

March 7, 1985

npi James G. Keppler
Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: License No. 12-18044-01MD 14-19990-01MD
20-21227-01MD 37-18461-01MD
37-19586-01MD 37-21322-01
48-17466-01MD

Reference: EA 84-100 Order Modifying Licenses of Nuclear
Pharmacy, Inc. (NPI): Dated October 26, 1984

Hydro Nuclear Services Comprehensive Radiation
Protection Program Evaluation: Dated February 21,
1985.

Dear Mr. Keppler:

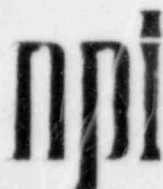
As required by Item V.B. of the NRC's referenced Order, enclosed is Nuclear Pharmacy Incorporated's written response to the conclusions of Hydro Nuclear Services' (HNS) report of their evaluation of NPI's radiation protection program. As documented in the enclosure, NPI does not take issue with any of HNS's findings. Each finding has been either incorporated into our program or longer term corrective actions have been initiated to be completed as expeditiously as possible. Once these longer term corrective actions are completed we are confident that NPI's radiation safety program will not only be in full compliance with all of your regulations, but also will be among the best programs inspected by your staff.

Although each individual item is addressed in the enclosure, certain areas need to be emphasized. We have undergone a complete reorganization. By rehiring Robert McClintock as our Vice President of Quality and Regulatory Affairs, we have brought a professional Health Physicist into our management team. In addition, Bob is an independent, tough-minded regulator who will not allow regulatory concerns in the pharmacies to remain unheard by management. By transferring our former Vice President of Professional and Regulatory Affairs, Steve Dessel, to Vice President of Operations, we are assured that the Operations Division is fully integrated with Regulatory at all levels. Changes of the District Manager and Pharmacy Manager in Chicago bring more experience and dedication to those critical positions. Staffing increases in Chicago will minimize overwork and eliminate employee burnout.

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In order to maintain a high level of management oversight, I will continue to be personally involved in the Operations of the NRC regulated pharmacies. In addition, the audit program has been greatly expanded to include regulatory, district manager and pharmacy manager audits which will concentrate on followup and corrective actions rather than just on problem identification. A summary of all audit findings will be presented monthly to the Radiation Safety Committee by the Vice President of Quality and Regulatory Affairs. By expanding the Committee to include all company officers and by scheduling monthly meetings, senior management is assured that all regulatory concerns and audit results are fully discussed by all effected management personnel.

The new NPI computer system has been installed, debugged and made operational in Des Moines. We plan to have similar systems in Harrisburg, Boston and Milwaukee within a month. Progress in debugging the software in Chicago and Philadelphia has been slower than anticipated due to the complexity of operations in these facilities. However, we are confident that the system will be fully operational by summer. This system will not only prevent many of the mistakes made in Chicago, but also will act as an independent verifier for management to assure that all of the required tests, assays and surveys are performed as required.

All of HNS's technical suggestions have been incorporated into our program. NPI is pleased that our Radiation Safety program was subjected to an intensive review without major changes. Our actions in this area will concentrate on documenting the program in a workable procedures manual and initiating an extensive training program, including videotapes, to assure all employees are thoroughly familiar with the contents of the manual.

It is our hope that the NRC recognizes that NPI has responded to the Order in good faith. The Order has been traumatic to the company in personnel, operational and financial aspects. We are therefore eager to get back into a routine, non-crisis management mode. For this reason we are requesting that Hydro Nuclear Services include an evaluation of the NPI audit program in their next audits. If the next HNS audits show that the NPI compliance program is continuing its present high



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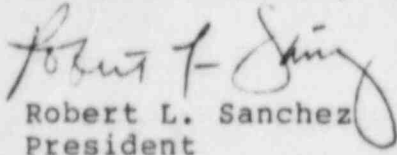
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standard and if HNS' evaluations of the NPI audit program is favorable, then we plan to request the Order be lifted, that our licenses be amended to include our corrective actions, and that no further enforcement action be taken.

If you have any questions concerning this report, please contact me.

Sincerely,

NUCLEAR PHARMACY, INC.

A handwritten signature in cursive script, appearing to read 'Robert L. Sanchez', is written over the typed name and title.

Robert L. Sanchez
President

Enclosure: NPI response to HNS report

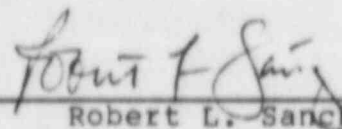
RLS/gav

cc: J. Taylor (NRC-HQ)
D. Neely (HNS)

EVALUATION OF HYDRO NUCLEAR SERVICES'
COMPREHENSIVE RADIATION PROTECTION
PROGRAM EVALUATION DATED FEBRUARY 21, 1985

MARCH 7, 1985

APPROVED BY



Robert L. Sanchez, President

Introduction

Nuclear Pharmacy Incorporated has evaluated HNS's referenced document. We do not take issue with any of their recommendations. The following document describes how NPI plans to incorporate and implement the recommendations. Appendix A is a schedule for implementation.

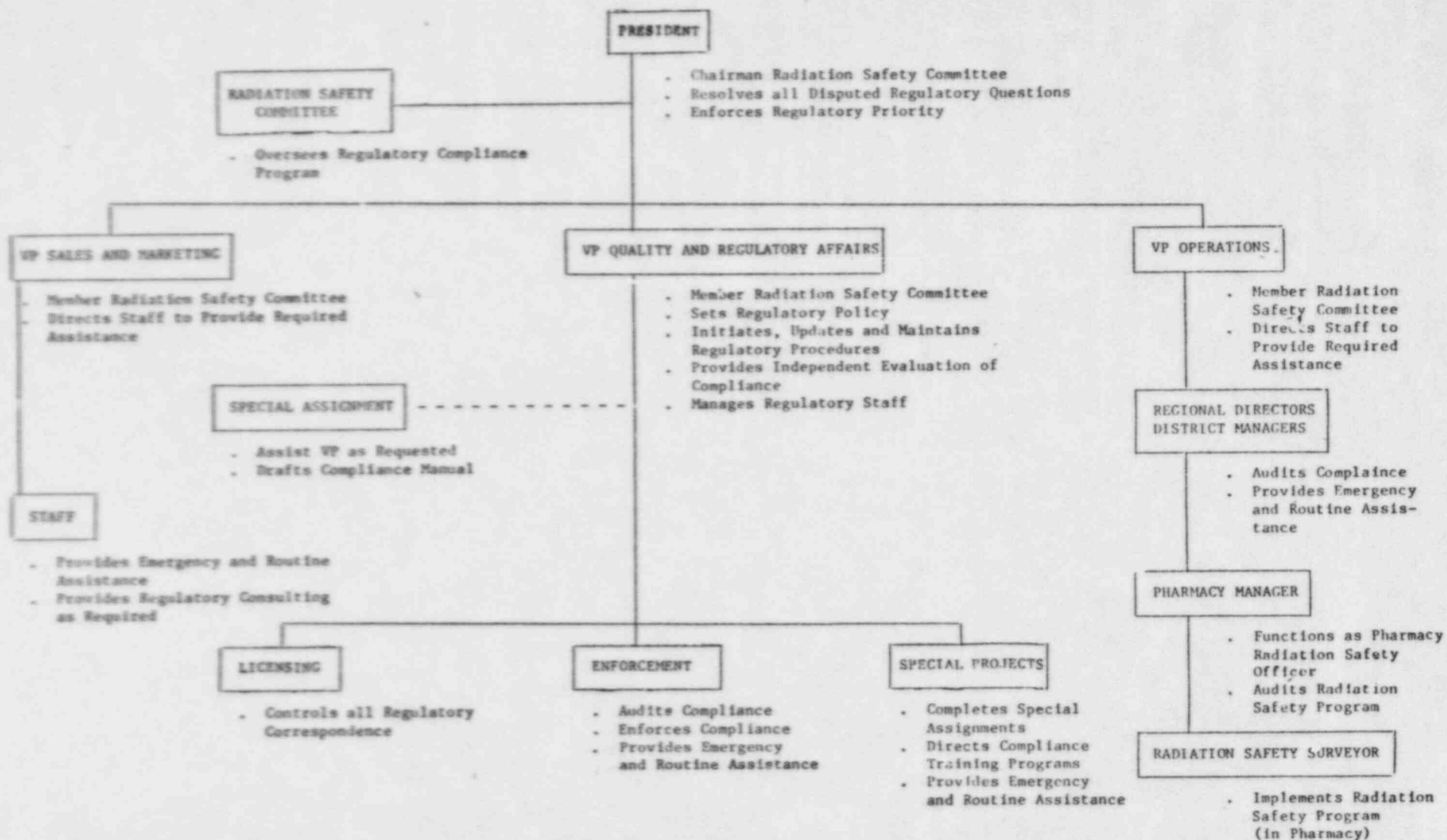
Section 1.0 Organization and Staffing

Section 2.0 Personnel Selection and Qualification

NPI has undergone a complete reorganization of the various elements of the company that have authorities and responsibilities toward regulatory compliance. The resultant organizational chart is enclosed. This organization, and the new personnel filling key slots, will be systematically integrated into the present interim organization in the NRC regulated pharmacies. Robert Sanchez, President will continue an active role in the operations of these pharmacies assisted by the new Vice President of Operations, Steven Dessel. Mr. Dessel will also continue an active role in regulatory aspects of the NRC regulated pharmacies assisted by Robert McClintock, the new Vice President of Quality and Regulatory Affairs. These dual responsibilities will continue until the NRC regulated pharmacies show by their performance that they can maintain a compliant program. At that time Mr. Sanchez will move to his management oversight role as President and Chairman of the Radiation Safety Committee. Mr. Dessel and Mr. McClintock will assume full responsibilities for their respective assignments.

In addition to changes in Senior Management, the Regional Manager/District Manager program has been streightened. Additional training for middle management has been initiated which includes management techniques, regulatory requirements, audit procedures and computer usage. Finally, pharmacy manager changes and increased staffing has been completed in Chicago and several other pharmacies to increase regulatory compliance.

A task force has been assigned to perform a complete task analysis of regulatory functions and prepare an organizational chart and a document which delineates the responsibilities based upon the task analysis. The task force also will update position descriptions reflecting these responsibilities. The members of this task force include Bob McClintock, CHP, Madonna Bixby, NPI Personnel Manager, and Cathy Clark, CNMT. Future training, qualifications programs and staffing decisions will be based upon the findings of this group.



Section 3.0 Training

NPI has assigned a task force to develop, implement and maintain the procedural and training recommendations contained in the HNS report. The members of the task force include Bob McClintock, CHP, Bill Guthrey, R.Ph., Cathy Clark, CNMT, and Laurie Tushaus, CNMT.

