UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

February 25, 2005

Docket No. 03005210 License No. 29-00018-02
Control No. 136014

Jack S. Kace, Ph.D.
Vice President, Corporate Environment & Safety
Hoffman-La Roche, Inc.
340 Kingsland Street
Nutley, NJ 07110

SUBJECT: HOFFMAN-LA ROCHE, INC., ISSUANCE OF LICENSE RENEWAL, CONTROL NO. 136014

Dear Dr. Kace:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, "Request for Taxpayer Identification Number," is enclosed.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify the NRC in writing of any change in mailing address.

3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license

   a) when you decide to terminate all activities involving materials authorized under the license; or

   b) if you decide not to acquire or possess and use authorized material.

4. Request and obtain a license Amendment before you:

a) change Radiation Safety Officers;

b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or

c) add or change the areas of use, or addresses of use identified in the license application or on the license; or

d) change the name or ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 55

NRC Web site addresses
NRC regulations
http://www.nrc.gov/reading-rm/doc-collections/cfr/
Licensing guidance
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/
General Policy and Procedure for NRC Enforcement Actions
Http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf
206 of the Energy Reorganization Act of 1974
http://www.nrc.gov/who-we-are/governing-laws.html

cc:
Michael Drzyzga, Radiation Safety Officer

DOCUMENT NAME: E:\Filenet\ML050590082.wpd

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	JNicholson/JJN		EUlrich/EXU					
DATE	02/25/2005		02/25/2005					

OFFICIAL RECORD COPY

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 55

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the application dated November 22, 2004,
1. Hoffmann-LaRoche, Inc.	3. License number 29-00018-02 is amended in its entirety to read as follows:
2. 340 Kingsland Street Nutley, New Jersey 07110	4. Expiration date February 28, 2015
	5. Docket No. 030-05210 Reference No. 29-30817-02

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic number 1 through 83	A. Any	A. Not to exceed 50 millicuries per radionuclide and 1 curie total
B. Hydrogen 3	B. Any	B. 400 curies
C. Carbon 14	C. Any	C. 15 curies
D. Nickel 63	D. Foil or plated sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.	D. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State
E. Cesium 137	E. Sealed Source (3M Model 4E6P)	E. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-00018-02

Docket or Reference Number
030-05210/29-30817-02

Amendment No. 55

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
F. Cesium 137	F. Sealed Sources (ORNL Model A-0096 or J.L. Shepherd Model 6810)	F. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State
G. Americium 241	G. Any	G. 1 millicurie

9. Authorized use:

A. through C. Research and development as defined in 10 CFR 30.4; animal studies; manufacture of radiochemicals and radiopharmaceuticals ; and calibration and checking of the licensee's instruments.

D. To be used for sample analysis in compatible gas chromatography devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

E. Calibration and checking of the licensee's instruments.

F. For use in J. L. Shepherd Model 143-45a self-contained irradiator for the irradiation of materials.

G. Research and development as defined in 10 CFR 30.4 and calibration and checking of the licensee's instruments.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 340 Kingsland Street, Nutley, New Jersey and 1080 U.S. Highway 202 South, Branchburg, New Jersey.

11. A. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.

B. The Radiation Safety Officer for this license is Michael Drzyzga.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-00018-02

Docket or Reference Number
030-05210/29-30817-02

Amendment No. 55

12. The licensee shall not use licensed material in or on human beings.

13. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

15. This license does not authorize commercial distribution of licensed material.

16. Notwithstanding 10 CFR 33.17(a)(4), the licensee is authorized to manufacture radioactive drugs containing radionuclides for transfer to specific licensees.

17. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-00018-02

Docket or Reference Number
030-05210/29-30817-02

Amendment No. 55

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

18. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

19. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

20. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

21. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

22. Pursuant to 10 CFR 20.1302(c) and 10 CFR 20.2002, the licensee is authorized to dispose of licensed material by incineration, provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20.

23. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with atomic numbers 1 through 83, except as identified below, as ordinary waste in a landfill provided that the concentration of radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values of Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99, and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B. If more than one radionuclide is present in the ash, then the sum of fractions rule applies.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-00018-02

Docket or Reference Number
030-05210/29-30817-02

Amendment No. 55

24. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

    A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

    B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

    C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

25. Radioactive waste possessed under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the application dated November 22, 2004.

26. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

27. Notwithstanding the requirements of License Condition 28, the licensee is authorized to make program changes and changes to procedures specifically identified in the condition, which were previously approved by the U.S. Nuclear Regulatory Commission and incorporated into the license without prior Commission approval as long as:

    A. The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation.

    B. The revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.

    C. The licensee's staff is trained in the revised procedures prior to implementation.

    D. The licensee's audit program evaluates the effectiveness of the change and its implementation.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
29-00018-02

Docket or Reference Number
030-05210/29-30817-02

Amendment No. 55

28. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated November 22, 2004 (ML043430225)
B. Letter dated February 14, 2005

For the U.S. Nuclear Regulatory Commission

Date February 25, 2005

By *Original signed by Elizabeth Ullrich*

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Roche

Pharmaceuticals

Licensing Assistant Branch
Nuclear Materials Safety Branch
US Nuclear Regulatory Commission, Region I
475 Allendale Ave.
King of Prussia, PA 19406-1415
Nov. 22, 2004

03005210

Subj: License Number 29-00018-02 RENEWAL APPLICATION

Dear Sir/Madam:

This timely submission, in duplicate, consists of a complete renewal application for broadscope license 29-00018-02 issued to Hoffmann La-Roche. Inc.

If you have any questions regard this application, please contact the undersigned by any of the means listed below.

Very truly yours,

Michael J. Drzyzga
Manager, Radiation Safety Officer
(v) 973-235-3418
(Fax) 973-235-4893
Michael.drzyzga@roche.com

MJD
Enclosures

RECEIVED
REGION 1
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136014

NRC FORM 313 (8-2000) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 08/31/2002

Estimated burden per response to comply with this mandatory collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0000), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

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:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

03005210

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 JURISDICTIONS.

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 29-00018-02

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Hoffmann-La Roche, Inc.
340 Kingsland Street
Nutley, NJ 07110

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

A. Hoffmann-La Roche, Inc.
340 Kingsland St.
Nutley, NJ 07110

(B) Roche Diagnostics
1080 US Hway 202 So.
Branchburg, NJ 08876

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mr. Michael Drzyzga

TELEPHONE NUMBER

973-235-3418

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 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.

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

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AEAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY | AMOUNT ENCLOSED $

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

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, 36, 39, 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

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
JACK S. KACE, V.P. ENVIR. & SAFETY	Jack S. Kace	11/22/04

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		136014
APPROVED BY				DATE	

5. Radioactive Material

a. Element/mass	b. Chemical Form	c. Max Activity
i. Any byproduct w/ At.No. 3 - 83	Any	Not to exceed 50 mCi ea. and 1 Ci. total
ii. H-3	Any	400 curies
iii. C-14	Any	15 curies
iv. Am-241	Any	1 millicurie
v. Cs-137	JL Shepherd Model 28 Beam Calibrator, Sealed Source	120 millicuries
vi. Cs-137	JL Shepherd Model 6810 irradiator	2200 curies
vii. Ni-63	Foils and/or sealed sources	75 millicuries

6. Purposes for Use

i. - iv. R&D as defined in 10 CFR 30.4; Instrument Calibration.
ii. - iii. Notwithstanding 10 CFR 33.17(a)4), formulate new drugs in small quantities to be transferred to a licensee authorized to perform human clinical studies (this use is not "manufacture", nor commercial distribution of "radiopharmaceuticals".)
v. instrument calibration - copy of SSD registration is on-file.
vi. irradiation of research related items in Model 143-45a irradiator - copy of SSD registration is on-file.
vii. sample analysis in gas chromatography instruments.

Roche does not intend to use radioactive material to perform portable gauging at temporary job locations.

Roche does not intend to use radioactive material in field studies.

7. Individuals Responsible for Radiation Protection

7.a. Organizational Chart - Attachment 7.a. shows the direct line of authority from the CEO, through Corporate Compliance (Corporate Officer) to the RSOr.

7.b. **Current members of the RSC**

Dr. Jack Kace, Vice Pres., Corp. Environ and Safety Affairs (Chairman)
Mr. Michael Drzyzga, Manager, RSOr, (Exec. Sec.)
Dr. Teresa Truitt, Sr. Res. Scientist,
Dr. Joseph Grimsby, Sr. Res. Leader
Dr. Lubo Vassilev, Sr. Res. Scientist

Mr. Jack Alexander, Law Dept.
Dr. Robert Kosecki, Dept. Head, Roche Diagnostics (Branchburg, NJ)
Dr. Peter Belica, Sr. Res. Chemist, Radioisotope Synthesis
Mr. Jeff Fulton, Principal Scientist, Non-Clinical Drug Safety

7.c. **Functions of the RSC**
The RSC meets at least four times per year, once per calendar quarter, or more often as needed. A meeting is valid with a quorum consisting of the Chairman, or designated alternate, a member of Management, and one more than half of the total members. The RSOr compiles an agenda for every RSC meeting, oversees scheduling, and sends a meeting notice to each member with the agenda.

