

APPENDIX A

**NUCLEAR MEDICINE INSPECTION RECORD  
(TEMPORARY INSTRUCTION 2800/029)**

Inspection record No. \_\_\_\_\_ Region \_\_\_\_\_ License No. \_\_\_\_\_  
Licensee (Name and Address): \_\_\_\_\_ Docket No. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Location (Authorized Site) Being Inspected:

\_\_\_\_\_  
\_\_\_\_\_  
Licensee Contact: \_\_\_\_\_ Telephone No. \_\_\_\_\_

Priority: \_\_\_\_\_ Program Code: \_\_\_\_\_

Date of Last Inspection: \_\_\_\_\_ NMED/Event No(s): \_\_\_\_\_  
Date of This Inspection: \_\_\_\_\_

Type of Inspection: ☐ Announced ☐ Unannounced  
☐ Routine ☐ Special  
☐ Initial

Next Inspection Date \_\_\_\_\_ ☐ Normal ☐ Reduced ☐ Extended

Justification for change in normal inspection frequency:

Summary of Findings and Actions:

- ☐ No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- ☐ Non-cited violations
- ☐ Violation(s), Form 591 issued
- ☐ Violation(s), regional letter issued
- ☐ Followup on previous violations

Inspector(s) \_\_\_\_\_ Date \_\_\_\_\_  
(Sign Name)

\_\_\_\_\_  
(Print Name)

Approved \_\_\_\_\_ Date \_\_\_\_\_  
(Sign Name)

\_\_\_\_\_  
(Print Name)

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

- [illegible]

## 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. NOTE: Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or the patient's privacy.*

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)

2. PERSONNEL CONTACTED:

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

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:  
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)
  
4. OTHER:  
(e.g., posting and labeling)

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

1. ADEQUATE PROGRAM SURVEILLANCE AND CORRECTIVE ACTIONS  
YES \_\_\_ 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)

2. KNOWLEDGEABLE STAFF AND MANAGEMENT YES \_\_\_ NO \_\_\_

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

3. OCCUPATIONAL AND PUBLIC DOSES WITHIN REGULATORY LIMITS

YES \_\_\_ 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)

4. 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)

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)

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)

#### **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)
2. OTHER:

END