

November 27, 2001

Paul Bjelicka, President
Mid-America Analytical & Co.
14440 Bethel Road
Platte City, MO 64079

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION; OFFICE OF INVESTIGATIONS
REPORT NO. 3-2001-016)

Dear Mr. Bjelicka:

This refers to the inspection conducted at Mid-America Analytical & Co. (MAAC) on March 21 and June 12, 2001, with continued NRC in-office review through November 8, 2001. The in-office review included an assessment of the results of leak tests and removable contamination surveys conducted by the inspectors, as well as the results of a follow-up confirmatory survey of the facilities, and an investigation by the NRC Office of Investigations (OI). The purpose of the inspection was to determine whether your activities were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you.

As a result of the inspection, OI conducted an investigation to determine if MAAC deliberately violated any NRC regulatory requirements. The NRC has completed its investigation into this matter and determined that MAAC did not willfully violate any NRC regulatory requirements. A copy of the Region III OI report synopsis is enclosed. This concludes our investigation into this matter.

The inspectors' leak tests and removable contamination survey results were negative except for the leak test of the sealed source Serial L5919 which indicated 0.013 microcurie of removable contamination. Although this value was above the NRC's limit of 0.005 microcurie, the identified contamination did not pose an undue risk to your employees. Robert Gattone of my staff discussed the results of the surveys and leak tests with you on April 2, 2001.

The NRC identified a violation of NRC regulatory requirements. The violation involves possession of byproduct material without an NRC license. The violation is cited in the enclosed Notice of Violation (Notice).

Based on telephone conversations between you and Robert Gattone on November 9, 2001, and Jan Palmer of your staff and Robert Gattone on November 15, 2001, it is our understanding that: (1) the violation occurred because you did not promptly identify when nickel-63 source holders were received; (2) you transferred all byproduct material to an authorized firm as of August 14, 2001; (3) you will instruct your customers to transfer their nickel-63 source holders to an authorized firm prior to sending their gas chromatographs to you; and (4) you will promptly determine if received gas chromatographs contain nickel-63 source holders and immediately send any received nickel-63 source holders to an authorized firm. Therefore, the NRC has concluded that information regarding the reason for the violation

and the corrective actions taken and planned to correct the violation and prevent recurrence is already addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures 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/reading-rm/adams.html> (the Public Electronic Reading Room).

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

Sincerely,

/RA/

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

Docket No. N/A (Non-Licensee)
License No. N/A (Non-Licensee)

Enclosures: As stated

bcc: PUBLIC IE-07
A. Kock, RIII
DEG, RIII

DOCUMENT NAME: G:\SEC\Mid-America.wpd See Previous Concurrence

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	RIII	RIII	RIII	RIII	RIII	RIII
NAME	Gattone:js	Martin	Shear	Paul	Clayton <i>PT</i>	Pederson <i>MD</i>
DATE	11/ /01	11/ /01	11/ /01	11/ /01	11/27/01	11/27/01 <i>for</i>

OFFICIAL RECORD COPY

and the corrective actions taken and planned to correct the violation and prevent recurrence is already addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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

Sincerely,

Cynthia D. Pederson, Director
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OFFICE	RIII	<input checked="" type="checkbox"/>	RIII	<input checked="" type="checkbox"/>	RIII	<input checked="" type="checkbox"/>	RIII	<input type="checkbox"/>	RIII	<input type="checkbox"/>	RIII	<input type="checkbox"/>
NAME	Gattone:js	<input checked="" type="checkbox"/>	Martin	<input checked="" type="checkbox"/>	Shear	<input checked="" type="checkbox"/>	Paul	<input checked="" type="checkbox"/>	Clayton	<input type="checkbox"/>	Pederson	<input type="checkbox"/>
DATE	11/20/01	<input checked="" type="checkbox"/>	11/21/01	<input checked="" type="checkbox"/>	11/21/01	<input checked="" type="checkbox"/>	11/21/01	<input checked="" type="checkbox"/>	11/ /01	<input type="checkbox"/>	11/ /01	<input type="checkbox"/>

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NOTICE OF VIOLATION

Mid-America Analytical & Co.
Platte City, Missouri

Docket No. N/A (Non-Licensee)
License No. N/A (Non-Licensee)

During an NRC inspection conducted on March 21 and June 12, 2001, with continued NRC in-office review through November 8, 2001, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

10 CFR 30.3 requires, in part, that except for persons exempted, no person shall possess or use byproduct material except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations.

Contrary to the above, for several weeks as of March 21, 2001, Mid-America Analytical & Co. possessed six source holders each containing approximately 15 millicuries of nickel-63 without a valid NRC license, and was not exempt from the requirements for a license. Mid-America Analytical & Co. possessed one of the sources since November 1999.

