

REQUEST FOR OMB REVIEW

(Under the Paperwork Reduction Act and Executive Order 12291)

Important — Read instructions (SF-83A) before completing this form. Submit the required number of copies of SF-83, together with the material for which review is requested to:

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

1. Department/Agency and Bureau/Office originating request U.S. Nuclear Regulatory Commission	3. Name(s) and telephone number(s) of person(s) who can best answer questions regarding request Chip Cameron (301)443-5981
2. 6-digit Agency/Bureau number (first part of 11-digit Treasury Account No.) 3 1 5 0	4. 3-digit functional code (last part of 11-digit Treasury Account No.) 2 7 6
5. Title of Information Collection or Rulemaking 10 CFR 35.27, Records of Teletherapy Inspections and Servicing	C. Is this a rulemaking submission under Section 3504(h) of P.L. 96-511? (Check one) 1 <input type="checkbox"/> No (Section 3507 submission) 2 <input type="checkbox"/> Yes, NPRM. Expected date of publication: _____ 3 <input type="checkbox"/> Yes, final rule. Expected date of publication: _____ Effective date: _____
6. A. Is any information collection (reporting or recordkeeping) involved? (Check one) 1 <input checked="" type="checkbox"/> Yes and proposal is attached for review 2 <input type="checkbox"/> Yes but proposal is not attached — skip to question D. 3 <input type="checkbox"/> No — skip to question D. B. Are the respondents primarily educational agencies or institutions or is the purpose related to Federal education programs? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	D. At what phase of rulemaking is this submission made? (Check one) 1 <input type="checkbox"/> Not applicable 2 <input type="checkbox"/> Major rule, at NPRM stage 3 <input type="checkbox"/> Major Final rule for which no NPRM was published 4 <input type="checkbox"/> Major Final rule, after publication of NPRM 5 <input checked="" type="checkbox"/> Nonmajor rule, at NPRM stage 6 <input type="checkbox"/> Nonmajor rule, at Final stage

COMPLETE SHADED PORTION IF INFORMATION COLLECTION PROPOSAL IS ATTACHED

7. Current (or former) OMB Number 3150-0010 Expiration Date 6/30/83	8. Requested Expiration Date 6/30/83	12. Agency report form number(s) N/A 13. Are respondents only Federal agencies? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
9. Is proposed information collection listed in the information collection budget? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	14. Type of request (Check one) 1 <input type="checkbox"/> preliminary plan 2 <input type="checkbox"/> new (not previously approved or expired more than 6 months ago) 3 <input checked="" type="checkbox"/> revision 4 <input type="checkbox"/> extension (adjustment to burden only) 5 <input type="checkbox"/> extension (no change) 6 <input type="checkbox"/> reinstatement (expired within 6 months)	
10. Will this proposed information collection cause the agency to exceed its information collection budget allowance? (If yes, attach amendment request from agency head.) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	11. Number of report forms submitted for approval NONE	

15. a. Approximate size of universe (if sample) N/A b. Size of sample N/A c. Estimated number of respondents or record keepers per year 84 d. Reports annually by each respondent (item 25) 1 e. Total annual responses (item 15c x 15d) 84 f. Estimated average number of hours per response .5 g. Estimated total hours of annual burden in Fiscal Year (item 15e x 15f) 42	16. Classification of Change in Burden (explain in supporting statement) <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>No. of Responses</th> <th>No. of Reporting Hours</th> <th>Cost to the Public</th> </tr> </thead> <tbody> <tr> <td>a. In inventory</td> <td align="center">7,220</td> <td align="center">69,237</td> <td align="right">\$ 390,000</td> </tr> <tr> <td>b. As proposed</td> <td align="center">7,304</td> <td align="center">69,279</td> <td align="right">\$ 600,000</td> </tr> <tr> <td>c. Difference (b-a)</td> <td align="center">84</td> <td align="center">42</td> <td align="right">\$ 210,000</td> </tr> <tr> <td colspan="4">Explanation of difference (indicate as many as apply)</td> </tr> <tr> <td colspan="4">Adjustments</td> </tr> <tr> <td>d. Correction-error</td> <td align="center">±</td> <td align="center">±</td> <td align="right">± \$</td> </tr> <tr> <td>e. Correction-reestimate</td> <td align="center">±</td> <td align="center">±</td> <td align="right">± \$</td> </tr> <tr> <td>f. Change in use</td> <td align="center">±</td> <td align="center">±</td> <td align="right">± \$</td> </tr> <tr> <td colspan="4">Program changes</td> </tr> <tr> <td>g. Increase</td> <td align="center">+</td> <td align="center">+</td> <td align="right">\$ 210,000</td> </tr> <tr> <td>h. Decrease</td> <td align="center">-</td> <td align="center">-</td> <td align="right">-</td> </tr> </tbody> </table>		No. of Responses	No. of Reporting Hours	Cost to the Public	a. In inventory	7,220	69,237	\$ 390,000	b. As proposed	7,304	69,279	\$ 600,000	c. Difference (b-a)	84	42	\$ 210,000	Explanation of difference (indicate as many as apply)				Adjustments				d. Correction-error	±	±	± \$	e. Correction-reestimate	±	±	± \$	f. Change in use	±	±	± \$	Program changes				g. Increase	+	+	\$ 210,000	h. Decrease	-	-	-
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17. Abstract—Needs and Uses (50 words or less)

Proposed amendment to Part 35 requires all teletherapy licensees to establish a program for the periodic inspection and servicing of teletherapy machines and the keeping of records to verify compliance.

18. Related report form(s) (give OMB number(s), IRCN(s), internal agency report form number(s) or symbol(s))

None

20. Catalog of Federal Domestic Assistance Program Number
N/A

21. Small business or organization Yes No

19. Type of affected public (Check as many as apply)

- 1 individuals or households
- 2 state or local governments
- 3 farms
- 4 businesses or other institutions (except farms)

22. Type of activity of affected public—indicate 3-digit Standard Industrial Classification (SIC) code(s) (up to 10) — if over 10, check Multiple or All

8 0 6

23. Brief description of affected public (e.g., "retail grocery stores," "State education agencies," "households in 50 largest SMSAs")

NRC teletherapy licensees

24. Purpose (Check as many as apply. If more than one, indicate predominant by an asterisk)

- 1 application for benefits
- 2 program evaluation
- 3 general purpose statistics
- 4 regulatory or compliance
- 5 program planning or management
- 6 research

26. Collection method (Check as many as apply)

- 1 mail self-administered
- 2 other self-administered
- 3 telephone interview
- 4 personal interview
- 5 recordkeeping requirement
Required retention period: 5 years
- 6 other—describe:

25. Frequency of Use

- 1 Nonrecurring
- Recurring (check as many as apply)
- 2 on occasion 6 semiannually
- 3 weekly 7 annually
- 4 monthly 8 biennially
- 5 quarterly 9 other—describe every 5 years

27. Collection agent (Check one)

- 1 requesting Department/Agency
- 2 other Federal Department/Agency
- 3 private contractor
- 4 recordkeeping requirement
- 5 other—describe:

28. Authority for agency for information collection or rulemaking—indicate statute, regulation, judicial decree, etc. Atomic Energy Act of 1954, as amended

30. Do you promise confidentiality? (If yes, explain basis for pledge in supporting statement.) Yes No

29. Respondent's obligation to reply (Check as many as apply)

- 1 voluntary
- 2 required to obtain or retain benefit
- 3 mandatory—cite statute, not CFR (attach copy of statutory authority)

31. Will the proposed information collection create a new or become part of an existing Privacy Act system of records? (If yes, attach Federal Register notice or proposed draft of notice.) Yes No

32. Cost to Federal Government of information collection or rulemaking \$ 1,120.00

COMPLETE ITEMS 33 THRU 35 ONLY IF RULEMAKING SUBMISSION

33. Compliance costs to the public
\$ _____

34. Is there a regulatory impact analysis attached?
 Yes No

35. Is there a statutory or judicial deadline affecting issuance?
 Yes. Enter date _____
 No

CERTIFICATION BY AUTHORIZED OFFICIALS SUBMITTING REQUEST—We certify that the information collection or rulemaking submitted for review is necessary for the proper performance of the agency's functions, that the proposal represents the minimum public burden and Federal cost consistent with need, and is consistent with applicable OMB and agency policy directives. Signature and title of:

APPROVING POLICY OFFICIAL FOR AGENCY	DATE	SUBMITTING OFFICIAL	DATE
Patricia G. Norris	9-21-82	R. Stephen Scott	9/21/82

SUPPORTING STATEMENT

Proposed Amendment, 10 CFR Part 35.27 Requiring Records of Teletherapy Inspections and Servicing

1. Justification

It is proposed that all teletherapy licensees establish a program for the periodic inspection and servicing of teletherapy machines to assure proper functioning of the source exposure mechanism. Records of inspection and servicing would be retained for a period of five years. Current 10 CFR 35.25 would be modified and redesignated as 35.27.

The NRC is aware of several teletherapy unit malfunctions that had the potential for causing serious overexposures to patients and operating staff. Unshielded teletherapy sources can generate radiation fields on the order of hundreds of rems per minute in areas accessible to patients and operators. The malfunctions on record have involved the mechanism designed to control the source exposure status, and resulted from excessive wear, misalignment, inadequate lubrication, etc. The proposed amendments are intended to codify an existing licensing requirement for inspection and servicing programs which are believed to significantly reduce the frequency of occurrence of such malfunctions. Records of the required maintenance procedures are necessary for better performance by the licensee and inspection and enforcement by the NRC.

Records of inspection will be used to assure that previously noted deficiencies have been corrected. This new recordkeeping requirement is an important component of an essential inspection and servicing program for NRC teletherapy licensees. The minimal cost is justified by a significant improvement in the radiation safety of patients and operators. The records provide inspectable evidence that an important radiation protection procedure has been performed. Information gained on the kinds of component problems discovered can be used by teletherapy manufacturers to effect better design and quality control. The gains in patient and operator radiation protection will significantly outweigh the economic impact on licensees.

2. Description of the Information Collection

The proposed requirement impacts approximately 420 teletherapy licensees. According to information available to the NRC, all of these licensees are currently complying with the requirement as per previously established licensing conditions.

The licensing condition and the proposed rule require inspection and servicing of the teletherapy source exposure mechanism whenever the source is replaced or at intervals not to exceed five years. Thus a record of the inspection and servicing will be established on the same frequency and retained for five years.

3. Time Schedule

The recordkeeping requirement is already in effect at all teletherapy licensees and is applicable to all new license applicants. Records of inspection and servicing of the teletherapy source exposure mechanism are not submitted to the NRC but are retained for a period of five years subject to routine inspection by the NRC.

4. Consultation Outside NRC

The proposed rule has been published in the Federal Register and affected licensees and applicants have been individually notified in order to solicit comments on the recordkeeping requirement.

5. Estimate of the Compliance Burden

Licensee cost for the inspection and servicing program is estimated at less than \$500.00 per teletherapy unit per year. For the 420 licensees, this means a total estimated cost of \$210,000.00 annually. However, the cost of generating and maintaining a record of the inspection is a small fraction of this cost.

It is estimated that the time for generating and maintaining a record of the inspection is approximately one-half hour every five years for each teletherapy licensee. This is an average of 84 licensees and 42 hours annually for the entire group of 420 teletherapy operators.

6. Sensitive Questions

None

7. Estimate of Cost to Federal Government

Implementation of the program for inspection and servicing of teletherapy units will incur an inspection and enforcement effort by NRC. Inspections occur on a 2-3 years frequency and will now include approximately 10 minutes for review of the licensees' record. This is a total time cost to the Government of 28 hours per year for a total cost of \$1,120.00.