Cardinal Health
Nuclear Pharmacy Services
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.4120
fax 614.652.4598

www.cardinal.com

CardinalHealth

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Q-5

April 21, 2011

Betsy Ullrich
Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. NRC Region I
475 Allentown Road
King of Prussia, PA 19406-1415

34-32720-02

Re: Application for Radioactive Materials License, Docket No. 030-38331, Control No. 573262, Cardinal Health PET Manufacturing Services, East Hartford, CT.

Licensing / Ms. Ullrich:

Cardinal Health Nuclear Pharmacy Services and Manufacturing Services (hereafter Cardinal Health) submits a revised application for a Positron Emission Tomography (PET) Cyclotron Production license, according to your letter dated March 22, 2011. The Cardinal Health Tax Identification Number is [redacted] The cyclotron production facility is located adjacent to the Cardinal Health nuclear pharmacy located at the same address listed on the Cardinal Health U.S. Nuclear Regulatory Commission (NRC) radioactive material license 34-29200-01MD, as follows: 131 East Hartford Street, East Hartford, CT 06108.

The PET cyclotron facility is registered for the use of radioactive material in Connecticut, (reg. number 01567). The applicable regulatory guidance in NUREG 1556, Volume 21, Cardinal Health is used to provide a description of the activities to be licensed for production of radioactive materials using a particle accelerator, also known as a cyclotron. The production and drug manufacturing processes are linked together for synthesis of radioactive drugs according to the U.S. Food and Drug Administration requirements. These proprietary methods or processes are considered trade secrets. All references to proprietary methods, facility design or procedures will be marked [ Confidential, Proprietary, Trade Secret or Security-Related ] and referenced in a separate parallel application document to be submitted within the provisions of 10-CFR-2.390; and according to our request for withholding or exemption from public disclosure.

Examples of fostering and maintaining a positive Safety Conscious Work Environment (SCWE) will be used in the supporting documents for the application for the use of radioactive material and all related policies and procedures.

573262

NMSS/RGN1 MATERIALS-002

If you have any questions regarding this request, please contact Dan Hill at 614.757.5074.

Sincerely,

Willie Regits, Ph D.
Corporate Radiation Safety Officer
Director, Health Physics
Nuclear Pharmacy Services

Encl: Original Application + 1 copy
Amendment Fee $6500 Paid (Copy)

NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION
(3-2009)
10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

# APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012

Estimated burden per response to comply with this mandatory collection request: 4.3 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 and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), 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.

**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:**

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

**ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:**

**IF YOU ARE LOCATED IN:**

**ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:**

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

**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
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

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

L 32780
03038331
03210

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

(34-32780-02)

**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)*

- [x] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

**CARDINAL HEALTH 414, LLC**
**7000 Cardinal Place**
**Dublin OH 43017**

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

**SEE ATTACHED ITEM 3**

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

**Willie Regits, Ph.D.**

TELEPHONE NUMBER

**(614) 757-4120**

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.
SEE ATTACHED ITEM 5

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
SEE ATTACHED ITEM 5

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
SEE ATTACHED ITEM 7

9. FACILITIES AND EQUIPMENT.
SEE ATTACHED ITEM 9

10. RADIATION SAFETY PROGRAM.
SEE ATTACHED ITEM 10

11. WASTE MANAGEMENT.
SEE ATTACHED ITEM 11

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY **3.S. [03210]** AMOUNT ENCLOSED **$ 6,500.00**

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

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED 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 |
|---|---|---|
| **Willie Regits, Ph.D. Corporate Radiation Safety Officer** | | **04/15/2011** |

**FOR NRC USE ONLY**

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



573262

CardinalHealth

# Radioactive Materials License Application

# Cardinal Health PET Manufacturing Services East Hartford, CT

Prepared by:

Cardinal Health
Nuclear Pharmacy Services
Quality & Regulatory Department

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## Item 05
## Radioactive Material / Uses

| | Radioactive Material | | Chemical and/or Physical Form | | Maximum Activity Requested Per Facility |
|---|---|---|---|---|---|
| A. | F-18 | A. | Any | A. | 1.11 TBq (30 Ci) |
| B. | N-13 | B. | Any | B. | 370 GBq (10 Ci) |
| C. | O-15 | C. | Any | C. | 370 GBq (10 Ci) |
| D. | C-11 | D. | Any | D. | 370 GBq (10 Ci) |
| E. | Incidental radioactive material. Any radionuclides with atomic numbers 3-83 inclusive | E. | Activated foils, Activated target body or Activated magnet coils, yoke, vacuum tank and concrete shield | E. | 185 GBq (5 Ci) no source to exceed 200 millicuries |
| E.1 | Zinc-63 | | Activated Target Body | | 15 millicuries |
| E.2 | Zinc-65 | | Activated Target Body | | 15 millicuries |
| E.3 | Cobalt-60 | | Activated Target Body | | 15 millicuries |
| E.4 | Niobium-94m | | Activated Target Body | | 100 millicuries |
| E.5 | Niobium-93m | | Activated Target Body | | 15 millicuries |
| E.6 | Molybdenum-93m | | Activated Target Body | | 100 millicuries |
| E.7 | Manganese-52 | | Activated Foils | | 200 millicuries |
| E.8 | Manganese-52m | | Activated Foils | | 200 millicuries |
| E.9 | Cobalt-56 | | Activated Foils | | 200 millicuries |
| E.10 | Cobalt-57 | | Activated Foils | | 100 millicuries |
| E.11 | Cobalt-58 | | Activated Foils | | 50 millicuries |
| E.12 | Chromium-51 | | Activated Foils | | 50 millicuries |
| E.13 | Copper-60 | | Activated Foils | | 50 millicuries |
| E.14 | Copper-61 | | Activated Foils | | 25 millicuries |
| E.15 | Vandium-47 | | Activated Foils | | 15 millicuries |
| E.16 | Vandium-48 | | Activated Foils | | 15 millicuries |
| E.17 | Scandium-48 | | Activated Foils | | 15 millicuries |
| E.18 | Cobalt-64 | | Activated Magnet Coils, Yoke, Vacuum Tank or Shielding | | 10 millicuries |
| E.19 | Manganese-54 | | Activated Magnet Coils, Yoke, Vacuum Tank or Shielding | | 10 millicuries |
| E.20 | Manganese-56 | | Activated Magnet Coils, Yoke, Vacuum Tank or Shielding | | 10 millicuries |
| E.21 | Sodium-24 | | Activated Magnet Coils, Yoke, Vacuum Tank or | | 10 millicuries |

## Item 05
## Radioactive Material / Uses

| | | | |
|---|---|---|---|
| | | Shielding | |
| E.22 | Aluminum-28 | Activated Magnet Coils, Yoke, Vacuum Tank or Shielding | 10 millicuries |
| E.23 | Rhenium-183 | Activation Foils | 10 millicuries |
| E.24 | Rhenium-184 | Activation Foils | 10 millicuries |
| E.25 | Technetium-95m | Activation Foils | 10 millicuries |
| E.26 | Technetium-96 | Activation Foils | 10 millicuries |
| F. | Any radionuclide with atomic numbers 3-83 inclusive | F. Sealed or solid sources manufactured under specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State. | F. Total not to exceed 30 millicuries, with no single source to exceed 15 millicuries. |
| F.1 | Sodium-22 | Eckert-Ziegler Model RV-022 | 200 microcuries |
| F.2 | Sodium-22 | Eckert-Ziegler Model Type R | 1 microcurie |
| G. | Tc-99m | G. Unsealed | G. 5 Ci |

A - D Produced via accelerated proton induced nuclear reaction using a General Electric 16 MeV PETtrace cyclotron. F-18 will be processed to a radiochemical form for distribution to facilities authorized to possess such material. The remaining radionuclides area result of production and used for methods testing at this facility.

