



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

*Duplicate copy for
microfiche*

June 2, 1981



Dr. Rodney D. Ice
Certified Health Physicist
Health Sciences Center
The University of Oklahoma at Oklahoma City
P. O. Box 26901
Oklahoma City, OK 73190

IN RESPONSE REFER
TO FOIA-81-100

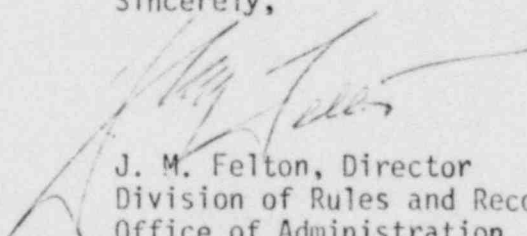
Dear Dr. Ice:

This is in further response to your letter of March 6, 1981, in which you requested, pursuant to the Freedom of Information Act, two categories of documents pertaining to inspection reports and preliminary notification reports (PNOs) for licenses issued under category 02500 for 1979 and 1980.

On April 30, 1981 you agreed, in a telephone conversation with Ms. Sarah N. Wigginton of my staff, to limit your request for inspection reports for the year 1980 for the present time, with the understanding that you might also need the reports for 1979 in the event your statistical sample is not large enough.

Please find enclosed the 35 documents listed on Appendix A. The dates on the reports reflect the latest date of inspection; in some cases, you will see that the inspections were not conducted in 1980. This is due to the fact that inspections are carried out on a cyclical, rather than annual, basis. However, we have included them in the event they may be of use to you in your research. One licensee, Western Diagnostics Services, has not as yet been inspected. In addition, 14 inspection reports have been requested from the NRC regional offices. As soon as we receive those reports, we will forward them to you.

Sincerely,


J. M. Felton, Director
Division of Rules and Records
Office of Administration

Enclosures: As stated

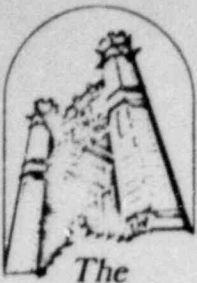
8106250 219

APPENDIX A

1. April 13, 1981 Letter to Mallinckrodt, Inc., from James G. Keppler, re: IE Report No. 81-01 (11 pages)
2. March 13, 1981 Letter to Norland Instruments from D. G. Wiedeman, re: Notice of Violation (3 pages)
3. February 12, 1981 Letter to Diagnostic Management, Inc., from W. L. Fisher, re: Notice of Violation and Inspection Report (26 pages)
4. February 4, 1981 Letter to Bio-Dynamics/bmc from W. L. Fisher, re: Notice of Violation (4 pages)
5. December 18, 1980 Letter to Pharmatopes, Inc., from Boyce H. Grier, re: Report No. 30-14826/80-01 (17 pages)
6. November 20, 1980 Letter to Pacific Radiopharmacy, Ltd., from H. E. Book, re: Notice of Violation and Notice of Deviation (5 pages)
7. November 7, 1980 Letter to University of Utah from Glen D. Brown, re: Inspection Report (3 pages)
8. August 14, 1980 Letter to New England Nuclear Corporation from John D. Kinneman, re: Inspection Report Numbers 30-4579/80-01; 30-4581/80-02 and 30-4704/80-01 (12 pages)
9. August 11, 1980 Letter to Diagnostic Isotopes, Inc., from Boyce H. Grier, re: Notice of Violation and Inspection Report (18 pages)
10. August 7, 1980 USNRC Inspection Findings and Licensee Acknowledgment for Virginia Commonwealth University
11. August 7, 1980 Letter to Minnesota Mining and Manufacturing Company from A. B. Davis, re: Inspection Report (23 pages)
12. July 10, 1980 Letter to Pharmaco Nuclear, Inc., from John D. Kinneman, re: Routine inspection
13. June 27, 1980 Letter to RAD/IRID, Inc., from John D. Kinneman, re: Notice of Violation (3 pages)
14. June 26, 1980 Letter to University of Minnesota from James G. Keppler, re: Notice of Violation and Inspection Reports (28 pages)
15. April 25, 1980 Letter to William Beaumont Hospital from James G. Keppler, re: Notice of Violation (8 pages)
16. April 21, 1980 Letter to Nuclear Pharmacy, Inc., from A. B. Davis, re: Inspection Report (12 pages)

