors of generally licensed devices are required to provide reports quarterly describing all transfers of generally licensed devices. The information may be reported on NRC Form 653 or in a report containing all the information required by NRC Form 653. These reports are required quarterly because of the frequent transfers of these devices by both vendors and general licensees and the need to maintain current information about the general licensee and the device(s) locations. In the case of medical use products, the NRC must be certain that products used by medical use licensees are received, acquired, possessed, and used only by authorized personnel for the purposes described in the regulations. Certificates of registration for sealed sources and devices are necessary so that sufficient information about such things as design and potential hazards, provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. This information is necessary for the NRC to determine the adequacy of the radiation safety properties of the source or device under the expected conditions of use.

The labeling requirements are needed to inform the person exempt from the regulations that the product contains radioactive material and so consumers may then make a choice as to whether they want a radioactive or non-radioactive product in their home, if a choice is available. Also, in the event of a recall or problem with the item, the public and the NRC can readily determine who the initial distributor is from all the non-licensed distributors in the marketing chain. Labeling is also necessary so that individuals who handle these packages will know they contain radioactive material and in the event of an accident will know the type of isotope involved and the amount. In addition, appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material will be available to the user. The general licensee must be informed of their specific responsibilities by means of labels and product information requirements, which would include the specific importance of proper disposal and the potential costs. Certain medical use licensees must also be informed of their specific responsibilities by means of labels.

For more specific information regarding why each information collection requirement is needed, see Appendix A of this document.

2. Agency Use of Information

The records that 10 CFR Part 32 requires the licensees to maintain are reviewed during inspections to evaluate compliance with NRC radiation safety requirements for manufacture or transfer of certain items containing byproduct material.

The records of transfer of byproduct material are reviewed by the NRC inspectors to determine compliance with regulatory requirements and the reports are used by the NRC to keep track of the type and quantity of products and the amount of radioactivity that have been introduced into materials that could enter the environment and/or have been

distributed to persons exempt from licensing requirements or distributed to general licensees.

The records needed to generate the transfer reports must be kept long enough for NRC to receive and process the information, identify and resolve any discrepancies, or require any needed clarifications.

3. Reduction of Burden through Information Technology

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 80% of the 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.

5. Effort to Reduce Small Business Burden

Most 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, NRC will have no way to assess whether this category of licensee is operating within the radiation safety requirements applicable to the manufacture or transfer of certain items containing byproduct material. 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 OMB Guidelines in 5 CFR 1320.6(f), Sections 32.25(b), 32.29(b), 32.32(b), 32.51(a)(3)-(5) & 32.51a(d), 32.54(a) & (b), 32.71(c)-(e), 32.72(a)(4), 32.201, and 32.210 require that the licensee commit to labeling requirements for the life of the product. This is to ensure that the labels are maintained on the product as originally stated in the application and they will be inspected periodically by NRC.

Contrary to the OMB Guidelines in 5 CFR 1320.6(f) 32.72(c) requires that the licensee have procedures for use of the instrumentation to measure the radioactivity of radioactive drugs, pursuant to Section 32.72, as long as the instrumentation is used, which may exceed 3

years. Retention of the procedures for as long as the instrument is used to measure radioactivity, pursuant to Section 32.72, is necessary to ensure that licensees use the instrumentation correctly to measure the amount of radioactivity in drugs being prepared for administration to patients.

8. Consultations outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the Federal Register on April 2, 2019 (84 FR 12643). Four licensees, Varian Medical Services; Owlstone, Inc.; Elekta, Inc.; and Advanced Combat Solutions Inc.; were contacted via email to obtain feedback on the information collection for the public consultations. The NRC received one comment from one of the four consultants that were contacted by email. Comment: The commenter agreed that the collection of information is important for the NRC. The commenter did not have any additional comments. NRC Response: The NRC appreciates the commenter's input and agrees with their comments.

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 is requested.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimate of Burden and Burden Hour Cost

The burden estimates are based on the numbers of various types of licenses that are affected by applicable regulations and estimates of the time necessary to comply with these regulations. These estimates are based on information that was gathered in 2018. The numbers of licensees and the time necessary to comply with reporting and recordkeeping requirements are not expected to change significantly in the next three years. The cost to licensees and applicants is calculated at a rate of \$275 per hour for professional staff that prepare the technical information submitted in response to the additional cost for the information collection requirements.

NRC Licensees:

The total annual burden is estimated to be 26,946 hours per year for the 204 NRC licensees and manufacturers or original distributors that requested new, or revisions to existing, registration certificates (of which 78 are maintaining records) that are expected to report and keep records annually plus 159 third-party disclosure recordkeepers for NRC covered

by 10 CFR Part 32. The details are shown in Tables 1, 3, and 5. The total cost for the NRC licensees would be \$7,410,150 (26,946 hours x \$275/ hour).

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." A map of Agreement States and non-Agreement states is located on NRC's website at <http://nrc-stp.ornl.gov/rulemaking.html>. The NRC has established compatibility requirements for Agreement states to implement their own regulations in a manner consistent with NRC regulations.

The recordkeeping, reporting and third-party disclosure burden on the Agreement State licensees is based on several assumptions, including:

1. The majority of the Agreement States implement 10 CFR Part 32 Section 32.51 through Section 32.210 in a manner that is essentially identical to that of the NRC. The reporting frequency for Agreement State licensees is no different than that of the NRC licensees.
2. The Agreement State licensees are estimated to be approximately 6.6 times the number of NRC Licensees for Sections 32.51 through Section 32.74. The Agreement States reviews of new, or revisions to existing, registration certificates are estimated to be approximately 4.8 times the corresponding number of reviews conducted by the NRC under Section 32.210. This is based on historical information provided to the NRC regarding the number of NRC licensees and new and amended registration certificates issued by the NRC compared to the corresponding licensees and new and amended registration certificates under Agreement States jurisdiction and taking into account that the State of Georgia no longer performs Section 32.210 source and device evaluations.

