NRC FORM 386 (RIII)
(4-2004)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 1/12/2010

NUMBER OF PAGES: 6
(including this page)

SEND TO: BEN BLOMEKE, R. Ph., RSO

LOCATION: HOT SHOTS NUCLEAR MEDICINE

FAX NUMBER: 269 - 254 - 8577 ☐ ***VERIFY BY CALLING SENDER***

FROM:
(SENDER) Colleen Carol Casey

TELEPHONE NUMBER: 630 - 829 - 9841 FAX NUMBER: 630 - 515 - 1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

We can discuss these items during our visit on Jan. 13, 2010.

Thank you.

Colleen Carol Casey

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address , by U.S. Mail. Thank you.

COLLEEN CAROL CASEY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9841 FAX: (630) 515-1078

CONVERSATION RECORD | TIME | DATE

ACTUALLY FAXED? YES. **January 12, 2010**
Transmitted on 01/12/08 for site visit on 01/13/10

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Benjamin F. Blomeke, proposed RSO for Hot Shots Nuclear Medicine		269-254-8575 Fax: 269-254-8577

SUBJECT
License No.: PENDING Control No.: **318604**

SUMMARY
We have reviewed your application dated October 20, 2009, and your faxed letter dated December 10, 2009, requesting a new byproduct materials license and find that we need additional information as follows:

1. **At this time, in order to complete processing of your new license, you should change the mailing address for Hot Shots Nuclear Medicine ("Hot Shots") to the Kalamazoo address, since the facility is built out and receiving mail, etc. now. Please provide a written response with the complete, correct mailing address, telephone numbers and fax number.**

2. **Please identify the owner(s) of Hot Shots and their relationship, if any, to senior management in the organization chart you provided.**

3. **It was not clear from your application whether you will be doing any work dispensing Positron Emission Tomography (PET) radiopharmaceuticals. Please clarify your expectations in this regard and, as appropriate, provide additional details to your application with respect to shielding of PET materials, safe handling procedures, radiation levels external to shielded transport containers "pigs," etc.**

4. **Your application requests authorization for "cobalt-57 sealed sources for redistribution for instrument calibration." You also requested authorization for "any byproduct material permitted by 10 CFR 35.65(a) for instrument calibration and redistribution for instrument calibration."**

   These are redundant requests. It appears that the only authorization you need is the second one, which includes cobalt-57 for the same purposes. Please

reconsider and, as appropriate, withdraw your request for the cobalt-57 sealed sources authorization.

5. Please identify where the personnel hand and foot monitoring stations are located in your restricted areas, so that persons exiting these areas may survey themselves to ensure they are not contaminated before moving into unrestricted areas.

6. Please confirm that all proposed ANP's, including the RSO, should have "R.Ph." listed after their names, as their names appear on the referenced license.

7. Please reconsider your decision to make the after-hours radioactive package dropoff area an "unrestricted area." As this area is secured for your couriers only, it appears to be a "restricted area," per the definitions of these terms in 10 CFR 20.1003. Please confirm that this area will be changed to a restricted area. (Attachment 4, Item 9.2)

8. Attachment 4, Item 9 of your application describes the "Ante-area." Please explain what is meant by "component staging of personnel" entering the dispensing area of the pharmacy.

9. Attachment 5, Item 9 of your application describes two charcoal filters to be used in the I-131 fume hood and your procedure for analyzing these filters for saturation. However, your procedure does not state that this charcoal is "activated," i.e., chemically enhanced to increase its absorptive ability to trap volatile iodine-131, usually with TEDA, which is mentioned elsewhere in your application. Please confirm that you will use appropriately activated charcoal for these filters.

10. Your application did not describe what your safety procedures would be in the event of a xenon-133 spill inside the lab, such utilization of an "elephant trunk suction/exhaust" system. Please describe your safety procedures for such an event and, in doing so, you may also factor in the following: do you expect to dispense xenon-133 from multi-dose containers or do you only expect to dispense/redistribute unit dosages of xenon-133? Will the negative pressure in your fume hood be sufficient to capture and exhaust such a spill in a timely fashion?