The initial assignment of the task force will be to draft a complete procedures manual which integrates operational and compliance requirements. Concurrently the position descriptions and task analysis will be completed as documented in Section 1.0 of this report. In coordination with the completion of these assignments the task force will develop a formal training program including course guidelines, lesson plans, schedules and written tests. Intensive use of videotaping is anticipated to facilitate repetitive, introductory training.

In order to ensure that all employees throughout the various facilities have been reached and that programs are uniform, the coordination of company wide training has been assigned to the regulatory group. It should be noted that this training does not include the authorized user training program at Mercer University. This program, and similar University programs which have been approved by the NRC, were not mentioned in the HNS report. They will continue to be used by NPI to enhance staff professionalism and meet authorized user requirements.

- Section 4.0 External Exposure Control
- Section 5.0 Internal Exposure Control
- Section 6.0 Radiological Surveillance Program
- Section 7.0 Radioactive Waste Management
- Section 8.0 ALARA Program
- Section 9.0 Facilities and Equipment

The recommendations contained in these six sections represent improvements of the existing program without modifying the program itself. Therefore, implementation of these recommendations has been accomplished by normal intercompany communications. In addition, each recommendation will be included in the training and procedures manual covered in Sections 3.0 and 10.0 to assure they are fully implemented into the final program.

Section 10.0 Procedure Development

As documented in Section 3.0 above, NPI has assigned a task force to develop, implement and maintain a procedures manual that integrates radiation protection requirements into pharmacy operations. The manual drafted by the task

force will be distributed to all management levels for review and will be tested in a large and a small pharmacy for completeness prior to distribution.

In addition a formal protocol will be developed to assure adequate control, review, revision and distribution of this manual and other critical documents.

Section 11.0 Radioactive Materials Control Program
Section 12.0 Operation Quality Assurance

The computer field system referenced in the HNS report has been installed, debugged, and made operational in the Des Moines pharmacy. The system is planned to be operational in Boston, Harrisburg and Milwaukee by April, 1985. Due to the complexity of operations in Philadelphia and Chicago debugging of the computer software is not complete at this time. After debugging, the staff at these two pharmacies will be trained and the system made operational.