This is a Severity Level IV violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed in the letter transmitting this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001.

If you choose to respond, your response will be made 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/reading-rm/adams.html> (the Public Electronic Reading Room). Therefore, to the extent possible, it should not include any personal, privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. Under the authority of Section 182 of Act 42 U.S.C. 2232, any response shall be submitted under oath or affirmation.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 27 day of November 2001

SYNOPSIS

This investigation was initiated on April 16, 2001, by the U.S. Nuclear Regulatory Commission, Office of Investigations, Region III, to determine if a company had willfully possessed unauthorized byproduct material.

Based upon the evidence developed, this investigation did not substantiate that the company willfully possessed unauthorized byproduct material.

APPENDIX A

INDUSTRIAL/ACADEMIC/RESEARCH INSPECTION RECORD

Inspection Report No. N/A Region III License No. N/A

Non-Licensee (Name and Address): Docket No. N/A

Mid-America Analytical & Co.
14440 Bethel Road
Platte City, MO 64079

Location Being Inspected

14440 Bethel Road, Platte City, MO

Non-licensee Contact: Paul Bjelicka Telephone No. 816-464-5000

Priority: N/A Program Code: N/A

Date of Last Inspection: N/A

Date of This Inspection: 3/21, 6/12/01, with continued NRC in-office review through 11/8/01

The in-office review included receipt and review of the results of removable contamination surveys performed by the inspectors, a follow-up confirmatory survey of the facilities, and completion of an OI investigation.

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

Next Inspection Date N/A ☐ Normal ☐ Reduced ☐ Extended
Justification for change in normal inspection frequency:

N/A

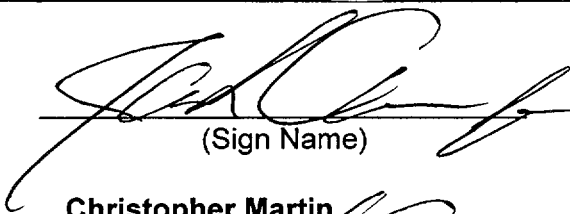
Summary of Findings and Actions:

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

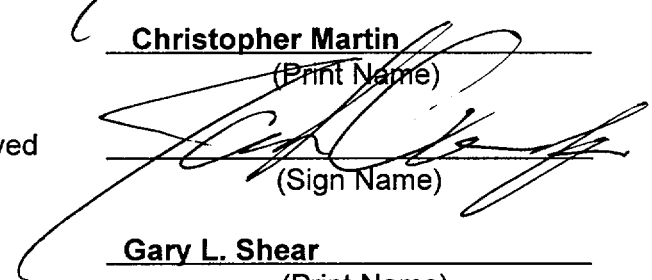
Inspector(s) Robert G. Gattone Jr.
(Sign Name)

Date 11/21/01

Robert G. Gattone, Jr.
(Print Name)


(Sign Name) Date 11/27/01

Christopher Martin
(Print Name)

Approved 
(Sign Name) Date 11/27/01

Gary L. Shear
(Print Name)

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

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
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N/A

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

N/A

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

N/A

PART II - INSPECTION DOCUMENTATION

- * References that correspond to each inspection documentation topic are in Inspection Procedure 87110, Appendix B, "Industrial/Academic/Research Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

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 non-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 non-licensee documents and records needed to support violations.

1. ORGANIZATION AND SCOPE OF PROGRAM:

(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

Mid-America Analytical & Co.'s (MAAC) organization was as follows:

Paul Bjelicka, President
Theresa Smither, Office Manager
Kevin Jones, Technician

MAAC was in the business of refurbishing gas chromatographs (GCs) and other lab instruments. Hewlett Packard and Varian GCs were typically worked on. About 60 GCs were received annually from labs.

2. MANAGEMENT OVERSIGHT:

(Management support to radiation safety; Radiation Safety Committee (RSC); Radiation Safety Officer (RSO); program audits, including annual reviews of program and as low as is reasonably achievable (ALARA) reviews; control by authorized users)

N/A

3. FACILITIES:

(Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding; air flow)

N/A

4. EQUIPMENT AND INSTRUMENTATION:

(Operable and calibrated survey equipment; procedures; 10 CFR Part 21)

N/A

5. MATERIAL USE, CONTROL, AND TRANSFER:

(Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

Based on discussions between the president and Hewlett Packard and Varian, the president was informed that if MAAC's customers shipped GC source holders to an authorized firm prior to transferring the empty GCs to MAAC, then MAAC need not have an NRC license. The Hewlett Packard representative did not tell the president about the need for an NRC license if GCs are received with the sources inside. The president interpreted this to mean that MAAC would not violate NRC regulatory requirements if MAAC: (1) instructed customers to remove the sealed sources and transfer them to an authorized firm (e.g., Hewlett Packard) prior to transferring the GC (without the sources in it) to MAAC; and (2) received source holders and promptly transferred them to an authorized firm.

