

DEPARTMENT OF VETERANS AFFAIRS
VETERANS HEALTH ADMINISTRATION
MASTER MATERIALS LICENSE
READINESS REVIEW

QUESTIONNAIRE

Reporting Period: October 1, 1998 to February 1, 2001 (reported by Fiscal Years)

INSTRUCTIONS

This questionnaire is being furnished to you by e-mail as well as in printed form. Send your responses by March 15, 2001, by internet to Mr. James Lynch, the readiness review Team Leader, at (JLL2@NRC.GOV), and with cc to Headquarter's Coordinator, Dr. Donna-Beth Howe (DBH@NRC.GOV).

The questionnaire is divided into seven generic performance indicators to organize the information needed for review, make it easier for the review team to prepare for the review, and save time during the site visits.

Of particular interest to the NRC are the lessons learned and changes made to your program as a result of your continuing experience in licensing, inspection, incident response, allegations, and implementing central control. As appropriate, you should describe how you evaluate actions (or lack of actions), determine lessons learned, and implement changes. When changes are made, you should explain why the changes were made. For example, if as a result of an audit or monitoring an escalated enforcement case, you learned new insight into the regulatory process or see how to improve your program, then you should explain the lesson learned and the resulting program change. To ensure prompt response to this questionnaire, if you determine, while collecting information to respond to this questionnaire, that there was a lesson learned and a resulting program change is needed, you can pass that information on to the review team at a later date.

When responding to any question, you may reference specific sections of your September 30, 1998, license application, or October 26, 1998, March 5, 1999, or October 26, 2000 letters, as long as you provide a specific reference to where the information is located and a summary of the information requested.

The document "Materials Requested to be Available for the Onsite Portion of the Readiness Review," (Enclosure 2) is located after the questionnaire. We request that the Department of Veterans Affairs have the items listed prepared prior to the Readiness Review team's arrival.

Enclosure 1

PERFORMANCE INDICATORS

1. Central Control, Management Oversight, and Radiation Control Program Procedures

The information you provide for this indicator will document when the VA achieved central control of its radiation control program and provide data that can be used to evaluate the effectiveness of that control. NRC will evaluate the entire review period, October 1, 1998 to February 1, 2001, with special emphasis on the period following achievement of central control.

1. At what date was central control over the Department of Veterans' Affairs NRC licensed program achieved by the NHPP and the NRSC? How has the VA confirmed that central control has been fully implemented?
2. Please list the dates that the National Radiation Safety Committee (NRSC) met and indicate by title, the members that were absent or not otherwise represented. Provide a list of significant deliberations and decisions made by the committee at these meetings.
3. Identify other meetings of committee members in which significant deliberations and decisions were made, identify the topics of significant deliberations, provide the decisions, and identify who participated in each of these meetings.
4. Identify the members of the National Radiation Safety Committee that have left the committee? Explain why they left? Were any members removed because of lack of attendance? If a new member has a different position (job title) than that specified in the application, please explain. How many vacancies remain? How long were the positions vacant? If there are still vacancies, what corrective actions have been taken or are planned?
5. Excluding the VHA Readiness Review, identify and describe other internal management audits or reviews that have been performed to assess the implementation of the centralized radiation control program, their findings, and how the findings have been addressed.
6. Please list all currently effective policies, procedures and internal regulations that affect the radiation control program (RCP).
7. List the VHA licensees that have been inspected by the NRC and indicate which resulted in the issuance of a Notice of Violation letter and/or Escalated Enforcement. For each, describe the actions taken by management and the NHPP staff to assist the licensee in responding to the inspection results and in identifying corrective actions to resolve cited violations. Describe any lessons learned and/or changes made to the VA's central control program as a result of these inspections or enforcement actions. Please provide the following:

Licensee Name License No. Program Type Inspection Date Results*

* Include lessons learned and/or changes made to the VA's central control program

8. Describe any lessons learned or changes made to facilitate central control of your program as a result of gaining experience in trying to implement central control.

II. Status of Materials Inspection Program

This indicator is used to examine the location, frequency, timeliness, and results of inspections performed by the NHPP and to provide information on changes to the program resulting from increased inspection experience. It also provides data for evaluating the staffing adequacy of the centrally controlled program.

1. Please prepare a table identifying the licensees that the NHPP staff have inspected from October 1, 1998 to February 1, 2001 (reported by Fiscal Years). Identify those inspections that were made in response to notification that NRC was performing a reactive inspection and those reactive inspections initiated by the NHPP. Describe any lessons learned and/or changes made to the VA's central control program as a result of these inspections. The table should include the following:

Licensee Name License No. Program Type Date* Inspector Results** Reactive

* Indicate whether the inspection was announced or unannounced

** Include lessons learned and/or changes made to the VA's central control program

2. Did you establish numerical goals for the number of inspections to be performed from October 1, 1998 to February 1, 2001 (reported by Fiscal Years)? If so, please describe your goals, the number of inspections actually performed, and the reasons for any differences between the goals and the actual number of inspections performed.

