

FINAL SUPPORTING STATEMENT
FOR
10 CFR PART 81
STANDARD SPECIFICATIONS FOR THE GRANTING OF PATENT LICENSES

(3150-0121)

EXTENSION

Description of the Information Collection

The Nuclear Regulatory Commission (NRC) may grant licenses to its patented inventions. Licenses are ordinarily available to all responsible applicants. An applicant may be granted an exclusive license for a limited time; however, to provide a financial incentive to develop the technology to a point where it can be practically applied.

All license applicants must report information that includes the nature and type of their business, the purpose for which the patent will be used, and the location where it will be used. Applicants who request exclusive use of the patent must report additional information regarding status; specifically, whether they are a small business, minority-owned, located in a surplus labor area, or located in a low-income area. Applicants for exclusive licenses must also include information to justify the need for a financial incentive by describing the time, expenditures, and all actions that will be necessary to bring the invention to the point where it can be practically applied. In addition, an applicant must explain how widely the invention is expected to be used in private industry and the Government.

All patent-license holders must submit periodic reports on efforts to bring the invention to a point of practical application and the extent to which they are making the benefits of the invention reasonably accessible to the public. Exclusive license holders who seek to extend their license's duration must submit sufficient information to show that the additional time is necessary to permit the license holder to enter the market and recoup its investment by bringing the invention to a point where it can be practically applied. If an exclusive license holder initiates a patent infringement lawsuit, it must promptly submit to the Government of the United States, upon request, copies of all pleadings, evidence and other filings in the lawsuit.

A. JUSTIFICATION

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

The NRC must collect the information to make determinations on whether to grant, establish terms, or take other actions on the licensing of NRC patents in accordance with standard specifications in 10 CFR. Part 81. Failure to collect this information would prevent the NRC from making the regulatory determinations required under these regulations, which have been promulgated under the authority of section 156 of the Atomic Energy Act of 1954, as amended. The regulations which specify the information required to be submitted by license applicants and licensees are below.

Section 81.20(a)(5) Non-exclusive license holders must submit reports annually (unless otherwise specified in the license) on efforts to bring the invention to a point of practical application and the extent to which license holders continue to make the benefits of the invention reasonably accessible to the public.

Section 81.20(a)(10) Before revoking or restricting any license granted pursuant to this subpart, the Commission shall mail to the licensee and any sublicensee of record, at the last address filed with the Commission, a written notice of the Commission's intention to revoke or restrict the license, and the licensee and any sublicensee shall be allowed 30 days after the mailing of such notice, or within such period as may be granted by the Commission, to remedy any breach of any covenant or agreement as referred to in paragraph(a)(8)(iii) of this section, or to show cause why the license should not be revoked or restricted.

Section 81.32(a)(2) NRC inventions may be available for the grant of limited exclusive licenses to responsible applicants who will make the benefits of these inventions practically applicable and publicly accessible. The length of the license will be negotiated (but will not exceed 5 years) and include a period of exclusivity specified in it, which relates to the period necessary to provide a reasonable incentive for the licensee to invest the necessary risk capital to make the invention practically applicable. The license cannot be extended unless the Commission determines, based on a written submission supported by a factual showing, that a longer period is necessary to permit the licensee to enter the market and recoup the investment in bringing the invention to the point of practical application. The license must also include a terminal portion that is sufficient to make the invention reasonably available for the granting of nonexclusive licenses under § 81.20, during which the licensee may have a nonexclusive license if the licensee continues to make the invention reasonably accessible to the public.

Section 81.32(a)(8) The license can be extended to wholly owned subsidiaries of the licensee but cannot be assigned or transferred without Commission approval, unless assignments are made upon Commission notice to successors of the licensee's business.

Section 81.32(a)(9) Exclusive licensees can issue sublicenses only upon Commission approval. Such a sublicense or assignment is subject to the terms and conditions of the exclusive license, including all rights retained by the Government, and a copy of each sublicense or assignment must be provided to the Commission.

Section 81.32(a)(10) A holder of an exclusive license to NRC inventions must submit periodic reports on efforts to achieve practical application of the invention and the extent to which a holder continues to make the benefits of the invention reasonably accessible to the public.

Section 81.32(a)(12) Before modifying or revoking any license under this subpart, the Commission will mail to the licensee and any sublicensee at the last address filed with the Commission a written notice of the Commission's intention to modify or revoke the license. The licensee and any sublicensee is then given 30 days after the notice is mailed, or within any period granted by the Commission, to remedy any breach of covenant or agreement in paragraph (a)(11)(iv) of this section or to show cause why the license should not be modified or revoked.

Section 81.32(a)(13) An exclusive licensee has the right to sue at its own expense any party who infringes the rights included in the license and the licensed patent. Upon consent of the Attorney General, the licensee may join the Government as a complainant in such suit, but without expense to the Government so that the licensee shall pay costs and any final judgment or decree that may be rendered against the Government in such a suit. The Government has an absolute right to intervene in any such suit at its own expense. Upon request, the licensee is obligated to promptly supply to the Government copies of all pleadings and other papers filed in any such suit, as well as evidence from proceedings relating to the licensed patent. If, as a result of any such litigation, the patent is declared invalid, the licensee has the right to surrender the license and be relieved from any further obligation thereunder.

Section 81.32(a)(14) A licensee can surrender the license any time before termination of the license upon notice to the Commission and approval of the Commission, but the licensee will not be relieved of the obligations thereunder without Commission approval.

Section 81.40 Applicants for exclusive and non-exclusive licenses to NRC inventions are required to provide information which may provide the basis for granting the requested license.

2. Agency Use of Information

In order to determine whether to grant a license or to modify or revoke a license, either as an exclusive license or a non-exclusive license, the NRC must make regulatory findings that require the collection of information on invention and patent number; the applicant's identity and citizenship; the applicant's business; the purpose for which the license is desired and the field of use in which the applicant intends to practice the invention; and the geographic area in which the applicant will practice the invention as well as other incidental information. The NRC may require additional information regarding the applicant's identity and location, as well as its ability to develop the invention and use the rights which may be granted, so that the agency can make the regulatory findings necessary for an exclusive license. The NRC also requires exclusive licensees to submit periodic reports containing information on efforts to achieve a practical application of an invention and make it accessible to the public so that the agency can determine whether the license should be modified or revoked.

The NRC requires the information to make the regulatory determinations required for approval of license extensions, sublicensing assignments,

and license transfers. The NRC also requires information to allow the agency to perform its license monitoring functions, permit revision or revocation of the license when appropriate, be kept informed of any litigation concerning the licensed patent and maintain the agency's licensing records.

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 page, by Optical Storage Media (OSM) (e.g., CD-ROM, DVD), by facsimile or by e-mail. It is currently estimated that approximately 100% of the potential responses will be filed electronically. 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.

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

Currently there are no applicants or exclusive/non-exclusive licensees and, thus, no anticipated burden on small businesses.

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

The collection frequency is deemed the minimum necessary to achieve the objectives of the requirements. Less frequent collection of information would prevent the NRC from obtaining information necessary to implement its regulations in 10 CFR Part 81.

7. Circumstances Which Justify Variation from OMB Guidelines

Not applicable.

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 September 18, 2023 (88 FR 63981). As no potential respondents have been identified, the NRC was unable to conduct any public consultations beyond the publishing of the *Federal Register* Notice. No 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).

11. Justification for Sensitive Questions

No questions of a sensitive nature are asked under these requirements.

12. Estimated Burden and Burden Hour Cost

The NRC estimates that it will receive 3.5 responses from 10 respondents annually under this information collection. The estimated total annual burden is 10 hours or \$3,000 (at \$300 per hour). See Table 1.

The \$300 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 2023 (88 FR 39120, June 15, 2023).

13. Estimate of Other Additional Costs

No other additional costs are anticipated.

14. Estimated Annualized Cost to the Federal Government

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.

Based on the estimated number of annual responses received, the following costs to the Government are anticipated:

Activity	Estimated Review Time	Estimated Cost
Review a report submitted on a nonexclusive license	4 hours	\$1,200

Review information supporting a request for an extended license period	5 hours	\$1,500
Review a license assignment or transfer notice	2 hours	\$600
Review a copy of any sublicense or assignment	3 hours	\$900
Review a practical application progress report	4 hours	\$1,200
Prepare and give written notice to the licensee about the intention to modify or revoke the license	Subject to complexity	
Review court pleadings		
Review a licensee's surrendered license		
Review an application		

The total annual cost to the NRC for all of these requirements is estimated to be approximately \$5,400.

15. Reasons for Change in Burden or Cost

This renewal reflects a more accurate estimate, in Table 1, of this clearance. 10 respondents that comes from the 10 different subparts of the collection (i.e., it assumes separate respondents for each aspect of the collection), and the 3.5 responses annually is the average number of responses that would be expected annually under these collections to report, given their different frequencies, NRC estimates they were all active at once and all had only 1 respondent each. This is instead of treating all the same information collection response activity as part of "1 response" submitted by "1 respondent" in the previous clearance.

There has, however, been an increase in the NRC's professional hourly fee rate from \$278 to \$300.

16. Publication for Statistical Use

The collections of information under these requirements will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The recordkeeping and reporting requirements for this information collection are associated with regulations and are not submitted on instruments such as forms or surveys. For this reason, there are no data instruments on which to display an OMB expiration date. Further, amending the regulatory text of the CFR to display information that, in an annual publication, could become obsolete would be unduly burdensome and difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

TABLE 1

LICENSEE REPORTING BURDEN, 10 CFR PART 81
PATENT LICENSES

Section	Description	Respondents	Annual responses	Burden per response	Total burden	Cost at \$300/hr
10 CFR 81.20(a)(5)	Reports on nonexclusive licenses	1	1	2	2.0	\$600
10 CFR 81.20(a)(10)	Revocation of nonexclusive licenses	1	0.2	2	0.4	\$120
10 CFR 81.32(a)(2)	Extensions of exclusive licenses	1	0.2	5	1.0	\$300
10 CFR 81.32(a)(8)	License transfer of exclusive licenses	1	0.2	2	0.4	\$120
10 CFR 81.32(a)(9)	Sublicenses for exclusive licenses	1	0.2	3	0.6	\$180
10 CFR 81.32(a)(10)	Reports on exclusive licenses	1	1	2	2.0	\$600
10 CFR 81.32(a)(12)	License revocation/modification of exclusive licenses	1	0.2	2	0.4	\$120
10 CFR 81.32(a)(13)	Patent lawsuits for exclusive licenses	1	0.1	9	0.9	\$270
10 CFR 81.32(a)(14)	Surrender of exclusive licenses	1	0.2	4	0.8	\$240
10 CFR 81.40	License applications (nonexclusive and exclusive licenses)	1	0.2	6	1.2	\$360
TOTAL		10	3.5		9.7	\$2,910