17. April 2, 1980 Letter to Gamma Diagnostic Laboratories from George H. Smith, re: Notice of Violation (4 pages)
18. February 20, 1980 Letter to Nuclear Pharmacy, Inc., (Elfreth Alley Apothecary) from Boyce H. Grier, re: Inspection Report (8 pages)
19. January 18, 1980 Letter to Pharmatopes, Inc., from J. Philip Stohr, re: Notice of Violation (3 pages)
20. January 2, 1980 Letter to Pharmaco Nuclear from A. B. Davis, re: Notice of Violation (2 pages)
21. December 17, 1979 Letter to Amersham Corporation from A. B. Davis, re: Notice of Violation and Inspection Reports (13 pages)
22. September 24, 1979 Letter to Minnesota Mining and Manufacturing Co. from A. B. Davis, re: Notice of Violation and Inspection Reports (21 pages)
23. September 18, 1979 Letter to Capintec Instruments, Inc., from Robert O. McClintock, re: Notice of Violation (4 pages)
24. August 17, 1979 Letter to Nuclear Pharmacy, Inc., from James G. Keppler, re: Inspection Report (22 pages)
25. August 16, 1979 USNRC Inspection Findings and Licensee Acknowledgment for Pharmaco Nuclear
26. June 29, 1979 Letter to Medi+Physics, Inc., from James G. Keppler, re: Notice of Violation (4 pages)
27. February 1, 1979 Letter to Abbott Laboratories from A. B. Davis, re: Notice of Violation (3 pages)
28. December 5, 1978 USNRC Inspection Findings and Licensee Acknowledgment for The Proctor & Gamble Company
29. November 15, 1978 USNRC Inspection Findings and Licensee Acknowledgment for Pharmatopes, Inc.
31. October 27, 1978 USNRC Inspection Findings and Licensee Acknowledgment for The University of Oklahoma Health Sciences Center
32. August 23, 1978 Letter to Pharmatopes, Inc., from A. B. Davis, re: Notice of Violation
33. May 11, 1978 Letter to The Regents of the University of Michigan from A. B. Davis, re: Notice of Violation (3 pages)
34. April 11, 1978 Letter to Pharmatopes, Inc., from W. L. Fisher, re: Notice of Violation

35. January 26, 1977 Letter to Leahy Nuclear Corporation from James M. Allan, re: Item of Noncompliance (3 pages)



The University of Oklahoma at Oklahoma City • Health Sciences Center

College of Pharmacy

March 6, 1981

Chairman
Nuclear Regulatory Commission
Washington, DC 20555

FREEDOM OF INFORMATION
ACT REQUEST

FOIA-81-100
Rec'd 3-16-81

Dear Mr. Chairman:

Under the provisions of the Freedom of Information Act, 5-USC-552, I am requesting access to the following:

1. Inspection reports of nuclear pharmacies under license category 02500 for the years 1979 and 1980.
2. Copies of any PNO (Preliminary Notification Reports) involving any incidences occurring with licensees licensed under 02500 for the years 1979 and 1980.

I am requesting this information so that I might technically analyze the rate of noncompliance by nuclear pharmacies from a statistical consideration and to develop a paper that, with time, will identify the parameters that effect the incidence noncompliance rate.

As you know the act permits you to reduce or waive fees when the use of the information is considered as "primarily benefiting the public." I believe that this request fits that category and therefore ask you to waive any fees.

