U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-03790/89-002

Docket No. 030-03790

License No. 06-05869-01 Priority 3 Category 03611

Licensee: Pfizer, Incorporated
Eastern Point Road
Groton, Connecticut 06340

Enforcement Conference At: Region I, King of Prussia, Pennsylvania

Enforcement Conference Conducted: May 18, 1989

Prepared by: Elizabeth Ullrich, Health Physicist — 6/20/89 date signed

Approved by: John D. Kinneman, Chief
Nuclear Materials Safety Section B — 6/20/89 date signed

Enforcement Summary: Enforcement Conference held in King of Prussia, Pennsylvania on May 18, 1989. Licensee representatives discussed corrective and preventive actions taken and planned as a result of the improper disposal of radioactive waste at a public site and the results of the NRC Inspection conducted on March 27, 1989. NRC representatives discussed their concerns regarding factors leading to the improper disposal including the lack of management attention to the radiation safety program in the research laboratories. Enforcement options available to the Commission were reviewed.

DETAILS

1. Attendance

Pfizer, Inc.

Dr. Manfred Schach von Wittenau, Vice President of Safety Evaluation
Dr. Sanford K. Figdor, Radiation Safety Officer
William D. Huhn, Corporate Counsel
Daniel P. Brannegan, Manager, Environmental Health

Nuclear Regulatory Commission

Malcolm R. Knapp, Director, Division of Radiation Safety and Safeguards
Lee H. Bettenhausen, Chief, Nuclear Materials Safety Branch
John D. Kinneman, Chief, Nuclear Materials Safety Section B
Elizabeth Ullrich, Health Physicist
Richard Provencher, Health Physicist
Jenny M. Johansen, Office of Enforcement

2. Conference Summary

Introductions were made, and the representatives of Pfizer, Inc. were welcomed to Region I by Malcolm R. Knapp, Director, Division of Radiation Safety and Safeguards. Mr. Knapp explained the purpose of the conference and indicated that the NRC was concerned not only about the specific violations cited, but also with the apparent programmatic deficiencies that the findings indicated.

Dr. Manfred Schach von Wittenau, Vice President of Safety Evaluation, Pfizer, Inc., discussed the improper disposal of waste by an individual employee. He stated that this violation of NRC and corporate procedures is not typical of Pfizer, Inc. employees, but that the investigation of the incident identified a number of weaknesses in the Radiation Safety program, particularly concerning the laboratories which use several millicuries or less of licensed material. He stated Pfizer's strong commitment to effective corrective action for the weaknesses identified and for all violations.

The inspection findings were reviewed and licensee representatives responded to each apparent violation. Mr. Daniel Brannegan, Manager of Environmental Health at Pfizer, Inc., discussed the current radioactive waste disposal program and the actions planned to strengthen the program. Dr. Sanford Figdor, the Radiation Safety Officer at Pfizer, Inc., discussed the current status of and planned improvements to the training program, laboratory surveys and inspections, and package opening and survey procedures. These corrective actions are detailed in Attachment A to this report, provided by the licensee at the conference. Licensee questions regarding acceptable training programs and package survey procedures were discussed.

3. Closing

Keith Christopher, Enforcement Specialist, outlined the NRC's enforcement options. Mr. Knapp thanked the licensee representatives for their attendance and presentation. He concluded by saying that the information presented at the meeting would be considered in deciding the enforcement action to be taken.

Pfizer

CENTRAL RESEARCH

PFIZER INC. EASTERN POINT ROAD, GROTON, CONNECTICUT 06340

203-441-4100

NRC ENFORCEMENT CONFERENCE

Thursday, May 18, 1989

2:30 p.m.

King of Prussia, PA

Dr. M. von Schach
Mr. D. P. Brannegan
Dr. S. K. Figdor
Mr. W. D. Huhn

Attachment A
Report No. 30-3790/89-002

License No. 06-05869-01
Docket No. 030-03790
EA No. 89-94

RESPONSE TO NRC LETTER OF MAY 2, 1989

Item 2. Unauthorized Waste Disposal

Past Practices:

Pfizer Central Research has had an established low level radioactive waste disposal program for many years. Since 1982 the present radioactive waste disposal program has been a part of the Groton Central Research Safety Manual, Section 19. This program has been managed by the Safety and Environmental Health Office.

