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COTTAGE GROVE CARDIOLOGY, PC
711 Cottage Grove Rd., Bloomfield, CT 06002, Tel. 860-242-8756

USNRC, Region 1 Office
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

June 28, 2019

RE: Amendment request for NRC Materials License #06-30260-01 / 03034007

Dear Sir or Madam:

This letter serves to inform your offices of our request to amend the USNRC license.

ITEM 1

Request to add a PET/CT imaging service for cardiovascular studies employing the BRACCO CardioGen-82 generator of the Sr-82 pet-imaging agent. These materials are licensed under 10 CFR 35.200.

Enclosed please find the following materials and documents for your review:

1. The approved facility layout to the Ground Floor level of our building wherein the PET/CT unit will be located in what is the current imaging space, and, the two existing gamma cameras will be relocated into another space. Some modifications will be made to the reception area and the hot lab space as well.
2. The PET/CT shielding report, prepared by Applied Medical Physics in Radiology, Inc. for the safe use of the PET/CT system within our building.

And,

3. The stated commitments of our practice for the Safe Use and Handling of the BRACCO Rb-82 Generator and Infusion System.

ITEM 2

Possession of a Ge-68 calibration source for the GE PET/CT unit; it requires one Eckert & Zeigler Model HEGL-0132 line source containing an activity of 1.5 mCi. A maximum possession of 5 mCi activity is requested. This item falls into material permitted under 10 CFR 35.500 and should be added to the license.

NOTE: The Ge-68 line source is regularly replaced at intervals of approximately 24 months.

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BRACCO MATERIALS-002

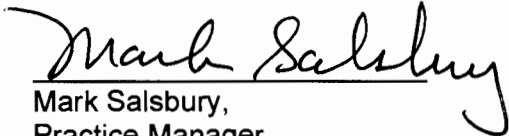
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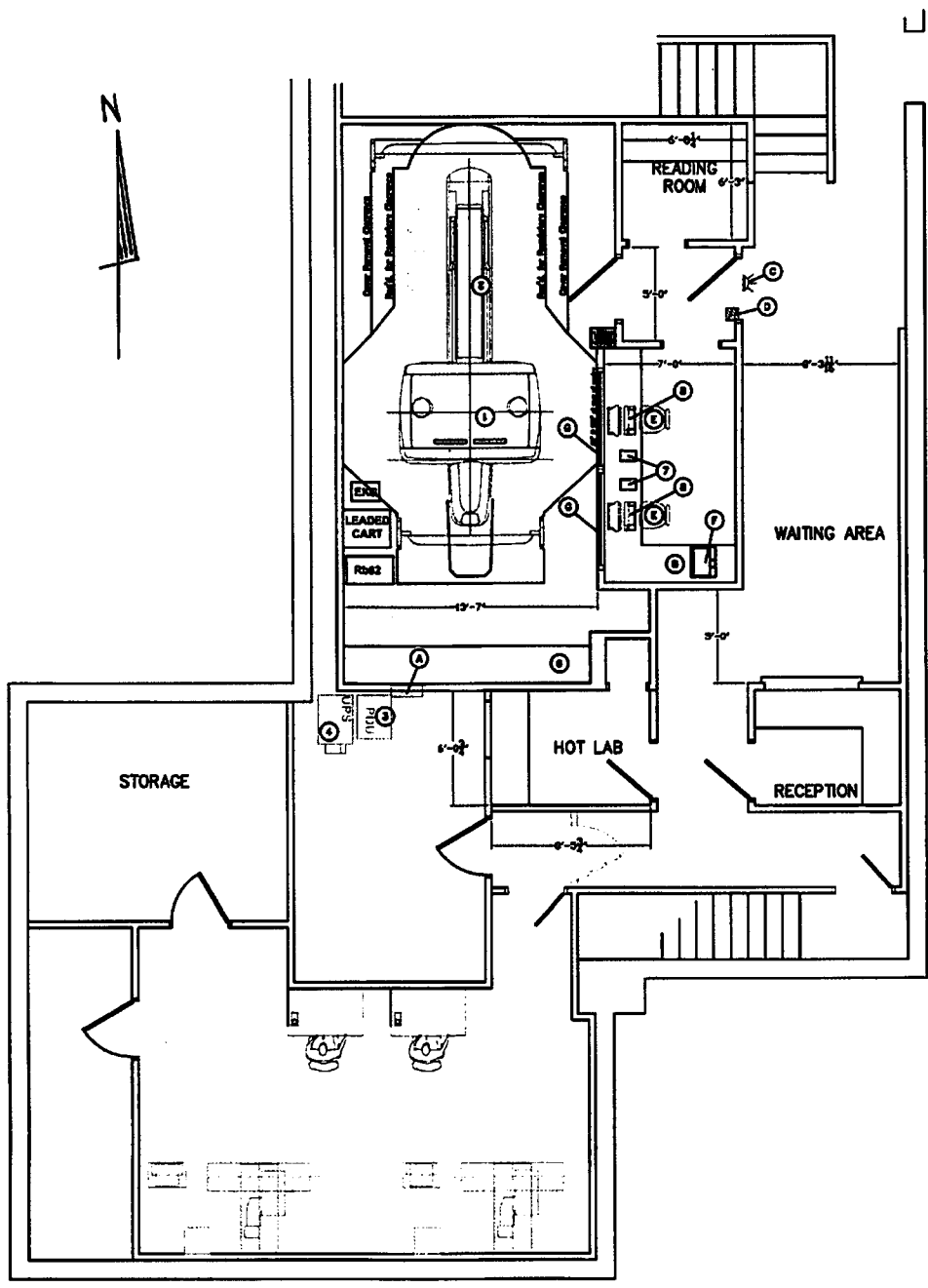
ITEM 3