E. These items are target foils, target bodies or machine components, which are activated during the nuclear reaction, created by the accelerated protons. They will be held for decay on site or shipped for proper disposal through a licensed radioactive waste disposal firm.

F. Sealed sources used for instrument calibrations and quality checks.

G. Unsealed source for calibration of instruments.

## Item 07
## Radiation Program Personnel

The Corporate Radiation Safety Officer (CRSO) will have the duties and responsibilities for the CRSO, described in the Radiation Safety Program section 10.8 of this application.

### Authorized Users

Cardinal Health requests the ability to self approve authorized users/cyclotron operators for this facility. All authorized users/cyclotron operators will have received training in the use of the cyclotron used at this location. There will also be didactic training and radioisotope handling experience requirements as defined in NUREG 1556, Volume 21, Appendix F. Each Authorized User (AU) / cyclotron operator will be approved in writing by the CRSO. Training documentation for each authorized user shall be maintained for 3 years after the end of his/her employment. Documentation of training for the following authorized users may contain personal information which is CONFIDENTIAL. The Cardinal Health training program and training records of cyclotron operators and maintenance engineers containing personal information is also referenced in a parallel secure application for this facility license. Authorized users for this license are, specifically: James Matthews, Joel Burgess, Wally Cotto-Bellido, Philip Dietrich, Arshad Mehmood, Andy Rodriguez, Dao Pho, Paul Gotti, David Missildine, Robert Chicoine, Olof Robert Nilsson, Sean Nicol, Jacob Kilian, Norman Medina, Robert Droege and William Rahardjo.

### Training for Authorized Users and Cyclotron Operators

Authorized users and cyclotron operators will have the equivalent training and experience requirements as described in NUREG 1556, Vol. 21, sections 8.7.2, 8.8 and Appendix F

### Radiation Safety Officer

The facility radiation safety officer (RSO) will be referred to as the Manufacturing Radiation Safety Officer, (MRSO). The MRSO will satisfy the training and experience requirements as described in NUREG 1556, Vol. 21, sections 8.7, 8.8 and Appendix F. The MRSO will implement and direct the corporate radiation safety program. Since the corporate program, when implemented, consists of an ongoing audit of personnel whole body and extremity exposures, of all documentation required to comply with the conditions of the license and Federal regulations, it is expected that the MRSO will have to spend a minimum of 10% of their time directing the radiation safety program. Documentation of the facility RSO training, duties and sample delegation of authority is attached.

The Manufacturing Radiation Safety Officer (MRSO) will be:

| | | |
|---|---|---|
| James Matthews | Office Phone: | 860.291.9135 |
| | Emergency Phone: | 412.977.6714 |
| | Email: | healthphysics@cardinalhealth.com |

Corporate management has provided a firm commitment to provide and maintain the staff, ancillary support, and oversight necessary to assure that the MRSO will have the time available on continuing basis for radiation safety officer duties.

The day-to-day duties of the MRSO are as follows:

1. General surveillance over all activities involving radioactive material production and handling, including routine monitoring and special surveys.

2. Ensuring compliance with Federal regulations as well as conditions of the Radioactive Material License.

3. Provide oversight of a comprehensive ALARA program.

4. Monitoring the performance of fume hoods that are associated with isotope work.

5. Monitoring the performance of effluent monitoring systems that are associated with isotope production/work.

6. Serving as the primary source of radiation protection information for personnel at all levels of responsibility.

7. Supervising and coordinating the packaging, labeling, and delivery of all shipments of radioactive material being distributed to nuclear pharmacies.

8. Supervising the distribution and processing of personnel monitoring equipment.

9. Conducting training programs in proper procedures for the safe use of radioactive material.

10. Supervising and coordinating the radioactive waste disposal program.

11. Supervising the safe storage of all radioactive materials not in current use.

12. Ensuring that sealed sources are leak-tested at proper intervals.

13. Provide coordination in the event of an emergency.

14. Maintaining an inventory of all radioactive materials and limiting the quantity of radionuclides at the facility to the amounts authorized by the license.

15. Authorization from the Corporate Radiation Safety Committee to cease any and all operations which the MRSO deems to be unsafe to employees, the public or environment, or activities that are in violation of Federal regulations and the radioactive materials license, as it pertains to radioactive materials or transport thereof. Please see the sample Delegation of Authority which authorizes this.

16. The MRSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter.

**NOTE:** In the absence of the MRSO (e.g., in the early morning when only one authorized user is present, when the MRSO is sick or on vacation), authorized users must assume the duties of the MRSO and ensure compliance with Federal (U.S. NRC and FDA) regulations as well as conditions of the Radioactive Material License.

**Item 07**
**Radiation Program Personnel**

**TO:** All Employees, Location # 5869, East Harford, CT

**FROM:** Willie Regits, Ph.D., Corporate RSO, Director, Health Physics
Nuclear Pharmacy Services

**DATE:** **SAMPLE**

**SUBJECT:** Delegation of Authority

---

_____ has been appointed Manufacturing Radiation Safety Officer and is responsible for ensuring the safe use of radioactive materials. The Manufacturing Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Manufacturing Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

1. Have unhampered access to all activities at his or her facility involving radioactive materials to identify radiation safety problems;

2. Immediately stop, without coordination with management, any activity at his or her facility involving the use of licensed materials by any user that might result in an unsafe situation or a violation of Federal requirements;

3. Initiate, recommend, or implement appropriate corrective actions; and

4. Verify the implementation of actions taken to correct radiation safety problems.

The Manufacturing Radiation Safety Officer is also responsible for assisting the Corporate Radiation Safety Committee and Corporate Radiation Safety Officer in the performance of their duties.

All of us have a critical responsibility in ensuring the safe use of radioactive materials. I ask that you lend your full support to this important function.

I understand and accept the above duties and responsibilities,

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| MRSO Name | Date | Willie Regits, Ph.D. CRSO | Date |

## Item 07
## Radiation Program Personnel

### Radiation Safety Training Program

Prior to assuming duties for handling nuclear substances, or individuals working in or frequenting restricted areas where radioactive materials are used or stored, will receive instructions, commensurate with their duties to work in the vicinity of radioactive materials:

1. Individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 millirem) will receive at a minimum the following instructions:

    a. Information on the storage, transfer or use of radiation and/or radioactive material.

    b. Health problems associated with exposure to radiation or radioactive material; Precautions or procedures to minimize exposure; The purposes, functions and operations of protective devices employed.

    c. Applicable parts of U.S. NRC regulations and licenses for the protection of personnel for exposure to radiation or radioactive material. Other regulations or license commitments pertinent to the job description.

    d. Responsibility to promptly report to management any condition that may lead to or cause a violation of Federal or applicable regulations, license conditions, or unnecessary exposure to an individual to radiation or radioactive material.

    e. Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.

    f. Right to be informed of their radiation exposure and bioassay results.

    g. Locations where the nuclear Manufacturing RSO has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by the Federal regulations.

2. This information will be provided initially upon employment prior to assuming unsupervised job duties, and annually thereafter. The extent of the instructions will be commensurate with potential radiological health protection problems in the work place.