Key elements of the computer program may include:

1. Checks the R.A.M. license expiration date and possession limit for the requested product.
2. Provides a daily printout of customer licenses which are in timely renewal or which will expire within 30 days.
3. Requires elution data be entered into computer within a specified time of assay. Corporate RSO is notified if not accomplished.
4. Calculates expiration time based on USP limit of 0.15 uCi/mCi.
5. Flags and notifies the operator of any expiration time less than 24 hours.
6. Notifies the operator, the Corporate RSO, and disallows the use of any elution with a 6 hour or less expiration time.
7. Maintains an instrument database with several numbers and calibration dates - provides a printout of calibration dates.
8. Flags and notifies the Corporate RSO of any incoming packages whose D.O.T. limits are exceeded.
9. Provides for traceability internal control number, vendor lot number or Rx number.

10. Provides a daily printout of any Health Physics task which are within their flagged period.
11. Provides a constant screen reminder of Health Physics tasks which are due on the current date.
12. Notifies the Corporate RSO if any HP task is past due.

The recommendations concerning the NPI audit system will be implemented by both regulatory and operations audits. The regulatory audits will be conducted by the Vice President of Quality and Regulatory Affairs and his staff. The audits will be patterned after regulatory inspections with formal enforcement. The operational audits by the pharmacy Managers, District and Regional Managers will emphasize followup and implementation of corrective actions in addition to problem identification. All audits will be reported to the regulatory staff and summarized monthly for the Radiation Safety Committee.

In addition to formal audits, all NPI employees who travel extensively, including company officers and the sales and marketing staff, have been instructed to report to the regulatory staff any pharmacy they believe to be in noncompliance.

Section 13.0 Management Oversight

As documented in Sections 1.0, 2.0, 3.0, 10.0, 11.0 and 12.0 the major thrust of NPI's corrective actions has been to improve management oversight and controls. The formalization of position descriptions, procedures and training and the upgrading of the computer and audit programs were implemented to assure that individual actions at the pharmacies were in conformance with management commitments to regulatory compliance and to assure that management is made aware of, and corrects, employee noncompliance if it occurs.

In addition to the above, the role of the Radiation Safety Committee has been enhanced to oversee the implementation of the recommendations contained in the HNS report as well as all other regulatory matters. The committee has been expanded to include all senior management personnel and has been holding monthly meetings since November. A formal committee charter and protocol is being developed.

APPENDIX A

SCHEDULE FOR IMPLEMENTATION

1.0 Organization and Staffing

- 1.3.1.1 Organizational Document
 - . organizational changes completed
 - . task force appointed
 - . document milestones
 - . draft June 1985
 - . final August 1985
- 1.3.1.2 Position Descriptions
 - . task force appointed
 - . document milestones
 - . draft April 1985
 - . final May 1985
- 1.3.1.3 Position Guide Training
 - . included in 3.0
 - . training milestones
 - . initiated May 1985
 - . completed July 1985
- 1.3.1.4 Organization Chart
 - . organizational changes completed
 - . chart prepared March 1985
- 1.3.2.1 Task Analysis
 - . task force appointed
 - . document milestones
 - . draft May 1985
 - . final July 1985
- 1.3.2.2 Staffing
 - . current staffing completed
 - . planned staffing on going

2.0 Personnel Selection and Qualification

- 2.3.1 Selection Criteria
 - . task force appointed
 - . document milestones
 - . draft June 1985
 - . final August 1985

- 2.3.2 Qualification Program
 - . included in 2.3.1 and 12.3.3
 - . program milestone
 - . initiated July 1985
 - . completed September 1985

3.0 Training

- 3.3.1 Formal Training Program
 - . task force appointed
 - . program milestones
 - . initiated April 1985
 - . program completed August 1985
 - . videotaping completed September 1985
- 3.3.2 Course Guidelines, Lesson Plans
 - . included in 3.3.1
- 3.3.3 Training Schedule
 - . included in 3.3.1
- 3.3.4 Written Tests
 - . included in 3.3.1
- 3.3.5 Certificate Program
 - . evaluation initiated
- 3.3.6 Training Coordinator
 - . coordination responsibility assigned to regulatory staff