In addition to this information, exceptions to the above assumptions are:

1. Fourteen Agreement States elected not to perform implementation of 10 CFR 32.210, and delegated this function to the NRC. The States that delegated the function to the NRC are: Arkansas, Georgia, Iowa, Minnesota, New Jersey, New Mexico, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, Utah, Virginia, and Wisconsin.
2. Not all of the Part 32 licenses in the Agreement States are issued by the Agreement States. Exempt Distribution Licenses, under Subpart A, and their certificates of registration, if required, for byproduct material and devices, are issued exclusively by NRC.

The total annual burden is estimated to be 110,625 hours per year for approximately 595 Agreement State licensees and manufacturers or original distributors that requested new, or revisions to existing, registration certificates and 331 Agreement State third-party disclosure participants that are expected to report and keep records annually. The total cost for the Agreement State licensees is expected to be \$30,421,875 (110,625 hours x \$275/hour). The

details are shown in Tables 2, 4, and 6.

TOTALS:

| | |
|--|---|
| Number of NRC licensees and new or amended registration certificates annually: | 204 |
| Number of A/S licensees and new or amended registration certificates annually: | 595 |
| Number of NRC third-party: | 159 |
| Number of A/S third-party: | <u>331</u> |
| Total licensees and new or amended registration certificates and third-party annually: | 1,289 |
| Total reporting burden: | 18,496 hrs (3,165hrs/NRC + 15,331 hrs/AS) |
| Total recordkeeping burden: | 1,106 hrs (151 hrs/NRC + 955 hrs/AS) |
| Total third-party disclosure burden: | <u>118,048 hrs</u> (23,630 hrs/NRC + 94,418 hrs/AS) |
| Total Burden: | 137,650 hrs |

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).

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 percent of the recordkeeping burden cost. Therefore, the records storage cost for this clearance is \$122 [1,106 recordkeeping hours x 0.0004 x \$275/hour].

In addition, approximately \$545,000 in contract costs is budgeted for activities associated with the database on Section 31.5 general licensees and 32.51 specific licensees. Therefore, the total estimated annualized cost for the 10 CFR Part 32 information collection requirements is \$545,122 (\$122 + \$545,000).

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 staff to review the records and reports required by 10 CFR Part 32 is estimated to be 2,959 hours at \$275/hr or \$813,725.

15. Reasons for Changes in Burden or Cost

The overall burden has decreased from the previous reporting (i.e., the previous estimated burden was 164,608 and the current burden is 137,650); the various elements that comprise this estimate have changed and the most significant are noted here:

- a. For Section 32.29(b), there was a decrease in the number of third-party disclosure recordkeepers by 3 from 17 to 14 and the corresponding burden by 810 hours from 4,590 to 3,780 hours. The current estimate is based on the number of NRC licensees to which the requirements in this section apply.
- b. For Section 32.32(b), there is a decrease in the number of third-party disclosure recordkeepers by 1 from 3 to 2 and the corresponding burden by 100 hours from 300 to 200 hours. The current estimate is based on the number of NRC licensees to which the requirements in this section apply.
- c. For Section 32.51(a)(3)-(5) and 32.51a(d), there is a decrease in the number of third-party disclosure recordkeepers by 7 from 53 to 46 and the corresponding burden by 440 hours from 2,671 to 2,231 hours. The current estimate is based on the number of NRC licensees to which the requirements in this section apply. A ratio of 6.6 (A/S to NRC licensees) was used to estimate the burden for A/S licensees.
- d. For Section 32.72(a)(4), there was a decrease in the number of respondents to this third-party disclosure (labeling) requirement. The current estimate is based on an updated number of active NRC licenses to which the requirements in Section 32.72(a)(4) apply. The NRC staff queried the Web-based Licensing system (WBL) to determine the number of current NRC licensees. Data from the WBL indicates that since the last renewal cycle, the number of licensees to whom this requirement applies decreased from 45 licensees to 35 licensees. Because obtaining and holding a license is a voluntary activity, the number of licensees may fluctuate over time based on financial and other business considerations that are not reported to, or controlled by, the NRC. The NRC staff uses data on the number of current licensees, in conjunction with any information available regarding the current state of the industry and any available projections, to estimate burden for the clearance period. An estimated ratio of 6.6 (AS to NRC licensees) was used to estimate the number of AS licensees; therefore, NRC staff estimated a total of 231 Agreement State licensees subject to this requirement (35 NRC licensees x 6.6 = 231). As a result, the total number of licensees since the last renewal decreased by 76 from 342 (45 NRC licensees and 297 AS licensees) to 266 (35 NRC licensees and 231 AS licenses). Because the burden associated with this labeling requirement is relatively high (390 hours per respondent), the corresponding burden decreased by 29,640 hours from 133,380 to 103,740 hours.
- e. For Section 32.210, there was an increase in the 1.) number of reporting respondents by 104 from 232 to 336; 2.) number of responses by 260 from 580 to 840; and 3.) burden by 5,460 hours from 12,180 hours to 17,640. The current estimate is based on the average number of 32.210 cases processed by the NRC from 2016 to 2018. A ratio of 4.8 (A/S to NRC cases) was used to estimate the burden for A/S licensees and registration certificate holders.

It should be noted that there was a change in the cost because the hourly rate increased from \$268 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. Reasons for Not Displaying the Expiration Date

The requirement is 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. Exception to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not Applicable.

TABLE 1 - Part 32 Reporting Burden for NRC Licensees

| Section | Description | Number of Respondents | Number of Responses Per Respondent | Total Annual Responses | Burden Hrs Per Response | Total Annual Burden (Hrs) | Cost @ \$275/Hr |
|---|--|------------------------------|------------------------------------|------------------------|-------------------------|---------------------------|-----------------|
| 32.12 | Records and material transfer reports | 5 | 1 | 5 | 0.3 | 1.5 | \$413 |
| 32.16 | Records and material transfer reports | 49 | 1 | 49 | 0.3 | 14.7 | \$4,043 |
| 32.20 | Records and material transfer reports | 18 | 1 | 18 | 0.3 | 5.4 | \$1,485 |
| 32.22(a)(3) | Device registration required | Burden is included in 32.210 | | | | | |
| 32.23 | Safety criteria | Burden is included in 32.210 | | | | | |
| 32.25(c) | Records and material transfer reports | 11 | 1 | 11 | 0.3 | 3.3 | \$908 |
| 32.27 | Safety criteria | Burden is included in 32.210 | | | | | |
| 32.29(c) | Records and material transfer reports | 14 | 1 | 14 | 0.3 | 4.2 | \$1,155 |
| 32.31 | Safety criteria | Burden is included in 32.210 | | | | | |
| 32.32(c) | Records and material transfer reports | 2 | 1 | 2 | 0.5 | 1 | \$275 |
| 32.51a(c) | Alternative approach to informing customers | 0 | 0 | 0 | 1.5 | 0 | \$0 |
| 32.51a(e) | Bankruptcy requirements | 0 | 0 | 0 | 1.5 | 0 | \$0 |
| 32.52(a); NRC Form 653 Responses to NRC | Reports to NRC of transfers of generally licensed material | 6 | 4 | 24 | 0.6 | 14.4 | \$3,960 |

TABLE 1 - Part 32 Reporting Burden for NRC Licensees—Continued

| Section | Description | Number of Respondents | Number of Responses Per Respondent | Total Annual Responses | Burden Hrs Per Response | Total Annual Burden (Hrs) | Cost @ \$275/Hr |
|---|---|------------------------------|------------------------------------|------------------------|-------------------------|---------------------------|-----------------|
| 32.52(b); NRC Form 653 Distributor reports to A/S | Reports to Agreement States of transfers of generally licensed material | 6 | 24 | 144 | 0.4 | 57.6 | \$15,840 |
| 32.56 | Reports of transfers of luminous safety devices | 0 | 1 | 0 | 2 | 0 | \$0 |
| 32.72(b)(5) | Documentation of qualifications of nuclear pharmacists | 35 | 1 | 35 | 0.5 | 17.5 | \$4,813 |
| 32.210 | Registration of product information | 58 | 2.5 | 145 | 21 | 3,045 | \$837,375 |
| 32.211 | Inactivation of certificates of registration | Burden is included in 32.210 | | | | | |
| TOTALS | | 204 | | 448 | | 3165 | \$870,375 |

TABLE 2 - Part 32 Reporting Burden for Agreement States Licensees

| Section | Description | No. of Respondents | No. of Responses Per Respondent | Total Annual Responses | Burden Hrs Per Response | Total Annual Burden [hrs] | Cost @ \$275/hr |
|---|--|--------------------|---------------------------------|------------------------|-------------------------|---------------------------|-----------------|
| 32.51a(c) | Alternative approach to informing customers | 0 | 0 | 0 | 1.5 | 0 | \$0 |
| 32.51a(e) | Bankruptcy requirements | 0 | 0 | 0 | 1.5 | 0 | \$0 |
| 32.52(a) NRC Form 653 Reports to NRC* | Reports to NRC of transfers of generally licensed material | 40 | 4 | 160 | 0.6 | 96 | \$26,400 |
| 32.52(b) NRC Form 653 Reports to A/S* | Reports to Agreement States of transfers of generally licensed | 40 | 32 | 1,280 | 0.4 | 512 | \$140,800 |
| 32.56 | Reports of transfers of luminous safety devices | 6 | 1 | 6 | 2 | 12 | \$3,300 |
| 32.72(b)(5) | Documentation of qualifications of nuclear pharmacists | 231 | 1 | 231 | 0.5 | 115.5 | \$31,763 |
| 32.210** | Registration of product information | 278 | 2.5 | 695 | 21 | 14,595 | \$4,013,625 |
| 32.211 Burden included in 32.210 | Inactivation of certificates of registration | | | | | | |
| TOTALS | | 595 | | 2,372 | | 15,331 | \$4,215,888 |

NOTE: Activities under 10 CFR Part 32 Subpart A, "Exempt Concentrations and Items," are licensed and regulated solely by the NRC, not by the Agreement States. Therefore, the burden for the requirements under Subpart A sections is included in Table 1, instead of Table 2.

* NOTE: To account for the number of Agreement States to which reporting is required, the No. of Responses per Respondent is 32.

** NOTE: A ratio of 4.8 (rather than 6.6) Agreement State Respondents to NRC Respondents

was used to more accurately estimate the number of respondents with regard to 10 CFR 32.210 in Agreement States.

TOTAL – Part 32 Reporting Burden

| Section | Number of Respondents | Number of Responses Per Respondent | Total Annual Responses | Burden Hrs Per Response | Total Annual Burden (Hrs) | Cost @ \$275/Hr |
|----------------------|-----------------------|------------------------------------|------------------------|-------------------------|---------------------------|-----------------|
| Reporting Totals NRC | 204 | | 448 | | 3,165 | \$870,375 |
| Reporting Totals AS | 595 | | 2,372 | | 15,331 | \$4,216,025 |
| TOTALS | 799 | | 2,820 | | 18,496 | \$5,086,400 |