3. Occupationally exposed employees will provide personal information in order to be provided with personnel monitoring devices and maintain current dosimetry records. Records of previous occupational exposure history will be requested from the worker previous employer, if applicable.

4. Every occupational exposed employee who becomes aware that she is pregnant will inform their supervisor in writing; and be given instructions for wearing additional personnel monitoring devices to measure the fetal exposure during the gestation period.

5. The locations of policies, procedures, pertinent regulations, notices, postings, and pertinent licenses, license conditions and correspondence will be made known to occupationally exposed employees.

6. Documentation of appropriate training will be maintained for a period mandated by 10-CFR-19.

**Item 07**
**Radiation Program Personnel**

## Example of Training Record*
## *Records may be CBT or equivalent (electronic)

Employee name:

CardinalHealth

**Certificate of completion**

_____

has completed the training item titled

**3001 - Radiation Safety and ALARA**

Completed on eClass on 23-Mar-2009.

**Date issued 12-Jun-2009**

Subjects: Radiation physics and instrumentation
Radiation protection
Mathematics pertaining to the use and measurement of radioactivity
Chemistry of radioactive material for medical use
Radiation biology

## TRAINING RECEIVED IN BASIC RADIOSOTOPE HANDLING TECHNIQUES

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys.

2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha-, beta-, or positron-emitting radionuclides.

3. Calculating, assaying and safely preparing dosages for patients or human research subjects.

4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of byproduct or accelerator-produced material.

5. Using procedures to prevent or minimize contamination and using proper decontamination procedures.

6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.

7. Production of radioactive materials via bombardment in a nuclear reaction.

## GENERAL TRAINING REQUIREMENTS & FREQUENCY

1. All personnel will receive instruction from a qualified individual (RSO or authorized user) before assuming their duties with, or in the vicinity of, radioactive materials. Training shall be provided:

   a. When an employee is hired (Initial Training)
   b. Annually after the Initial Training (Refresher Training)
   c. Whenever there is a significant change in duties, regulations, or terms of the radioactive materials license (In-Service Training)
   d. Whenever a deficiency is identified in an employee's radiation safety practices (In-Service Training)
   e. Whenever a deficiency is identified in a facility's radiation safety program (In-Service Training)

2. All personnel must receive Initial Radiation Safety Training prior to working in the restricted area.

3. No employee may work in the restricted area without on-site supervision (by the RSO or an Authorized User) until the employee has been approved in writing as AU/cyclotron operator and/or added to the radioactive materials license as an Authorized User.

## NEW EMPLOYEE TRAINING

New employee training covers a wide variety of topics, including radiation safety, transportation of radioactive materials, chemical safety, blood-borne pathogen safety, and general laboratory health and safety.

## RADIATION SAFETY TRAINING

The goal of the radiation safety training program is to provide adequate training for occupationally exposed employees and ancillary personnel commensurate with the scope of their activities in the cyclotron radiopharmaceutical production facility.

The Quality & Regulatory Department has developed a comprehensive radiation safety training program. This program covers various aspects of radiation safety for all levels of personnel. The training program includes:

- Cardinal Health internal computer-based training (CBT)
- PowerPoint presentations
- Written training materials, including handbooks, pamphlets, posters, etc.
- Evaluation materials and procedures.

Any training given includes hands-on instruction. Hands-on instruction gives the trainer the opportunity to evaluate the trainee's technique and gives the trainee an opportunity to put the instruction received into practice. During any training sessions and subsequently thereafter, employees are given the opportunity to ask questions.

<u>Computer based training</u>

Cardinal Health uses a computer-based training program. The program was developed to assist radiation safety officers in delivering standardized training to all levels of

employees. Computer-based training must be completed as part of the initial and refresher training for all employees.

Computer-based training consists of several courses. A list of computer-based training topics currently available is shown below. After selecting a course, an Items Details screen is displayed. These courses contain a combination of text and visual materials. After finishing the course, a test is administered to ensure comprehension of the training materials. Employees must pass the test in order to successfully complete the course.

After successfully passing a test and completing a course, the software generates a Certificate of Completion.

**Computer-Based Training**

LIST OF COURSES
(TRAINING TOPICS)

**[ PROPRIETARY & CONFIDENTIAL – WITHHOLD UNDER 10-CFR-2.390 ]**

## TRAINING OF NON-HANDLERS, ANCILLARY PERSONNEL AND VISITORS

A non-handler is defined as administrative support personnel with no duties to handle radioactive material but may need to enter the restricted area infrequently.

A visitor is defined as any individual not employed by Cardinal Health.

Instruction for non-handlers includes general radiation safety as described in applicable computer-based training courses, described herein.

The following instruction must be given to visitors and ancillary personnel prior to allowing these individuals to enter and/or work in the restricted area. The visitors log documents the receipt of training.

1. All visitors must be escorted at all times while in the restricted area.
2. Identification of the radiation symbol and its significance.
3. Information on whom to contact for questions, concerns or emergencies involving radioactive materials.
4. Dosimeter must be worn at all times.
5. No eating, drinking, smoking, applying cosmetics or placing objects in the mouth in the restricted area.
6. All tools, equipment and people must be surveyed prior to exiting the restricted area.
7. Proper attire and personal protective equipment must be worn while in the restricted area. (e.g. shoecovers, gloves, buttoned lab coat, etc.)
8. Prohibition on handling potentially contaminated items. Avoid areas of high exposure. Utilize ALARA principles (time, distance, shielding).

The security of the restricted area must be maintained at all times. Only members of the staff and their escorted guests may enter the restricted area. Do not prop open any doors and leave them unattended.

## Item 9
## Facilities and Equipment

### 1 Site Description

1. This facility is located in a commercial/industrial type area at:

   Cardinal Health
   131 East Hartland Street
   East Hartford, Connecticut 06108

2. This single-story, multi-tenant structure's heating and cooling system is a multiple zone system and is for the sole use of Cardinal Health. Separate HVAC zones are employed for the restricted and unrestricted areas. The common walls between the adjacent tenant, Cardinal Health Nuclear Pharmacy, are demising firewalls that extend to the roof of the building.

3. Figure 1 and 2 show the site plan and neighborhood map.

4. Security is provided by dead bolts or combination locks on all entrances to the restricted area. A centrally monitored security system combining motion detectors and door contacts will be used for security of Cardinal Health's space.

5. The release point for the fume hood stack is located at least 6 feet above the roof-line, and is at least 30 feet from the nearest point of access to the building or any air intake.

6. We confirm that operation of a cyclotron for production of nuclear materials does not conflict with local codes and zoning laws.

7. Police and fire departments are notified annually with the letter shown in Figure 3, unless the local Fire Marshall's office inspects the facility annually.

8. The landlord has been made explicitly aware of Cardinal Health's intent to operate as a production cyclotron, which involves the handling of radioactive materials.

