

APPENDIX E

NOTE: All areas indicated in field notes
are not required to be addressed during
each inspection

INDUSTRIAL/ACADEMIC/RESEARCH INSPECTION FIELD NOTES
Region I

Inspection Report No. 94-001

License No. 06-13053-04

Licensee (Name & Address):

Docket No. 030-30292

Miles, Inc.

400 Morgan Lane

West haven, CT 06516-4175

Licensee Contact June Tamkin (RSO)

Telephone No. 203-931-5175

Last Amendment No. 03

Date of Amendment 3/31/94

Priority: 2

Program Code 03610

Date of Last Inspection 12/16/92

Date of This Inspection 12/8/94

Type of Inspection:

☐ Announced

☒ Unannounced

☒ Routine

☐ Special

☐ Initial

☐ Reinspection

Next Inspection Date 12/96

☒ Normal ☐ Reduced ☐ Extended

Summary of Findings and Action:

☒ No violations cited, Clear 591 issued

☐ Violation(s), 591 issued

☐ Violation(s), Regional letter issued

☐ Followup on Previous Violations


Were non-cited violations identified during this inspection?

☐ Y ☒ N

Was proprietary information reviewed by or received by the
inspector?

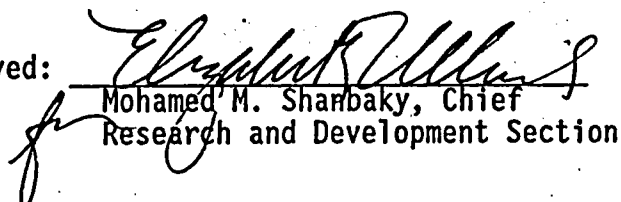
☐ Y ☒ N

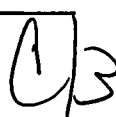
Inspector:


Kathleen Dolce, Health Physicist

Date 12/14/94

Approved:


Mohamed M. Sharbaky, Chief
Research and Development Section

Date 12/19/94 

Issue Date: XX/XX/XX

E-1

87100, Appendix E

1. INSPECTION HISTORY

() N/A - Initial inspection

- A. Violations were identified during any of the last two inspections or two years, whichever is longer (X) Y () N
 B. Response letter dated 1/26/93
 C. Open violations from previous inspections: () N/A

		Status	
<u>Requirement</u>	<u>Violation</u>	<u>Corrective Action Taken (Y/N)</u>	<u>Open/Closed</u>
tie-down	dosimeter exchange frequency	Y	Closed
tie-down	thyroid bioassay results	Y	Closed

- D. Explain any previous violation(s) not corrected or repeated (X) N/A

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Organizational Structure

- +* June Tamkin (RSO)
- +* John Amatruda (RSC Chair and Director, Institute for Metabolic Disorders)
- +* Fred Line (Director, Health, Environment & Safety)
- +* Roberta Bianca (Radiation Safety Specialist)
- +* Joseph Dietrich (Radiation Safety Specialist)
- + Ann Lees (temporary Administrative Assistant for the RSO)

- + Carla Forte (I-125 user)
- + Bill Pickle (S-35 user)
- + Tony Rossomando (AU: 25 mCi of P-32 per experiment)
- + Pat Loulakis (badge interviewee)
- + Mary Gerittson (badge interviewee)
- + Rich Earls (computer programmer)
- + George Parent (Shipping/Receiving Supervisor)
- + Walt Jacqueline (Receiving personnel)
- + Brian Rowland (Receiving personnel)
- + Judy Steinis (Security supervisor)
- + Mark Bellaert (Director of Security)
- + Jeff Nievis (Main Gate Security Guard)

- * William Carley (RSC member and Institute Rep for Bone and Joint Disorders)
- * Wolfgang Hartwig (Vice President for Research)
- * Gary A. Wilson (Director of Licensing and Management Rep for RSC)
- * Peter Rae (Chairperson of Scientific Safety Committee and Director of Institute for Research Technologies)
- * Hanno Roder (Institute's RSC Rep for Dementia Research)

RSO reports to the Director of Health, Environment & Safety who reports up the Production side of the house. The RSC Chairperson reports to the R&D side of the house. Both line managements converge at the upper echelon level. (President of the Company).

