**JUSTIFICATION FOR CHANGE IN AN OMB CLEARANCE PACKAGE**
**10 CFR 35**
**(3150-0010)**

The Nuclear Regulatory Commission (NRC) amended its regulations to include jurisdiction over discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. This provides a regulatory framework by which to license and regulate byproduct material in accordance with the new, expanded definition. The amended regulations ("the NARM rule") impacted numerous existing information collections. The NRC packaged all of the impacted information collections into one new information collection which OMB approved and assigned control number 3150-0203.

One of the areas of existing Nuclear Regulatory Commission (NRC) regulations revised was 10 CFR 35. The following sections impacted the existing information collections cleared under OMB number 3150-0010:

Section 35.6(b) requires a licensee, who is conducting medical research on human subjects under the Federal Policy for the Protection of Human Subjects, to obtain review and approval of the research by an "Institutional Review Board (IRB)" and to obtain "informed consent" from the human research subject. The universe of licensees affected by this regulation is increased by an estimated 8 NRC licensees and 30 new Agreement State licensees. There is an annualized one-time implementation burden for 32 NRC and 118 Agreement State licensees.

Section 35.6(c) requires a licensee who is conducting medical research on human subjects but who is not under the Federal Policy for the Protection of Human Subjects, to apply for and receive approval of a specific amendment to its NRC medical use license before conducting such research. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees. There is an annualized one-time implementation burden for 8 NRC and 30 Agreement State licensees.

Section 35.12 requires that an application for a license for medical use of byproduct material as described in Sections 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by filing an original and one copy of NRC Form 313, "Application for Material License." The burden for this is included in the information collection burden for NRC Form 313 (OMB Clearance No. 3150-0120).

Section 35.13 requires a licensee to apply for and receive a license amendment before receiving, preparing, or using byproduct material for medical uses that are permitted under Part 35 before permitting anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license. The information is necessary to determine the licensee's ability to control radiation dose to workers, patients, and the public; and for NRC to contact the licensee or conduct an inspection of the licensee's program. The information also is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to use byproduct material safely, and has the facilities and equipment necessary to ensure protection of public health and safety. The burden for this is included in the information collection burden for NRC Form 313 (OMB Clearance No. 3150-0120).

Sections 35.14(a) & (b) - require licensees to provide licensing permits, preceptor attestations and specialty board certifications, or other licensing documentation, to the Commission, and to notify the Commission of personnel changes, so that the NRC can determine whether the licensee has individuals with adequate training and experience to use byproduct material safely. The universe of licensees affected by this regulation is increased by an estimated 28 NRC licensees and 95 new Agreement State licensees. There is an annualized one-time implementation burden for 180 NRC and 666 Agreement State licensees.

Section 35.19 provides an application process for exemptions from the regulations in Part 35. One additional NRC licensee and 3 additional Agreement State licensees are expected to be affected by this provision.

Section 35.24(a) requires a licensee's management written approval on various license application, renewal, or amendment documents prior to submittal; approve work of authorized individuals; or approve changes to the radiation protection program permitted under Section 35.26. The universe of licensees affected by this regulation is increased by an estimated 6 NRC licensees and 22 new Agreement State licensees. There is an annualized one-time implementation burden for 370 NRC and 1369 Agreement State licensees.

Section 35.24(b) requires a licensee's management to appoint and record the acceptance of a Radiation Safety Officer who is responsible for implementing the radiation protection program. The universe of licensees affected by this regulation is increased by an estimated 6 NRC licensees and 22 new Agreement State licensees. There is an annualized one-time implementation burden for 60 NRC and 222 Agreement State licensees.

Section 35.24(c) requires notification procedures of a licensee that appoints a temporary Radiation Safety Officer who is responsible for implementing the radiation safety program. The burden for this notification is covered under Section 35.14(b).

Section 35.24(f) requires certain licensees to establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The requirement to establish a Radiation Safety Committee to oversee the radiation protection program provides assurance both to the licensees and to NRC that all of the different departments and diverse professional staff are aware of changes, needs, and issues related to the licensee's radiation protection program. There is an annualized one-time implementation burden for an estimated 20 NRC licensees and 74 new Agreement State licensees.

Section 35.26 allows a licensee to revise its radiation protection program without Commission approval if the revision does not require an amendment under Section 35.13; the revision is in compliance with the regulations and the license; the revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and the affected individuals are instructed on the revised program before the changes are implemented. The recordkeeping burden for this retaining a record of each change is under Section 35.2026.

