



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

August 20, 2001

Thomas L. Garthwaite, M.D.
Under Secretary for Health
Department of Veterans Affairs
Washington, D.C. 20420

SUBJECT: MASTER MATERIALS LICENSE READINESS REVIEW REPORT

Dear Dr. Garthwaite:

This refers to the Master Materials License Readiness Review, conducted from January 24 to June 22, 2001, of the Department of Veterans Affairs (DVA) radiation control program. In December 1996, the DVA submitted an application for a Master Materials License. The NRC identified fundamental weaknesses in the program which resulted in your withdrawal of the application. You submitted a substantially revised application in September 1998. In May 1999, we suspended license review due to our observations which indicated problems with DVA's fundamental chain of command, structure, operations, communications, and timeliness. On October 26, 2000, you notified the NRC that the problems had been corrected and that the DVA was ready to undergo a readiness review, which could lead to the DVA's becoming a Nuclear Regulatory Commission (NRC) Master Materials Licensee.

The readiness review examined the DVA's performance in implementing the commitments made in your Master Materials License application, including central control of the program, inspections, and licensing.

The review was conducted in a manner similar to the way NRC evaluates the performance of Agreement States and its own Regional programs. Six performance indicators were used in reviewing the DVA radiation control program. The review team consisted of experienced licensing, inspection, and administrative NRC staff members from the Regions and Headquarters. The review included numerous site visits to DVA facilities by these team members.

On June 22, 2001, we held an exit meeting at your National Health Physics Program office in North Little Rock, Arkansas. Gregory Neuner, Deputy Chief Patient Care Services Officer, represented DVA management at that meeting. All six performance indicators were rated as satisfactory.

The readiness review demonstrated a strong DVA radiation control program, as implemented by your National Health Physics Program. This result will be one input into the ongoing master materials licensing review. This readiness review does not ensure that the DVA will receive a Master Materials License.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available **electronically** for public inspection in the NRC Public Document Room **or** from the *Publicly Available Records (PARS) component of NRC's document system (ADAMS)*. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

We will gladly discuss any questions you have concerning this review.

Sincerely,

/RA/

Cynthia D. Pederson, Director,
Division of Nuclear Materials Safety

Enclosure: As stated

cc w/encl: E. Lynn McGuire, Director, National Health Physics Program

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READINESS REVIEW
DEPARTMENT OF VETERANS AFFAIRS
MASTER MATERIALS PROGRAM

January 24 - June 22, 2001

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the Department of Veterans Affairs (DVA) master materials license readiness review. The review was conducted during the period January 24 to June 22, 2001, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC). Team members are identified in Appendix A. The review was conducted in accordance with Performance Indicator guidance developed from the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review were discussed with the Deputy Chief Patient Care Services, on June 22, 2001.

In December 1996, the DVA submitted an official application for a Master Materials License. An NRC Working Group reviewed the application. In September 1997 and August 1998, the NRC issued two major deficiency letters. The NRC staff also met with DVA management in June 1998, to discuss the five global issues which the Working Group identified as fundamental weaknesses in the application.

The DVA withdrew the previous submissions and submitted a substantially revised application in September 1998. Application supplements were added in October 1998 and March 1999 in response to NRC's requests for additional information.

In May 1999, the NRC suspended license review by letter from the Director of the Office of Nuclear Material Safety and Safeguards. This action resulted from NRC observations which indicated problems with the DVA's fundamental chain of command, structure, operations, communications and timeliness.

In response, the DVA initiated a comprehensive radiation control program assessment and an action plan. The action plan, approved by the National Radiation Safety Committee in October 1999, included an assessment of the radiation control program; development of a master materials license strategy, including performance indicators; and implementation of the resulting strategic plan. The assessment included an external review by an outside consultant and benchmarking the DVA program with those of the Air Force and Navy master materials licenses. The external review and the National Radiation Safety Committee Working Group review, completed in early 2000, concluded that the radiation control program was ready for a master materials license, based on NRC guidelines.

The DVA radiation control program is administered by the National Health Physics Program (NHPP). The NHPP Director reports directly to the Chief Patient Care Services who, in turn, reports to the Under Secretary for Health. Organization charts for DVA are included as Appendix B.

The NRC currently regulates 125 licenses at 118 medical centers. Forty-nine of the licenses have a primary program code of inspection priority 1 or 2. The other 76 have primary program codes of 3 or 5. The NRC is contemplating issuing the master materials license in two phases, the first being those smaller facilities with primary program codes of 3 or 5. Upon successful demonstration of regulatory oversight of those facilities, the broadscope licenses would be phased into the DVA program. This readiness review was not limited to a review of just the lower priority licenses. Conclusions drawn from this report are valid for the whole program.

In preparation for the review, a questionnaire addressing the six performance indicators was sent to the DVA on February 14, 2001. The DVA provided a response to the questionnaire on April 11, 2001.

The review team's general approach for conduct of this review consisted of: (1) examination of DVA's response to the questionnaire; (2) field accompaniments of five NHPP inspectors and NHPP Director; (3) licensing visits to the NHPP central office and four regional offices; (4) communication visits to 44 DVA facilities nationwide; and (5) a team visit to the NHPP office in North Little Rock, Arkansas for file reviews and interaction with staff. The team evaluated the information that it gathered against the performance criteria for each performance indicator and made an assessment of the radiation control program's performance, as described in Section 2 below. Section 3 summarizes the review team's findings.

2.0 PERFORMANCE INDICATORS

Six performance indicators were used in reviewing the DVA radiation control program. These indicators are: (1) Management Oversight and Radiation Control Program Procedures; (2) Status of Materials Inspection Program; (3) Technical Quality of Materials Inspections; (4) Technical Staffing and Training; (5) Technical Quality of Materials Licensing Actions; and (6) Response to Incidents and Reported Radiation Safety Concerns and Allegations.

2.1 Management Oversight and Radiation Control Program Procedures

This indicator focuses on the ability of the licensee organization to effectively oversee and control a master materials license. The review team evaluated the effectiveness of the DVA's National Radiation Safety Committee to assure public health and safety through its implementation of a radiation control program. To this end, the team also assessed the DVA's organization, communications, internal audits, policies and procedures.

In response to the NRC concerns identified in 1999, DVA management directed that the NHPP become a separate program entity rather than a program component administered through the Nuclear Medicine and Radiation Safety Service office in Ann Arbor, Michigan. This consolidation of program activities and records to North Little Rock, Arkansas occurred in December 1999. The NHPP Director reports directly to the Chief Patient Care Services and has ready access to DVA executive management.

Regional Program Managers are located in Mare Island, California; Seattle, Washington; Ann Arbor, Michigan; Perry Point, Maryland; and North Little Rock, Arkansas and have periodic telephone conference calls and quarterly meetings in the North Little Rock office. The "virtual office" strategy utilized by NHPP is described in Sections 2.4 and 2.5 below. Good communications between NHPP and the Program Managers were observed during the readiness review.

