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April 4, 1997

Paul Gargan, President
American Biogenetic Sciences, Inc.
1539 North Ironwood Drive
South Bend, IN 46635

SUBJECT: NOTICE OF VIOLATION DATED MARCH 7, 1997

Dear Mr. Gargan:

This acknowledges receipt of Kirk Guyer's letter dated March 20, 1997, in response to our letter dated March 7, 1997, transmitting a Notice of Violation.

We have reviewed your corrective actions, which appear to be adequate, and have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,
Original Signed by Gary L. Shear

Roy J. Caniano, Acting Director
Division of Nuclear Materials Safety

License No. 13-26719-01
Docket No. 030-34124

cc: K. Guyer

bcc w/ltr dtd 03/20/97: PUBLIC

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AMERICAN BIOGENETIC SCIENCES, INC.

1539 North Ironwood Drive, South Bend, IN 46635 • Tel: (219) 271-3415 Fax: (219) 271-3423

March 20, 1997

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety
United States Regulatory Commission, Region III
801 Warrenville Road
Lisle, Il 60532-4351

SUBJECT: "REPLY TO A NOTICE OF VIOLATION"

Dear Ms. Pederson:

This refers to the Notice of Violation issued on March 7, 1997 to Dr. Paul Gargan, President of American Biogenetic Sciences, Inc. The following are responses to the two cited violations found during the inspection conducted on January 14, 1997. Attached is a copy of the letter addressed to Dr. Gargan for your convenience.

1. Violation to 10 CFR 20.1906(b) and (c)

1. The violation occurred due to a change in the Code of Federal Regulations which was explained in Appendix X of which I did not possess a copy.

2. Ambient package surveys were being performed using a handheld survey meter. However, upon notification of the required removable contamination surveys (wipe tests), we immediately initiated the performance of such surveys on incoming packages that met the established quantities.

3. All personnel handling or working with radioactive materials have been informed of the survey requirements and periodic internal audits include a review of such surveys to insure their performance.

4. Full compliance was achieved as of January 30, 1997.

2. Violation to Condition 18 of License No. 13-26719-01

1. The violation occurred because of a misinterpretation of the requirements of the license. In the initial license submission a guideline was cited that explained the survey program. When additional information was requested I thought that it would supercede the original information because the supplement was more specific in nature.

2. When it was explained that the supplement was in addition to all original submissions, the weekly survey of waste storage areas was initiated.

License No. 13-26719-01
Docket No. 030-34124

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New York Office: 1375 Akron Street, Copiague, New York 11726 • Tel: (516) 789-2600 Fax: (516) 789-1661

AMERICAN BIOGENETIC SCIENCES, INC.

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3. A thorough review of survey requirements contained in our license was performed and a schedule established for the performance of such surveys.

4. Full compliance was achieved as of January 30, 1997.

If you are in need of further information or explanation of the cited violations, please contact me at your earliest convenience.

Sincerely,

Kirk E. Guyer, RSO

Kirk E. Guyer, Radiation Safety Officer

License No. 13-26719-01
Docket No. 030-34124

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

March 7, 1997

Paul Gargan
President
American Biogenetic Sciences, Inc.
1539 North Ironwood Drive
South Bend, IN 46635

SUBJECT: NRC INSPECTION AND NOTICE OF VIOLATION

Dear Mr. Gargan:

This refers to the inspection conducted on January 14, 1997 (with continued NRC in-office review through February 11, 1997) at American Biogenetic Services, Inc., Mishawaka, Indiana. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with members of your staff.

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. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements and observation of activities in progress.

Based on the results of this inspection, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice). A written response is required.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,

Gary L. Shear for

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

9703110275 BRP

License No. 13-26719-01
Docket No. 030-34124

Enclosure: Notice of Violation

NOTICE OF VIOLATION

American Biogenetic Sciences, Inc.
South Bend, Indiana

License No. 13-26719-01
Docket No. 030-34124

During an NRC inspection conducted on January 14, 1997, with continued NRC in-office review through February 11, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (60 FR 34381; June 30, 1995), the violations are listed below:

1. 10 CFR 20.1906(b) and (c) require that each licensee monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71. This monitoring shall be performed as soon as practicable, but not later than three hours after receipt of the package during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

   Contrary to the above, as of January 14, 1997, the licensee received packages labeled with a Radioactive White I label, the package was not exempt from the monitoring requirement for radioactive contamination, and the licensee did not perform the required monitoring. Specifically, the packages received by the licensee contained millicurie quantities of technetium-99m in liquid form.

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

2. Condition 18 of License No. 13-26719-01 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in letter dated June 26, 1996 (with attachments).

   Item 10.9 of the letter dated June 26, 1996, requires implementation of the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2.

   Under the subtitle, "Removable Contamination Surveys" of Appendix N to Regulatory Guide 10.8, Revision 2, Item 1.a. requires, in part, that weekly removable contamination surveys be performed in radiopharmaceutical preparation areas. Additionally, Item 1.b. requires, in part, that weekly removable contamination surveys be performed in radiopharmaceutical storage and radiopharmaceutical waste storage areas.

ambient test
wipe.

Contrary to the above, as of January 14, 1997, the licensee did not perform the required surveys. Specifically, the licensee did not perform weekly removable contamination surveys in the lab where: (1) radiopharmaceuticals were prepared; (2) radiopharmaceuticals were stored; and (3) radiopharmaceutical waste was stored.

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

Pursuant to the provisions of 10 CFR 2.201, American Biogenetic Sciences, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351 within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be placed in the NRC Public Document Room (PDR), 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. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated at Lisle, Illinois
this 7th day of March 1997