11. Your application did not describe the frequency at which you would obtain bioassay tests for workers who dispense or may be exposed to volatile iodine-131. Please confirm that you will, at a minimum, perform baseline bioassays on all workers who dispense or may be exposed to volatile iodine-131 and describe and justify the frequency for bioassay tests thereafter, such as routine bioassays and those taken after a spill.

12. Please describe what these bioassay tests will consist of, such as thyroid assays or other types of assays. Please describe the equipment you will use to perform bioassay tests on workers who dispense or may be exposed to volatile iodine-131 and the procedures you will use, your analysis of results and your action levels.

13. **Please describe all labels to be affixed to dispensed radioactive drugs, including the colors to be used – this last detail, the colors to be used, was missing from your application.**

14. **For each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package), provide:**

    - **the radionuclide and the maximum activity for each type of container (e.g., vial, syringe),**
    - **and the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.**

    This information was missing from your application and is requested in Item 8.10.12 in NUREG 1556, Vol. 13, Rev. 1.

15. **To minimize exposures to persons handling and dispensing radioactive drugs, do you expect to utilize shielded pulley systems or similar devices, in addition to more traditional remote handling tools?**

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

ACTION REQUIRED

Submit the requested information within 10 calendar days (by January 22, 2010) by referencing control number 318604 to facilitate proper handling. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address. You may transmit your response to the fax no. above, 630-515-1078, and, if you do send a fax, please, at least leave a voicemail message for me, so I'll know to look for it. We will then continue our review.

If you cannot meet the requested response date please call me to arrange for an alternative date to respond. Please note that I will be on leave from Jan. 15 – 24, 2010.

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9841 or (800) 522-3025.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey	Colleen Carol Casey	January 12, 2010

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Shallow-dose equivalent (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

Site boundary means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

Source material means—

(1) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or

(2) Ores that contain, by weight, one-twentieth of 1 percent (0.05 percent), or more, of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

Special nuclear material means—

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

Stochastic effects means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

Supplied-air respirator (SAR) or *airline respirator* means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Survey means an evalulation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

Total Effective Dose Equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Uranium fuel cycle means the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these activities directly support the production of electrical power for public use. Uranium fuel cycle does not include mining operations, operations at waste disposal sites, transportation of radioactive material in support of these operations, and the reuse of recovered non-uranium special nuclear and byproduct materials from the cycle.

User seal check (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates.

NOTE: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

Week means 7 consecutive days starting on Sunday.

Weighting factor w_T, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING F

Organ or tissue	
Gonads	
Breast	
Red bone marrow	
Lung	
Thyroid	
Bone surfaces	
Remainder	
Whole Body	

[1] 0.30 results from 0.06 for each of 5 "(excluding the skin and the lens of the eye highest doses.

[2] For the purpose of weighting the ext dose (for adding it to the internal dose), factor, w_T=1.0, has been specified. The use factors for external exposure will be appro case basis until such time as specific guida

Whole body means, for pu ternal exposure, head, trun male gonads), arms above t legs above the knee.

Working level (WL) is an tion of short-lived radon da radon-222: polonium-218, le muth-214, and polonium-21 radon-220: polonium-216, le muth-212, and polonium-212 of air that will result in t emission of 1.3×10^5 MeV o alpha particle energy.

Working level month (WLM exposure to 1 working le hours (2,000 working hours months per year=approxi hours per month).