The National Radiation Safety Committee, comprised of senior DVA managers, Headquarters office representatives and field representatives, meets quarterly. The Committee is chaired by the Chief Patient Care Services. The Under Secretary for Health, to which the Chief Patient Care Services reports, is a member of the National Radiation Safety Committee. The NHPP, in accordance with procedures, coordinates the

meeting schedule and agenda. The agenda and core performance indicator results are sent to National Radiation Safety Committee members in advance. The NHPP Director serves as Executive Secretary for the Committee.

The entire review team attended one National Radiation Safety Committee meeting. In addition, one team member participated in another meeting by telephone. The review team also interviewed several Committee members about their roles in the program. Team observations generally indicated effective management of the radiation control program by the National Radiation Safety Committee; however, a lack of aggressiveness by the Committee with regard to incident follow-up was noted. This was discussed with the Deputy Chief Patient Care Services during the North Little Rock visit. He indicated that he would discuss the issue with the National Radiation Safety Committee. Although the National Radiation Safety Committee was less aggressive than expected, the review team noted that the NHPP, through Committee delegation, does, in fact, manage the radiation control program, including incident follow-up, in an assertive manner.

Previous interactions with DVA identified that communications between the NHPP and individual medical center licensees did not demonstrate the kind of centralized program necessary for a effective master materials license. The routing of NHPP correspondence to medical centers was modified in 1999 to go directly to the facilities rather than through the Veterans Integrated Service Networks (VISNs). This change improved the communications between NHPP and individual medical centers.

The review team tested the NHPP's communications ability by personally interviewing a large number of medical center radiation safety officers (RSOs). Team members visited 44 of the 118 licensed DVA facilities. Six standard questions (see Appendix C) were asked of each RSO during the interviews.

All of the interviewed RSOs were able to clearly describe the function and purpose of the NHPP and reported regular communications via telephone or e-mail with various NHPP technical staff. The RSOs applauded the responsiveness and technical quality of the NHPP staff, but they regretted the change from the more "hands-on" advice they used to get. This change, from a more consulting mode by the NHPP to a regulatory approach, was embraced by NHPP over the last two years. The monthly "NHPP Scatterings" newsletter and the "Frequently Asked Questions" portion of the NHPP website are tools to assist the licensees in the absence of the "consultant" role.

RSOs also have another resource for resolution of technical issues. An RSO consulting group, "Radiation Safety Center for Inquiry," is available, via web, for all RSOs. This mailgroup, of nine experienced RSOs, responds directly to questioners and is independent of NHPP.

Most of the medical centers that the team visited had been inspected by NHPP within the past two years. Inspection findings were communicated by NHPP through an inspection exit briefing followed by a written report. The RSOs were aware of the requirement to submit license amendment requests directly to NHPP and most had done so with one or more requests. They were also aware that they needed to notify the NHPP of reportable incidents and allegations.

Overall, the RSO visits identified a positive communication trend over the past three years. The team concluded that communications between NHPP and DVA medical centers are indicative of a functioning central program.

In June 1999, after receiving the negative response from the NRC, a program assessment plan was initiated with a preliminary assessment visit by an outside radiation safety consultant with master materials license experience. That assessment was followed by a radiation control program review by NHPP in summer 1999 which developed a master materials license action plan. An internal assessment in late 1999 monitored the action plan, performance indicators and milestones.

The next external assessment of the program, in February-March 2000, was performed by two consultants with master materials license experience. The consultants concluded that the DVA had a centrally controlled radiation program in place and was prepared to manage an NRC master materials license.

A National Radiation Safety Committee Working Group performed a program review, concluding in April 2000. This review used a checklist for major programmatic elements for a master materials license. The latest assessment was the National Radiation Safety Committee management evaluation. The Committee reviewed the program assessment results and other program data in its evaluation. The summary report, which indicated readiness for a masters material license, was presented to the Under Secretary for Health in August 2000. The review team evaluated the summary report and found it to be detailed and comprehensive.

The DVA master materials license application outlined six standard operating procedures (SOPs) which establish the essential programmatic elements for implementation of the license. These SOPs describe programs for: permitting, inspections, enforcement, training, incident response and allegations management. A total of 36 internal procedures were developed to execute the SOP requirements. The internal procedures are continually evaluated by NHPP staff to make them more effective. Adherence to SOPs and internal procedures by NHPP staff was noted by the review team.

Based on the evaluation criteria, the review team finds DVA's performance with respect to the indicator, Management Oversight and Radiation Control Program Procedures, satisfactory.

2.2 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licensees, and timely dispatch of inspection findings. The review team's evaluation is based on the DVA's questionnaire responses relative to this indicator, data gathered independently from the DVA's licensing and inspection data tracking system, the examination of completed inspection casework, and interviews with the staff.

The team confirmed that the DVA's inspection frequencies for the various types of licenses are at least as frequent as similar license types listed in the NRC Inspection Manual Chapter 2800, except in those cases where inspections were not scheduled due to recent NRC inspections. The DVA uses an algorithm to determine if a facility should be

inspected. For priority 1 or 2 licenses, the inspection is performed if a previous NRC or NHPP inspection was completed over one year previously. Frequencies for other priorities are done (as a minimum) if the time since the previous NRC or NHPP inspection exceeds 3 years.

In late 1999, the NHPP established an inspection goal of 60 inspections per year and a timeliness goal for transmitting inspection findings of 30 days from the inspection completion. There were 59 inspections completed in calendar year 2000. Of those 59 inspections, all but two inspection reports (issued in less than 40 days) were issued within 30 days. In the first two months of 2001, the NHPP performed 12 inspections. This performance level is consistent with actual work load anticipated for the NHPP if it had full master materials license responsibilities. The NRC performed 43 inspections of DVA licenses in 2000.

The staff maintains paper license files which contain complete documentation of all correspondence from each inspection conducted by the NHPP. Inspection reports, Notices of Violation, licensee reply letters and other correspondence from the inspection are maintained in the file.

The NHPP did not have any new licenses to inspect and does not anticipate any new licenses, however, they anticipate future consolidation of some licenses.

Based on the evaluation criteria, the review team finds DVA's performance with respect to the indicator, Status of Materials Inspection Program, satisfactory.

2.3 Technical Quality of Materials Inspections

The review team evaluated the inspection reports, enforcement documentation and inspection field notes, and interviewed inspectors for 19 inspections conducted during the review period. The casework included all five NHPP Regional Program Managers (inspectors) and covered inspections of various types including broadscope medical institutions, limited medical institutions and research and development laboratories. Appendix E lists the inspection casework evaluated for completeness and adequacy, with case-specific comments. None of the reports revealed programmatic weaknesses. The technical quality demonstrated by each of the NHPP inspectors was comparable to that observed with NRC inspectors. Team inspections were performed when appropriate. Based on casework evaluations, the review team noted that NHPP inspections covered all aspects of licensees' radiation safety programs.