TABLE 3 – Part 32 Recordkeeping Burden for NRC Licensees

| Section | Description | Number of Recordkeepers | Hours Per Recordkeeper | Total Annual Burden Hours | Cost @ \$275/Hr |
|----------|---|-------------------------|------------------------|---------------------------|-----------------|
| 32.12 | Records and material transfer reports | 5 | 0.5 | 2.5 | \$688 |
| 32.16 | Records and material transfer reports | 49 | 0.5 | 24.5 | \$6,738 |
| 32.20 | Records and material transfer reports | 18 | 0.5 | 9 | \$2,475 |
| 32.25(c) | Records and material transfer reports | 11 | 0.5 | 5.5 | \$1,513 |
| 32.29(c) | Records and material transfer reports | 14 | 0.5 | 7 | \$1,925 |
| 32.32(c) | Records and material transfer reports | 2 | 1 | 2 | \$550 |
| 32.52(c) | Maintenance of records | 6 | 0.22 | 1.32 | \$363 |
| 32.72(c) | Measurement of radioactivity in products | 35 | 0.2 | 7 | \$1,925 |
| 32.201 | Serialization of nationally tracked sources | 3 | 45 | 135.0 | \$37,125 |
| TOTALS | | 78 | | 151 | \$41,525 |

TABLE 4 - PART 32 Recordkeeping for Agreement Licensees

| Section | Description | Number of Recordkeepers | Hours Per Recordkeeper | Total Annual Burden Hours | Cost @ \$275/Hr |
|---------------|---|-------------------------|------------------------|---------------------------|------------------|
| 32.52(c) | Maintenance of records | 40 | 0.22 | 8.8 | \$2,420 |
| 32.72(c) | Measurement of radioactivity in products | 231 | 0.2 | 46.2 | \$12,705 |
| 32.201 | Serialization of nationally tracked sources | 20 | 45 | 900.0 | \$247,500 |
| TOTALS | | 363 | | 955 | \$262,625 |

NOTE: Activities under 10 CFR Part 32 Subpart A, "Exempt Concentrations and Items," are licensed and regulated solely by the NRC, not by the Agreement States. Therefore, the burden for the requirements under Subpart A sections is included in Table 2, not Table 4.

TOTAL - Part 32 Recordkeeping Burden

| Section | Number of Recordkeepers | Total Annual Burden Hours | Cost @ 275/Hr |
|--------------------------|-------------------------|---------------------------|------------------|
| Recordkeeping Totals NRC | 78 | 151 | \$41,525 |
| Recordkeeping Totals AS | 363 | 955 | \$262,625 |
| TOTALS | 441 | 1,106 | \$304,150 |

TABLE 5- Part 32 Third-Party Disclosure for NRC

| Section | Description | Number of Recordkeepers | Hours Per Recordkeeper | Total Annual Burden Hours | Cost @ \$275/Hr |
|---------------------------|---|-----------------------------|------------------------|---------------------------|-----------------|
| 32.15(d) | Labeling and marking products | 49 | 100 | 4,900 | \$1,347,500 |
| 32.19(c) | Labeling of products | 18 | 4.5 | 81 | \$22,275 |
| 32.19(d) | Labeling of products | Burden included in 32.19(c) | | | |
| 32.21a | Labeling of products | 1 | 50 | 50 | \$13,750 |
| 32.25(b) | Labeling of products | 11 | 30 | 330 | \$90,750 |
| 32.29(b) | Labeling of products | 14 | 270 | 3780 | \$1,039,500 |
| 32.32(b) | Labeling of products | 2 | 100 | 200 | \$80,025 |
| 32.51(a)(3)-(5)&32.51a(d) | Labeling of products | 6 | 48.5 | 291 | \$80,025 |
| 32.51a(a)&(b) | Information provided to general licensees | 6 | 48.5 | 291 | \$80,025 |
| 32.54(a)&(b) | Labeling of products | 0 | 50 | 0 | \$0 |
| 32.58 | Labeling of products | 0 | 3 | 0 | \$0 |
| 32.61(d) | Labeling of products | 0 | 0 | 0 | \$0 |
| 32.71(c) | Labeling of products | 2 | 7.5 | 15 | \$4,125 |
| 32.71(d) | Labeling of products | Burden included in 32.71(c) | | | |
| 32.71(e) | Labeling of products | Burden included in 32.71(c) | | | |
| 32.72(a)(4) | Labeling of products | 35 | 390 | 13,650 | \$3,753,750 |
| 32.74(a)(3) | Labeling of products | 15 | 2.8 | 42 | \$11,550 |
| TOTALS | | 159 | | 23,630 | \$6,498,250 |

TABLE 6- Part 32 Third-Party Disclosure for Agreement States

| Section | Description | Number of Recordkeepers | Hours Per Recordkeeper | Total Annual Burden Hours | Cost @ \$275/Hr |
|---------------------------|---|-----------------------------|------------------------|---------------------------|---------------------|
| 32.51(a)(3)-(5)&32.51a(d) | Labeling of products | 40 | 48.5 | 1,940 | \$533,500 |
| 32.51a(a)&(b) | Information provided to general licensees | 40 | 48.5 | 1,940 | \$533,500 |
| 32.54(a)&(b) | Labeling of products | 7 | 50 | 350 | \$96,250 |
| 32.58 | Labeling of products | 0 | 3 | 0 | \$0 |
| 32.61(d) | Labeling of products | 0 | 0 | 0 | \$0 |
| 32.71(c) | Labeling of products | 13 | 7.5 | 98 | \$26,813 |
| 32.71(d) | Labeling of products | Burden included in 32.71(c) | | | |
| 32.71(e) | Labeling of products | Burden included in 32.71(c) | | | |
| 32.72(a)(4) | Labeling of products | 231 | 390 | 90,090 | \$24,774,750 |
| 32.74(a)(3) | Labeling of products | NA | | 0 | 0 |
| TOTALS | | 331 | | 94,418 | \$25,964,950 |

| TOTAL - Part 32 Third-Party Disclosure | | | |
|---|-------------------------|---------------------------|---------------------|
| | Number of Recordkeepers | Total Annual Burden Hours | Cost @ \$275/Hr |
| Third-Party Totals NRC | 159 | 23,630 | \$6,498,250 |
| Third-Party Totals AS | 331 | 94,418 | \$25,964,950 |
| TOTALS | 490 | 118,048 | \$32,463,200 |