- The central component of the program is a centralized collection area. All waste is transferred directly by laboratory personnel to the waste coordinator who records the identity of isotope, as well as the estimated activity. The laboratory personnel who generate the waste and are skilled in handling it are the ones who transport it to the collection area. We do not entrust this to our custodians.

- The program has remained essentially unchanged since 1982.

- We submit that the existing waste program has worked effectively in the past. The program handled waste from the facility without a single incident prior to the recent matter. We recognize that further improvements are appropriate in view of the incident which occurred.

- Our established standard procedures require laboratory personnel to segregate and label waste. Laboratory personnel have been trained in this procedure through seminars, safety meetings, memorandums and personal instruction. The Central Research Environmental Health Technician is responsible for collecting and recording low level radioactive waste at the central waste collection area and is in a position to oversee the materials brought to the central collection area. It is the technician's experience that laboratory personnel have a high level of understanding of the standard procedures and that compliance is good.

- The radioactive waste collection area is presently located in part of the stockroom loading platform and in the past has been accessible to employees during working hours. Of course, our entire research facility is secure, and is not accessible to the public. The loading platform is locked and fully secure after hours and on weekends.

CORRECTIVE ACTIONS

Item 2. Unauthorized Waste Disposal

- The low level radioactive waste disposal procedure, Section 19, of the Research Safety Manual will be reissued to all Groton Central Research personnel. A second distribution of this procedure will be sent to each radioactive film badge holder. This procedure will have a cover letter explaining the importance of the procedures and will incorporate a signed return request confirming receipt of the procedure.

- A 'Waste Disposal Card' has been instituted for all low level radioactive waste. This card will be completed by the laboratory personnel for each type of waste. This card will be given to the waste supervisor at the time of collection. In addition to the waste type, isotope and estimated activity, the card will record the name of the generator; lab number; date of transfer and purchase order or lot number of the isotope.

- The area now is secured (locked) when unattended. A wire screen fence and gate have been installed. This gate is closed and locked when the collection area is unattended.

- Low level radioactive waste procedures will be outlined in a wall chart distributed to each laboratory. This wall chart will describe the major components of the waste procedure and provide a visible, easily accessible reminder of this procedure.

RESPONSE TO NRC LETTER OF MAY 2, 1989

Item 4. Training of Individuals

Past Practices: Formal training presentations were given as follows in recent years:

1)	03/03/89	Radiation Safety Seminar (*June Tamkin, Pilot Program*)
2)	08/02/88 08/17/88	Occupational Exposure, Women of Childbearing Age (*S. K. Figdor*)
3)	05/22/86	Radiochemical Safety (*New England Nuclear*)
4)	08/30/85	Presentation to Drug Metabolism Department "Radiation Safety in Animal Experimentation" (*S. K. Figdor*)
5)	08/06/85	Presentation to Dermally Applied Drug Group "Radiation Safety" (*S. K. Figdor*)
6)	04/18/85 04/25/85	"Safe Use and Handling of Radioactive Materials" (*S. K. Figdor*) "Low Level Radioactive Waste Disposal" (*D. P. Brannegan*)
7)	04/22/85	Repeat of No. 6 to Drug Metabolism Department

In addition to those formal training sessions, personnel are informed about radiation safety through a variety of other avenues. Some typical examples are provided below:

1. All new employees are instructed, during the New Employee Safety Orientation, that they must contact the RSO and obtain a film badge in order to work with radioactive materials.

   When employees are assigned a film badge they are instructed on the safe use of radioactive isotopes. This information contains:

   1) Radiation Safety Rules
   2) Swipe Test procedure.
   3) NRC regulations – Parts 19 and 20
   4) Isotope Data sheet
   5) Radiological Laboratory Safety Practices
   6) NRC Form 3, Notices to Employees

   Personnel are also questioned about past experience, and the isotope they expect to work with.

