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 @ $278/Hr
35.6(b)	Research application information needed if the research is conducted, funded, supported, or regulated by another Federal agency.	44	1	44	4	176	$ 48,928
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	$ 6,672
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).	123	2	246	0.25	61.5	$ 17,097
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.	32	1	32	0.25	8	$ 2,224
35.14(b)(6)	Requires a licensee to notify the NRC if it receives certain sealed sources without first obtaining a license amendment.	471	2	942	0.25	235.5	$ 65,469

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 @ $278/Hr
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	$ 1,112
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.	9	1	9	1	9	$ 2,502
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					
35.75(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).	462	20	9240	0.17	1570.8	$ 436,682

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 @ $278/Hr
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	$ 556
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	$ 2,224
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.	12	1	12	1	12	$ 3,336
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	$ 834
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.	138	155	21390	0.25	5347.5	$ 1,486,605

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 @ $278/Hr
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.	14	260	3640	0.25	910	$ 252,980
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.	8	1	8	0.5	4	$ 1,112

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 @ $278/Hr
35.3045(d)	Requires licensees to submit a written report to NRC within 15 days of the discovery of the medical event.	8	1	8	8	64	$ 17,792
35.3045(g)	Requires the licensee to: (1) annotate a copy of the medical event report provided to the NRC with spicific infromation outlined in thi section.	9	1	9	0.5	4.5	$ 1,251
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	$ 139
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	$ 2,224

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 @ $278/Hr
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	$ 556
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	$ 139
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	$ 278
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	$ 278
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	$ 278
Total				35,619		8,458	$ 2,351,268

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.24(a)	Approval in writing by management of other administrative changes.	936	5	0.50	2,340.00	$ 650,520	5 years
35.24(b)	Appointment of associate RSOs in writing.	87	2	0.25	43.50	$ 12,093	
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.	247	1	0.50	123.50	$ 34,333	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.	856	1	0.50	428.00	$ 118,984	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).	856	1	1	856	$ 237,968	

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/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.	157	1	1.00	157.00	$ 43,646	
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.	503	7	0.25	880.25	$ 244,710	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.	503	10	0.25	1257.50	$ 349,585	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).	511	1	0.50	255.50	$ 71,029	Duration of license
35.41(c)		Burden covered in 35.2041					

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
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.	856	1	0.03	25.68	$ 7,139	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					

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/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.	819	2126	0.02	34,823.88	$ 9,681,039	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.	38	20	1.00	760.00	$ 211,280	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)							

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.204(d)		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	24	1	1.00	24	$ 6,672	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.	24	12	0.10	28.8	$ 8,006	Duration of treatment
35.390(a)		OMB Clearance 3150-0120					
35.390(b)(2)							
35.392(a)							
35.392(c)(3)							
35.394(a)							
35.394(c)(3)							

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.396 (c)							
35.396 (d)							
35.404(c)							
35.406(c)							
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.	45	1	1.00	45	$ 12,510	
35.67(a)							
35.410(b)							
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.	45	5	0.10	22.5	$ 6,255	Duration of treatment
35.432(d)							
35.433(b)							
35.490(a)							
35.490(b)(3)							

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.491 (c)		OMB Clearance 3150-0120					
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.	152	1	1.00	152.00	$ 42,256	Possession of unit
35.610(b)	Requires licensees to physically locate a copy of the procedures at the unit console.	152	1	0.03	4.56	$ 1,268	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.	152	1	0.50	76.00	$ 21,128	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.						

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
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.	152	1	1.00	152.00	$ 42,256	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.	152	1	0.50	76.00	$ 21,128	
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	$ 1,112	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	$ 834	3 years
35.642(f)		Burden covered in 35.2642					

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.643(b)	Requires licensees to perform spot check measurements in accordance with written procedures established by the AMP.	136	1	4.00	544.00	$ 151,232	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.	136	155	0.25	5270.00	$ 1,465,060	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.	14	1	4.00	56.00	$ 15,568	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.	14	260	0.25	910.00	$ 252,980	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					

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.690(a) 35.690(b)(3)		OMB Clearance 3150-0120					
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.	856	5	0.25	1,070.00	$ 297,460	5 years
35.2024(b)	Requires licensees to retain a copy of both the authority, duties, and responsibilities of the RSO	856	2	0.10	171.20	$ 47,594	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.	31	1	1.00	31.00	$ 8,618	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.	856	1	0.25	214.00	$ 59,492	5 years
35.2040 ()	Requires licensees to retain a copy of each written directive.	511	104	0.05	2,657.20	$ 738,702	3 years
35.2041	Requires licensees to retain a copy of the procedures for administrations requiring a written directive	564	1	0.05	28.20	$ 7,840	Duration of license
35.2060()	Requires licensees to maintain a record of instrument calibrations required by § 35.60 for 3 years.	156	255	0.02	795.60	$ 221,177	3 years

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.2061	Requires licensees to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years.	856	1.5	0.25	321.00	$ 89,238	3 years
35.2063	Requires licensees to maintain a record of dosage determinations required by § 35.63 for 3 years.	830	2126	0.02	35,291.60	$ 9,811,065	3 years
35.2067(a)	Requires licensees to retain records of leak tests required by 35.67 (b) for 3 years.	856	3	0.06	154.08	$ 42,834	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.	856	2	0.06	102.72	$ 28,556	3 years
35.2070()	Requires a licensee to retain a record of each survey required by § 35.70 for 3 years.	321	43	0.02	276.06	$ 76,745	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.	451	14	0.25	1,578.50	$ 438,823	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).	451	2	0.20	180.40	$ 50,151	3 years

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/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).	38	20	0.03	22.80	$ 6,338	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.	56	260	0.10	1,456.00	$ 404,768	3 years
35.2092	Requires licensees to retain records of the disposal of licensed materials, as required by § 35.92 for 3 years.	856	52	0.02	890.24	$ 247,487	3 years
35.2204	Requires licensees to maintain records of molybdenum-99 concentration tests required by § 35.204(b) for 3 years.	72	108	0.08	622.08	$ 172,938	3 years
35.2204	Requires licensees to maintain records of molybdenum-99 concentration tests required by § 35.204(b) for 3 years.	36	1	13.00	468.00	$ 130,104	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.	211	1	0.10	21.10	$ 5,866	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.	18	1	1.00	18.00	$ 5,004	3 years

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.2404	Requires licensees to maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years.	213	97	0.02	413.22	$ 114,875	3 years
35.2406	Requires licensees to maintain records of brachytherapy source accountability required by § 35.406 for 3 years.	81	15	0.20	243.00	$ 67,554	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.	81	15	0.20	243.00	$ 67,554	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.	15	70	0.50	525.00	$ 145,950	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.	153	5	2.00	1,530.00	$ 425,340	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.	152	2	0.05	15.20	$ 4,226	Possession of unit

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
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.	154	1	0.50	77.00	$ 21,406	3 years
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.	142	4.6	4.00	2,612.80	$ 726,358	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	$ 1,668	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	$ 14	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.	132	155	1.00	20,460.00	$ 5,687,880	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.	132	1	0.05	6.60	$ 1,835	Possession of unit

Table 2 – Annual Recordkeeping Requirements
NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.2645(a)	Requires licensees to retain records of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.	13	260	2.00	6,760.00	$ 1,879,280	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.	13	1	0.05	0.65	$ 181	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.	2	260	0.50	260.00	$ 72,280	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.	153	1	0.50	76.50	$ 21,267	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.	15	0.2	1.00	3.00	$ 834	Duration of use of unit
Total		856			128,925.47	$ 35,841,281	

Table 4 – NRC Licensee Burden for One-time Implementation Requirements from Medical Use of Byproduct Material, Medical Event Definitions, Training and Experience, and Clarifying Amendments Final Rule

NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Total Number of Records	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.24(b)	Burden covered in 35.2024(c)							
35.41(a)	Burden covered in 35.2041							
35.41(b)(5)	Covered in 35.41(a) (570)							
35.41(b)(6)	Covered in 35.41(a) (454)							
35.41(c)	Covered in 35.2041							
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.	8	1	8	2.00	16.00	$4,448	Inventory and leak testing 3 years
35.2024(c)	Copy of the written document appointing the Associate RSO signed by the licensee's management	856	1	856	1.00	856.00	$229,408	5 years after ARSO is removed from license

Table 4 – NRC Licensee Burden for One-time Implementation Requirements from Medical Use of Byproduct Material, Medical Event Definitions, Training and Experience, and Clarifying Amendments Final Rule

NRC Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Total Number of Records	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.2041	Requires licensees to retain a copy of the procedures for administrations requiring a written directive, required by § 35.41, for the duration of the license.	856	1	856	9.00	7,704.00	$2,064,672	Duration of the license
Total		856				8,576.00	$2,384,128	
Annualized Total		285				2,858.67	$766,123	

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 @ $278/Hr
35.3045(e)	Notification of medical event to the referring physician and individual who is the subject of the medical event within 24 hours	6	1	6	2	12	$ 3,336
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).	2	1	2	0.25	0.5	$ 139
Total				8		12.5	$ 3,475

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 @ $278/HR
35.6(b)	Research application information needed if the research is conducted, funded, supported, or regulated by another Federal agency.	317	1	317	4	1,268	$ 98,904
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.	44	1	44	4	176	$ 13,728
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).	886	2	1772	0.25	443	$ 123,154

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.	230	1	230	0.25	57.50	$ 15,985
35.14(b)(6)	Requires a licensee to notify the NRC if it receives certain sealed sources without first obtaining a license amendment.	3391	2	6,782	0.25	1,695.50	$ 471,349
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.	29	1	29	1	29	$ 8,062
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.	65	1	65	1	65	$ 18,070
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)

35.75(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).	3326	20	66520	0.17	11,308	$ 3,143,735
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.	14	1	14	1	14	$ 3,892
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.	58	1	58	1	58	$ 16,124

Table 5 – Annual Reporting Requirements

Agreement State Licensees (3150-0010)

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.	86	1	86	1	86	$ 23,908
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.	7	12	84	0.25	21	$ 5,838
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.	994	155	154070	0.25	38,518	$ 10,707,865
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.	101	260	26260	0.25	6,565	$ 1,825,070
35.1000()		OMB Clearance 3150-0120					

Table 5 – Annual Reporting Requirements

Agreement State Licensees (3150-0010)

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.	58	1	58	0.5	29	$ 8,062
35.3045(d)	Requires licensees to submit a written report to NRC within 15 days of the discovery of the medical event.	58	1	58	8	464	$ 128,992
35.3045(g)	Requires the licensee to: (1) annotate a copy of the medical event report provided to the NRC with spicific infromation outlined in thi section.	65	1	65	0.5	33	$ 9,035
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).	7	1	7	0.5	4	$ 973
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).	7	1	7	8	56	$ 15,568

Table 5 – Annual Reporting Requirements

Agreement State Licensees (3150-0010)

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).	7	1	7	2	14	$ 3,892
35.3047(f)	Requires the licensee to annotate a copy of the report provided to the NRC with specific details of the affected individual.	7	1	7	0.5	4	$ 973
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.	7	1	7	1	7	$ 1,946
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).	7	1	7	0.25	1.75	$ 487

Table 5 – Annual Reporting Requirements

Agreement State Licensees (3150-0010)

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).	7	1	7	2.00	14.00	$ 3,892
Total				256,561		60,929	$ 16,938,304

Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.24(a)	Approval in writing by management of other administrative changes.	6163	5	0.50	15,407.50	$ 4,283,285	5 years
35.24(b)	Appointment of associate RSOs in writing.	626	2	0.25	313.00	$ 87,014	
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.	1779	1	0.50	889.50	$ 247,281	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.	6163	1	0.50	3,081.50	$ 856,657	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	$ 1,713,314	

Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ $278/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.	1130	1	1.00	1,130.00	$ 314,140	
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.	3622	7	0.25	6,338.50	$ 1,762,103	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.	3622	10	0.25	9,055.00	$ 2,517,290	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).	3680	1	0.50	1,840.00	$ 511,520	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)							

Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ $278/HR	Record Retention
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.	6163	1	0.03	184.89	$ 51,399	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	562.50	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.	5897	2126	0.02	250,740.44	$ 69,705,842	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 @ $278/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.	274	20	1.00	5,480.00	$ 1,523,440	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.	173	1	1.00	173.00	$ 48,094	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.	173	12	0.10	207.60	$ 57,713	Duration of treatment

Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ $278/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)		OMB Clearance 3150-0120					
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.	324	1	1.00	324.00	$ 90,072	
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.	324	5	0.10	162.00	$ 45,036	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)		OMB Clearance 3150-0120					

Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ $278/HR	Record Retention
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.	1095	1	1.00	1095.00	$ 304,410	Possession of unit
35.610(b)	Requires licensees to physically locate a copy of the procedures at the unit console.	1095	1	0.03	32.85	$ 9,132	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.	1095	1	0.50	547.50	$ 152,205	Possession of unit
35.610(d)	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.	1095	1	1.00	1095.00	$ 304,410	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.	1095	1	0.50	547.50	$ 152,205	
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					

Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ $278/HR	Record Retention
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	$ 8,896	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	$ 6,672	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.	980	1	4.00	3920.00	$ 1,089,760	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.	980	155	0.25	37975.00	$ 10,557,050	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.	101	1	4.00	404.00	$ 112,312	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.	101	260	0.25	6565.00	$ 1,825,070	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 @ $278/HR	Record Retention
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.	6163	5	0.25	7703.75	$ 2,141,643	5 years
35.2024(b)	Requires licensees to retain a copy of both the authority, duties, and responsibilities of the RSO	6163	2	0.10	1232.60	$ 342,663	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.	224	2	1.00	448.00	$ 124,544	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.	6163	1	0.25	1540.75	$ 428,329	5 years
35.2040()	Requires licensees to retain a copy of each written directive.	3680	104	0.05	19136.00	$ 5,319,808	3 years
35.2041	Requires licensees to retain a copy of the procedures for administrations requiring a written directive	4061	1	0.05	203.05	$ 56,448	Duration of license

Table 6 – Annual Recordkeeping Requirements for Agreement State Licensees

Section	Description	Recordkeepers	Records per Licensee	Burden hours per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.2041	Requires licensees to retain a copy of the procedures for administrations requiring a written directive	183	1	183	9.00	$ 2,502	
35.2060()	Requires licensees to maintain a record of instrument calibrations required by § 35.60 for 3 years.	1124	255	0.02	5732.40	$ 1,593,607	3 years
35.2061	Requires licensees to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years.	6163	1.5	0.25	2311.13	$ 642,493	3 years
35.2063	Requires licensees to maintain a record of dosage determinations required by § 35.63 for 3 years.	5976	2126	0.02	254099.52	$ 70,639,667	3 years
35.2067(a)	Requires licensees to retain records of leak tests required by 35.67 (b) for 3 years.	6163	3	0.06	1109.34	$ 308,397	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.	6163	2	0.06	739.56	$ 205,598	3 years
35.2070()	Requires a licensee to retain a record of each survey required by § 35.70 for 3 years.	2312	43	0.02	1988.32	$ 552,753	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.	3248	14	0.25	11368.00	$ 3,160,304	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).	3248	2	0.20	1299.20	$ 361,178	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 @ $278/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).	274	20	0.03	164.40	$ 45,703	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.	404	260	0.10	10504.00	$ 2,920,112	3 years
35.2092	Requires licensees to retain records of the disposal of licensed materials, as required by § 35.92 for 3 years.	6163	52	0.02	6409.52	$ 1,781,847	3 years
35.2204	Requires licensees to maintain records of molybdenum-99 concentration tests required by § 35.204(b) for 3 years.	519	108	0.08	4484.16	$ 1,246,596	3 years
35.2204	Requires licensees to maintain records of molybdenum-99 concentration tests required by § 35.204(b) for 3 years.	260	1	13	3380.00	$ 939,640	
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.	1520	1	0.10	152.00	$ 42,256	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.	130	142	1	18460.00	$ 5,131,880	3 years
35.2404	Requires licensees to maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years.	1534	61	0.02	1871.48	$ 520,271	3 years
35.2406	Requires licensees to maintain records of brachytherapy source accountability required by § 35.406 for 3 years.	584	15	0.20	1752.00	$ 487,056	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 @ $278/HR	Record Retention
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.	584	15	0.20	1752.00	$ 487,056	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.	108	70	0.50	3780.00	$ 1,050,840	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.	1102	5	2.00	11020.00	$ 3,063,560	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.	1095	2	0.05	109.50	$ 30,441	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.	1109	1	0.50	554.50	$ 154,151	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.	1023	4.6	4.00	18823.20	$ 5,232,850	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	$ 13,344	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 @ $278/HR	Record Retention
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	$ 111	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.	951	155	1.00	147405.00	$ 40,978,590	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.	951	1	0.05	47.55	$ 13,219	Possession of unit
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.	94	260	2.00	48880.00	$ 13,588,640	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.	94	1	0.05	4.70	$ 1,307	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.	15	260	0.50	1950.00	$ 542,100	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.	1102	1	0.50	551.00	$ 153,178	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.	108	0.2	1.00	21.60	$ 6,005	Duration of use of unit
Total		6163			944,811	$ 262,657,432	

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 @ $278/hr
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.	43	1	43	2	86	$ 23,908
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).	14	1	14	2	28	$ 7,784
Total				57		114	$ 31,692

Table 8 – One-time Implementation Requirements from Medical Use of Byproduct Material, Medical Event Definitions, Training and Experience, and Clarifying Amendments Final Rule

AS Licensees (3150-0010)

Section	Description	No of Recordkeepers	Records per Licensee	Total Number of Records	Burden per record	Total Annual Burden	Cost @ $278/HR	Record Retention
35.24(b)	Requires that a licensee's management appoint a RSO who agrees, in writing, to be responsible for implementing the radiation protection program.	Burden covered in 35.2024(c)						
35.41(a)	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).	Burden covered in 35.2041						
35.41(b)(5)	Requires licensees to develop, implement, and maintain written procedures for any administration requiring a WD to determine if a medical event, as defined in § 35.3045, has occurred.	Covered in 35.41(a)						

Table 8 – One-time Implementation Requirements from Medical Use of Byproduct Material, Medical Event Definitions, Training and Experience, and Clarifying Amendments Final Rule

AS Licensees (3150-0010)

35.41(b)(6)	Requires licensees to develop, implement, and maintain written procedures for permanent implant brachytherapy.	Covered in 35.41(a)						
35.41(c)	Requires the licensee to retain a copy of the procedures required by § 35.41(a) in accordance with § 35.2041	Covered in 35.2041						
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.	58	1	58	2.00	116.00	$32,248	Inventory and leak testing 3 years
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.	6163	1	6,163	1.00	6,163.00	$1,713,314	5 years after ARSO is removed from license
35.2041	Requires licensees to retain a copy of the procedures for administrations requiring a written directive, required by § 35.41, for the duration of the license.	6163	1	6,163	9.00	55,467.00	$15,419,826	Duration of the license

Table 8 – One-time Implementation Requirements from Medical Use of Byproduct Material, Medical Event Definitions, Training and Experience, and Clarifying Amendments Final Rule

AS Licensees (3150-0010)

Total		6163		12,384.00		61,746.00	$17,165,388	
Annualized Total		6163				20,582.00	$5,721,796	

	Burden	Responses	Cost @ $278/hr
NRC licensee reporting	8,458	35,619	$ 2,351,268
NRC licensee recordkeeping	131,784	856	$ 36,635,990
NRC third party	13	8	$ 3,475
AS reporting	60,929	256,561	$ 16,938,304
AS recordkeeping	965,393	6,163	$ 268,379,228
AS third party	114	57	$ 31,692
Specialty certifying entities	4	2	$ 1,112
Total	1,166,694	299,266	$ 324,341,069

	Burden	Responses	Cost @ $278/hr
NRC licensees TOTAL	140,254	36,483	$ 38,990,733
AS licensees TOTAL	1,026,436	262,781	$ 285,349,223
Specialty certifying entities	4	2	$ 1,112
TOTAL	1,166,694	299,266	$ 324,341,069

Part 35 Totals	Burden	Responses	Cost @ $278/hr
Reporting	69,391	292,182	$ 19,290,684
Recordkeeping	1,097,177	7,019	$ 305,015,218
Third Party Disclosure	127	65	$ 35,167
Total	1,166,694	299,266	$ 324,341,069

Part 35 Respondents	
NRC licensees	856
Agreement State licensees	6,163
Specialty certifying entities	2
Total	7,021

Other costs (item #13)	$ 122,006

Part 35 Burden Totals	Previous submission	Current Request	Change
Reporting	65,571	69,391	3,820
Recordkeeping	1,038,933	1,097,177	58,244
Third Party Disclosure	80	127	47
Total	1,104,583	1,166,694	62,111