**Figure 1:** Map for cyclotron showing building location in relation to surrounding area.

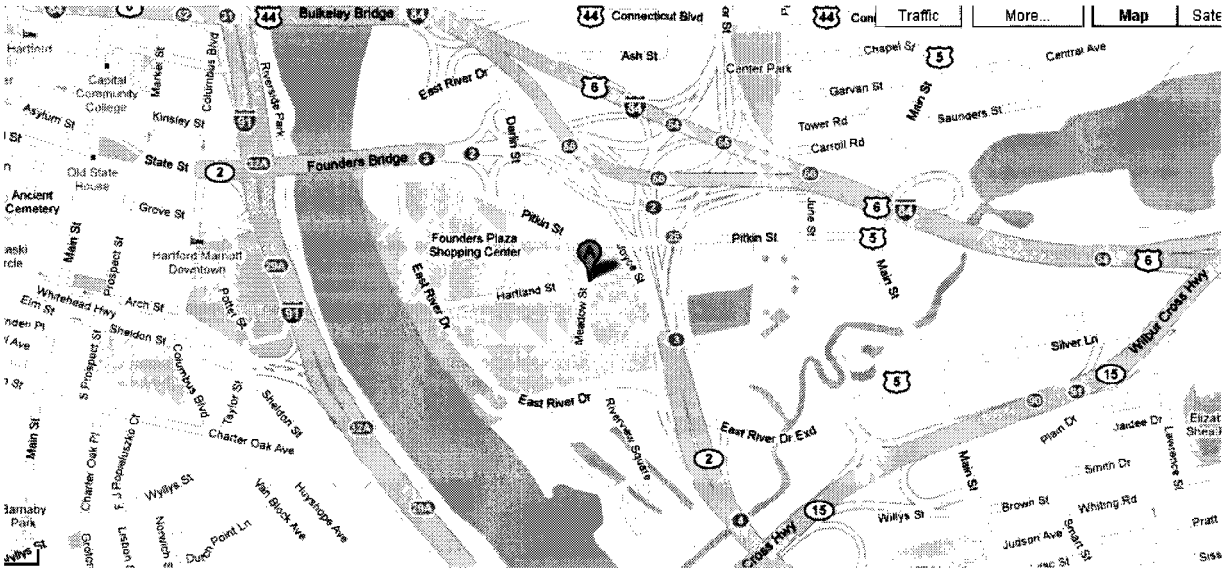
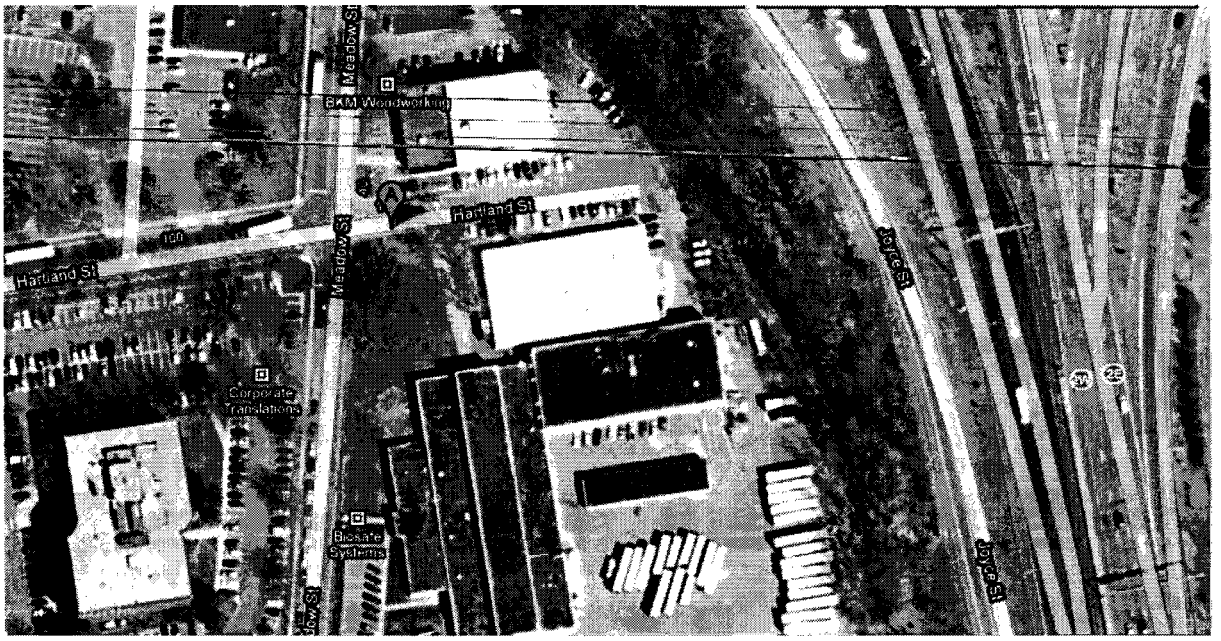



**Figure 2:** Site plan for cyclotron showing building in relation to surrounding buildings.



Date:

Address:

Attention: (Chief of the Police Department)
(Chief of the Fire Department)

We are required by the State to notify you that we are utilizing radioactive materials under an Agreement State license at:

Cardinal Health
Street Address *
City, State, Zip *
Business Hours Phone: *
Emergency Phone (after business hours) *

This notification is for your information in case of a fire or disaster that might involve this building.

The material with which we work is for use by physicians for medical purposes, and, therefore, is comprised of short-lived radiopharmaceuticals.

Very little danger would exist in case of a fire or disaster; however, precaution should be exercised by fire fighting personnel should it be necessary to enter the room in which the radioactive material is stored. In the case of a fire, the non-volatile material would remain confined to this room, due to the nature of this building's construction.

Should it become necessary and possible to enter the restricted area, survey instruments are readily available, located in rooms adjacent to the radioactive storage room. Also, personnel trained in the use of survey instruments and familiar with hazardous radiation levels would be available to assist your personnel.

If you have any questions concerning this notification, or if you would like to visit our facility to familiarize yourself with our location, do not hesitate to contact us.

* The appropriate information will be filled in specifically for this location.

**Figure 3:** Sample letter mailed to the Police Chief and Fire Chief.

## 2 General Description of Facility

Cardinal Health has leased space for use as a cyclotron facility. The floor plan and facility layout is shown in Figure 4.

### I. RESTRICTED AREA

The restricted area is divided into several zones. Each zone and use of the zone is described below.

Cyclotron Vault

This area houses the cyclotron used for the production of radioisotopes for commercial distribution as well as the shielding for the vault. The construction of this room is of high density concrete with walls ranging in thickness of approximately 2.4 - 4.4 feet. An emergency stop button is positioned in this area by the cyclotron. There is an area monitor located in this area for monitoring exposure rates near the cyclotron, and a negative pressure will be maintained with respect to the remainder of the restricted area. This room is labeled *VAULT* on the diagram. The maze to the vault contains a storage pit used for storage-in-decay of activated targets or cyclotron components.

Power Supply/Equipment Room

This room houses the electrical, pneumatic and power supply and controls for cyclotron operations. There is one emergency shut off switch in this room. This area is also used for the storage and decay of waste materials. Waste materials will be stored in the cyclotron vault as well.

Hot Lab & Production Area

This room is used for the synthesis, packaging and preparation for transportation of the manufactured radioisotope products. In addition, cyclotron operation and product quality control activities are conducted in this location.

Cyclotron Control Area

This area is dedicated for use of the control panel used to operate the cyclotron and isotope production. The equipment in this area consists of a computer terminal that controls the cyclotron and the pneumatic delivery of product material to the synthesis area. There is an emergency shut off switch next to the control panel.

Quality Control Area

This area is dedicated for the analysis of raw and product materials as well as the analysis of health physics surveys (wipe tests). Additionally, inventory control will be processed in this area. Equipment in this area will consist of various analytic devices (i.e., TLC and GC) for the analysis of product integrity. Additionally, radio-analytic devices will be located in this area for counting radioactive samples and wipe tests.

