

**Table 1 – Annual Reporting Requirements  
NRC Licensees (3150-0010)**

Section	Description	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ \$290/Hr
35.6(b)	Research application information needed if the research is conducted, funded, supported, or regulated by another Federal agency.	61	1	61	4	244	\$ 70,760
35.6(c)	Research application information needed for ammendment to NRC medical use license, if the research is not conducted, funded,supported or regulated by another Federal agency.	6	1	6	4	24	\$ 6,960
35.12(b), (c), & (d)		OMB Clearance 3150-0120					
35.13		OMB Clearance 3150-0120					
35.14(a) & (b)	Describes the requirements that need to be satisfied to notify the Commission, to function as an authorized user (AU), authorized medical physicist (AMP), ophthalmic physicist (OP), or authorized nuclear pharmacist (ANP).	105	2	210	0.25	52.5	\$ 15,225
35.14(b)(1)	Requires a licensee to notify the Commission within 30 days of when an ARSO discontinues performance of duties under the license or has a name change.	48	1	48	0.25	12	\$ 3,480
35.14(b)(6)	Requires a licensee to notify the NRC if it receives certain sealed sources without first obtaining a license ammendment.	464	2	928	0.25	232	\$ 67,280

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35.19	Provides that upon application of any interested person or upon its own initiative, the Commission may grant exemptions from the regulations in Part 35 that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.	4	1	4	1	4	\$ 1,160
35.24(c)	Provides that a licensee may permit an individual qualified to be a RSO, to function as a temporary RSO and to perform the functions of a RSO.	5	1	5	1	5	\$ 1,450
35.67(e)(2)	Requires licensees to file a report with the NRC within 5 days in accordance with § 35.3067 if leakage of a sealed source is detected.	Burden covered in 35.3067					
35.204(e)		Burden covered in 35.3204(a) & (b)					
35.315(b)	Requires that the licensee promptly notify the RSO, or his or her designee, and the AU as soon as possible if the patient has a medical emergency or dies.	2	1	2	1	2	\$ 580

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35.415(c)	Requires that the licensee notify the RSO, or his or her designee, and AU as soon as possible if the patient or human research subject has a medical emergency or dies.	8	1	8	1	8	\$ 2,320
35.615(f)(4)	Requires a licensee to notify the RSO, or his/her designee, and an AU as soon as possible if the patient or human research subject has a medical emergency or dies. This notification is required so that the RSO, or his/her designee, or AU can take whatever actions are necessary for radiation safety.	15	1	15	1	15	\$ 4,350
35.642(c)	Requires that the AMP review the results of each spot-check and notify the licensee in writing of the results of each spot checks.	1	12	12	0.25	3	\$ 870
35.643(c)	With regards to periodic spot-checks for remote afterloader units this section requires licensees to have the AMP review the results of each spot-check required by paragraph (a) within 15 days of the check and to notify the licensee as soon as possible in writing of the results of each spot check.	144	155	22320	0.25	5580	\$ 1,618,200
35.645(b)(2)	Requires licensees to have the AMP review the results of each spot-check of a gamma stereotactic radiosurgery unit within 15 days of each spot-check and to notify the licensee as soon as possible in writing the results of each spot-check.	15	260	3900	0.25	975	\$ 282,750

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35.1000()		OMB Clearance 3150-0120					
35.3045(a) & (b)		Burden covered in 35.3045(c) & (d)					
35.3045(c)	Requires licensees to notify the NRC by telephone no later than the next calendar day after discovery of the medical event.	5	1	5	0.5	2.5	\$ 725
35.3045(d)	Requires licensees to submit a written report to NRC within 15 days of the discovery of the medical event.	5	1	5	8	40	\$ 11,600

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35.3045(g)	Requires the licensee to: (1) annotate a copy of the medical event report provided to the NRC with specific information outlined in this section.	5	1	5	0.5	2.5	\$ 725
35.3047(a) & (b)		Burden covered in 35.3047(c) & (d)					
35.3047(c)	Requires the licensee to notify by telephone the NRC Operation Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report under § 35.3047(a) or (b).	1	1	1	0.5	0.5	\$ 145
35.3047(d)	Requires the licensee to submit a written report to the appropriate NRC Regional Office no later than 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under § 35.3047(a) or (b).	1	1	1	8	8	\$ 2,320
35.3047(e)	Requires the licensee to notify the referring physician and also notify the pregnant individual or mother (both hereafter referred to as the mother) no later than 24 hours after discovery of an event that would require reporting under paragraph § 35.3047(a) or (b).	1	1	1	2	2	\$ 580

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35.3047(f)	Requires the licensee to: (1) annotate a copy of the report provided to the NRC with the: (a) name of the pregnant individual or the nursing child who is the subject of the event; and (b) social security number or other identification number, if one has been assigned.	1	1	1	0.5	0.5	\$ 145
35.3067	This section requires licensees to report detection of a leaking source by submitting a written report within 5 days after a leakage test required by § 35.67 reveal the presence of 185 Bq (0.005 microcurie) or more of removable contamination.	1	1	1	1	1	\$ 290
35.3204(a)	Requires radiopharmacy and medical use licensees to notify both the NRC Operations Center and the distributor of the generator by telephone within 7 days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a).	1	1	1	0.25	1	\$ 290
35.3204(b)	Requires radiopharmacy and medical use licensees to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 30 days after discovery of an eluate exceeding the permissible concentration listed in § 35.204(a).	1	1	1	2.00	1	\$ 290
Total				27,541		7,216	\$ 2,092,495

**Table 2 – Annual Recordkeeping Requirements  
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Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ \$290/HR	Record Retention	
35.24(a)	Approval in writing by management of other administrative changes.	862	5	0.50	2,155.00	\$ 624,950	5 years	
35.24(b)	Appointment of associate RSOs in writing.	89	2	0.25	44.50	\$ 12,905		
35.24(e)	Authority, duties, and responsibilities of the RSO in writing.	Burden covered in 35.2024						
35.24(f)	Requirement to establish a Radiation Safety Committee to oversee the radiation protection programs.	227	1	0.50	113.50	\$ 32,915	Industry practice	
35.24(h)	Requires that a licensee record and retain actions taken pursuant to the authority and responsibilities within the radiation protection program.	Burden covered in 35.2024						
35.26(a)(3)&(4)	Requires 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.	862	1	0.50	431.00	\$ 124,990	5 years	
35.26(b)	Requires a record of each change to be retained in accordance with 35.2026.	Burden covered in 35.2026						
35.27(a)	Requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an AU as allowed by § 35.11(b).	862	1	1	862	\$ 249,980		

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35.27(b)	A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user.	162	1	1.00	162.00	\$ 46,980	
35.40(a)(1)	Requires the information in the oral directive to be documented as soon as possible in writing in the patient's record and a written directive must be prepared within 48 hours of the oral directive.	425	7	0.25	743.75	\$ 215,688	3 years
35.40(c)(1)	Permits a written revision to an existing written directive if the revision is dated and signed by an AU before the administration or the next fractional dose.	425	10	0.25	1062.50	\$ 308,125	3 years
35.40(d)	Requires the licensee to retain a copy of the written directive in accordance with § 35.2040.	Burden covered in 35.2040					
35.41(a)&(b)	Requires licensees to develop, implement and maintain written procedures for any administration requiring a written directive to provide high confidence that the patient or human research subject's identity is verified prior to each administration and that each administration is in accordance with the written directive (WD).	474	1	0.50	237.00	\$ 68,730	Duration of license
35.41(c)		Burden covered in 35.2041					



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35.50(a)		OMB Clearance 3150-0120					
35.50(b)(2)							
35.51(a)							
35.51(b)(2)							
35.55(a)							
35.55(b)(2)							
35.60(c)		Burden covered in 35.2060					
35.61(a)(3)	Requires that the licensee conspicuously note on a survey instrument the date that the instrument was calibrated. This information is necessary to show that survey instruments are calibrated and operational.	862	1	0.03	25.86	\$ 7,499	Equipment duration
35.61(c)		Burden covered in 35.2061					
35.63(e)		Burden covered in 35.2063					
35.65(b)(2)	Prohibits the bundling or aggregating of single sealed sources to create a sealed source with an activity greater than the maximum activity authorized by § 35.65.	2	2	2.50	5.00	\$1,390	Inventory and leak testing 3 years
35.67(a)		Burden covered in 35.2067					
35.67 (d)		Burden covered in 35.2067					

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Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.69	Requires that each syringe and vial that contains unsealed byproduct material must be labeled, and that each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.	776	2126	0.02	32,995.52	\$ 9,568,701	Equipment duration
35.70(c)		Burden covered in 35.2070					
35.75(c)		Burden covered in 35.2075(a)					
35.75(d)		Burden covered in 35.2075(b)					
35.80(a)(1)	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.	25	20	1.00	500.00	\$ 145,000	3 years after last service
35.80(c)		Burden covered in 35.2080					
35.92(b)		Burden covered in 35.2092					
35.190(c)(2)		OMB Clearance 3150-0120					
35.190(a)							

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Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.204(d)		Burden covered in 35.2204					
35.290(a)		OMB Clearance 3150-0120					
35.290(c)(2)		OMB Clearance 3150-0120					
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.	22	1	1.00	22	\$ 6,380	Annual
35.310(b)		Burden covered in 35.2310					
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. This posting and note are required so that employees and visitors receive information necessary for radiation safety.	22	12	0.10	26.4	\$ 7,656	Duration of treatment
35.390(a)		OMB Clearance 3150-0120					
35.390(b)(2)		OMB Clearance 3150-0120					
35.392(a)		OMB Clearance 3150-0120					
35.392(c)(3)		OMB Clearance 3150-0120					
35.394(a)		OMB Clearance 3150-0120					
35.394(c)(3)		OMB Clearance 3150-0120					

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35.396 (c)							
35.396 (d)							
35.404(c)					Burden covered in 35.2404		
35.406(c)					Burden covered in 35.2406		
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.	43	1	1.00	43	\$ 12,470	
35.67(a)					Burden covered in 35.2067		
35.410(b)					Burden covered in 35.2310		
35.415(a)(3)	Requires a note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.	43	5	0.10	21.5	\$ 6,235	Duration of treatment
35.432(d)					Burden covered in 35.2432		
35.433(b)					Burden covered in 35.2433		
35.490(a)							
35.490(b)(3)							

OMB Clearance 3150-0120

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35.491 (c)							
35.590(a)							
35.604(b)		Burden covered in 35.2404					
35.605(d)		Burden covered in 35.2605					
35.610(a)(4)	Requires licensees to develop, implement, and maintain written procedures for responding to an abnormal situation.	160	1	1.00	160.00	\$ 46,400	Possession of unit
35.610(b)	Requires licensees to physically locate a copy of the procedures at the unit console.	160	1	0.03	4.80	\$ 1,392	Possession of unit
35.610(c)	Requires licensees to post instructions for individuals who operate the devices at the device console providing the location of the procedures and emergency names and telephone numbers.	160	1	0.50	80.00	\$ 23,200	Possession of unit
35.610(d)(1)	Requires all individuals who will operate remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units to receive vendor operational and safety training prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit.	160	1	1.00	160.00	\$ 46,400	Possession of unit

