

# 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.**

<p>1. Agency/Subagency originating request <b>U.S. Nuclear Regulatory Commission</b></p>	<p>2. OMB control number  <input checked="" type="checkbox"/> a. <b>3150 - 0171</b>      <input type="checkbox"/> b. None</p>
<p>3. Type of information collection (check one)</p> <p><input type="checkbox"/> a. New collection</p> <p><input type="checkbox"/> b. Revision of a currently approved collection</p> <p><input checked="" type="checkbox"/> c. Extension of a currently approved collection</p> <p><input type="checkbox"/> d. Reinstatement, <b>without change</b>, of a previously approved collection for which approval has expired</p> <p><input type="checkbox"/> e. Reinstatement, <b>with change</b>, of a previously approved collection for which approval has expired</p> <p><input type="checkbox"/> f. Existing collection in use without an OMB control number</p>	<p>4. Type of review requested (check one)</p> <p><input checked="" type="checkbox"/> a. Regular      <input type="checkbox"/> c. Delegated</p> <p><input type="checkbox"/> b. Emergency - Approval requested by (date): _____</p> <p>5. Will this information collection have a significant economic impact on a substantial number of small entities?  <input type="checkbox"/> a. Yes  <input type="checkbox"/> b. No</p> <p>6. Requested expiration date  <input type="checkbox"/> a. Three years from approval date  <input checked="" type="checkbox"/> b. Other (Specify): <b>10/31/2002</b></p>
<p>7. Title <b>10 CFR 35, Quality Management Program and Misadministrations</b></p>	
<p>8. Agency form number(s) (if applicable) <b>Not applicable</b></p>	
<p>9. Keywords <b>Byproduct material, Reporting and recordkeeping requirements</b></p>	
<p>10. Abstract <b>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.</b></p>	
<p>11. Affected public (Mark primary with "P" and all others that apply with "X")</p> <p><input type="checkbox"/> a. Individuals or households      <input type="checkbox"/> d. Farms</p> <p><input checked="" type="checkbox"/> b. Business or other for-profit      <input checked="" type="checkbox"/> e. Federal Government</p> <p><input checked="" type="checkbox"/> c. Not-for-profit institutions      <input checked="" type="checkbox"/> f. State, Local or Tribal Government</p>	<p>12. Obligation to respond (Mark primary with "P" and all others that apply with "X")</p> <p><input type="checkbox"/> a. Voluntary</p> <p><input type="checkbox"/> b. Required to obtain or retain benefits</p> <p><input checked="" type="checkbox"/> c. Mandatory</p>
<p>13. Annual reporting and recordkeeping hour burden</p> <p>a. Number of respondents      <u>6,300</u></p> <p>b. Total annual responses      <u>3,194</u></p> <p>1. Percentage of these responses collected electronically      <u>0.0</u> %</p> <p>c. Total annual hours requested      <u>34,743</u></p> <p>d. Current OMB inventory      <u>34,743</u></p> <p>e. Difference      <u>0</u></p> <p>f. Explanation of difference</p> <p>1. Program change _____</p> <p>2. Adjustment _____</p>	<p>14. Annual reporting and recordkeeping cost burden (in thousands of dollars)</p> <p>a. Total annualized capital/startup costs      <u>0</u></p> <p>b. Total annual costs (O&amp;M)      <u>0</u></p> <p>c. Total annualized cost requested      <u>0</u></p> <p>d. Current OMB inventory      <u>0</u></p> <p>e. Difference      <u>0</u></p> <p>f. Explanation of difference</p> <p>1. Program change _____</p> <p>2. Adjustment _____</p>
<p>15. Purpose of information collection (Mark primary with "P" and all others that apply with "X")</p> <p><input type="checkbox"/> a. Application for benefits      <input type="checkbox"/> e. Program planning or management</p> <p><input type="checkbox"/> b. Program evaluation      <input type="checkbox"/> f. Research</p> <p><input type="checkbox"/> c. General purpose statistics      <input checked="" type="checkbox"/> g. Regulatory or compliance</p> <p><input type="checkbox"/> d. Audit</p>	<p>16. Frequency of recordkeeping or reporting (check all that apply)</p> <p><input checked="" type="checkbox"/> a. Recordkeeping      <input checked="" type="checkbox"/> b. Third-party disclosure</p> <p><input checked="" type="checkbox"/> c. Reporting</p> <p><input checked="" type="checkbox"/> 1. On occasion      <input type="checkbox"/> 2. Weekly      <input type="checkbox"/> 3. Monthly</p> <p><input type="checkbox"/> 4. Quarterly      <input type="checkbox"/> 5. Semi-annually      <input type="checkbox"/> 6. Annually</p> <p><input type="checkbox"/> 7. Biennially      <input type="checkbox"/> 8. Other (describe) _____</p>
<p>17. Statistical methods</p> <p>Does this information collection employ statistical methods?</p> <p><input type="checkbox"/> Yes      <input checked="" type="checkbox"/> No</p>	<p>18. Agency contact (person who can best answer questions regarding the content of this submission)</p> <p>Name: <u>Frank Cardile</u></p> <p>Phone: <u>301-415-6185</u></p>

## 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 <i>Brenda J. Shelton</i> Brenda J. Shelton, NRC Clearance Officer, Office of the Chief Information Officer	Date 9/17/01