The license files (both hard copy and electronic) for each DVA facility appeared complete from early 2000 to the present. 1999 was a transition period during which inspection reports and related documents took on a distinct NRC format. Prior to 1999 the files are less complete and not as well organized. Beginning in 2000, the inspection reports and violations have been written in a formal manner generally following NRC format. Follow-up documentation regarding corrective actions for violations and final corrective action acknowledgment letters were evident in all inspection files reviewed. NHPP does not use NRC Form 591-type field inspection forms.

Each of the five Program Managers were evaluated by a team member who accompanied them on inspections at DVA medical centers in Portland, OR; Augusta, GA; Northport, NY; Providence, RI and Birmingham, AL in February and March, 2001. During the accompaniments, all inspectors demonstrated appropriate inspection skills and knowledge of the regulations. They were well prepared and thorough in their review of licensee programs. Overall, the review team observed that the inspectors utilized good health physics practices and their interviews with licensee personnel were performed in an effective manner. The inspections were adequate to assess radiological health and safety at the licensed facilities.

Recently, the NHPP Director has been assigning occasional "out of region" inspections for each Program Manager. These are viewed as beneficial assignments by allowing both the DVA medical centers and Program Managers to experience each other's styles and programs.

The NHPP communicates effectively with the DVA radiation protection staff and management to resolve occasional misunderstandings and unresolved items. The NHPP Director reviews and concurs on all inspection reports, permittee replies and corrective actions and communicates with inspectors if there are questions or discrepancies.

Inspection accompaniments and inspection reports confirmed that instrumentation used by the Program Managers during their inspections were appropriate for the areas visited and were functioning properly and in calibration.

All of the Program Managers receive an annual inspection accompaniment and written evaluation by the NHPP Director. The review team observed the NHPP Director during an accompaniment. He was well prepared, gave sound, constructive advice to the inspector and related well with the licensee. The accompaniment was effectively performed.

Based on the evaluation criteria, the review team finds DVA's performance with respect to the indicator, Technical Quality of Materials Inspections, satisfactory.

2.4 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the DVA's questionnaire responses relative to this indicator, interviewed program management and staff, reviewed the DVA training program and job position descriptions, and considered any possible workload backlogs.

The NHPP personnel are assigned as headquarters-level staff reporting to the Chief Patient Care Services. The NHPP is staffed with a Director, five Program Managers, and six administrative personnel. There have been four staffing turnovers in the past three years. The former Director retired and one of the Program Managers was promoted into the position. The resulting vacant Program Manager's position was filled within two months. Two administrative personnel have left, one position was filled within two months, one position had been vacant one month at the time of this review. Candidates to be interviewed for that position have been selected.

The NHPP has initiated a virtual office concept as of January 2000. The five Program Managers are located in Arkansas, California, Maryland, Michigan and Washington, with the central office in Arkansas. The Director manages the program from the Arkansas location; where the records repository is maintained. The Director has sole signature authority for permit issuance. All permits and inspection reports are issued from the central office. The Director and Program Managers are all qualified to perform both licensing and inspection functions. The flexibility of the virtual office concept, and the cross training of the staff, allows the workload to be assigned based on needed expertise or experience, and allows the work to progress while personnel are on leave or on assignment. Different Program Managers are also assigned areas in which they have developed additional expertise. For example, there are specialists in the areas of decommissioning and high dose rate remote brachytherapy. The support staff are also cross-trained to perform all administrative functions and have completed rotational assignments in the Arkansas office.

The team determined that the program has a well balanced staff, and a sufficient number of trained personnel to carry out the regulatory duties of a master materials license program.

The NHPP developed a written training program, based on the requirements specified in NRC Inspection Manual Chapter 1246, for the technical staff, including the use of qualification journals and a oral qualification board. The NHPP program, however, does not contain the non-medical specialized training, since the DVA is limited to medical and academic/research radionuclide use. The Program Managers have all completed the NRC's basic inspection and licensing courses, as well as some of the other NRC courses. The NHPP is scheduling its Program Managers for the other NRC courses as space becomes available, while maintaining the inspection and licensing work load.

The team reviewed the training and experience of the current technical staff, including the Director, and found the following: all have an undergraduate degree in an applicable discipline, most have a Masters degree, and one of the Program Managers has a Doctoral degree. All have served as the Radiation Safety Officer for a broadscope materials license and have experience in the field of health physics ranging from 15 to 25 years.

The NHPP has implemented an aggressive ongoing training program. Regulatory and technical issues are addressed during the Program Managers' quarterly meetings in Arkansas where technical reading is assigned, and staff are encouraged to participate in training outside of the DVA.

The team confirmed the technical staff's qualifications thorough a review of their training and experience and verified their performance through licensing and compliance casework and inspection accompaniments.

Based on the evaluation criteria, the review team finds DVA's performance with respect to the indicator, Technical Staffing and Training, satisfactory.

2.5 Technical Quality of Materials Licensing Actions

The review team examined licensing casework and interviewed staff for 17 specific DVA licenses. Licensing actions were evaluated for completeness, consistency, proper

isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality. Casework was evaluated for timeliness; adherence to good health physics practices; reference to appropriate regulations; product certifications or other supporting documents; consideration of enforcement history on renewals; pre-licensing visits; supervisory review as indicated; and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions that were reviewed for DVA programs during the review period. The sampling included the following types: medical broadscope, limited medical institution, research and development broadscope and teletherapy. Types of licensing actions selected for evaluation included 12 amendments to existing licenses, three license renewals, and two terminations. In discussion with the Program Managers, it was noted that there were no new license requests or license actions submitted with potential significant environmental impact or complex decommissioning activities. A list of the licenses evaluated with case-specific comments may be found in Appendix F.

In addition to examining licensing casework, the review team performed an assessment of the NHPP Permit Control Tracking System (Virtual Office). The system is utilized by the NHPP to track licensing casework and maintain an electronic centrally controlled file database. Licensing actions are submitted to the NHPP North Little Rock office by medical center Radiation Safety Officers. Upon receipt, licensing actions to be reviewed are entered into the database, scanned and electronically filed and archived. The licensing actions are then electronically provided to a Program Manager's office for review. Upon completion of the review, the licensing actions are submitted to the NHPP Director via the tracking system for final review and approval. The approved licensing actions are then forwarded to NRC for review, approval and issuance of the license amendment.

The review team found the tracking system to be very user friendly, extremely efficient, and a useful tool in assisting the NHPP staff in reviewing the license requests. The review team noted that the tracking system allowed the staff to have the appropriate access to license guidance documents (i.e., license files, guide criteria, inspection history, etc.). In addition, the tracking system provided every staff reviewer with the capability to review the status of any licensing action from start to completion. The system also assures that information will be readily retrievable for staff use and for program assessments.

The casework evaluation indicated that the staff follows appropriate licensing guides, policies, procedures and directives during the review process to ensure that the submitted information supports the licensing request. The review team found the licensing checklists used for each type of program to be comprehensive. A detailed checklist was developed for each type of license reviewed. These checklists contained excellent information to assist the staff with their review of the applications. The review team observed notable consistency between the reviewers as a result. Deficiencies identified during the license review were addressed by letters and documented telephone conversations. The review team determined that the letters and telephone conversations contained appropriate regulatory language and detailed, useful information. All licensing actions are signed by the NHPP Director and forwarded to NRC.

It should be noted that none of the licensing actions examined by the team required a financial assurance submission. The team found that terminated actions were well documented. The license files included the appropriate material transfer and survey records, including proper disposal records.

Overall, the review team found that the licensing casework was thorough, complete, consistent, and of high quality, with health and safety issues adequately addressed. No potentially significant health and safety issues were identified.

Based on the evaluation criteria, the review team finds that DVA's performance with respect to the indicator, Technical Quality of Materials Licensing Actions, satisfactory.

2.6 Response to Incidents and Reported Radiation Safety Concerns and Allegations

In evaluating the effectiveness of the DVA's actions in responding to incidents, the review team examined the DVA's response to the questionnaire regarding this indicator and evaluated all nine incidents reported for the period October 1, 1998 to March 1, 2001. The "Nuclear Material Events Database" (NMED) was checked against those incidents contained in the DVA's files.

The DVA reported no allegations received for the period. Although this is not consistent with the number of NRC allegations received from the DVA facilities during the same period, it may reflect a tendency for individuals to seek an independent agency review. NHPP contact information is posted at each medical center for reporting of incidents and allegations. The DVA recorded one radiation safety concern received by the executive management at a medical center. NHPP responded with a site visit as requested by the facility management. Interviews were conducted, the concern was reviewed, and appropriately addressed.

Nine incidents were reviewed by the review team and are listed in Appendix G. They included lost material, misadministrations, procedural failures, equipment failures, and the receipt of a contaminated package. When notification of an incident or an allegation is received, the Program Manager and staff normally meet to discuss the initial response and the need for an on-site investigation. The safety significance of the incident/allegation is evaluated to determine the type of response that the DVA will take.

The small size of the DVA program allows for the prompt dissemination of information regarding the event to all personnel in the program. Radiological incidents can be reported 24 hours a day through the use of the Department's emergency telephone number and paging system. NHPP has established internal procedures for handling incidents and generally follows NRC written guidance for handling allegations. The review team identified one difference between DVA and NRC allegation programs. NHPP plans to visit a site when an allegation is received, prior to submitting the allegation for review by an allegation review board. The NHPP Director believes this will allow them to collect additional information that may be useful to those who will determine the best course of action for the evaluation of the allegation.

The review team found that the DVA's responses to incidents were within the performance criteria. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. Inspectors were dispatched for

on-site investigations when appropriate and the DVA took suitable action. The review team found the documentation of the incidents to be appropriately maintained.

Based on the evaluation criteria, the review team finds that DVA's performance with respect to the indicator, Response to Incidents and Reported Radiation Safety Concerns and Allegations, satisfactory.

3.0 SUMMARY

As noted in Section 2 above, the review team found the DVA's performance to be satisfactory for all six performance indicators. Accordingly, the team concluded that the DVA is ready, from an organizational and technical standpoint, to effectively implement a master materials license.

LIST OF APPENDICES

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Appendix D	Communications Visits
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Appendix F	License Casework Reviews
Appendix G	Incident Casework Reviews

Appendix A

READINESS REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Lynch, Region III	Team Leader Management Oversight and Radiation Control Program Procedures
James Montgomery, Region IV	Technical Quality of Materials Inspections
Cassandra Frazier, Region III	Technical Quality of Materials Licensing Actions
Orysia Masnyk Bailey, Region II	Technical Staffing and Training
Thomas Thompson, Region I	Status of Materials Inspection Program Response to Incidents and Reported Radiation Safety Concerns and Allegations
Maureen Moriarty, NMSS	Technical Quality of Materials Licensing Actions

