MS-16
P2

CENTOCOR

244 GREAT VALLEY PARKWAY, MALVERN, PA 19355 • (215) 296-4488
TELEX: 173-190
FAX: (215) 644-7558

June 2, 1987

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

Dear Dr. Glenn:

In response to your questions regarding the renewal application for NRC License No. 37-19413-03 (Control No. 106725), I am supplying the following information.

Attached you will find the parts of License No. 37-19413-01, which were referenced in the above application. In addition, I have included our recent amendment to License No. 37-19413-01, which contains some information relevant to the irradiator program at Centocor.

The survey instrument being used in the irradiator laboratory is a Ludlum Model 177 alarm rate meter equipped with a Ludlum Model 44-6 thin-wall Geiger-Mueller probe. It has a sensitivity of 0.005 mRem/hr. This instrument, as well as all of our survey meters, is calibrated at 6-month intervals by Radiation Management Corporation of Philadelphia (NRC License No. 37-13129-01).

Our Radiation Safety training consists of three parts. The first phase is a one-half day seminar by Dr. Kenneth Mossman, Ph.D., our Radiation Safety consultant. Included are the following topics:

1. Ionizing Radiation
2. Radioactive Materials
3. Half-Life
4. Measurement of External Radiation Exposure
5. Measurement of Internal Radiation Exposure
6. Basic Safety Concepts
7. Biological Effects of Radiation
8. NRC Regulations

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CENTOCOR

The second phase of Radiation Safety training consists of a 2-3 hour course presented by the Radiation Safety officer. Topics include:

1. Centocor Radiation Safety Manual

2. Isotopes in use at Centocor

3. Centocor Safety Policy
   a. Facility monitoring
   b. Personnel monitoring
   c. Waste Disposal
   d. Ordering/Shipping/Receiving of Radioactive Materials
   e. Introduction to the Gamma Irradiator
   f. NRC Regulatory Guide 8.13
   g. 10 CFR Part 19 and Part 20
   h. 3 short films about Radiation Safety

4. Operation of Survey Instruments

Upon completion of these seminars, a quiz is administered to each employee to assess his or her understanding of the material. (A copy is attached.) A passing grade of 75% is needed for the employee to be allowed to work with radioisotopes. Employees failing the quiz are required to repeat the course.

The third phase of training occurs on the job and is handled by the employee's supervisor. This training involves the specifics of the procedures being performed in the laboratory.

I trust that this material clarifies the questions you had concerning our license application. If I can be of further assistance, please contact me at Centocor.

Sincerely,

Debra L. Travers
Radiation Safety Officer

DLT:lam

Attachments
54070

12. PERSONNEL MONITORING

Personnel monitoring in the form of film badges will be provided to all workers in restricted areas (defined as "any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation." 10CFR 20.3 (a) (14) in accordance with 10CFR 20.202 in keeping with ALARA (10CFR 20.1) although our review of personnel badge records indicate that doses per calendar quarter are less than 25% of the limits established in 10CFR 20.101(a) for restricted areas. No personnel monitoring will be provided to employees working exclusively in nonrestricted areas [defined as "any area access to which is not controlled by the licensee for purpose of protection of individuals from exposure to radiation..." 10CFR 20.3 (s) (17)] since these individuals would not be occupationally exposed to radiation and would therefore be far below the 25% limit for badging as required in 10CFR 20.202(a) (1). Personnel working with IN-111, I-123, TC-99M, I-131, and production quantities of I-125 will be required to wear ring badges in addition to film badges.

Film badges and ring badges will be exchanged on a monthly basis and sent to Teledyne Isotopes, Westwood, New Jersey, for evaluation. The RSO will review film badge and ring badge reports monthly. The reports will be displayed on a company bulletin board for viewing by all employees. In addition, employees may request their exposure records from the RSO at any time in accordance with 10CFR 19.13.

The NRC will be notified immediately of any exposure of the magnitude described in 10CFR 20.403 and 20.405. In addition, any film badge or ring badge exposure in excess of 10% of the limits set forth in 10CFR 20.101 (a) will be reviewed completely by the RSO for cause and corrective actions taken. This will involve a conference and a review of procedures with the worker. This 10% administrative action limit has been established after careful review of past film badge records. At no time up to and including the present film badge reports, has any worker reached this 10% action limit.

Ten percent action limits are also established for minors (less than 18 years of age). Specifically, in accordance with 10CFR 20.104, no minor shall be exposed to doses in excess of 10% of the limits established in 10CFR 20.101 (a). Administrative action will be taken, as described above, when 1% of the limits established in 10CFR 20.101 (a) have been exceeded. In general, minors (i.e., high school students working part time or in the summer) do not work directly with radioactive materials at Centocor, but may on occasion come into contact with radiolabeled materials as part of their laboratory work.

Fertile age women and pregnant women employees at Centocor will be similarly subject to the 1% limits and administrative action levels set for minors. The recommended limits for pregnant workers is 500 mRems per gestational period as stated in NRC Regulatory Guide 8.13. We have elected to apply the 1% limit to fertile age women since many women are not aware of a pregnancy in its early stages.