Based on interviews with the president, MAAC instructed customers wanting to transfer their GCs to MAAC to remove the sealed sources and send them to an authorized firm (e.g., Hewlett Packard) prior to transferring the GC (without the sources in it) to MAAC. Gas chromatographs were typically received without the sources inside, refurbished, and transferred to customers who arranged to have the sources sent to them from an authorized firm. Nonetheless, about every six months for the last two years, the GCs were transferred to MAAC with the sealed sources inside. When this occurred, MAAC intended to promptly send the sources to an authorized firm (e.g., Varian, C. J. Bruyn & Co.). However, MAAC did not always verify whether or not sealed sources were received within GCs. Consequently, several sealed sources within GCs were received by MAAC, and they were not promptly sent to an authorized recipient. Possession of the sealed sources was considered a violation of 10 CFR 30.3 (i.e., unauthorized possession of byproduct material).

Based on a demonstration of how a technician had removed source holders from GCs, two screws were removed from a mounting bracket, and four wires were disconnected. The source holder could not be opened by MAAC because a special tool was needed to do so and source holders were handled for very brief periods.

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses)

N/A

7. TRAINING AND INSTRUCTIONS TO WORKERS:
(Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency situations; and supervision by authorized users)

N/A

8. RADIATION PROTECTION:
(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

N/A

9. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents, and compactors; license conditions for special disposal method)

N/A

10. DECOMMISSIONING:
(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted)

N/A

11. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

Based on review of instructions that were provided to MAAC from C. J. Bruyn & Co. regarding how to prepare excepted packages for source holder shipment to C. J. Bruyn & Co. and a demonstration of how a technician had prepared the source holders for transfer to the authorized firm, no violations or problems were identified. The inspectors noted that the source holders were placed within a plastic bag that was subsequently rolled and taped closed, wrapped in paper, and placed within a box prior to transfer via a common courier.

12. NOTIFICATIONS AND REPORTS:
(Reporting and followup of theft; loss; incidents; overexposures; change in RSO, authorized user; and radiation exposure reports to individuals)

N/A

13. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

The inspectors observed that Serial Nos. L6582, L5381 were labeled as required.

14. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with non-licensee's results and regulations; and instrument type and calibration date)

On 3/21/01, the inspectors used a Ludlum Model 2403, Serial 161607 that was interfaced with a pancake GM probe and last calibrated on 1/8/01 to measure a maximum of (bkg was < 50 cpm):

- **< 50 cpm at the surface of the Hewlett Packard Model 19233, Serial L5381 source holder containing a nominal 15 mCi of Ni-63;**

- < 50 cpm at the surface of the Hewlett Packard Model 19233, Serial L6582 source holder containing a nominal 15 mCi of Ni-63;
- 500 cpm at the surface of the Hewlett Packard Model 19233, Serial L5919 source holder (with no mounting bracket on it, unlike the other source holders) containing a nominal 15 mCi of Ni-63;
- < 50 cpm at the surface of the Hewlett Packard Model G1223A, Serial F7252 source holder containing a nominal 15 mCi of Ni-63;
- 22 kcpm at the surface of an unlabeled source holder mounting bracket, and the radiation was beta exclusively based on survey results with the pancake positioned to survey with and without the thin window; and
- 500 cpm at the surface of an unlabeled GC ventilation tube.

The inspectors also performed leak tests of the aforementioned source holders. Additionally, the inspectors performed removable contamination surveys of the unlabeled source holder mounting bracket and the unlabeled GC ventilation tube that yielded positive ambient exposure rate survey results.

During the site inspection on 3/21/01, the licensee agreed to quarantine the four source holders, unlabeled source holder mounting bracket, and unlabeled GC ventilation tube until the inspectors informed the licensee about the results of the leak tests and removable contamination surveys.

The inspectors' leak tests and removable contamination survey results were negative except for the leak test of Serial L5919 that indicated 0.013 microcurie. On April 2, 2001, the inspectors informed the president that, based on a verbal report of the RIII analysis, Serial L5919 containing 15 mCi of Ni-63 as of 12/89 was leaking (i.e., > 0.005 microcuries was identified), and all other samples were negative. The inspectors informed the president that he needed to arrange for authorized transfer of the leaking source, the three non-leaking sources, and the hardware with fixed contamination. The president indicated that he would work with Agilent (formerly Hewlett Packard) for authorized transfer. The inspectors informed the president that care must be taken regarding the leaking source (i.e., follow the authorized firm's instructions or have them come out and prepare the package for transfer).