If all or any part of this request is denied, please site the specific exemptions which you think justify your refusal to release the information and inform me of the appeal procedures available to me under the law.

I would appreciate your handling this request as quickly as possible and I'll look forward to hearing from you within 10 days as the law stipulates.

Sincerely,

Rodney D. Ice, Ph.D.
Dean
Certified Health Physicist

RDI/smg

Dupe of 8104200222 (1pg)



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
759 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

APR 13 1981

IE FILE COPY

Mallinckrodt, Inc.
ATTN: Mr. M. Costello
Director of Operations
Box 10172 Lambert Field
St. Louis, MO 63145

License No. 24-04206-01
License No. 24-05804-03
License No. 24-04206-03G
License No. 24-04206-04MA ✓
License No. 24-17450-01
License No. 24-04206-05MD
License No. 24-05804-02
License No. SUC-872
License No. STB-401

Gentlemen:

This refers to the telephone conversation between you and your staff and Mr. C. E. Norelius and others of my staff on March 5, 1981. The purpose of the call was to inform you of our program for Systematic Appraisal of Licensee Performance (SALP) and to discuss the results of our appraisal of your NRC licensed activities.

The subjects discussed are enclosed in the Office of Inspection and Enforcement Report and the Licensee Performance Appraisal.

It is our view that this meeting was effective in communicating to you and your staff the results of our evaluation of your performance of licensed activities.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

*Dupe of
8104220276
PDR*

APR 13 1981

No reply to this letter is necessary; however, we will gladly discuss any questions you have concerning this appraisal.

Sincerely,

James G. Keppler
Director

Enclosure: IE Inspection
Report No. 81-01

cc: LFMB ltr only

cc w/encl:

Don Soldan, Corporate
Radiological Safety Officer
Richard Costic, Plant
Manager
Central Files
Reproduction Unit NRC 20b
PDR
NSIC

RIII 2/5/81 Burgin/jp Obergerg	RIII Wiedeman 4/7/81	RIII Fisher 4/7/81	RIII Streeter 4/9/81	RIII Schultz 4-10-81	RIII Davis 4/10/81	RIII Keppler 4/13/81
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U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

Report No. 81-01

License No. 24-04206-01; 24-05804-03;
24-04206-03G; 24-04206-04MA;
24-17450-01; 24-04206-05MD;
24-05804-02; SUC-872; STB-401

Licensee: Mallinckrodt, Inc.

Facility: Mallinckrodt/Diagnostics, Inc.
Maryland Heights, MO
Mallinckrodt Chemical Works
St. Louis, MO

Meeting: Telephone conversation between licensee management and Region III
representatives on March 5, 1981

NRC Representatives: *C. E. Norelius*
C. E. Norelius, Acting Director
Division of Engineering and
Technical Inspection

4/9/81

W. L. Fisher
W. L. Fisher, Chief
Technical Inspection Branch

4/7/81

H. H. Schultz
H. H. Schultz
Enforcement Coordinator

4/10/81

D. G. Wiedeman
D. G. Wiedeman, Acting Chief
Material Radiation Protection
Section No. 1

4/7/81

C. T. Oberg
C. T. Oberg, Radiation Specialist
Material Radiation Protection
Section No. 1

4/7/81

Approved By: *A. E. Davis*
A. E. Davis, Deputy Director

4/10/81

Summary:

Telephone conversation on March 5, 1981 (Report No. 81-01)

Subjects Discussed: The purpose of the communication was to acquaint licensee
management of Licensee Performance (SALP)
inspection history relates to the NRC's

DUPLICATE DOCUMENT

Entire document previously
entered into system under:

ANO 8104220286

No. of pages: 9



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

MAR 13 1981

Norland Instruments
ATTN: Dr. Russel H. Nord
Route 4, Norland Drive
Fort Atkinson, WI 53538

License No. 48-13403-01
License No. 48-13403-02MD ✓

30-11258

Gentlemen:

This refers to the routine safety inspection conducted by Dr. Wm. J. Adam of this office on February 27, 1981, of activities at Norland Instruments authorized by NRC Byproduct Material Licenses No. 48-13403-01 and No. 48-13403-02MD and to the discussion of our findings with you at the conclusion of the inspection.