The RSC reviews application forms containing detailed information submitted by employees who require the use of radioactive material, and either grants or withholds the authorization of these employees to become authorized Principal Radiation Users (PRUs). The reviewers scrutinize the information on the application form to determine the sufficiency of the applicant's training and experience and that the facility set-up, safety equipment, and radiation detection instrumentation are appropriate for the type of work the applicant intends to do. The reviewers also determine if the applicant and subordinate radiation users attended the Radiation Safety Orientation Lecture. PRU's responsibility is listed in section 7.f. below.

Minor changes to the RSO procedures that have been submitted to the USNRC are reviewed and approved by the RSC to assure that the procedural changes do not reduce the effectiveness of the RSP. The RSC assures that the spirit of the ALARA principle is maintained in the RSP.

The RSC also reviews internal reports from the RSOr regarding employee exposure incidents, environmental releases of radioactive material, LLRW disposal operations, audit findings, and other such pertinent information.

The RSC has directed the RSOr to retain an outside consultant to perform routine audits of the RSP. Audit findings are presented to the RSC and appropriate modifications to the RSP are directed to the RSOr for implementation.

The RSC has published a RSM which contains RSP policy and procedures, practical radiation safety information, emergency response actions, and other facts which may require distribution to key personnel within the organization. The RSC periodically updates the RSM, with revised procedures and information needed to improve the RSP. The RSC has been granted the authority by Executive Management to enforce all RSP policies and procedures, thus has the authority and ability to withdraw the authorization of PRUs if such action is necessary to achieve a high level of compliance with all program requirements.

The Recording Secretary keeps an accurate account of meetings in

minutes form. The draft minutes are reviewed by key members of the RSC, then finalized for distribution to the full RSC. The RSO maintains a readily-available and orderly file of the minutes.

The RSC periodically (at least once per year) audits restricted areas to inspect laboratory operations, radiation user work practices, and general compliance items.

The RSC members approve the use of training material presented to RUs and periodically attend the RSOL.

7.d. Radiation Safety Officer (RSOr)
The current RSOr is positioned as a Manager in the Site Environmental Health Safety Department (SiteEH&S). As such, the RSOr is responsible to develop and manage a capital and expense budget in support of the RSLab, develop and implement a five-year strategic plan, develop and implement an annual RSO work plan, oversee proper use of a Roche vehicle, and report monthly to management on the status of such plans. The budget allows for the continuous improvement of the training of the RSOS by attendance at professional society meetings and attending educational seminars, and maintaining a current set of text books, references, and publications from organizations such as the NCRP, ICRP, IATA, and ANSI.

The RSO earned a B.S. degree in Chemistry (Seton Hall), a M.S. degree in Radiation Science (Rutgers University), and acquired 32 years practical experience in Health Physics associated with sealed sources, nuclear pharmacy operations, clinical laboratory licensees, Diagnostic Kit Manufacturing (RIA), and cyclotrons and 5 MW reactor - radiopharmaceutical production facilities.

Foremost is the RSOr's DOA: in the RSM, the RSC clearly states that the RSOr has "the authority to grant, withhold, or withdraw authorization to possess and use radioactive materials or ionization producing equipment, subject to final approval of the RSC."

Additionally, the RSOr provides a constant overview of activities of the RSO staff whereby reviews are performed of laboratory air and waste water effluent sampling data and records, personnel exposure records, instrument calibrations, routine and special contamination and radiation level surveys, managing of LLRW, reviewing security conditions of the facility, reviewing radionuclide inventory records, approving the procurement of radioactive materials, complete packaging and shipping of radioactive samples, provide training programs to a wide-range of company workers, and all other aspects of the RSP.

7.e. Radiation Safety Office Staff (RSOS)
In addition to the RSOr, the RSOS consists of:

One Asst. Radiation Safety Officer: B.A. degree in Physics, M.S. candidate in Rutgers University's Radiation Science Program, many professional enrichment courses at HP meetings and other seminars

in practical radiation protection, member of national HPS and the NJ Chapter HPS, ANS; is certified in auditing nuclear Quality Assurance Programs, and acquired 21 years wide-ranging experience.

One Admin. Asst. (a dedicated, full time employee): 20 years professional business experience, 17 years of this at Roche with 5 yrs (part-time) in the RSO.

7.f. PRUs have the following responsibilities:

a. Provide supervisory oversight of operations in restricted areas. The oversight includes implementing actions to verify that all RUs are following safety procedures and license requirements,
b. Provide information regarding general safe handling procedures applicable to the local work area to new employees prior to the employee's attendance to the RSOL.
c. Procure radiation safety equipment and detection instruments based on requirements set by the RSOS.
d. Maintain inventory records and report radionuclide inventory to the RSOS when requested,
e. Decontaminate areas found to exceed contamination survey action levels,
f. Notify the RSOS of changes in the PRUs' operations,
g. Submit purchase requests for radioactive materials to the RSOS for approval.

8. Training Programs

a. All PRU applicants meet with the RSOr for an initial training program which includes an introduction to the RSP, explanations of the responsibilities of a PRU, and the process of becoming an authorized PRU.

b. All PRU applicants and RUs attend a 3-hour RSOL which includes information provided on the attached RSOL outline (Attachment 8.b). Additionally, should the PRU require the use of a less commonly used radionuclides, or in larger activity levels, that may possess special handling requirements (such as the Radioiosotope Synthesis), the PRU and associated RUs will receive additional training specifically on the safe handling requirements for that radionuclide. The re-training interval is about 2.5 yr. The participants are required to successfully complete a multiple question quiz to demonstrate that they understand the information presented. Should an attendee not do well, re-training is provided.

c. All RUs that are authorized to use the self-contained irradiator are provided an additional training session that covers the specific hazards associated with Cs-137, security measures, the

proper use of the irradiator, and special procedures to follow should an undesirable condition arise.

d. All RUs that are authorized to perform radioiodinations are provided an additional training session that includes air effluent monitoring requirements, thyroid bioassay procedures, special personnel protection requirements, and use of a special facility.

e. Hazardous Material Handlers and Safety Specialist from other service groups within Roche provide support to the RSOS to collect LLRW for disposal and transfer containers of LLRW within the facility. These employees receive specific training for the tasks in which they participate.

f. Ancillary staff such as the Environmental Response Squad, Security Force, Maintenance Dept. workers, Laboratory Animals

Resource staff, and Cleaning Dept. workers receive general training regarding the use and control measure for radiation protection, and particular instructions for their work area.

g. The personnel in the Receiving and Shipping Departments and the RSOS receive a one-hour lecture and demonstration regarding the control measures for radiation protection and the packaging, marking, labeling, and paperwork requirements to comply with USDOT and IATA regulations.

h. The RSOr keeps a standard attendance record for all group training sessions.

i. The RSOS has made special arrangements, in certain situations, to use an interpreter to help train non-English speaking workers, or to use an individual trained in sign language to help train a hearing-impaired worker. An information "Hand-out" is provided for the workers in the Cleaning Dept., and is available in English, Spanish and Polish languages.

j. In cases where the RU is unfamiliar with the use of radiation detection instruments, LLRW disposal practices, or other practical aspects of the RSP, the RSOS uses a (performance based) "hands-on" approach and goes to the work place and demonstrates to the RU whatever is required to safely perform the job.

k. Attendance record sheets are maintained for all initial and refresher training. The record sheets includes the title of the training session, the date, time interval, location, and the name of the trainer(s) and trainee(s).

9. Facilities and Equipment designed and established for special use:

a. Self-contained small volume irradiator, (J.L. Shepherd)
Nutley site Building 123 Room 0511

b. Tritium/Carbon-14 Radioisotope Synthesis Labs (RIS)
Nutley site Building 66 Room 217

c. Iodine-125 radio-labeling facilities
Nutley site Building 66 Room 217

d. Decay-in-storage locations
i. Nutley site (DSM) Building 30 Basement Cages
ii. Nutley Site (Liquids) Building 123, Room 0511
iii. Branchburg site Building 500 Waste Storage Bunker and Room 2318.

e. Long-term(Interim)Storage Facility (ISF)
Nutley site Building 30 Basement Cages

f. Laboratory Animal Resources
Nutley Site Bldg. 123A Animal Housing Facility
(No animals used at the Branchburg facility)

g. Drawings:
Attachments 9.a., 9.d.i. and 9.f. are annotated drawings of special facilities at the Nutley and Branchburg locations.

h. Hazard Level Classification:
Roche continues to use a model developed early in our Radiation Safety Program, which classifies areas in the company which are restricted for the purpose of radiation protection. This model was recently re-fashioned to be closely aligned with that classification scheme presented in NUREG 1556, vol. 11. The classification scheme "Relative Radionuclide Hazard Levels" is shown in Attachment 9.h. This scheme has demonstrated over many years of implementation to provide effective radiation protection.

i. Radioisotope Synthesis Labs. (RIS)
In the early part of 2000, Roche completely renovated a chemical research building (Bldg. 66) into a modern, well-designed research facility. Part of the renovations included the building of a new radioisotope synthesis suite of labs, consisting of three rooms and service area. The RSO staff engaged in the design and implementation of the renovations in order to assure that the best design and materials were used. This enhances the contamination control program and demonstrates Roche's commitment to ALARA.