III. Technical Quality of Inspections

This indicator includes documentation of the inspection procedures used, quality of the inspections, quality of associated measurement instrumentation, and the management accompaniment program. It also documents changes made to the quality of the inspection program based on increased inspection experience. Actual review of inspection reports will be performed during the on site portion of the readiness review.

1. What inspection procedures were used from October 1, 1998 to February 1, 2001, (reported by Fiscal Years) and what, if any, changes were made to these written inspection procedures? Identify changes to the procedures based on lessons learned from performing inspections.
2. Prepare a table showing the number and types of supervisory accompaniments made from October 1, 1998 to February 1, 2001 (reported by Fiscal Years). Include:

<u>Inspector</u>	<u>Supervisor</u>	<u>License Cat.</u>	<u>Date</u>
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3. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field. Have your internal procedures changed as a result of performing supervisory accompaniments? If so, describe the changes. If supervisory accompaniments were documented, please provide copies of the documentation for each accompaniment.
4. Describe or provide an update on your instrumentation and methods of calibration. Are all instruments properly calibrated at the present time?

IV. Technical Staffing and Training

This indicator collects information on the current staffing of the National Radiation Safety Committee as well as the technical and administrative National Health Physics Office staff. It includes future staffing plans, staff retention and staff hiring activities. The staff training aspect of this element addresses the training program, current qualifications of the technical staff and radiation safety committee members, as well as training of the current technical staff and radiation safety committee members.

In reviewing the VA's October 26, 2000, submission, NRC staff determined that the training program described in SOP 4 was not equivalent to the training programs described in NRC's Inspection Manual Chapter, that the NHPP inspectors might not have completed the training courses required of MML inspectors, and that the VA may have waived training requirements the NRC does not waive for its own staff. These deficiencies were discussed with the NHPP Director, and corrections to these deficiencies are the focus of questions 4 and 7. Questions 5 and 6 are intended to determine the actual training of the staff and the use of waivers.

1. Please provide either a staffing plan or a complete listing, using the suggested format below, of the professional (technical) person-years (full time equivalents (FTE)) of effort applied to the National Health Physics Program and National Radiation Safety Committee for the radioactive material program by individual. Include the name, position, and the fraction of time spent in the following areas: National Radiation Safety Committee, administration, materials licensing & inspection, emergency response, and other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

<u>Name</u>	<u>Position</u>	<u>Area of Effort</u>	<u>FTE%</u>
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2. Describe staffing and administrative support changes resulting from moving the Headquarters from Ann Arbor, Michigan, to Little Rock, Arkansas. Describe other staffing and administrative support changes made or proposed as a result of the VA's implementation and increased experience with a centrally controlled radiation safety program.
3. Please provide a listing of all new professional personnel hired and National Radiation Safety Committee members appointed from October 1, 1998 to February 1, 2001, (reported by Fiscal Years). Indicate the degree(s) they hold, if applicable, and additional training and years of experience in health physics, or other disciplines, if appropriate.
4. The training program in SOP 4 is not equivalent to that in NRC's Inspection Manual Chapter 1246. What is your schedule for revising the training program in SOP 4 to be

consistent with NRC's inspector and license reviewer training programs? (Note that this document must be revised and submitted to NRC prior to issuance of a MML license.)

5. For each professional staff member, identify the required training course(s) in IMC 1246 the person has successfully completed, when the course was completed, and provide other documentation demonstrating that the staff member is competent to issue licensing permits and conduct safety inspections for inspection priority 3 and 5 licensees.
6. Please list all professional staff who were granted a waiver from meeting the qualification requirements detailed in Inspection Manual Chapter 1246 for license reviewer and materials inspection staff. For each professional staff member that was granted a waiver, identify each training course for which a waiver was granted and provide justification for each waiver.
7. Provide your schedule for enrolling your staff in the NRC training courses listed in Inspection Manual Chapter 1246. The core courses relevant to medical uses and broad scope research licenses (e.g., H-201, H-304, H-313, G-109, H-308) as well as inspection mechanics and approaches (i.e., G-101 or G-108, G-205, G-304, and non core course H-120 for a decommissioning inspector) need to be completed prior to full qualification of your staff. (You should coordinate with the NRC Technical Training Center (Dr. John Ricci at (423) 855-6514) for assistance in scheduling enrollment of your staff in these NRC training courses.)
8. Please list all professional staff who have not met the qualification requirements of license reviewer/materials inspection staff (Inspection Manual Chapter 1246) and all National Radiation Safety Committee members who have not received training in the VA's centrally controlled radiation safety program and their duties. For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.
9. Please identify the technical staff who left the NHPP program from October 1, 1998 to February 1, 2001 (reported by Fiscal Years).
10. List the vacant positions in the NHPP, the length of time each position has been vacant, and a brief summary of efforts and corrective action plan to fill a vacancy.

V. Technical Quality of Licensing Actions

This indicator is used to examine the number, type, frequency, timeliness, and results of licensing actions reviewed by the NHPP and to provide information on changes to the program resulting from increased licensing experience. The role of NHPP management and the NRSC in the licensing review process is also examined. Data from this indicator is used for evaluating the staffing adequacy of the centrally controlled program. Actual review of licensing reviews and actions will be performed during the on site portion of the readiness review.

1. Please provide a list of the licensing actions that were routed through the NHPP from October 1, 1998 to February 1, 2001 (reported by Fiscal Years). Describe any lessons learned and/or changes made to the VA's central control program as a result of these licensing actions. Please provide the following information:

Licensee License No. Action Type Date Received Date to NRC Results*

* Include lessons learned and/or changes made to the VA's central control program

2. Describe the role of the NHPP Director and the NRSC in the licensing actions routed through the NHPP from October 1, 1998 to February 1, 2001. Describe any lessons learned and/or changes made to the VA's central control program as a result of the roles of the NHPP Director and NRSC in licensing activities.
3. Describe any major, unusual, or complex licenses which were reviewed and which required substantial interaction between the NHPP staff and the licensee to resolve technical issues prior to forwarding to the NRC. Describe any lessons learned and/or changes made to the VA's central control program as a result of these licensing interactions.
4. Provide a list of pending licensing actions which have not been forwarded to the NRC. Please provide the following information:

Licensee License No. Action Type Date Received

VI. Responses to Incidents and Allegations

The first component of this indicator addresses the function of the NHPP to respond to incidents, determine the types of incidents, evaluate whether information associated to the incidents were disseminated to the NRC, Federal or State agency with a regulatory interest or other affected VA licensees. The number and duration of incident responses provides data for evaluating the staffing adequacy of the centrally controlled program.

The second component of the indicator addresses the frequency, in which the NHPP is sought out to respond to employee safety concerns, the NHPP staffs ability to identify employee safety concerns that the NRC may consider to be allegations, and how the NHPP responds to them.

1. Please provide a list of the reportable incidents (i.e., medical misadministration, overexposures, lost and abandoned sources, incidents requiring 24 hour or less notification, etc.) that occurred from October 1, 1998 to March 1, 2001 (reported by Fiscal Years). Describe any lessons learned and/or changes made to the VA's central control program as a result of receiving or responding to these incidents. The list should be in the following format:

<u>Licensee Name</u>	<u>License #</u>	<u>Date of Incident/Report</u>	<u>Type of Incident</u>	<u>Results*</u>
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*Include lessons learned and/or changes made to the VA's central control program

2. From October 1, 1998 to February 1, 2001 (reported by Fiscal Years), did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other VHA licensees who might be affected notified? Was timely notification made to NRC?
3. For incidents involving failure of equipment or sources, was information on the incident provided to the NRC or appropriate Agreement State responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.
4. From October 1, 1998 to February 1, 2001 (reported by Fiscal Years), were there any cases involving possible wrongdoing that were reviewed or are presently undergoing review? If so, please describe the circumstances for each case. Describe any lessons learned and/or changes made to the VA's central control program as a result receiving or responding to incidents or wrongdoing. Please follow the requirement of 10 CFR 2.790 if providing information that is to be withheld from public disclosure. For ease of handling, information that cannot be disclosed to the public should be provided as a separate enclosure.
5. Identify any reports of radiation safety concerns or allegations that were received by the NHPP from October 1, 1998 to March 1, 2001 (reported by Fiscal Years). If any

reports of radiation safety concerns or allegations were received, describe how they were resolved. Describe any lessons learned and/or changes made to the VA's central control program as a result of receiving and responding to allegations or reports of radiation safety concerns.

VII. General

Provide a brief description of your program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, problems, or difficulties which occurred during this review period. They should also include a description of any lessons learned and/or changes made to the VA's central control program as a result of identifying program strengths and weaknesses.

MATERIALS REQUESTED TO BE AVAILABLE FOR THE ONSITE PORTION OF THE READINESS REVIEW

ORGANIZATION CHARTS

Provide the site team the following organizational charts with names and positions in readable type and preferably sized 8½ X 11"

- One showing positions from Senior Management Official down to the NHPP Director
- One showing positions of current radiation control program with NHPP Director as Head
- One showing the RSC membership

CASE LISTS AND LOGS

Provide the site team with the following:

- List of open license cases, with date of original request, and dates of follow up actions
- Copy of current log or other document used to track licensing actions
- Copy of current log or other document used to track inspections
- Listing or log of all incidents and allegations occurring during the review period. Show whether incident is open or closed and whether it was reported to the NRC

SUPPORTING DOCUMENTS (CURRENT AND PROPOSED FOR MML)

- All NHPP regulations
- Technical procedures for licensing, model licenses, review guides
- Instrument calibration records
- Inspection procedures and guides
- Inspection report forms
- Records of results of supervisory accompaniments of inspectors
- Emergency plan and communications list
- Procedures for investigating allegations
- Enforcement procedures, including procedures for escalated enforcement, severity levels, penalties (as applicable)
- Copies of job descriptions
- Copies of RSC meeting minutes
- Copies of management audits/reviews