



CENTOCOR

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TELEX: 834823 CENTOCORMARN
FAX: 215-644-7558

July 17, 1985

Docket Nos. 030-17571
030-19257
030-19551

License Nos. 37-19413-01
37-19413-02G
37-19413-03

Mr. John D. Kinneman, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

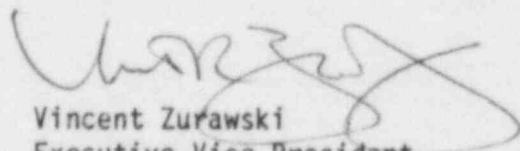
Dear Mr. Kinneman:

As a result of the NRC inspection conducted on February 25, 1985, certain activities were observed at Centocor which were not in full compliance with NRC requirements. As a result of that inspection, Centocor has implemented corrective measures for the violations noted in your letter of June 17, 1985. These corrective measures are outlined in Appendix I of this letter, along with the compliance date established for each corrective measure.

For Item C, a letter is being obtained from Dr. Mossman indicating that he is an authorized representative of Best Industries and therefore authorized to perform leakage and/or contamination tests on the Best Industries Irradiator. A copy of this letter is enclosed.

It is Centocor's intention to maintain a safe environment for all its employees. To this end, we will cooperate fully with the NRC to maintain procedures, practices, and policies aimed at maintaining a safe and healthy environment.

Sincerely,


Vincent Zurawski
Executive Vice President
& Technical Director

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REG1 LIC30
37-19413-01 PDR

/br

Att.

APPENDIX I

7/17/85

ITEM NO.

- A. Procedures are in effect to rectify Item A for lost or destroyed badges. Please see memorandum dated 3/4/85.

Compliance: Effective 4/1/85

- B-1. Centocor policy has been to prohibit eating, drinking, or smoking in laboratories or production areas. This policy has been reemphasized as per the memorandum dated 4/17/85. Areas of non-smoking, eating, or drinking have been further identified to clarify any uncertainty. In addition, disciplinary action for violators will be enforced.

Compliance: Ongoing

- B-2. Berthold meters are not for official surveys, but are to be used for extra sensitive checks of surveyed areas. These units are not calibrated externally since their extreme sensitivity to breakage in shipping has precluded to use of any external vendor. These units are periodically checked using a source supplied by Berthold.

Compliance: Effective 7/1/85

Centocor has resumed daily calibration of dose calibrator and proportional counter. Beginning July 1, 1985, calibration will be conducted on a daily basis.

Compliance: Effective 7/1/85

- B-3. Meters measuring exposure rate will be employed to survey incoming packages as per Item B-2.

Compliance: 3/1/85

- B-4. Alarms will be checked on a monthly basis as per procedure entitled, "Verification of Photohelic Alarms."

Compliance: 7/9/85

- B-5. An employee has been identified who is conducting surveys as outlined in our applications.

Compliance: 3/4/85

- B-6. Employees conducting iodinations will be scanned within 48 hours as per our application. Please see our memorandum dated 7/9/85.

Compliance: 7/9/85

- C. Dr. K. Mossman is our consultant and also is an authorized representative of Best Industries as per the attached letter.

Compliance: We feel that Dr. Mossman is a representative of Best Industries fulfills the requirements of License No. 32-19413-03.

- D. "Centocor Radioactive Material" signs have been posted in areas where licensed material is used or stored.

Compliance: 3/1/85

- E-1. Employees using the 137 Irradiator have been informed that they must maintain records of irradiations in the log book provided. See memorandum dated 3/6/85 entitled, "Irradiator Log Sheets."

Compliance: 3/1/85

- E-2. The name and phone number of the RPO has been posted.

Compliance: 3/1/85



INTER OFFICE MEMO

TO: V. Zurawski

FROM: J. Barnes *B*

SUBJECT: Employee Dose Assignment

DATE: 3/4/85

As the result of a recent NRC inspection, we will now be required to assign radiation dosages to any employee whose assigned badge is lost. The following procedures will be adopted immediately.