Within these labs, the chemists can draw H-3 gas into a vacuum transfer system, wherein about 100 Ci H-3 is bound to 15 gm

of Depleted Uranium. The chemists can access as little as 0.5 Ci of H-3, thus reducing the handling risks and LLRW volume. Also, the chemists have C-14 Barium Carbonate stored in a 1 Ci bottle, and would weigh-out between 20 mCi and 500 mCi on a digital balance enclosed in an enclosure which is vented into a fume hood.

Bldg. 66 is a two-story concrete and block structure, entirely fire resistant, dedicated to chemistry research and development. The facility has three access points, each under electronic ID card access control. The RIS labs occupy the north end of the second floor. The entire building is protected from fire with an overhead water sprinkler system. Each lab has an eye-wash station and safety shower system, which are functionally tested for proper operation routinely.

The entrance door to the RIS labs is also under electronic ID card access control. The entrance door is equipped with a pass-through which allows workers to place items into a portal, enter the labs, and then retrieve the items from the other side. The concrete floors are covered with vinyl square tiles, then covered with either rubber or vinyl rolled-down floor covering. Inside the entrance area is a tacky-mat "step-area" with a chair for changing into/out-from disposable shoe coverings.

The bench and cabinets are painted metal casework with stainless steel bench tops and fume hoods. The fume hoods are monitored for adequate flow rate and equipped with alarms to indicate to the worker if flow rate problems occur. Additionally, the hoods are on a site-wide preventative maintenance program which includes the functional testing of the hoods for flow rate and air capture ability.

The area ventilation system is balanced to assure that supply air to the RIS flows from the outer hallway, though the labs, then into the fume hoods.

The "house vacuum" is available for used with non-radioactive materials work. Small self-contained vacuum pumps, vented into the hoods, are used during synthesis with radioactive materials, reduces the future cost of decommissioning.

The effluent air from all the hoods are ducted through a seamless metal ductworks into a dedicated roof-top facility which contains an array of standard HEPA filters, with a bag-in/bag/out design. These are also part of the site-wide preventative maintenance program. Magna-helic gauges are used to determine the pressure drop across the filters. The effluent stack is open-ended, designed to maximize the exit velocity rate, and sized to allow for effective dispersion into the atmosphere.

The waste water effluent from cup sinks in the hoods or the

two other sinks enters a new PCV-pipe drain system which leaves Bldg. 66 into a main sewer line feeding into large Environmental Control Facility (ECF). The operators of the facility have the ability, on demand, to divert the site's waste water into containment area, for subsequent analysis and processing, as needed. The ECF is equipped with a sampling pump whose sampling rate is proportional to the effluent rate, and takes a continuous sample of the waste water. A 24-hr. period sample, each day, is provided to the RSO for radioactive material concentration analysis (Public Dose assessments).

j. Specifications for facility design and equipment are based on assessments made by the RSOS and take into account the radionuclides(s) handled, the activity used at any given time, the chemical properties of the radioactive material, and the characteristics of the experimental protocol or handling procedures.

10. Radiation Safety Program

10.1 Radiation Detection Instruments

a. Radiation Safety Office: The RSO maintains a wide range of high technology radiation surveying and measuring instruments. For performing radiation level measurements, the RSOS uses instruments including Searle (Texas Nuclear) Ion-Chamber rate-meters, a Bicron Analyst, a Bicron low-energy microrem meter. For performing fixed contamination surveys, the RSOS staff uses scintillation detectors such as the Ludlum 44-116, 44-148; or Bertold LB122 proportional meter. For general survey work, the RSOS uses Ludlum 3, 16, or 18s with model 44-9 GM detectors or 44-3 scintillation detectors. For analyzing samples for radioactive content, the RSOS uses automatic multi-channel LSCs (Wallac WinSpect 1414 or Beckman LS6000s) or automatic NaI(Tl) GSCs (Intertechnique GC30 or Wallac Wizard 1480). For performing thyroid bioassays, ash sample analysis, and other special gamma spect. analysis, the RSOS will use either of two EG&G/Ortec Multi-channel Analyzers (MCA).

b. Radiation Users: RUs throughout the various locations also have a wide range of radiation detection equipment for monitoring purposes. Many laboratories have a Ludlum survey meter or equivalent with a detection probe suitable for the radiation in use. There are also a large number of Beckman, Wallac, and automatic multi-channel LSCs and a Wallac 1480 NaI(Tl) GSC in service in the R&D area.

c: The Branchburg site has an Eberline ESP-2 wide-range digital monitoring instrument for measuring radiation level, two Beckman LS6500 LSCs for sample analysis, and a variety of Ludlum survey meters.

d. Calibration:

i.) Instruments used for measuring radiation levels and quantifying radioactivity are calibrated at least annually. The Searle Ion-chambers and Bircron low-energy analyzers are calibrated by the RSOS using a J.L.Shepherd Model 28 Cesium-137 port beam irradiator. Our Calibration Procedure is attached (Attachment 10.1.). The current location of the Calibration Facility is in Bldg. 30, basement. The calibration of LSCs, GSCs and MCAs are checked weekly using sealed reference standards, and/or custom quenched standard sets are assayed (for the LSCs). The primary assay instruments are on a Service Contract with the vendor, and that contract requires that the vendor complete an annual calibration of each instrument.

With the scheduled demolition of Bldg. 30, Roche Management has provided the RSO with another suitable space to set-up the J.L Shepherd irradiator -- in the south side of Bldg. 36. This larger area is freshly refinished including a secured entrance and a fenced area to partition the space. Bldg 36 has been a "service building", and is constructed using pale-brick on a concrete slab with a metal roof, including a fire suppression sprinklers and good lighting and ventilation. The perimeter of this area will be monitored with low-range environmental dosimeters as is Bldg. 30's area now.

ii.) Instrument Used for monitoring: Those hand-held survey rate-meters that are utilized for performing routine contamination surveys, are calibrated, and certified as such, by the instrument manufacturer at the time of purchase. Afterwards, every time a RU uses the survey meter, it undergoes a quick, yet effective check to assure that the survey meter is operating consistently as when it was purchased. See this procedure in the "General Guidelines" Attachment 10.6.1., item 11. The RSOS has been trained by professional electronic repair technicians to troubleshoot and complete minor repairs to Ludlum survey meters, thereby, Roche has a highly effective ability to provide operating survey meters to the hands of RUs.

10.2. Audits and Appraisals

a. The RSC has two methods to audit the RSP. First, the RSC directed the RSOr to contract with an outside independent consulting firm to perform audits of the RSP. Currently, the RSOr has a contract with Van Pelt Associates, a Certified HP with a proven record in the health physics program review and implementation. Second, The RSOS compiles an annual report containing summary and actual data from the operations of the RSP. The report is critically reviewed by all members of the RSC, and subsequent comments and discussion added to the final version. This report also provides a permanent record of activities associated with the RSP for historical purposes.

b. RSOS audits:

Safety evaluations are part of the RSP audits that are performed during the routine contamination surveys performed by the RSOS, and the audits conducted by the RSOr. The RSOr maintains a file containing notes on such audits, and often writes a follow-up memo to the PRU to document the process. If the RSOS identifies handling techniques or procedures which should be changed to improve or enhance the overall safety, the RUs in the area are asked to make such improvements. If the RSOS feels that such changes must be implemented, the RSOr will take action to verify that the changes are implemented and are effective.

10.3. Inventory Control and Material Accountability

There are three parts of the RSP used to verify that Roche does not exceed its license limits, and accounts for materials. First, a Quarterly Radionuclide Inventory based on a computer-prepared inventory form is sent to all PRUs at the end of each calendar quarter. Each PRU performs a physical accounting of all radioactive materials under his/her control, and records the specific data on the form. The forms are signed, dated and returned to the RSOS for compilation. A PC-based database is used to total all the PRU inventory data into a summary report. The report is reviewed by the RSOr, action taken if circumstance warrant, and filed in permanent records. Second, the PRU Radionuclide Order/Receipt Records contain data for radioactive material orders/receipt for each PRU. Third, a PC-based electronic spreadsheet contains data regarding LLRW awaiting shipment or, if necessary, in interim storage. This spreadsheet calculates total radioactivity in the LLRW for every radionuclide present, and calculates the decay for those with a relatively short half-life.

10.3.1 Procurement of radioactive materials is controlled by the RSOS. In order for the Purchasing Department to process an order for radioactive material, the RSOS must authorize the purchase request through on on-line Roche Intranet based procurement system. The RSOS will not authorize (approve) such purchase request unless it contains the name of an authorized PRU, and the type and quantity of radioactive material ordered is within the PRU's authorization.

10.3.2 Receiving Radioactive Material.

At the Nutley site, the RSOS has a procedure established with the Corp. Receiving Dept. staff. A "labeled" radioactive material package upon receipt requires prompt notification of the RSOS. With a co-coordinated effort, the package is transferred directly to the RSOS for compliance inspection. Once the package is deemed "authorized", the package is transferred to the RU, who signs a package receipt record. The RU is responsible to open the box, and inspect and survey the contents. The markings and labels on the package are obliterated prior to disposal as paper trash.

At the Branchburg site, a similar procedure is in effect, except that the Receiving Dept. staff delivers the package directly to a PRU who is trained on performing a completed compliance inspection.

