

**DRAFT SUPPORTING STATEMENT
FOR 10 CFR PART 40
DOMESTIC LICENSING OF SOURCE
MATERIAL – AMENDMENTS/INTEGRATED SAFETY ANALYSIS,
PROPOSED RULE**

(3150-0020)

Description of the Information Collection

This Supporting Statement is for information collection requirements that would result from a proposed rule to amend the existing Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40. The proposed rule would add a new Subpart H to the existing 10 CFR Part 40, making it more risk-informed and performance based. The proposed rule would only affect current and future licensees that are authorized to possess 2000 kilograms (4400 pounds) or more of uranium hexafluoride (UF₆). Currently there is only one NRC licensee that meets this requirement.

The proposed rule would not apply to NRC and Agreement State licensees that are currently in the process of decommissioning. The majority of the proposed modifications to 10 CFR Part 40 are found in a new Subpart H, “Additional Requirements for Certain Licensees Authorized to Possess 2000 Kilograms (4400 lbs) or More of Uranium Hexafluoride,” that consists of 10 CFR 40.80 through 40.88. These proposed modifications to Part 40, 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.

The information included in the applications, reports and records required by the proposed rule will be reviewed by the U.S. Nuclear Regulatory Commission (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 there from form the basis for NRC licensing and inspection decisions. Information concerning the requirements imposed by specific sections is provided below.

A. JUSTIFICATION

1. Need for and Practical Utility of the Information Collection

Section 40.81(a) requires each licensee or applicant subject to Subpart H to evaluate, based on its integrated safety analysis (ISA), whether it meets the safety performance criteria of § 40.81 paragraphs (b), (c), and (d).

Section 40.81(e) 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 40.82(a) requires that each licensee establish and maintain records that demonstrate that its safety program satisfies performance requirements of § 40.81. It also requires that each licensee establish and maintain records, available for NRC inspection, documenting each discovery that an item relied on for safety has failed to perform its function. This record 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 40.82(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 40.82(c)(3)(i) requires existing licensees to submit for NRC approval, 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 40.82(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. Because the ISA would be a living document with continuous updating it would be valid for the duration of the facilities' expected lifetime. For conversion/deconversion facilities the life expectancy of the facility is at least 20 years.

Section 40.82(d) requires each applicant or licensee to establish management measures to provide continuing assurance of compliance with the performance requirements of section 40.81. 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 40.83(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 40.84(a) states that in addition to the contents of license applications required by § 40.31, each application must contain a description of the applicant's safety program established under § 40.82, including the ISA 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 40.84(b) is not a new requirement. Section 40.31 already requires an emergency plan or an evaluation.

Section 40.84(c) 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 40.86(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 40.86(c) allows licenses to make certain changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without submitting a license amendment. Currently, licensees must amend their licenses to make these changes under the provisions of § 40.44. Approximately 4 license amendments per year for would no longer be required.

Section 40.86(d)(1) requires that for any change that requires pre-approval, the licensee shall file an application for an amendment of its license, as specified in §§ 40.44 and 40.84. This is not a new requirement as the current regulations require a license amendment for these changes.

Section 40.86(d)(2) 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 a brief summary of all changes to the records that demonstrate compliance with the requirements of § 40.81(b) through (d) within 30 days after the end of the calendar year during which the changes occurred. 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 to ensure that the licensee's evaluations of potential impacts to health and safety were accurate.

Section 40.86(d)(3) requires licensees to submit to the NRC annually, within 30 days after the end of the calendar year during which the changes occurred, revise integrated safety analysis summary pages. This would allow NRC staff to review the changes being made to the facility to ensure that the licensee's evaluations of potential impacts to health and safety were accurate.

Section 40.86 (e) requires that on-site documentation be promptly updated for changes covered by § 40.86.

Section 40.86(f) requires that each licensee maintain records of changes to its facility carried out under § 40.86. 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 are available to support any incident investigations that may arise in the future.

Section 40.87 lists the regulations that apply to license renewal applications; the proposed rule would add § 40.85 to the existing requirements in § 40.43. Because the new § 40.86 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 would result in a substantial savings to licensees and to the NRC for carrying out the activities associated with § 40.87.

Section 40.88(a) requires each licensee to report all events described, in addition to the requirements in § 40.60(a), within 1 hour of discovery to the NRC Operations Center including supplemental information as it becomes available. A written report would be required to be sent to the NRC within 30 days following the event. 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. Reportable information is derived from the specifics of the new Subpart H, such as sequence of events and whether the event was evaluated in the ISA. Each licensee also must provide reasonable assurance that reliable communication with the NRC Operations Center is available during each event,

Section 40.88(b) requires each licensee to report all events described, in addition to the requirements in § 40.60(b), within 24 hours of discovery to the NRC Operations Center including supplemental information as it becomes available. A written report would be required to be sent to the NRC within 30 days following the event. 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. Reportable information is derived from the specifics of the new Subpart H, such as sequence of events and whether the event was evaluated in the ISA. Each licensee also must provide reasonable assurance that reliable communication with the NRC Operations Center is available during each event,

Section 40.88(e) requires each licensee who makes a report required by § 40.88(a) and (b) to provide a written report which contains the information required by § 40.88(d)(1) and information described in this section. This information is needed to permit future NRC review of the effectiveness of licensee actions and history of incidents.