Section 35.40(a) requires licensees that perform certain specified medical administrations involving I-131 sodium iodide greater than 1.11 Megabequerels (MBq),

any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material, to prepare a dated and signed written directive prior to performing the medical administration. The universe of licensees affected by this regulation is increased by an estimated 200 NRC licensees and 740 new Agreement State licensees.

Section 35.40(a)(1) requires licensees that perform certain specified medical administrations involving I-131 sodium iodide greater than 1.11 Megabequerels (MBq), any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material, to prepare a dated and signed written directive prior to performing the medical administration. The universe of licensees affected by this regulation is increased by an estimated 20 NRC licensees and 74 new Agreement State licensees.

Section 35.40(c) requires licensees to document written revisions and oral revisions to an existing written directive if the revision is dated and signed by an authorized user before the administration or the next fractional dose. The universe of licensees affected by this regulation is increased by an estimated 100 NRC licensees and 370 new Agreement State licensees.

Section 35.40(d) requires licensees to retain a copy of the written directive in accordance with Section 35.2040. Preparation of a written directive is necessary to provide high confidence that byproduct material will be administered as directed by the authorized user physician. The burden for this retaining a record of each change is under Section 35.2040.

Section 35.41(a) requires licensees to develop, implement and maintain written procedures for written directives. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees. There is an annualized one-time implementation burden for 200 NRC and 740 Agreement State licensees.

Section 35.80 requires a licensee providing mobile service to obtain a letter signed by the management of each client that permits the use of byproduct material at the client's address and delineates the authority and responsibility of the licensee and the client. This record is necessary to show that the client's management has permitted this work and to clearly delineate the authority and responsibilities of each entity. The burden for this is under Sections 35.2080 (a) and (b).

Sections 35.204(c) and (d) are revised to require records retention of each measurement of permissible strontium-82 or strontium-85 concentrations in preparing a rubidium-82 radiopharmaceutical. The burden for this is under Section 35.2204.

Section 35.310(a) requires that licensees provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material and cannot be released in accordance with § 35.75. The universe of licensees affected by this regulation is increased by an estimated 35 NRC licensees and 129 new Agreement State licensees.

Section 35.310(b) requires licensees to retain a record of individuals receiving instruction required by Section 35.310(a) in accordance with Section 35.2310. The burden for this retaining a record of persons receiving instruction is under Section 35.2310.

Section 35.315(a)(3) requires a licensee to note on the door or in the patient's chart indicating where and how long visitors may stay in the patient's room. The universe of licensees affected by this regulation is increased by an estimated 35 NRC licensees and 129 new Agreement State licensees.

Section 35.404 requires a licensee to make surveys after brachytherapy source implementation and removal, keeping a record in accordance with Section 35.2404. The burden for this retaining a record is under Section 35.2404.

Section 35.406 requires a licensee to make a record of brachytherapy source accountability in accordance with Section 35.2406. The burden for this retaining a record is under Section 35.2406.

Section 35.410(a) requires licensees to provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are receiving brachytherapy and cannot be released in accordance with § 35.75. The universe of licensees affected by this regulation is increased by an estimated 20 NRC licensees and 74 new Agreement State licensees.

Section 35.415(a)(3) requires that the licensee post the patient's or human research subject’s room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject’s chart where and how long visitors may stay in the room. The universe of licensees affected by this regulation is increased by an estimated 14 NRC licensees and 52 new Agreement State licensees.

Section 35.415(c) requires that the licensee notify the Radiation Safety Officer, or his or her designee, and authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. The universe of licensees affected by this regulation is increased by an estimated 4 NRC licensee and 14 new Agreement State licensees.

Section 35.432 requires licensees to retain a record of calibration measurements made on brachytherapy sealed sources in accordance with Section 35.2432. The burden for retaining this record is under Section 35.2432.

Section 35.2024(a) requires licensees to retain a record of actions taken by the licensee’s management, for 5 years. The universe of licensees affected by this regulation is increased by an estimated 370 NRC licensees and 1,369 new Agreement State licensees.

Section 35.2024(b) requires licensees to retain a copy of both the authority, duties, and responsibilities of the Radiation Safety Officer, among other documents, for the duration of the license. The universe of licensees affected by this regulation is increased by an estimated 60 NRC licensees and 222 new Agreement State licensees.

Section 35.2026 requires licensees to retain a record of each radiation protection program change, for 5 years. The universe of licensees affected by this regulation is

increased by an estimated 370 NRC licensees and 1,369 new Agreement State licensees. There is an annualized one-time implementation burden for 370 NRC and 1369 Agreement State licensees.

Section 35.2040 requires licensees to retain a copy of each written directive, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 200 NRC licensees and 740 new Agreement State licensees.

Section 35.2041 requires licensees to retain a copy of the procedures for administrations requiring a written directive, for the duration of the license. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.2060 requires licensees to maintain a record of instrument calibrations, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 25 NRC licensees and 92 new Agreement State licensees.

Section 35.2061 requires licensees to maintain a record of radiation survey instrument calibrations, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 60 NRC licensees and 222 new Agreement State licensees.

Section 35.2063 requires licensees to maintain a record of dosage determinations, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 80 NRC licensees and 296 new Agreement State licensees.

Section 35.2067(a) requires licensees to retain records of leak tests for 3 years. The universe of licensees affected by this regulation is increased by an estimated 88 NRC licensees and 325 new Agreement State licensees.

Section 35.2067(b) requires licensees to retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources for 3 years. The universe of licensees affected by this regulation is increased by an estimated 88 NRC licensees and 325 new Agreement State licensees.

Section 35.2070 requires licensees to retain records of radiation surveys, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 28 NRC licensees and 104 new Agreement State licensees.

Section 35.2075(a) requires licensees to retain a record of the basis for authorizing the release of an individual, containing a radiopharmaceutical or an implant, from the control of the licensee. The universe of licensees affected by this regulation is increased by an estimated 28 NRC licensees and 104 new Agreement State licensees.

Section 35.2075(b) requires licensees to retain a record that instructions were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisievert (0.5 rem). The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.2080(a) requires licensees, providing mobile medical services, to retain a copy of each letter that permits the use of byproduct material at a client's address. The

universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.2080(b) requires licensees to maintain a record of certain radiation surveys, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.2092 requires licensees to retain records of the disposal of licensed materials, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 60 NRC licensees and 222 new Agreement State licensees.

Section 35.2204 is revised to require licensees to maintain records of strontium-82 or strontium-85 concentration tests required by Section 35.204(d) for three years. This record is needed to show that the concentration measurement was made and that the maximum strontium-82 and strontium-85 concentration level was not exceeded. The universe of licensees affected by this regulation is increased by an estimated 9 NRC licensees and 33 new Agreement State licensees.

Section 35.2310 requires licensees to maintain records of safety instructions training, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 29 NRC licensees and 107 new Agreement State licensees.

Section 35.2404 requires licensees to maintain a record of the surveys required by Sections 35.404 and 35.604 for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey. This record is used to show that all sources were removed from the patient or human research subject, and that no sources have been misplaced. The universe of licensees affected by this regulation is increased by an estimated 100 NRC licensees and 370 new Agreement State licensees.

Section 35.2406 requires licensees to maintain records of brachytherapy source accountability, for 3 years. The universe of licensees affected by this regulation is increased by an estimated 100 NRC licensees and 370 new Agreement State licensees.

Section 35.2432 requires licensees to maintain a record of calibrations of brachytherapy sources, for 3 years after the last use of the source. The universe of licensees affected by this regulation is increased by an estimated 20 NRC licensees and 74 new Agreement State licensees.

Section 35.3045(c) requires licensees to notify NRC by telephone no later than the next calendar day after discovery of a medical event and to provide specified information. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.3045(d) requires licensees to submit a written report to NRC within 15 days of the discovery of a medical event and provide specified information. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.3045(e) requires licensees to notify patients and their referring physician(s) of a medical event. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

Section 35.3045(g) requires the licensee to annotate the event report provided to NRC with patient information and provide it to the physician no later than 15 days after the discovery of an event. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 7 new Agreement State licensees.

**The currently approved burden for Part 35 is as follows:**

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|---|---|
| Responses: | 259,332 responses (55,208 NRC and 204,124 Agreement States). |
| Respondents: | 8,751 respondents (1,862 for NRC Licensees plus 6,889 for Agreement State Licensees). |
| Burden Hours | 987,764 hours (251,200 hours for NRC Licensees plus 736,564 hours for Agreement State Licensees) |

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

| | |
|---|---|
| Responses: | 2,062 (421 NRC + 1,641 Agreement State) |
| Respondents: | 123 (28 NRC + 95 Agreement State) |
| Burden Hours: | 38,194 hours (8,313 NRC + 29,881 Agreement State) |