The second phase of the personnel monitoring program at Centocor is the bioassay program for I-125. Although I-125, I-123 and I-131 are all used in certain research, development and production activities, only I-125 is used in quantities which necessitate the implementation of bioassay program in accordance with Table 1 of NRC Regulatory Guide 8.20 (1 mCi for operations performed in a fume hood). Radioiodine in quantities exceeding a few microCuries is used in fume hoods designed for this purpose. The locations of these hoods are noted on the attached diagrams of laboratory facilities at Centocor found under Item No. 13. I-123 and I-131 are used in microCurie amounts per procedure exempting them from the bioassay program.

Bioassay procedures will be required for all individuals working with milliCurie amounts of I-125 and those sufficiently close to iodination procedures so that intake is possible. The frequency of bioassay will depend on the I-125 use. Research & Development personnel performing iodinations on an irregular basis are required to have thyroid scans between 24 and 48 hours following the procedure. Tracer Production personnel who do iodinations on a daily basis will be required to do a thyroid scan each week. Bioassay for I-125 will be available on a monthly basis for any other employee using I-125 who desires to monitor his/her thyroid. This schedule falls well within the frequency described in Regulatory Guide 8.20 Position 4. Baseline thyroid scans are done for all new workers using I 125 during the first week of employment as recommended in Regulatory Guide 8.20 Position 3a.

Each new employee is instructed by the Radiation Safety Officer in the proper technique for performing thyroid scans. The detector is placed on the throat in contact with the skin above the notch of the collarbone. The count is done for one minute. The process is repeated on each side of the thyroid and the three values are averaged. A distal count of an extremity is taken to determine individual background. A phantom with a 8.3 nCi source (NEN Lot # 222078OA; SN-NES-222) is used to calibrate the counter so that personnel thyroid counts can be converted from CPM to nCi by the RSO. These records will be kept on file in the Radiation Safety Office and may be requested by any employee for review. The thyroid counter is calibrated and serviced once every six months by RMC of Philadelphia.

In compliance with Regulatory Guide 8.20 Position 5, any thyroid burden greater than 120 nCi of I-125 will result in a full investigation by the RSO including an interview with the worker and a complete review of all procedures and equipment used. The worker will be temporarily reassigned until the source of the exposure is discovered and corrected if this investigation reveals that further work in the area might cause the worker to exceed the limits established in 10CFR 20.103. Corrective actions to eliminate or decrease the potential for further exposure will be implemented. Repeat bioassays will be done on a weekly basis until levels of I-125 reach acceptable levels. The Radiation Safety Officer will document the incident and supply a copy to the worker and keep the original on file in the Radiation Safety Office.

If at any time, a scan indicates a thyroid burden in excess of 500 nCi of I-125, the above steps will be taken. In addition, the worker would be referred to Paoli Hospital in Paoli, Pennsylvania, for medical treatment with thyroid blocking agents.

Bioassay for tritium is not done at Centocor. Tritium is currently used in research and development procedures including cell labeling and tissue culture. Our possession limit is 100mCi; however, only a fraction of that amount would be on hand at any one time. Consequently, according to the draft NRC Regulatory on Applications of Bioassay for Tritium, since concentrations of tritium at Centocor are far below the limits established for implementation of a bioassay program (Table 1), none has been implemented.

13. FACILITIES AND EQUIPMENT

Centocor is located at 244 Great Valley Parkway in Malvern, Pennsylvania. The attached floor plan shows the location of restricted (yellow) vs. nonrestricted areas. Locations of iodination hoods, sinks for radioactive waste disposal, and storage areas are designated in red.

a. Presently at Centocor, there are three iodination hoods with plans for a fourth in the "E" wing of the building which is currently under construction. These six foot hoods are equipped with both HEPA and activated charcoal filters. The two hoods in the manufacturing area are equipped with air velocity alarms which are activated if the air velocity falls below the required 100 linear feet/min. Air velocity checks are done each day of use to ensure that this requirement is being met. Laboratories in which iodination hoods are located are under negative pressure to prevent any release of radiation into the hallways and adjoining laboratories. Lead aprons and charcoal masks are provided for workers in addition to disposable lab coats, shoe covers, and gloves.

Five sinks are designated for disposal of low level liquid radioactive waste. These sinks are clearly marked with radioactive tape. All waste disposal via these sinks is recorded on log sheets near the sink. A complete description of sink disposal can be found in Item 14.

b. Radioisotopes are used or stored in areas which are conspicuously marked with a "CAUTION: RADIOACTIVE MATERIALS" sign. On the following pages is a list of the shielding for the radioisotopes used at Centocor.

13. FACILITIES AND EQUIPMENT (Continued)

Material	Shielding
Carbon 14	N/A
Selenium 75	Lead
Sulfur 35	N/A
Hydrogen 3	N/A
Iodine - 125	Lead
Chromium 51	Lead
Phosphorous 32	Plastic

13. FACILITIES AND EQUIPMENT (Continued)

Material	Shielding
Gallium 67	Lead
Indium 111	Lead
Technitium 99	Lead
Iodine 131	Lead
Molybdenum 99	Lead
Iodine - 123	Lead
Cesium 137	Sealed Source - Lead

13. FACILITIES AND EQUIPMENT (Continued)

Waste containers are approved 55 gallon steel drums supplied by the commercial waste disposal service. These containers are stored away from personnel. The waste holding area is monitored on a weekly basis to assure that the radiation exposure to personnel is minimized or eliminated.

c. N/A

d. N/A

15. RADIATION PROTECTION PROGRAM

The Centocor radiation protection program is based on ALARA. Personnel training, ongoing facility and personnel monitoring, and seminars provided by the RSO and our consultant, Dr. Kenneth Mossman, of Georgetown University provide our employees a thorough knowledge of approved radiation safety practices. A copy of our radiation safety manual which is distributed to each new employee during his/her first week at Centocor is provided in Appendix III.