- + Individuals contacted during inspection
- * Individuals present at exit meeting

1. Meets license requirements [L/C] (X) Y () N
2. Multiple authorized locations of use and/or laboratories () Y (X) N
If yes, may use ATTACHMENT A as a guide for location(s) or lab(s) inspected and note lab numbers where violations are found. (X) N/A
3. Briefly describe scope of activities, including types and quantities of use involving byproduct material, frequency of use, staff size, etc.

Miles employees 1400 people at the West Haven, CT site. Licensee's radiation safety program changed from a 03620 (R&D other) to a 03610 (Type A Broad Scope program with a RSC). There are approximately 383 users of RAM (100 AU and 200 Junior Scientists), 80 RAM laboratories, 233 film badges exchanged monthly, 48 ring dosimeters exchanged quarterly, 8 area film badge monitors exchanged monthly, and 314 packages received per quarter.

- B. Radiation Safety Committee required [L/C] (X) Y () N
 1. RSC fulfills license requirements [L/C] (X) Y () N
 2. Records maintained [L/C] (X) Y () N
- C. Radiation Safety Officer
 1. Authorized on license [L/C] (X) Y () N
 2. Fulfills duties as RSO (X) Y () N
- D. Use by authorized individuals [L/C] (X) Y () N

Remarks:

The RSC met on 4/25/94, 7/19/94, and 10/28/94. A meeting is scheduled for 12/14/94. Topics discussed include: review of RSC minutes, protocol reviews, ALARA reports, radiation survey reports, and special items of interest. A review of the RSC minutes was conducted and found to be adequate. Sufficient detail is captured in the meeting minutes.

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

- A. Instructions to workers/students per [10 CFR 19.12] (X) Y () N
- B. Training program required [L/C] NI
- C. Individuals understanding of procedures and Regulations is adequate (X) Y () N
 1. Current operating procedures (X) Y () N
 2. Emergency procedures (X) Y () N
 3. Use of survey instrumentation (X) Y () N
- D. Revised Part 20

Workers cognizant of requirements for:

- | | | | | | |
|----|--|-----|---|-----|-----------|
| 1. | Radiation Safety Program [20.1101] | (X) | Y | () | N |
| 2. | Annual dose limits [20.1301, 1302] | (X) | Y | () | N |
| 3. | New forms 4 and 5 | (X) | Y | () | N/A |
| 4. | 10% monitoring threshold [20.1502] | (X) | Y | () | N |
| 5. | Dose limits to embryo/fetus and declared pregnant worker [20.1208] | (X) | Y | () | N |
| 6. | Grave Danger Posting [20.1902] | () | Y | () | N (X) N/A |
| 7. | Procedures for opening packages [20.1906] | (X) | Y | () | N () N/A |
| 8. | Sewer disposal limits [20.2003] | (X) | Y | () | N () N/A |

NOTE: Deficiencies in this area, while not always a violation, should be brought to the attention of licensee management at the exit meeting and in the cover letter transmitting the inspection report or NOV.

Remarks:

Interviews with laboratory personnel demonstrated their knowledge and understanding of the radiation safety policy and procedures.

Thirteen of Miles's security staff received training in 9/94. This only applies to the security guards that have access to the inside of the buildings and who perform rounds during all work shifts. Records for this training were reviewed and found to be adequate.

4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

- | | | | | | |
|----|---|-----|---|-----|----|
| A. | Audits are required [L/C] | (X) | Y | () | N |
| B. | Audits or inspections are conducted | (X) | Y | () | N |
| | (1) Audits conducted by RSO | | | | |
| | (2) Frequency at least annually | | | | |
| C. | Content and implementation of the radiation protection program reviewed annually by the licensee [20.1101(c)] | (X) | Y | () | N |
| D. | Records maintained [20.2102] | | | | NI |

5. FACILITIES

- | | | | | | |
|----|--|-----|---|-----|-----|
| A. | Facilities as described in license application [L/C] | (X) | Y | () | N |
| B. | Describe any Self-contained dry-source-storage irradiators [Part 36] and/or survey instrument calibrators (model, radionuclide, activity, use, etc.) | (X) | | | N/A |

Remarks: GM meters are used for contamination monitoring; not for qualitative analysis. These instruments are calibrated by the licensee. Quantitative survey instruments are sent to a calibration laboratory and the licensee maintains these calibration records.