Year means the period of ning in January used to compliance with the provis part. The licensee may starting date of the year us mine compliance by the li vided that the change is m beginning of the year and t

g pressure respirator means a
or in which the pressure inside
iratory inlet covering exceeds
bient air pressure outside the
or.

ed air-purifying respirator
means an air-purifying res-
that uses a blower to force the
t air through air-purifying ele-
o the inlet covering.

ure demand respirator means a
e pressure atmosphere-supplying
tor that admits breathing air to
cepiece when the positive pres-
reduced inside the facepiece by
tion.

ic dose means the dose received
nember of the public from expo-
o radiation or to radioactive ma-
released by a licensee, or to any
source of radiation under the
ol of a licensee. Public dose does
nclude occupational dose or doses
ved from background radiation,
any medical administration the
idual has received, from exposure
dividuals administered radioactive
rial and released under §35.75, or
voluntary participation in med-
research programs.

alitative fit test (QLFT) means a
fail fit test to assess the adequacy
spirator fit that relies on the indi-
al's response to the test agent.

uality Factor (Q) means the modi-
g factor (listed in tables 1004(b).1
1004(b).2 of §20.1004) that is used to
ive dose equivalent from absorbed
e.

uantitative fit test (QNFT) means an
essment of the adequacy of res-
ator fit by numerically measuring
amount of leakage into the res-
ator.

Quarter means a period of time equal
one-fourth of the year observed by
e licensee (approximately 13
nsective weeks), providing that the
ginning of the first quarter in a year
incides with the starting date of the
ar and that no day is omitted or du-
icated in consecutive quarters.

Rad (See §20.1004).

Radiation (ionizing radiation) means
lpha particles, beta particles, gamma
ays, x-rays, neutrons, high-speed elec-
rons, high-speed protons, and other
articles capable of producing ions. Ra-
liation, as used in this part, does not
include non-ionizing radiation, such as
radio- or microwaves, or visible, infra-
red, or ultraviolet light.

Radiation area means an area, acces-
sible to individuals, in which radiation
levels could result in an individual re-
ceiving a dose equivalent in excess of
0.005 rem (0.05 mSv) in 1 hour at 30 cen-
timeters from the radiation source or
from any surface that the radiation
penetrates.

Reference man means a hypothetical
aggregation of human physical and
physiological characteristics arrived at
by international consensus. These
characteristics may be used by re-
searchers and public health workers to
standardize results of experiments and
to relate biological insult to a common
base.

Rem (See §20.1004).

Residual radioactivity means radioac-
tivity in structures, materials, soils,
groundwater, and other media at a site
resulting from activities under the li-
censee's control. This includes radioac-
tivity from all licensed and unlicensed
sources used by the licensee, but ex-
cludes background radiation. It also in-
cludes radioactive materials remaining
at the site as a result of routine or ac-
cidental releases of radioactive mate-
rial at the site and previous burials at
the site, even if those burials were
made in accordance with the provisions
of 10 CFR part 20.

Respiratory protective device means an
apparatus, such as a respirator, used to
reduce the individual's intake of air-
borne radioactive materials.

Restricted area means an area, access
to which is limited by the licensee for
the purpose of protecting individuals
against undue risks from exposure to
radiation and radioactive materials.
Restricted area does not include areas
used as residential quarters, but sepa-
rate rooms in a residential building
may be set apart as a restricted area.

Sanitary sewerage means a system of
public sewers for carrying off waste
water and refuse, but excluding sewage
treatment facilities, septic tanks, and
leach fields owned or operated by the
licensee.

TRANSMISSION VERIFICATION REPORT

TIME : 01/12/2010 20:59
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER.# : 000A7J925774

DATE,TIME	01/12 20:57
FAX NO./NAME	82692548577
DURATION	00:02:33
PAGE(S)	06
RESULT	OK
MODE	STANDARD ECM

NRC FORM 386 (RIII)
(4-2004)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 1/12/2010

NUMBER OF PAGES: 6
(including this page)

SEND TO: BEN BLOMEKE, R.Ph., RSO

LOCATION: HOT SHOTS NUCLEAR MEDICINE

FAX NUMBER: 269-254-8577 ☐ ***VERIFY BY CALLING SENDER***

FROM: Colleen Carol Casey
(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE