FINAL OMB SUPPORTING STATEMENT FOR 10 CFR PART 20 "STANDARDS FOR PROTECTION AGAINST RADIATION" (3150-0014)

Extension

Description of the Information Collection

The general requirements for radiation protection, that are applicable to all NRC licensees, are contained in 10 CFR Part 20, "Standards for Protection Against Radiation." The provisions of 10 CFR Part 20 apply to individuals licensed by the NRC to possess byproduct, source, or special nuclear material. 10 CFR Part 20 also contains criteria for decommissioning of facilities and termination of the facility license. 10 CFR Part 20 is intended to ensure that occupationally exposed individuals and members of the public are adequately protected from the potential hazards of exposure to radiation and/or radioactive materials (for example, by requiring licensees to report theft or loss of licensed radioactive materials and specific incidents causing substantial exposures to or release of radioactive material).

The recordkeeping and reporting requirements for possession of material are in Subpart L -- Records (20.2102 - 2110) and Subpart M – Reports (20.2201-2207). Recordkeeping and reporting requirements for license termination are contained in Subpart E.

Two record retention periods appear in Part 20: 3 year retention for most survey records, and retention for the lifetime of an active NRC license for those records of doses (or records that provide a basis for dose estimates) received by individual workers or members of the public.

A. JUSTIFICATION

The statutory authority of the NRC derives from the Atomic Energy Act of 1954 (AEA), as amended; the Energy Reorganization Act of 1974, as amended, the Uranium Mill Tailings Radiation Control Act of 1978, as amended; the Low-Level Radioactive Waste Policy Act of 1980; the Nuclear Waste Policy Act of 1982; and the National Environmental Policy Act of 1969. The basic authorities from the AEA include licensing and regulation of production, use, ownership, and distribution of special nuclear materials, source material, and byproduct materials, and licensing and control over the manufacture, production, possession, use, importation, or exportation of production and utilization facilities.

Section 161b of the AEA provides that the Commission may establish such standards as the Commission deems necessary to protect public health and safety. Section 161o gives the Commission authority to require by rule, regulation, or order, such reports, and the keeping of such records as may be necessary to carry out the purposes of the AEA.

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

The information collected is used to evaluate the effectiveness of NRC regulations and to discern any trends, problems, or special situations requiring additional controls. The NRC uses information on worker exposures and effluents from facilities such as nuclear power plants to analyze trends and compare licensee performance. This information is also published in annual reports for use by industry and other interested organizations. The NRC also uses the information to assess applications for decommissioning and license termination. The Description of Information Collections are listed in Appendix A.

2. <u>Agency Use of Information</u>

The NRC uses the required information collection and reports to ensure that doses to workers and members of the public do not exceed limits, are as low as is reasonably achievable, that radioactive materials are stored and handled, and that facilities are decommissioned in a way that will adequately protect the health and safety of workers and the public.

3. Reduction of Burden Through Information Technology

The NRC has issued *Guidance for Electronic Submissions to the NRC*, which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web site, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by facsimile or by e-mail. It is estimated that approximately 75 percent of the responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

5. Effort to Reduce Small Business Burden

Some of the licensees who use byproduct, source, and special nuclear materials are small businesses. However, since the health and safety consequences of improper handling or use of these materials are the same for large and small entities, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures.

6. <u>Consequences to Federal Program or Policy Activities if the Collection is Not</u> Conducted or is Conducted Less Frequently

Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments are submitted only once. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will adequately protect the health and safety of the public. If the information were not

collected, it would not be possible for NRC to intervene if safety were to decline at a licensed facility in order to ensure the continued health and safety of the public and workers.

7. Circumstances that Justify Variation from OMB Guidelines

<u>10 CFR 20.1906, 20.2201, and 20.2202</u> require licensees to report information in less than 30 days. These immediate and 24-hour reporting requirements are necessary for NRC to provide rapid response to incidents and to ensure public health and safety.

Appendix G, Section III, Paragraph (E) requires licensees to report information in less than 30 days. This notification time period is needed so that state and local authorities can be mobilized to assist in locating lost radioactive materials as quickly as possible to minimize the potential hazard to members of the public.

Records pertaining to the radiation doses and radionuclide intakes by individual workers, to effluents released to air and water, and to the resultant radiation exposure of members of the public must be retained for the life of the license and transferred to the NRC upon termination of the license. This retention is required so that the past exposure history of any worker can be reconstructed to allow the worker to move from licensed facility to licensed facility and to permit the identification of trends, so that declining licensee performance can be detected and corrected.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the *Federal Register* on April 10, 2018 (83 FR 15411). NRC received two comments on the information collection requirements.

Comment 1: The commenter stated their objections to wind turbines.

Response: NRC considers this comment to be out-of-scope and is not related to the questions asked in our request for comments posted in the Federal Register on April 10, 2018 (83 FR 15411).

Comment 2: The commenter expressed concern that radiation dose information available does not fully represent how the body reacts to radiation exposure. The commenter stated that the NRC will not be able to predict the outcome of radiation exposure or how the public can be protected unless information about the biological impact of radiation exposure and the role of hydrogen peroxide in inflammation and immunity is collected.

Response: NRC considers this comment to be out-of-scope and is not related to the questions asked in our request for comments posted in the Federal Register on April 10, 2018 (83 FR 15411).