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35.610(d)(2)	Requires licensees to provide initial instruction and annual refresher instruction to all individuals who operate the unit in the procedures identified in § 35.610(a) and the operating procedures for the unit.	160	1	1.00	160.00	\$ 46,400	Possession of unit
35.610(e)	Requires licensees to ensure that operators, AMPs, and AUs participate in drills of the emergency procedures, initially and at least annually.	160	1	0.50	80.00	\$ 23,200	
35.610(f)		Burden covered in 35.2310					
35.610(g)		Burden covered in 35.2610					
35.630(c)		Burden covered in 35.2630					
35.632(g)		Burden covered in 35.2632					
35.633(i)		Burden covered in 35.2632					
36.635(g)		Burden covered in 35.2632					
35.642(b)	Requires licensees to perform spot check measurements in accordance with written procedures established by the AMP.	1	1	4.00	4.00	\$ 1,160	Possession of unit
35.642(c)	Requires that the AMP review the results of each spot-check and notify the licensee in writing of the results of each spot checks.	1	12	0.25	3.00	\$ 870	3 years
35.642(f)		Burden covered in 35.2642					

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Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.643(b)	Requires licensees to perform spot check measurements in accordance with written procedures established by the AMP.	144	1	4.00	576.00	\$ 167,040	Possession of unit
35.643(c)	Requires licensees to have the AMP review the results of each spot-check required by paragraph (a) within 15 days of the check and to notify the licensee as soon as possible in writing of the results of each spot check.	144	155	0.25	5580.00	\$ 1,618,200	3 years
35.643(f)		Burden covered in 35.2643					
35.645(b)(1)	Requires licensees to perform spot-check measurements in accordance with written procedures established by the AMP.	15	1	4.00	60.00	\$ 17,400	Possession of unit
35.645(b)(2)	Requires licensees to have the AMP review the results of each spot-check of a gamma stereotactic radiosurgery unit within 15 days of each spot-check and to notify the licensee as soon as possible in writing the results of each spot-check.	15	260	0.25	975.00	\$ 282,750	3 years
35.645(g)		Burden covered in 35.2645					
35.647(e)		Burden covered in 35.2647					
35.652(c)		Burden covered in 35.2652					
35.655(c)		Burden covered in 35.2655					
35.690(a)		OMB Clearance 3150-0120					

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35.690(b)(3)							
35.2024(a)	Requires licensees to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years.	862	5	0.25	1,077.50	\$ 312,475	5 years
35.2024(b)	Requires licensees to retain a copy of both the authority, duties, and responsibilities of the RSO	862	2	0.10	172.40	\$ 49,996	Duration of license
35.2024(c)	Requires the licensee to keep the written documents signed by the licensee's management for each ARSO appointed under § 35.24(b) for 5 years after the ARSO is removed from the license.	88	1	1.00	88.00	\$ 25,520	5 years after ARSO is removed from license
35.2026	Requires licensees to retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years.	862	1	0.25	215.50	\$ 62,495	5 years
35.2040 ()	Requires licensees to retain a copy of each written directive.	425	104	0.05	2,210.00	\$ 640,900	3 years
35.2041	Requires licensees to retain a copy of the procedures for administrations requiring a written directive	425	1	0.05	21.25	\$ 6,163	Duration of license
35.2060()	Requires licensees to maintain a record of instrument calibrations required by § 35.60 for 3 years.	161	255	0.02	821.10	\$ 238,119	3 years
35.2061	Requires licensees to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years.	862	1.5	0.25	323.25	\$ 93,743	3 years



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35.2063	Requires licensees to maintain a record of dosage determinations required by § 35.63 for 3 years.	776	2126	0.02	32,995.52	\$ 9,568,701	3 years
35.2067(a)	Requires licensees to retain records of leak tests required by 35.67 (b) for 3 years.	862	3	0.06	155.16	\$ 44,996	3 years
35.2067(b)	Requires that licensees retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years.	862	2	0.06	103.44	\$ 29,998	3 years
35.2070()	Requires a licensee to retain a record of each survey required by § 35.70 for 3 years.	300	43	0.02	258.00	\$ 74,820	3 years
35.2075(a)	Requires licensees to retain a record of the basis for authorizing the release of an individual in accordance with § 35.75.	425	14	0.25	1,487.50	\$ 431,375	3 years
35.2075(b)	Requires licensees to retain a record that the instructions required by § 35.75(b) 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).	425	2	0.20	170.00	\$ 49,300	3 years

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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, as required by § 35.80(a) (1).	25	20	0.03	15.00	\$ 4,350	3 years after last service
35.2080(b)	Requires licensees to maintain a record of each survey required by § 35.80(a) (4) for 3 years.	25	260	0.10	650.00	\$ 188,500	3 years
35.2092	Requires licensees to retain records of the disposal of licensed materials, as required by § 35.92 for 3 years.	862	52	0.02	896.48	\$ 259,979	3 years
35.2204	Requires licensees to maintain records of molybdenum-99, strontium-82, and strontium-85 concentration tests required by § 35.204(b) for 3 years.	40	108	0.08	345.60	\$ 100,224	3 years
35.2310	Requires licensees to maintain a record of safety instructions required by §§ 35.310 and 35.410 and the operational and safety instructions required by § 35.610 for 3 years.	225	1	0.10	22.50	\$ 6,525	3 years
35.2404	Requires licensees to maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years.	215	97	0.02	417.10	\$ 120,959	3 years
35.2406	Requires licensees to maintain records of brachytherapy source accountability required by § 35.406 for 3 years.	95	15	0.20	285.00	\$ 82,650	3 years

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35.2432	Requires licensees to maintain a record of calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source.	95	15	0.20	285.00	\$ 82,650	3 years
35.2433	Requires licensees to maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source.	12	70	0.50	420.00	\$ 121,800	Life of source
35.2605	Requires licensees to retain records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years.	160	5	2.00	1,600.00	\$ 464,000	3 years
35.2610()	Requires licensees to maintain records of procedures required by § 35.610(a) (4) and (d) (2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.	160	2	0.05	16.00	\$ 4,640	Possession of unit
35.2630()	Requires licensees to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.	163	1	0.50	81.50	\$ 23,635	3 years

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35.2632	Requires licensees to maintain records of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years.	160	4.6	4.00	2,944.00	\$ 853,760	3 years
35.2642(a)	Requires licensees to retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.	1	12	0.50	6.00	\$ 1,740	3 years
35.2642(c)	Requires licensees to retain a copy of the written procedures for periodic spot-checks for teletherapy units established by the AMP.	1	1	0.05	0.05	\$ 15	Possession of unit
35.2643(a)	Requires licensees to retain records of each spot-check for remote afterloader units required by §§ 35.643 for 3 years.	125	155	1.00	19,375.00	\$ 5,618,750	3 years
35.2643(c)	Requires licensees to retain a copy of the written procedures for periodic spot-checks for remote afterloader units established by the AMP.	125	1	0.05	6.25	\$ 1,813	Possession of unit
35.2645(a)	Requires licensees to retain records of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.	15	260	2.00	7,800.00	\$ 2,262,000	3 years

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NRC Licensees (3150-0010)**

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.2645(c)	Requires licensees to retain a copy of the written procedures for periodic spot-checks for gamma stereotactic radiosurgery units established by the AMP.	15	1	0.05	0.75	\$ 218	Possession of unit
35.2647	Requires licensees to retain records of each check for mobile remote afterloader units required by § 35.647 for 3 years.	1	260	0.50	130.00	\$ 37,700	3 years
35.2652	Requires licensees to maintain records of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.	160	1	0.50	80.00	\$ 23,200	Duration of use of unit
35.2655	Requires licensees to maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.	16	0.2	1.00	3.20	\$ 928	Duration of use of unit
Total		862			122,771.38	\$ 35,603,700	

**Table 3 – Annual Third Party Disclosure Requirements  
NRC Licensees (3150-0010)**

Section	Description	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ \$290/Hr
35.75(b)	Requires licensees to provide an individual who has been administered unsealed byproduct material or implants containing byproduct material and who is being released from the licensee's control in accordance with § 35.75(a) with instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem).	425	20	8500	0.17	1445	\$ 419,050
35.3045(e)	Notification of medical event to the referring physician and individual who is the subject of the medical event within 24 hours	5	2	10	2	20	\$ 5,800

**Table 3 – Annual Third Party Disclosure Requirements  
NRC Licensees (3150-0010)**

35.3204(a)	Requires radiopharmacy and medical use licensees to notify both the NRC Operations Center and the distributor of the generator by telephone within 7 days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a).	1	1	1	0.25	0.25	\$ 73
Total				8511		1465.25	\$ 424,923

**Table 5 – Annual Reporting Requirements**

**Agreement State Licensees (3150-0010)**

Section	Description	Number of Respondents	Responses Per Respondent	Total Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ \$290/HR
35.6(b)	Research application information needed if the research is conducted, funded, supported, or regulated by another Federal agency.	458	1	458	4	1,832	\$ 531,280
35.6(c)	Provides the criteria needed in amendment request if the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy.	45	1	45	4	180	\$ 52,200
35.12(b), (c), & (d)		OMB Clearance 3150-0120					
35.13							
35.14(a) & (b)	Describes the requirements that need to be satisfied to notify the Commission, to function as an authorized user (AU), authorized medical physicist (AMP), ophthalmic physicist (OP), or authorized nuclear pharmacist (ANP).	788	2	1576	0.25	394	\$ 114,260



**Table 5 – Annual Reporting Requirements**

**Agreement State Licensees (3150-0010)**

35.14(b)(1)	Requires a licensee to notify the Commission within 30 days of when an ARSO discontinues performance of duties under the license or has a name change.	360	1	360	0.25	90.00	\$ 26,100
35.14(b)(6)	Requires a licensee to notify the NRC if it receives certain sealed sources without first obtaining a license amendment.	3480	2	6,960	0.25	1,740.00	\$ 504,600
35.19	Provides that upon application of any interested person or upon its own initiative, the Commission may grant exemptions from the regulations in Part 35 that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.	30	1	30	1	30	\$ 8,700
35.24(c)	Provides that a licensee may permit an individual qualified to be a RSO, to function as a temporary RSO and to perform the functions of a RSO.	38	1	38	1	38	\$ 11,020
35.67(e)(2)	Requires licensees to file a report with the NRC within 5 days in accordance with § 35.3067 if leakage of a sealed source is detected.	Burden covered in 35.3067					

**Table 5 – Annual Reporting Requirements**

**Agreement State Licensees (3150-0010)**

35.204(e)	Burden covered in 35.3204(a) & (b)						
35.315(b)	Requires that the licensee promptly notify the RSO, or his or her designee, and the AU as soon as possible if the patient has a medical emergency or dies.	15	1	15	1	15	\$ 4,350
35.415(c)	Requires that the licensee notify the RSO, or his or her designee, and AU as soon as possible if the patient or human research subject has a medical emergency or dies.	60	1	60	1	60	\$ 17,400
35.615(f)(4)	Requires a licensee to notify the RSO, or his/her designee, and an AU as soon as possible if the patient or human research subject has a medical emergency or dies. This notification is required so that the RSO, or his/her designee, or AU can take whatever actions are necessary for radiation safety.	113	1	113	1	113	\$ 32,770
35.642(c)	Requires that the AMP review the results of each spot-check and notify the licensee in writing of the results of each spot checks.	8	12	96	0.25	24	\$ 6,960

**Table 5 – Annual Reporting Requirements**

**Agreement State Licensees (3150-0010)**

35.643(c)	With regards to periodic spot-checks for remote afterloader units this section requires licensees to have the AMP review the results of each spot-check required by paragraph (a) within 15 days of the check and to notify the licensee as soon as possible in writing of the results of each spot check.	1080	155	167400	0.25	41,850	\$ 12,136,500
35.645(b)(2)	Requires licensees to have the AMP review the results of each spot-check of a gamma stereotactic radiosurgery unit within 15 days of each spot-check and to notify the licensee as soon as possible in writing the results of each spot-check.	113	260	29380	0.25	7,345	\$ 2,130,050
35.1000()	OMB Clearance 3150-0120						
35.3045(a) & (b)	Burden covered in 35.3045(c)(d)&(e)						
35.3045(c)	Requires licensees to notify the NRC by telephone no later than the next calendar day after discovery of the medical event.	52	1	52	0.5	26	\$ 7,540
35.3045(d)	Requires licensees to submit a written report to NRC within 15 days of the discovery of the medical event.	52	1	52	8	416	\$ 120,640
35.3045(g)	Requires the licensee to: (1) annotate a copy of the medical event report provided to the NRC with specific information outlined in this section.	38	1	38	0.5	19	\$ 5,510
35.3047(a) & (b)	Burden covered in 35.3047(c) & (d)						

**Table 5 – Annual Reporting Requirements**

**Agreement State Licensees (3150-0010)**

35.3047(c)	Requires the licensee to notify by telephone the NRC Operation Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report under § 35.3047(a) or (b).	8	1	8	0.5	4	\$ 1,160
35.3047(d)	Requires the licensee to submit a written report to the appropriate NRC Regional Office no later than 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under § 35.3047(a) or (b).	8	1	8	8	64	\$ 18,560
35.3047(e)	Requires the licensee to notify the referring physician and also notify the pregnant individual or mother (both hereafter referred to as the mother) no later than 24 hours after discovery of an event that would require reporting under paragraph § 35.3047(a) or (b).	8	1	8	2	16	\$ 4,640
35.3047(f)	Requires the licensee to annotate a copy of the report provided to the NRC with specific details of the affected individual.	8	1	8	0.5	4	\$ 1,160
35.3067	Requires licensees to report detection of a leaking source by submitting a written report within 5 days after a leakage test required by § 35.67 reveal the presence of 185 Bq (0.005 microcurie) or more of removable contamination.	8	1	8	1	8	\$ 2,320

**Table 5 – Annual Reporting Requirements**

**Agreement State Licensees (3150-0010)**

35.3204(a)	Requires radiopharmacy and medical use licensees to notify both the NRC Operations Center and the distributor of the generator by telephone within 7 days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a).	8	1	8	0.25	2.00	\$ 580
35.3204(b)	Requires radiopharmacy and medical use licensees to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 30 days after discovery of an eluate exceeding the permissible concentration listed in § 35.204(a).	8	1	8	2.00	16.00	\$ 4,640
Total				206,729		54,286	\$ 15,742,940

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.24(a)	Approval in writing by management of other administrative changes.	6465	5	0.50	16,162.50	\$ 4,687,125	5 years
35.24(b)	Appointment of associate RSOs in writing.	668	2	0.25	334.00	\$ 96,860	
35.24(e)	Authority, duties, and responsibilities of the RSO in writing.	Burden covered in 35.2024					
35.24(f)	Requirement to establish a Radiation Safety Committee to oversee the radiation protection programs.	1703	1	0.50	851.50	\$ 246,935	Industry practice
35.24(h)	Requires that a licensee record and retain actions taken pursuant to the authority and responsibilities within the radiation protection program.	Burden covered in 35.2024					
35.26(a)(3)&(4)	Requires 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.	6465	1	0.50	3,232.50	\$ 937,425	5 years
35.26(b)	Requires a record of each change to be retained in accordance with 35.2026.	Burden covered in 35.2026					
35.27(a)	Requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an AU as allowed by § 35.11(b).	6163	1	1.00	6,163.00	\$ 1,787,270	

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.27(b)	A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user.	1215	1	1.00	1,215.00	\$ 352,350	
35.40(a)(1)	Requires the information in the oral directive to be documented as soon as possible in writing in the patient's record and a written directive must be prepared within 48 hours of the oral directive.	3188	7	0.25	5,579.00	\$ 1,617,910	3 years
35.40(c)(1)	Permits a written revision to an existing written directive if the revision is dated and signed by an AU before the administration or the next fractional dose.	3188	10	0.25	7,970.00	\$ 2,311,300	3 years
35.40(d)	Requires the licensee to retain a copy of the written directive in accordance with § 35.2040.	Burden covered in 35.2040					
35.41(a)&(b)	Requires licensees to develop, implement and maintain written procedures for any administration requiring a written directive to provide high confidence that the patient or human research subject's identity is verified prior to each administration and that each administration is in accordance with the written directive (WD).	3555	1	0.50	1,777.50	\$ 515,475	Duration of license
35.41(c)		Burden covered in 35.2041					
35.50(a)		OMB Clearance 3150-0120					
35.50(b)(2)							
35.51(a)							
35.51(b)(2)							
35.55(a)							

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.55(b)(2)							
35.60(c)		Burden covered in 35.2060					
35.61(a)(3)	Requires that the licensee conspicuously note on a survey instrument the date that the instrument was calibrated. This information is necessary to show that survey instruments are calibrated and operational.	6465	1	0.03	193.95	\$ 56,246	Equipment duration
35.61(c)		Burden covered in 35.2061					
35.63(e)		Burden covered in 35.2063					
35.65(b)(2)	Prohibits the bundling or aggregating of single sealed sources to create a sealed source with an activity greater than the maximum activity authorized by § 35.65.	15	1	2.50	37.50	\$10,875	Inventory and leak testing 3 years
35.67(d)		Burden covered in 35.2067					
35.67(g)		Burden covered in 35.2067					
35.69	Requires that each syringe and vial that contains unsealed byproduct material must be labeled, and that each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.	5820	2126	0.02	247,466.40	\$ 71,765,256	Equipment duration
35.70(c)		Burden covered in 35.2070					
35.75(c)		Burden covered in 35.2075(a)					
35.75(d)		Burden covered in 35.2075(b)					



**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.80(a)(1)	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.	188	20	1.00	3,760.00	\$ 1,090,400	3 years after last service
35.80(c)		Burden covered in 35.2080					
35.92(b)		Burden covered in 35.2092					
35.190(a)		OMB Clearance 3150-0120					
35.190(c)(2)							
35.204(b)		Covered under 35.2204					
35.204(c)		Burden covered in 35.2204					
35.290(a)		OMB Clearance 3150-0120					
35.290(c)(2)							
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.	165	1	1.00	165.00	\$ 47,850	Annual
35.310(b)		Burden covered in 35.2310					
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. This posting and note are required so that employees and visitors receive information necessary for radiation safety.	165	12	0.10	198.00	\$ 57,420	Duration of treatment

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licenses**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.390(a)							
35.390(b)(2)							
35.392(a)							
35.392(c)(3)							
35.394(a)							
35.394(c)(3)							
35.396 (c)							
35.396 (d)							
35.404(c)							Burden covered in 35.2404
35.406(c)							Burden covered in 35.2406
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.	323	1	1.00	323.00	\$ 93,670	
35.410(b)							Burden covered in 35.2310
35.415(a)(3)	Requires a note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.	323	5	0.10	161.50	\$ 46,835	Duration of treatment
35.432(d)							Burden covered in 35.2432
35.433(b)							Burden covered in 35.2433
35.490(a)							
35.490(b)(3)							
35.491 (c)							
35.590(a)							
35.604(b)							Burden covered in 35.2404

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.605(d)		Burden covered in 35.2605					
35.610(a)(4)	Requires licensees to develop, implement, and maintain written procedures for responding to an abnormal situation.	1200	1	1.00	1200.00	\$ 348,000	Possession of unit
35.610(b)	Requires licensees to physically locate a copy of the procedures at the unit console.	1200	1	0.03	36.00	\$ 10,440	Possession of unit
35.610(c)	Requires licensees to post instructions for individuals who operate the devices at the device console providing the location of the procedures and emergency names and telephone numbers.	1200	1	0.50	600.00	\$ 174,000	Possession of unit
35.610(d)(1)	Requires all individuals who will operate remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units to receive vendor operational and safety training prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit.	1200	1	1.00	1200.00	\$ 348,000	Possession of unit
35.610(d)(2)	Requires licensees to provide initial instruction and annual refresher instruction to all individuals who operate the unit in the procedures identified in § 35.610(a) and the operating procedures for the unit.	1200	1	1.00	1200.00	\$ 348,000	Possession of unit
35.610(e)	Requires licensees to ensure that operators, AMPs, and AUs participate in drills of the emergency procedures, initially and at least annually.	1200	1	0.50	600.00	\$ 174,000	
35.610(f)		Burden covered in 35.2310					
35.610(g)		Burden covered in 35.2610					
35.630(c)		Burden covered in 35.2630					

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licenses**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.632(g)		Burden covered in 35.2632					
35.633(i)		Burden covered in 35.2632					
36.635(g)		Burden covered in 35.2632					
35.642(b)	Requires licensees to perform spot check measurements in accordance with written procedures established by the AMP.	8	1	4.00	32.00	\$ 9,280	Possession of unit
35.642(c)	Requires that the AMP review the results of each spot-check and notify the licensee in writing of the results of each spot checks.	8	12	0.25	24.00	\$ 6,960	3 years
35.642(f)		Burden covered in 35.2642					
35.643(b)	Requires licensees to perform spot check measurements in accordance with written procedures established by the AMP.	1080	1	4.00	4320.00	\$ 1,252,800	Possession of unit
35.643(c)	Requires licensees to have the AMP review the results of each spot-check required by paragraph (a) within 15 days of the check and to notify the licensee as soon as possible in writing of the results of each spot check.	1080	155	0.25	41850.00	\$ 12,136,500	3 years
35.643(f)		Burden covered in 35.2643					
35.645(b)(1)	Requires licensees to perform spot-check measurements in accordance with written procedures established by the AMP.	113	1	4.00	452.00	\$ 131,080	Possession of unit