On 6/12/01, the inspector used a Ludlum Model 2403, Serial 161610 that was interfaced with a pancake GM probe and last calibrated on 12/11/00 to measure selected areas of the facilities where GC parts were stored, and the results were indistinguishable from background (i.e., < 50 cpm).

Based on a conversation with a Technician on 7/24/01, MAAC shipped the aforementioned sources to C.J. Bruyn in 6/01.

Based on a conversation with a Technician on 7/24/01, MAAC found two additional sources inside of old GCs at the facility in 6/01. One was a Hewlett Packard Model 18724C, Serial H3112 that contained 15 mCi of Ni-63, and the other was a Perkin Elmer Model 600C204, Serial 1993 that contained 15 mCi of Ni-63. The dates of receipt by MAAC were unknown, but the technician estimated that they were at the facility for a long time.

Based on a conversation with the president on 10/18/01, MAAC: (1) transferred all byproduct material to an authorized firm; (2) committed to instructing its customers to transfer their nickel-63 source holders to an authorized firm prior to sending their gas chromatographs to MAAC; and (3) committed to immediately sending any received nickel-63 source holders to an authorized firm in the event that any are sent contrary to MAAC's instructions.

15. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

(State requirement and how and when non-licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all non-licensee documents needed to support violations.)

VIO/10 CFR 30.3/10 CFR 30.3 requires, in part, that except for persons exempted, no person shall possess or use byproduct material except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations. Contrary to 10 CFR 30.3, on March 21, 2001, Mid America Analytical & Co. possessed six nickel-63 sources (each containing a nominal activity of 15 millicuries) without a valid NRC license, and was not exempt from the requirements for a license.

Note: Contrary to 10 CFR 31.5(c)(8), on November 21, 1999, Industrial Testing Labs. (a general licensee) transferred two generally-licensed GC sources (i.e., Hewlett Packard Model 19233, Serial L5919, and Hewlett Packard Model G1223A, Serial F7252), each containing approximately 15 millicuries of nickel-63, to MAAC. Industrial Testing Labs. self-identified the violation. The NRC informed Industrial Testing Labs that it was not issuing any enforcement action for the violation in accordance with the Interim Enforcement Policy for Generally Licensed Devices (Enforcement Manual, Section 8.6, (May 1, 2000; 65 FR 25368).

Contrary to 10 CFR 31.5(c)(8), in March 2001, DataChem Labs (a general licensee) located at 4388 Glendale Milford Road, Cincinnati, OH 45242-3706, transferred a Hewlett Packard Model 5890A, Serial 2643A10323 GC containing two nickel-63 sources each containing 15 millicuries (i.e., Model 19233, Serial Nos. L5381 and L6582) to MAAC. NRC notified DataChem Labs about the apparent violation and that the matter was relayed to the Ohio Department of Health since Ohio was an Agreement State. According to DataChem Labs' Lab Manager, DataChem Labs will implement procedures to ensure that future GC transfers are in accordance with 10 CFR 31.5.

16. PERSONNEL CONTACTED:

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

***Paul Bjelicka, President**

***Theresa Smither, Office Manager**

***#Kevin Jones, Technician**

Ed Slick, Lab Manager, DataChem Labs

Chrissa Schremp, Organic Group Leader, Industrial Testing Labs

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting

17. PERFORMANCE EVALUATION FACTORS (PEFs):

- | | | | |
|----|--|-----------|-------------|
| A. | Lack of senior management involvement with the radiation safety program and/or RSO oversight | N/A | () Y () N |
| B. | RSO too busy with other assignments | N/A | () Y () N |
| C. | Insufficient staffing | N/A | () Y () N |
| D. | RSC fails to meet or functions inadequately | (x) N/A | () Y () N |
| E. | Inadequate consulting services or inadequate audits conducted | (x) N/A | () Y () N |

Remarks (Consider the above assessment and/or other pertinent PEFs with regard to the non-licensee's oversight of the radiation safety program.):

None

18. SPECIAL CONDITIONS OR ISSUES:

(Special license conditions; year-2000 effects of computer software and embedded systems)

None

PART III - POST- INSPECTION ACTIVITIES

1. REGIONAL FOLLOWUP ON PEFs:

None

2. DEBRIEF WITH REGIONAL STAFF:

[Post-inspection communication with supervisor, regional licensing staff (if separate), Agreement State Officer; and/or State Liaison Officer]

The inspectors discussed the inspection findings with Darrel Wiedeman, Acting Branch Chief prior to the site exit meeting. The inspectors discussed the inspection findings with Marc Dapas, Geoff Wright, Ken Lambert, Gary Shear, and Jamnes Cameron, Acting Branch Chief.

3. YEAR-2000 ISSUES:

(Convey, to the NMSS Year-2000 Coordinator, all year-2000 non-licensee-identified problems and corrective actions taken.)

N/A