NRC also contacted three licensees by email with no responses received. No additional comments were received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

No sensitive information is requested under these regulations.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

The \$263 hourly rate used in the burden estimates is based on the Nuclear Regulatory Commission's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the basis of this rate, see the Revision Of Fee Schedules; Fee Recovery For Fiscal Year 2017 (82 FR 30682; June 30, 2017).

NRC Licensees

The burden for NRC licensees to respond to the collection is shown in Tables 1, 3, and 5. The total burden for NRC licensees is 91,545 hours (5,479 hours for reporting + 342 hours for third-party disclosure + 85,724 hours for recordkeeping) at a cost of \$24,076,335 (91,545 hours x \$263/hour).

An estimated 3000 NRC licensees respond to the 10 CFR Part 20 information collections. These are licensees who are directly regulated by the NRC and includes materials and reactor licensees.

Agreement State Licensees

Section 274 of the AEA provides a statutory basis under which NRC relinquishes to the States portions of its regulatory authority to license and regulate byproduct materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials. The mechanism for the transfer of NRC's authority to a State is an agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with section 274b of the AEA. Licensees operating in these "Agreement States" are referred to in this supporting statement as "Agreement State Licensees."

The NRC has established compatibility requirements for Agreement States to implement their own regulations in a manner consistent with NRC regulations. The number of NRC licensees is known, whereas the total number of Agreement State licensees is an estimate based on NRC's best information available from the Agreement States. NRC uses the ratio of the total of NRC licensees (subject to 10 CFR Part 20) to the total number Agreement State licensees to estimate the number of Agreement State respondents for each section. NRC uses this ratio approach as the total number of Agreement State licensees subject to various 10 CFR Part 20 Sections. The current ratio, based on the number and size of NRC regulated states

to Agreement States, is approximately 1:6 (NRC licensees: Agreement State licensees).

The burden for Agreement State licensees to respond to the collection is shown in Tables 2, 4, and 6. The total burden for Agreement State licensees is 549,231 hours (32,874 hours reporting + 2,052 hours third-party disclosure + 514,305 hours recordkeeping) at a cost of \$144,447,753 (549,231 x \$263/hour).

Total

The total burden for the collection is 640,776 hours (91,545 hours for NRC licensee respondents and 549,231 hours for Agreement State licensee respondents), at a total cost of \$168,524,088 (640,776 hours x \$263/hour). See Tables 7 and 8.

13. Estimate of Other Additional Costs

The NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the records storage cost has been determined to be equal to 0.0004 percent of the recordkeeping burden cost. Therefore, the records storage cost is estimated to be \$63,123 (85,724 NRC recordkeeping hours + 514,305 Agreement State recordkeeping hours x 0.0004 x \$263/hour).

14. <u>Estimated Annualized Cost to the Federal Government</u>

The staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses.

The estimated annualized cost to the Federal Government is \$2,091,639 (see Table 9). This cost is calculated using 7,953 total annual hours at a labor rate of \$263/hour to review reports submitted by NRC licensees. Note that costs do not include costs to review Agreement State licensee actions, as this is a responsibility that has been relinquished to the Agreement States.

The NRC costs associated with this collection are recovered through license fees assessed to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Change in Burden or Cost

The estimate of the total number of burden hours has remained the same at 640,776 hours. There have been no changes to the numbers of respondents or the burden per respondent.

In addition, the hourly fee rate decreased from \$279 to \$263.

16. Publication for Statistical Use

This information will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The requirement is contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

TABLE 1
REPORTING BURDEN FOR NRC LICENSEES

SECTION	NO. OF RESPONDENTS	RESPONSES PER RESPONDENT	TOTAL RESPONSES	ANNUAL BURDEN PER RESPONDENT	TOTAL ANNUAL BURDEN	NOTES	
20.1101(d)			see § 20.2	2203	I		
20.1202			see § 20.2	2206			
20.1203			see § 20.2	2206			
20.1204			see § 20.2	2206			
20.1206			see § 20.2	2204			
20.1208			see § 20.2	2206			
20.1301(d)	0	0	0	4	0	None expected	
20.1302(c)	2	1	2	10	20		
20.1403(a),(c),(d),(e)(1)	3	1	3	23	69		
20.1403(e)(2)	1	1	1	10	10		
20.1404	0	0	0	20	0		
20.1406	10	1	10	20	200		
20.1601(c)	10	1	10	8	80		
20.1703(b)	15	1	15	40	600		
20.1705(a)&(b)	15	1	15	40	600		
20.1906(d)	14	1	14	3	42		
20.2002	20	1	20	20	400		
20.2004	Burden included	under 10 CFR 50) (OMB clearan	ce no. 3150-0011	1)		
20.2006	Burden included 3150-0165)	under NRC Form	ns 540-542 (OM	IB clearance nos	. 3150-0164,	3150-0166,	
20.2201(a)	30.3	1	30.3	3	90.9		
20.2201(b)	30.3	1	30.3	3	90.9		
20.2201(d)	5.3	1	5.3	3	15.9		
20.2202(a)	10	1	10	1	10		
20.2202(b)	38	1	38	40	1,520		
20.2203(a)&(b)	20	1	20	6	120		
20.2204	5	1	5	5	25		
20.2205	Burden included in 20.2203(a) except for doses to individuals (see Table 3)						
20.2206	Burden included under NRC Form 5 (OMB clearance 3150-0006)						
20.2207(a), (b), (c), (d), (e), (f)	Burden included in OMB clearance for NRC Form 748 (OMB clearance 3150-0202)						
20.2207 (g)	1,425	1	1,425	1	1,425		
20.2207(h)	One time report completed						
20.2301	20	1	20	5	100		
App G	3	1	3	20	60		
TOTAL	1,425		1,677		5,479		

TABLE 2 REPORTING BURDEN FOR AGREEMENT STATE LICENSEES

SECTION	NO. OF RESPONDENTS	RESPONSES PER RESPONDENT	TOTAL RESPONSES	ANNUAL BURDEN PER RESPONDENT	TOTAL ANNUAL BURDEN	NOTES
20.1101(d)			see § 20.22	03		
20.1202			see § 20.22	06		
20.1203			see § 20.22	06		
20.1204			see § 20.22	06		
20.1206			see § 20.22	04		
20.1208			see § 20.22	06		
20.1301(d)	0	0	0	4	0	None expected
20.1302(c)	12	1	12	10	120	
20.1403(a),(c),(d),(e)(1)	18	1	18	23	414	
20.1403(e)(2)	6	1	6	10	60	
20.1404	0	0	0	20	0	
20.1406	60	1	60	20	1,200	
20.1601(c)	60	1	60	8	480	
20.1703(b)	90	1	90	40	3,600	
20.1705(a)&(b)	90	1	90	40	3,600	
20.1906(d)	84	1	84	3	252	
20.2002	120	1	120	20	2,400	
20.2004	Burden included	under 10 CFR 5	0 (OMB clearar	nce no. 3150-001	1)	•
20.2006	Burden included 0166, 3150-0165	under NRC Forr	ms 540-542 (ON	/IB clearance nos	s. 3150-016	4, 3150-
20.2201(a)	182	1	182	3	546	
20.2201(b)	182	1	182	3	546	
20.2201(d)	32	1	32	3	96	
20.2202(a)	60	1	60	1	60	
20.2202(b)	228	1	228	40	9,120	
20.2203(a)&(b)	120	1	120	6	720	
20.2204	30	1	30	5	150	
20.2205	Burden included in 20.2203(a) except for doses to individuals (see Table 4)					
20.2206	Burden included under NRC Forms 4 and 5 (OMB clearance 3150-0005 & 3150-0006)					
20.2207(a), (b), (c), (d), (e), (f)	Burden included in OMB clearance for NRC Form 748 (OMB clearance 3150-0202)					
20.2207 (g)	8,550	1	8,550	1	8,550	
20.2207(h)	One time report completed					
20.2301	120	1	120	5	600	
App G	18	1	18	20	360	
TOTAL	8,556		10,062		32,874	

TABLE 3
THIRD PARTY DISCLOSURE BURDEN FOR NRC LICENSEES

SECTION	NO. OF RESPONDENTS	RESPONSES PER RESPONDENT	TOTAL RESPONSES	ANNUAL BURDEN PER RESPONDENT	TOTAL ANNUAL BURDEN	NOTES	
20.1901(b)&(c)	750	1	750	0.1	75		
20.1904	750	1	750	0.1	75		
20.1906(d)	14	1	14	3	42		
20.2006(b)	Burden included under NRC Forms 540-542 (OMB clearance nos. 3150-0164, 3150-0166, 3150-0165)						
20.2205	25	1	25	6	150		
Appendix G, Section III, Paragraphs (A)- (D)	Burden for Sections I and II included under NRC Forms 540-542 (OMB clearance nos. 3150-0164, 3150-0166, 3150-0165)						
TOTAL	750		1,539		342		

TABLE 4
THIRD PARTY DISCLOSURE BURDEN FOR AGREEMENT STATE LICENSEES

SECTION	NO. OF RESPONDENTS	RESPONSES PER RESPONDENT	TOTAL RESPONSES	ANNUAL BURDEN PER RESPONDENT	TOTAL ANNUAL BURDEN	NOTES	
20.1901(b)&(c)	4,500	1	4,500	0.1	450		
20.1904	4,500	1	4,500	0.1	450		
20.1906(d)	84	1	84	3	252		
20.2006(b)	Burden included under NRC Forms 540-542 (OMB clearance nos. 3150-0164, 3150-0166, 3150-0165)						
20.2205	150	1	150	6	900		
Appendix G, Section III, Paragraphs (A)- (D)	Burden for Sections I and II included under NRC Forms 540-542 (OMB clearance nos. 3150-0164, 3150-0166, 3150-0165)						
TOTAL	4,500		9,234		2,052		

TABLE 5 RECORDKEEPING BURDEN FOR NRC LICENSEES

SECTION	NO. OF RECORD- KEEPERS	BURDEN PER RECORD- KEEPER	TOTAL ANNUAL BURDEN	RECORD RETENTION	NOTES
20.1101(a)			see § 2	0.2102	
20.1202			see § 2	20.2106	
20.1203			see § 2	20.2106	
20.1204			see § 2	20.2106	
20.1206			see § 2	20.2105	
20.1208			see § 2	20.2106	
20.1403(d)	3	20	60	RULT ¹	
20.1501			see § 2	20.2103	
20.1703(c)(2)			see § 2	20.2103	
20.1703(c)(4)	100	80	8,000	RULT	
20.1901	750	0.1	75	RULT	
20.1905(e)	600	0.2	120	LOC ²	
20.1906(e)	1,803	1	1,803	RULT	
20.2005(c)			see § 2	20.2108	
20.2006	Burden ind	cluded under F		42 (OMB clearar 3150-0165)	nce nos. 3150-0164,
20.2102(a)&(b)	3,003	4	12,012	(a)(1)=RULT, (a)(2)=3 yrs	
20.2103(a)&(b)	,		,	(a)=3 yrs,	
	3,003	8	24,024	(b)=RULT	
20.2104			see § 2	20.2106	
20.2105	0	3	0	RULT	none expected
20.2106 (records of dose)	Burden inclu	ided under NF		-0006)	nce nos. 3150-0005 &
20.2106 (declaration of pregnancy)	150	1	150	RULT	
20.2107(a)	3,000	5	15,000	RULT	
20.2108(a)&(b)	3,000	8	24,000	RULT	
20.2110	No additional burden (included in 20.2102 through 20.2108)				
20.2207(a), (b), (c), (d), (e)	Burden included in OMB clearance for NRC Form 748 (3150-0202)				
App. G	3	160	480	RULT	Burden for Sections I and II included under NRC Forms 540-542 (OMB clearance nos. 3150-0164, 3150- 0166, 3150-0165)
TOTAL	3,003		85,724		

¹ RULT = Retained until license termination ² LOC = Life of container

TABLE 6 RECORDKEEPING BURDEN FOR AGREEMENT STATE LICENSEES

SECTION	NO. OF RECORD- KEEPERS	BURDEN PER RECORD- KEEPER	TOTAL ANNUAL BURDEN	RECORD RETENTION	NOTES
20.1101(a)			see § 2	0.2102	
20.1202			see § 2	0.2106	
20.1203			see § 2	0.2106	
20.1204			see § 2	0.2106	
20.1206			see § 2	0.2105	
20.1208			see § 2	0.2106	
20.1403(d)	18	20	360	RULT ³	
20.1501			see § 2	0.2103	
20.1703(c)(2)			see § 2	0.2103	
20.1703(c)(4)	600	80	48,000	RULT	
20.1901	4,500	0.1	450	RULT	
20.1905(e)	3,600	0.2	720	LOC ⁴	
20.1906(e)	10,815	1	10,815	RULT	
20.2005(c)			see § 2	0.2108	
20.2006	Burden in	cluded under	Forms 540-54 3150-0166,		ce nos. 3150-0164,
20.2102(a)&(b)	18,015	4	72,060	(a)(1)=RULT, (a)(2)=3 yrs	
20.2103(a)&(b)	18,015	8	144,120	(a)=3 yrs, (b)=RULT	
20.2104	10,010	<u> </u>	see § 2		
20.2105	0	3	0	RULT	none expected
20.2106	Burden inclu	uded under Ni	RC Forms 4 8	5 (OMB clearar	nce nos. 3150-0005 &
(records of dose)			3150-0		
20.2106 (declaration of pregnancy)	900	1	900	RULT	
20.2107(a)	18,000	5	90,000	RULT	
20.2108(a)&(b)	18,000	8	144,000	RULT	
20.2110	No additional burden (included in 20.2102 through 20.2108)				
20.2207(a), (b), (c), (d), (e)	Burden included in OMB clearance for NRC Form 748 (3150-0202)				
App. G	18	160	2,880		Burden for Sections I and II included under NRC Forms 540-542 (OMB clearance nos. 3150-0164, 3150- 0166, 3150-0165)
TOTAL	18,015		514,305		

³ RULT = Retained until license termination ⁴ LOC = Life of container

TABLE 7 **BURDEN SUMMARY**

	Hours	Responses
NRC Licensee Reporting	5,479	1,677
NRC Licensee 3rd Party Disclosure	342	1,539
NRC Licensee Recordkeeping	85,724	3,003
Agreement State Reporting	32,874	10,062
Agreement State 3rd Party Disclosure	2,052	9,234
Agreement State Recordkeeping	514,305	18,015
TOTAL	640,776	43,530

TABLE 8 TOTALS FOR NRC LICENSEES AND AGREEMENT STATE LICENSEES

	Hours	Responses
NRC Licensees Total	91,545	6,219
Agreement State Licensees Total	549,231	37,311
TOTAL	640,776	43,530

Total Number of recordkeepers: 21,018 (3,003 NRC licensee recordkeepers +

18,015 Agreement State licensee recordkeepers)

21,018 (3,003 NRC licensees + 18,015 Agreement State licensees) Number of respondents:

TABLE 9

ANNUALIZED COST TO THE FEDERAL GOVERNMENT (NRC Staff Burdens Associated with 10 CFR Part 20)

SECTION	TOTAL HOURS	NOTES
20.1101	0	see § 20.2102
20.1202	0	see § 20.2106
20.1203	0	see § 20.2106
20.1204	0	see § 20.2106
20.1206	0	see § 20.2106
20.1208	0	see § 20.2106
20.1301(d)	0	none expected
20.1302(c)	4	
20.1403(a-e)	60	
20.1404	0	
20.1406	200	
20.1501	0	see § 20.2103
20.1601(c)	8	
20.1703(b)	300	
20.1703(c)(2)	0	see § 20.2103
20.1703(c)(4)	200	
20.1705(a)&(b)	300	
20.1904	50	
20.1905(e)	9	
20.1906(d)	6	
20.1906(e)	9	
20.2002	150	
20.2004	0	Burden included in OMB Clearance for Part 50 (OMB clearance no. 3150-0011)
20.2005(c)	0	see § 20.2108
20.2006	0	Burden included in OMB clearance for NRC Forms 540-542 (OMB clearance nos. 3150-0164, 3150-0166, 3150-0166)