A. Radiation Survey Program

In accordance with 10CFR 20.201, an extensive radiation survey program is in place at Centocor. This includes surveys for removable contamination, airborne radiation and effluent monitoring. Iodination laboratories will be surveyed with a survey meter at the end of each day in which an iodination procedure has been done and decontaminated if necessary. Laboratory areas where only small quantities of radioactive materials (less than 200 uCI at any one time) are used will be surveyed on a monthly frequency. All other areas will be surveyed at weekly intervals. Weekly and monthly surveys will consist of measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem/hr and wipe tests which will be described below. All of the results of said surveys will be reviewed by the Radiation Safety Officer at regular intervals. All surveys are performed in accordance with NRC Regulatory Guide 8.23, sections 1.2 and 1.4.

Wipe tests are done for both gamma and beta emitters in restricted areas at Centocor depending on radioisotope usage for that particular laboratory. Wipe tests for gamma emitters consists of wiping an alcohol saturated cotton swab over a 100 cm area and then counting in a Nuclear Enterprises Model 1600 (SN #473 or 802) or an equivalent instrument. Wipe tests for beta emitters are done by wiping the 100 cm^2 area with an alcohol-saturated glass fiber disc (available from Fisher Scientific) and counting in an LKB, Model Wallace 1215 Rack Beta II (SN# 15398) or equivalent instrument using a suitable scintillation fluid. All wipe tests at Centocor are performed by the radiation safety officer or by personnel specifically trained by the radiation safety officer.

The following schedule will dictate the frequency with which wipe tests are done at Centocor:

Bldg.	Room No.	Room Use	Frequency
244A	20	RIA; Western blots using I-125; S-35 and H-3 labeling of cells; P-32 probing and CR-51 release assays.	Weekly
244A	20E	Cells culture experiments with H-3 and P-32 done an infrequent basis.	Monthly

244A	CR-10	Walk in refrigerator where I-125 H-3 and S-35 are used in uCI amounts.	Monthly
244A	31	H-3 used in nCi amounts on an infrequent basis.	Monthly
244A	29	Glassware processing for research group Also, combination radioactive/biohazard waste autoclaved in this area.	Monthly
244A	28	HPLC's done on radiolabeled proteins using H-3 and I-125 in nCI amounts.	Monthly
244A	26	DNA sequencing using P-32 and S-35 in mCi amounts.	Weekly
244A	26	Molecular biology lab where nCI amounts of P-32 and S-35 are used in experiments.	Monthly
244A	22	uCi amounts of H-3 used for tissue culture experiments.	Monthly
244A	25	Biological containment facility where mCi amounts of I-125 are used in animal studies.	Weekly
244A	24	Biological containment facility where mCi amounts of I-125 and uCi amount of H-3 and S-35 are used for experiments.	Weekly
244B	15	Shipping and receiving area through which all radioactive materials coming into or leaving the company must pass.	Monthly
244B	9	RIA's using I-125 in uCi amounts on an infrequent basis.	Monthly
244B	7	RIA's using I-125 in uCi amounts on an infrequent basis.	Monthly
244B	5B	Iodination lab for tracer manufacturing. I-125 used in mCi amounts on a daily basis.	Weekly
244B	5	Tracer packaging laboratory where mCi amounts of I-125 are handled.	Weekly
244B	8	RIA's using I-125 in uCi amounts are done infrequently.	Monthly
244B	1	RIA's using I-125 and C-14 in uCi amounts.	Monthly

244B	6	Labeling of bottles of tracer: 200 bottles @10-20 uCi at a time.	Weekly
244B	2	RIA's using I-125 in uCI amounts done daily.	Weekly
244B	4	RIA's using I-125 in uCI amounts done infrequently.	Monthly
244C	14	I-125 and IN-111 used in mCi amounts. Also a TC-99 generator is housed in a small room off of this area.	Weekly
244C	32	I-125 P-32, S-35, H-3 used and stored in mCi amounts.	Weekly
244D	32A	Iodination laboratory for research personnel.	Weekly

Using the recommended action levels for removable surface contamination in medical institutions described in NRC Regulatory Guide 8.23, Table 2, we have adopted the following action limits at Centocor. In areas where only C-14, H-3, S-35 or other low risk beta emitters are used, the action limit is set at 22,000 dpm/100 cm^2. In all other areas where wipe tests are performed, the action level is set at 2,200 dpm/100cm^2. Any areas exceeding these limits will be decontaminated immediately and retested within 24 hours. Work in the area will be suspended until clean-up procedures are completed. Administrative action will also involve a review of procedures with the employees working the area by the RSO and a written report which will be filed in the Radiation Safety Office.

Area surveys will be done according to the schedule outlined by NRC Regulatory Guide 8.23, Table 1, using one of the many calibrated survey meters listed in Section 10 of this license application. In accordance with 10CFR 20.101, areas which might exceed 10% of the limits listed therein in any one calendar quarter will be part of the survey program. These areas include iodination laboratories, shipping/receiving, waste storage areas and the laboratory in which the TC-99 generator is housed. Spot checks will also be done on a random basis of trash containers, glassware processing, refrigerators and other areas which are not on the routine survey program. As recommended by the NRC Regulatory Guide 8.23, Section 1.2, any level of radiation greater than 1 mRem/hr at 1 meter will require corrective active such as added shielding, protective clothing, or clean-up. A report will be filed with the Radiation Safety Office in the event of such an occurrence.

Air monitoring is done in areas where operations could at any one time expose workers to 10% of more of the concentration values given in Table 1, Column 1, of Appendix B to 10CFR Part 20. At Centocor, an exposure of this magnitude would only be possible in the iodination laboratories. In eacn iodination lab, air is sampled in several locations including the worker's breathing zone. Charcoal filter discs available from Schleicher and Schuell are placed in cartridges which are attached to hoses and a pump capable of pulling at least 10L/min. Sampling is done on a continuous basis in the manufacturing iodination facility and during each iodination procedure in the research iodination laboratory. The filters are evaluated after the day's work is completed by counting on a suitable gamma counter. CPM's are converted to uCI/ml by the RSO accounting for collection efficiency of the filter and counting efficiency of the instrument.

Using the concentration limits for I-125 established in Appendix B Table 1, Column 1 of 10CFR 20 (5×10^{-9} uCi/ml) and the volume of air breathed by an employee in one calendar quarter (6.3×10^{8}ml) found in Regulatory Guide 8.20, Section 4(b)(2), and a 10% action limit suggested in Regulatory Guide 8.23, Section 1.3, Centocor has adopted the following policy. Any level which might result in a concentration greater than .315uCi/calendar quarter will require an investigation by the RSO in order to determine the causes and corrective actions which must be taken to ensure the safety of workers in the area. Further work in the area will be suspended until the problem has been corrected.

Effluent monitoring is done for both liquid and airborne discharges that Centocor releases. Liquid monitoring is described in Item 14 of this license application. Effluents from iodination hoods are monitored with a calibrated survey meter at quarterly intervals in order to confirm that the limits for air concentration of I-125 as established in 10CFR 20, Appendix B, Table 2, Column 1 are not being exceeded. Leakage of any radioactive material from the charcoal filtered stacks would be cause for replacement of the filters which must be supervised by the RSO.

B. Records Management System

All records of facility monitoring, personnel monitoring and exposure, inventory and waste disposal along with documentation of all problems and accidents are kept on file in the Radiation Safety Office. Personnel exposure records, waste disposal records, and inventory are reviewed on a monthly basis by the RSO. Facility monitoring records are reviewed upon completion of the surveys by the RSO. Unusual incidents such as spills are reviewed immediately and a Radiation Safety Commiitee convened if the RSO feels that it is necessary.

C. Sealed Source Leak Test Procedures

The only sealed source at Centocor is a Cesium 137 source located in the Gamma Irradiator used in our animal colony. This item is covered under a separate license (NRC License No.37-19413-03) and will, therefore, not be addressed in this application.This item is covered under a separate license (NRC License No. 37-19413-03) and will, therefore, not be addressed in this application.

D. Instructions to Personnel

A copy of the Centocor Radiation Safety Manual which is distributed to all company employees can be found in Appendix II of this license application.

CENTOCOR

244 GREAT VALLEY PARKWAY, MALVERN, PA 19355 • (215) 296-4488
TELEX: 173-190
FAX: (215) 644-7558

June 16, 1986

Mr. Jack Davis
U.S. Nuclear Regulatory Commission
Region I Office
King of Prussia, PA 19406

Dear Mr. Davis:

I am writing this letter in response to the phone conversation which we had in May. I would like to address the following concerns which you voiced regarding our pending Byproduct Materials License (# 37-19413-01).

1. Bioassay Action Levels
2. Airborne Surveys: Action Levels and Log Sheet
3. Wipe Test Action Levels
4. Low Level Aqueous Waste Disposal / Effluent Monitoring

It is our objective at Centocor to provide an environment which is safe for all employees who work with and around radioisotopes. To that end, at your recommendation, we have revised the above sections of our license application to ensure that we will be keeping exposure of our employees as low as reasonably achievable and in comlpiance with 10CFR.

1. Bioassay Action Levels

In keeping with the philosophy of ALARA, we will agree to the following action levels for our I 125 bioassay program. Any 10 nCi increase of I 125 in the thyroid will initiate an investigation by the Radiation Safety Officer including a review of all procedures with the worker and an inspection of all equipment involved. A written report of the incident will be kept on file in the Radiation Safety Office. In addition, a 50 nCi thyroid burden will result in suspension of work in the laboratory and reassignment of the worker to another area until the cause for exposure is discovered and corrected. Any employee exceeding the limits specified in Regulatory Guide 8.20 would be referred to a physician for medical evaluation.

CENTOCOR

2. Airborne Surveys: Action Levels and Log Sheets

In accordance with ALARA, we will agree to the follwing action levels for the airborne surveys currently done in our iodination laboratories. Any potential exposure of 0.002 uCi/ml/8 hour work day will result in an investigation by the Radiation Safety Officer including a review of procedures with the worker and an inspection of the safety equipment involved. In addition, the employee's thyroid will be monitored carefully to evaluate I 125 uptake. A copy of our new Air Monitoring Log Sheet is provided for your review. Note the addition of a column for concentration of I 125.

3. Action Levels for Wipe Tests

In keeping with ALARA, we will agree to the following action levels for removable contamination at Centocor. Wipe tests exceeding 500 DPM/100 cm will result in immediate notification of the laboratory manager so that decantamination procedures can be expedited. Wipe tests exceeding 1000 DPM /100 cm will result in a written citation to the laboratory manager. All wipe tests reading in excess of 500 DPM /100 cm will be followed within 24 hours by a repeat wipe test of the area to ensure that decontamination procedures have been adequate. All reports of such incidents will be kept on file in the Radiation Safety Office.

4. Low Level Aqueous Waste Disposal

Low level aqueous waste is disposed of into the sanitary sewer system. Each sink into which this waste is disposed has posted nearby instructions for disposal and a log sheet for recording the volumes and activity of the waste. These values (CPM/ml) will be converted to uCi/ml on a weekly basis and then divided by the average weekly water usage to ensure compliance with 10CFR 20.303.

It is hoped that these revisions will assure you that Centocor's Radiation Safety Program is committed to providing a safe environment for its employees. If I can be of any further assistance concerning this application please contact me at Centocor.

Sincerely,

Debra Travers, RSO

John Iuliucci, Dir. Regulatory Affairs

AIR MONITORING LOG SHEET

IMPORTANT! NOTIFY YOUR SUPERVISOR AND THE RSO IF COUNTS EXCEED 80/HR OR 2000/24HR

DATE	NAME	FLOW RATE	TIME ON	TIME OFF	ELAPSED TIME	FILTER #	mCi I125 USED	FILTER CPM	CONC I 125(uCi/ml

NRC FORM 313
(7-86)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 37-19413-01
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Centocor, Inc.
244 Great Valley Parkway
Malvern, Pennsylvania 19355

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

244 Great Valley Parkway and 224 Great Valley Parkway, Malvern, PA 19355

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Debra S. Travers, Radiation Safety Officer

TELEPHONE NUMBER: 215-296-4488

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time: see attached

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED: see attached

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE: refer to current license

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS: refer to current license

9. FACILITIES AND EQUIPMENT: see attached

10. RADIATION SAFETY PROGRAM: refer to current license

11. WASTE MANAGEMENT: refer to current license

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY: 3A
AMOUNT ENCLOSED: $ 120.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Howard T. Holden	Howard T. Holden	Dir. Corporate Reg. Affairs	3-17-87

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–$500K
- [ ] $500K–$750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE

Centocor, Inc.
244 Great Valley Parkway
Malvern, Pennsylvania 19355

Ammendment to NRC License # 37-19413-01

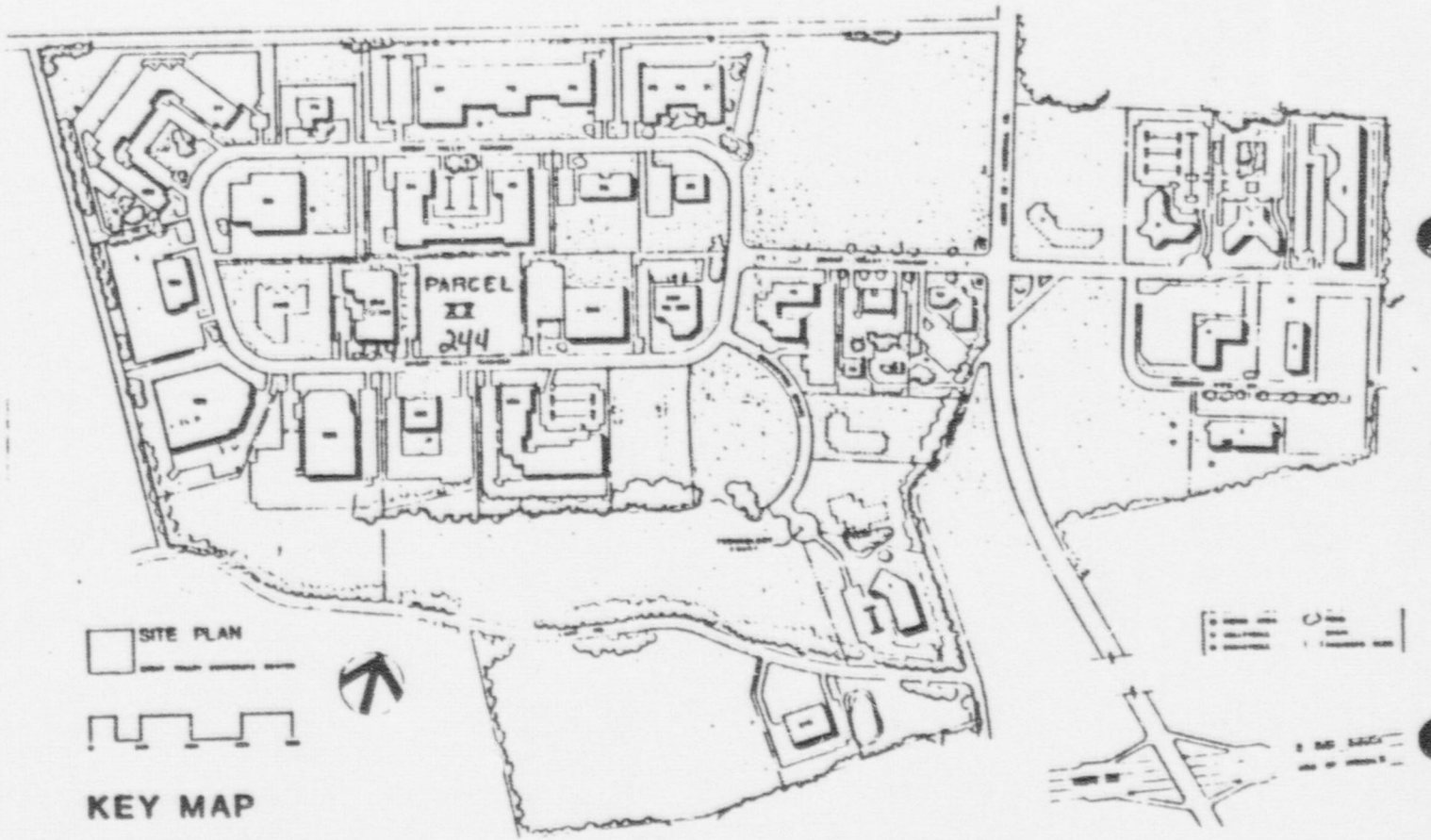
Table of Contents

Inclusion of New Floor Space

We are currently expanding our Great Valley facility to include space in an adjacent building at 224 Great Valley Parkway. The area involved contains approximately 6000 additional square feet of space. We plan to move the Labeling Department, Packaging Department and Shipping/Receiving into this facility. All procedures currently followed in the areas used for these purposes at the 244 address will be implemented in the new facility. In addition, radioactive materials will be moved from one building to another via a driveway between the two facilities by means of a truck owned by Centocor.

FACILITY FLOORPLAN

WATER MANANGEMENT - THE UNCONTROLLED
OF WATER INTO THE BASIN WILL NOT EXCEED
VERAGE COVERAGE WITH IMPERVIOUS SURFACE
WAS THE DESIGN CRITERIA FOR THESE BASINS)
VAL OF THE GREAT VALLEY CORPORATE CENTER
BE OBTAINED PRIOR TO THE INTRODUCTION OF
NCONTROLLED WATER INTO THE PERMANENT
S. ON EACH FUTURE DEVELOPMENT PLAN IN
ADDITIONAL UNCONTROLLED WATER IS TO BE
ARGED INTO THE PERMANENT BASINS, A PLAN
BE SUBMITTED DOCUMENTING THE AVERAGE
AGE AND THE AMOUNT OF UNCONTROLLED WATER
NTLY BEING DISCHARGED INTO THE BASIN
FED.



A) EARTH WORK STAGING ACTIVITIES

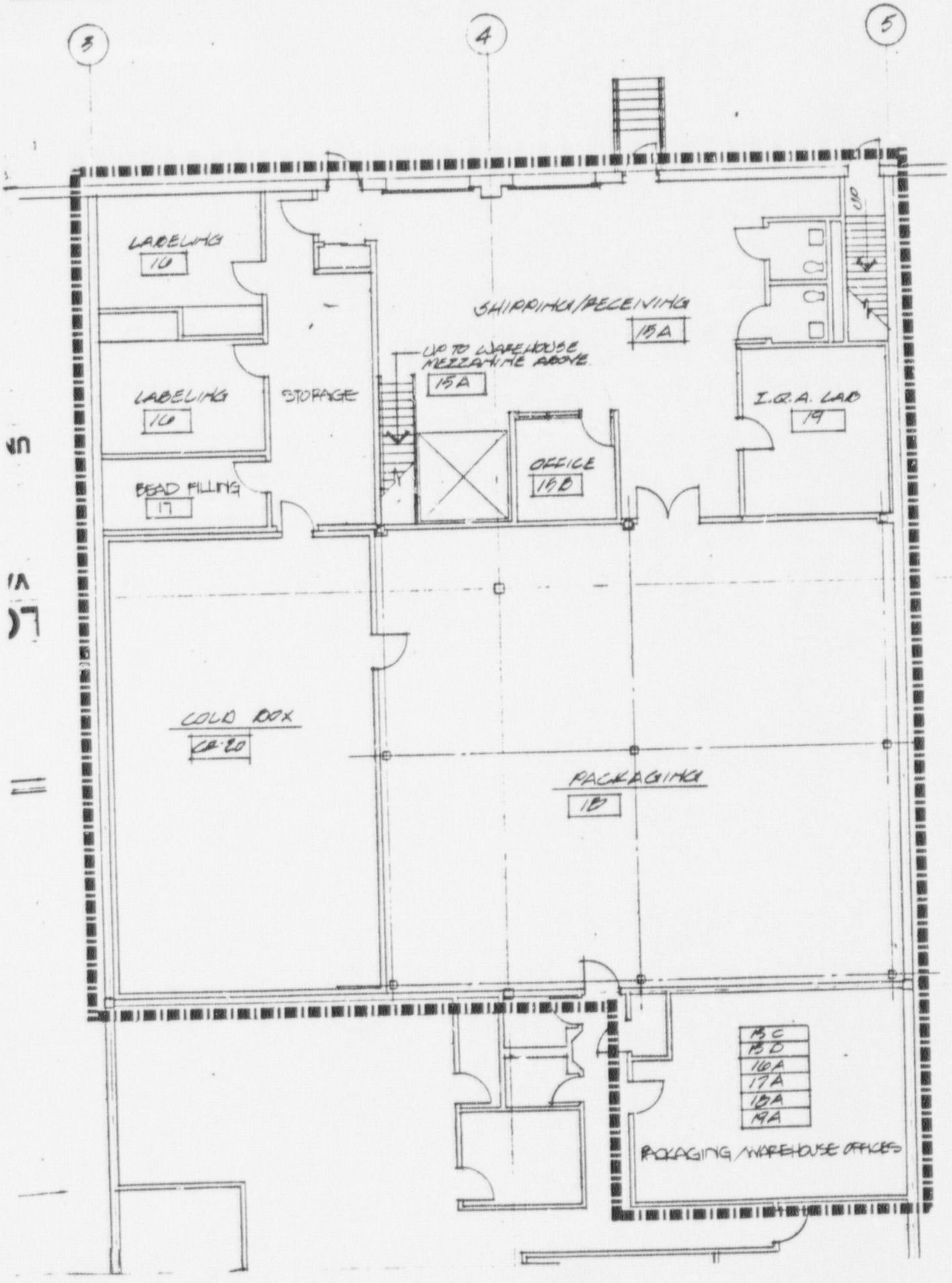
1. PLACE STRAWBALE SILT BARRIERS AS SHOWN AND PROVIDE STONE TIRE CLEANER FOR CONSTRUCTION ENTRANCE AT TECHNOLOGY COURT.
2. STRIP TOP SOIL FROM PROPOSED BUILDING EXTENSION AREA AND FROM PROPOSED EAST PARKING AREA. STOCKPILE TOP SOIL AT CORNER OF SITE. APPLY TEMPORARY SEEDING AND INSTALL SILT BARRIER AS NECESSARY.
3. STRIP TOP SOIL FROM PROPOSED WEST PARKING AREA AND STOCKPILE AT NORTHWEST CORNER OF SITE. APPLY TEMPORARY SEEDING AND INSTALL SILT BARRIER AS NECESSARY.
4. REMOVE AND DISPOSE OF EXISTING CURB AND PAVING AS REQUIRED.

EAST WHITELAND TOWNSHIP

ZONING DATA

IND-2-INDUSTRIAL DISTRICT

	REQUIRED	PROVIDED
MIN. LOT AREA	135,000 SF	163,032 SF
MIN. LOT WIDTH	150'	407.58'
MAX. BLDG. COVERAGE	55%	33%
MIN. FRONT YARD	60'	61'


3
4
5
LABELING
10
LABELING
10
STORAGE
BEAD FILLING
17
SHIPPING/RECEIVING
15A
UP TO WAREHOUSE MEZZANINE ABOVE
15A
OFFICE
15B
I.Q.A. LAB
19
COLD ROOM
20
PACKAGING
18
15C
15D
16A
17A
18A
19A
PACKAGING/WAREHOUSE OFFICES

Increase in Current Radioisotope Limits

Radioisotope	Present Limit	Requestd Limit
Iodine - 125	500 mCi	1000 mCi
Molybdenum 99	2000 mCi	4000 mCi
Technetium 99m	2000 mCi	4000 mCi

Our petition for increase in Iodine - 125 is based on increased production needs due to the recent FDA approval of one of our in-vitro RIA kits and the anticipated approval of at least two others within the next two years.

The request to increase our limits of Molybdenum 99 and Technetium 99m arises as a result of the creation of a new Radiochemistry department at Centocor whose task it will be to develop new imaging products.

Current procedures employed for use of these radioisotopes will continue.

Inclusion of New Radioisotope

We would like to add Technesium 99 in any form to our existing license. Quantities would not exceed 100 mCi. This material will be used for labeling of proteins in research and development experiments.

Change in Centocor Regulatory Personnel

Please remove John D. Iuliucci from our license as Director of Corporate Regulatory Affairs and add Howard T. Holden. Dr. Holden's resume is attached.

HOWARD HOLDEN RESUME

CURRICULUM VITAE

Name: Dr. Howard T. Holden

Date and Place of Birth: December 10, 1944; Newark, NJ

Citizenship: United States

Marital Status: Married; two children

Education:

1962-1966	B.A. (Zoology), Drew University, Madison, NJ
1966-1968	Graduate Student, Seton Hall University, South Orange, NJ
1968-1973	Graduate Student, University of Miami School of Medicine, Miami, FL
1973	Ph.D. (Microbiology), University of Miami School of Medicine, Miami, FL

Brief Chronology of Employment:

1966-1968	-	Teaching Assistantship, Department of Biology, Seton Hall University, South Orange, NJ
1969-1971	-	Teaching Assistantship, Department of Microbiology, University of Miami School of Medicine, Miami, FL
1971-1972	-	N.D.E.A. Fellowship, University of Miami School of Medicine, Miami, FL #69-00709.1
1973-1974	-	Postdoctoral Fellow, Cellular and Tumor Immunology Section, Laboratory of Cell Biology, National Cancer Institute, Bethesda, MD #CA55361
1974-1975	-	Postdoctoral Fellow, Laboratory of Immunodiagnosis, National Cancer Institute, Bethesda, MD #CA02305
1975-1981	-	Senior Investigator, Laboratory of Immunodiagnosis, National Cancer Institute, Bethesda, MD
1982-1983	-	Senior Investigator, Biological Therapeutics Branch, Biological Response Modifiers Program, National Cancer Institute, Frederick Cancer Research Facility
1983	-	Acting Section Head, Immunobiology Section, Laboratory of Molecular Immunoregulation, Biological Response Modifiers Program, National Cancer Institute, Frederick Cancer Research Facility
1983-1986	-	Senior Investigator, Drug Regulatory Affairs Section, Investigational Drug Branch, Cancer Therapy Evaluation Program, National Cancer Institute, Bethesda, MD
1986	-	Section Head, Drug Regulatory Affairs Section, Regulatory Affairs Branch, Cancer Therapy Evaluation Program, National Cancer Institute, Bethesda, MD
1986-present	-	Director, Corporate Regulatory Affairs, Centocor, Inc., Malvern, PA

Societies:

American Association for the Advancement of Science
American Society for Microbiology
Sigma Xi
American Association of Immunologists
American Association for Cancer Research
Reticuloendothelial Society
American Society of Clinical Oncology
Regulatory Affairs Professional Society
The Drug Information Association

Honors & Other Special Scientific Recognition:

Scientific Program Chairman, National Annual Meeting, Reticuloendothelial Society - 1980
Faculty Member, Workshop on Laboratory Application in Cell Separation, W. Alton Jones Cell Science Center, Lake Placid, New York - 1980
Faculty Member, Reticuloendothelial Society PreMeeting Workshop - 1981
Faculty Member, Reticuloendothelial Society PreMeeting Workshop - 1982
Faculty Member, Laboratory Workshop in Cell Separation Techniques, University of Alabama in Birmingham - 1982
Member, Board of Trustees of American Type Culture Collection 1983-1985

Present Address: 1807 Maple Avenue
Paoli, Pennsylvania 19301

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Procedure Change in Existing License

Change in Item 5 - Part E to read for TC-99m, mCi instead of uCi.

CENTOCOR

RADIATION SAFETY QUIZ

Circle the best answer

1. When an accident involving radioisotopes occurs in the lab, one should do what first?

   a) clean up the spill
   b) treat any injuries
   c) notify the Radiation Safety Officer

2. Radioactive materials coming into the Company should be:

   a) delivered to the requisitioner
   b) delivered to the Radiation Safety Officer
   c) left outside the lab in the hallway

3. Appropriate shielding for Beta emmitters, such as Phosphorus 32, is:

   a) lead
   b) plastic
   c) gloves

4. When radiation is capable of penetrating matter and creating ion pairs along its path, it is called:

   a) ionizing radiation
   b) microwaves
   c) electromagnetic radiation

5. Three types of ionizing radiation are:

   a) gamma rays, x-rays, and radio waves
   b) gamma rays, alpha particles, and lasers
   c) gamma rays, beta particles, and alpha particles

6. Radioactive materials contain atoms with too much:

   a) mass
   b) Iodine-125
   c) energy

7. The rate at which radioactive atoms decay is called:

   a) half-life
   b) activity
   c) mRem/hr

8. The rate of radioactive decay is commonly measured in:

   a) activity
   b) counts per minute (CPM)
   c) half-life

9. If Iodine-125 has a half-life of 60 days, and on January 1, a bottle of labeled protein has an activity of 10 mCi, what would the activity be on March 1 (60 days later)?

   a) 2 mCi
   b) 7.5 mCi
   c) 5 mCi

10. The dose equivalent is a measure of how radiation affects an organism and is measured in what units?

    a) REM
    b) CPM
    c) Curies

11. The Centocor Radiation Safety Program is based on the philosophy of:

    a) Time - Distance - Shielding
    b) ALARA (As Low As Reasonably Achievable)
    c) Inverse Square Law

12. Appropriate shielding for gamma emitters such as Iodine-125 is:

    a) gloves
    b) plastic
    c) lead

13. Personnel monitoring at Centocor is generally done by means of:

    a) wipe tests
    b) biopsy
    c) film badges

14. Wipe tests are done to detect:

    a) personnel contamination
    b) removable contamination
    c) releases of radioactivity into the environment

15. Personnel using any radioisotopes at Centocor are required to wear:

    a) gloves and labcoats
    b) lead aprons
    c) respirators

16. All accidents involving radioisotopes must be reported to the:

a) NRC
b) Director of Operations
c) Radiation Safety Officer

17. Biological effects of radiation include:

a) cell death
b) cell alterations (cancer, mutations)
c) genetic alterations
d) all of the above

18. Thyroid scans are done at Centocor to determine thyroid uptake of:

a) Phosphorus-32
b) radioactive iodine
c) Indium-111

19. Low-level aqueous radioactive waste may be disposed of down the sink as long as sample of the waste is assayed and has a CPM/ml of less than:

a) 10^6
b) 10^3
c) 10^{12}

20. Lost film badges and rings should be reported to the Radiation Safety Officer:

a) when badges are exchanged
b) as soon as it is discovered missing
c) within one week of the loss

True or False

T 21. Violations of Radiation Safety Policy can result in termination of employment.

F 22. An employee can be fired for going to the NRC about internal Radiation Safety problems before consulting the Radiation Safety Officer.

F 23. Pregnant employees are not allowed to work with radioisotopes.

T 24. Infectious waste must be decontaminated prior to disposal in a radioactive waste barrel.

F 25. Film badges may be worn home.