6. MATERIALS

- | | | | | | |
|----|--|-----|---|-----|----|
| A. | Isotope, chemical form, quantity and use as authorized [L/C] | (X) | Y | () | N |
| B. | Licensed materials secured to prevent unauthorized removal or access [20.1801, 1802] | (X) | Y | () | N |
| C. | Leak tests and Inventories [L/C] | | | | NI |

Remarks:

As of December 8, 1994 the licensee has the following radioactive material on-hand:

Radionuclide	License Limit (millicuries)	On-Site Amount (millicuries)
H-3	5,000	96.381
C-14	5,000	1.572
P-32	10,000	81.197
P-33	10,000	7.023
S-35	10,000	125.944
Ca-45	350	0
I-125	1,000	18.051

Security: The security guard at the main entrance is not a Miles employee. This person only has access to the guard house and the cafeteria. The inspector was given access to the site, but entry into a laboratory environment was not attainable. The security system of Miles actually begins at the building perimeter. All buildings require an identification badge to gain access. This badge is coded for various security levels. For instance, entrance into the licensee's iodination laboratory has only been given to a select few (those authorized to perform iodinations and the radiation safety staff).

The head and chief of security were interviewed regarding this matter. There have been no break-ins or theft of RAM.

A camera has been installed in the multi-use hotlab to prevent widespread or gross contamination events. Due to the nature of a multi-use room, when a spill occurred, the culprit was not easily identified and the spill was not quickly reported. By increasing the survey frequency of the room and the installation of the surveillance equipment there has been one spill and it was quickly reported to the Radiation Safety Office.

7. RADIATION SURVEYS

- A. Instruments and equipment: NI
- B. Briefly describe area survey requirements [20.1501(a), L/C]: NI
- C. Performed as required [20.1501(a), L/C] NI
- D. Records maintained [20.2103, L/C] NI
- E. Protection of members of the public
 - 1. Licensee made adequate surveys to demonstrate either (1) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (2) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [20.1301(a)(1), 1302(b)] (X) Y () N
 - 2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] (X) Y () N
 - 3. Records maintained [20.2103, 2107] (X) Y () N

Remarks:

In addition to air effluent monitors, there are 8 area film badge monitors at various locations throughout the licensee's facility to monitor for the above. The film badges are placed in the break area room, lobbies, entrance ways, mail room and common areas that a member of the public may encounter. Results of area film badges indicate minimal (less than 10 mrem).

8. RADIOACTIVE WASTE

NI

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

A. Describe how packages are received and by whom: () N/A

Receiving personnel deliver RAM packages promptly to the multi-use hotlab and notify Radiation Safety. A Radiation Safety Specialist performs receipt surveys in compliance with 20.1906.

- B. Written package opening procedures established and followed [20.1906(e)] (X) Y () N
- C. All incoming packages with DOT labels wiped, unless exempted (gases and special form) [20.1906(b)(1)] (X) Y () N
- D. Incoming packages surveyed per [20.1906(b)(2)] (X) Y () N
- E. Monitoring in (c) and (d) performed within time specified [20.1906(c)] (X) Y () N
- F. Transfer(s) between licensees performed per [30.41] NA
- G. All sources surveyed before shipment and transfer [20.1501(a), 49 CFR 173.475(i), L/C] NA
- H. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51] (X) Y () N
- I. Transfers within licensee's authorized users or locations performed as required [L/C] () Y () N (X) N/A
- J. Arrangements made for Type A packages [20.1906(a)] (X) Y () N
- K. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302] (X) Y () N () N/A

Remarks: Radiation Safety Specialist demonstrated how he surveys incoming packages.