SECTION	TOTAL HOURS	NOTES
20.2102(a)	2250	
20.2103(a)	3000	
20.2103(b)	0	see §20.2103(a)
20.2104	0	see § 20.2106
20.2105	0	none expected
20.2106 (records of dose)	0	Burden included in OMB Clearance for NRC Forms 4 and 5 (OMB clearance nos. 3150-0005, 3150-0006)
20.2106 (declaration of pregnancy)	0	none expected
20.2107(a)	7	
20.2107(b)	0	see §20.2107(a)
20.2108(a)	510	
20.2108(b)	0	see §20.2108(a)
20.2110	0	format requirement only
20.2201(a)	91	
20.2201(b)	91	
20.2201(d)	5	
20.2202(a)	60	
20.2202(b)	117	
20.2203(a)	320	
20.2203(b)	0	see § 20.2203(a)
20.2204	100	
20.2206(b)&c)	0	Burden included in OMB Clearance for NRC Forms 4 and 5 (OMB clearance nos. 3150-0005, 3150-0006)
20.2207(a), (b), (c), (d), (e), (g)	0	Burden included in OMB clearance for NRC Form 748
20.2207(h)	0	One time report completed
20.2301	100	
Арр G	6	For Sections I and II, Burden included in OMB Clearance for NRC Forms 540-542 (OMB clearance nos. 3150-0164, 3150-0166, 3150-0165)
TOTAL	7,953	

Appendix A: Description of Information Collections for 10 CFR Part 20

- 10 CFR 20.1003 defines a declared pregnant woman as a woman who has voluntarily informed the licensee in writing that she is pregnant. Licensees are required to maintain records of doses to the embryo/fetus and the declared pregnant woman in 10 CFR 20.2106. Licensees are also required by 10 CFR 20.2106(e) to keep the declaration on file, although it may be maintained separately from the dose records.
- <u>10 CFR 20.1101</u> requires licensees to develop, document and implement radiation protection programs; establish radiation protection procedures; and perform program reviews periodically. This is necessary to ensure the health and safety of the workers and the general public. The burden for recordkeeping requirements is contained in 10 CFR 20.2102.
- 10 CFR 20.1201 and 20.1202 set limits for occupational exposures. The recordkeeping requirements for this section are contained in 10 CFR 20.2106. Dose limits are necessary to ensure the health and safety of the workers. The reporting requirements for this section are contained in 10 CFR 20.2206. Both requirements are covered under the OMB clearance for NRC Forms 4 and 5 (3150-0005 and 3150-0006, respectively).
- 10 CFR 20.1203 requires licensees to determine dose from airborne radioactive material. This is necessary to ensure compliance with dose limits. The recordkeeping and reporting requirements for this section are contained in 10 CFR 20.2106 and 20.2206 respectively and are covered under a separate OMB clearance for NRC Forms 4 and 5 (OMB 3150-0005 and 3150-0006).
- <u>10 CFR 20.1204</u> requires licensees to make measurements as needed to assess internal exposures of occupationally exposed individuals. The recordkeeping and reporting requirements for this section are contained in 10 CFR 20.2106 and 20.2206 respectively and are covered under a separate OMB clearance for NRC Forms 4 and 5 (OMB 3150-0005 and 3150-0006).
- <u>10 CFR 20.1206</u> sets limits for planned special exposures. This is necessary to ensure the health and safety of workers. The recordkeeping and reporting requirements for this section are contained in 10 CFR 20.2105 and 20.2204 respectively.

<u>10 CFR 20.1208</u> sets limits for doses to an embryo/fetus of a declared pregnant worker. This is necessary to protect the health and safety of the embryo/fetus.

10 CFR 20.1301(d) allows licensees to apply to the Commission to increase the dose limit for the general public from 0.1 rem/year to up to 0.5 rem/year. This is needed to ensure that a temporary deviation from the established dose limits adequately protects the health and safety of workers and the public.

<u>10 CFR 20.1302(c)</u> allows licensees to apply to the Commission for permission to use alternate effluent release concentration limits based on actual physical and chemical characteristics of the effluent released. This is needed to ensure that if alternate values are used by licensees, then the values are adequate to protect the health and safety of the public.

10 CFR 20.1403(a)-(c) and (e)(1) require that, if restrictions on future use of the site are proposed, the information that the licensee must provide is as follows: (1) further reductions in residual radioactivity necessary to release the site for unrestricted use would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are as low as is reasonably achievable (ALARA); (2) adequate provisions for legally enforceable institutional controls that provide reasonable assurance that the total effective dose equivalent (TEDE) from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem per year; (3) provisions have been made for sufficient financial assurance to enable an independent third party to assume and carry out responsibilities for any necessary control and maintenance of the site; and (4) residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed 100 mrem per year.

10 CFR 20.1403(d) requires that a decommissioning plan or License Termination Plan (LTP) be submitted to the Commission by the licensee indicating the licensee's intent to decommission in accordance with 10 CFR Parts 30.36(d), 40.42(d), 50.82(a) and (b), 70.38(d), or 72.54, and specifying that the licensee intends to decommission by restricting use of the site, and that the decommissioning plan or LTP document how the advice of individuals or institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice. In seeking advice on issues associated with restricted use, licensees are required to provide for participation by a broad cross section of community interests who may be affected by the decommissioning, provide an opportunity for comprehensive, collective discussion on the issues by the participants represented, and prepare a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

- 10 CFR 20.1403(e)(2) requires that, as an option to the 100 mrem per year level, a level of 500 mrem/year may be allowed if the licensee demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/year value are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm, that provisions exist for durable institutional controls, and that there is sufficient financial assurance to enable a responsible government entity, or independent third party, both to carry out periodic rechecks of the site no less frequently than every 5 years and to assume and carry out responsibilities for any necessary control and maintenance of those controls.
- 10 CFR 20.1404 requires that, if the licensee proposes to use alternate criteria, the information the license must provide is as follows: (1) an analysis of possible sources of exposure that provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/year (100 mrem/year) limit of Subpart D of 10 CFR Part 20; (2) an indication that restrictions on site use according to the provisions of 10 CFR 20.1403 have been employed to the extent practical to minimize exposures at the site; (3) doses have been reduced to ALARA levels; and (4) a decommissioning plan or LTP has been submitted indicating the licensee's intent to decommission in accordance with 10 CFR Parts 30.36(d), 40.42(d), 50.82(a) and (b), 70.38(d), or 72.54, and specifying that the licensee proposes to decommission by use of alternate criteria, and documenting in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.
- <u>10 CFR 20.1406</u> requires applicants for licenses to describe in the application how facility design and procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste.
- <u>10 CFR 20.1501</u> requires licensees to conduct surveys and to monitor radiological conditions. These are necessary to ensure that the licensee is aware of all the radiological conditions that could contribute to dose in order to comply with dose limits. The recordkeeping requirements for this section are contained in 10 CFR 20.2103.
- <u>10 CFR 20.1601(c)</u> allows licensees to apply to the Commission for approval of alternate methods for controlling access to high radiation areas. This is needed to ensure that any proposed deviation from established mechanisms adequately protects the health and safety of workers and the public.
- <u>10 CFR 20.1703(b)</u> allows licensees to submit an application to the Commission for permission to use respiratory protection equipment that has not been tested or certified for use by the National Institute for Occupational Safety and Health. Records of this application and its approval are required to ensure that licensee practices are in compliance with regulations.

- 10 CFR 20.1703(c)(2) requires licensees to perform surveys and bioassay as needed to evaluate actual intakes. The recordkeeping requirement for this paragraph is contained in 10 CFR 20.2103. These records are needed so that NRC can ensure, through inspection, that the licensee is adequately protecting the health and safety of workers.
- <u>10 CFR 20.1703(c)(4)</u> requires licensees to have written procedures regarding the proper issue and use of respiratory protection equipment. This is needed to ensure, through inspection, that these devices are used consistent with the goal to maintain occupational doses ALARA and in a safe manner.
- 10 CFR 20.1705(a) and (b) required licensees to submit an application to the Commission before using assigned protection factors higher than those in Appendix A to 10 CFR Part 20 for the purpose of calculating exposures. Records of this application and its approval are required to ensure that respiratory protective equipment is being used in a manner that will protect the health and safety of workers.
- <u>10 CFR 20.1901(b) and (c)</u> allows licensees to label sources, source holders, or device components containing sources of licensed materials and to provide additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize exposures.
- <u>10 CFR 20.1904</u> requires that labels used to identify radioactive material containers use specified formats and wording. This is needed to minimize potential doses or releases of radioactive material due to worker confusion.
- <u>10 CFR 20.1905(e)</u> requires that licensees maintain records of radioactive material containers that cannot be labeled in accordance with this Part due to special circumstances for the life of the container. This is necessary to ensure that radioactive material is properly monitored at all times.
- 10 CFR 20.1906(d) requires licensees to notify the carrier and the NRC Operations Center upon receipt of a radioactive material package which is damaged, contaminated, or where radiation levels exceed limits. This is needed so that NRC can, through inspection, ensure that shipment procedures and practices are adequate to protect the health and safety of workers and the public.
- <u>10 CFR 20.1906(e)</u> requires licensees to develop, maintain and retain written procedures regarding radioactive material shipment. This is needed to ensure that the packages containing radioactive material will be opened in a manner consistent with the protection of the health and safety of the public and workers.
- 10 CFR 20.2002 allows licensees to apply to the Commission for approval of procedures not otherwise allowed in this Part regarding the disposal of licensed material. The application must include: (a) a description of the waste, (b) an environmental analysis, (c) the nature and location(s) of other potentially affected facilities, and (d) analyses and procedures to ensure that doses are ALARA. This is needed to ensure that licensed material is handled in a manner that will adequately protect the health and safety of the public and workers.

10 CFR 20.2004 requires Part 50 licensees who incinerate waste oils onsite to report any changes or additions to the information supplied under 10 CFR 50.34 and 50.34a, and to follow the procedures of 10 CFR 50.59 with respect to such changes. This is needed so that NRC can ensure that radioactive effluents associated with incineration of waste oils conform to the requirements of Appendix I to 10 CFR Part 50.

10 CFR 20.2005(c) requires licensees to maintain records of waste disposal. The recordkeeping requirement for this section is contained in 10 CFR 20.2108. This is needed to allow NRC to ensure, through inspection, that waste disposal is in accordance with NRC regulations.

