

November 6, 2000

Mary Lopas, M.T.  
Laboratory and Diagnostic Imaging Director  
Door County Memorial Hospital  
330 South 16<sup>th</sup> Place  
Sturgeon Bay, WI 54235

Dear Ms. Lopas:

This refers to the inspection conducted on October 26, 2000, at Door County Memorial Hospital, Sturgeon Bay, Wisconsin, with continuing NRC review through November 3, 2000. The inspection was conducted to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. At the conclusion of the inspection, the findings were discussed with you and Mr. VanOs via telephone on November 3, 2000.

During the inspection period, your conduct of licensed activities was generally characterized by safety-conscious use of licensed material in your nuclear medicine operations.

Based on the results of this inspection, no violations of NRC requirements were identified.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter 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).

Sincerely,

/RA/

Geoffrey C. Wright, Chief  
Materials Inspection Branch

Docket No. 030-31488  
License No. 48-26123-01

cc: Michael L. Paciorek, M.D.  
Radiation Safety Officer

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M. Lopas

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APPENDIX A

NUCLEAR MEDICINE INSPECTION RECORD  
(TEMPORARY INSTRUCTION 2800/029)

Region 3

Inspection record No. 00-001  
Licensee (Name and Address):

License No. 48-26123-01  
Docket No. 030-31488

**Door County Memorial Hospital**  
**330 South 16<sup>th</sup> Place**  
**Sturgeon Bay, WI 54235**

Location (Authorized Site) Being Inspected:  
**As Above**

Licensee Contact: Michael Paciorek, MD, RSO Telephone No. 920-746-3540  
Priority: G3 Program Code: 2120

Date of Last Inspection: 7/27/95 NMED/Event No(s): \_\_\_\_\_  
Date of This Inspection: 10/26/00

Type of Inspection: ( ) Announced (X) Unannounced  
(X) Routine ( ) Special  
( ) Initial

Next Inspection Date 11/05 ( ) Normal ( ) Reduced (X) Extended

Justification for change in normal inspection frequency:

**Overall good performer last two inspections.**

Summary of Findings and Actions:

- (X) No violations cited, clear letter issued.
- ( ) Non-cited violations
- ( ) Violation(s), Form 591 issued
- ( ) Violation(s), regional letter issued
- ( ) Followup on previous violations

Inspector(s) S.J. Mulay  
(Sign Name)

Date 11/3/00

**S.J. Mulay, Radiation Specialist**

Approved G.C. Wright  
(Sign Name)

Date 11/6/00

**G. C. Wright, Chief, Nuclear Materials Inspection Branch**

## PART I-LICENSE INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. INSPECTION AND ENFORCEMENT HISTORY:  
(Unresolved issues; previous and repeat violations including NCVs; Confirmatory Action Letters; and orders)

**No violations last inspection.**

2. INCIDENT/EVENT HISTORY:  
(List any incidents, recordable events, or misadministrations reported to NRC since the last inspection. Citing "None" indicates that the NRC nuclear material events database, regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

**According to licensee representatives, no incidents or misadministrations have occurred since the last inspection.**

## PART II - INSPECTION DOCUMENTATION

*The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all focus elements are to be addressed during each inspection.*

*All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.*

1. ORGANIZATION AND SCOPE OF PROGRAM:  
(Management organization; authorities and responsibilities; authorized locations of use; type, quantity, and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects)

**Gerald Worrick, CEO**

**Craig Stradley, VP**

\* # + **Mary Lopas, Director of Lab/Radiology**

**Ron Kruger, Supervisor-Radiology**

**Michael Paciorek, MD, RSO**

# \* + **Casey Van Os, CNMT**

# Contacted during the inspection

\* Attended Entrance Meeting

+ Attended Exit Meeting conducted 11/3/00

#### **SCOPE OF PROGRAM:**

**This 50 bed hospital performs about 80 procedures per month utilizing one full-time technologist. The department currently is staffed Monday-Friday. The licensee obtains a 1.5 Curie generator weekly. The licensee does not perform radiotherapy.**

2. PERSONNEL CONTACTED:  
(Identify licensee personnel contacted during the inspection [including those individuals contacted by telephone].)

**See section 1**

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:  
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)

**Hot Lab area: 0.7mr/hr over generator storage area.**

**Imaging area: 0.03mr/hr**

**Unrestricted area: 0.03mr/hr**

**Bkg: 0.02mr/hr**

**Readings compared well with licensee results. NRC instrument used: Ludlum 2403, calibrated 12/16/99.**

4. OTHER:  
(e.g., posting and labeling)

Patient doses containing are prepared, labeled and shielded prior to administration. The overall hot lab/imaging area was posted as required. No thefts, losses, incidents, or overexposures have occurred according to licensee representatives.

