



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington, DC 20420

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In Reply Refer To: 598/115HP/NLR

Ujagar S. Bhachu
Nuclear Regulatory Commission (NRC)
Nuclear Materials Safety and Safeguards
Division of Industrial and Medical Nuclear Safety
Two White Flint North Building (Mail Stop: T-8F5)
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Mr. Bhachu:

I am sending this letter to respond to the 10 CFR 2.206 petition under Control Number 2003-00029.

The enclosed detailed comments are for the second version of the petition.

I look forward to providing any additional information required to resolve this issue. If you have any questions, please contact me at (501) 257-1571.

Sincerely,

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

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The following specific comments are for an undated petition under 10 CFR 2.206.

1. Petition paragraph 1aAa.

a. The petition statements refer to the results of a Nuclear Regulatory Commission (NRC) inspection.

b. Contrary to the petition statement, the NRC inspection report of September 15, 2000, does not specifically identify executive management actions as an issue. The NRC did not cite the licensee for any violations.

c. The NRC inspection record did have comments and statements related to a lack of executive management oversight.

d. A subsequent National Health Physics Program (NHPP) inspection cited the licensee for a Severity Level III problem. One underlying violation was "the medical center failed to provide management oversight..."

2. Petition paragraph 1aAb.

a. The petition statements refer to the status of various VA Radiation Safety Officers.

b. Contrary to the petition statement, the current Indianapolis Radiation Safety Officer is a long-term employee and held the position before formation of the NHPP.

c. Contrary to the petition statement, the current St. Louis Radiation Safety Officer is a long-term employee and held the position before the formation of NHPP.

d. Contrary to the petition statement, the NRC had purview for the regulatory actions related to Philadelphia. The NHPP did not have a specific role other than to benchmark to NRC actions.

e. The NHPP has not received any radiation safety concerns or allegations related to the stated Radiation Safety Officer terminations or situations.

f. The turnover for licensees with full-time VA Radiation Safety Officer positions is approximately four percent annually, as determined from a review of calendar years 2000 through 2002.

g. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

3. Petition paragraph 1aAc.

a. The petition statements refer to the VA communication policy for licensees.

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b. Contrary to the petition statement, the VA communication policy for licensees is consistent with applicable regulations. The NRC required the VA to establish the policy to demonstrate a centrally controlled radiation control program and readiness for a master materials license.

c. The VA communication policy does not preclude or interfere with employee or worker opportunity to report safety concerns or to participate in other protected activities under 10 CFR 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.

d. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

4. Petition paragraph 1aAd.

a. The petition statements refer to the National Radiation Safety Committee.

b. The National Radiation Safety Committee has a total membership of 15, of which nine are physicians. The committee members represent the various disciplines and functional areas as are appropriate for executive management oversight of a regulatory compliance program. The NRC approved the committee membership.

c. Contrary to the petition statement, the National Radiation Safety Committee is proactive in taking actions to ensure regulatory compliance and direct NHPP efforts. The committee members who are part of the VA central office routinely provide oversight for VA activities within their functional areas.

d. Contrary to the petition statement, the committee member who represents the field Radiation Safety Officers has complete and frequent opportunity to raise issues. This committee member is routinely included in the annual program assessment process to ensure the Radiation Safety Officer perspective is considered in NHPP efforts. Also, the Radiation Safety Center for Inquiry (RSCI), a VA group formed to support the Radiation Safety Officer community consultation needs, is represented on the National Radiation Safety Committee.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

5. Petition paragraph 1aAe.

a. The petition statements refer to federal budget issues and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) "mock" results for one licensee.

b. The NHPP does not address budget issues, though appreciates the usual federal budgetary challenges in the health care environment. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

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c. The VA JCAHO scores, which include an evaluation of safety, are consistently higher than those of the private sector. In 2002, the VA average score was 95, nearly two points higher than the average for the private sector. The most recent score, in 2000, was 96 for the licensee where the petitioner was the Radiation Safety Officer.

d. The petition does not identify any adverse outcomes or program deficiencies that might be associated with the “mock” score and require a response. The JCAHO hospital accreditation system is nationally recognized by the health care industry as a major, independent review of health care. The JCAHO process includes an evaluation of safety programs. Hospitals often complete a “mock” JCAHO inspection to help prepare for upcoming formal JCAHO inspections. The score for a “mock” JCAHO inspection helps identify areas for improvement and includes a consolidated score for a range of clinical care, training, facility, and safety issues.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

6. Petition paragraph 1aAf.

a. The petition statements refer to turnover for executive management.

b. The NHPP does not provide staffing recommendations to licensees. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