10 CFR 20.2006(a) requires that licensees establish a manifest tracking system to control transfers of low-level radioactive waste intended for disposal at a land disposal facility so that NRC can inspect to ensure that adequate control of this material exists as specified in Appendix G to 10 CFR Part 20.

10 CFR 20.2006(b) requires that licensees use NRC's Uniform Low-level Radioactive Waste Manifest and transfer this information to the intended consignee, as specified in Section I of Appendix G to 10 CFR Part 20.

10 CFR 20.2006(c) requires a certification by the waste generator, processor, or collector as specified in Section II of Appendix G to 10 CFR Part 20.

The information in 10 CFR 20.2006 (a)-(c) is needed to control shipments and disposal of Low Level Waste (LLW) to ensure public health and safety and to protect the environment. The specific requirements are discussed in more detail in Appendix G to 10 CFR Part 20.

These reporting requirements are covered under the clearances for NRC Forms 540, 541, and 542 (OMB Clearance numbers 3150-0164, 3150-0166, and 3150-0165).

<u>10 CFR 20.2102(a)</u> requires licensees to maintain records of the radiation protection program, including ALARA provisions and program reviews. This is needed so that NRC can ensure, through inspection, that the health and safety of workers and the public is adequately protected.

10 CFR 20.2102(b) requires licensees to retain records of radiation protection programs until the Commission terminates the license. This is needed so that workers will have ready access to radiation protection programs and procedures as long as the facility is in operation. This paragraph further requires that licensees retain records of radiation protection program reviews for 3 years. This is needed so that adequate records will exist at the time of inspection to determine if the radiation protection program adequately protects the health and safety of workers and the public.

<u>10 CFR 20.2103(a)</u> requires licensees to maintain records showing the results of surveys and calibrations required by this Part. These records will be maintained for 3 years after the records are created. This is needed to ensure, through inspection, that surveys required for adequate radiation protection have been made.

- 10 CFR 20.2103(b) requires licensees to maintain records that form the basis of dose estimates, results of air sampling surveys, and bioassays required under the Radiation Protection Standard and results of measurements and calculations used to evaluate radioactive effluents released to the environment be maintained for as long as the facility is licensed by NRC. This is needed to ensure that adequate records exist at the time of routine inspection to support an assertion that adequate radiation surveys have been performed and to ensure that adequate records exist to reconstruct a worker's dose estimate at any time during the period in which the facility is licensed by NRC.
- <u>10 CFR 20.2104</u> requires licensees to attempt to obtain records of prior occupational exposures prior to authorizing entry into restricted or controlled areas by individuals for whom personnel radiation monitoring is required. This recordkeeping requirement is covered in a separate OMB clearance for NRC Form 4 (OMB clearance number 3150-0005).
- <u>10 CFR 20.2105</u> requires licensees to maintain records of planned special exposures until the Commission terminates the license since they form the basis for assessing dose to an individual.
- <u>10 CFR 20.2106</u> requires licensees to record and maintain the results of individual monitoring until the Commission terminates the license. This recordkeeping requirement is covered in a separate OMB clearance for NRC Form 5 (OMB clearance number 3150-0006).
- <u>10 CFR 20.2107(a)</u> requires licensees to maintain records of compliance with does limit for individuals of the public. This is needed to permit assessment of the dose to the public that might result from these radionuclide releases in order to confirm compliance with dose limits.
- <u>10 CFR 20.2107(b)</u> requires that the records required in 10 CFR 20.2107(a) be maintained until the license is terminated by the Commission as they form the basis for estimating dose.
- 10 CFR 20.2108(a) requires licensee to maintain records of waste disposal to permit (1) routine inspection for compliance with the provisions of the sections in 10 CFR Part 20 related to waste disposal, (2) inspection against constraints on the kinds and quantities of licensed material in the possession of the licensee at any given time, and (3) assessment of the kinds and quantities of radioactive material disposed of by various methods and the potential dose to the public.
- <u>10 CFR 20.2108(b)</u> requires that the waste disposal records be retained until the termination of the license by the Commission.
- <u>10 CFR 20.2110</u> establishes the quality, format and retention of records required by this Part. There are no additional recordkeeping or reporting requirements associated with this section. This establishes a common format to minimize confusion for workers moving from licensee to licensee in the course of their employment and to facilitate inspection.