OVERALL BURDEN SUMMARY

TOTAL RESPONDENTS: 799 (204 NRC + 595 Agreement States)

TOTAL RESPONSES: 3,751 [2,820 responses (448 NRC responses + 2,372 Agreement State responses)] + 441 recordkeepers (78 NRC + 363 Agreement States) + 490 third-party recordkeepers (159 NRC + 331 Agreement States)]

TOTAL BURDEN: 137,650 (18,496 reporting + 1,106 recordkeeping + 118,048 third-party)

TOTAL BURDEN COST: \$37,853,750 (\$7,410,150 NRC + \$30,443,600 Agreement States)

Appendix A: Information Collections Requirements

Section 32.12 requires that persons licensed under Section 32.11 maintain records of transfer of material and file a report with the NRC annually, or at the time of license termination. The report must identify the specifically licensed distributor, their license number, the material that was transferred for use under 10 CFR 30.14, or Agreement State equivalent, the type and quantity of each product or material into which byproduct material was introduced, the name and address of the person who owned or possessed the product or material into which the byproduct material was introduced, the type and quantity of each radionuclide introduced, and the concentration at the time of transfer. The record of transfer must be retained for 1 year after the event is included in a report to the Commission. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements.

These records and reports are necessary so that the NRC will be aware of what types and quantities of byproduct materials are introduced into materials which could enter the environment and/or be used by persons not subject to any regulatory requirements. Even in the event there have been no transfers, a report is required so that the NRC will know that all licensees required to report under Section 32.12 have accounted for all distribution of material.

Section 32.15(d) requires that persons licensed under Section 32.14 label or mark each unit, except for timepieces, hands or dials containing tritium or promethium-147, and its container so that the manufacturer or the initial transferor of the product and the byproduct material in the product can be identified by the consumer and, if necessary, the NRC. In addition, smoke detectors must be labeled with "CONTAINS RADIOACTIVE MATERIAL" and the point-of-sale package must be labeled with "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS" or a substantially similar statement.

This requirement is necessary in order to inform the person exempt from the regulations that the product contains radioactive material and so that in the event of a recall or problem with the item, the public and the NRC can readily determine who the initial distributor is from all the non-licensed distributors in the marketing chain.

Section 32.16 requires that persons licensed under Section 32.14 maintain records of transfer of material and submit a report to NRC annually or at the time of license termination. The report must identify the specifically licensed distributor, their license number, the material that was transferred for use under 10 CFR 30.15, giving the specific paragraph designation, or Agreement State equivalent, the type of product and model number, if applicable, the total quantity of each radionuclide for each product or model number, and the number of units of each type of product distributed over the reporting period by model number, if applicable. The record of transfer must be retained for 1 year after the event is included in a report to the Commission.

These records and reports are necessary so that the NRC will be aware of the type and quantity of products and amount of radioactive material distributed to persons exempt from licensing. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements. Even in the event there have been no transfers, a

report is required so that NRC will know that all licensees required to report under Section 32.16 have accounted for all distribution of material.

Section 32.19(c) requires that persons licensed under Section 32.18 label the immediate container of each quantity or separately packaged fractional quantity of byproduct material with the radioisotope, the quantity of radioactivity, and the words "Radioactive Material."

This requirement is necessary so that individuals who handle these packages will know they contain radioactive material and in the event of an accident will know the type of isotope involved and the amount.

Section 32.19(d) requires, in addition to the labeling information required by Section 32.19(c), that persons licensed under Section 32.18 label the immediate container of each product with, or include in an accompanying brochure a statement that the contents are exempt from licensing requirements; the words "Radioactive Material-Not for Human Use-Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited-Exempt Quantities Should Not Be Combined"; and the appropriate radiation safety precautions and instructions for the handling, use, storage, and disposal of the radioactive material.

This requirement is necessary so that individuals who actually handle inner containers will know that the material is exempt from NRC or Agreement State licensing, but in any event is not for human use in any manner, and so that appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material will be available to the user.

Section 32.20(a) requires that persons licensed under Section 32.18 maintain records of transfer of material. The records must identify each person, by name and address, to whom byproduct material is transferred for use under Section 30.18 and the kinds and quantities of material transferred. The record of transfer must be retained for 1 year after the event is included in a report to the Commission. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements.

Sections 32.20(b), (c), and (d) require that licensees file a summary report of the total quantity of each isotope transferred under the specific license; identify the specifically licensed distributor, their license number, the material that was transferred for use under 10 CFR 30.18, or Agreement State equivalent; for each radionuclide in each physical form, the report shall indicate the total quantity of each radionuclide and the physical form transferred under the specific license. The report must be filed with NRC annually or at the time of license termination.

These records and reports are necessary so that NRC will be aware of the amount of radioactive material distributed to persons over whom there are no regulatory controls. Even in the event there have been no transfers, a report is required so that NRC will know that all licensees required to report under Section 32.20 have accounted for all distribution of material.

Section 32.21a specifies the labeling requirements for capsules containing carbon-14 urea and requires that the label identify the radioisotope, the physical and chemical form, and the quantity of radioactivity at a specific date, contain information on use and disposal, and a

statement that the contents are exempt from NRC or Agreement State licensing requirements. This information is necessary so that NRC can assure proper distribution and use of the material and so that individuals who handle these packages will know they contain radioactive material and in the event of an accident will know the type and amount of the isotope involved.

Section 32.22(a)(3)(ii) requires that the product be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the product to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.23 requires that an applicant for a license under Section 32.22 must demonstrate that the product is designed and will be manufactured so that specified safety criteria will be met to ensure that doses to individuals do not exceed indicated limits.

This information is necessary so that NRC may determine the adequacy of the product and that the product meets the safety criteria for such products as set forth in NRC regulations. These criteria are addressed in the registration certificate issued under Section 32.210.

Section 32.25(b) requires that persons licensed under Section 32.22 label or mark each unit so that the manufacturer, processor, producer, or initial transferor and the byproduct material can be identified.

