

**JUSTIFICATION FOR CHANGE IN AN OMB CLEARANCE PACKAGE
10 CFR 30, RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF
BYPRODUCT MATERIAL**

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 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 Part 30. The following sections impacted the existing information collections cleared under OMB number 3150-0017:

Section 30.3(b) and (c) requires that these new entities be licensed but is revised to authorize entities currently conducting activities that will now require specific NRC licenses as a result of the expansion of the definition of byproduct material, to continue those activities for varying periods of time prior to obtaining those licenses. The effect is to prevent disruption of current activities and delay the information requirements associated with applications for licenses for the new universe of licensees. License and amendment applications are cleared under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

Section 30.9(b) requires that an applicant or licensee notify the Commission of information which the applicant or licensee recognizes as having significant implications for public health and safety or the common defense and security. This requirement applies only to information which is not already required to be provided to the Commission by other reporting or updating requirements. The information must be provided within 2 working days to the administrator of the appropriate NRC regional office. The universe of licensees reporting under this regulation is estimated to be increased by one for NRC licensees and by 4 for Agreement State licensees.

Section 30.32 enumerates specific information requirements that must be included in an application for a specific license for possession and use of byproduct material. The universe of licensees affected by this regulation is increased by an estimated 335 NRC licensees. This information is cleared under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

Section 30.32(g) adds the requirement that the manufacturer and model number for sources and devices containing radium-226 from registration from a state and describes information that can be submitted for legacy sources that are not registered. This information is cleared under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

Section 30.32(j) adds requirements for authorization to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use. The universe of licensees affected by this

regulation is estimated to be 15. This information is cleared under NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120.

Section 30.32(j)(4) adds the requirement that licensees must notify NRC when an existing authorized nuclear pharmacist (ANP) begins working at the pharmacy that produces PET drugs. Fifteen additional NRC licensees and 60 additional Agreement State licensees are expected to be affected by this provision.

Section 30.34(e)(4) adds Orders and Safeguards requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of byproduct material. In addition, reports and the keeping of records may be required, as necessary, to fulfill the purposes of the Atomic Energy Act and regulations of the Commission. No additional NRC licensees will be affected by this provision. An additional 4 Agreement State licensees will be affected by Orders and 20 Agreement State licensees will be affected by Safeguards requirements.

Section 30.34(g) adds the requirement to test generator eluates for strontium-82 and strontium-85 contamination to the currently required eluates testing. The licensee must record the results of each test and retain each record for 3 years after the record is made. No licensees are expected to be affected by this provision.

Section 30.34(h) requires that each specific licensee and certain general licensees immediately notify the appropriate NRC regional administrator, in writing, following the filing of a bankruptcy petition by or against the licensee or a controlling or affiliate entity. One additional NRC licensee and 4 additional Agreement State licensees are expected to be affected by this provision.

Section 30.34(j)(2)(i) is a new requirement that each licensee authorized to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must satisfy the labeling requirements in 10 CFR 32.72(a)(4) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium. Fifteen additional NRC licensees and 60 additional Agreement State licensees are expected to be affected by this provision.

Section 30.34(j)(2)(ii) is a new requirement that each licensee authorized to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter. Fifteen additional NRC licensees and 60 additional Agreement State licensees are expected to be affected by this provision. There is an annualized one-time implementation burden for 15 NRC and 60 Agreement State licensees.

Sections 30.35(a) & (b) - Certification - require licensees to submit a decommissioning funding plan or a certification that financial assurance for decommissioning has been provided. Five additional NRC licensee and 20 additional Agreement State licensees are expected to be affected by this provision. There is an annualized one-time implementation burden on 5 NRC licensees. There is no one-time impact to Agreement

State licensees because NARM is already regulated by Agreement States and the one-time burden was incurred in the past.