2. Some of the above items are periodically reissued as a reminder:

    1) Swipe Test procedure
    2) Isotope Data sheet
    3) Radiological Laboratory Safety Practices

3. Additional information related to radioactive materials is provided to employees via the Central Research Safety Committee.

    1) Revised standard Procedure for the Safety Manual which includes a section on radioisotopes (issued January 4, 1988).

    2) A Research Safety Bulletin on safety signs that includes radiation signs (issued February 1986).

    3) Central Research Safety Committee Meetings.

        1) Meeting of 10/21/88 – Discussion of Spill Procedure for radioactive materials and a review of Central Research Safety Manual Standard Procedure No. 23.

        2) Meeting of 7/25/88 – Discussion of recent NRC inspection results.

        3) Meeting of 3/24/88 – Discussion of procedures for the disposal of liquid scintillation waste and potential methods for waste minimization (e.g. new B-plate counters).

4. New information is brought to the attention of researchers, as it occurs.

    1) Unrecognized Hazards of Sulfur-35, reporting information on the volatile component of sulfur-35 amino acids (issued September 30, 1988).

    2) General Pharmacology Department Safety Memo discussing the Radiation Safety Seminar scheduled for December 1988 (memo issued November 7, 1988).

3) Trip Report discussing topics covered at the U.S. Ecology Low-level Radioactive Waste Disposal Seminar in Las Vegas, October 11-13, 1988 (memo issued 10/25/88).

4) Laboratory Clean-Up Announcement and Clean-Up Laboratory Checklist were issued to all laboratories. The checklist and cover letter both contain reminders about the storage and disposal of radioactive materials, lab surveys and lab inspections (issued September 23, 1988 and May 5, 1988).

5) General Pharmacology Department Safety Memo discussing laboratory inspections by the NRC and reviewing procedures for swipe tests (memo issued August 22, 1988).

6) The Groton Central Research Weekly Calendar for July 11 - 25, 1988 contains a notice of the time and location of radioactive waste collection.

Pfizer Position - Our employees are well informed. In fact, during other NRC inspections we have been complimented on our employee awareness. We include, as Attachment 1, the internal minutes of our last NRC inspection (June 29, 1988) and the NRC report of that inspection.

CORRECTIVE ACTION

Item 4. Training of Individuals

Our standard training program contains three presentations: Introduction to Radioactivity, Laboratory Safety, and Radioactive Waste Disposal. It was our observation that experienced personnel resisted repeated exposure to these sessions and we decided to develop a new format and employ outside professional speakers. In mid 1988 we contacted Yale University with a request to provide a training program and a speaker. An outline of a presentation was submitted August 26, 1988 by a Yale health physicist. Through a series of unforeseen delays, including illness, the actual presentation was not given until March 3, 1989. The presentation was not well received, and we searched for another source. We have engaged Radiation Safety Associates, Inc. of Hebron, Connecticut and a training session is scheduled for June, 1989. If we find this organization to be appropriate, all personnel in Pfizer Central Research who handle radioactive materials will be required to attend during 1989. If Radiation Safety Associates is judged to be inappropriate, Pfizer personnel (S. K. Figdor, D. P. Brannegan) will resume the training program.

RESPONSE TO NRC LETTER OF MAY 2, 1989

Item 6. Radiation and Contamination Surveys

Past Practices: Responsibility for laboratory surveys and swipe tests were assigned to laboratory supervisors. General inspections and laboratory swipe tests were also conducted by the RSO. Certain laboratories handling special isotopes received special attention.

CORRECTIVE ACTION

Item 6. Radiation and Contamination Surveys

We recognize that under the conditions of a broad license, improved surveillance is necessary. At this time we are in the process of inspecting every laboratory where radioactive materials are employed. We have completed approximately one-third of the laboratories since March. A formal inspection report is issued with a copy to the laboratory supervisor and a copy to his/her department director. In the future, all laboratories will be routinely inspected once a year. Records of all inspections will be maintained.

Swipe Tests. All laboratories that use radioactive materials will be required to conduct a swipe test on a monthly basis, with a copy of the results sent to the Radiation Safety Officer.

RESPONSE TO NRC LETTER OF MAY 2, 1989

Item 7. Waste Disposal

Past Practice: In the past we have not monitored all packages prior to discard.

