

DRAFT SUPPORTING STATEMENT FOR
10 CFR PART 81
STANDARD SPECIFICATIONS FOR THE GRANTING OF PATENT LICENSES
(3150-0121)
EXTENSION

Description of the Information Collection

Section 81.20(a)(5) Non-exclusive license holders are required to submit periodic reports, at least annually, 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 thirty (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 its benefits 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 making the invention publicly accessible and reasonably available for the granting of non-exclusive licenses under §81.20. Under that provision, the licensee may have a nonexclusive license if the licensee continues to make the invention publicly accessible.

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.

A. JUSTIFICATION

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

NRC needs the information requested to determine whether NRC inventions should be made available to applicants desiring to practice the invention and to make its benefits reasonably accessible to the public. The application for an exclusive or non-exclusive license (§81.40) is reviewed by the NRC patent counsel to determine whether a license may be granted and whether it should be granted to the applicant as requested. Failure to collect this information would prevent the NRC from insuring that NRC patents are properly issued under license to and used by the licensee as authorized by Section 156 of the Atomic Energy Act of 1954. as amended.

2. Agency Use of Information

In order to determine whether the NRC grants a license or continues it in effect, either as an exclusive license (§81.32) or a non-exclusive license (§81.20), the NRC needs and uses 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. Other incidental information is also required. Additional information regarding the applicant's identity, location and ability to develop the invention and use the rights which may be granted are required of an applicant for an exclusive license (§ 81.40). Periodic reports are then required of

licensees to ensure that the license is being used in the manner previously intended (§§ 81.20(a)(5) and 81.32(a)(10)).

The NRC needs and uses the information required under § 81.32(a)(8) and § 81.32(a)(9) which covers license extensions, sublicensing assignments and transfers; under § 81.32(a)(10) for review by the NRC patent counsel to determine the advisability of extending the term of a license, to keep track of any transfer of the license, and to ensure the licensee's continued qualification for the exclusive license: under § 81.32(a)(12) on modifications and revocations; under § 81.32(a)(13) on patent infringement suits; under § 81.32(a)(14) on surrendering licenses to allow the NRC to perform its license monitoring functions, to permit revision or revocation of the license when appropriate, to be kept informed of any litigation concerning the licensed patent, and to maintain the agency's licensing records.

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, the infrequency of submissions does not readily allow the efficient use of information technology under this clearance.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automatic System (IRCAS) was searched to determine duplication and none was found. There is no similar information available to the NRC.

5. Effort to Reduce Small Business Burden

Currently there are no applicants or exclusive/non-exclusive licensees.

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

The collection frequency contained in these requirements is deemed the minimum necessary to achieve the objectives of the requirements.

7. Circumstances Which Justify Variation from OMB Guidelines

The requirements under §§ 81.20, 81.32, and 81.40 conform to the OMB Guidelines in 5 CFR 1320.6.

8. Consultations Outside the NRC

The notice for opportunity for public comment has been published in the Federal Register.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

The NRC provides no pledge of confidentiality for this collection of information.

11. Justification for Sensitive Questions

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

12. Estimated Burden and Burden Hour Cost

As under paragraph 14 below, no reports are anticipated under these requirements. If they were submitted, the total anticipated burden and costs to a respondent are 37 hours or \$5,809.00 (at \$157 per hour). Burden and costs are broken out as follows:

a. The estimated annual burden per response for--

licensees under § 81.20 is estimated to be 2 hours;
licensees under § 81.20(a)(10) is estimated to be 2 hours
licensees under § 81.32(a)(2) is estimated to be 5 hours;
licensees under § 81.32(a)(8) is estimated to be 2 hours;
licensees under § 81.32(a)(9) is estimated to be 3 hours;
licensees under § 81.32(a)(10) is estimated to be 2 hours;
licensees under § 81.32(a)(12) is estimated to be 2 hours;
licensees under § 81.32(a)(13) is estimated to be 9 hours;
licensees under § 81.32(a)(14) is estimated to be 4 hours;
and licensees under § 81.40 is estimated to be 6 hours.

b. The estimated annual cost per response for--

licensees under § 81.20 is estimated to be \$314.00;
licensees under § 81.20(a)(10) is estimated to be \$314.00
licensees under § 81.32(a)(2) is estimated to be \$785.00;
licensees under § 81.32(a)(8) is estimated to be \$314.00;
licensees under § 81.32(a)(9) is estimated to be \$471.00;
licensees under § 81.32(a)(10) is estimated to be \$314.00;
licensees under § 81.32(a)(12) is estimated to be \$314.00;
licensees under § 81.32(a)(13) is estimated to be \$1,413.00;
licensees under § 81.32(a)(14) is estimated to be \$628.00;
and licensees under § 81.40 is estimated to be \$942.00.

13. Estimate of Other Additional Costs

No other additional costs are anticipated.

14. Estimated Annualized Cost to the Federal Government

Currently, it is anticipated that no reports will be submitted under these requirements and, therefore, there is no burden to the Government. However, if reports were submitted, the following costs are anticipated:

a. It takes the NRC patent counsel approximate 4 hours to review a report submitted pursuant to §81.20. At \$157 per professional staff hours, total annual cost to the NRC could be \$628.00

b. It takes the NRC patent counsel approximately 5 hours to review information supporting a request for an extended license period (§81.32(a)(2)); 2 hours to review a license assignment or transfer notice (§81.32(a)(8)); 3 hours to review a copy of any sublicense or assignment (§81.32(a)(9)); 4 hours to review a practical application progress report (§81.32(a)(10)); 4 hours to prepare and give written notice to the licensee about the intention to modify or revoke the license (§81.20(a)(10))(2hrs) and (§81.32(a)(12))(2 hrs); up to 4 hours, depending on the complexity of the case, to review court pleadings (§81.31(a)(13)); and 4 hours to review a licensee's surrendered license (§81.32(a)(14)). At \$157 per professional staff hour, total annual cost to the NRC could be \$4,082.00.

c. It takes the patent counsel approximately 4 hours to review an application (§81.40). At \$157 per professional staff hour, total annual cost to the NRC is estimated to be \$628.00.

d. Total annual cost to the NRC for all of these requirements is estimated to be \$5,338.00 per respondent.

This cost is fully recovered by fees charged to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Change in Burden or Cost

This renewal represents no increase in the burden on potential respondents. Since no submittals were made nor are anticipated, the actual burden is anticipated to be zero.

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 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

None.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.