7. Petition paragraph 1aAg.

a. The petition statements refer to federal budget issues.

b. The NHPP does not address budget issues, though appreciates the usual federal budgetary challenges in the health care environment. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

8. Petition paragraph 1aAh.

a. The petition statements refer to licensee budget issues.

b. The NHPP does not address budget issues, though appreciates the usual federal budgetary challenges in the health care environment. Rather, the NHPP evaluates radiation safety

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programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

9. Petition paragraph 1aAi.

a. The petition statements refer to the status of VA safety programs, Radiation Safety Officer viewpoints, and how budgeting is completed for one organization.

b. Contrary to the petition statement, the VA is quite proactive, and often recognized as a national leader, in patient safety initiatives and achievements. The VA commitment of resources and staff to patient safety, including the master materials license effort, belies the contrary statements in the petition.

c. The NHPP completes permitting actions and inspections consistent with the master materials license application and NRC guidelines while providing focused information to assist licensees and Radiation Safety Officers. The Radiation Safety Officers are likely to have a diversity of opinions about the NHPP, master materials license, and relative success of each.

d. The NHPP does not address budget issues, though appreciates the usual federal budgetary challenges in the health care environment. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

e. Contrary to the petition statement, a conflict of interest is not apparent for a senior manager at a field facility to make appropriate staffing and budgeting decisions at the field level and also represent VA-wide diagnostic radiology issues on the National Radiation Safety Committee.

f. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

10. Petition paragraph 1aAj.

a. The petition statements refer to the organizational structure for licensees and supervision for the Radiation Safety Officer.

b. The NHPP does not provide staffing or organizational structure recommendations to the licensees, other than those that are consistent with the organizational structure issues outlined in NUREG-1556, Volume 11. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

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11. Petition paragraph 1aAk.

- a. The petition statements refer to performance ratings for executive managers.
- b. Contrary to the petition statement, VA Facility Director Performance Plans have the comprehensive task of "Organizational Stewardship" under "Core Competencies," with a specific task as "Operates an effective safety and occupational health program that meets VA, JCAHO, and OSHA standards."
- c. Contrary to the petition statements, a Department of Labor occupational safety and health program evaluation of the VA concluded "...management at all levels of the VHA participate in significant aspects of the safety and health program and are held accountable for supporting the goals of the program and promoting efforts to achieve expected results."
- d. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

12. Petition paragraph 1b.

- a. The petition statements refer to an ongoing Merit System Review Board case.
- b. The NHPP does not have comments for an ongoing Merit System Review Board case.
- c. The NHPP has not received any radiation safety concerns or allegations related to such a personnel action.

13. Petition paragraph 1cAa and 1cAaa through 1cAad.

- a. The petition statements refer to NHPP inspections and compare NRC and NHPP inspection findings.
- b. Contrary to the petition statements, the number of days onsite by NHPP inspectors did not exceed three for any one inspection visit.
- c. Contrary to the petition statements, the NHPP inspection reports cited violations that represented well-documented deviations from regulatory requirements and license commitments.
- d. The NRC completed a comprehensive readiness review for the VA in 2001 that resulted in a satisfactory report without any recommendations. The readiness review consisted of a thorough review of NHPP inspection and permitting (licensing) actions and staff performance and qualifications. The NRC has continued oversight of the VA centrally controlled radiation control program and ongoing efforts to function as if a master materials licensee.
- e. One NHPP commitment is to complete inspections consistent with the master materials license application and NRC inspection guidelines. The readiness review discussed above did not identify any significant deficiencies in the NHPP inspection process or results. Annual

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external assessments by outside independent experts with master materials license experience have not identified any significant deficiencies in the NHPP inspection process or results.

f. The master materials licensees have historically cited more violations than NRC. In addition, a master materials licensee has broad authority to be more restrictive and prescriptive in radiation safety program requirements for their permittees. This includes completing inspections at a time and frequency deemed appropriate to the past enforcement history and requiring permitting actions to conform to specific guidelines deemed appropriate to the scope of radioactive materials used and past enforcement history.

g. NRC and master materials licensees inspections are separate and independent with limited expectation that inspections at a specific licensee (or permittee) in the same time period would necessarily identify the same violations. In addition, inspectors use different approaches within their professional discretion to inspect and to provide comments to licensee staff. Some inspectors provide "value-added" comments, whereas other inspectors restrict their comments only to specific regulatory issues or violations.

h. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

14. Petition paragraph 1d.

a. The petition statements refer to an interpretation of 10 CFR 35.21 and Radiation Safety Officer authority.

