

OMB SUPPORTING STATEMENT FOR
Proposed Rule Amending 10 CFR Part 70
Domestic Licensing of Special Nuclear Material Revision
(3150-0009)

Description of the Information Collection

This Supporting Statement is for revised information collection requirements that would result from a proposed rule to amend the existing 10 CFR Part 70. The proposed rule would revise and add a new Subpart H to the existing 10 CFR Part 70, making it more risk-informed and performance based. Except for changes to section 70.50^(a), the proposed rule affects only “each licensee authorized to possess a critical mass of special nuclear material (SNM) that is or plans to be engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scraps recovery, decommissioning of facilities used for these activities, or any other activity that the Commission determines could significantly affect public health and safety.” The licensees to which it applies at present operate the seven major fuel fabrication facilities^(a). (The rule does not apply to the U.S. Enrichment Corporation’s (USEC) gaseous diffusion plants that are regulated under Part 76.) The majority of the proposed modifications to 10 CFR Part 70 are found in a new subpart, “Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material,” that consists of 10 CFR 70.60 through 70.74. These proposed modifications to Part 70, which are discussed in detail below, are required to protect the public, health, and safety. The details of the modifications to the recordkeeping and reporting sections are described in the justification section.

A. JUSTIFICATION

1. Need for and Practical Utility of the Information Collection

The information included in the applications, reports and records required by the proposed rule will be reviewed by the NRC staff to assess the adequacy of the applicant’s or licensee’s physical plant, equipment, organization, training, experience, procedures and plans for protection of public health and safety. The NRC review and the findings derived therefrom form the basis for NRC licensing and inspection decisions related to SNM in quantities sufficient to form a critical mass. Information concerning the requirements imposed by specific sections is provided below.

Section 70.50(c): The changes to this section redefine the information to be provided to the NRC in telephone and written reports. The revised information derives from the specifics of the new Subpart H, such as sequence of events and whether the event was

^(a) §70.50 applies to all Part 70 licensees, not just those subject to the new Subpart H.

evaluated in the integrated safety analysis (ISA). Section 70.50(c) requires such information as: caller's name, position title and call back telephone number; description of the event; external conditions affecting the event; actions taken by the licensee; status of the event; notifications related to the event; status of any press releases related to the event ; the probable cause of the event; corrective actions taken or planned; and, for licensees subject to Subpart H of this Part, whether the event was identified and evaluated in the Integrated Safety Analysis

Section 70.61(a) requires each licensee or applicant subject to Subpart H to evaluate, based on its ISA, whether it meets the safety performance criteria of section 70.61 paragraphs (b), (c), and (d).

Section 70.61(f) requires each licensee to establish a controlled area within which the licensee may permit persons to perform work not subject to NRC licensing, in addition to radiation workers, provided the licensee either (1) evaluates the risk to those persons and determines that it is no greater than the criterion for members of the general public, or (2) ensures that those persons are aware of the risks to them from the potential accidents at the nuclear facility and have received appropriate training and access to information.

Section 70.62 (a) requires that each licensee establish and maintain records that demonstrate that its safety program satisfies performance requirements of §70.61. It also requires that each licensee establish and maintain a log, available for NRC inspection, documenting each discovery that an item relied on for safety has failed to perform its function. This log is needed to facilitate inspection of items relied on for safety and to confirm the licensee's assumptions regarding the availability and reliability of items relied on for safety as originally evaluated in their safety program. Because a long performance history is needed to accurately evaluate reliability and maintenance performance and trends, these records should be retained for the life of the facility.

Section 70.62 (b) requires each licensee to compile and maintain a set of process safety information. This information is needed to enable the licensee to perform a proper ISA. Although not explicitly stated in the rule, the process safety information used to support an ISA should be retained as long as the ISA that it supports is still valid.

Section 70.62(c)(3)(i) requires existing licensees to submit for NRC approval, within six months after the effective date of the final rule, a plan that describes the ISA approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process. This requirement is needed to ensure, in the early stages of development, that the licensees will develop ISAs that are compatible with the rule requirements.

Section 70.62 (c)(3)(ii) requires existing licensees to perform an ISA, correct all unacceptable deficiencies identified in the ISA, and submit a summary of the ISA within

four years of the effective date of the final rule.

Section 70.62 (d) requires each applicant or licensee to establish management measures to provide continuing assurance of compliance with the performance requirements of section 70.61. Management measures include: a) configuration management; b) maintenance; c) training and qualifications; d) procedures; e) audits and assessments; f) incident investigations; g) records management; and h) other quality assurance elements.

Section 70.64(a) requires all applicants for licenses for new facilities to address baseline design criteria in the design of those facilities. Existing licensees must address these criteria in the design of new processes at existing facilities that require a license amendment, but are not required to retrofit existing facilities or processes. Licensees must maintain the application of these criteria unless an evaluation demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria. Quality assurance records of items relied on for safety must be maintained for the life of the facility.

Section 70.65(a) states that in addition to the contents of license applications required by §70.22, each application for a license to possess a critical mass of SNM for use in the activities described in §70.60, must contain a description of the applicant's safety program established under §70.62, including the integrated safety analysis summary and a description of management measures that ensure items relied on for safety will be available and reliable when needed to perform their safety function.

Section 70.65(b) requires that the ISA summary be submitted to the NRC, with a license or renewal or amendment application, and prescribes the content of the summary.

Section 70.72 (a) requires the licensee to establish a configuration management system to evaluate, implement and track changes. It also requires the licensee to develop written procedures that assure each change is adequately analyzed. The purpose of this requirement is to cause the impact of changes on health and safety to be properly considered and to cause licensee personnel to get the information about changes needed for them to conduct their work safely.

Section 70.72 (d)(1) requires that for any changes that affect the ISA summary and that do not require NRC pre-approval, the licensee shall submit to the NRC revised pages to the ISA summary within 90 days of the change. This will allow the NRC to maintain an up-to-date safety basis for the licensed facility and will allow NRC staff to review the changes being made to the facility, on a timely basis, to ensure that the licensee's evaluations of potential impacts to health and safety were accurate.

Section 70.72 (d)(2) requires that for any change that requires pre-approval, the licensee shall file an application for an amendment of its license, as specified in §§70.34 and

70.65.

Section 70.72 (d)(3) requires licensees to submit to the NRC every 12 months a brief summary of all changes to the records that demonstrate compliance with the requirements of §§70.62 (b) - (d) that did not require prior NRC approval. This would allow NRC staff to review the changes being made to the facility in enough time to ensure that the licensee's evaluations of potential impacts to health and safety were accurate.

Section 70.72 (e) requires that on-site documentation be promptly updated for changes covered by §70.72.

Section 70.72 (f) requires that each licensee maintain records of changes to its facility carried out under §70.72. These records must include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval. These records must be maintained until termination of the license in order that they be available to support any incident investigations that may arise in the future.

Section 70.73 lists the regulations that apply to license renewal applications; the proposed rule would add §70.65 to the list. Because the new §70.72 will require a licensee to keep the NRC informed of changes on a timely basis, little new material should need to be submitted and reviewed at the time of license renewal. This will result in a substantial savings to licensees and to the NRC for carrying out the activities associated with §70.73.

Section 70.74 (a) requires each licensee to report all events described in Part 70 Appendix A to the NRC Operations Center, including supplemental information as it becomes available. This information is needed to allow NRC oversight of ongoing incidents and to allow NRC to be able to respond to public inquiries about the incident. The provided information must include a description of the event and other information specified in §70.50(c)(1). Each licensee also must provide reasonable assurance that reliable communication with the NRC Operations Center is available during each event.

Section 70.74 (b) requires each licensee who makes a report required by section 70.74 (a)(1) to provide a written report within 30 days of the initial report. The written report must contain the information prescribed in §70.50(c)(2). This information is needed to permit future NRC review of the effectiveness of licensee actions and history of incidents.

Part 70, Appendix A specifies the events requiring reporting through one-hour and 24-hour reports, as required by 10 CFR 70.74.

2. Agency Use of the Information

Information required to be submitted with license applications or with applications for

amendments to those licenses are used by NRC in evaluating compliance with licensing requirements for possession and use of SNM.

The records that 10 CFR Part 70 requires the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC requirements for possession and use of SNM.

Reports of significant safety events are used by the agency in evaluating the protective actions required to avoid exposures to radiation or releases of radioactive materials that could exceed regulatory limits and, therefore, impact public health and safety, the common defense and security, and the environment.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. Licensees are encouraged to use automated information technology whenever it will reduce the burden on them. However, because of the types of information and the infrequency of submission, the applications and other reports may not lend themselves readily to the use of automated information technology for submission.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System (IRCAS) was searched to determine duplication. None was found.

5. Effort to Reduce Small Business Burden

The information collection burden of the proposed rule impacts only major fuel cycle licensees that do not fit the definition of small businesses.

6. Consequences to Federal Program of Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently

Required reports are collected and evaluated on a continuing basis as events occur. An application for a new license or for an amendment to an existing license is submitted only once. Applications for renewal of licenses are generally submitted every ten years for fuel cycle facilities. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary, currently not exceeding 10 years, to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of the public health and safety.

7. Circumstances Which Justify Variation from OMB Guidelines

- a) Number of Copies Contrary to the OMB Guidelines in 5 CFR 1320.5(d), 10 CFR 70.21 (which is not affected by this rulemaking) requires that licensees submit more than an original and two copies of certain documents. For applications for a SNM license, §70.21 requires that six copies be filed. The new §70.65 specifies additional material for which, in accord with §70.21, six copies are to be supplied with the license application submitted, including the ISA summary. Information provided to the NRC in compliance with new §§70.62(c)(3) and 70.72(d)(1) also would be submitted in the number of copies specified by §70.21.

The complexity of NRC's review and decision making process necessitates the filing of multiple copies by applicants. The application may be extremely complex, consisting of multiple foldouts, engineering drawings, and other printed material of various sizes that are difficult for NRC to reproduce properly or quickly. The NRC reviews typically involve numerous technical reviewers within the Office of Nuclear Material Safety and Safeguards. In addition, documentation must be provided for concurrent review by other NRC offices, technical consultants and contractors, and other participants in the proceeding. The complexity of the review, the need for concurrent review, and the need for timely completion of the review, dictate the requirement for multiple copies. Delays resulting from an insufficient number of copies may have a much more deleterious impact on applicants than the requirement for multiple copies.

- b) Reporting Frequency and Time to Report Also contrary to the OMB Guidelines, proposed §70.74 and Appendix A to Part 70 require each licensee to notify NRC within 1 hour of discovery of certain events. This immediate notification is necessary to inform NRC of incidents with potentially severe consequences in licensed facilities or activities. The information will be used by NRC to determine whether immediate response or corrective action is needed to protect public health and safety and to be prepared to respond to inquiries from the public and its representatives. The same justification applies to requiring licensees to notify NRC as soon as possible but not more than 24 hours after discovery of certain events defined in Appendix A. This immediate notification is necessary to inform NRC of incidents with serious but less than severe consequences, or of the potential for serious consequences, in licensed facilities or activities. The information will be used by NRC to determine whether immediate response or corrective action is needed to protect public health and safety and to be prepared to respond to inquiries from the public and its representatives.
- c) Record Retention The proposed rule would require licensees to maintain certain records until termination of the license; OMB Guidelines are three years. These are records that demonstrate compliance with NRC regulations. They will be used

by inspectors to assure that items relied on for safety have been adequately designed and do not contain hidden flaws due to gaps in maintenance.

8. Consultations Outside the NRC

An opportunity for public comment on the information collection requirements in the proposed rule 70 is being provided in the Federal Register Notice published in connection with this clearance request. Appropriately noticed public meetings and an interactive Internet web site have been used to solicit stakeholders' views during the process of formulating the proposed rule. The NRC contractor who collected information for the Regulatory Analysis visited two licensees to discuss costs of the requirements.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

NRC provides no assurance of confidentiality to respondents in connection with this information collection. However, to the extent allowed by law, proprietary and classified information may be exempt from public disclosure as provided for in 10 CFR 2.790.

11. Sensitive Questions

None.

12. Estimated Burden and Burden Hour Cost

See the attached charts.

13. Estimate of Other Additional Costs

There are no other additional costs.

14. Estimate of Cost to the Federal Government

It is expected that there will be no impact of the proposed rule on the NRC cost to license and inspect the major fuel cycle licensees affected by the proposed new requirements. While there will be changes in effort required to review some individual license renewal applications and to review the initial ISA required to be performed by existing licensees, the schedule and depth of reviews are to be adjusted to be able to be accomplished within the present fuel cycle licensing and inspection budget.

15. Reasons for Change in Burden

The proposed amendments to 10 CFR Part 70 that affect the burden or cost of complying with the regulations constitute the elements for a safety program NRC considers essential to provide a risk-informed, performance-based approach for increasing confidence in the margin of safety for licensees authorized to possess a critical mass of SNM. These elements include specifying radiological and non-radiological risks to be protected against and requiring licensees and applicants to perform a systematic and comprehensive ISA to evaluate their safety program against those risks, to establish means for ensuring the reliability and availability of items relied on for safety, to control changes so as to prevent inadvertent degradation of items relied on for safety, and to report incidents of failure of items relied on for safety. The existing 10 CFR Part 70 is at best vague and non-specific regarding the content of a safety program and against which risks it is required to protect.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying Expiration Date

The requirements will be 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

None.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

^(b) **Reporting**

Section	No. of Licensee Responses Annually	Licensee Staff Hrs/Submittal in excess of current requirements	Total Licensee Annual Burden Hours in excess of current requirements	Total Annual Costs in excess of current requirements at \$141/hour
70.50(c)	13	No new reports required by proposed changes to 70.50.	0	\$ 0
70.62(c)(3)(i)	^(c) 0.35	40	14	\$ 1,974
70.62 (c)(3)(ii)	0.35	8,800	3,080	\$ 434,200
70.65(a)	Included with 70.65(b)			
70.65(b)	0.35	200	70	\$ 9,870
70.72 (d)(1)	^(d) 7.49	800	6,000	\$ 846,000
70.72 (d)(2)	^(e) 4.67	600	2,800	\$ 394,800
70.72 (d)(3)	7	40	280	\$ 39,480
70.73	0.7	^(f) (12,000)	(8,400)	\$ (1,184,400)
70.74 (a)	Included with 70.74(b)			
70.74 (b)	30	40	1,200	\$ 168,000
Appendix A	Included with 70.74(b)			

^(b) Data in these charts is based on the Regulatory Analysis for the proposed rule, except for 70.50(c), which is based on 134 reportable events listed in NRC's "Nuclear Material Events Database" for 70.50 reporting requirements from 06/16/89 to 06/16/99.

^(c) One-time submittal by seven respondents averaged over assumed 20 year remaining life of plants.

^(d) Based on estimated 17% of complex systems having changes annually. Regulatory Analysis estimated an equivalence of 15.5 complex systems per licensee on average.

^(e) Estimated 11% of complex systems on average having changes annually that require license amendments.

^(f) Annualized savings at 10-year license renewals estimated to result from requirement to keep ISA and ISA summary up to date.

Section	No. of Licensee Responses Annually	Licensee Staff Hrs/Submittal in excess of current requirements	Total Licensee Annual Burden Hours in excess of current requirements	Total Annual Costs in excess of current requirements at \$141/hour
Total licensees additional annual number of responses:	51	Total licensees additional annual reporting burden:	5044	\$ 711,204
Total additional responses per licensee:	7.3	Total additional annual reporting burden per licensee:	721	\$ 101,661
		Average burden hours per response:	99	

Recordkeeping

Section	No. of Record-keepers	Annual Hours per Record-keeper	Total Annual Record-keeping Hours	Record Retention Period
70.61(a)	Included with 70.62(d).			
70.61(f)	Included with 70.62(d).			
70.62 (a)	7	100	700	life of facility
70.62 (b)	7	160	1,000	life of facility
70.62 (d)	7	300	2,100	life of facility
70.64(a)	included with 70.62(a)			
70.72 (a)	included with 70.62(d)			
70.72 (e)	included with 70.72(d)			
70.72 (f)	included with 70.72(d)			
Total recordkeeping hours:		560	3,800	
Total reporting hours:		721	5,044	
Total burden hours:			8,844	