PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement, and any additional documentation to: **Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.**

1. Agency/Subagency originating request

U.S. Nuclear Regulatory Commission

2. OMB control number

[√] a. **3150 - 0171** [ ] b. None

3. Type of information collection *(check one)*

[ ] a. New collection
[ ] b. Revision of a currently approved collection
[√] c. Extension of a currently approved collection
[ ] d. Reinstatement, **without change**, of a previously approved collection for which approval has expired
[ ] e. Reinstatement, **with change**, of a previously approved collection for which approval has expired
[ ] f. Existing collection in use without an OMB control number

4. Type of review requested *(check one)*

[√] a. Regular [ ] c. Delegated
[ ] b. Emergency - Approval requested by (date):

5. Will this information collection have a significant economic impact on a substantial number of small entities?

[ ] a. Yes [ ] b. No

6. Requested expiration date

[ ] a. Three years from approval date
[√] b. Other (Specify): **10/31/2002**

7. Title

10 CFR 35, Quality Management Program and Misadministrations

8. Agency form number(s) *(if applicable)*

Not applicable

9. Keywords

Byproduct material, Reporting and recordkeeping requirements

10. Abstract

The Quality Management Rule requires licensees to provide reports and keep records relating to medical byproduct misadministrations and requires the physician to provide written directives to patients treated with byproduct material.

11. Affected public *(Mark primary with "P" and all others that apply with "X")*

[ ] a. Individuals or households
[P] b. Business or other for-profit
[X] c. Not-for-profit institutions
[ ] d. Farms
[X] e. Federal Government
[X] f. State, Local or Tribal Government

12. Obligation to respond *(Mark primary with "P" and all others that apply with "X")*

[ ] a. Voluntary
[ ] b. Required to obtain or retain benefits
[P] c. Mandatory

13. Annual reporting and recordkeeping hour burden

a. Number of respondents	6,300
b. Total annual responses	3,194
1. Percentage of these responses collected electronically	0.0 %
c. Total annual hours requested	34,743
d. Current OMB inventory	34,743
e. Difference	0
f. Explanation of difference	
1. Program change	
2. Adjustment	

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*

a. Total annualized capital/startup costs	0
b. Total annual costs (O&M)	0
c. Total annualized cost requested	0
d. Current OMB inventory	0
e. Difference	0
f. Explanation of difference	
1. Program change	
2. Adjustment	

15. Purpose of information collection *(Mark primary with "P" and all others that apply with "X")*

[ ] a. Application for benefits
[ ] b. Program evaluation
[ ] c. General purpose statistics
[ ] d. Audit
[ ] e. Program planning or management
[ ] f. Research
[P] g. Regulatory or compliance

16. Frequency of recordkeeping or reporting *(check all that apply)*

[√] a. Recordkeeping [√] b. Third-party disclosure
[√] c. Reporting
[√] 1. On occasion [ ] 2. Weekly [ ] 3. Monthly
[ ] 4. Quarterly [ ] 5. Semi-annually [ ] 6. Annually
[ ] 7. Biennially [ ] 8. Other (describe)

17. Statistical methods

Does this information collection employ statistical methods?

[ ] Yes [√] No

18. Agency contact *(person who can best answer questions regarding the content of this submission)*

Name: **Frank Cardile**

Phone: **301-415-6185**

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8 (b) (3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It uses plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention periods for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8 (b) (3):

- (i) Why the information is being collected;
- (ii) Use of information;
- (iii) Burden estimate;
- (iv) Nature of response (voluntary, required for a benefit, or mandatory);
- (v) Nature of extent of confidentiality; and
- (vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the instructions);

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Authorized Agency Official	Date
Signature of Senior Official or designee	**Date**
Brenda Jo. Shelton, NRC Clearance Officer, Office of the Chief Information Officer	9/17/01