2. Agency Use of the Information

Information required to be submitted with license applications or with applications for amendments to those licenses is used by the NRC in evaluating compliance with licensing requirements.

The records that 10 CFR Part 40 requires the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC requirements.

Reports of significant safety events are used by the agency in evaluating the protective actions required to avoid exposures to radiological and chemical hazards 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. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. 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. It is estimated that approximately 10% of the potential 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. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

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. Reporting Frequency and Time to Report Also contrary to the OMB Guidelines, proposed § 40.88 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 § 40.88. 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.

- b. 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 has been published in the Federal Register.

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).

11. Sensitive Questions

None

12. Estimated Burden and Burden Hour Cost

Currently there is only one NRC licensees that would be affected by this proposed rule.

The total annual burden for this proposed rule is 295 hours (-130 reporting hours + 425 recordkeeping hours) and at \$259.00 per hour equals \$76,405. See attached burden tables for details

13. Estimate of Other Additional Costs

NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the recordkeeping storage cost has been estimated to be equal to .0004 percent of the recordkeeping burden. Therefore, the additional recordkeeping storage cost for the proposed rule is estimated to be \$44.03 (425 recordkeeping hours x \$259 x .0004). The NRC has also determined each licensee will incur a one-time only cost to purchase a file cabinet at a cost of \$500. This equals a total cost of \$544.03 in the first year and a cost of \$44.03 in subsequent years.

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

This proposed rule will increase the overall burden by 295 hours from 65,418 to 65,713 hours. The proposed amendments to 10 CFR Part 40 that affect the burden and/or cost for 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 significant amounts of UF₆. 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 a 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 40 does not provide structured risk-informed approach for evaluating the consequences of facility accidents.

16. Publication for Statistical Use

None

17. Reason for Not Displaying Expiration Date

The requirements will be contained in a regulation. Amending the CFR 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

REPORTING

Table 1 – One Time Reporting Requirements

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Responses	Brdn per Response	Total Burden Hours	Cost @ \$259/Hr	Note
40.82(c)(3)(i)	1	1	1	40	40	\$10,360	
40.82(c)(3)(ii)	1	1	0.05	6600	330	\$85,470	Based on a 20-year life expectancy of the facility
40.84(a)	1	0.10	0.10	20	2.00	\$518	Based on a 10-year license renewal period
40.84(c)	1	0.10	0.10	20	2.00	\$518	Based on a 10-year license renewal period
TOTAL			1.3		374	\$96,866	

Table 2 – Annual Reporting Requirements

Section	No. Of Rspndts	Rsp. Per Rspndt	Total Annual Responses	Brdn per Response	Total Annual Burden Hours	Cost @ \$259/Hr	Note
40.86(c)	1	4	4	-20	-80	-\$20,720	Based on 4 amendments/per year that would not be required by § 40.44
40.86(d)(2)	1	1	1	10	10	\$2,590	
40.86(d)(3)	1	1	1	10	10	\$2,590	
40.43	1	-0.10	-0.10	1000	-100	-\$25,900	Based on a 10-year license renewal period - Savings is from current § 40.43 requirements being reduced by § 40.87
40.88 (a)	1	0.5	0.5	15	7.5	\$1,942.5	Based on a reportable event occurring every 2 years
40.88(b)	1	0.5	0.5	15	7.5	\$1,942.5	Based on a reportable event occurring every 2 years
40.88(e)	1	0.5	0.5	30	15	\$3,885	Based on a reportable event occurring every 2 years
Total for Part 40			7.4		-130	-\$33,670	

RECORDKEEPING

Section	Number of Record keepers	Burden Hrs. Per Record keeper	Total Annual Burden Hours	Cost @\$259/Hr.	Notes and Retention Period
40.81(a)	1	100	100	\$25,900	
40.81(e)	1	50	50	\$12,950	
40.82(a)	1	50	50	\$12,950	life of facility
40.82(b)	1	100	100	\$25,900	life of facility
40.82(d)	1	25	25	\$6,475	life of facility
40.83(a)	1	25	25	\$6,475	life of facility
40.86(a)	1	25	25	\$6,475	
40.86(e)	1	25	25	\$6,475	
40.86(f)	1	25	25	\$6,475	life of facility
Total for Part 40			425.00	\$110,075	

Annual Hourly Burden

Total hours for Reporting	-130
Total hours for Recordkeeping	425
Total hours for Part 40	295
Total Burden Cost for Part 40	\$76,405