10.3.3 Transfer Controls

Roche's RSP procedures do not allow RUs to transfer radioactive materials to others without the approval of the RSOS. In cases where radioactive material will be transferred from one PRU to another, a "transfer form" is completed and a copy approved by the RSOS. In cases where radioactive materials must be transferred to another licensee, the RSOS co-ordinates the transfer, which verifies that the recipient is authorize to receive the material, and that the shipment is properly completed according to USDOT requirements. All transfer records are kept in the RSO files.

10.4 Personnel Monitoring Devices and Methods

A. The use of Luxel OSD whole-body badges and thermo luminescent (TLD) ring dosimeters is coordinated and administered through the RSO, including the maintenance of extensive historical records of personnel radiation exposure. Every RU is issued a personnel dosimeter unless the PRU in the work group is only authorized for H-3, C-14, and/or S-35.

B. Ring-type TLDs are provided to all RUs performing radio-iodinations, RUs handling P-32 in total quantity of 2 mCi (or more) per week, and RUs of high energy gamma emitters if the amount or frequency of use so requires.
All dosimeters are exchanged every other month.
The dosimeter supplier is Landauer Inc., a NVLAP accredited Service Company.

C. **Bioassays (in-vitro for H-3 and C-14, and in-vivo for I-125)**
A bioassay program is provided by the RSO in order to detect internal contamination resulting from inhalation, skin absorption, or ingestion of radioactive materials. Urine Sample Bioassay procedures are conducted on a routine basis or are specially scheduled when radionuclides are dispatched to the RU by the RSOS. The RSOS follows the guidelines below to determine when bioassay procedures are necessary:

1.) Tritium bioassay is required for all RUs who use greater than 50 mCi of any tritiated substance at one time, except for tritium contained in a sealed or totally enclosed process or storage vessel, in which case the lower limit for bioassay is 100 Curies. Carbon-14 bioassay is required for all RUs who use greater than 25 mCi of volatile C-14 material. The frequency of bioassay is approximately weekly if usage is frequent or continuous. For single or infrequent uses, urine collection is required prior to the start of the usage and within 96 hours after the end of the usage. The following action levels are incorporated into

the urine bioassay program:

i.If urinary excretion rates are between 3 and 15 uCi/l for tritium or 0.8 and 2.0 uCi/l for C-14, the following course of action will be taken:

a) The RU and/or the PRU will be notified and the circumstances of the exposure will be investigated.

b) Feasible and reasonable correction actions intended to reduce future uptake will be implemented.

2.) If urinary excretion rates fall between 15 and 160 uCi/l for tritium or 2.0 and 4.0 uCi/l for C-14, the following course of action will be taken:

a) An investigation of the operations involved would be carried out to determine the cause(s) of exposure and to evaluate potential for future exposures.

b) All reasonable and feasible corrective actions indicated by the investigation, which may lower the potential for future exposures, will be implemented.

c) One or more repeat urine samples will be taken at approximately weekly intervals to further delineate the extent and circumstances of the exposure.

d) Any evidence from paragraphs 2.a, 2.b, and 2.c above indicating that further work in the area might result in additional significant radiation dose shall result in the removal of any affected employees from the work area until the source of exposure is located and corrected.

3) If urinary excretion rates exceed tritium 160 uCi/l or C-14 4.0 uCi/l the following course of action will be taken:

a) All steps as indicated in 2.a through 2.d above will be carried out.

b) If the calculated whole body Committed Effective Dose Equivalent exceeds 5 rem, the incident would be reported to the Nuclear Regulatory Commission.

c) The case would be referred to appropriate medical or health physics consultation for recommendation regarding therapeutic procedures that may be carried out to accelerate removal of tritium or Carbon-14 from the body and reduce the dose equivalent to as low as reasonably achievable.

d) Repeat urine sampling will be carried out at approximately one week intervals as long as samples show a minimum excretion rate of tritium 160 uCi/l or C-14 4.0 uCi/l or more. If there is a possibility of long term organic compartments of tritium or C-14 that require evaluation, the sampling will continue as long as necessary to ensure

that appreciable exposures from these other compartments do not go undetected.

D. Thyroid bioassay program for Iodine-125 is conducted as described in the USNRC Reg. Guide 8.20 dated September, 1979 regarding frequency and minimum use requirements. The only difference is that at Hoffmann-La Roche facilities, the first action level is 0.4 uCi (0.002 ALI non-stochastic).

E. **Air Sampling for Restricted Work Area:** In work areas where there is a potential for airborne radioactivity due to primary protection failures; that is, in areas where volatile substances are used or produced, and contained in sealed vessels or vented by fume hoods, the RSOS requires air sampling. Currently, restricted work area monitoring is performed in the C-14 radio-synthesis Lab., Bldg. 66, Room 217 at the Nutley facility. The criteria presented in USNRC Reg. Guide 8.25, Rev.1 will be (continued) as part of this program. Calibration: Air Sampling systems are calibrated annually using a frictionless primary standard method. Either a bubble-type Gilibrator or a BIOS Inc. electronic flow rate device is used to assure that the air sampling rate accurately represents the rate used in calculations of radionuclide air concentration.

Should an internal deposition of radioactive materials significant, the RSOS uses ICRP 30 models to determine the CEDE and will add the annual CEDE to the worker's EDE to order to record the workers TEDE.

10.5 Public Dose Assessment

10.5.1. Fume Hood Effluent Monitoring: Hood effluent air sampling for I-125 is performed whenever radiolabeling with 0.5 mCi or more of I-125 occurs at the Nutley facility. Hood effluent air sampling for H-3 is performed whenever 100 mCi or more potentially volatile material is used. Stack effluent air sampling will be performed for H-3 and C-14 at the incinerator stack whenever LLRW is disposed of by incineration (see Section 11 for details).

Fume Hood Air Flow Rate: All laboratory fume hoods are subject to periodic inspection and air flow rate verification based on OSHA standards. This is implemented through a well-established procedure implemented through a work group consisting of members of site Industrial Hygiene staff and Maintenance Departments. In most of the modern renovated lab areas the hoods are equipped with an alarming hood air flow sensor to alert the lab staff of low flow conditions.

Additionally, the RSOS has an Alnor moving-reed velometer to spot check hood air flow rates should there be evidence that the hood is not properly operating.

10.5.2. USEPA Comply Code Evaluations. The RSOS is very experienced using this model to evaluate the off-site dose from the Incinerator operation and the hood effluent from Radioisotope Synthesis (Bldg.

66). The RSOS staff will evaluate both release points annually and prints a paper report for file.

10.5.3 Fence-line monitoring On a special occasions, the RSOS uses 5 environmental air monitoring stations that are located at strategic compass headings around the Nutley site. Usually, a Silica Gel sampler is used to evaluate the average air concentration of H-3. Also, the RSOS can implement, at the same locations, a CO_2 trapping bubbler for monitoring C-14 in that form.

10.6 Safe Materials Use and Emergency Response

10.6.1 Safe Use Guidelines

Attachment 10.6.1 is Roche's comprehensive "General Laboratory Extended Guidelines with Radionuclides". This is handed-out to all attendees of the RSOL, and key points are discussed during the RSOL.

10.6.2 Emergency Response

Spills: Attachment 10.6.2 is the Accident/Spill Response Procedure. It is included in the RSM, is provided to all RUs as a hand-out in the RSOL, and is discussed during the RSOL. This RSO procedure has demonstrated in the past to sufficiently mitigate incidents and provide control over the undesirable situation.

The RSOS has sufficient spill control material, with the aid of an on-site Environmental Response Squad (ERS), to establish barrier containment of contaminated areas, implement advanced techniques for spill containment, and perform decontamination of the area. The ERS is part of the SiteEH&S Department, and the members have been trained by the RSOS and are familiar with the scope of Roche's RSP.

Fires: Roche has an automatic fire-alarm call-out to both the Clifton and Nutley's fire departments, who respond to the site from the near-by fire stations. Roche hosts joint drills with the local community's emergency responders, and the RSOr has provided specific training to these individuals. Also, Roche has a professionally trained and experienced group of fire fighters, who guide and aid the local responders. These workers have been trained by the RSOS and are familiar with the RSP at Roche. The RSOS is part of the plant-wide 24-hour emergency notification system (including personnel beepers) and is notified for response if a fire were to occur in a restricted area.

Releases of radioactive material: The RSOS performs air and water effluent monitoring. Should an untoward release occur, the RSOS would use the actual counting data to evaluate the magnitude of the release. This evaluation would include calculation of

radiation doses off site, necessity to report to the USNRC,

root-cause analysis and implementation of corrective measures, and documentation of the incident.

Accidental Contamination of Personnel: The RSOS is trained and experienced in decontamination of personnel. The RSOr and Assistant are knowledgeable in the use of a PC-based dose calculation PC application named VARSKIN. Should the need arise, the non-removable contamination is measured and used as input to VARSKIN for skin dose calculations.

10.7 Radiation Contamination Surveys

A. Routine: The RSOS performs swipe-type contamination surveys of all radionuclide laboratories, storage and adjacent unrestricted areas. The surveys are performed in order to detect fixed and removable contamination, and ambient radiation levels. A quarterly (13 week) survey schedule is designed so that every laboratory is checked for untoward radiation contamination at least every three months. Laboratories are surveyed one or more times per quarter, depending on the intensity of use of radioactive materials, the nature of the work being performed, and the history of the work habits of RUs in the area. One example of increased survey frequency is the higher-level radio-synthesis laboratories, which are surveyed usually every other week, or whenever a radiochemical synthesis is complete, whichever occurs first.

B. Special: The RSOS also performs special contamination surveys whenever necessary or upon the request of any RU.

C. Close-out: A specific contamination survey is performed when a restricted area will be relinquished for unrestricted use.

D. Survey Method: A laboratory contamination survey consists of filter paper wipes of exposed surfaces including bench tops, floors, and equipment; and a direct indication of contamination with a hand-held radiation survey meter with a Geiger-Muller, proportional or scintillation probe. The filter paper swipes are assayed for removable radioactivity by liquid or gamma scintillation counting. Based on the results of the contamination survey, appropriate follow-up action is taken to correct excessive contamination. **Attachment 10.7.D.** is the action level guideline. The results of contamination surveys are recorded on detailed floor plans for each lab or area, and the records are maintained in the RSO.

E. Sealed Source Leak tests - The RSOS has a scheduled program to inventory and leak test all "sealed sources" that come under the control of the broad-scope license. The leak test consists of wiping the sealed source, in areas most likely to show untoward contamination, with a cotton swab wetted with an aprotic solvent.

classified by the EPA as a Part B hazardous waste area, and is therefore equipped with an overhead automatic water sprinkler fire suppression system. The hazardous materials are on a separate floor in the building. The construction of the building has proven to withstand the effects of earthquakes, hurricanes, ice-storms, and heavy rainfall associated with the types of weather in northern NJ. There are no industrial processes in areas adjacent to the ISF.

It is expected that Bldg. 30 will be scheduled for demolition within a year of this application. Therefore, the RSC has reviewed another location provided by Senior Management and directed the RSOS to construct a suitable new ISF. This area is on the west side of the single-level Bldg. 50. The area was a boiler room, now vacated and improved for LLRW storage. The concrete floor is coated with deck enamel, the concrete block walls are painted, the new metal roll-up door is electrically operated and access is controlled by ID card scanner. There is a fire suppression water sprinkler system. The area is well lighted with new fluorescent tubes, and well ventilated. All of the RSP elements associated with Bldg.30 will be transferred to Bldg. 50.

Types of LLRW and Containers:

The LLRW placed into interim storage will be dry solid material, the composition is laboratory trash: rubber and plastic gloves; tyvek disposable lab coats; paper and tyvex shoe covers; glass jars, bottles, lab ware; plastic lab ware, plastic and glass tubes, chromatography paper, acrylimide gels, and others. In smaller volumes, we may keep special H-3 and C-14 waste solidified with a solidifying agent currently accepted as a disposal form. The packages of LLRW for interim storage will be DOT type 17E or 17H steel drums.

There is No LLRW consisting of animal carcasses, liquid scintillation vials, or liquids to be placed into interim storage. Activity levels are usually within CLASS A limits, but may exceed CLASS C as defined in 10 CFR 61. The license possession limit, requested in Part 5 of this application, is sufficient for the total activity in use and in the ISF.

Radiation Protection:

The drums or boxes are placed on wooden pallets, and the floor plan designed so that the pallets make neat rows to allow for easy access and inspection.

The ISF is part of the routine radiation safety survey schedule; the RSOS maintains at least twice per quarter-year surveys, now performed for LLRW awaiting shipment. Should interim storage actually occur, the frequency will increase based upon an evaluation of the activity in storage.

The caged area is posted with metal warning signs, emergency response information, and a wall-mounted information and display

case.

The exposure rates at the boundary of the restricted area should never exceed ambient background levels. To demonstrate that the radiation levels are "as low as reasonably achievable", the perimeter of the ISF is monitored using Passive Environmental dosimeters changed on a monthly interval.

11.3. Decay in Storage - Roche requests authorization to hold for decay radionuclides with half-lives less than 120 days. The well-established guidance provided by the USNRC has been incorporated into Roche's RSP.

Nutley Site: The LLRW placed into a separate area in the ISF for decay-in-storage consists of DSM, in steel drums or loosely-packed fiberboard boxes (for incineration or off-site thermal destruction after the decay period elapsed time). The maximum expected volume is 30 cu. Ft. per year.

Liquid LLRW in smaller volumes (maximum of 55 gallons/year), usually accumulated in 2 - 5-gallon polyfluoroethylene jugs or glass-lined metal cans are held for decay in a specially designed area, Building 123, Room 0511 (see Attachment 9.D.2.) This room is designed for liquid storage; it has a raised dyke for spill containment, a one-piece epoxy coated floor, and epoxy painted walls. It is subject to all the security and surveillance programs that are in effect at the other Roche storage facilities.

Each container will marked with the date place into storage to assure sufficient decay time has elapsed. At the end of the decay period, the DSM waste will be survey in a low background area, with shielding material absent, and with a very sensitive scintillation detector to assure no residual activity remains. For Liquid LLRW, a sample of the decayed material will be assayed by LSC or Gamma Scintillation to demonstrate background activity levels. Each container is labeled with the necessary dates and survey data. Only the RSOS staff can dispose of decayed LLRW and the records are kept readily available.

Branchburg, NJ Site. Roche is currently decaying mostly P-32 aqueous liquids and DSM lab trash in a specially designed area (as detailed) in Section 9 of this application. Roche averages 6 - 7, 55-gal drums per year, shipped to PermaFix Inc. in Gainsville, FL. The RSOS staff keeps detailed records of this procedure.

11.4. Sewer Disposal

The RSOS has a sewer disposal program that has been refined over the last thirty years into a safe and efficient way to dispose of liquid LLRW. The Nutley site has a permit from the Passaic Valley Sewer Commission. This liquid biological-material waste disposal program contains two mechanisms to demonstrate

compliance with the appropriate parts of 10 CFR 20.1301 and 20.2003. First, the liquid LLRW from individual work areas is combined into a large volume storage drums, then sampled and assayed by the RSOS to determine radionuclide content and radioactivity, and then released to the sewer system under controlled conditions. A record showing each batch released and an annual running total for each radionuclide is maintained in a spreadsheet file. RUs do not dispose of LLRW into the sewer in individual laboratories, except under special cases controlled by the RSOS. Second, a daily sample of the Nutley facility waste water effluent, taken by a proportional metering sampler located at the Environmental Control facility (ECF), is assayed by LSC and gamma scintillation methods and a record kept of the radioactive material concentrations. The MDA for low-energy beta emitters is 0.003 uCi/liter.

No Liquid LLRW is disposed of into the sewer system at the Branchburg, NJ facility due to local ordinances that forbid such material in the sewer.

11.5. Incineration of LLRW

A. LLRW forms: animal carcasses and bedding, dry solid material consisting of laboratory trash (tyvek booties and lab coats, latex and rubber gloves, disposable plastic lab ware, glassware, paper tissue-wipes, paper towels, rubber floor mats, air filter media, etc.) and non-hazardous spent LS Vials.

B. Daily maximum radioactivity, release concentrations, and ALARA

Radio-nuclide	DAILY Activity	DAILY AVE. STACK Concentration (uCi/cc)	GROUND LEVEL Concentration (uCi/cc)	ANNUAL %DAC Limit
H-3	94.0 mCi	2×10^{-8}	2×10^{-12}	<1
C-14	282.0 mCi	6×10^{-8}	6×10^{-12}	<1
I-125	282.0 uCi	6×10^{-11}	6×10^{-15}	<1
S-35	18.8 mCi	4×10^{-9}	4×10^{-13}	<1
P-33	9.4 mCi	2×10^{-9}	2×10^{-13}	<1
P-32	0.94 mCi	2×10^{-10}	2×10^{-14}	<1
Others	1 mCi			

The Nutley site operational plan, submitted to and approved by the NJDEP, allows performing batch burns, one burn per week, and 24 burns per year. The LLRW for each burn will be selected by the RSOS from the LLRW in accumulation areas, so that the lowest possible impact (ALARA) per burn will be achieved. The weather conditions based the observations of Roche's modern on-site meteorological station, will be considered when planning disposal burns. The radionuclide release rates from the incinerator stack have been processed by the USEPA computer code "COMPLY" ver.1.0d, and the current operation is in compliance with NESHAPS.

C. Incinerator Site and Description

The incinerator is located on the Nutley site, identified as Bldg. 43 on the northern end of the facility (See Attachment 11.C) has been operating very successfully for nearly ten years. The north and west side of this site are not residential areas. The northern side faces NJ Route 3 with a wide range of commercial properties and operations on the other side of the highway. The nearest residence is about 1,330 feet. The west side faces commercial operations up to residential areas that begin about 2,700 feet away. Residential areas are adjacent to the site in the south and east directions, with homes 2,000 and 1000 feet, respectively. The nearest schools are nearly one mile distant and the nearest hospital is more than two miles away.

The incinerator consists of a rocking kiln primary combustion chamber protected on the inside with refractory lining and enclosed in a steel shell. The incinerator has a secondary combustion chamber and can operate in various modes whereby different amounts of fuel and air are supplied to the two chambers. The entire operation is controlled and monitored by a computer management system located in a 2nd floor control room that overlooks the feed-floor. On the feed ramp where sealed boxes of LLRW are staged, a digital scale captures the weight of each box so that the total burn weight is accurately recorded.

When burning LLRW, the kiln will operate at an optimum temperature (near 2,000 degrees F) thereby completing the burn-out of solid organic matter. The kiln's diameter tapers from 5 feet to 3 feet. Ash is released by a control system that rolls the kiln during a rotation of 180 degrees. The uncapped stack height is 118 ft. with 11,500 SCFM (4.7×10^{12} cc/day) air flow during normal operation.

The environmental emission controls have been reviewed and approved by the NJDEP's Air Permit group. The pollution control devices include a series of electrostatic precipitators, an ammonia injection system, and water spray ring-jet scrubber, and effluent gas reheat system. The liquid discharged from the scrubber enters directly into an effluent line that joins the facility waste discharge system. This waste liquid effluent is subject to the sampling and radioactive material content analysis as described in the previous Section, 11.d.

Roche has successfully obtained all NJ and local permits for this incinerator. The successful path included: hiring an outside independent engineering consultant to help collect the proper information for submission to the permit grantors, holding two public meetings, (one in Clifton and one in Nutley), modifying the County solid waste management plan accounting for the loss of waste from our facility, and receiving two comprehensive operating permits, one from the NJDEP's Solid Waste group and another from the Air Permit group. During 9/2004, Members of the

Clifton Board of Health were on-site and present while LLRW was being incinerated.

D. Stack monitoring for Radionuclides

Stack monitoring will be performed on those days that LLRW is burned. The monitor is an electric vacuum pump and calibrated air flow meters attached to a series of samplers for C-14, H-3 and I-125. These samplers are the same as those in-service for the other air monitoring program at Roche and have repeatedly proven their effectiveness at determining the concentration of these three radionuclides. The sampling point is through a dedicated port installed in the stack on the top floor of the building.

E. Ash Surveys and Disposal

The incinerator generates both "bottom" and "fly" ash. Both are handled in a well-planned manner including access controls, storage in a secured building 43, and dust-prevention controls. The NJDEP approved our required ash management plan which includes sampling of the ash for hazardous material (TCLP) before the ash is released to an unsecured landfill.

The ash from batches of LLRW burns that contain LLRW contaminated with low energy beta-emitting radionuclides with long half-lives (H-3, C-14,) is analyzed to determine the H-3 and/or C-14 concentration. A catalytic combustion process of ash samples is performed using an industrial Combustion Oxidation Analyzer. This process produces CO_2 and H_2O as analyzer effluent. The CO_2 is collected in an amine solution, and the H_2O is collected by condensation. Both samples are assayed by LSC methods producing a MDA of 1.0E-5 uCi/gm for H-3 and 7.0E-6 uCi/gm for C-14. The effectiveness of this method has been verified by splitting actual ash samples with an independent contract lab. Roche demonstrated that our method is at least as good (proven better) that the contract lab method.

Ash will be disposed of according to the USNRC, Policy and Guidance Directive PG 8-10, dated Jan. 7, 1997.

The ash from batches of LLRW burns that consist solely of LLRW contaminated with short-lived radionuclides (P-33, S-35, P-32, I-125, Cr-51) will be held for decay in accordance with the standard procedures for decay-in-storage disposal, and then released as non-radioactive ash.

The ash from batches of LLRW that consist of long-lived gamma or beta-emitting radionuclides (Ca-45, Na-22), will be stabilized and disposed of as solid LLRW at a licensed facility, or shipped to a processor that can further oxidize the material.

F. Incinerator Operator Exposure Control

The incinerator operators are part of an Environmental Service

group that handles other hazardous waste materials generated at Roche. The operators are specially trained on the hazards from radioactive materials. The operators are also provided with personnel dosimeters. During the LLRW batch feed, the RSOS surveys the boxes of LLRW prior to final release into the kiln in a low background area to assure that no significant external radiation levels are present. For ash collection, the RSOS provides dedicated containers, appropriately marked and labeled, and the RSOS handles the containers, and ash sampling. At the end of a batch burn, the Bldg. 43 is surveyed by the RSOS to determine that the operation has not contaminated the facility, and the records are part of the routine survey system.

11.6. **Volume Reduction Operations** - No Compactors in use at this time.

List of Attachments

7.A. Organization Chart

7.E Resume - Asst. RSO, Mr. J. Guenther

8.B. Outline of Radiation Safety Orientation Lecture

9.a. Drawing, Building 123, Room 0511, Cs-137 Irradiator & Liquid LLRW Process

9.d.i. Drawing, Building 30, Interim Storage Facility/ DSM Decay

9.d.ii Bldg. 500 LLRW Accumulation Area/ Decay in Storage

9.h. Relative Hazard Level Classification

10.1. Instrument Calibration Procedure

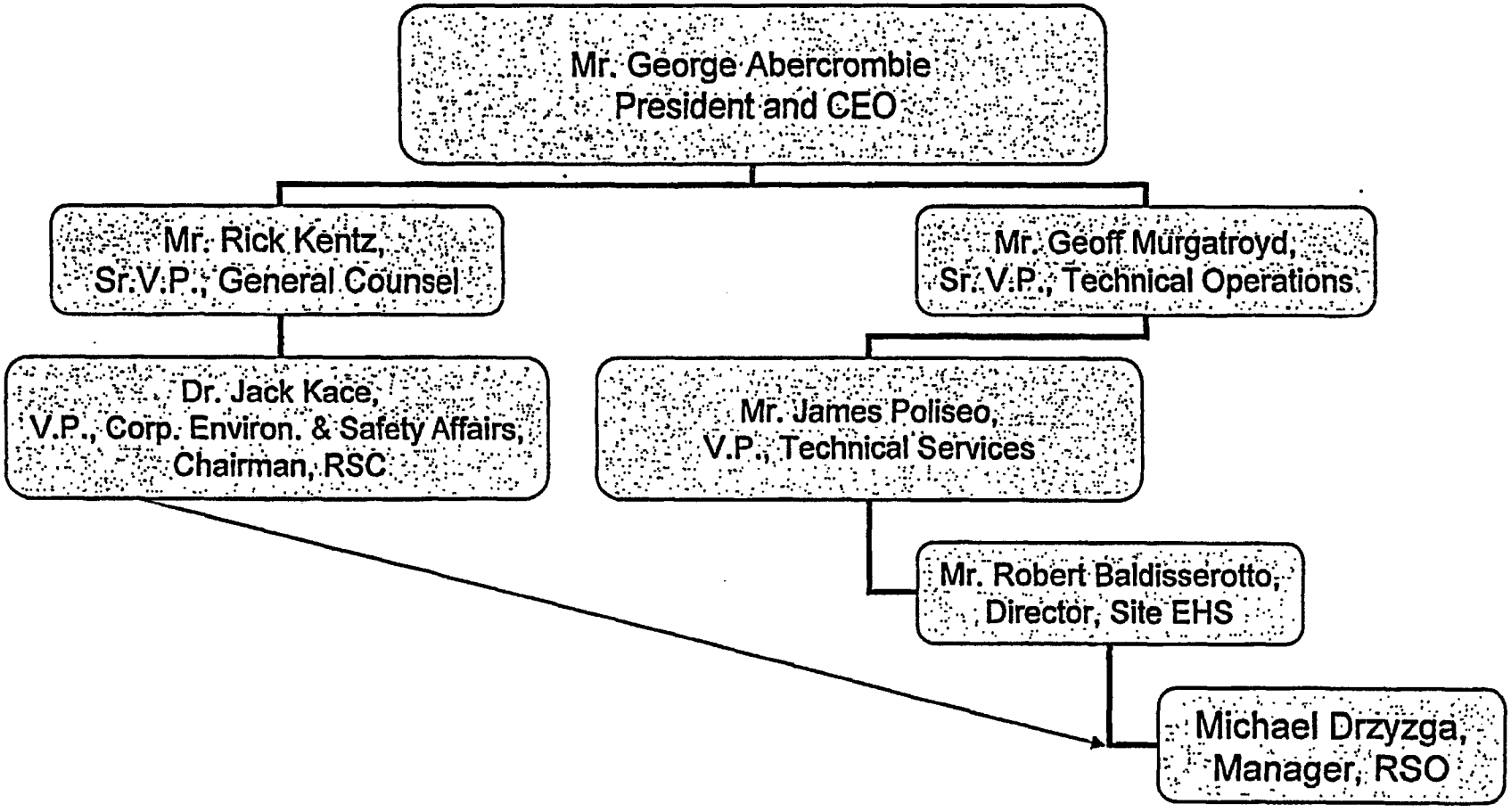
10.6.1 General Guidelines for Using Radioactive Materials

10.6.2. Spill/Emergency Procedures

10.7.d. Contamination Survey Results, Action Levels

11.C. Drawing, Nutley Site Facility Map

Hoffmann-La Roche, Inc.
Radiation Protection Organization



RSO, 4/2004 rev. 6, w:ppt

JEFFREY M. GUENTHER [redacted] Ex6

QA MANAGER / RADIATION SAFETY OFFICER / SR. OPERATIONS MANAGER

OBJECTIVE

Seeking a challenging quality assurance, radiation safety or senior management position where my skills, experience, and educational background will enable me to define new opportunities for profitable corporate growth and personal development.

SELECTED RESPONSIBILITIES AND ACHIEVEMENTS

- **Managed Quality Assurance and Radiation Safety programs** for manufacturing and service operations. Negotiated with regulators to reduce severity of audit findings. Facilitated acceptance of corrective actions. Performed annual audits, documented and monitored non-conformance issues and implemented corrective actions.
- **Implemented enhanced procedures** of sample receiving and processing for radiochemistry laboratory. Streamlined process and coordinated schedules among internal customers. Increased throughput by 15% and reduced turn around times by 30%.
- **Analyzed the implementation of Quality Assurance and Radiation Safety programs.** Reviewed quality and safety protocols, regulatory requirements, compliance issues and record keeping practices. Provided guidance ensuring satisfactory ratings from USNRC and various state regulators.
- **Managed radioactive tracer projects** at refineries throughout the U.S. and internationally. Designed injection systems, wrote and implemented project and safety plans, liaised with state and federal regulatory agencies, obtained tracer production facilities and performed injections. Resulting data led to an average of 40% increase in refinery yields.

PROFESSIONAL EXPERIENCE

Teledyne Brown Engineering – Environmental Services, Emerson, NJ. May 1990 – Present

Manager

As the Manager of Radiological Services and the Radiation Safety Officer (January 2000 – Present) I supervised a staff of five technical and administrative individuals and performed services for operations (health physics, dosimetry, auditing, inspections, radioactive waste brokering, radiation safety surveys, decommissioning projects and instrument calibrations). Prepared staff and material budgets for all operations, prepared and presented weekly business reviews, monthly sales reports, and rolling forecasts. Developed and marketed new services. Expanded client base and increased sales. Successfully relocated office operations without interruption of services to clients. Managed all aspects of the in-house radiation safety program

As the Operations Manager and Alternate Radiation Safety Officer (January 1999 – January 2000) I managed all aspects of day to day operations of the analytical radiochemistry with annual sales of $3M. Prioritized sample work schedules to meet monthly sales expectations. Assisted General Manager in the development of budgets and forecasts. Designed laboratory reorganization to increase efficiency of sample movement. Supervised Alpha Spectrometry and Tritium Laboratories. Ensured staff compliance with all facility safety and radiation safety operating procedures.

As the Quality Assurance Manager (May 1990 – March 1999) I maintained multiple quality assurance programs for all manufacturing and service operations. Performed annual audits of several departments in multiple facilities. Documented and monitored non-conformances, documented and implemented corrective actions, developed and approved procedures, wrote and revised quality assurance and quality control manuals, trained personnel in quality assurance and radiation safety principles and approved reports prior to being released to clients. Incorporated ISO 9000, GLP and GMP principles into the 10CFR50 quality assurance programs. Assisted in design and implementation of in-house Laboratory Information Management System (LIMS).

Cintichem, Inc., Tuxedo, NY. September 1989 - May 1990
Health Physicist
Responsible for the site environmental monitoring program for a 5 MW research reactor. Supervised staff of six Health Physics technicians. Developed and implemented sample collection and counting procedures. Developed protocols for monitoring personnel exiting the reactor building to ensure conformance to the site, USNRC and State regulatory requirements and the radiation, industrial safety and environmental programs. Maintained an on-site eight-detector gamma spectrometry laboratory, reviewed analytical data, and generated reports to management.

Teledyne Isotopes Inc., Westwood, NJ. March 1983 - September 1989
Health Physicist (Alternate Radiation Safety Officer)
Responsible for on-site and off-site radiation safety programs and radioactive material licenses. Supervised three health physics staff technicians for commercial and in-house health physics services and programs (radiation surveys, air sampler installation, sealed source leak testing, x-ray surveys, facility decontamination, exposure calculations and the preparation and review of survey reports).

Managed and performed radioactive tracer projects globally at oil refineries. Designed, planned and evaluated the in-house health physics program for all operations. Implemented the radiation safety program for five Nuclear Regulatory Commission broad scope by-product material licenses, a special nuclear material license, a source material license and New Jersey and Illinois State radioactive material licenses. Developed and implemented the respiratory protection program.

EDUCATION

Rutgers University
New Brunswick, New Jersey
Masters of Science Candidate, Radiation Science Department

Trenton State College
Trenton, New Jersey
Bachelor of Arts, Physics 1981
Minors in Mathematics and Earth Science

PROFESSIONAL AFFILIATIONS

National Health Physics Society (1983-present)
New Jersey Chapter of the Health Physics Society (1984-present)
Northern New Jersey Section of the American Nuclear Society (1990-1996), Chair (1993-1995)
American Nuclear Society (1991-present)
Executive Committee - Environmental Sciences Division (1996-2000)
American Society for Quality (1991-present)

CERTIFICATIONS

Associate Member - American Board of Health Physics (Part I)
Auditing Nuclear Quality Assurance Programs

Excellent references will be provided upon request.

USNRC Lic 29-00018-02
ATTACHMENT 8.b.

OUTLINE
RADIATION SAFETY ORIENTATION LECTURE

I. *Introduction and Purpose*

II. Administrative Structure and Controls
- A. Radiation Safety Committee
- B. Radiation Safety Office

III. Radiation and Radioactive Materials
- A. Atomic Structure
- B. Radioactivity, Decay Rate and Half-Life
- C. Interactions with Matter
- D. Biological Effects
- E. Attenuation and Shielding
- F. Radiations Units and Measures
- G. Survey Instruments
- H. Risk - Benefit Analysis
- I. Sources and Levels of Background Radiation

IV. Functions of Radiation Safety Office

V. Relative Hazard Levels and Quantities of Radioactive Material and General Radiation Protection Methods

VI. Safety Procedures with Radioactive Material and Emergency Procedures

VII. As Low as Reasonably Achievable

VIII. 10 CFR 19; Enforcement Policy; Pregnancy Policy

IX. Security of Radioactive Material; Visitor's Policy

X. Low-Level Radioactive Material Waste Disposal

XI. Quiz

END

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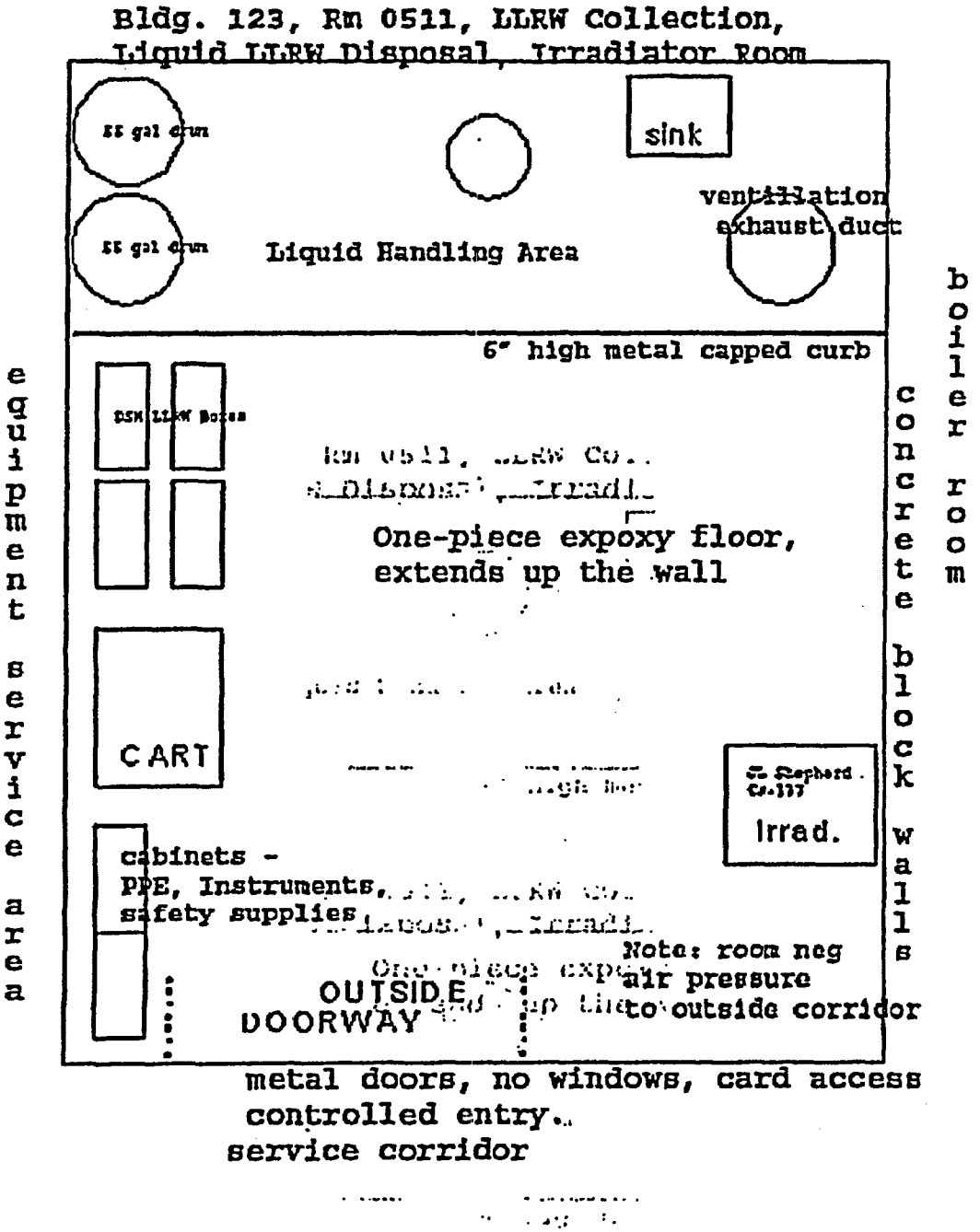