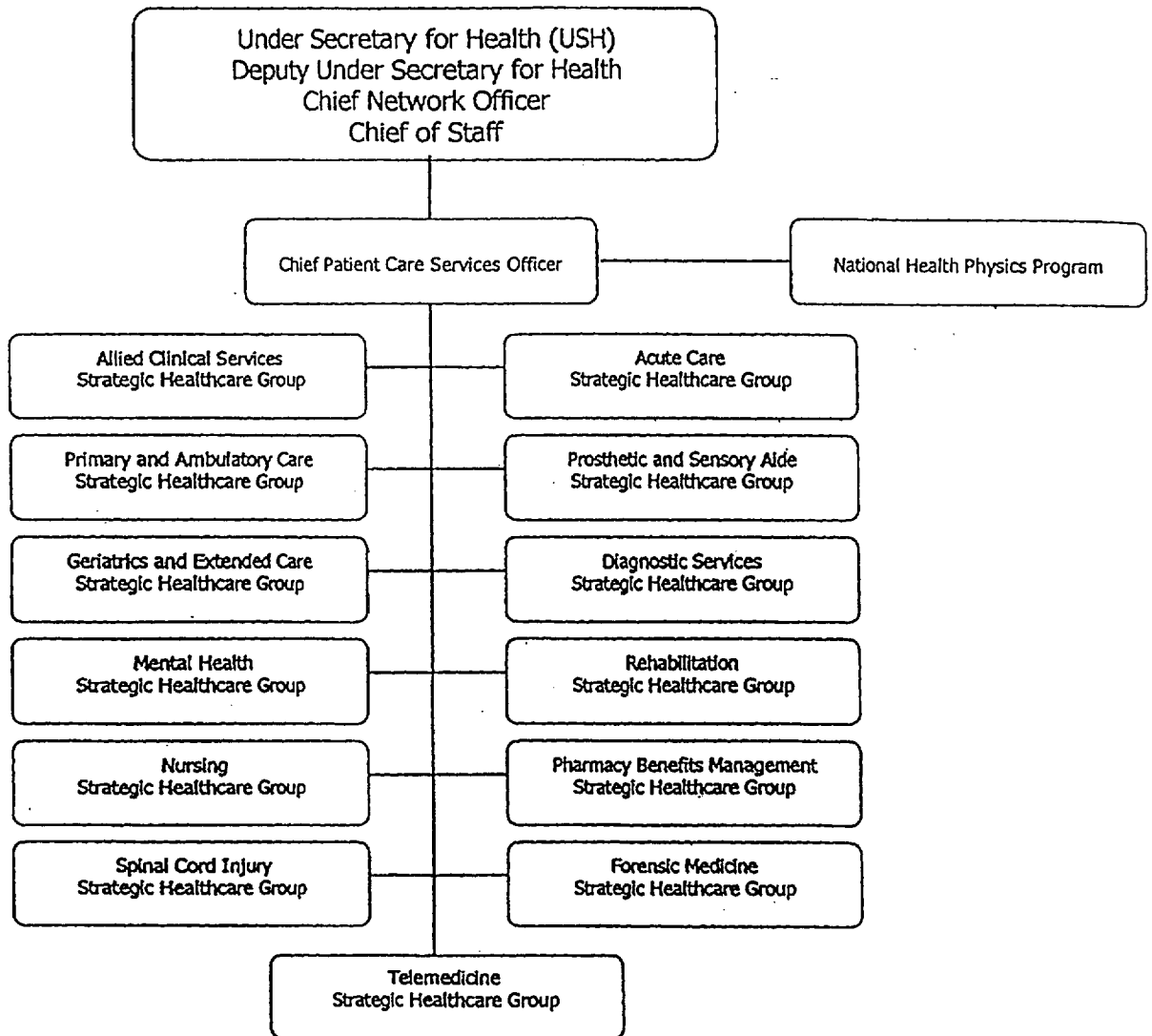
Appendix B

Department of Veterans Affairs

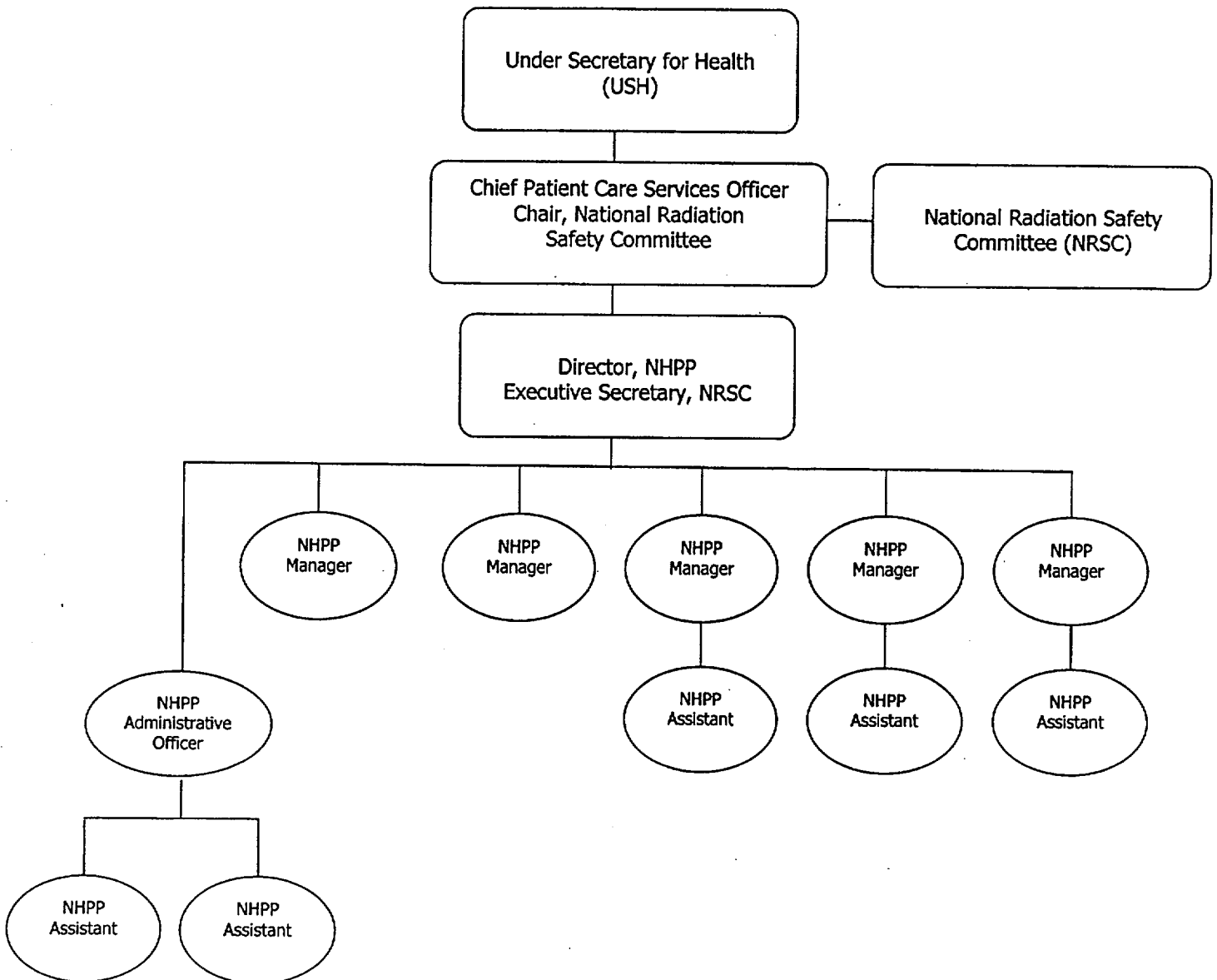
Veterans Health Administration

Organization Charts

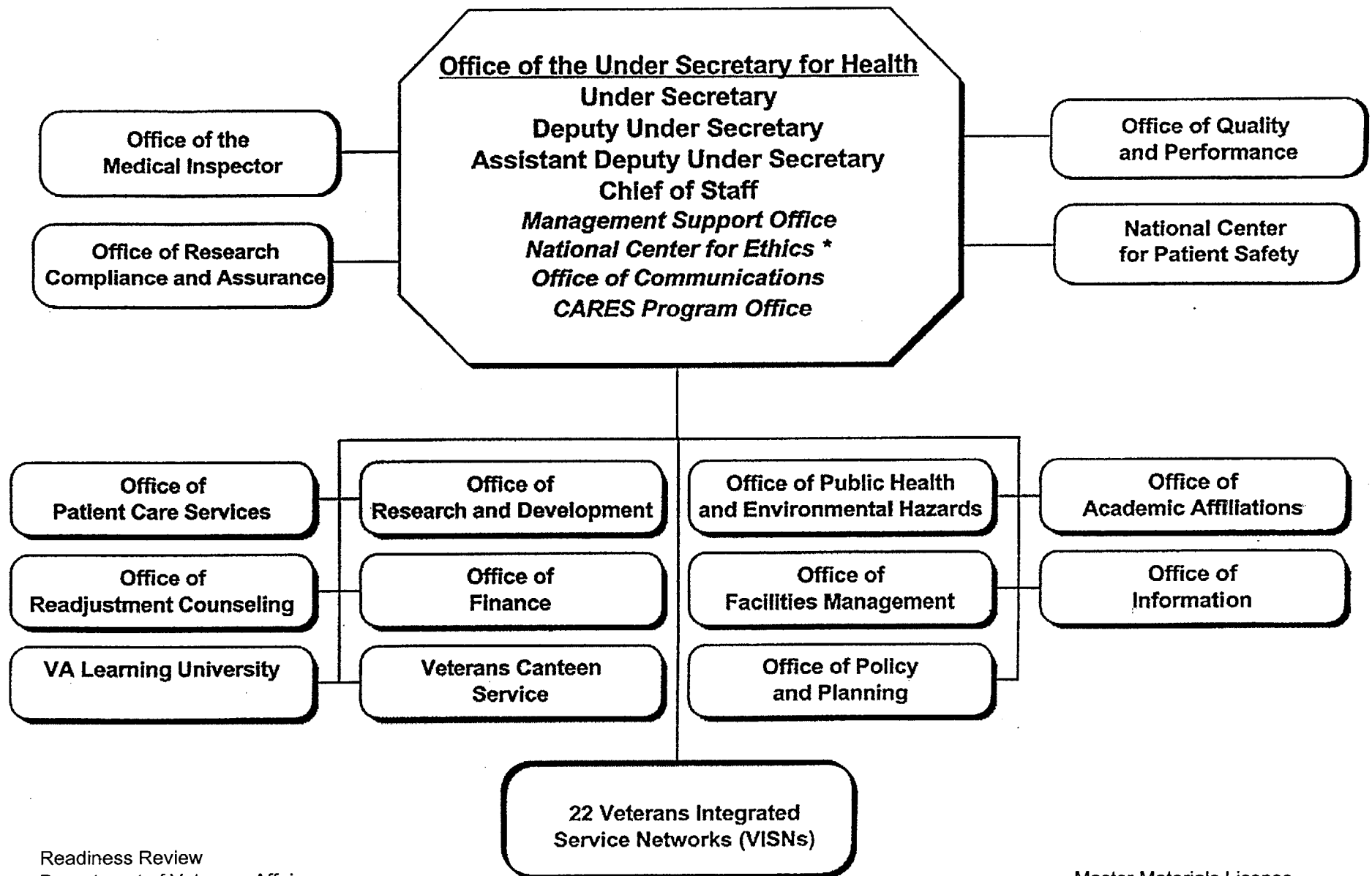
Veterans Health Administration



Veterans Health Administration
National Radiation Safety Committee (NRSC)
and the
National Health Physics Program (NHPP) Organization



VETERANS HEALTH ADMINISTRATION



Appendix C

COMMUNICATIONS VISIT SURVEY

Questions to ask RSOs during VA visits

1. Describe, to the best of your knowledge, the function and purpose of the VHA National Health Physics Program (NHPP).
2. How does the NHPP communicate with you? Who specifically?
3. Have you found the need to contact the NHPP?
4. How often does the NHPP perform an inspection at your facility? Who did the last inspection? Did NHPP communicate the results of their inspection?
5. Describe the process that you would follow if you needed an amendment to your license/permit?
6. Describe the process that you would follow to report an incident, e.g., a misadministration or an allegation/concern.

Appendix D

COMMUNICATION VISITS

Facility: Birmingham, AL
Date: 3/27/01

License No. 01-00643-02
NRC Reviewer: JL

Facility: Tuskegee, AL
Date: 3/26/01

License No. 01-03042-02
NRC Reviewer: JL

Facility: Tucson, AZ
Date: 3/28/01

License No. 02-06186-01
NRC Reviewer: KN

Facility: Phoenix, AZ
Date: 3/27/01

License No. 02-10072-01
NRC Reviewer: KN

Facility: Prescott, AZ
Date: 3/29/01

License No. 02-12726-01
NRC Reviewer: KN

Facility: Little Rock, AR
Date: 6/5/01

License No. 03-01082-01
NRC Reviewer: OB

Facility: W. Los Angeles, CA
Date: 4/5/01

License No. 04-00181-04
NRC Reviewer: JM

Facility: Long Beach, CA
Date: 4/6/01

License No. 04-00689-07
NRC Reviewer: JM

Facility: Sepulveda, CA
Date: 4/5/01

License No. 04-00916-04
NRC Reviewer: JM

Facility: Martinez, CA
Date: 6/11/01

License No. 04-02956-02
NRC Reviewer: JM

Facility: San Diego, CA
Date: 4/6/01

License No. 04-15030-01
NRC Reviewer: JM

Facility: Loma Linda, CA
Date: 4/5/01

License No. 04-17862-01
NRC Reviewer: JM

Facility: Wilmington, DE
Date: 5/7/01

License No. 07-09495-01
NRC Reviewer: TT

Facility: Miami, FL
Date: 5/1/01

License No. 09-00239-06
NRC Reviewer: OB

Facility: Gainesville, FL
Date: 5/4/01

License No. 09-12467-02
NRC Reviewer: OB

Facility: Augusta, GA Date: 2/6/01	License No. 10-08389-03 NRC Reviewer: OB