This label is required to be available on the device so that if the device is lost, or there is an accident, the appropriate party can be contacted for information to determine the degree of possible hazard.

Section 32.25(c) requires that persons licensed under Section 32.22 maintain records and file reports of transfers. The report must be filed with NRC annually or at the time of license termination. The records and reports must identify the specifically licensed distributor, their license number, that the material that was transferred was for use under 10 CFR 30.19, or Agreement State equivalent, the type of product and, for each radionuclide in each type of product and each model number, and the report shall indicate the total quantity of each radionuclide; and the number of units for each product transferred by model number. The record of transfer must be retained for 1 year after the event is included in a report to the Commission. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements.

These records and reports are necessary so that NRC will be aware of the kinds of products distributed, the number of products distributed, and the amount of radioactive material in the products. Even in the event there have been no transfers, a report is required so that NRC will know that all licensees required to report under Section 32.25(c) have accounted for all distribution of material.

Section 32.26(c)(2) requires that the product be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the product to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.27 requires that an applicant for a license under Section 32.26 must demonstrate that the product is designed and will be manufactured so that specified safety criteria will be met to ensure that doses to individuals do not exceed indicated limits.

This information is necessary so that NRC may determine the adequacy of the product and that the product meets the safety criteria for such products as set forth in NRC regulations. These criteria are addressed in the registration certificate issued under Section 32.210.

Section 32.29(b) requires that persons licensed under Section 32.26 label each detector and its point-of-sale package. The label or marking on the detector is to contain the statement, "CONTAINS RADIOACTIVE MATERIAL;" the name of the radionuclide and quantity of activity; and the identification of the person licensed under Section 32.26 to transfer the detector for use under Section 30.20. The label or marking on the external surface of the point-of-sale package is to contain the name of the radionuclide and quantity of activity, the identification of the person licensed under Section 32.26 to transfer the detector for use under Section 30.20, and the statement that the detector contains radioactive material and has been manufactured in compliance with NRC safety criteria.

The information is necessary so that potential users will be put on notice that the item contains a radioactive substance, so that they may then make a choice as to whether they want to use a radioactive device. This labeling information is for the use of users, not the NRC.

Section 32.29(c) requires that persons licensed under Section 32.26 maintain records and file reports of transfers. The report must be filed with NRC annually or at the time of license termination. The records and reports must describe or identify the specifically licensed distributor, their license number, that the material that was transferred was for use under 10 CFR 30.20, or Agreement State equivalent, the type of product and, for each radionuclide in each type of product and each model number, and the report shall indicate the total quantity of each radionuclide; and the number of units for each product transferred by model number. The record of transfer must be retained for 1 year after the event is included in a report to the Commission. The records are reviewed by NRC inspectors to determine compliance with transfer documentation requirements.

These records and reports are necessary so that NRC will be aware of the kinds of products distributed, the number of products distributed, and the amount of radioactive material in the products. Even if there have been no transfers, a report is required so that NRC will know that all licensees required to report under Section 32.29(c) have accounted for all distribution of material.

Section 32.30(c)(3) requires that the device be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the device to all jurisdictions (NRC and Agreement States) as the

products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.31 requires that an applicant for a license under Section 32.30 must demonstrate that the product is designed and will be manufactured so that specified safety criteria will be met to ensure that doses to individuals do not exceed indicated limits. These criteria are addressed in the registration certificate issued under Section 32.210.

Section 32.32(b) requires that persons licensed under Section 32.30 label or mark each device and its point-of-sale package. The label or mark on the device is to contain the statement, "CONTAINS RADIOACTIVE MATERIAL"; the name of the radionuclide(s) and quantity of activity; the identification of the person licensed under Section 32.30 to transfer the device for use under Section 30.22; and instructions and precautions (or reference to operating and service manuals) regarding safe use of the device. The label or marking on the external surface of the point-of-sale package is to contain the name of the radionuclide(s) and quantity of activity, the identification of the person licensed under Section 32.30 to transfer the device for use under Section 30.22, and the statement that the device contains radioactive material and has been manufactured in compliance with NRC safety criteria.

The information is necessary so that potential users will be put on notice that the item contains a radioactive substance, so that they may then make a choice as to whether they want to use a radioactive device. This labeling information is for the use of users, not the NRC.

Section 32.32(c) requires that persons licensed under Section 32.30 maintain records and file reports of transfers. The report must be filed with NRC annually or at the time of license termination. The records and reports must describe or identify the specifically licensed distributor, their license number, that the material that was transferred was for use under Section 30.22, or Agreement State equivalent, the type of product and, for each radionuclide in each type of product and each model number, the report shall indicate the total quantity of each radionuclide; and the number of units for each product transferred by model number. The record of transfer must be retained for 1 year after the event is included in a report to the Commission.

These records and reports are necessary so that NRC will be aware of the kinds and number of products distributed. Even if there have been no transfers, a report will be required so that NRC will know that all licensees required to report under Section 32.32(c) have accounted for all distribution of material.

Section 32.51(a)(3) requires that persons licensed under Section 32.51 label each product distributed with instructions, precautions, and requirements for safe installation, operation, servicing of the device, leak testing (or lack of the requirement for leak testing), and testing any on-off mechanism and indicator. The label must also identify each radioisotope, quantity of radioactivity and date of determination of the quantity, and indicate that receipt, possession, use, and transfer of the device are subject to the general license. Section 32.51(a)(4) requires an additional label on any separable source housing containing the device model and serial number, the isotope and quantity, and the name of the manufacturer or initial distributor.

The requirements in Section 32.51(a)(3) & (4) are necessary because a generally licensed device is intended to be used safely by persons not trained in radiological protection. It is therefore necessary to instruct and warn all persons who come in contact with each device, what it is, and what safety procedures must be used in connection with the device (such as whether a leak test is necessary and, if so, when it should be done). The condition imposed does not require any submission to NRC, but informs the general licensee of his status and duties as an NRC licensee. The label on the separable source housing is required so that this housing, if separated from the remainder of the device, can also be identified.