When badges are not returned for dose readings, Steve DiDomenico will contact the individual and determine where the badge(s) are, and will hopefully collect most missing badges in this way. If a badge has been lost or destroyed, the personnel may be assigned a dosage if previous film badge reports indicate sustained dosage. The RPO will examine records for the three previous months and determine an average dosage for that period. If the dose quantity for the most recent three-month period is less than 1/10 the MPB as specified in 10CFR20.101 (i.e., 0.1×1.25 REM for whole body), then no radiation assignment will be made to permanent employee records. If the average reading exceeds this threshold then Teledyne Isotopes will be contacted by mail and instructed to assign dosage equal to the amount calculated from the mentioned data.


Please give me any comments and I will implement this system as soon as possible.

/br



INTER OFFICE MEMO

TO: ALL CENTOCOR EMPLOYEES

FROM: R. Hevey 

SUBJECT: Centocor Facilities - Restricted Areas

DATE: 4/17/85

As a reminder to all Centocor employees, smoking, eating, and drinking is prohibited in restricted areas. For your convenience, these areas are delineated by a yellow and red stripped taped line. This restriction also applies to offices located within the laboratories.

Your cooperation in helping us maintain a safe and nealthy environment is appreciated.

/br

7/8/85

Equipment: Verification of Photohelic Alarms
Location: Room #8 - Tracer Laboratory - Production
Calibration Frequency: Monthly

Calibration Procedure:

- 1) With the hood operational and the sash open, verify that the indicating gauge reads greater than the low level alarm set point.
- 2) Pinch or remove the tubing connection so that the indicator reaches the low level alarm setpoint.
- 3) Verify that the unit indicates an alarm condition when indicator reaches the low level alarm setpoint.



INTER OFFICE MEMO

TO: R. Vogel
D. Boscher

FROM: P. Brock (PB)

SUBJECT: Thyroid Scan

DATE: 7/9/85

Effective immediately, please scan your thyroid every day. Current regulations in our NRC license require scans 24-48 hours after working with iodine. Since you perform many iodinations during the week, daily checks seem to be the easiest solution.

Thank you for your cooperation.

/br



INTER OFFICE MEMO

TO: All Irradiator Users

FROM: J. Barnes *JB*

SUBJECT: Irradiator Log Sheets

DATE: 3/6/85

It is critical that a running user log be kept for the cesium irradiator. Failure to complete such a log may be a violation of our NRC license. The original forms recording time, user name, and operational comments, are located on the clipboard found on the machine. You should always fill in the required information on these forms in addition to signing out the keys. When new supplies of blank forms are required, please contact John Barnes or Adrienne Quinn.

Thank you for your cooperation.

/br

KENNETH L. MOSSMAN, Ph.D.

Radiation Biologist

4601 North Park Avenue #111

Chevy Chase, Maryland 20015

202/625-7901 (o)

301/654-8424 (h)

July 11, 1985

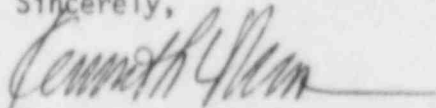
Mr. Richard Hevey
Centocor, Inc.
244 Great Valley Parkway
Malvern, PA 19355

Dear Dick:

At the recent NRC inspection, which took place in February 1985, I understand one of the concerns of the NRC inspector was the wipe testing of the Cesium-137 irradiator. According to the NRC license, a representative of Best Industries is responsible for the wipe testing every six months. This letter is to document that as co-developer of the irradiator and as consultant to Best Industries, I will conduct the wipe test in accordance with the NRC license.

If you have any questions concerning the wipe testing procedures, please do not hesitate to contact me.

Sincerely,



Kenneth L. Mossman, Ph.D.

cc: Dr. Vincent Zurawski
Mr. John Barnes

KLM/sh