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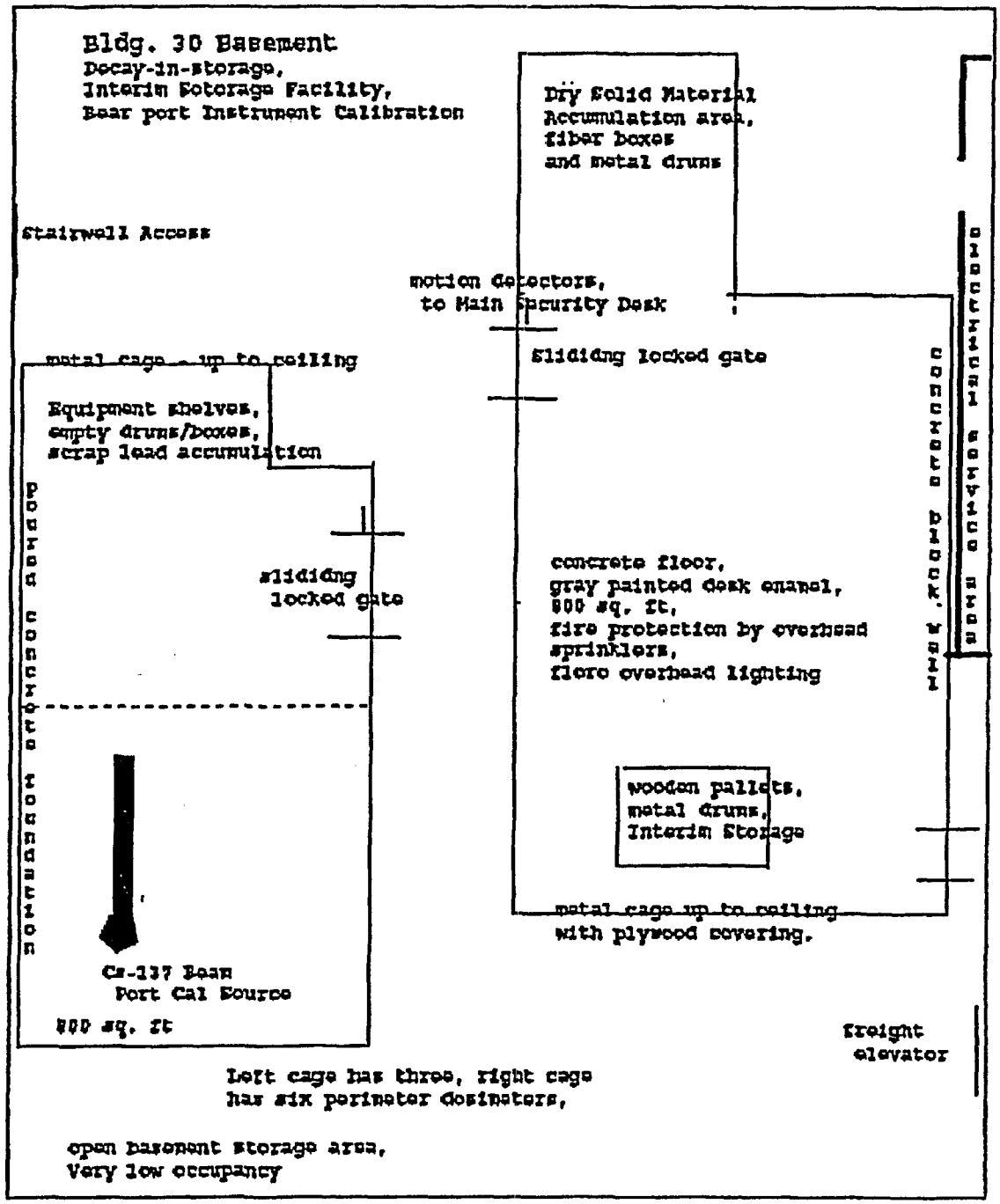
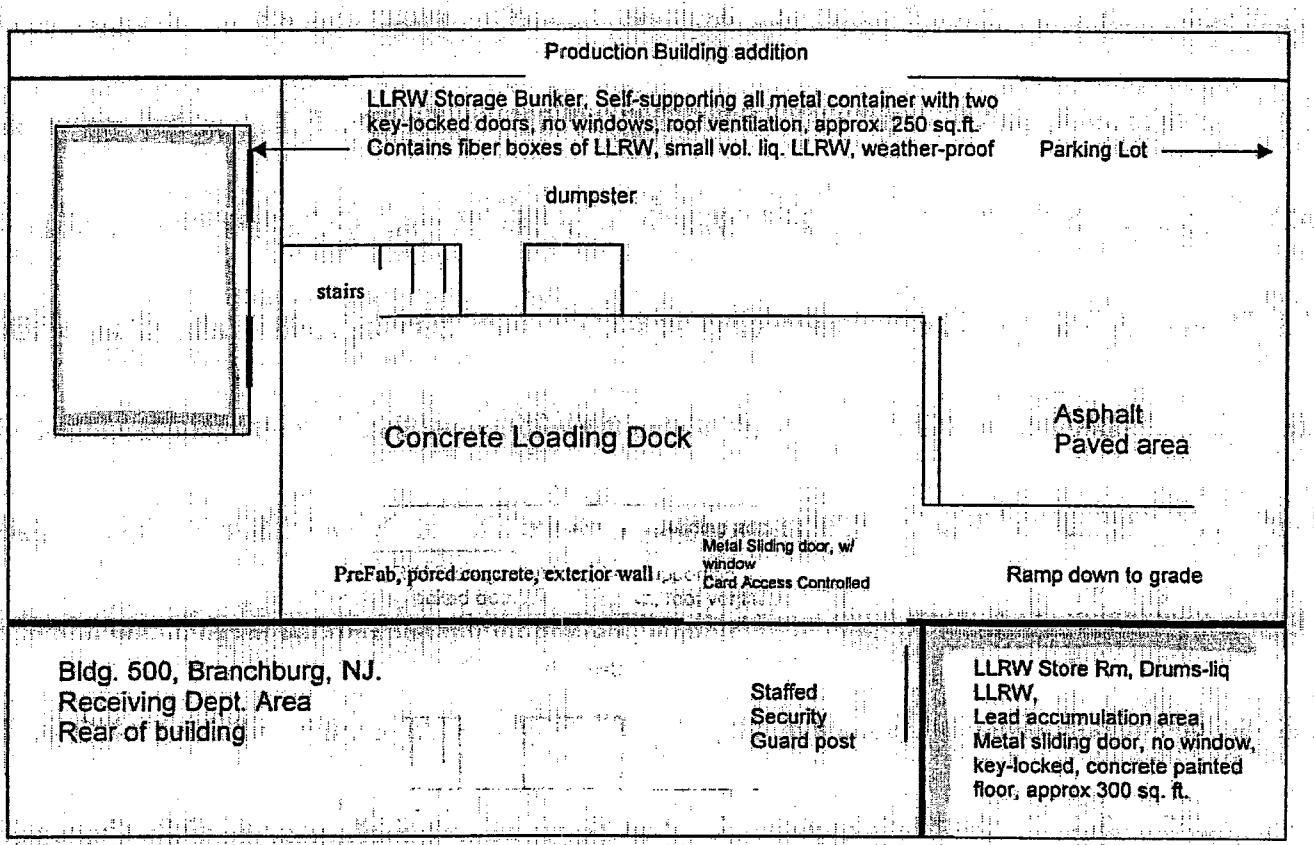

Bldg. 30 Basement
Decay-in-storage,
Interim Storage Facility,
Bear port Instrument Calibration
Dry Solid Material
Accumulation area,
fiber boxes
and metal drums
Stairwell Access
motion detectors,
to Main Security Desk
metal cage - up to ceiling
Slidding locked gate
Equipment shelves,
empty drums/boxes,
scrap lead accumulation
sliding
locked gate
concrete floor,
gray painted desk enamel,
800 sq. ft,
fire protection by overhead
sprinklers,
floro overhead lighting
wooden pallets,
metal drums,
Interim Storage
metal cage up to ceiling
with plywood covering.
Cs-137 Beam
Port Cal Source
800 sq. ft
freight
elevator
left cage has three, right cage
has six perimeter dosimeters,
open basement storage area,
Very low occupancy


Production Building addition
LLRW Storage Bunker, Self-supporting all metal container with two key-locked doors, no windows, roof ventilation, approx. 250 sq.ft.
Contains fiber boxes of LLRW, small vol. liq. LLRW, weather-proof
Parking Lot
dumpster
stairs
Concrete Loading Dock
Asphalt Paved area
Metal Sliding door, w/ window Card Access Controlled
PreFab, pored concrete, exterior wall
Ramp down to grade
Bldg. 500, Branchburg, NJ.
Receiving Dept. Area
Rear of building
Staffed Security Guard post
LLRW Store Rm, Drums-liq LLRW,
Lead accumulation area
Metal sliding door, no window, key-locked, concrete painted floor, approx 300 sq. ft.