The authorization of the RSO and licensed authorized user, Carolyn M. Kosack, MD, for material listed under 10 CFR 35.500.

Please advise us of the results to your review and we look forward to a continued safe and effective program with licensed materials.

Respectfully Submitted,


Mark Salsbury,
Practice Manager

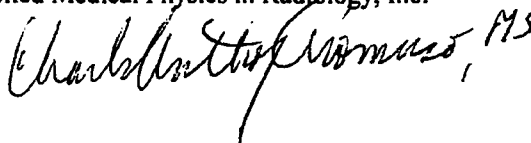


**RADIATION DESIGN CRITERIA
FOR A
PET IMAGING SUITE**

Designed for:
CDL Nuclear

Cottage Grove Cardiology
Broomfield, CT

Prepared by: Charles Anthony Giomuso, MS, MBA
Applied Medical Physics in Radiology, Inc.

A handwritten signature in black ink that reads "Charles Anthony Giomuso, MS". The signature is written in a cursive style and is positioned below the printed name.

April 11, 2019

Diagram and information supplied by Joe Jackson of CDL in emails dated April 9 and 10, 2019

The following is the design criteria for a PET Rb-82 Suite

Note that this facility is to be licensed with the State of Connecticut for radioactive materials use. Consideration for the following isotopes should be given in the application:

Rb-82 1 Ci possession limit for Generator

Basis for computations

The following design criteria have been computed using the recommendations of the National Council of Radiation Protection and Measurement (NRC) as set forth by reports Nos. 91, 136 and 147. In addition, reference can be made to AAPM Task Group 108 publication for PET/CT shielding for the conversion of lead to concrete thicknesses.

Introduction

This suite is designed for Cardiac Imaging using Rb-82 only. Calculations were performed based on a PET/CT. These calculations have been based on 60 mCi of Rb-82 administered twice to same patient per protocol. Attenuation Correction is to be performed by use of the CT portion of the scanner. The CT unit will not be used for diagnostic purposes.

The following protocol was reference for the calculations:

Drug: Rest/Dipyridamole Stress Rb-82 Myocardial Perfusion

An attenuation scan will be acquired for attenuation correction of the rest image. This will be followed by infusion of approximately 60 mCi of Rb-82, 60 to 100 seconds after which resting images will be acquired with ECG-gating. Following rest imaging, 0.56 mg/kg of dipyridamole will be infused over 4 minutes. Three minutes after the completion of the infusion, approximately 60 mCi of Rb-82 will be infused. Peak stress images will be acquired with ECG-gating, starting 90 seconds after the beginning of the infusion of Rb-82 and continuing for 5 minutes.

Or as an alternate:

Drug: Rest/Lexiscan(TM) Stress Rb-82 Myocardial Perfusion

An attenuation scan will be acquired for attenuation correction of the rest image. This will be followed by infusion of approximately 60 mCi of Rb-82, 60 to 100 seconds after which resting images will be acquired with ECG-gating. Following rest imaging, 400 umg of Lexiscan(TM) will be injected, and then approximately 60 mCi of Rb-82 will be infused. Peak stress images will be acquired in list mode with ECG-gating, starting 90 seconds after the beginning of the infusion of Rb-82 and continuing for 5 minutes.

Assumptions

The following assumptions are being made in the shielding design for this PET facility to include the imaging, patient holding and hot lab areas:

- * 60 mCi Rb-82 administered per patient (x2).
- * For Rb-82, patient has no waiting time as scan will begin once injection is made. 9 patients per day 45 patients per week.
- * Specific gamma constant, for Rb-82, = 6.1 R/hr/mCi.
- * Occupancy factors (reference NRC Report #147).
- * Distances from the patient on a table to the various walls of the imaging room were conservatively given based on the floor plan that was submitted and emailed with Mr. Jackson.
- * Patient attenuation factor was used in formula (0.36) and mean half life used.
- * Imaging room is located on the ground floor with an office space above.
- * Any shielding required on walls should reach at least 7 feet.
- * Shielding on any door on a wall. requiring shielding should also have same as wall shielding.

Occupancy Factors that will be used:

- T = 1 for office space (labs, reception, attended waiting rooms, nurse station)
- T = 1/2 for patient exam and treatment
- T = 1/5 for corridors, patient rooms, and staff toilets
- T = 1/8 for corridor doors
- T = 1/20 for public toilets, storage rooms, patient holding areas
- T = 1/40 for outdoor areas, parking lots, elevators, janitor closets

Design Goal

As recommended in NCRP Report 147, the design goals were to maintain the cumulative effective dose to less than 100 mRem/year in uncontrolled areas and 500 mRem/year in controlled areas.

Calculations

Distances were determined from a floor plan (emailed to me by Joe Jackson of CDL Nuclear on April 9, 2019). The attached information will indicate specific walls with associated distances to the radiation field.

Note that the directions (North, South, East and West) are referenced as you look at the floor plan. Patient Doses are located within the shielded generator for Rb-82. The patient will not be radioactive following the end of the scan due to the short half-life of Rb-82. The patient will be radioactive for approximately 20 minutes while being scanned (total of 15 hours per week), ie. 45 patients/week x 20 min/pt = 900 min/60 min = 15 hours).

PET shielding for Rb-82 use:

North Exterior Wall - No shielding is required.

East Control Room - No shielding is required. Suggest 1/16" as point of ALARA for occupational employees and waiting room behind control room.

South Mechanical Room - No shielding is required.

West Exterior Wall - No shielding is required.

Office on 2nd Floor - 1/16" lead required on floor of 2nd floor office. You can eliminate this if patient volume or dose is reduced.

Note: No lead is required in the Hot Lab for Rb-82 use. Suggest leaded storage container for waste products generated by the Rb-82 generator.

It is suggested that this information be sent to the design architect that is working on the job. Detailed calculations are available for the State agency upon request. Should you have any questions regarding the above, please feel free to contact me at 216-272-4669 or cag7ampr@sbcglobal.net

Sincerely,



Charles Anthony Giomuso, MS, MBA
Applied Medical Physics in Radiology, Inc.

Rb-82 Shielding Calculation

CDL - Cottage Grove Cardiology Broomfie

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Isotope	Adm dose mCi/pat	Energy	Gamma Rcm2/mCiHr	Gamma mRM/mCiHr
Rb-82	120	0.511	6.1	0.61

Half-life = 1.3min

(A) Dose 120 W= 45 Pat/Week
 (B) Decay 0.0312 (60min) u(Pb)= -0.139 /mm
 (C) Atten 0.36 10cm u(H2O)= -0.0097 /mm
 Effect=AxBxC 1.34784 u(conc)= -0.013 /mm

Dose Const M= 0.8221824 mR/pat
 Weekly dose@M = 36.998208 mR/week@M

Control			
Goal UR	2	mR/week	0.054056672
Goal R	10	mR/week	0.270283361
Design UR	20.99	mmPb	
Design R	9.41	mmPb	

Wall	Distance (Meters)	Occupancy T	Design Goal mR/week	Required Pb millimeters	Required mm concrete
North Changing Room	2.86	0.2	2	-5.7	
East Control Room	2.86	1	10	-5.7	
South Mechanical Rm	4.77	0.025	2	-28.0	
West Exterior Wall	2	0.025	2	-15.5	
Office above PET/CT	4	1	2	1.0	

Std inch	mm
1/32	0.79
1/16	1.59
3/32	2.38
1/8	3.18
5/32	3.97
3/16	4.77
7/32	5.55
1/4	6.35
3/8	9.53
1/2	12.7
5/8	15.88
3/4	19.05
1	25.4

HVL Pb= 5mm
 TVL Pb= 16.6mm
 HVL CC= 53mm
 TVL CC= 176mm

Prepared by: *Charles R. Roman, MS*
 AMPR, Inc.

Safe Use and Handling of BRACCO Rb-82 generator infusion system (CardioGen):

- Cottage Grove Cardiology P.C. will request the minimum required licensing nuclides and amounts: Strontium (Sr)-82 = 200 mCi, Rubidium (Rb)-82 = 200mCi and Sr-85= 1Ci (as a contaminant). This allows for generator exchange.
- Cottage Grove Cardiology P.C. will commit to the current Quality Control Procedures developed by the manufacturer and approved by the U.S. Food and Drug Administration (FDA) as revised March 2012 or any date(s) later.
- Cottage Grove Cardiology P.C. will commit to and will submit a copy of the current Bracco Diagnostics "Infusion System User Guide" if requested by any/all Licensing agencies.
- Cottage Grove Cardiology P.C. will commit to and submit a copy of the current Prescribing Information (PI) for the CardioGen-82 generator if requested by any/all Licensing agencies.
- Cottage Grove Cardiology P.C. will submit the manufacture and model number for the dose calibrator if requested by any/all Licensing agencies.
- Cottage Grove Cardiology P.C. submit the quality control procedures for the dose calibrator for performing the standard testing if requested by any/all Licensing agencies.
- Cottage Grove Cardiology P.C. will commit to the daily step by step PET (Sr-82, SR-85, and Rb-82) quality control procedures for the dose calibrator.
- Cottage Grove Cardiology P.C. will commit to the procedures for the proper storage and disposal of Sr-85 waste, including procedures for daily surveys of the Sr-85 generator waste and the disposal of the Sr-85 generator waste that shall be documented.
- Cottage Grove Cardiology P.C. will commit to ensuring proof of the manufacturer's initial training for all of the AU's, RSO's and any/all users (Certified Nuclear Medicine Technologists).
- Cottage Grove Cardiology P.C. will ensure that anyone who uses or supervises the use of the generator will receive device specific training by the manufacturer prior to initial use.
- Cottage Grove Cardiology P.C., Inc will ensure that any/all Certified/Registered Nuclear Medicine Technologists who use the generator and the RSO, must annually receive the manufacturer's refresher or recertification training for this device.
- Cottage Grove Cardiology P.C. will commit to completing the Sr-82/Sr-85 Testing worksheet, Calibration worksheet, Volume Tracking worksheet and the Monthly Receipt/Return Worksheet to include the generator lot number, serial number and calibration date.
- Cottage Grove Cardiology P.C. will ensure each generator user will maintain an on-going record of all eluate volumes (washing, testing and dosing volumes) including a summary of the cumulative volume of eluate.

- Cottage Grove Cardiology P.C. will commit to measuring and calculating the Strontium 82 (Sr-82) / Rubidium 82 (Rb-82) and Strontium 85 (Sr-85)/Rb-82 concentrations using an approved dose calibrator set on its most sensitive microcurie (uCi) scale and record all values with at least one significant figure and at least two places to the right of the decimal place according the following schedule below.
- Daily on days of use prior to administration; and
 - Additional daily test at the midpoint of the day should the initial test concentrations of Sr-82 reach:
 - 0.002 uCi per millicurie (mCi) of Rb-82; or
 - The initial test concentrations of Sr-85 reach 0.02 uCi per mCi of Rb-82; or
 - When 14 liters of total eluate has passed through the generator at the time points determined by the day's elution volumes where tests are performed at every 750 milliliters eluate use for that day.
- Cottage Grove Cardiology P.C. hereby commits we will stop using the generator on patients at the expiration limits listed below:
- 17 liters for the generator's cumulative eluate volume; or
 - 42 days post generator calibration date; or
 - An eluate concentration of Sr-82 of equal to or greater than 0.01 uCi per mCi of Rb-82; or
 - An eluate concentration of Sr-85 of equal to or greater than 0.10 uCi per mCi of Rb-82.
- Cottage Grove Cardiology P.C. will commit to following the manufacturer's annual preventative maintenance schedule for the Infusion Cart System and complete all of the recommended corrective actions.
- Cottage Grove Cardiology P.C. will commit to participating in the manufacturer's generator and infusion cart system online monitoring programs to determine use or stability of these products.
- Cottage Grove Cardiology P.C. will commit to reporting to the RAM Program/in house ALARA Safety Council any generator leaks, generator or cart failures, and each occurrence when the eluate concentration of Sr-82 equals or exceeds 0.02 uCi per mCi of Rb-82 or the eluate concentration of Sr-85 equals or exceeds 0.20 uCi per mCi of Rb-82.
- Cottage Grove Cardiology P.C. will ensure all records of these tests and all reports will be maintained for three years and be available for inspection by any/all Licensing Agency.



Signature

Date: 7/9/2019



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Cottage Grove Cardiology, PC ATTN: Ronald J. Bloom, President 711 Cottage Grove Road Bloomfield, CT 06002	Date July 17, 2019
	License Number(s) 06-30260-01
	Mail Control Number(s) 613333
	Licensing and/or Technical Reviewer or Branch Medical Branch

This is to acknowledge receipt of your: Letter and/or Application Dated: 06/28/2019

The initial processing, which included an administrative review, has been performed.
 Amendment Termination New License Renewal

There were no administrative omissions identified during our initial review.

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239