DOT Area (Shipments may not be subject to DOT regulations)

This area is reserved for the preparation of outgoing shipments and used for the

processing of shipping containers returned from customers. The appropriate survey meters and measuring tools will reside in this area.

Synthesis Area

Fluorine and fluorine products are synthesized, prepared, and made ready for distribution in this area. This area is used for preparation and dispensing of radiopharmaceuticals. This area is home to the cassette chemistry module for product synthesis and hot cell with remote manipulators. A dose calibrator and product dispensing equipment are located in the hot cell.

Ante Room

This area is used as a buffer between the synthesis area and the clean area during acceptance testing of supply products, consistent with FDA regulations.

Clean Area

This area is for preparation of the product vials used in the dispensing of the final product. Also, sterility tests are prepared and processed in this area.

Quarantine Area

This area is used for receipt and storage of product components and also serves as the entrance or exit to the PET Lab.

## II. UNRESTRICTED AREA

The unrestricted area is divided into several zones. Each zone and use of the zone is described below.

Vestibule

This area is not pictured in the PET Lab drawing, however it is located in the adjacent nuclear pharmacy for the receipt of packages during non-business hours. Delivery personnel have keyed access to the vestibule only, and the remainder of the facility is secured from the delivery personnel.

The following zones are self-described in the unrestricted area.

Mechanical Room

Supply Data/Telecom Room

Wholesale / Supply

Staff

Admin

Conference Room

Manager's Office

**[ SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10-CFR-2.390 ]**
**Figure 4:** East Hartford, CT PET Manufacturing Facility Floor Plan

## 3 Cyclotron and Safety Features

### I. Cyclotron

The cyclotron is a General Electric PETtrace 16.5 MeV system used for the production of isotopes via an $H^-$ collision with a target material. The cyclotron is installed and operated at the address specified in this license application only. The manufacturer's operating manual, QC/QA Procedures and emergency procedures are on file and followed at the facility. Typically, these are located near the cyclotron control console. In addition, a copy of the current operating, emergency and spill procedures are kept at the cyclotron control panel. Should Cardinal Health sell this equipment they will not install it for the customer. Any transfer of this device from the control of Cardinal Health will be indicated to the appropriate agency prior to any physical relocation of the device.

### II. Cyclotron Control Console

The cyclotron control console is located in the PET Lab Area. A surveillance camera is installed to permit the continuous observation of material being irradiated, transferred or conveyed within the cyclotron vault. The viewing monitor is located such that the simultaneous surveillance of the control console and vault activities can be achieved. Emergency and shutdown procedures and electrical schematics for the cyclotron and interlock systems are located at the cyclotron control console.

### III. Safety Interlocks

Interlocks are installed on all access points to the cyclotron vault. This includes all doors and transfer and conveyance systems that pass through the cyclotron vault wall. The interlocks will immediately shut down the cyclotron when activated. Interlocks, once activated, can only be reset manually. In addition, emergency shutoff switches are located as shown on the floor plan.

### IV. Other Safety Features

Dead bolts or combination locks on all entrances to the restricted area provide security. A centrally monitored security system combining motion detectors, door contacts and an alarm are used for security.

There are warning lights that flash at the entrance to the cyclotron vault and are visible at the cyclotron control console. These warning lights activate during cyclotron operation, specifically when the beam is on. Additionally, the entrance to the cyclotron vault is in the restricted area to ensure only authorized personnel can enter the vault.

## 4 Emergency Stop Systems

The cyclotron facility is equipped with emergency stop buttons to immediately shut down the cyclotron. These emergency stop buttons are located in convenient locations to the operator should they be in the vault, vault control or production rooms. The emergency stop buttons, when activated, will initiate the shutdown sequence for the cyclotron, discontinuing the nuclear collision process. This will significantly reduce the radiation exposure levels in the cyclotron vault from neutron and prompt gamma radiations. Since delayed radiations are a result of activation there is no way of eliminating exposure from this source in an emergency shut down situation.

### Cyclotron Emergency Stop

In the event of an emergency, terminate the source of radiation exposure by immediately turning off the cyclotron. Follow the emergency procedure in the operating manual at the cyclotron control console. If in a remote location use any of the emergency stop buttons located in the facility to turn the off power to the device. Verify that the radiation levels immediately drop. If high exposure rates continue, consult with the MRSO and, using ALARA principles, locate the source using the appropriate instruments. Use shielding as appropriate or evacuate the area/building as necessary.

## 5 Vault Design & Integrity Verification

The shielding calculations of the vault are calculated in accordance with the recommendations of the National Council on Radiation Protection (NCRP) as set forth in reports numbered 51, 91, 38, and 39. See the attached Physicist's Radiation Protection Shielding Design **[ PROPRIETARY ]** report for more detailed information. *(included only with parallel application for agency review)* Initial vault integrity testing was completed prior to production.

## 6 Air Handling and Effluent Monitoring [ PROPRIETARY details in parallel application]

Cardinal Health commits to using ventilation systems to ensure that effluents are ALARA within the dose limits of 10-CFR-20.1301 and within constraints for air emissions established under 10-CFR-30.1101(d); using methods described in Regulatory Guide 4.20 or equivalent to demonstrate the annual average concentration of airborne radioactive material released to the environment does not exceed 20% of the values in Column I of Table 2 in Appendix B to 10-CFR, Part 20.

## 7 Equipment

### Instrumentation

We commit to using radiation detection or analytical instruments that meet the radiation monitoring instrument specifications published in Appendix I to NUREG 1556, Volume 21, 'Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator'.

### Material Accountability System

We have developed a proprietary computer-based product accountability and control system for licensed material. We will implement and maintain written procedures for the accountability and control system to ensure that:

- License possession limits are not exceeded;
- Licensed material in storage is secured from unauthorized access or removal;
- Licensed material not in storage is maintained under constant surveillance and control; and
- Records of production, transfer, and disposal of licensed material are maintained.

And,

- We will conduct physical inventories of sealed sources of licensed material not to exceed 6 months as described in the Radiation Safety Program.

# Item 10
# Radiation Safety Program

## 1 Material Accountability System

We have developed a proprietary computer-based product accountability and control system for licensed material. We will implement and maintain written procedures for the accountability and control system to ensure that:

- License possession limits are not exceeded;
- Licensed material in storage is secured from unauthorized access or removal;
- Licensed material not in storage is maintained under constant surveillance and control; and
- Records of production, transfer, and disposal of licensed material are maintained.

And,

- We will conduct physical inventories of sealed sources of licensed material not to exceed 6 months as described in the Radiation Safety Program.

## 2 Occupational Dose

We have developed and will implement and maintain written procedures for monitoring occupational dose that meet the requirements in 10-CFR-20.1501, 10-CFR-20.1502, 10-CFR-20.1201, 10-CFR-20.1202, 10-CFR-20.1203, 10-CFR-20.1204, 10-CFR-20.1207, 10-CFR-20.1208, 10-CFR-20.2106, as applicable.

### Personnel Monitoring Program

We confirm that we have established and agree to implement written personnel monitoring procedures. As a minimum, these procedures will require:

1. That whole body dosimetry be provided to personnel who enter restricted areas under the circumstances described in State regulations and are likely to exceed 10% of the annual limit, or upon request.

2. That whole body dosimetry and finger extremity monitors be provided to personnel who elute, prepare, assay, or dispense millicurie quantities of radioactive material.

3. The neutron dosimetry be provided to personnel who have the potential to be exposed to free neutrons as a result of cyclotron operation.