Section 32.51(a)(5) requires a permanent label affixed to the source housing if separable, or the device if the source housing is not separable, on devices meeting the criteria for generally licensed material registration (Section 31.5(c)(13)) that indicates the device contains radioactive material and, if practicable, the radiation caution symbol.

This provision provides assurance that, even when a device has been exposed to other than normal conditions; (e.g., theft, loss, or damage, such as when a building has been demolished with the device in place) the label will be intact and the device may be identified as containing radioactive material, and proper actions can be taken. Also, this reduces the likelihood of incidents resulting in unnecessary exposures to the public and contamination of property.

Section 32.51(a)(6) requires that the device be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the device to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Sections 32.51a(a) and (b) require that distributors provide copies of Section 31.5 to general licensees to whom they transfer devices. The distributor is also required to provide copies of additional applicable sections of the regulations (Sections 31.2, 30.51, 20.2201, and 20.2202); a listing of the services that can only be performed by a specific licensee; in the case of NRC general licensees, a statement concerning high civil penalties for improper disposal of sources; and information regarding disposal options for the devices being transferred, including the estimated costs of disposal. In the case of general licensees in Agreement States, distributors can provide either the equivalent regulations of the Agreement State or the NRC regulations accompanied by a note explaining that use of the device is regulated by the Agreement State. In addition, the distributor will furnish the name or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained. The information must be provided before the device may be transferred.

These requirements are necessary to inform potential users concerning their responsibilities under the general license, including specifically the importance of proper disposal and the potential costs.

Section 32.51a(d) requires that each device transferred one year after the effective date of the regulation be labeled in accordance with the labeling requirements of Section 32.51(a)(3) through (5).

This section makes labeling in accordance with commitments made in the application for license a condition of the license and sets a time for existing licensees to upgrade labels to meet revised requirements.

Section 32.51a(e) requires distributors to provide, upon request, to the NRC and appropriate Agreement States, records of final disposition of devices in the case of bankruptcy or termination of license.

This will assist the NRC and Agreement State agencies in tracking individual devices and better enable the NRC to verify the location and disposition of these devices.

Sections 32.52(a) and (b) require distributors to report quarterly to NRC and to the appropriate Agreement States all transfers and receipts of devices generally licensed under Section 31.5 and the persons to whom they have been transferred. These reports include information on devices received, information on changes made to required label information, the name and license number of the reporting company, and the reporting period. The information may be reported on NRC Form 653 or in a report containing all of the information required by NRC Form 653.

These reports are necessary so that NRC and the Agreement States will be aware of the location of devices in the possession of general licensees. These reports are the only means the Commission and the Agreement State regulatory bodies have to keep track of the location of these generally licensed radioactive devices. The information in the reports allows NRC and the Agreement States to contact the general licensees and to provide information to those actually knowledgeable of the device and the regulations for possession, in order to ensure compliance with the terms and conditions of the general license in Section 31.5 (and comparable provisions in Agreement State regulations) by these general licensees.

Section 32.52(c) requires distributors to maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

The records needed to generate the transfer reports must be kept long enough for NRC to receive and process the information, identify and resolve any discrepancies, or require any needed clarifications.

Section 32.53(f) requires that the device be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the device to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.54(a) requires that persons licensed under Section 32.53 label each product distributed under Section 32.53 with the radiation symbol, disposal instructions, model number, serial number, isotope used and its quantity, the name of the manufacturer,

assembler, or initial transferor, and a statement that the receipt, possession, use, and transfer of the device are subject to a general license.

This requirement is necessary so that in the event the device is lost or there is an accident, the appropriate party can be contacted for information to determine the degree of possible hazard. The required information is for the use of the general licensee.

Section 32.54(b) provides an alternative to the labeling requirements of Section 32.54(a) when it is not feasible to attach a label to the device which contains all the information called for in Section 32.54(a). The alternative is to attach a label identifying only the manufacturer, assembler, or initial transferor and the isotope used. The additional information which cannot fit on the label must be included in a leaflet which must accompany the device. The required information is for the use by the general licensee.

Section 32.56 requires that persons licensed under Section 32.53 submit an annual report of material transfers to NRC and to the appropriate Agreement States. The reports must identify each general licensee by name, must specify the kinds and numbers of luminous devices transferred, and must specify the quantity of tritium or promethium-147 in each device.

This report is necessary so that NRC and the Agreement States may be aware of the persons using the devices and how many are transferred. The information is used for inspection purposes for determining compliance by general licensees with the terms and conditions of the general license in Section 31.7, and equivalent Agreement State general licenses.

Section 32.58 requires that persons licensed under Section 32.57 label each source or storage container for a calibration or reference source containing americium-241 or radium-226, distributed to persons generally licensed under Section 31.8 with sufficient information relative to safe use and storage of the source, a statement that receipt, possession, use, and transfer of the source are subject to a general license, and the model and serial numbers. It is expected that no new such sources containing radium will be produced.

This requirement is necessary to ensure that recipients or others who may come in contact with them, know what they are, and their model and serial numbers in the event they are lost and need to be identified. The required information is for the use of the general licensee

Section 32.61(d) requires that persons licensed under Section 32.61 label each device distributed with the radiation caution symbol, a statement that the device contains strontium-90 and its quantity, instructions for disposal, that the device may be possessed under to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited, and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices.

This requirement is necessary to instruct and warn all persons who come in contact with each device, what it is, what safety procedures and restrictions apply to use the device, and who should be notified in case a lost device is found.

Section 32.61(g) requires that the device be evaluated and registered in the Sealed Source and Device Registry.