Sections 30.35(a) & (b) - Financial Plan - require a certain amount of financial assurance for decommissioning held in a specific financial instrument. Five additional NRC licensee and 20 additional Agreement State licensees are expected to be affected by this provision. There is an annualized one-time implementation burden on 5 NRC licensees. There is no one-time impact to Agreement State licensees because NARM is already regulated by Agreement States and the one-time burden was incurred in the past.

Section 30.35(g) requires licensees to keep records of information important to the safe and effective decommissioning of the facility until the license is terminated by the Commission. The universe of licensees affected by this regulation is increased by an estimated 14 NRC licensees and no additional Agreement State licensees. There is an annualized one-time implementation burden for 14 NRC and 56 Agreement State licensees.

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

Section 30.36(d) requires each licensee to notify the Commission in writing of its decision not to renew its license and to either begin decommissioning its site or submit within 12 months of notification a decommissioning plan. The universe of licensees affected by this regulation is increased by an estimated 1 NRC licensee and 4 Agreement State licensees.

Section 30.36(g) requires that a decommissioning plan be submitted, if required by license condition or if the procedures and activities necessary to carry out the decommissioning have not been previously approved by the Commission, and these procedures could increase potential health and safety impacts to workers or to the public. The universe of licensees affected by this regulation is increased by an estimated 1 NRC licensee and 4 Agreement State licensees.

Section 30.36(h) requires licensees in certain circumstances to request license termination through a license amendment process. The burden and cost for this is included in Section 30.36.

Section 30.36(j) requires, as a final step in decommissioning, that a licensee certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314, "Certificate of Disposition of Materials." One additional NRC licensee is expected to be affected by this provision. This information is cleared under OMB Clearance No. 3150-0028.

Sections 30.41(c) & (d) require that, before transferring byproduct material to a specific licensee or a general licensee who is required to register prior to receipt of byproduct material, the transferor must verify that the transferee's license authorizes receipt of the type, form, and quantity of byproduct material to be transferred. It also specifies

methods acceptable to the Commission for accomplishing the required verification. The universe of licensees affected by this regulation is increased by an estimated 60 NRC licensees and 240 new Agreement State licensees.

Sections 30.50(a), (b) & (c) require licensees to notify NRC of events or conditions that threaten the health and safety of individuals either using or potentially exposed to licensed material. Licensees must make the reports by telephone to the NRC Operations Center, and must submit a written follow-up report to the telephone report. The universe of licensees affected by this regulation is increased by an estimated 2 NRC licensees and 8 new Agreement State licensees.

Section 30.72(c) adds radium-226 to the list of radioactive material that require consideration of the need for an emergency plan. None of the licensees potentially affected by this regulation are expected to have that level of possession so that there is no burden impact.

Part 30, Appendix D requires licensees to notify the NRC regarding adjustments to financial data committed to decommissioning funding assurance. One additional NRC licensee and 4 additional Agreement State licensees are expected to be affected by this provision. There also is an annualized one-time implementation burden for 8 NRC licensees and no additional Agreement State licensees

Part 30, Appendix E requires licensees who are nonprofit colleges, universities and hospitals to notify the NRC regarding adjustments to financial data committed to decommissioning funding assurance. No additional licensees will be affected by this provision for annual reporting. There is an annualized one-time implementation burden for 7 NRC and no additional Agreement State licensees.

NRC seeks to transfer the burden associated with these revisions from 3150-0203 to 3150-0017.

The previously approved burden for Part 30 (3150-0017):

Number of Responses: 35,178 responses (7,648 NRC + 27,530 Agreement States)
Respondents: 20,631 (4,485 NRC licensees + 16,146 Agreement State licensees)
Burden Hours: 248,034 (NRC licensees = 25,983 reporting + 27,965 recordkeeping, Agreement States = 93,431 reporting + 100,655 recordkeeping)

Burden Hour increase for Part 30 as a result of the final rule (see Tables 1-4), currently cleared under 3150-0203:

Responses: 492 (92 NRC + 400 Agreement State)
Respondents: 25 (5 NRC + 20 Agreement State)
Burden Hours: 33,757 hours (NRC licensees = 479 reporting + 6,380 recordkeeping + Agreement States = 1,938 reporting + 24,960 recordkeeping)