4. That whole body dosimeters and finger extremity monitors will be exchanged at a frequency commensurate with the risk of exposure. At a minimum, whole body badges will be exchanged for processing quarterly, and finger extremity monitors will be exchanged for processing at least monthly.

5. That whole body and extremity monitor badges be processed by a commercial dosimetry service company and/or a processor accredited by the National Voluntary Laboratory Accreditation Program.

6. That any pocket ion chamber dosimeters used to measure exposure from licensed material be calibrated and tested for drift at least annually.

7. That records of personnel dosimetry will be kept until the license is terminated.

## 3 Public Doses

Doses to the general public will be controlled through constant monitoring of external radiation fields, vault and shielding integrity testing and continuous monitoring of effluents.

Effluents from various processes within the facility are collected, filtered and emitted from one centrally monitored emission point. This emission point is monitored with a real-time integrating monitoring system that will alert staff should action limits for released materials are exceeded. Action limits will be set such that that represent approximately 10% of the annual release concentration as given in Appendix B of 10CFR20, Table 2.

We will demonstrate by measurement or calculation that the exposure (TEDE) to the individual most likely to receive the highest dose from licensed operations does not exceed the annual limit for members of the public, using methods as described in NUREG 1556, Volume 21, Appendix J.

Records will be maintained to demonstrate compliance with the above referenced requirements until the license is terminated, including but not limited to: surveys, monitoring records of ambient radiation and effluent radioactivity concentrations.

## 4 Safe Handling of Radionuclides and Emergency Procedures

We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M to NUREG 1556, Volume 21.

Leak tests of sealed sources will be performed at the intervals approved by NRC or an Agreement State and specified in the Sealed Source and Device Registry Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licenses or using a leak test kit supplied by an organization authorized by the NRC or an Agreement State, to provide leak test kits to other licenses and according to the sealed source or plated foil manufacturer's and kit supplier's instructions. As an alternate, we will implement the model leak test program published in Appendix N to NUREG 1556, Volume 21.

## A. Procedures for Receiving Shipments Containing Radioactive Material

1. An authorized user, or their designee, will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. The receiving area will be located so that the radiation levels in areas outside of the licensee's control do not exceed the limits specified in State regulations.

3. When the cyclotron facility is open, carriers will be instructed to deliver radioactive packages directly to the receiving area of the cyclotron facility.

4. When the cyclotron facility is closed, delivery firms will have written instructions to place packages in the receiving area of the cyclotron facility. If the carrier notices that the package is wet or appears to be damaged, he will be instructed to immediately contact the authorized user on call who will then come to the cyclotron facility to inspect the package. The carrier will be asked to remain at the cyclotron facility until it can be determined that neither the carrier nor the delivery vehicle is contaminated. Carriers will not have access to the restricted area of the cyclotron facility.

5. Records of radioactive material received and transferred will be kept for three (3) years after receipt or transfer of the material.

## B. Procedures for Safely Opening Packages Containing Radioactive Material

1. Package receipt and check-in procedures will be in accordance with State regulations.

2. The following steps will be performed for all incoming packages containing radioactive material which contain Type A quantities or greater:

   A. Packages will be monitored for surface contamination and external radiation levels as soon as practicable after receipt, but no later than three (3) hours after receipt if received during normal working hours or three (3) hours from the beginning of the next working day if received after normal working hours.

   B. Measure the exposure rate at 1 meter from the package surface and record it. If greater than 10 mR/hr, immediately notify the MRSO or their designee.

   C. Measure the surface exposure rate and record it. If greater than 200 mR/hr, immediately notify the MRSO or their designee.

   D. Wipe the external surface of the package and move the wipe to a low-background area. Check wipes with appropriate instrumentation. Take precautions against the spread of contamination, as necessary. Record the results.

   E. The appropriate regulatory agency and the final delivering carrier will be notified, by telephone or telegraph, if removable contamination exceeds 22 dpm per $cm^2$ on the external surfaces of the package, or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 1 meter.

   F. Records of exposure rate and contamination surveys in Items B.2, B.3 and B.4. will be maintained for three (3) years after the record is made.

3. The following procedures must be carried out for all labeled (White I, Yellow II or Yellow III) incoming packages containing radioactive material:

   A. Put on waterproof gloves to prevent hand contamination.

   B. Visually inspect the package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop and notify the MRSO.

   C. Open the outer package (following manufacturer's directions, if supplied), and remove the packing slip.

   D. Open the inner package and verify that the contents agree with those on the packing slip. Compare the requisition, packing slip, and label on the bottle.

   E. Check the integrity of the final source container (i.e., inspect for broken seals or vials, loss of liquid, and discoloration of packaging material).

   F. Check that the shipment does not exceed possession limits.

   G. Wipe the external surface of the final source container shield and remove the wipe to a low-background area. Check wipes with appropriate instrument. Take precautions against the spread of contamination, as necessary.

H. Monitor the packing material and packages with appropriate instrumentation for contamination before discarding.

1. If contaminated, treat as radioactive waste.

2. If not contaminated, obliterate the radiation labels before discarding in the non-radioactive trash.

## C. General Procedures for the Safe Use of Radioactive Material

1. Always wear laboratory coats or other protective clothing in areas where radioactive materials are used.

2. Always wear disposable gloves when handling radioactive materials.

3. Monitor hands and shoes for contamination before leaving the restricted area.

4. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

5. Do not store food, drink, or personal effects with radioactive material.

6. Always use shielding when preparing and dispensing radioactive materials.

7. Always wear personnel monitoring devices in areas where radioactive materials are used or stored. Whole body badges should be worn at chest level (preferably on the shirt collar). Personnel monitoring devices, when not being worn to monitor occupational exposures, must be stored in the designated low-background area and with control badges.

8. Always wear extremity badges when preparing, assaying, or dispensing mCi quantities of radioactive material.

9. Never pipette by mouth.

10. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

11. Survey the QC, product preparation, and other work areas for contamination after each procedure or at the end of the day. Decontaminate, if necessary.

12. Confine radioactive solutions in covered containers that are clearly identified and labeled with the name of the compound, radionuclide, date, and activity.

13. Always follow posted instructions for the use of interlocks and alarms.

14. Use absorbent materials to cover countertops where unsealed radioactive material is used.

15. Use the fume hood or other positively vented area where the potential for gas or volatile byproducts is present.

## D. Emergency Procedures

Procedures for safe handling of radionuclides and emergencies will be developed and documented before production of licensed material. The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surface contamination, as well as the radiotoxicity of the spilled material.

To determine if the spill is major or minor, the amount of radioactivity spilled should be estimated. Guidance for determining whether to initiate a major or minor spill procedure may be based on the following dividing line. Spills above these values may be considered major, below may be considered minor:

| Radionuclide | Millicuries | Radionuclide | Millicuries |
|---|---|---|---|
| F-18 | 10 | Tc-99m | 100 |
| N-13 | 10 | | |

A copy of these procedures will be posted in each area where radioactive material is used or stored. A decontamination kit is located within the restricted for cleanup of radiological spills. The posting will include the name of the MRSO, and contact information for the MRSO, as well as alternates designated by the MRSO.

1. Minor Spills

   A. NOTIFY: Notify persons in the area that the spill has occurred.

   B. PREVENT THE SPREAD: Cover the spill with absorbent paper.

   C. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper. Insert into a plastic bag. Also, insert into the plastic bag all other contaminated materials, such as disposable gloves. Put the plastic bag into the radioactive waste container.

   D. SURVEY: With a low-range, thin-window GM survey meter or other appropriate meter, check the area around the spill, hands, and clothing for contamination.

   E. REPORT: Report the incident to the MRSO.

2. Major Spills

   A. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

   B. PREVENT THE SPREAD: Cover the spill with absorbent paper or pads, but do not attempt to clean it up. Confine the movement of all potentially contaminated personnel to prevent the spread.

   C. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

D. CLOSE THE ROOM: Leave the room and lock the doors to prevent entry.

E. CALL FOR HELP: Notify the MRSO immediately.

F. PERSONNEL DECONTAMINATION: Remove contaminated clothing and store for further evaluation by the MRSO. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

G. Report the spill to Quality & Regulatory.

Radiation Safety Program procedures will be revised only if: (1) the changes are reviewed and approved by the Radiation Safety Committee and the RSO in writing, (2) the staff is provided training in the revised procedures prior to implementation, (3) the changes are in compliance with NRC regulations and the license conditions, and (4) the changes do not degrade the effectiveness of the program.

## 5 Procedures for Returning Non-Radioactive Waste

Cardinal Health will collect transportation containers, shielding products, and incidental materials, which may be contaminated, from the nuclear pharmacy. Cardinal Health commits to only collecting, and returning to the cyclotron facility, materials supplied by Cardinal Health. These materials or otherwise non-radioactive wastes will primarily consist of:

5.1. Type A or other reusable transport containers; and

5.2. Unit dose, multi-dose, vial or other Cardinal Health owned shielding containers.

Any radioactive waste not resulting from Cardinal Health supplied material will be refused or returned to the customer.

## 6 Transfer for Distribution Procedure

Cardinal Health proposes to operate an isotope production facility capable of making curie quantities of positron-emitting isotopes, primarily Flourine-18. This isotope will be synthesized into [F-18] labeled agents and transferred to a Cardinal Health nuclear pharmacy or another licensed nuclear pharmacy or authorized recipient to be dispensed as radioactive material for medical use on a unit dose or multiple dose basis.

Cardinal Health may also transfer some radioactive materials for non-human use. Radioactive materials for non-human use will be transferred to licensees of the Nuclear Regulatory Commission or an Agreement State. Examples may include transfers to universities for research purposes, transfers of sealed sources to other licensees, or transfers to veterinarians for their use in the practice of veterinary medicine.

Transportation will be an act licensed under the nuclear pharmacy or transferee licensee in all cases. Cardinal Health PET Manufacturing Services will not transport radioactive material from the manufacturing and production locations.

Cardinal Health Nuclear Pharmacy Services will transfer or distribute only to authorized recipients and other nuclear pharmacies licensed for distribution, as described above.

## 7 Procedures for Packaging and Transporting Radioactive Materials

### 7.1. Co-located or close proximity Licensees

When transferring radioactive materials to licensees located within the same building or parking lot, the following procedures pertaining to packaging of radioactive materials will be used. Note that these packages will not be transported on public roads or highways.

A. Apply the appropriate radiation warning label to the outside of the package.
B. Packages are wipe tested to ensure there is no removable contamination greater than 6600 dpm/300 $cm^2$.
C. Place the shipping container with adequate bracing to support the inner package.
D. Stabilize the shipping container on a cart and roll it to the co-located pharmacy

### 7.2. Licensees Receiving via Highway or Air Transport

The manufacturing facility will comply with applicable regulations for packaging and transportation of radioactive material as specified in U.S. NRC regulations or U.S. DOT regulations in Titles 10-CFR and 49-CFR, respectively.

A. Packaging of radioactive material for transport by a common carrier or Cardinal Health vehicles:

1. Only approved DOT 7A Type A packaging will be used for transport of Type A radioactive material. Each Type A package will be labeled and marked according to DOT requirements.

2. The appropriate radioactive label will be applied to the outside of the package when shipping Type A radioactive material. Determination of the transport index is accomplished by placing the package one meter distant from a calibrated survey meter, then reading the transport index in mR/hr. Determination of the Radioactive White I, Radioactive Yellow II, or Radioactive Yellow III, is accomplished by taking a surface reading of the package as well as the T.I. The following criteria is used:

| Transport Index | Maximum Radiation Level at Any Point on the External Surface | Label Category |
|---|---|---|
| Less than or equal to **0.05** | Less than or equal to **0.5** mrem/hr | White-I |
| Greater than **0.05** but less than or equal to **1.0** | Greater than **0.5** mrem/hr but less than or equal to **50** mrem/hr | Yellow-II |
| Greater than **1.0** but less than or equal to **10** | Greater than **50** mrem/hr but less than or equal to **200** mrem/hr | Yellow-III |

3. Packages are wipe tested to ensure there is no removable contamination greater than 6600 dpm/ 300 $cm^2$.

4. Shipping papers for radioactive material will be generated for each Labeled package.

5. Each package will show the name and address of the consignee if the package is to be transferred by a commercial carrier.

6. The outside of each package containing Type A radioactive material will incorporate a feature, such as a seal, which is not readily breakable and which, while intact, will be evidence that the package has not been opened.

Each container shipped will have only one customer's order in it.

## 8 Independent Audit Program and Corporate Radiation Safety Program

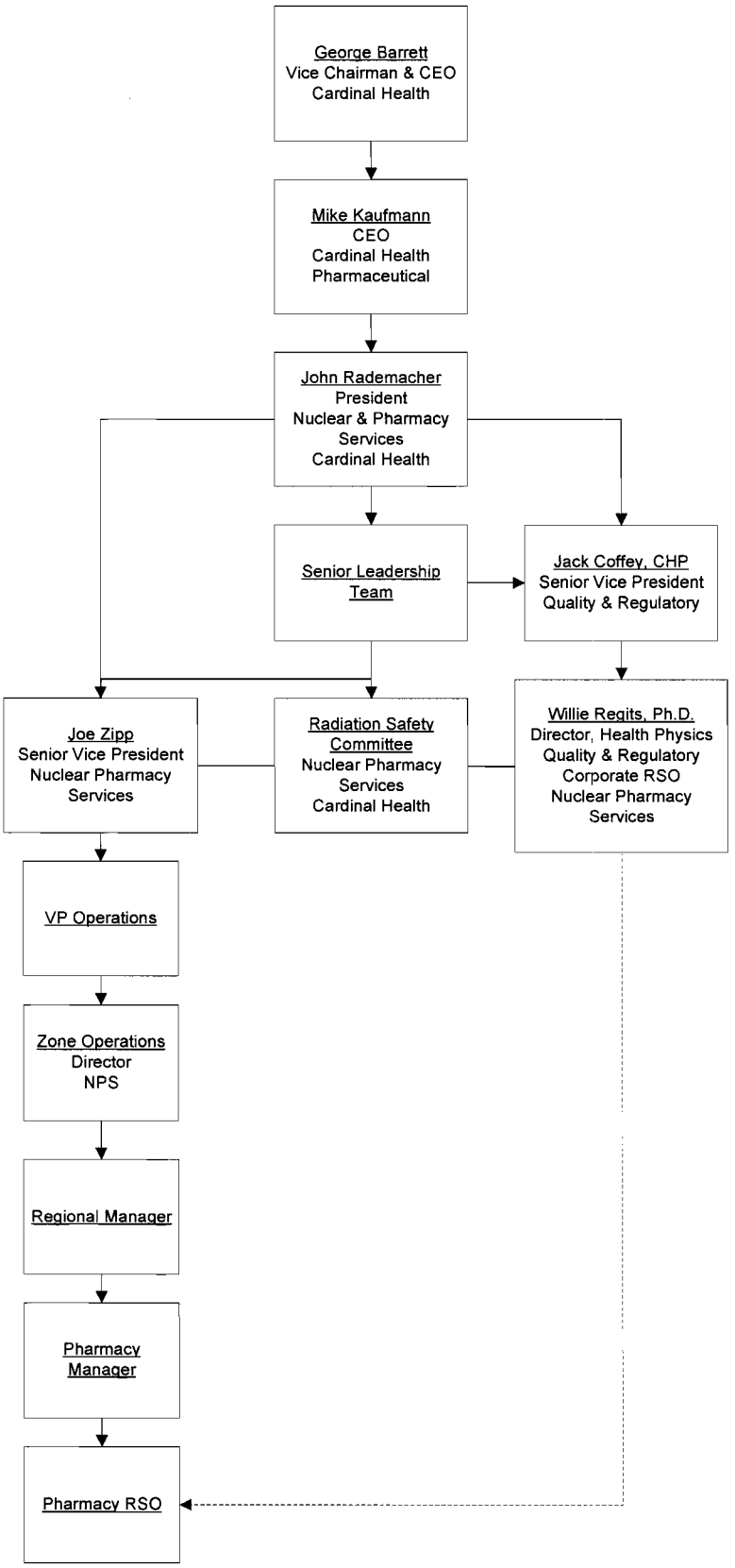
The Quality and Regulatory Department (Q&R) of the Cardinal Health PET Manufacturing Cyclotron facility and Nuclear Pharmacy Services business is responsible for the development and implementation of a company wide radiation safety program. The Corporate RSO has the authority to delegate duties and responsibilities to the cyclotron Manufacturing RSO. This program represents a centralized approach to regulatory compliance, training, and health physics practices. The basic premise of this radiation safety program is compliance with federal regulations and conditions of our U.S. NRC license(s). To this end, each manager and RSO is expected to be conversant with the details of his or her license and to operate his or her pharmacy in full compliance with Federal and applicable regulations including the conditions of the license.