It is necessary to provide the summary of safety information and the approved licensing and use conditions for the device to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.71(c) requires that persons licensed under Section 32.71 label each prepackaged unit of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), cobalt-57, iron-59, selenium-75, or mock iodine-125 distributed to persons generally licensed under Section 31.11 with a durable, clearly visible label identifying the radioactive contents as to chemical form and radionuclides, as well as display the radiation caution symbol and the words, "Caution, Radioactive Material," and "Not for Internal or External Use in Humans or Animals."

This requirement is necessary for the safe use of the products by the general licensee and the licensee's employees.

Section 32.71(d) requires that persons licensed under Section 32.71 label each repackaged unit of iodine-125, iodine-131, carbon-14, tritium, cobalt-57, iron-59, selenium-75, or mock iodine-125 distributed to persons generally licensed under Section 31.11, or provide a brochure which accompanies the package, with information which states that only specified types of persons may acquire, possess, and use the material, and a statement that it is only for in vitro clinical or laboratory tests not involving administration to humans or animals. The label must also state that the radioisotope's use, receipt, acquisition, possession, and transfer are subject to the regulations and a general license of the NRC or Agreement State.

This requirement is necessary because generally licensed material is intended to be used safely by persons not having training in radiological protection. Consequently, any person who comes in contact with the material must be informed as to what it is and who may receive, possess, and use the material.

Section 32.71(e) requires that persons licensed under Section 32.71 label each prepackaged unit of iodine-125, iodine-131, carbon-14, tritium, cobalt-57, iron-59, selenium-75, or mock iodine-125, for distribution to persons generally licensed under Section 31.11, or provides a brochure which accompanies the package, with adequate information on the precautions to be observed in handling and storing such byproduct material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Section 20.2001.

This requirement is necessary because generally licensed material is intended to be used safely by persons not trained in radiological protection. Consequently, there must be a means to inform any person who comes into possession of the material of the precautions to be observed in handling and storing such byproduct material. This requirement is for the use of the general licensee.

Section 32.72(a)(4) requires that an applicant for a license under Section 32.72 satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other

container used to hold a radioactive drug to be transferred for commercial distribution. The label for each transport shield must include the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL;" the name of the drug; and the quantity of radioactivity at a specified date and time (the time may be omitted for radioactive drugs with a half-life greater than 100 days. The label for each container must include the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL," and an identifier so that the container can be correlated with the information on the transport radiation shield label.

This requirement is necessary to inform individuals coming in contact with the package what it contains.

Section 32.72(b)(5) applies to licensees that are licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution. These licensees are required to provide the Commission a copy of each individual's certification by the recognized specialty board, the Commission or Agreement State license, the permit issued by a master materials licensee, or the permit issued by a licensee or master materials permit holder of broad scope, and a copy of the State pharmacy licensure or registration, no later than 30 days after the date the licensee allows the individual to work as an authorized nuclear pharmacist.

This information collection requirement is necessary to allow NRC to review certifications to verify that the individual meets the requirements of an authorized nuclear pharmacist.

Section 32.72(c) requires that a licensee that possesses and uses instrumentation to measure radioactivity of radioactive drugs, under Section 32.72, shall have procedures for use of the instrumentation. The licensees may use procedures provided by the manufacturer of the instrumentation.

These procedures are necessary to ensure that licensees use the instrumentation correctly.

Section 32.74(a)(3) requires that persons licensed under Section 32.74 label the source or device, or its permanent storage container, with the name of the radionuclide, quantity and date of assay, and a statement that the source or device is licensed by the NRC for distribution to persons licensed to use byproduct material identified in Sections, 35.65, 35.400, 35.500, and 35.600, or under an equivalent license of an Agreement State. This requirement is necessary for the safety and use of the licensee and licensee's employees.

Section 32.74(a)(4) requires that sources or devices transferred under 32.74 be evaluated and registered in the Sealed Source and Device Registry. It is necessary to provide the summary of safety information and the approved licensing and use conditions for the source or device to all jurisdictions (NRC and Agreement States) as the products are distributed nationally. Thus this information is included in a registration certificate rather than the license.

Section 32.201 requires licensees who manufacture nationally tracked sources to assign a unique serial number to each nationally tracked source. In order to track the movement of sources, a unique way to identify the specific source is necessary. The National Source Tracking System will use the combination of the manufacturer, model, and the serial number to track the sources.

Section 32.210 specifies that a manufacturer or initial distributor of a sealed source or a device containing a sealed source, whose product is intended for use under a specific license, may submit a request to NRC for evaluation of radiation safety information about its product and for registration of the product. The request must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing, and additionally, in the case of a device, sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. It also refers to other portions of Part 32 where there are specific criteria applicable to certain exempt products and certain generally licensed devices, and to specific provisions that apply to certain specifically licensed items. It delineates which specifically licensed sources and devices need not be registered.

This information is necessary for the NRC to determine the adequacy of the radiation safety properties of the source or device under the expected conditions of use and that the product meets applicable safety criteria for such products as set forth in NRC regulations.

Section 32.210(h) allows for the NRC to review and reissue registration certificates and require additional information from the certificate holders.

This information is necessary to ensure that products described in registration certificates remain in compliance with current regulatory standards.

Section 32.211 requires inactivation of sealed source and device registration certificates for sources and devices no longer distributed. When a registration certificate is inactivated; the safety information about the sealed sources or devices is maintained, but the NRC and the Agreement States also know which sealed sources and devices are authorized to be distributed. The provision requires requests for inactivation to be made within two years of ceasing distribution of covered sources and devices, except in the situation where a determination that there will be no further distribution occurs more than two years after the last transfer of a covered source or device. In this case, the request is to be made within 90 days of this determination and briefly explain the circumstances. It also provides that a registration certificate must be inactivated in order to terminate the associated distribution license.

The safety information about the products continues to be necessary as long as the products may still be in use, so that NRC and the Agreement States may determine that the products can be safely used under the applicable requirements for the particular product. It is also important for the NRC and the Agreement States know which sources and devices are no longer authorized to be distributed.