Facility: Hines, IL Date: 4/5/01	License No.: 12-01087-07 NRC Reviewer: CF
Facility: Chicago-WS, IL Date: 4/5/01	License No. 12-01403-01 NRC Reviewer: CF
Facility: Chicago-LS, IL Date: 4/5/01	License No. 12-02642-06 NRC Reviewer: CF
Facility: Danville, IL Date: 2/13/01	License No. 12-16473-01 NRC Reviewer: JL
Facility: North Chicago, IL Date: 4/4/01	License No. 12-10057-04 NRC Reviewer: CF
Facility: Indianapolis, IN Date: 2/14/01	License No. 13-00694-03 NRC Reviewer: JL
Facility: Togus, ME Date: 5/10/01	License No. 18-07561-01 NRC Reviewer: TT
Facility: Baltimore, MD Date: 5/7/01	License No. 19-01058-02 NRC Reviewer: TT
Facility: Boston, MA Date: 5/10/01	License No. 20-00671-02 NRC Reviewer: TT
Facility: Ann Arbor, MI Date: 5/22/01	License No. 21-00159-04 NRC Reviewer: CF
Facility: Minneapolis, MN Date: 4/13/01	License No. 22-01859-01 NRC Reviewer: JL
Facility: St. Louis, MO Date: 4/11/01	License No. 24-00144-05 NRC Reviewer: CF
Facility: Kansas City, MO Date: 4/12/01	License No. 24-00496-06 NRC Reviewer: CF
Facility: Manchester, NH Date: 5/9/01	License No. 28-27885-01 NRC Reviewer: TT
Facility: East Orange, NJ Date: 3/23/01	License No. 29-04481-01 NRC Reviewer: OB
Facility: New York, NY Date: 3/22/01	License No. 31-00032-04 NRC Reviewer: OB

Facility: Albany, NY
Date: 5/8/01

License No. 31-02755-05
NRC Reviewer: TT

Facility: Northport, NY
Date: 3/19/01

License No. 31-13511-04
NRC Reviewer: OB

Facility: Bronx, NY
Date: 3/21/01

License No. 31-00636-07
NRC Reviewer: OB

Facility: Portland, OR
Date: 3/22/01

License No. 36-01395-01
NRC Reviewer: JM

Facility: Wilkes-Barre, PA
Date: 5/8/01

License No. 37-13483-01
NRC Reviewer: TT

Facility: Philadelphia, PA
Date: 6/18/01

License No. 37-00062-07
NRC Reviewer: OB

Facility: San Juan, PR
Date: 6/8/01

License No. 52-04359-01
NRC Reviewer: JL

Facility: San Antonio, TX
Date: 6/18/01

License No. 42-15881-01
NRC Reviewer: JM

Facility: White River Jct., VT
Date: 5/9/01

License No. 44-05123-01
NRC Reviewer: TT

Facility: Seattle, WA
Date: 5/8/01

License No. 46-00990-01
NRC Reviewer: JM

Facility: Madison, WI
Date: 2/12/01

License No. 48-01183-01
NRC Reviewer: KN

Facility: Milwaukee, WI
Date: 5/24/01

License No. 48-02130-02
NRC Reviewer: CF

Appendix E

INSPECTION CASEWORK REVIEWS

File No. 1

Licensee: Indianapolis, IN
License Type: Broadscope Medical
Inspection Date: 2/14-15/01