The licensee possesses a Syncor-15R dose calibrator. Dose calibrator constancy, linearity and accuracy were reviewed and were performed at the required frequencies. Readings did not vary by more than 10%. Geometry was not reviewed.

The licensee performs daily surveys and weekly wipes as required. A record review from 10/1/00-10/25/00 did not indicate contamination in excess of established trigger levels. Survey meter operational checks are also performed.

Sealed source inventory and leak tests are performed quarterly and each six months respectively with appropriate records maintained. No leakage was evident and all sources appeared to be accounted for.

Licensee possesses two Ludlum-14C survey meters each calibrated within the last twelve months. Response check with the NRC instrument revealed good comparison for the primary unit used by the licensee.

Doses are checked for accuracy in the dose calibrator prior to administration. All necessary postings were properly displayed.

### **PART III - FOCUS ELEMENTS**

1. ADEQUATE PROGRAM SURVEILLANCE AND CORRECTIVE ACTIONS  
YES X NO

(Adequate program reviews, including corrective actions for licensee findings and NRC-identified violations; resources [financial and personnel] dedicated to the program; recurring problems; radiation safety officer [RSO] present; RSO authority and effectiveness; radiation safety committee involvement [if required]; management support of program; radioactive material surveys)

The licensee contracts with an outside consultant to perform annual program audits which adequately oversee program activities. RSC meeting minutes were reviewed for 5/17/00 and 9/29/00. Overall proper membership and good discussion content were evident for minutes reviewed. Licensee representatives indicated adequate RSO involvement and/or availability.

Overall management support is well implemented for program activities.

2. KNOWLEDGEABLE STAFF AND MANAGEMENT YES X NO     

(Use by qualified and knowledgeable individuals; safe work practices; all levels of management possess sufficient knowledge to provide effective oversight of the program)

**Interviews conducted with available staff, revealed an adequate level of understanding of emergency and material handling procedures and techniques.**

**Technologist injection techniques were observed and included gloves, personnel dosimetry, syringe shields and proper clothing. Area and package surveys as well as dose calibrator constancy checks were successfully demonstrated/described. The technologist also demonstrated an generator elution molybdenum check with no problems noted.**

3. OCCUPATIONAL AND PUBLIC DOSES WITHIN REGULATORY LIMITS  
YES X NO     

(Offsite contamination events; effective event response; trending as low as reasonably achievable; release pursuant to 10 CFR 35.75; substantial potential for overexposure; monitoring and dose assessment program; release for unrestricted use; notification)

**1999**

**2000 (thru August)**

**WB: 217mR**

**82mR**

**Ext: 852mR**

**150mR**

**Based on the above data, it appears that personal dosimetry is being worn during preparation and administration of licensed material. ALARA appears well implemented.**

**Mr. VanOs, was hired in July 2000. Prior to that, the licensee employed a technologist from a temporary service from January-July 2000. The above readings represent exposure data primarily from the temporary technologist.**

ADEQUATE SECURITY AND CONTROL OF LICENSED MATERIAL

YES ☒ NO ☐

(Security and control measures commensurate with the hazard of the material involved; inventory; proper ordering, receipt and transfer of RAM; RAM in unrestricted/uncontrolled area; proper shipping; loss of RAM; proper disposal; notification)

**The hot lab and imaging areas were observed adequately surveilled upon arrival and during the inspection. According to Mr. VanOs, material stored and used in the hot lab area is surveilled during business hours and doors to the hot lab and imaging areas are locked after hours.**

**Generator receipt records were reviewed for 10/13/00 and 10/20/00 and revealed all appropriate visual inspections, surveys and wipes. Return shipments of spent generators are surveyed and wiped and returned via courier to generator vendor.**

**The licensee did not indicate nor did record reviews confirm package contamination in excess of licensee trigger levels.**

**The licensee maintains radioactive waste in decay in storage for 10 half-lives. The material is surveyed to background levels and disposed as trash. The last disposal occurred on 10/10/00 with surveys to background.**

5 USE OF LICENSED MATERIAL ONLY AS AUTHORIZED YES ☒ NO ☐

(Authorized users, uses, types and quantities of materials, and locations; adequate supervision by authorized users)

**Uses, types, quantity of licensed material as well as location of use were in accordance with submitted documentation. No problems were noted in this program area.**

6. RADIOPHARMACEUTICAL ADMINISTRATIONS CONFORMING TO THE PHYSICIAN'S WRITTEN DIRECTIVES YES ☐ NO ☐

(Quality management program - written directives, implementation, reviews; Misadministrations - identification, notifications, reports, and records)

**The licensee does not perform radiopharmaceutical therapy. Therefore, not applicable.**



#### **PART IV - POST- INSPECTION ACTIVITIES**

1. DEBRIEF WITH REGIONAL STAFF:  
(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer, and/or State Liaison Officer)

**Branch Chief and Deputy Division Director.**

2. OTHER:  
NA

**END**