The RAM user has access to the computerized order/entry system. Authorized Users license limits are incorporated into this system. The user places the order. The order is sent to the Radiation Safety Office and the radiation safety staff places the order. If a user places an order for more than is allowed, the computer flags this order and the order is not placed.

An AU demonstrated this ordering system. He placed a phony order for 50 mCi of P-32 and the order was denied. His authorized limit is 25 mCi.

This system also takes into account a debit system. For instance once material is used, the user will input the amount of material used, the amount remaining and how much went to waste. This allows the user to order more material. It can be compared to a checking account at a bank.

10. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 170-189)

NI

11. PERSONNEL RADIATION PROTECTION

- A. Licensee performed exposure evaluation [20.1501] (X) Y () N
- B. Licensee incorporated ALARA considerations in the Radiation Protection Program [20.1101(b)] (X) Y () N
- C. External Dosimetry () N/A
1. Licensee monitors workers [20.1502(a), L/C] (X) Y () N
 2. External exposures account for contributions from airborne activity [20.1203] NI
 3. Supplier Landauer Frequency Monthly film (G1) and quarterly rings (U3)
 4. Supplier is NVLAP-approved [20.1501(c)] (X) Y () N
 5. Dosimeters exchanged at required frequency [L/C] (X) Y () N

D. Internal Dosimetry () N/A

1. Licensee monitors workers [20.1502(b), L/C] (X) Y () N
2. Briefly describe licensee's program for monitoring and controlling internal exposures [20.1701, 1702, L/C]:

Thyroid bioassays are performed before and after iodinations. In addition, safety personnel are routinely monitored. The licensee has performed 40 thyroid bioassays for 1994 (6 iodinations occurred in 1994). No internal body burdens were detected. The results are maintained in dpm and compared to the MDA of the system. The licensee stated that they would convert this data to reflect a more meaningful unit (i.e., nanocurie quantity). In addition, the licensee stated that they would record the purpose of the scan (i.e., pre-iodination, post-iodination, routine, baseline, spill, safety personnel). As the records are kept, one can compare the I-125 incoming RAM package shipments to the bioassay log to determine the purpose of the scan.

3. Air sampling performed (X) Y () N
4. Monitoring/controlling program implemented (X) Y () N
5. Respiratory protection equipment [20.1703, L/C] NA

E. Reports () N/A

1. Reviewed by RSO Frequency
2. Inspector reviewed personnel monitoring records for period 12/92 to 9/94
3. Prior dose determined for individuals likely to receive doses [20.2104] NA
4. Maximum exposures TEDE 20 mrem for 1994 Other
5. Maximum CDEs 0 Organs
6. Maximum CEDE 0
7. Licensee sums internal and external [20.1202] NA
8. TEDEs and TODEs within limits [20.1201] (X) Y () N
9. NRC Forms or equivalent [20.2104(d), 2106(c)]

- a. NRC-4 (X) Y () N Complete: (X) Y () N
- b. NRC-5 () Y (X) N Complete: NA

10. Worker declared her pregnancy in writing during inspection period (review records) ☐ Y ☒ N ☐ N/A
 If yes, licensee in compliance with [20.1208] ☒ Y ☐ N
 and records maintained [20.2106(e)] NI
- F. Who performed PSEs at this facility (number of people involved and doses received) [20.1206, 2104, 2105, 2204] ☒ N/A
- G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106, L/C] ☒ Y ☐ N

Remarks:

In 1992, 2 out of 175 badged individuals received less than 20 mrem to the whole body total. This was the maximum whole body exposure for the year. The maximum extremity exposure was 120 mrem. In 1993, 4 out of 206 received less than 40 mrem to the whole body total. This was the maximum exposure for the year. The maximum extremity exposure was 90 mrem. In 1994, the maximum whole body and extremity exposure is 20 mrem and 70 mrem respectively.

