

| <b>APPENDIX A<br/>NUCLEAR MEDICINE INSPECTION RECORD<br/>(TEMPORARY INSTRUCTION 2800 / 029)</b> |  |  |                                     |                                     |                         |                                     |                  |  |  |
|---|--|--|-------------------------------------|-------------------------------------|-------------------------|-------------------------------------|------------------|--|--|
| <b>REGION IV</b>  |  |  |                                     |                                     |                         |                                     |                  |  |  |
| Insp. Record No.  | <b>00-01</b>                           | License #  | <b>35-27653</b>                     |                                     |                         | Docket #                            | <b>030-35292</b> |  |  |
| Licensee Name   | <b>Jerome P. Mathias, M.D., Inc.</b>   |  |                                     |                                     |                         |                                     |                  |  |  |
| Street Address  | <b>8121 National Avenue, Suite 200</b> |  |                                     |                                     |                         |                                     |                  |  |  |
| City, State, Zip  | <b>Midwest City, Oklahoma 73110</b>    |  |                                     |                                     |                         |                                     |                  |  |  |
| Location<br>(Authorized Site)<br>Being Inspected  | <b>Same as noted above</b>             |  |                                     |                                     |                         |                                     |                  |  |  |
| Licensee Contact Name   | <b>Jagadeesh R. Sonnad, Ph.D.</b>      |  |                                     |                                     | Phone #                 | <b>405-271-5261</b>                 |                  |  |  |
| Priority  | <b>05</b>                              | Program Code   | <b>02201</b>                        |                                     | NMED or Event No(s)     | <b>None</b>                         |                  |  |  |
| Description   |  | <b>Private Practice - No QMP required.</b>                     |                                     |                                     |                         |                                     |                  |  |  |
| Date of Last Inspection:  |  | <b>N/A - Initial</b>   |                                     |                                     | Date of This Inspection |                                     | <b>8/3/00</b>    |  |  |
| Type of Insp.   | Announced                              | <input checked="" type="checkbox"/>                            | Routine                             |                                     | Initial                 | <input checked="" type="checkbox"/> |                  |  |  |
|   | Unannounced                            |  | Special                             |                                     |                         |                                     |                  |  |  |
| Next Insp. Date   | <b>200507</b>                          | Normal   | <input checked="" type="checkbox"/> | Reduced                             |                         | Extended                            |                  |  |  |
| Justification for change in normal inspection frequency:  |  | <b>Initial Inspection - No change in inspection frequency.</b> |                                     |                                     |                         |                                     |                  |  |  |
| <b>Summary of Findings and Actions</b>  |  |  |                                     |                                     |                         |                                     |                  |  |  |
| No violations, Clear 591 or letter issued   |  |  |                                     | <input checked="" type="checkbox"/> | Non-cited violations    |                                     |                  |  |  |
| Violation(s), 591 issued  |  | Violation(s), letter issued                                    |                                     |                                     |                         |                                     |                  |  |  |
| Follow up on previous violations:   |  |  | <b>N/A</b>                          |                                     |                         |                                     |                  |  |  |
| Inspector - Printed Name  |  | <b>Randy R. Erickson</b>                                       |                                     |                                     |                         |                                     |                  |  |  |
| - Signature   |  | <b>/RA/</b>  |                                     |                                     |                         | Date                                | <b>08/09/00</b>  |  |  |
| Approved - Printed Name   |  | <b>Mark R. Shaffer</b>   |                                     |                                     |                         |                                     |                  |  |  |
| - Signature   |  | <b>/RA/</b>  |                                     |                                     |                         | Date                                | <b>08/19/00</b>  |  |  |

|  |   |
|--|---|
| <b>PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY</b>   |   |
| <b>1.</b>  | <b>INSPECTION AND ENFORCEMENT HISTORY</b> |
| Unresolved issues; previous and repeat violations including NCV's; Confirmatory Action Letters; and orders.  |   |
| <b>None - Initial Inspection</b>   |   |
| <b>2.</b>  | <b>INCIDENT/EVENT HISTORY</b>             |
| 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. |   |
| <b>None - NMED search on 7/24/00</b>   |   |

## 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.

**Vivek J. Bhaktaram, M.D. / Jerome P. Mathias, M.D ⇒ Sheldon Bray, RT (N),  
Technologist**

**Private Cardiology office performing nuclear cardiology studies. One authorized users and one technologist. Licensee performs ~75 patient studies per month using unit doses of Tc99m only. No Generators or bulk doses. Injections are administered in the scan room. The treadmill is located within the scan room. The first dose was received April 2000.**