**TOTAL REQUESTED BURDEN HOURS FOR PART 35**
**(Currently approved burden plus final rule):**

| | |
|---|---|
| Responses: | 261,394 responses (55,629 for NRC Licensees plus 205,765 for Agreement State Licensees). |
| Respondents: | 8,874 respondents (1,890 for NRC Licensees plus 6,984 for Agreement State Licensees). |
| Burden Hours | 1,025,958 hours (259,513 hours for NRC Licensees plus 766,445 hours for Agreement State Licensees) |

**10 CFR Part 35 (3150-0010)**
**Annual Reporting Requirements for NRC Licensees**
**BURDEN TO BE TRANFERRED FROM 3150-0203**

| Section | No. Of Rspndts | Rsps. Per Respndt | Total Responses | Brdn per Response | Total Annual Burden Hours |
|---|---|---|---|---|---|
| 35.6(b) | 8 | 1 | 8 | 4 | 32 |
| 35.6(c) | 2 | 1 | 2 | 4 | 8 |
| 35.14(a)&(b) | 28 | 1 | 28 | .5 | 14 |
| 35.19 | 1 | 1 | 1 | 1 | 1 |
| 35.415(c) | 4 | 1 | 4 | 1 | 4 |
| 35.3045(c) | 2 | 1 | 2 | .5 | 1 |
| 35.3045(d) | 2 | 1 | 2 | 8 | 16 |
| 35.3045(e) | 2 | 1 | 2 | 2 | 4 |
| 35.3045(g) | 2 | 1 | 2 | .5 | 1 |
| **Total Part 35 Reporting** | | Not Applicable | 51 | | 81 |

**Recordkeeping Requirements for NRC Licensees**
**BURDEN TO BE TRANFERRED FROM 3150-0203**

| Section | Number of Record-keepers | Number of Records per Licensee | Burden Hrs. Per Record | Total Annual Burden Hours |
|---|---|---|---|---|
| 35.24(a) | 6 | 1 | 2.5 | 15 |
| 35.24(b) | 6 | 1 | .5 | 3 |
| 35.40(a) | 200 | 1 | 13 | 2,600 |
| 35.40(a)(1) | 20 | 1 | .7 | 14 |
| 35.40(c)(1) | 100 | 1 | 1 | 100 |
| 35.41(a) | 2 | 1 | .5 | 1 |
| 35.310(a) | 35 | 1 | 1 | 35 |
| 35.315(a)(3) | 35 | 1 | 1.8 | 63 |
| 35.410(a) | 20 | 1 | 1 | 20 |
| 35.415(a)(3) | 14 | 1 | .5 | 7 |
| 35.2024(a) | 370 | 5 | .25 | 463 |
| 35.2024(b) | 60 | 1 | .1 | 6 |
| 35.2026 | 370 | 1 | .25 | 93 |
| 35.2040 | 200 | 52 | .05 | 520 |
| 35.2041 | 2 | 1 | .05 | 1 |
| 35.2060 | 25 | 255 | .02 | 128 |
| 35.2061 | 60 | 1.5 | .25 | 23 |
| 35.2063 | 80 | 2,126 | .02 | 3,402 |
| 35.2067(a) | 88 | 3 | .06 | 16 |
| 35.2067(b) | 88 | 2 | .06 | 11 |
| 35.2070 | 28 | 55 | .02 | 31 |
| 35.2075(a) | 28 | 6 | .25 | 42 |
| 35.2075(b) | 2 | 2 | .2 | 1 |
| 35.2080(a) | 2 | 20 | .03 | 1 |

| Section | Number of Record-keepers | Number of Records per Licensee | Burden Hrs. Per Record | Total Annual Burden Hours |
|---|---|---|---|---|
| 35.2080(b) | 2 | 260 | .1 | 52 |
| 35.2092 | 60 | 52 | .02 | 62 |
| 35.2204 | 9 | 52 | .08 | 37 |
| 35.2310 | 29 | 1 | .10 | 3 |
| 35.2404 | 100 | 61 | .02 | 122 |
| 35.2406 | 100 | 15 | .2 | 300 |
| 35.2432 | 20 | 15 | .2 | 60 |
| **Total Part 35 Recordkeeping** | | 2,997 | | 8,232 |

**PART 35 NRC Licensee Totals to be transferred from 3150-0203:**

| | |
|---|---|
| Number of Responses: | 421 (51 responses + 370 additional recordkeepers) |
| Number of Respondents: | 28 |
| Total Burden Hours: | 8,313 hours (81 hours reporting + 8,232 hours recordkeeping) |