Q&R has developed a standard set of documentation forms that are incorporated into computer software programs. Q&R has also established a trend analysis program to monitor dosimetry reports, audit reports, and NRC and state inspection reports. This information is used to evaluate radiation safety program effectiveness.

Q&R has established a hazard reporting system whereby individual Cardinal Health employees can submit reports of potential unsafe working conditions. Regulatory, technical, and corporate policy information is provided through company newsletters. A comprehensive, corporate-wide radiation safety program has been established to achieve full and continuing compliance with NRC and/or Agreement State requirements.

Results of internal audits are maintained on site for inspection.

## Corporate Radiation Safety Program Organizational Chart



## 9 Cyclotron Operation

9.1. Document cyclotron operation after each use.

9.2. Perform maintenance and emergency operations according to the procedures posted at the cyclotron control console.

9.3. Post a list of Authorized Users allowed to operate and/or service and repair the cyclotron at the cyclotron control console.

9.4. Post electrical circuit diagrams of the cyclotron and interlock systems at the cyclotron control console.

9.5. Test safety and warning systems, including interlocks, at least once each month. Record test results in the cyclotron log. These records will be maintained for at least five (5) years.

## 10 PET Radiopharmaceutical Production

10.1. Document each Product Manufacturing/Synthesis cycle after each run.

10.2. Obtain MRSO or CRSO approval for all non-routine operations. Document all non-routine operations.

10.3. Monitor hands (gloves) and shoes frequently in order to detect contamination and prevent its spread. Decontaminate as necessary.

10.4. Monitor work areas after each use. Decontaminate as necessary.

# Item 11
# Waste Management

## 1 Waste Generated

Radioactive waste generated at the cyclotron facility is mostly short-lived with half-lives of less than 120 minutes. Cardinal Health has a system that segregates waste according to half-life for decay in storage. Any waste accumulated by Cardinal Health that has a half-life of greater than 120 days will be disposed through a licensed radioactive waste disposal firm. Sealed sources may be returned to the manufacturer or distributor for proper disposal using the manufacturer's packaging and labeling instructions. Cardinal Health commits to only collecting, and returning to the cyclotron facility, materials supplied by Cardinal Health. Radioactive waste generated at the facility consists of any item contaminated with radioactive material resulting from the operation of the facility such as gloves, absorbent material, vials, syringes, etc.

### Activated Cyclotron Parts

Activated cyclotron parts fall into two categories; consumable and non-wear parts. Consumable parts are parts that will need to be replaced from time to time due to wear or failure, for example, target foils or frit filters. Non-wear parts are components of the cyclotron that become activated but will not be replaced or disposed of until the facility is decommissioned, for example, cyclotron magnetic coils, yokes or beam ports.

## 2 Waste Classification System [ PROPRIETARY – WITHHOLD UNDER 10-CFR-2.390 ]

Cardinal Health has established a waste classification system to be used for segregating various types of material according to half-life. *( full description provided in parallel secure copy of this application )*

1. very short half-life
2. short half-life
3. long half-life

## 3 Methods for Holding Waste – Decay in Storage

### Very Short Lived and Short Lived Wastes

1. A sufficient number of lead shielded bunkers or concrete pits are used to store waste. A lead plate may be used as a lid.

2. A container emptying rotation cycle is established to ensure that all material has been stored until radiation exposure rate at the surface cannot be distinguished from background radiation levels.

3. When a container is filled, it is sealed, the date is placed on the container, and the radiation level at the surface of the container is determined.

### Long Lived Wastes

1. Consumable parts will be bagged, labeled, logged and stored in an isolated area inside the cyclotron vault.

2. On a routine basis, the consumable parts will be characterized either in-house or by an outside vendor, and sent for disposal.

3. It is Cardinal Health's intention to process activated parts in a timely fashion to avoid the accumulation of large quantities of materials.

4. Non-wear parts will be processed at the time of decommissioning, unless exposure rates dictate otherwise.

## 4 Waste Disposal Procedures

1. Survey Procedures for Disposal of Waste as Non-Radioactive

   a. Always wear disposable gloves when handling waste.

   b. Use a low-level survey meter and ensure it is operating properly prior to use.

   c. Record background of survey meter on waste disposal record. Obtain background in low background area.

   d. Select waste from a container that has been held for at least ten half-lives.

   e. Measure radiation level over the entire surface of plastic bag with the survey meter. If waste contains beta emitters, make sure beta shield is open.

   f. If radioactive waste measures background:
      i. Remove all radioactive tags or obliterate RAM labels.
      ii. Dispose of into normal trash.

   h. If radioactive waste measures above background and less than 2 mR/hr, it may be placed within the waste container or outside of the waste container for further decay in storage.

   i. If radioactive waste measures above 2 mR/hr, return to waste container for further decay in storage.

   j. Record all findings on the radioactive waste disposal record.

   k. Records of waste disposal will be maintained for three (3) years.

2. Disposal of Radioactive Wastes of Long Lived Activation Products

   a. Always wear disposable gloves when handling waste.

   b. Always use remote manipulating devices (e.g., tongs or forceps) as need to reduce exposure when handling waste.

   c. Waste characterization will be determined either in-house or by an outside vendor.

   d. Package waste in vendor supplied containers or equivalent.

   e. Label shipping container as per waste broker's specifications.

   f. Complete waste manifest in accordance with waste broker's guidelines.

   g. Records of waste disposal will be maintained per state regulations.