### 2. PERSONNEL CONTACTED

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

**Entrance:  
Vivek J. Bhaktaram, M.D.  
Jeremy King, BS RT(N), CNMT  
Cheryl Burch, Office Manager**

**Exit:  
Jeremy King, BS RT(N), CNMT  
Cheryl Burch, Office Manager**

|   |  |
|---|--|
| 3.  | <b>INDEPENDENT AND CONFIRMATORY MEASUREMENTS</b> |
| Areas surveyed; comparison of data with the licensee's results and regulations; and instrument type and calibration date.   |  |
| <p><b>Hot Lab, scan room, and surrounding rooms were surveyed with Victoreen Model 190, S/N: 2074, NRC: 058864, Cal: 8/10/99.</b></p> <p><b>Bkgd: ~14 uR/hr</b></p> <p><b>Within scan room: ~ 14-22 uR/hr</b></p> <p><b>Adjoining areas around scan room: ~background</b></p> |  |
| 4.  | <b>OTHER</b>                                     |
| e.g. Posting and labeling   |  |
| <p><b>NRC Form 3, Section 206 of the Atomic Energy Act and the locations of applicable regulations and documents posted as required. Hot lab and scan room were properly posted with Caution RAM signs. Inspected transport containers were properly labeled.</b></p>         |  |

## PART III - FOCUS ELEMENTS

| 1.   | Adequate Program Surveillance and Corrective Actions   | Yes | X | No |
|--|--|-----|---|----|
| <p>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 materials surveys.</p>                    |  |     |   |    |
| <p><b>The licensee does not have a radiation safety committee but does have a consultant. The radiation protection program regulatory requirements were discussed with the licensee, however, no audits have been performed.</b></p> <p><b>The radiation safety officer/manager appeared to have adequate oversight of the program.</b></p>  |  |     |   |    |
| 2.   | Knowledgeable Staff and Management                     | Yes | X | No |
| <p>Use of qualified and knowledgeable individuals; safe work practices; all levels of management possesses sufficient knowledge to provide effective oversight of the program.</p>   |  |     |   |    |
| <p><b>Licensee has one technologist responsible for handling millicurie quantities of byproduct material. The technologist had received training in an Oklahoma nuclear medicine technologist training program and holds a BS degree. The technologist works under the direct supervision of one physician and one authorized user. Procedures indicated that refresher training will be conducted annually.</b></p> |  |     |   |    |
| 3.   | Occupational and Public Doses Within Regulatory Limits | Yes | X | No |
| <p>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.</p>   |  |     |   |    |
| <p><b>Personnel dosimetry is provided by a NVLAP accredited vendor. High reading for 2000 to date: Ring: 680 mr, WB: 316 mr.</b></p> <p><b>Dosimeters have been provided to the physicians and the technologist during stress studies.</b></p> <p><b>The regulatory requirement for providing annual dose summaries to all badge wearers was discussed with the licensee.</b></p>                                    |  |     |   |    |

|  |   |     |   |    |  |
|--|---|-----|---|----|--|
| 4.   | <b>Adequate Security and Control of Licensed Material</b>                                   | Yes | X | 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.   |   |     |   |    |  |
| <p><b>Security and control of materials appeared to be very good. Sealed sources, unused doses, and waste are secured in a locked hot lab located inside a locked imaging room. Hot lab is secured when technologist is away from the area.</b></p> <p><b>Licensee receives unit doses of Tc-99m and possessed one sealed source: Cs-137, (S/N: 710-1-17), 211.3 uCi on 4/1/99.</b></p> <p><b>The sealed source had been leak tested by the manufacturer prior to shipment. The licensee acknowledged the requirements for leak testing and inventories.</b></p> <p><b>Tc-99m is delivered in unit doses. All incoming packages are surveyed and wiped for removable contamination.</b></p> <p><b>The licensee had not transported byproduct materials and unused doses are returned to the pharmacy. Initial HAZMAT training has been conducted. The regulatory requirement for 3 year HAZMAT recurrent training was discussed with the licensee.</b></p> |   |     |   |    |  |
| 5.   | <b>Use of Licensed Material Only as Authorized</b>  | Yes | X | No |  |
| Authorized users, uses, types and quantities of materials, and locations; adequate supervision by authorized users.  |   |     |   |    |  |
| <b>Byproduct materials had been used as authorized by the license under the supervision of one authorized user.</b>  |   |     |   |    |  |
| 6.   | <b>Radiopharmaceutical Administrations Conforming to the Physician's Written Directives</b> | Yes |   | No |  |
| Quality management program - written directives, implementation, reviews; Misadministrations - identification, notifications, reports, and records.  |   |     |   |    |  |
| <p><b>Not applicable</b></p> <p><b>No Quality Management Program Required. Licensee is authorized for 10 CFR 35.100 and 200 only.</b></p>  |   |     |   |    |  |

## 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.

**Inspectors debriefed with staff and division management on August 9, 2000.**

### 2. Other

**Program has adequate oversight**