**Part 35 Equivalency Reporting Burden for Agreement State Licensees**
**BURDEN TO BE TRANFERRED FROM 3150-0203**

| Section | No. Of Rspndts | Rsps. Per Respndt | Total Responses | Brdn per Response | Total Annual Burden Hours |
|---|---|---|---|---|---|
| 35.6(b) | 30 | 1 | 30 | 4 | 120 |
| 35.6(c) | 7 | 1 | 7 | 4 | 28 |
| 35.14(a)&(b) | 95 | 2 | 190 | .25 | 48 |
| 35.19 | 3 | 1 | 3 | 1 | 3 |
| 35.415(c) | 14 | 1 | 14 | 1 | 14 |
| 35.3045(c) | 7 | 1 | 7 | .5 | 4 |
| 35.3045(d) | 7 | 1 | 7 | 8 | 56 |
| 35.3045(e) | 7 | 1 | 7 | 2 | 14 |
| 35.3045(g) | 7 | 1 | 7 | .5 | 4 |
| **Total Part 35 Reporting** | | Not Applicable | 272 | | 291 |

**Part 35 Equivalency Recordkeeping Burden for Agreement State Licensees**
**BURDEN TO BE TRANFERRED FROM 3150-0203**

| Section | Number of Record-keepers | Number of Records per Licensee | Burden Hrs. Per Record | Total Annual Burden Hours |
|---|---|---|---|---|
| 35.24(a) | 22 | 5 | .5 | 55 |
| 35.24(b) | 22 | 2 | .25 | 11 |
| 35.40(a) | 740 | 1 | 13 | 9,620 |
| 35.40(a)(1) | 74 | 1 | .7 | 52 |
| 35.40(c)(1) | 370 | 1 | 1 | 370 |
| 35.41(a) | 7 | 1 | .5 | 4 |
| 35.310(a) | 129 | 1 | 1 | 129 |
| 35.315(a)(3) | 129 | 1 | 1.8 | 232 |
| 35.410(a) | 74 | 1 | 1 | 74 |
| 35.415(a)(3) | 52 | 1 | .5 | 26 |
| 35.2024(a) | 1,369 | 5 | .25 | 1,711 |
| 35.2024(b) | 222 | 1 | .1 | 22 |
| 35.2026 | 1,369 | 1 | .25 | 342 |
| 35.2040 | 740 | 52 | .05 | 1,924 |
| 35.2041 | 7 | 1 | .05 | 0.35 |
| 35.2060 | 88 | 255 | .02 | 449 |
| 35.2061 | 317 | 1.5 | .25 | 119 |
| 35.2063 | 288 | 2,126 | .02 | 12,246 |
| 35.2067(a) | 317 | 3 | .06 | 57 |
| 35.2067(b) | 317 | 2 | .06 | 38 |
| 35.2070 | 99 | 55 | .02 | 109 |
| 35.2075(a) | 99 | 6 | .25 | 149 |
| 35.2075(b) | 99 | 2 | .2 | 40 |
| 35.2080(a) | 9 | 20 | .03 | 5 |
| 35.2080(b) | 9 | 260 | .1 | 234 |

| Section | Number of Record-keepers | Number of Records per Licensee | Burden Hrs. Per Record | Total Annual Burden Hours |
|---|---|---|---|---|
| 35.2092 | 317 | 52 | .02 | 330 |
| 35.2204 | 160 | 52 | .08 | 666 |
| 35.2310 | 103 | 1 | .1 | 10 |
| 35.2404 | 120 | 61 | .02 | 146 |
| 35.2406 | 70 | 15 | .2 | 210 |
| 35.2432 | 70 | 15 | .2 | 210 |
| **Total Part 35 Recordkeeping** | | 3,002 | | 29,590 |

**PART 35 Agreement State Licensee Totals to be transferred from 3150-0203:**

Number of Responses: 1641 (272 responses + 1,369 additional recordkeepers)
Number of Respondents: 95
Total Burden Hours: 29,881 hours (291 hours reporting + 29,590 hours recordkeeping)

**PART 35 Totals (NRC and Agreement State Licenses) to be transferred from 3150-0203**

Number of Responses: 2,062 (421 NRC + 1641 Agreement State)
Number of Respondents: 123 (28 NRC + 95 Agreement State)
Total Burden Hours: 38,194 hours (8,313 NRC + 29,881 Agreement State)