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. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

Also reviewed during this inspection were the events surrounding the transfer of an iodine-125 sealed source to an unauthorized licensee.

During this inspection, certain of your activities appeared to be in non-compliance with NRC requirements, as described in the enclosed Appendix A, and a written response is required.

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

Sincerely,

D. G. Wiedeman, Acting Chief
Materials Radiation Protection
Section 1

Enclosure: Appendix A,
Notice of Violation

cc: LFMB, ltr only

cc w/encl:
Central Files
Reproduction Unit NRC 20b
PDR
NSIC

8107/50204
CF

Appendix A

NOTICE OF VIOLATION

Norland Instruments

License No. 48-13403-01

License No. 48-13403-02MD

As a result of the inspection conducted on February 27, 1981, and in accordance with the Interim Enforcement Policy, 45 FR 66754 (October 7, 1980), the following violations were identified:

License No. 48-13403-02MD

1. 10 CFR 30.41(7)(c) requires each licensee transferring material to verify that the transferee's license authorizes receipt of the type, form and quantity of byproduct material to be transferred. 10 CFR 30.41(d)(1) through (5) lists acceptable methods of verification.

Contrary to the above, during October 1980, a 200 mCi iodine-125 sealed source was transferred to the Veterans Administration Medical Center, Oklahoma City, OK., without verification in accordance with 10 CFR 30.41(d)(1) through (5).

This is a Severity Level V violation (Supplement VII).

License No. 48-13403-01

2. 10 CFR 20.401(b) requires that you maintain records showing the results of surveys conducted to comply with 10 CFR 20.205 "Procedures for Picking Up, Receiving and Opening Packages".

Contrary to the above, no records of results of surveys of incoming packages were maintained.

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

3. License Condition 13 requires a leak test of sealed sources be performed at six month intervals and prior to transfer to another licensee. Records of results of these leak tests are to be kept in units of microcuries and maintained for inspection by the Commission.

Contrary to the above, records of leak tests performed on spent sources being transferred to Atomic Energy of Canada, Ltd. are not being maintained.

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

Dpe
8104050208

MAR 13 1981

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within twenty-five days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Under the authority of Section 182 of the Atomic Energy Act of 1954, as amended, this response shall be submitted under oath or affirmation.

Dated

3/11/81

D. G. Wiedeman, Acting Chief
Materials Radiation Protection
Section 1



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

FEB 12 1981

30-17084

Diagnostic Management, Inc.
ATTN: Dennis R. Hoogland, Ph.D.
President
2233 University Avenue
Suite 220
St. Paul, MN 55114

License No. 22-19174-01MD

Gentlemen:

This refers to the routine safety inspection conducted by Mr. C. T. Oberg of this office on December 17 and 18, 1980, of activities at Diagnostic Management, Inc. authorized by NRC Byproduct Material License No. 22-19174-01MD and to the discussion of our findings with you at the conclusion of the inspection.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, and interviews with personnel.

During this inspection, certain of your activities appeared to be in non-compliance with NRC requirements, as described in the enclosed Appendix A, and a written response is required.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC's Public Document Room, except as follows. If the enclosures contain information that you or your contractors believe to be proprietary, you must apply in writing to this office, within twenty-five days of the date of this letter, to withhold such information from public disclosure. The application must include a full statement of the reasons for which the information is considered proprietary, and should be prepared so that proprietary information identified in the application is contained in an enclosure to the application.

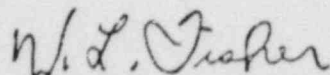
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FEB 12 1981

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

Sincerely,



W. L. Fisher, Acting Chief
Fuel Facility and Materials
Safety Branch

Enclosures:

1. Appendix A, Notice
of Violation
2. IE Inspection Report
No. 03017084/80-01

cc: LFMB, ltr only

cc w/encl:
Central Files
Reproduction Unit NRC 20b
NISC
TIC

Appendix A

NOTICE OF VIOLATION

Diagnostic Management

License No. 22-19174-01MD

As a result of the inspection conducted on December 17 and 18, 1980, and in accordance with the Interim Enforcement Policy, 45 FR 66754 (October 7, 1980), the following violations were identified:

1. License Condition No. 23 states the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in letter dated December 26, 1979. Item 5 of attachments to this letter specifies that the licensee will follow procedures outlined in Appendix D, Section 2, of Regulatory Guide 10.8, for the performance of tests on the dose calibrators.

Contrary to this requirement, on the dates of this inspection, the licensee could not locate records of the performance of linearity, geometrical, and accuracy tests performed at the time the dose calibrators were installed.

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

2. License Condition No. 23 states the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in application dated October 2, 1979, and letter dated December 26, 1979. Attachments to these state staff workers will have their thyroids monitored and that a record of these bioassays will be maintained. The thyroid measurements will be made initially upon employment and at six month intervals thereafter. A final measurement will be made at termination.

Contrary to these requirements, as of the dates of this inspection, records of the results of bioassays performed have not been maintained by the licensee.

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

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within twenty-five days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action

Dupe of 8LQ3260080

FEB 12 1981

Appendix A

- 2 -

to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Under the authority of Section 182 of the Atomic Energy Act of 1954, as amended, this response shall be submitted under oath or affirmation.

Dated 2/10/81

W. L. Fisher
W. L. Fisher, Acting Chief
Fuel Facility and Materials
Safety Branch

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

Report No. 03017084/80-01

Docket No. 03017084

License No. 22-19174-01MD

Priority I

Category B

Licensee: Diagnostic Management, Inc.
2233 University Avenue, Suite 220
St. Paul, MN 55114

Inspection Conducted: December 17 and 18, 1980

Inspector: W. H. Schultz / C. T. Oberg

2-9-81

Approved by: W. H. Schultz
W. H. Schultz, Acting Chief
Materials Radiological
Protection Section No. 1

2-9-81

Inspection Summary:

Inspection of December 17 and 18, 1980 (Report No. 03017084/80-01)

Areas Inspected: Organization; Licensee Audits; Training; Materials, Facilities and Equipment; Receipt and Transfer of Material; Exposure Controls - External; Exposure Controls - Internal; Exposure Controls - ALARA Program; Radioactive Effluents and Waste Disposal; Quality Assurance; Emergency Preparedness Programs; and Confirmatory Measurements. The inspection involved a total of seven inspector-hours by one inspector.

Results: Of the 12 areas inspected, two violations of NRC regulations were identified: Severity Level VI violation - records of dose calibrator linearity, geometrical, and accuracy tests performed initially on installation were not available; and Severity Level VI violation - records of the results of bioassays performed have not been maintained.

DUPLICATE DOCUMENT

Entire document previously
entered into system under:

ANO 8103200092

No. of pages: 22



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

IFEE 4/1984

Bio-Dynamics/bmc
ATTN: Mr. James Beard, Director of
Scientific & Regulatory Affairs
9115 Hague Road
Indianapolis, IN 46250

License No. 13-17999-01MA
License No. 13-17999-02
License No. 13-17999-03 ✓
License No. 13-17999-04G

Gentlemen:

This refers to the routine safety inspection conducted by Mr. D. G. Wiedeman and Dr. L. W. Shatterly of this office on January 7, 1981, of activities authorized by NRC Byproduct Material Licenses No. 13-17999-01MA, No. 13-17999-02, No. 13-17999-03 and No. 13-17999-04G and to the discussion of our findings with you and Messrs. D. Dunn and J. Clinton at the conclusion of the inspection.

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. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

During this inspection no items of noncompliance were identified for Licenses No. 13-17999-01MA and No. 13-17999-04G; however, for Licenses No. 13-17999-02 and No. 13-17999-03 certain of your activities appeared to be in noncompliance with NRC requirements, as described in the enclosed Appendix A. A written reply is required.

We are concerned that these noncompliances show a lack of management's attention to certain radiation safety provisions in that no program existed for air sampling, surveys or bioassays. At the conclusion of the inspection you assured our inspectors that you would take positive actions to correct the items of noncompliance found during this inspection and to prevent their recurrence. Our future inspections will further evaluate the effectiveness of management control over licensed activities. Should these inspections identify a continuation of significant noncompliance, escalated enforcement action may be taken.

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

Sincerely,

W. L. Fisher
W. L. Fisher, Acting Chief
Fuel Facility and Materials
Safety Branch

Enclosure: Appendix A,
Notice of Violation

cc: LFMB, ltr only

cc w/encl:
James Clinton, Assistant
Radiation Safety Officer
Central Files
Reproduction Unit NRC 20b
NSIC
TIC

Appendix A

NOTICE OF VIOLATION

Bio-Dynamics/bmc

License No. 13-17999-02
License No. 13-17999-03

As a result of the inspection conducted on January 7, 1981, and in accordance with the Interim Enforcement Policy, 45 FR 66754 (October 7, 1980), the following violations were identified:

Licenses No. 13-17999-02 and No. 13-17999-03

1. License Condition No. 13 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application received October 16, 1978. The letter dated January 8, 1979 in support of that application for use and possession of byproduct material under Licenses No. 13-17999-02 and No. 13-17999-03 states film badges and finger badges will be worn.

Contrary to the above requirements, it was determined through statements of licensee representatives and the NRC inspectors' review of personnel monitoring records, that this requirement is not being met. Specifically, finger badges were discontinued on October 25, 1979 and the licensee failed to amend the license to reflect this change.

This is a Severity Level V violation (Supplement VII).

2. 10 CFR 20.103(a)(3) states that for purposes of determining compliance with the requirements of this section the licensee shall use suitable measurements of concentrations of radioactive materials in air for detecting and evaluating airborne radioactivity in restricted areas and in addition, as appropriate, shall use measurements of radioactivity in the body, measurements of radioactivity excreted from the body, or any combination of such measurements as may be necessary for timely detection and assessment of individual intakes of radioactivity by exposed individuals.

Contrary to the above, no air samples have been taken in the laboratories where millicurie quantities of iodine-125 are handled.

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

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License No. 13-17999-02

3. License Condition No. 16 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated January 19, 1978, and application received October 16, 1978, and various dated letters. Item No. 14 of the January 19, 1978 application states weekly area surveys and wipe samples are performed.

Contrary to the above requirement, it was determined through statements of licensee representatives that this requirement is not being met. Specifically, wipe test were not performed prior to February 22, 1980 and licensee has not conducted wipe surveys and direct radiation surveys since July 25, 1980.

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

License No. 13-17999-03

4. License Condition No. 13 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application received October 16, 1978 and various dated letters. Letter dated January 8, 1979 in support of application for use and possession, manufacturing, and distribution of byproduct material, states under Item III-A "Bioassays will be performed on all personnel who, in the course of their normal work, come in contact with and use radioactive material."

Contrary to the above requirements, it was determined through statements of licensee representatives that this requirement is not being met. Specifically, the licensee failed to implement the bioassay program as described in the letter dated January 8, 1979.

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

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within twenty-five days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Under the authority of Section 182 of the Atomic Energy Act of 1954, as amended, this response shall be submitted under oath or affirmation.

Dated _____

W. L. Fisher, Acting Chief
Fuel Facility and Materials
Safety Branch



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
631 PARK AVENUE
KING OF PRUSSIA, PENNSYLVANIA 19406

JE FILE COPY

Docket No. 30-14826

DEC 18 1980

Pharmatopes, Inc.
ATTN: Mr. Mark Hebner
President
25721 Coolidge Highway
Oak Place, Michigan 48237

Gentlemen:

Subject: Inspection 30-14826/80-01

This refers to the routine inspection conducted by Mr. B. O'Neill and Ms. J. Johansen of this office on August 29, 1980 and by Mr. F. Costello and Ms. J. McGinness on September 25, 1980 at Pharmatopes, Inc., Washington, D.C. of activities authorized by NRC License No. 08-18308-01MD and to the discussions of our findings held by Mr. O'Neill with Messrs. Tang and Veticca of your staff on August 29, 1980 and by Mr. Costello with Messrs Tang and Veticca on September 25, 1980. This also refers to the meeting held at our office in King of Prussia, Pennsylvania between yourself and members of my staff on September 8, 1980. The subjects discussed in this meeting are described in the meeting summary which is attached as Appendix A to this letter. Appendix B is the attendance list.

Areas examined during this inspection are described in the Office of Inspection and Enforcement Inspection Report which is enclosed with this letter. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Enforcement correspondence for this inspection has been provided from our Headquarters.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter, the enclosed appendices and inspection report will be placed in the NRC's Public Document Room. If the appendices or this report contain any information that you (or your contractor) believe to be proprietary, it is necessary that you make a written application within 20 days to this office to withhold such information from public disclosure. Any such application must be accompanied by an affidavit executed by the owner of the information, which identifies the document or part sought to be withheld, and which contains a statement of reasons which addresses with specificity the items which will be considered by the Commission as listed in subparagraph (b) (4) of Section 2.790. The information sought to be withheld shall be incorporated as far as possible into a separate part of the affidavit. If we do not hear from you in this regard within the specified period, the appendices and the report will be placed in the Public Document Room.

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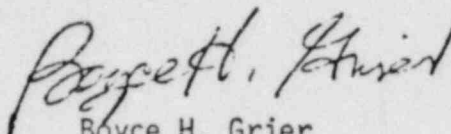
Pharmatopes, Inc.

2

DEC 19 1980

No reply to this letter is required; however, should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,



Boyce H. Grier
Director

Enclosures:

1. Office of Inspection and Enforcement Inspection
Report Number 30-14826/80-01
2. Appendix A, Meeting Summary
3. Appendix B, List of Attendees

cc w/encl:

A. McKusick, Manager
Pharmatopes, Inc.
4545 43rd Street N.W.
Washington, D.C. 20016

bcc w/encl:

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U. S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION I

Report No. 30-14826/80-01

Docket No. 30-14826

License No. 03-18308-01MD

Priority IV

Category E

Licensee: Pharmatopes, Inc.

4545 42nd Street, N.W.

Washington, D.C. 20016

Facility Name: Pharmatopes, Incorporated

Inspection At: Washington, D.C.

Inspection Conducted: August 29, 1980

Inspectors:

B. O'Neill, Radiation Specialist

10-24-80
date

B. Johansen, Radiation Specialist

10-27-80
date

F. Costello, Radiation Specialist

10-27-80
date

P. McGinness, Radiation Specialist (Intern)

10-27-80
date

Approved by:

P. Kinneman, Chief, Materials Radiological
Protection Section, FF&MC Branch

10-24-80
date

Inspection Summary:

Inspection on August 29, and September 25, 1980 (Report No. 30-14826/80-01)

Areas Inspected: Routine, unannounced, off-shift inspection of radiation protection program including: review of previous items in organization; review of previous items ion procedures; training of personnel; ng procedures; transfer of licensed material; surveys; and receipt of radioactive materials. r hours by four NRC regional based inspectors. ed, fifteen apparent items of noncompliance ure to wear personnel monitoring devices -

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