As stated in 10 CFR 20.205(b), "Each licensee upon receipt of a package of radioactive material, shall monitor the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents, except: Packages containing no more than 10 millicuries of radioactive material consisting solely of tritium, carbon-14, sulfur-35, or iodine-125." It has been our policy to routinely monitor for surface contamination the outer carton of those packages that contain 10 millicuries or more of the designated isotopes. Outer cartons containing lesser amounts of radioactivity are exempted from the monitoring procedure and are discarded as normal trash. It would be our intent to continue our past practice in this regard.

It has been our practice to require that radioactive labels must be removed or defaced before an empty carton can be removed to an unrestricted area. In general, we believe compliance has been good.

CORRECTIVE ACTION

Item 7. Waste Disposal

We recognize that the radioactive label must be removed or defaced before an empty carton can be removed to an unrestricted area. To assure this is accomplished we have included this in the revised procedures for low level radioactive waste disposal and the related training program (Section 19 of the Central Research Safety Manual). In addition we will send a separate reminder notice to all personnel who use radioactive material that this procedure must be followed.

July 8, 1988

TO: Dr. M. von Schach

FROM: S. K. Figdor

SUBJECT: Nuclear Regulatory Commission Inspection

On Wednesday, June 29, the Pfizer Central Research Facilities were subjected to an unannounced Nuclear Regulatory Commission Inspection. The inspector was Mr. Waymon L. Wallace, Health Physicist, from King of Prussia (Region 1). The inspection began at approximately 10:30 A.M. and was concluded at 3:30 P.M. with a brief pause for lunch. The usual thorough scrutiny of records, personnel, procedures, and facilities was conducted and is reported in greater detail below. Mr. Wallace was not able to identify a single item of non-compliance, and verbally reported so to Dr. R. L. Hinman* in his exit interview. His parting remark to me was that it is a pleasure to inspect a facility so well organized and run, and that it made his job easy.

The NRC license to Pfizer Inc. is a Broad Scope Institutional License. This allows us much discression and a great deal of latitude in carrying out our radiochemical studies. Considering the number of people who handle radioactive materials and the diversity of procedures employed the potential for non-compliance is enormous. That Mr. Wallace was unable to identify a single item of criticism is a tribute to the skill, dedication, and efforts of all our researchers who work with radioactive substances. I am personally delighted with the outcome of this inspection.

A written report of the inspection will be issued by Mr. Wallace and should be received in three or four weeks.

S. K. Figdor

/dmj

cc: Mr. D. P. Brannegan
Dr. H. G. Fouda
Dr. R. L. Hinman
Dr. D. C. Hobbs
Ms. N. Odryna

*NRC requires the inspector to make an oral report of the inspection to a senior member of management upon completion of the inspection. Dr. R. L. Hinman was the only member available at that time. .

Nuclear Regulatory Commission Inspection

of Pfizer Inc., June 29, 1988

Central Research

Radiochemical Facilities and Records. Mr. Wallace spent approximately 15 minutes with me to obtain an overview of the radiochemical activities conducted in Central Research. He outlined to me the scope of his inspection; the records, features, and facilities he wished to inspect and identified researchers he wished to interview.

He then spent approximately one hour with Ms. Odryna to review and inspect our record keeping process. This included the following:

The Film Badge Program

Educational and Training Programs

Laboratory Survey Procedures

Personnel Surveys (Bioassays)

Radiosynthesis Laboratory Procedures and Records

Radiochemical Inventory

Package Receipt Surveys

Procedures for the Transfer of Isotopes

Hood Effluent Records

Sealed Source Surveys (Gas Chromatographs)

Calibration Procedures for Liquid Scintillation Counters and Survey Meters

Emergency and General Safety Procedures

Mr. Wallace next inspected the Radiosynthesis Laboratory and searched for radiocontamination with his own survey meter; he found none. Security, safety, and procedures associated with this laboratory were reviewed. At this point Mr. Wallace enthusiastically complimented Ms. Odryna on her excellent record keeping system and her supervision and organization of the Radiosynthesis Laboratory. He repeated his praise for Ms. Odryna to Dr. Hinman during the exit interview.

Mr. Wallace next requested an interview with three researchers; one each who worked with tritium, phosphorous-32, and iodine, and to visit laboratories where these isotopes are employed.

Trituim: Evelyn Joerg and Dr. L. Tremaine.

He questioned Mrs. Joerg for the most part, with only a few questions directed to Dr. Tremaine. The focus was on the safety issues of handling tritium in the laboratory and concern for the generation of tritium water. Ms. Joerg did an excellent job of answering Mr. Wallace 's inquires. After a cursory examination of a few Drug Metabolism Laboratories we proceeded to the Molecular Genetics area.

Phosphorous - 32: Dr. D. Pereira

Dr. Pereira conducted a review of records and procedures for the receipt, distribution, and accountability of phosphorous-32. He then went into some detail of the actual laboratory use of phosphorous-32. Mr. Wallace questioned us about the use of film badges and finger rings, shielding, laboratory surveys, and general safety procedures. A tour of several laboratories followed. Mr. Wallace questioned laboratory personnel at random and conducted random surveys with his own meter; no radiocontamination was found. He seemed to be especially interested in the handling and storage of phosphorous-32 wastes. Mr. Wallace appeared to be perfectly satisfied with the use of phosphorous-32, and complimented Dr. Pereria for the excellent systems that are in place.

Iodine: Dr. D. Goldberg

We next met with Dr. D. Goldberg in his laboratory. After a brief look around the laboratory we retired to a lounge area where Mr. Wallace questioned Dr. Goldberg at length about iodine handling procedures and safety precautions. Dr. Goldberg gave an extended and excellent presentation about our iodine procedures and in the process answered many questions interjected by Mr. Wallace. Dr. Goldberg went out of his way to compliment Ms. Odryna and her supervision of iodine procedures in the Radiosynthesis Laboratory. Mr. Wallace was impressed with our control and safety precautions, and indicated this to Dr. Goldberg.

Radiochemical Wastes

Mr. D. Brannegan and Mr. W. Wolter reviewed radioactive waste disposal practices and records. All procedures were in accordance with regulations and all records were appropriately detailed and in excellent condition. Mr. Wallace reviewed the waste repository site, a trailer parked in the receiving area behind Building 118. Although this system of storage does not violate any regulations, Mr. Wallace expressed concern about a trailor site radioactive waste repository, and what he felt might be less than adequate security. Mr. Brannegan emphasized our perimeter security system, and indicated that security was adequate. Although no question of non-compliance was raised, it may be appropriate to seek a more permanent solution of radioactive waste storage.

This concluded the inspection of Central Research.

Chemical Division

The Chemical Division has recently purchased three cesium-137 sealed sources for use as level indicators and flow gauges. These items are identified in a separate license issued to the Chemical Division and are not related in any way to Central Research. Mr. Wallace visited the plant site under the guidance of Mr. C. Conway and inspected one of the devices. He requested that personnel access to the device be more restrictive.

At this time we proceeded to Dr. Hinman's office where Mr. Wallace verbally summerized the day's inspection process and his findings. As noted above the report was complimentary and no items of non-compliance were found. A written report by Mr. Wallace will be received in several weeks.

NOTE: The radioactive waste collection facility was moved from the trailer to a more secure area immediately after Mr. Wallace's visit.

S. K. Figdor
July, 1988

/dmj

5/17/89

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

01 AUG 1988

Docket Nos. 030-03790
030-30431

License Nos. 06-05869-01
06-05869-02

Pfizer, Incorporated
ATTN: Richard L. Hinman, Ph.D.
Senior Vice President
Eastern Point Road
Groton, Connecticut 06340

Gentlemen:

Subject: Routine Inspection No. 88-001

On June 29, 1988, Mr. Waymon Wallace of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you and Dr. Sanford Figdor at the conclusion of the inspection.

Within the scope of this inspection, no violations were identified.

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 will be placed in the Public Document Room. No reply to this letter is required.

Your cooperation with us is appreciated.

Sincerely,

John D. Kinneman, Chief
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of Connecticut
Sanford Figdor, Ph.D., Radiation Safety Officer

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