License No. 10-08389-03
Priority: 1
Inspector: JW

File No. 2

Licensee: Las Vegas, NV
License Type: Limited Medical
Inspection Date: 6/21-22/99

License No. 27-23287-02
Priority: 3
Inspector: EL

File No. 3

Licensee: Kerrville, TX
License Type: Limited Medical
Inspection Date: 12/8-9/99

License No. 42-17691-01
Priority: 3
Inspector: EL

File No. 4

Licensee: Shreveport, LA
License Type: Limited Medical
Inspection Date: 5/23-24/00

License No. 17-12273-01
Priority: 3
Inspector: EL

File No. 5

Licensee: Syracuse, NY
License Type: Limited Medical
Inspection Date: 4/4/01

License No. 31-00845-01
Priority: 3
Inspector: JW

File No. 6

Licensee: W. Palm Beach, FL
License Type: Limited Medical
Inspection Date: 2/28/00

License No. 09-25328-01
Priority: 3
Inspector: MS

File No. 7

Licensee: Wichita, KS
License Type: In-Vitro Laboratory
Inspection Date: 2/2/00

License No. 15-15618-01
Priority: 5
Inspector: EL

File No. 8

Licensee: Boston, MA
License Type: Broadscope Medical
Inspection Date: 6/21-22/00

License No. 20-00671-02
Priority: 1
Inspector: JW

File No. 9

Licensee: Bronx, NY
License Type: Limited Medical
Inspection Date: 1/19/00

License No. 31-00636-07
Priority: 3
Inspector: PY

File No. 10
Licensee: Castle Point, NY
License Type: Custom Medical
Inspection Date: 5/25/00

License No. 31-11399-01
Priority: 5
Inspector: PY

File No. 11
Licensee: Cincinnati, OH
License Type: Limited Medical
Inspection Date: 4/25-26/00

License No. 34-00799-03
Priority: 3
Inspector: JW

File No. 12
Licensee: Martinez, CA
License Type: Limited Medical
Inspection Date: 4/14/99

License No. 04-02956-02
Priority: 3
Inspector: EL

File No. 13
Licensee: Portland, OR
License Type: Limited Medical
Inspection Date: 3/21-22/01

License No. 36-01395-01
Priority: 3
Inspector: MS

File No. 14
Licensee: Asheville, NC
License Type: Limited Medical
Inspection Date: 3/21/00

License No. 32-05830-01
Priority: 3
Inspector: PY

File No. 15
Licensee: Salt Lake City, UT
License Type: Limited Medical, R&D Broadscope
Inspection Date: 11/15-16/00

License No. 43-03299-01
Priority: 2
Inspector: MS

File No. 16
Licensee: Augusta, GA
License Type: Limited Medical, R&D Broadscope
Inspection Date: 2/6-7/01

License No. 10-08389-03
Priority: 2
Inspector: EL

File No. 17
Licensee: Northport, NY
License Type: Limited Medical
Inspection Date: 3/19-20/01

License No. 31-13511-04
Priority: 3
Inspector: PY

File No. 18
Licensee: Providence, RI
License Type: Limited Medical
Inspection Date: 3/8/01

License No. 38-04946-01
Priority: 3
Inspector: JW

File No. 19
Licensee: Birmingham, AL
License Type: Limited Medical, R&D Broadscope
Inspection Date: 3/27-28/01

License No. 01-00643-02
Priority: 2
Inspector: GW

INSPECTOR ACCOMPANIMENTS

In addition, the following inspection accompaniments were performed as part of the readiness review.

Accompaniment No. 1

Licensee: Augusta, GA

License Type: Limited Medical, R&D Broadscope

Inspection Date: 2/6-7/01

License No. 10-08389-03

Priority: 2

Inspector: EL

Accompaniment No. 2

Licensee: Indianapolis, IN

License Type: Broadscope Medical

Inspection Date: 2/14-15/01

License No. 13-00694-03

Priority: 1

Inspectors: JW, LM

Comments:

- a) Supervisory accompaniment by NHPP Director.
- b) Inspector did not have dosimetry.

Accompaniment No. 3

Licensee: Providence, RI

License Type: Limited Medical

Inspection Date: 3/8/01

License No. 38-04946-01

Priority: 3

Inspector: JW

Comment:

- a) Inspector did not have dosimetry.

Accompaniment No. 4

Licensee: Northport, NY

License Type: Limited Medical

Inspection Date: 3/19-20/01

License No. 31-13511-04

Priority: 3

Inspector: PY

Accompaniment No. 5

Licensee: Portland, OR

License Type: Limited Medical

Inspection Date: 3/21-22/01

License No. 36-01395-01

Priority: 3

Inspector: MS

Accompaniment No. 6

Licensee: Birmingham, AL

License Type: Limited Medical, R&D Broadscope

Inspection Date: 3/27-28/01

License No. 01-00643-02

Priority: 2

Inspector: GW

Appendix F

LICENSING CASEWORK REVIEWS

File No. 1

Licensee: Hampton, VA
License Type: Limited Medical
Amendment No. N/A
Date Issued: Not yet Issued
Comment:

License No. 45-07569-01
Type of Action: Renewal
License Reviewer: GW

- a) The renewal application was forwarded to NRC without NHPP technical review due to timeliness requirements. Subsequently, however, an extensive review of the renewal was performed by NHPP, including a site visit of the facility. The NRC regional staff compared their review to the NHPP review and found similar deficiencies. The Regional Office has not yet issued the renewal.

File No. 2

Licensee: Nashville, TN
License Type: Limited Medical, R&D Broadscope
Amendment No. 44
Date Issued: 3/15/01
Comment:

License No. 41-00104-04
Type of Action: Amendment
License Reviewer: GW

- a) NHPP technical review of a request to add a Ir-192 Cordis Checkmate System failed to identify several issues identified during the NRC technical review. Note however, that NRC was in the process of establishing guidelines.

File No. 3

Licensee: Boston, MA
License Type: Broadscope Medical
Amendment No. 56
Date Issued: 9/19/00

License No. 20-00671-02
Type of Action: Amendment
License Reviewer: JW

File No. 4

Licensee: Milwaukee, WI
License Type: Limited Medical
Amendment No. 73
Date Issued: 10/28/00

License No. 48-02130-02
Type of Action: Amendment
License Reviewer: GW

File No. 5

Licensee: Indianapolis, IN
License Type: Broadscope Medical
Amendment No. 44
Date Issued: 10/24/00

License No. 13-00694-03
Type of Action: Amendment
License Reviewer: JW

File No. 6
Licensee: Saginaw, MI
License Type: Limited Medical
Amendment No. 07
Date Issued: 6/1/01
Comment:

License No. 21-25815-01
Type of Action: Amendment
License Reviewer: JW

- a) NHPP should categorize as program code 02121, "medical institution - QMP not required"

File No. 7
Licensee: San Juan, PR
License Type: Limited Medical
Amendment No. 38
Date Issued: 3/5/01

License No. 52-04359-01
Type of Action: Renewal
License Reviewer: GW

File No. 8
Licensee: Kansas City, MO
License Type: R&D
Amendment No. 73
Date Issued: 12/8/00

License No. 24-00496-06
Type of Action: Amendment
License Reviewer: GW

File No. 9
Licensee: Richmond, VA
License Type: Limited Medical, R&D Broadscope
Amendment No.: N/A
Date Issued: Not yet Issued
Comment:

License No. 45-09413-06
Type of Action: Renewal
License Reviewer: GW

- a) The renewal application was forwarded to NRC without NHPP technical review due to timeliness requirements. Subsequently, however, an extensive review of the renewal was performed by NHPP. The NRC regional staff compared their review to the NHPP review and found similar deficiencies. The Regional Office has not yet issued the renewal.

File No. 10
Licensee: Temple, TX
License Type: Limited Medical
Amendment No. 28
Date Issued: 3/14/01

License No. 42-10739-03
Type of Action: Amendment
License Reviewer: MS

File No. 11
Licensee: Albuquerque, NM
License Type: Broadscope Medical
Amendment No. 50
Date Issued: 5/15/01

License No. 30-01747-02
Type of Action: Amendment
License Reviewer: MS

File No. 12
Licensee: Kerrville, TX
License Type: Limited Medical
Amendment No. 20
Date Issued: 6/28/00

License No. 42-17691-01
Type of Action: Amendment
License Reviewer: EL

File No. 13
Licensee: Sioux Falls, SD
License Type: Limited Medical
Amendment No. 43
Date Issued: 2/14/00

License No. 40-16336-01
Type of Action: Amendment
License Reviewer: MS

File No. 14
Licensee: Syracuse, NY
License Type: Limited Medical
Amendment No. 65
Date Issued: 12/20/99

License No. 31-00845-01
Type of Action: Amendment
License Reviewer: JW

File No. 15
Licensee: San Juan, PR
License Type: Limited Medical
Amendment No. 39
Date Issued: 4/20/01

License No. 52-04359-01
Type of Action: Amendment
License Reviewer: GW

File No. 16
Licensee: W. Los Angeles, CA
License Type: Teletherapy
Amendment No. 16
Date Issued: 2/28/00

License No. 04-00181-12
Type of Action: Termination
License Reviewer: LM

File No. 17
Licensee: West Roxbury, MA
License Type: Broadscope Medical
Amendment No. 56
Date Issued: 9/19/00

License No. 20-08551-01
Type of Action: Termination
License Reviewer: JW

Appendix G

INCIDENT CASEWORK REVIEWS

File No. 1

Licensee: W. Los Angeles, CA

Date of Incident: 2/24/99

Type of Investigation: Telephone contact

Licensee No. 04-00181-12

Type of Incident: Door Interlock Malfunction

Investigation Date: 2/24/99

Summary of Incident and Final Disposition: Licensee reported that the teletherapy door interlock failed such that treatment was interrupted when the door opened, however, treatment would resume when the door was closed without resetting the unit. The manufacturer was contacted and repairs were made to the interlock switch. Clinical use was terminated in May 1999.

File No. 2

Licensee: Iowa City, IA

Date of Incident: 3/1/00

Type of Investigation: Site visit

Licensee No. 14-00181-12

Type of Incident: Damaged Sealed Source

Investigation Dates: 3/7-9/00

Summary of Incident and Final Disposition: Individuals servicing a liquid scintillation counter containing a generally licensed check source were not properly trained. An internal calibration source was damaged. Two violations were issued by the NHPP.

File No. 3

Licensee: Iowa City, IA

Date of Incident: 5/13/98

Type of Investigation: Site visit

Licensee No. 14-00181-12

Type of Incident: Procedural Failure

Investigation Dates: 1/13/99, 2/27/99

Summary of Incident and Final Disposition: A patient who received 40.29 millicuries of tin-117m may have been inadvertently released without proper instructions. The licensee classified the incident as a reportable event. NHPP accompanied NRC on 2/27/99 inspection and determined that the incident was not required to be reported. No violation was issued.

File No. 4

Licensee: Hines, IL

Date of Incident: 4/2/99

Type of Investigation: Site visit

License No. 12-01087-09

Type of Incident: Teletherapy Misadministration

Investigation Date: 4/8/99

Summary of Incident and Final Disposition: Wrong patient was treated with the teletherapy device. NHPP conducted an on-site inspection and subsequently issued a Confirmatory Action Letter. Four violations were issued relating to the misadministration and failure to report the misadministration within 24 hours.

File No. 5

Licensee: Hines, IL

Date of Incident: 9/23/99

Type of Investigation: Site visit

License No. 12-01087-09

Type of Incident: HDR Misadministration

Investigation Date: 9/27/99

Summary of Incident and Final Disposition: Treatment plan was incorrectly entered into the HDR operating console. NHPP performed an on-site visit and identified two violations associated with the event.

File No. 6

Licensee: Durham, NC

Date of Incident: 5/28/99

Type of Investigation: Site visit

License No. 32-01134-01

Type of Incident: Lost I-125 Seeds

Investigation Date: 6/1/99

Summary of Incident and Final Disposition: The licensee reported losing two iodine-125 prostate implant seeds when a patient's urine was disposed in the sanitary sewer, contrary to licensee's procedures. The NHPP forwarded the written report to NRC.

File No. 7

Licensee: Birmingham, AL

Date of Incident: 5/3/00

Type of Investigation: Telephone contact

License No. 01-00643-02

Type of Incident: Contaminated Package

Investigation Date: 5/3/00

Summary of Incident and Final Disposition: The licensee reported receiving an externally contaminated package (606 dpm per 100 square centimeters) of technetium-99m from a radiopharmacy. The licensee notified NRC and the radiopharmacy as required.

File No. 8

Licensee: Albany, NY

Date of Incident: 8/9/00

Type of Investigation: Site visit

License No. 31-02755-05

Type of Incident: I-131 Therapy Misadministration

Investigation Date: 8/30/00

Summary of Incident and Final Disposition: The licensee identified that a dose of Iodine-131 was not delivered as prescribed because one of two capsules was not administered. The licensee had an opportunity to call the patient back and administer the missed capsule but in consultation with the physician determined this was not necessary. The licensee contacted NRC on 8/14/00 to discuss. NRC determined this constituted a misadministration. NHPP conducted an onsite inspection and issued a violation.

File No. 9

Licensee: Palo Alto, CA

Date of Incident: 9/10/98

Type of Investigation: Telephone contact

License No. 04-23242-01

Type of Incident: Loss of Material

Investigation Date: 9/25/98

Summary of Incident and Final Disposition: The licensee identified the loss of a vial containing 1.35 millicuries of sulfur-35 and reported it to the NRC during an ongoing inspection 9/15/98. The licensee reported the incident to NHPP on 9/25/98. The NRC Operations Office was notified on 10/7/98.