b. Contrary to the petition statements, the interpretation is appropriate in that Radiation Safety Officers often delegate to clinical services authority to approve routine purchase of radioactive materials.

c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

15. Petition paragraph 1e.

a. The petition statements refer to NHPP interactions with executive management and a Veterans Integrated Service Network (VISN) office.

b. Contrary to the petition statements, the NHPP is a headquarters-level organization with strong executive management support for taking any appropriate enforcement actions including identifying failures by licensee executive management.

c. Contrary to the petition statements, the NHPP cited the licensee where the petitioner was the Radiation Safety Officer for a Severity Level III problem. One of the underlying violations was "the medical center failed to provide management oversight..." The inspection report extensively addressed the organizational issues that contributed to the violations.

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d. Contrary to the petition statements, the NHPP has not received any comments or requests related to NHPP inspections from a VISN. The NHPP is a headquarters-level organization and not subordinate to VISN offices.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

16. Petition paragraph 1f.

a. The petition statements refer to differences in and among inspectors for inspections and permit actions.

b. Both NRC and NHPP inspectors are individuals who might use different approaches within their professional discretion to inspect and provide comments to licensee staff. Some inspectors provide "value-added" comments whereas other inspectors restrict their comments only to specific regulatory issues or violations.

c. Inspections completed by different inspectors, whether NRC or NHPP, are separate and independent with limited expectation that inspections at a specific licensee in the same time period would necessarily identify the exact same violations. Inspections are performance-based and do not necessarily review in detail each separate radiation safety program element during a specific inspection.

d. The master materials licensees have broad authority to be more restrictive and prescriptive in radiation safety program requirements for their permittees. This includes requiring permitting actions to conform to specific guidelines deemed appropriate to the scope of radioactive materials used and past enforcement history.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

17. Petition paragraph 1g.

a. The petition statements refer to staffing issues.

b. The NHPP does not provide staffing recommendations to licensees. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. Contrary to the petition statements about the scope of the radiation safety program at the licensee where the petitioner was formerly the Radiation Safety Officer, the recent NHPP inspection in 2002 determined the number of active researchers at the Westside Division was six and the number at the Lakeside Division was four. The NRC inspection report of 2000 stated the number of active researchers at the Lakeside Division was one. In addition, the nuclear medicine clinical programs at both divisions are modest and have similar workloads. Neither division completes brachytherapy procedures. The former Radiation Safety Officer (who is the

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petitioner) and the current Radiation Safety Officer had or now have health physics contract support to assist with radiation surveys, training, dosimetry, and waste management.

d. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

18. Petition paragraph 1h and 1hAa through 1hAc.

a. The petition statements refer to NHPP inspections and compare NRC and NHPP inspection results.

b. Contrary to the petition statements, the NHPP has not received any comments or requests related to NHPP inspections from a VISN. The NHPP is a headquarters-level organization and not subordinate to VISN offices.

c. Contrary to the petition statements, the NHPP has not restricted any NHPP inspectors. The NHPP Director completes annual performance evaluations for NHPP inspectors with final approval by the National Radiation Safety Committee. Neither the National Radiation Safety Committee nor the NHPP Director has restricted an NHPP inspector from performing inspections. NHPP inspectors are assigned specific inspections and other tasks based on their previous training, experience, and staff workload demands.

d. Contrary to the petition statements, differences between NRC and NHPP inspection results are expected. The master materials licensees have historically cited more violations than NRC. In addition, a master materials licensee has broad authority to be more restrictive and prescriptive in radiation safety program requirements for their permittees. This includes completing inspections at a time and frequency deemed appropriate to the past enforcement history.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.

19. Petition paragraph 2.

a. The petition statements refer to the VA organization culture related to safety of and capability to manage a regulatory compliance program.

b. Contrary to the petition statements, the VA is recognized as a leader in health care in reports from the New England Journal of Medicine (2000) and the Institute of Medicine (2002). The VA patient safety program has received international recognition, including an award from the American Medical Association in 2001. The current Department of Veterans Affairs Secretary has noted that the patient safety program has "helped to create a culture of safety in the VA by emphasizing prevention rather than punishment."

c. Contrary to the petition statements, the NRC staff has determined the VA master materials license application, centrally controlled radiation safety program (including the professional

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staff), and ongoing efforts to function as if a master materials licensee meet or exceed criteria in NUREG-1556, Volume 10.

d. Contrary to the petition statements, a Department of Labor occupational safety and health program evaluation of the VA concluded "...management regards protection and promotion of employee safety and health as a fundamental value of the organization and applies commitment to safety and health with as much vigor as to other organizational purpose."

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that require corrective actions.