

DL-033197_05



March 31, 1997

Nuclear Materials Safety Section
United States Nuclear Regulatory Commission
Region II, Suite 2900
101 Marietta Street NW
Atlanta, GA 30323-0199

Business Group
Diagnostics

Bayer Corporation
8365 Valley Pike
PO Box 307
Middletown, VA 22645-0307
Phone: 540 869 3200
Fax: 540 869 5249

Dear NRC:

Bayer Corporation is requesting the termination of License No. 45-19163-02 issued to our Middletown, VA manufacturing facility. Since we were able to transfer all radioactive materials off site prior to April 1, 1997, we would like to apply for a refund of 50% of our FY 1997 licensing fee.

Enclosed is Form NRC-314, "Certificate of Disposition of Materials" showing all radioactive materials in our possession have been transferred to a licensed affiliated facility in Indiana. The Liquid Standard had been consumed and discarded earlier this year, per Bayer SOP G-075. (A copy of the SOP is included for your reference.) The balance of the inventory was sealed sources as listed.

Bayer decommissioned the site per 10 CFR §30.36 (j). The results of all the swipe and survey meter testing were at or below background. Copies of shipping papers and test results are included, along with a listing of the inventory transferred to Indiana.

If you have any questions, please contact me at (540) 869-8158 or at the address on this letterhead.

Thank you.

A handwritten signature in cursive script that reads "Marshall C. McCarty".

Marshall C. McCarty
Regulatory Affairs

207447

16-95
20-95
22-95
24-95

ESTIMATE UPON PER RESPONSE TO COMPLY WITH THIS MANDATORY INFORMATION COLLECTION
REQUIREMENT. THIS SUBMITTAL IS USED BY NRC AS PART OF THE BASIS FOR ITS
DETERMINATION THAT THE FACILITY HAS BEEN CLEARED OF RADIOACTIVE MATERIAL BEFORE THE
FACILITY IS RELEASED FOR UNRESTRICTED USE. FORWARD COMMENTS REGARDING BURDEN ESTIMATE
TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH, 1450 U.S. NUCLEAR REGULATORY
COMMISSION, WASHINGTON, DC 20545-0001 AND TO THE PAPERWORK REDUCTION PROJECT
CONTACT OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503. AN AGENCY MAY NOT
CONDUCT OR SPONSOR, AND A PERSON IS NOT REQUIRED TO RESPOND TO A COLLECTION OF
INFORMATION UNLESS IT DISPLAYS A CURRENTLY VALID OMB CONTROL NUMBER.

CERTIFICATE OF DISPOSITION OF MATERIALS

INSTRUCTIONS: ALL ITEMS MUST BE COMPLETED. PRINT OR TYPE.
SEND THE COMPLETED CERTIFICATE TO THE NRC OFFICE SPECIFIED ON THE REVERSE.

LICENSEE NAME AND ADDRESS

Ranger Corporation
PO Box 307 5365 Valley Lake
M. del. town, IN 2294-0307

LICENSE NUMBER

45-19163-12

LICENSE EXPIRATION DATE

4/2/95

A. MATERIALS DATA (Check one and complete as necessary)

THE LICENSEE OR ANY INDIVIDUAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE LICENSEE CERTIFIES THAT
(Check and/or complete the appropriate item(s) below.)

- 1 NO MATERIALS HAVE EVER BEEN PROCURED OR POSSESSED BY THE LICENSEE UNDER THIS LICENSE
- OR
- 2 ALL ACTIVITIES AUTHORIZED BY THE LICENSE HAVE CEASED AND ALL MATERIALS PROCURED AND OR POSSESSED BY THE LICENSE NUMBER CITED ABOVE HAVE BEEN DISPOSED OF IN THE FOLLOWING MANNER. (If additional space is needed, use the reverse side or provide attachments.)

Describe specific material transfer actions and, if there were radioactive wastes generated in terminating this license, the disposal actions including the disposition of low level radioactive waste, mixed waste, Greater than Class C waste, and sealed sources, if applicable. All sealed sources were transferred to Ranger Corp in Elkhart, IN. No other radioactive materials remain on site.

For transfers, specify the date of the transfer, the name of the license recipient, and the recipient's NRC license number or Agreement State name and license number. Date of transfer: 3/31/97
Transferred to: Ranger Corporation, Ken Gordon, NRC License 14-01249-01 (Elkhart, IN)

If materials were disposed of directly by the licensee rather than transferred to another licensee, licensed disposal site or waste contractor, describe the specific disposal procedures (e.g., decay in storage). All test kits were consumed in testing waste (e.g., empty bottles, test tubes, etc.) and spent per SEP 6-075 (copy attached).

B. OTHER DATA

- 1 OUR LICENSE HAS NOT YET EXPIRED. PLEASE TERMINATE IT.
- 2 A RADIATION SURVEY WAS CONDUCTED BY THE LICENSEE TO CONFIRM THE ABSENCE OF LICENSED RADIOACTIVE MATERIALS AND TO DETERMINE WHETHER ANY CONTAMINATION REMAINS ON THE PREMISES COVERED BY THE LICENSE. (Check one)
 - NO (Attach explanation)
 - YES THE RESULTS (Check one)
 - ARE ATTACHED, OR
 - WERE FORWARDED TO NRC ON (Date)

3 THE PERSON TO BE CONTACTED REGARDING THE INFORMATION PROVIDED ON THIS FORM

NAME: Christie Plance

TELEPHONE NUMBER: (219) 367-5336

4 MAIL ALL FUTURE CORRESPONDENCE REGARDING THIS LICENSE TO:

Christie Plance
Radiation Safety Officer

207417

CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

PRINTED NAME AND TITLE

Christie Plance, Director

SIGNATURE

[Handwritten Signature]

DATE

4/2/95

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. SECTION 1001 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 JURISDICTIONS.

FILE CERTIFICATES AS FOLLOWS:

IF YOU ARE A DISTRIBUTOR OF EXEMPT PRODUCTS, SEND TO:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON DC 20565 0001

ALL OTHERS, 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:**

LICENSING ASSISTANCE SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
476 ALLENDALE ROAD
KING OF PRUSSIA PA 19408 1415

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET NW, SUITE 2900
ATLANTA GA 30323 0199

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRLE ROAD
LISLE IL 60532 4361

**ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO,
HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA,
NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA,
OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA,
TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND
APPLICATIONS TO:**

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON TX 76011 8064

Shipper's Certificate

This parcel contains an excepted radioactive article.

Shipping Name: Excepted Radioactive Materials, Instruments and Articles

Hazard Class: Radioactive Material-Identification Number: UN 2911/UN 2910

Containing: ~~9 milliliters - Nickel-60~~ - Transportation Group IV - Solid Form

No. D.O.T. label required: ~~3~~ ² ~~micro Sodium-129~~

This is to certify that the above named article(s) are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to applicable regulations of the Department of Transportation, the IATA Dangerous Goods Regulations and the ICAO Technical Instructions for the safe transportation of dangerous goods by air.

D.O.T.: 49 CFR 173.422.

IATA: Section 5.7.28

ICAO: 7.5.3

Name and Address of Shipper:

Marshall C. McCarty

Shipping Date: 3/31/97

Bayer Corp

By: KENYON D. YODER

8365 Valley Pike

Title: RADIATION SAFETY OFFICER

Middletown, VA 22

Phone: 219/262-7574

Reason for return:

Decontamination

Disposal

Correct Defect

Explanation of Defect: Transfer to Elkhart facility from Middletown facility.

This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package - limited quantity of material, UN 2910.

Chemical cleaning per Purchase Order No. _____

Detector repair per Purchase Order No. _____

Credit (Part must be accompanied by return authorization.)

Send to:

Kenyon Yoder
Bayer corp. PO4.21.1
Receiving Area #1
1000 Randolph St.
Elkhart, IN 46514

Notes:

1. Categorization, labeling and Shipper's Declaration are not required.
2. Each article must be marked "RADIOACTIVE".
3. Securely package in cardboard container (minimum size 4' x 4').
4. Place a completed copy of this document inside the outer container.
5. The consignment must be described on the waybill as "Radioactive material excepted package-instruments". *limited quantity of material*

u4
3/31/97

257447

RADIOACTIVE SOURCE MATERIALS USED IN RIA TESTING IN THE IN-PROCESS LAB

| SOURCE DESCRIPTION | SERIAL NUMBER | RADIOISOTOPE | ACTIVITY | DATE | TYPE SOURCE | NUMBER |
|-------------------------------|---------------|------------------------------|----------------|----------|-----------------|--|
| ISOTOPE PRODUCTS LABORATORIES | 7422-44 | I-129 | 0.258 μ Ci | 2/1/80 | SEALED | 1 |
| ISOTOPE PRODUCTS LABORATORIES | 7247-4 | I-129 | 0.253 μ Ci | 11/1/79 | SEALED | 2 |
| NEW ENGLAND NUCLEAR | N/A | I-129 | 0.103 μ Ci | 1/9/81 | SEALED | 3 |
| NEW ENGLAND NUCLEAR | N/A | I-129 | 0.090 μ Ci | 2/6/79 | SEALED | 4 |
| THE NUCLEUS | N/A | MOCK I-129 I-129 & AM-241 | 0.056 μ Ci | 6/3/80 | SEALED | 5 |
| ABBOTT | N/A | BA-133 | 0.5 μ Ci | 7/1/78 | SEALED | 6 |
| UNKNOWN | 3478 | BA-133 | 0.5 μ Ci | 12/12/75 | SEALED | 7 |
| NEW ENGLAND NUCLEAR | N/A | CO-57 | 0.116 μ Ci | 1/19/81 | SEALED | 8 |
| THE NUCLEUS | N/A | CO-57 | 2.0 μ Ci | 8/89 | LIQUID STANDARD | 9 \rightarrow Discarded 1/17/97 Don S. |

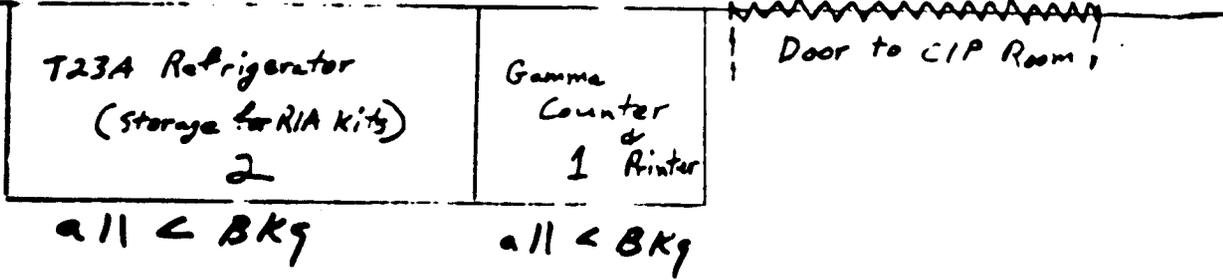
TOTAL ACTIVITY 3.876 μ Ci

FOR USE IN BERTHOLD MULTI CRYSTAL GAMMA COUNTER SERIAL NUMBER 1211

DON MARTIN
10/12/94 *DM 10/12/94*

GM Survey Meter

Perform Swipe Test on Numbered areas.



Bio-Formulation Area.
Background = .01 - .02 mRan/hr

all
< BKg

Work Area
3

all
< BKg.

Sink
4

Victoreen 491, Serial #923 probe 1.4mg/cm²
Calibration Date: 7-26-96

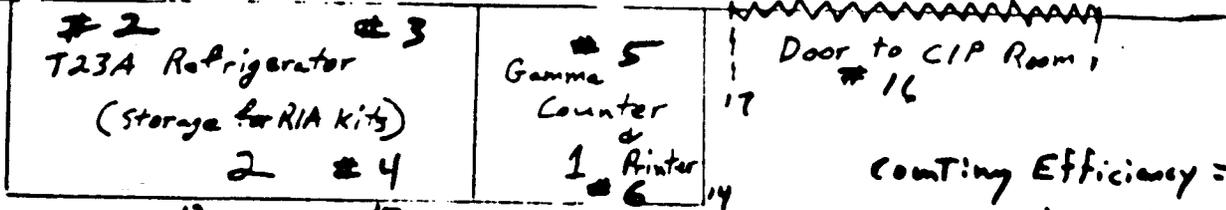
DMS
12/20/95

Ken/oder
Ken/oder
3/26/97

↑
Entrance

Perform Swipe Test on Numbered areas.

Berthold model LB-2101 gamma counter
 HV adjusted; standardized; efficiency determined
 against ⁶⁰Co Ulmest I-125



Counting Efficiency = 77%

| | | | CPM | DPM/100cm ² | |
|-------|----------------------|-----|-----|------------------------|----------------|
| 1 | Blank | # 7 | 0 | 0 | # 18 Desk |
| # 2-4 | Inside refrigerator | 1) | 0 | 0 | |
| 5-6 | Table beside counter | 2) | 0 | 0 | |
| 7 | Floor | 3) | 7 | 9 | |
| 8-9 | Work area surface | 4) | 6 | 8 | |
| # 10 | Floor | 5) | 0 | 0 | |
| 11 | Side of sink | 6) | 0 | 0 | |
| | Bio-Formulation Area | 7) | 0 | 0 | |
| | | 8) | 7 | 9 | # 19 Work Area |
| 12 | dr in pipe | 9) | 0 | 0 | |
| 13-14 | Surface ref. door | 10) | 2 | 3 | |
| 15 | Ref. door handle | 11) | 0 | 0 | |
| 16 | door | 12) | 0 | 0 | |
| 17 | light switch | 13) | 3 | 4 | |
| 18 | desk | 14) | 0 | 0 | |
| 19 | desk drawer handle | 15) | 8 | 10 | |
| 20 | desk Telephone | 16) | 5 | 6 | |
| 21 | Sink outside | 17) | 0 | 0 | # 21 Sink |
| 22 | Sink floor | 18) | 0 | 0 | # 22 |
| | | 19) | 0 | 0 | # 12 |
| | | 20) | 0 | 0 | |
| | | 21) | 6 | 8 | |
| | | 22) | 0 | 0 | |

DonS,
12/20/95

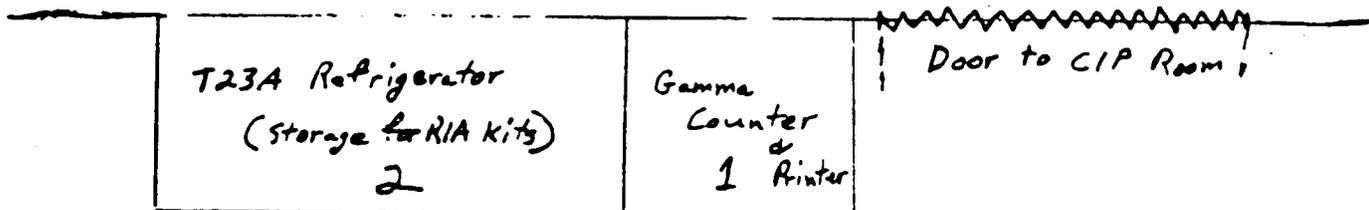
Ken Foder
 Ken Foder
 3-26-97



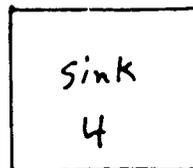
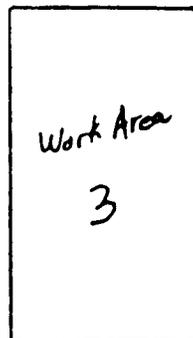
Map used to record test

Results
(for reference)

Perform Swipe Test on Numbered areas.



Bin-Formulation Area.



Don S.
12/20/95



| | | |
|--|-----------------------|-------------|
| BAYER STANDARD OPERATING PROCEDURE MIDDLETOWN, VIRGINIA | SOP No.: G-075 | Page 1 of 5 |
| | | Rev: 02 |
| TITLE: USE OF RADIOACTIVE MATERIAL | | |

HISTORY

Originator: C Clanci

| <u>CHANGE NUMBER</u> | <u>REVISION</u> | <u>DESCRIPTION OF CHANGE</u> | <u>AUTHOR</u> |
|----------------------|-----------------|---|---------------------------|
| S-0640 | 01 | Changed wording. Updated and removed forms from SOP. | <u>See Originator</u> |
| S-1452 | 02 | Name and format change, added Sections 3.4.4, 3.5.5 on form no. 386. "Running Total" column to form 385, and "Background CPM" column to form 386. All are NRC requirements. | <u><i>[Signature]</i></u> |

| <u>Initial when Reviewed</u> | <u>User Review Section</u> | <u>Effective Date</u> |
|------------------------------|----------------------------|-----------------------|
| <u><i>[Signature]</i></u> | _____ | _____ |
| <u><i>[Signature]</i></u> | _____ | _____ |
| <u><i>[Signature]</i></u> | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |

FEB 20 1995
 MIDDLETOWN
 DOCUMENTATION

TITLE: USE OF RADIOACTIVE MATERIAL

1.0 PROCEDURE

This procedure outlines the facility program for the control and use of radioactive materials in the form of Radioimmunoassay kits (RIA).

2.0 SCOPE

This procedure is applicable to the Middletown, VA facility.

Use of radioactive materials at this facility is limited to the purchase of commercially available in-vitro diagnostic RIA kit, containing low-level quantities of I^{125} or Co^{57} for testing of Bayer products. (Bayer products are non-radioactive).

A specific license will be maintained for the possession and use of these materials, issued by the U.S. Nuclear Regulatory Commission of State, as appropriate.

3.0 PROCEDURE

3.1 Radioactive Materials to be Used.

3.1.1 Radioactive materials to be used are restricted to I^{125} or Co^{57} in the form of commercially available prepackaged in-vitro RIA test kits, and sealed calibration sources ("Mock I^{125} ").

3.1.2 Total inventoried material will not exceed quantities allowed under a general NRC license, i.e. 200 uCi, individual tracer units not to exceed 10 uCi (I^{125}) or as specified in a specific license (Co^{57}).

3.2 Purpose for Which Radioactive Materials Will be Used.

3.2.1 Radioactive materials are used in the testing of Bayer products and for instrument (gamma counter) calibration, as previously described.

3.2.2 RIA testing will be performed according to the package instructions provided with kits.

3.3 Personnel

3.3.1 Radioactive material will be used by, or under the supervision of, the facility radioaction safety officer (RSO). The RSO will maintain the radiation safety program, training, and monitor procurement, receipt inventory, and disposal of all radioactive materials.

3.3.2 Only qualified, designated personnel will be allowed to perform testing using radioactive materials.

3.3.3 Training and qualifications of all personnel performing tests with radioactive materials will be documented. These records will be maintained in the employee's personal training file.

3.4 Facilities and Equipment

3.4.1 Radioactive materials procured by this facility will be used only at this location; no material will be transferred or distributed off-site.

3.4.2 RIA kits will be received and delivered directly to authorized personnel in the designated RIA area of the laboratory and stored only in the designated area of the refrigerator used for radioactive materials.

TITLE: USE OF RADIOACTIVE MATERIAL

3.4.3 The Berthold Multi-Crystal Gamma Counter, Model LB-2101, is used for sample analysis. Refer to Instrument Operation Manual.

3.4.4 Before performing testing, GM Monitor should be set to Monitor counts per minute (CPM) for approximately ½ hour to determine background (15-20 CPM is a typical background count). (See instrument manual for complete operating instructions.) A GM Tube survey meter will be used for area and hand monitoring.

3.5 Radiation Safety Program

3.5.1 Personnel training will include basic problems, procedures and policies associated with the safe utilization of radiological materials.

3.5.2 Radioactive materials will be stored and used only in designated areas. These areas will be monitored for contamination following activity.

3.5.3 "Caution-Radioactive Materials" sign will be posted on the outside of the refrigerator door where/when kits are being stored.

3.5.4 Record receipt and disposal of materials; the inventory log is to include total quantities of radioactivity per kit. This will represent total maximum activity on hand.

3.5.5 Wipe test will be performed at the completion of each day (when used) on Form 386. Swab over work areas, bench top, near gamma counter, etc. Count swabs on gamma counter.

3.6 Waste Management

3.6.1 The following: Liquids containing radioactive materials, residual kit contents, and test wastes, and rinsate from glassware and accessories will be disposed of in a designated laboratory sink, with copious quantities of water. This discharge is the sanitary sewage system.

3.6.2 When empty the User will peel or deface all radioactive emblems from kit vials and package when empty, and discard in normal trash receptacle.

4.0 ATTACHMENTS

4.1 Radioactive Materials Receipt & Inventory Log, Form No 385. (Example only)

4.2 Radioactivity Contamination Survey Log, Form No 386 (Example only)

5.0 RESPONSIBILITY

5.1 All facility personnel using radioactive materials are responsible for complying with this procedure.

5.2 The RSO is responsible for implementation and interpretation of this program

5.3 Plant Management is responsible for enforcement of this program