4.0 External Exposure Control

- 4.3.1 Dosimetry Positioning
 - . staff notified
 - . included in 10.3.1 and 3.3.1
- 4.3.2 Missing Dosimeters
 - . included in 10.3.1
- 4.3.3 Spiked Dosimetry
 - . included in 10.3.1

5.0 Internal Exposure Control

- 5.3.1 Upgrade Bioassay
 - . included in 10.3.1 and 3.3.1
- 5.3.2 Bioassay Procedure
 - . staff Notified
 - . included in 10.3.1 and 3.3.1
- 5.3.3 Bioassay Audits
 - . included in 12.3.3 and 10.3.1

- 5.3.4 Review Bioassay Frequency
 - . review initiated
- 5.3.5 Bioassay Procedures
 - . included in 10.3.1 and 3.3.1

6.0 Radiological Surveillance Program

- 6.3.1 Calibration of Instruments
 - . staff notified
 - . included in 10.3.1 and 3.3.1
- 6.3.2 Standard Counting Times
 - . included in 10.3.1 and 3.3.1
- 6.3.3 Instrument Evaluation
 - . included in 12.3.3 10.3.1 and 3.3.1
- 6.3.4 Personnel Monitoring Techniques
 - . included in 12.3.3 10.3.1 and 3.3.1
- 6.3.5 Air Sampling Review
 - . review initiated
- 6.3.6 Modify Procedures
 - . included in 10.3.1

7.0 Radioactive Waste Management

- 7.3.1 Procedure Modifications
 - . included in 10.3.1
- 7.3.2 Develop Waste Return Protocol
 - . Evaluation initiated
- 7.3.3 Waste Segregation
 - . Evaluation initiated
- 7.3.4 Investigate Alternate Methods
 - . Evaluation initiated

8.0 ALARA Program

- 8.3.1 Revise Extremity Limits
 - . included in 10.3.1
- 8.3.2 Include ALARA in Procedures
 - . included in 10.3.1

9.0 Facilities and Equipment

- 9.3.1 Equipment Loaner Program
 - . staff notified
 - . included in 10.3.1 and 3.3.1
- 9.3.2 Evaluate Package Cushioning
 - . evaluation initiated

10.0 Procedures Development

- 10.3.1 Written Procedures
 - . task force appointed
 - . document milestones
 - . initiated March 1985
 - . draft May 1985
 - . final July 1985
- 10.3.2 Procedure Review
 - . Included in 10.3.1 and 10.3.3
- 10.3.3 Develop Procedure Control Protocol
 - . task force appointed
 - . document milestones
 - . initiated March 1985
 - . draft May 1985
 - . final July 1985

11.0 Radioactive Materials Control Program

- 11.3.1 Review New Computer Field System
 - . review completed
 - . included in 10.3.1
- 11.3.2 Staffing
 - . included in 1.3.2.2

12.0 Operational Quality Assurance

- 12.3.1 Sterility and Pyrogenicity
 - . included in 11.3.1
- 12.3.2 Computer Field System Operational
 - . smaller, pharmacies
 - . hardware obtained
 - . software debugging completed
 - . installation milestones
 - . Des Moines Completed
 - . Boston, Harrisburg, Milwaukee March 1985

- . larger pharmacies
 - . hardware obtained
 - . milestones
 - . software debugged April 1985
 - . installation Philadelphia - May 1985
 - . Installation Chicago - May 1985

- 12.3.3 Formalize Audit Program
- . audit staff appointed
 - . program initiated
 - . Auditor Training milestones
 - . initiated February 1985
 - . completed April 1985
 - . program documented
 - . included in 10.3.1

- 12.3.4 Audit Program Improvements
- . Included in 12.3.3

13.0 Management Oversight

- 13.3.1 Management Training
- . included in 3.3.1
- 13.3.2 Routine Managers Meetings
- . evaluation initiated
- 13.3.3 District and Regional Managers
- . reorganization completed
 - . documentation
 - . included in 1.3.1.2
- 13.3.4 Pharmacy Managers
- . included in 1.3.1.2
- 13.3.5 Improve Communication
- . evaluation initiated
- 13.3.6 Clarify Job Descriptions
- . included in 1.3.1.2
- 13.3.7 Fill Vacancies
- . included in 1.3.2.2