TOTAL REQUESTED BURDEN HOURS FOR 3150-0017 (Previously approved burden plus final rule)

Number of Responses: 35,670 responses (7,740 NRC plus 27,930 Agreement States)
Respondents: 20,656 (4,490 NRC licensees + 16,166 Agreement State licensees)
Burden Hours: 281,791 (NRC licensees = 26,462 reporting + 34,345 recordkeeping, Agreement States = 95,369 reporting + 125,615 recordkeeping)

10 CFR Part 30 (3150-0017)
HOURS TO BE TRANSFERRED FROM 3150-0203

Table 1. Annual Reporting Requirements for NRC Licensees

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours
30.3(b)&(c)	Burden covered under 3150-0120				
30.9(b)	1	1	1	1	1
30.32	Burden covered under 3150-0120				
30.32(j)(4)	15	1	15	0.5	7.5
30.34(e)(4) Orders	0	1	0	1	0
30.34(e)(4) Safeguards	0	1	0	0.5	0
30.34(h)	1	1	1	0.5	0.5
30.35(a)&(b)- Certification	5	1	5	10	50
30.35(a)&(b)- Financial Plan	5	1	5	10	50
30.36(d)	1	1	1	1	1
30.36(g)	1	1	1	360	360
30.50(a)(b)&(c)	2	1	2	4	8
Appendix D	1	1	1	1	1
Appendix E	0	1	0	1	0
Total Part 30 Reporting		Not Applicable	32		479

Table 2. Recordkeeping Requirements for NRC Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours
30.34(j)(2)(I)	15	200	3,000
30.34(j)(2)(ii)	15	200	3,000
30.35(g)	14	10	140
30.41(c)&(d)	60	4	240
Total Part 30 Recordkeeping			6,380

PART 30 NRC Licensee Totals:

Number of Responses: 92 (32 responses + 60 additional recordkeepers)

Number of Respondents: 5

Total Burden Hours: 6,859 hours (479 hours reporting + 6,380 hours recordkeeping)

Table 3. Part 30 Equivalency Reporting Burden for Agreement State Licensees

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Annual Burden Hours
30.3(b)&(c)	Burden covered under 3150-0120				
30.9(b)	4	1	4	1	4
30.32	Burden covered under 3150-0120				
30.32(j)(4)	60	1	60	0.5	30
30.34(e)(4) Orders	4	3	12	1	12
30.34(e)(4) Safeguards	20	1	20	0.5	10
30.34(h)	4	1	4	0.5	2
30.35(a)&(b)- Certification	20	1	20	10	200
30.35(a)&(b)- Financial Plan	20	1	20	10	200
30.36(d)	4	1	4	1	4
30.36(g)	4	1	4	360	1,440
30.50(a)(b)&(c)	8	1	8	4	32
Appendix D	4	1	4	1	4
Appendix E	0	1	0	1	0
Total Part 30 Reporting		Not Applicable	160		1,938

Table 4. Part 30 Equivalency Recordkeeping Burden for Agreement State Licensees

Section	Number of Recordkeepers	Burden Hrs. Per Recordkeeper	Total Annual Burden Hours
30.34(j)(2)(i)	60	200	12,000
30.34(j)(2)(ii)	60	200	12,000
30.35(g)	0	10	0
30.41(c)&(d)	240	4	960
Total Part 30 Recordkeeping			24,960

PART 30 Agreement State Licensee Totals

Number of Responses: 400 (160 responses + 240 additional recordkeepers)
Number of Respondents: 20
Total Burden Hours: 26,898 hours (1,938 hours reporting + 24,960 hours recordkeeping)

PART 30 Totals

Number of Responses: 492 (92 NRC + 400 Agreement State)
Number of Respondents: 25 (5 NRC + 20 Agreement State)
Total Burden Hours: 33,757 hours (6,859 NRC + 26,898 Agreement State)