- <u>10 CFR 20.2201(a)</u> requires licensees to report any theft or loss of licensed material by telephone immediately or in writing within 30 days, dependent upon the potential risk to the health and safety of the public associated with the missing radioactive material. This is needed so that prompt corrective action can be taken.
- <u>10 CFR 20.2201(b)</u> requires licensees to follow up telephone reports with written reports of the incident within 30 days of the telephone report. This is needed to ensure that the proper follow-up actions were taken by the licensee.
- 10 CFR 20.2201(d) requires the licensees to report any additional information relevant to the loss of radioactive material, discovered subsequent to the written report, be submitted within 30 days of discovery. This is needed to ensure that the actions were taken to protect the health and safety of workers and the public are based on complete information regarding the event.
- <u>10 CFR 20.2202(a)</u> require that the licensee immediately notify the NRC upon becoming aware of specific incidents causing substantial exposures to or release of licensed material. This is needed so that the NRC can identify possible generic problems and notify other licensees.
- 10 CFR 20.2202(b) requires that the licensee notify the NRC within 24 hours upon becoming aware of specific incidents involving licensed material. This is needed to allow early evaluation of the incident by NRC to ensure that appropriate action can be taken to protect against further hazard to life or property.
- 10 CFR 20.2203(a) establishes that, in addition to the notification required by 10 CFR 20.2202, each licensee is required to submit a written report within 30 days after learning of specific incidents involving doses or concentrations of radioactive materials in excess of limits. This is needed to ensure that there are appropriate follow-up actions to avoid a recurrence.
- 10 CFR 20.2203(b) contains the requirements for the content of reports required by 10 CFR 20.2203(a).
- <u>10 CFR 20.2204</u> requires licensees to submit a written report to the NRC within 30 days after a planned special exposure. This is needed to ensure that the use of planned special exposures is in accordance with requirements.
- 10 CFR 20.2205 establishes that when a licensee is required, pursuant to 10 CFR 20.2203 or 20.2204 to report to the Commission any exposure of an identified occupational exposed individual, the licensee must also provide a copy of the report submitted to the Commission to the individual at the same time.
- 10 CFR 20.2206(b) and (c) require licensees to report the results of individual monitoring annually to NRC on NRC Form 5 or equivalent electronic media. These requirements are covered under a separate OMB clearance for NRC Form 5 (OMB clearance number 3150-0006).

10 CFR 20.2207 requires licensees who manufacture, transfer, receive, disassemble, or dispose of a nationally tracked source complete and submit a National Source Tracking Transition Report as specified in paragraphs (a) through (e) of this section. Paragraph (f) of this section specifies the timing requirements for the report, and the methods of submitting the report. These requirements are included in the clearance package for NRC Form 748 (OMB clearance number 3150-0202).

10 CFR 20.2207(g) requires licensees to correct errors in previously filed reports or file any missed transaction reports within 5 business days of the discovery. The section also requires licenses to reconcile and verify the inventory of nationally tracked sources possessed by the licensee against the licensee's data in the National Source Tracking System (NSTS) on an annual basis. This verification is necessary to maintain the accuracy and reliability of the system over time. The burden to correct errors and file missed transaction reports is included in the clearance package for NRC Form 748 (OMB clearance number 3150-0202). The burden to conduct an annual reconciliation with the NSTS database is included in this clearance package for 10 CFR Part 20.

10 CFR 20.2207(h) required licensees to report their initial inventory of Category 1 and Category 2 nationally tracked sources to the NSTS by January 31, 2009. The initial inventory report included the source information such as make, model, serial number, radionuclides, source strength, and date for which the source strength is reported. The report also included the licensee name, address, and license number along with the name of the individual that prepares the report. This information is needed to ensure accountability of nationally tracked sources. This is a one-time collection that has been completed.

<u>10 CFR 20.2301</u> allows licensees to apply to the Commission for exemption from this rule.

Appendix G, Section I requires that waste generators, collectors, and processors of LLW intended for ultimate disposal at a licensed low-level radioactive waste facility to prepare a manifest on NRC Forms 540, 541, and 542, as appropriate. The justification for the information collection requirements in these forms are covered in separate OMB clearances for NRC Forms 540, 541, and 542 (OMB clearance numbers 3150-0164, 3150-0166, and 3150-0165).

This section specifies the specific data to meet NRC manifest requirements (i.e., shipper, date, total radioactivity, container identification and description, physical and chemical description of the waste, chelating agents, classification of the waste, radiation levels, etc). This information is electronically submitted to the NRC (discussed in 10 CFR 61.80(I)), to enhance the ability of the NRC and State regulatory agencies to control and safely regulate disposal of LLW. Without this information the ability for the licensee and the regulatory agencies to assess the site's performance would be severely impacted and thus the regulatory agency responsibility to protect public health and safety and the environment could not be adequately accomplished.

<u>Appendix G, Section II</u> requires that all generators, processors, and collectors certify by signing and dating the shipment manifest, that the shipment is properly classified, described, packaged, marked and labeled to meet Department of Transportation, NRC, and State requirements. This is necessary to ensure that the proper company official verifies that appropriate requirements have been met prior to shipment.

Appendix G, Section III, Paragraphs (A)-(D) provides the specific manifesting procedures for generators, processors, collectors, and the land disposal facility operators during shipment and receipt of the LLW. This includes classification of and labeling of the LLW, conducting a quality assurance program to assure compliance with §§ 61.55 and 61.56, requirement to use the NRC Uniform Low- Level Radioactive Waste Manifest, requirements to provide the intended consignee the manifest information and acknowledgment of its receipt and procedures in the event acknowledgment is not received, and storage of manifest data. These procedures are necessary to ensure that LLW is tracked from generator shipment to ultimate disposal and that no LLW is unaccounted for. A quality assurance program is necessary to ensure companies are properly following the procedures. The receipt acknowledgment is necessary to ensure investigations are undertaken when LLW is not where it is supposed to be. The storage of the manifest information is necessary to conduct audits and in the event that any discrepancies or other problems needed to be investigated.

Sections A.5 (generators), B.3 (collectors), and C.6 (processors) authorize that the manifest data may be transmitted electronically instead of by hard copy. This is a voluntary option designed to allow the manifest system to work more effectively and efficiently.

<u>Appendix G, Section III, Paragraph (E)</u> requires investigations and reporting to NRC when LLW has not been accounted for. This information is needed to identify and locate missing LLW and to identify improper procedures.