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.645(b)(2)	Requires licensees to have the AMP review the results of each spot-check of a gamma stereotactic radiosurgery unit within 15 days of each spot-check and to notify the licensee as soon as possible in writing the results of each spot-check.	113	260	0.25	7345.00	\$ 2,130,050	3 years
35.645(g)		Burden covered in 35.2645					
35.647(e)		Burden covered in 35.2647					
35.652(c)		Burden covered in 35.2652					
35.655(c)		Burden covered in 35.2655					
35.690(a)		OMB Clearance 3150-0120					
35.690(b)(3)							
35.2024(a)	Requires licensees to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years.	6465	5	0.25	8081.25	\$ 2,343,563	5 years
35.2024(b)	Requires licensees to retain a copy of both the authority, duties, and responsibilities of the RSO	6465	2	0.10	1293.00	\$ 374,970	Duration of license
35.2024(c)	Requires the licensee to keep the written documents signed by the licensee's management for each ARSO appointed under § 35.24(b) for 5 years after the ARSO is removed from the license.	660	2	1.00	1320.00	\$ 382,800	5 years after ARSO is removed from license
35.2026	Requires licensees to retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years.	6465	1	0.25	1616.25	\$ 468,713	5 years

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.2040()	Requires licensees to retain a copy of each written directive.	3188	104	0.05	16577.60	\$ 4,807,504	3 years
35.2041	Requires licensees to retain a copy of the procedures for administrations requiring a written directive	3188	1	0.05	159.40	\$ 46,226	Duration of license
35.2060()	Requires licensees to maintain a record of instrument calibrations required by § 35.60 for 3 years.	1208	255	0.02	6160.80	\$ 1,786,632	3 years
35.2061	Requires licensees to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years.	6465	1.5	0.25	2424.38	\$ 703,069	3 years
35.2063	Requires licensees to maintain a record of dosage determinations required by § 35.63 for 3 years.	5820	2126	0.02	247466.40	\$ 71,765,256	3 years
35.2067(a)	Requires licensees to retain records of leak tests required by 35.67 (b) for 3 years.	6465	3	0.06	1163.70	\$ 337,473	3 years
35.2067(b)	Requires that licensees retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years.	6465	2	0.06	775.80	\$ 224,982	3 years
35.2070()	Requires a licensee to retain a record of each survey required by § 35.70 for 3 years.	2250	43	0.02	1935.00	\$ 561,150	3 years
35.2075(a)	Requires licensees to retain a record of the basis for authorizing the release of an individual in accordance with § 35.75.	3188	14	0.25	11158.00	\$ 3,235,820	3 years
35.2075(b)	Requires licensees to retain a record that the instructions required by § 35.75(b) 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).	3188	2	0.20	1275.20	\$ 369,808	3 years

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
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, as required by § 35.80(a) (1).	188	20	0.03	112.80	\$ 32,712	3 years after last service
35.2080(b)	Requires licensees to maintain a record of each survey required by § 35.80(a) (4) for 3 years.	188	260	0.10	4888.00	\$ 1,417,520	3 years
35.2092	Requires licensees to retain records of the disposal of licensed materials, as required by § 35.92 for 3 years.	6465	52	0.02	6723.60	\$ 1,949,844	3 years
35.2204	Requires licensees to maintain records of molybdenum-99 concentration tests required by § 35.204(b) for 3 years.	300	108	0.08	2592.00	\$ 751,680	3 years
35.2310	Requires licensees to maintain a record of safety instructions required by §§ 35.310 and 35.410 and the operational and safety instructions required by § 35.610 for 3 years.	1688	1	0.10	168.80	\$ 48,952	3 years
35.2404	Requires licensees to maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years.	1613	61	0.02	1967.86	\$ 570,679	3 years
35.2406	Requires licensees to maintain records of brachytherapy source accountability required by § 35.406 for 3 years.	713	15	0.20	2139.00	\$ 620,310	3 years
35.2432	Requires licensees to maintain a record of calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source.	713	15	0.20	2139.00	\$ 620,310	3 years
35.2433	Requires licensees to maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source.	90	70	0.50	3150.00	\$ 913,500	Life of source

**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.2605	Requires licensees to retain records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years.	1200	5	2.00	12000.00	\$ 3,480,000	3 years
35.2610()	Requires licensees to maintain records of procedures required by § 35.610(a) (4) and (d) (2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.	1200	2	0.05	120.00	\$ 34,800	Possession of unit
35.2630()	Requires licensees to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.	1223	1	0.50	611.50	\$ 177,335	3 years
35.2632	Requires licensees to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.	1200	4.6	4.00	22080.00	\$ 6,403,200	3 years
35.2642 (a)	Requires licensees to maintain records of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years.	8	12	0.50	48.00	\$ 13,920	3 years
35.2642 (c)	Requires licensees to retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.	8	1	0.05	0.40	\$ 116	Possession of unit
35.2643 (a)	Requires licensees to retain a copy of the written procedures for periodic spot-checks for teletherapy units established by the AMP.	938	155	1.00	145390.00	\$ 42,163,100	3 years
35.2643 (c)	Requires licensees to retain records of each spot-check for remote afterloader units required by §§ 35.643 for 3 years.	938	1	0.05	46.90	\$ 13,601	Possession of unit



**Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees**

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
35.2645 (a)	Requires licensees to retain a copy of the written procedures for periodic spot-checks for remote afterloader units established by the AMP.	113	260	2.00	58760.00	\$ 17,040,400	3 years
35.2645 (c)	Requires licensees to retain a copy of the written procedures for periodic spot-checks for gamma stereotactic radiosurgery units established by the AMP.	113	1	0.05	5.65	\$ 1,639	Possession of unit
35.2647	Requires licensees to retain records of each check for mobile remote afterloader units required by § 35.647 for 3 years.	8	260	0.50	1040.00	\$ 301,600	3 years
35.2652	Requires licensees to maintain records of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.	1200	1	0.50	600.00	\$ 174,000	Duration of use of unit
35.2655	Requires licensees to maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.	120	0.2	1.00	24.00	\$ 6,960	Duration of use of unit
Total		6465			920,464	\$ 266,934,454	

**Table 7 – Annual Reporting Requirements  
AS Licensees (3150-0010)**

Section	Description	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ \$290/hr
35.75(b)	Requires licensees to provide an individual who has been administered unsealed byproduct material or implants containing byproduct material and who is being released from the licensee's control in accordance with § 35.75(a) with instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem).	3188	20	63760	0.17	10,839	\$ 3,143,368
35.3045(e)	Requires the licensee to notify the referring physician and the individual who is the subject of the medical event, or that individual's responsible relative or guardian, no later than 24 hours after its discovery, or as soon as possible, if the patient or the referring physician cannot be reached within 24 hours.	52	2	104	2	208	\$ 60,320

**Table 7 – Annual Reporting Requirements  
AS Licensees (3150-0010)**

35.3204(a)	Requires radiopharmacy and medical use licensees to notify both the NRC Operations Center and the distributor of the generator by telephone within 7 days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a).	8	1	8	2	16	\$ 4,640
Total				63872		11,063	\$ 3,208,328

**Table 8 – Annual Recordkeeping Requirements  
Specialty Boards (3150-0010)**

NMSS Office Procedure MSST-70-03-2, "Procedures for Recognizing, Monitoring, and Terminating the Certification Process of Specialty Boards," (ML20351A389) establishes procedures for the specialty boards seeking to apply for or maintain an NRC-recognized certification program. The record

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
3.1 Applications for Recognition of a Specialty Board Certification Process	A specialty board should request NRC recognition of its certification process by applying to the NRC (i.e., application letter).	1	1	80.00	80.00	\$ 23,200	No requirement.
3.1.1(j) Certificate	Include a copy of the certificate(s) with any special terms or phrases that must appear on the certificate(s) and a "not valid" or "sample" watermark across the text of each certificate.	1	1	3.00	3.00	\$ 870	No requirement.
3.7 Notification of Change	Specialty boards should contact the NRC, in writing, regarding a change in certification procedures, change in certificate, name change, or other change.	2	1	4.00	8.00	\$ 2,320	No requirement.
3.11 Monitoring Continued Satisfaction of Recognition Requirements	The reviewers should contact each of the specialty boards with a written request that the specialty board confirm that it still satisfies the board recognition criteria, if the specialty board did not submit a notification of change, revised certificate, or any other communication within the last five years. The reviewers should request verification in writing on whether it has changed its name, the name of	8	2	8.00	128.00	\$ 37,120	No requirement.

**Table 8 – Annual Recordkeeping Requirements  
Specialty Boards (3150-0010)**

NMSS Office Procedure MSST-70-03-2, "Procedures for Recognizing, Monitoring, and Terminating the Certification Process of Specialty Boards," (ML20351A389) establishes procedures for the specialty boards seeking to apply for or maintain an NRC-recognized certification program. The record

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ \$290/HR	Record Retention
3.12 Terminating NRC Recognition of Specialty Boards	The board requests, in writing, that the NRC no longer recognize it.	1	1	6	6	\$ 1,740	No requirement.
Total		13			225.00	\$ 65,250	

	Burden	Responses	Cost @ \$290/hr
NRC licensee reporting	7,216	27,541	\$ 2,092,495
NRC licensee recordkeeping	122,771	862	\$ 35,603,700
NRC third party	1,465	8,511	\$ 424,923
AS reporting	54,286	206,729	\$ 15,742,940
AS recordkeeping	920,464	6,465	\$ 266,934,454
AS third party	11,063	63,872	\$ 3,208,328
AS approving specialty board application letter	80	1	\$ 23,200
Specialty Board	225	13	\$ 65,250
Total	1,117,570	313,994	\$ 324,095,290

	Burden	Responses	Cost @ \$290/hr
NRC licensees TOTAL	131,452	36,914	\$ 38,121,118
AS licensees TOTAL	985,893	277,067	\$ 285,908,922
Specialty Board TOTALS	225	13	\$ 65,250
TOTAL	1,117,570	313,994	\$ 324,095,290

Part 35 Totals	Burden	Responses	Cost @ \$290/hr
Reporting	61,807	234,284	\$ 17,923,885
Recordkeeping	1,043,235	7,327	\$ 302,538,154
Third Party Disclosure	12,528	72,383	\$ 3,633,251
Total	1,117,570	313,994	\$ 324,095,290

Part 35 Respondents	
NRC licensees	862
Agreement State licensees	6465
Specialty certifying entities	2
Total	7329

Other costs (item #13)	\$ 121,015
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Part 35 Burden Totals	Previous submission	Current Request	Change
Reporting	69,391	61,807	(7,585)
Recordkeeping	1,097,177	1,043,235	(53,942)
Third Party Disclosure	127	12,528	12,401
Total	1,166,695	1,117,570	(49,125)