A Radiation Safety Specialist is responsible for the timeliness of dosimetry returns. A log is kept of all late exchanges and followups. Computerized e-mail messages are sent regularly to all users reminding them of timely returns and reminding those who have not met the timeliness goals. The two individuals who are recurrently exchange their dosimetry late were interviewed. Both individuals do not use RAM, but would like a dosimeter in the event that they need to perform lab bench work in the future. A compromise was reached. If they ever need a badge, one would be made available to them in a matter of less than a day. They agreed to be taken off the dosimetry. Approximately ninety percent of all badges are late because the dosimeter was lost or misplaced. memos detailing these causes are on file and were reviewed during the inspection.

12. NRC INDEPENDENT MEASUREMENTS

A.	<u>Survey instrument</u>	<u>Serial No.</u>	<u>Last calibration</u>
	E-120	001087	4/4/94

- B. Inspector's measurements were compared to licensee's ☒ Y ☐ N
 C. Describe the type, location, and results of measurements:

Iodination laboratory: surveyed hood, floor, and equipment.

Found an unlabelled tube behind a lead brick (4,000 cpm with licensee's low-energy gamma scintillator survey meter) and unlabelled ice bucket containing P-32 compounds (650 cpm with E-120). Licensee immediately labeled containers.

13. NOTIFICATION AND REPORTS

() N/A

- A. Licensee in compliance with [19.13, 30.50] (reports to individuals, public and occupational, monitored to show compliance with Part 20) (X) Y () N () N/A
- B. Licensee in compliance with [20.2201, 30.50] (theft or loss) () Y () N (X) None
- C. Licensee in compliance with [20.2202, 30.50] (incidents) () Y () N (X) None
- D. Licensee in compliance with [20.2203, 30.50] (overexposures and high radiation levels) () Y () N (X) None
- E. Licensee aware of NRC Ops Center phone number (X) Y () N

14. POSTING AND LABELING

- A. NRC-3 "Notice to Workers" is posted [19.11] (X) Y () N
- B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted or a notice indicating where documents can be examined is posted [19.11, 21.6] (*) Y () N
- C. Other posting and labeling per [20.1902, 1904] and the licensee is not exempted by [20.1903, 1905] (*) Y () N

Remarks:

Licensee posted a note indicating that copies of Parts 19, 20 and 21 (et. al.) can be found in the RSO's office.

Licensee promptly and properly labelled containers in the hotlab that contained RAM and were not labelled. One was an ice bucket sitting on a lab bench and the other was a plastic tube behind a lead brick in the chemical fume hood.

15. RECORDKEEPING FOR DECOMMISSIONING

() N/A

- A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] NI
- B. Records include all information outlined in [30.35(g)] NI

Remarks: The inspector informed the licensee of these requirements.

16. BULLETINS AND INFORMATION NOTICES

- A. Bulletins, Information Notices, NMSS Newsletters, etc., received by the Licensee (X) Y () N
- B. Licensee took appropriate action in response to Bulletins, Generic Letters, etc. (X) Y () N

Remarks: Dr. Posner receives these correspondences and passes the information onto the RSO. Unfortunately the timeliness of this matter is questionable. This routing should be changed to the RSO.

17. SPECIAL LICENSE CONDITIONS OR ISSUES

(X) N/A

18. CONTINUATION OF REPORT ITEMS

(X) N/A

FYI: Directions are attached.

19. VIOLATIONS, NCVs, AND OTHER ISSUES

(X) N/A

Note: Briefly state (1) the requirement and (2) how and when the licensee violated the requirement. For non-cited violations, indicate why the violation was not cited.

20. PERFORMANCE EVALUATION FACTORS

Licensee (name & location)
Miles, Inc.
400 Morgan Lane
West Haven, CT

Inspector: Kathleen Dolce

Inspection Date 12/8/94

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

Remarks (consider above assessment and/or other pertinent PEFs):

The company will be undergoing a name change. Miles will become Bayer. There will be no change to the staffing or radiation safety program. All commitments made to the NRC by the licensee will still be in place.

The radiation safety program will be taking responsibility for the industrial hygiene monitoring program. Due to this increased responsibility, the RSO has to re-evaluate the radiation safety program's needs and not let additional responsibilities compromise a good program. This was discussed at the exit meeting.

Regional follow-up on above PEFs citations: