



CONVERSATION RECORD

02/05/2016

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Tracy King, consultant		DATE OF CONTACT 02/05/2016	TYPE OF CONVERSATION <input checked="" type="checkbox"/> E-MAIL <input type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS tking@mpcphysics.com		TELEPHONE NUMBER (734) 662-3197	

ORGANIZATION Botsford General Hospital	DOCKET NUMBER(S) 03002077
---	------------------------------

LICENSE NUMBER(S) 21-08892-01	CONTROL NUMBER(S) 588667
----------------------------------	-----------------------------

SUBJECT
Second Request for additional information

SUMMARY

We have reviewed your letter dated August 24, 2015, requesting renewal of your license and find that we will need additional information as follows:

"3. (as it appeared on my 01/28/2016 request)"
"Your renewal letter states that you are not using PET materials. However, the attached diagram for the Botsford Cancer Center appears to show several PET rooms on the right side of the diagram.

Please clarify whether you are or will be using PET materials. If not, please explain your diagram, which shows PET rooms. If you are going to use PET materials, you will need to submit shielding calculations in order for us to approve such use on this license."

Revised request as of 02/05/2016: attached to this second request for information is my generic request for PET shielding calculations that I put together myself for situations such as this one. Your response should be aligned with my requested information and not just a resubmittal of whatever may (or may not?) have been submitted before. Please do not assume that if you submitted

Continue on Page 2

ACTION REQUIRED (IF ANY)

Please submit a written response within 10 days of the date of this record (by February 15, 2016) or contact me to make alternative arrangements. Address your response to my attention at the address below in my signature block and reference it as "additional information to control number 588667."

Please respond directly to me for this case only; future new licensing requests should be addressed to the "Materials Licensing Branch Chief." Upon receipt of your written response we will continue our review.

Continue on Page 3

NAME OF PERSON DOCUMENTING CONVERSATION
Colleen Carol Casey

SIGNATURE
Colleen Carol Casey

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

something before that it will be approved now.

The point of license renewals is to "renew" the license and update all aspects of the radiation safety program, and not to just re-approve whatever was submitted in the past.

Please note that this request for additional information is preliminary as my complete review is not quite completed and additional issues may still arise. However, since we already had several issues identified, I wanted to communicate these to you as quickly as possible to arrange a more prompt response.

Please contact me via either telephone or email (email is probably quicker) to arrange a brief telephone call to discuss the issues above and ensure a correct and complete response. We will also need to discuss and agree on a response due date. I suggest 10 days from today, or February 15, 2016, at the very latest. We can discuss this and work something out.

Please be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this form will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Colleen
Colleen Carol Casey
Materials Licensing Reviewer
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352
(630) 829-9841 Direct, Central time zone
(630) 515-1078 Fax
NRC 24 HR Operations Center
(301) 816-5100, Eastern time zone

Gentle Reminders: Unless previously arranged with or requested by me directly, please do not submit any licensing requests, responses or correspondence via e-mail.

Please only submit one complete, signed copy of your correspondence to us.

Please prepare your licensing requests in accordance with NUREG 1556 Series Guidance, as appropriate.

Thank you very much!

Please also note that my full-time work schedule includes every other Friday off.

Ensuring the health and safety of
our people, our nation and
our environment

<http://www.nrc.gov/>

Additional Guidance for Licensing PET (F-18)

ABBREVIATED PET GUIDANCE AND TOOLS/REFERENCES/RESOURCES

General

Please be advised that, prior to performing positron emission tomography (PET) imaging, it will be necessary to amend your NRC license to include appropriate shielding information for your facility.

This information is also necessary in order to continue previously approved authorization for PET imaging when submitting your license renewal application.

You should include a copy of your facility diagrams and shielding calculations that show compliance with 10 CFR Part 20.1101, "Radiation Protection Programs," 20.1301 and 20.1302, "Radiation Dose Limits for Individual Members of the Public," and 20.1501, "Surveys and Monitoring."

In providing this information, please consider and include the following, as appropriate:

The following is a listing of some peer reviewed literature that addresses PET/CT design and shielding considerations and factors. It may be used to assist you in preparing your PET and PET/CT facility design and shielding calculations.

It is our understanding that PET use is commonly combined with CT use. So when this document refers to "PET" it is also referring to "PET/CT" even if not explicitly stated.

This is not intended to be an exhaustive, all-inclusive list:

http://www.aapm.org/pubs/reports/RPT_108.pdf

http://www.crcpd.org/Pubs/PET-CT-Fusion/02-18-04_1330-Martin.pdf

<http://www.radsafe.com/Papers/PETpaper.pdf>

Please provide shielding evaluations based on the "worst case scenario" for your proposed facility. For example, maximum activity used per patient, maximum number of patients injected and in queue at about the same time, distance assumptions, maximum potential exposure rates, etc.

F-18 will be the bounding isotope for any shielding evaluations provided.

Exposure results should be shown in units of millirem per hour and traditional units should be used throughout, but may be provided "in addition to" SI units.

Diagrams

If your PET room diagrams consist, even in part, of copies of blueprints, which we strongly discourage submitting (blueprints show a lot of information we do not need and very little of what we do need and they are often illegible), we will be unable to gain a full

understanding of your PET facilities. Kindly refrain from submitting blueprint diagrams or copies of them.

Please provide revised diagrams (simple, hand-drawn diagrams are good) that clearly show the entire PET usage stream, from the receipt and survey of incoming packages/doses to the injection areas, prep/quiet rooms, patient rest rooms, PET console/control area, PET and/or PET/CT scanning rooms, "post-dosed" or "post prepped" patient waiting rooms (should be separate from "pre-dose" waiting room where non-injected patients wait), and waste storage facilities.

Please clearly show the location and functional identity of **all contiguous rooms**, areas and/or spaces surrounding the PET facilities, especially the areas above and below the afore-mentioned rooms where the PET materials will be used in patients.

Your diagrams should be either drawn to scale or show actual dimensions and should:

*provide room numbers (if none, please so state or identify the room by another means);

*show the direction of north;

*show the functional identity of each room, space or area immediately surrounding all of the PET facility rooms and indicate clearly whether they are restricted (R) or unrestricted areas (U);

*show the elevation/grade clearly described and what spaces are above and beneath the PET rooms, their functional identity and whether they are restricted (R) or unrestricted areas (U); please include whether the roof will be restricted or unrestricted;

*indicate the expected path for a typical patient, such as waiting room, changing area, injection room, quiet area, rest room, PET scanner room, waiting room and/or changing room;

*describe for each barrier in each direction, including ceiling and floor:

**the specific composition (poured concrete, block concrete, Ledite (concrete with added metal aggregates enhancing shielding ability), lead, steel, gypsum board/drywall, etc.);

**thicknesses of each barrier (individually and total, expressed in inches, feet or centimeters); and,

*the distances from the patient/"exposed source" to the opposite, occupiable places for barriers/walls/ceilings/floors in all directions.

Please indicate clearly whether persons may gain access to an area above or below the proposed PET facilities. If these areas may be occupied during PET studies, please either submit exposure rate calculations to demonstrate that the doses received will not exceed the limits in 10 CFR 20.1301 or describe the administrative controls (training,

posting, surveillance, closed circuit television surveillance, lock-out, etc.) that will be put in place to prevent occupation during PET use.

Shielding Calculations

Please provide simple and complete shielding calculations, using traditional units (preferred), showing all of your work, barrier transmission factors (and calculation of them), appropriately detailed assumptions, defined terms, equations, constants, substitutions and parameters to demonstrate that radiation levels in all adjacent areas, including above and below the room, will not exceed levels in 10 CFR 20.1301.

It should be clearly shown what the anticipated worst case dose rates from PET/CT use are expected to be in each area before shielding is applied and then, after the specifically described shielding is factored in, what the shielded dose rates will be.

Please include the following details in your calculations:

- a. expected radiation levels for each under the most adverse and typical source term usage and workload;
- b. all parameters used to perform the calculations, including: dose rate constant values; typical dosage and expected worst case dosages amounts in millicuries; whether syringe shields, L-blocks, remote handling tools, portable shields, etc. will be used; distance to each area of concern, the type and thickness of material(s) used as shields, especially if portable shields will be used;
- c. the number of patients expected per week(i.e., workload);
- d. occupancy factors used for all adjacent areas, including areas above and below;
- e. demonstrate by calculation that the dose received by an individual member of the public likely to receive the highest dose from PET procedures when present in unrestricted area (in mrem/hr and mrem/yr) will not exceed the limits specified in 10 CFR 20.1301(a);
- f. sufficient information, in a readily understandable format to permit us to independently evaluate the adequacy of shielding in your proposed PET facilities.

Equipment and Training

Please describe the equipment (remote handling tools, syringe shields, portable shields, etc.) you will have available to keep exposures to all personnel, workers and patients, under the limits specified in 10 CFR Part 20.

It appears that personnel attending and working with PET patients will be likely to receive exposures exceeding the 100 millirem per year, as specified in 10 CFR 19.12.

Please describe your training program for these radiation workers, both initially and at least annually, as well as when the regulations affecting them and/or the license changes take place.