

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

W

CONVERSATION RECORD	TIME	DATE
ACTUALLY FAXED? YES.		September 25, 2008

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE Nos.
Terry Wade or Zhongshan (John) Zhang, MSc., DABR, proposed AMP for Oncology Hematology Associates of Southwest Indiana		812-485-5702 573-406-5814 FAX: 812-485-5719

SUBJECT
License No.: PENDING **Control No.: 317483**

*next def- used full
name signature on
all correspondence, even
faxes*

SUMMARY

We have reviewed your application dated June 2, 2008, and your faxes dated August 26, 2008, and September 15, 2008, requesting a new byproduct materials license and find that we need additional information as follows:

At this time I was unable to approve your request to issue a new byproduct materials license for the use of certain diagnostic materials, sealed and unsealed, and an HDR remote afterloading brachytherapy device because the information provided in your application dated June 2, 2008, and your fax dated August 26, 2008, ^{was} ~~are~~ insufficient to complete my review.

9/15/08

1. Your fax dated September 15, 2008, was ~~also~~ not entirely clear as to what you wanted to be licensed for in terms of sealed source diagnostic materials, Ge-68. So you do not need authorization for Ga-68, ^{with drawn} as requested in your original application? Please clarify.

*still a
problem
GE Discovery
def.*

Also, the model no. of the sealed source is given as "A3429 F4-Ge," which does not match up with the Sealed Source and Device Registry certifications. It is the "F4-Ge" language that confuses the issue so please clarify. Model No. A3429 can be used in either of two different PET CT devices. Please clarify the model no. for exactly which sealed sources you want, and specify which device, by model no. or model name, that you wish to be licensed for.

*still a
problem*

2. Attachment #2 of your fax dated September 15, 2008, item 3 states "The Authorized User and either the Medical Physicist or the Radiation Safety Officer must be physically present for all patient treatments."

ok ✓ This is contrary to 10 CFR 35.615(f)(2) and we cannot authorize this. Although your initial RSO will be an AMP, it is possible that a future RSO may not be an AMP, which could create a non-compliance issue, if physical presence differed from what the regulations permit.

Please withdraw this item from your response and confirm that you will allow physical presence in accordance with 10 CFR 35.615(f)(2) for HDR treatments.

3. My original deficiency question was: "Please specify what you want your proposed Authorized Users to be authorized for, with the exception of Drs. Miller and Kim, whom you already have specified authorization for."

John Sotkowski! only for Ge-68.
Your response stated that the remaining AU's should only be authorized for F-18. You named no AU's for use of the Ge-68 source in the PET/CT. Please name at least one AU for use of the Ge-68 source in the PET/CT device.

4. Please indicate on your revised HDR room diagram (page 5 of 9/15/08 fax) which areas will be considered restricted and which will be considered unrestricted.

Please also indicate the thinnest wall/barrier for the HDR room – is it three feet of poured concrete, 2.5 feet or a different value?

My deficiency record dated 9/6/08 requested that you provide "expected radiation levels for each adjacent area, under the most adverse and typical source orientations and maximum source activity." This was not done.

Instead, an abbreviated response was submitted at the bottom of your page 2 and top of your page 3. Please provide the information as requested to complete my understanding of your facility and radiation levels expected with use of the HDR.

If you have any questions concerning this information above please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is (630) 515-1078.

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

Please submit a written response to the above items within 15 days and reference it as "additional information to control number 317483. Note that this is a DIFFERENT control number than the one previously assigned to your original request. Your 9/15/08 fax did NOT reference the control number and this also factored into the mishandling incident when you sent it to us.

Please include my name on your written response and be sure to include ONLY your proposed licensed name, "Oncology and Hematology Associates." Do NOT refer to the hospital where you are currently located at all.

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

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	Date
Colleen Carol Casey		September 25, 2008

TRANSMISSION VERIFICATION REPORT

TIME : 09/25/2008 20:03
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER.# : 000A7J925774

DATE, TIME	09/25 20:01
FAX NO./NAME	88124855719
DURATION	00:01:12
PAGE(S)	04
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: 9/25/08 NUMBER OF PAGES: 4
(including this page)

SEND TO: TERRI WADE / JOHN ZHANG

LOCATION: ONCOLOGY + HEMATOLOGY ASSOCIATES

FAX NUMBER: 812 - 485 - 5719 **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

Please call me if you have questions,



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

*faxed 27:00pm
9/25/08*

TELEFAX TRANSMITTAL

DATE: 9/25/08

NUMBER OF PAGES: 4
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MESSAGE

Please call me if you have questions,

Thank you.

Colleen Carol Casey

Page 1

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.

TRANSMISSION VERIFICATION REPORT

TIME : 10/05/2008 19:55
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER.# : 000A7J925774

DATE, TIME 10/05 19:54
FAX NO./NAME 88124855719
DURATION 00:00:56
PAGE(S) 03
RESULT OK
MODE STANDARD
ECM

*C left VM msg for
Terry Wade 6:53pm
on 10/5/08*

NRC FORM 306 (R111)
(4-2004)



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

TELEFAX TRANSMITTAL

DATE: 10/5/08 NUMBER OF PAGES: 3
(including this page)

SEND TO: TERRI WADE/JOHN ZHANG

LOCATION: Oncology Hematology Associates

FAX NUMBER: 812-485-5719 **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

I will not be available Mon. afternoon, Oct. 6 but you can leave a voicemail message on my office phone, if you need to, and I'll



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2443 Warrenville Road, Suite 210
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NUMBER OF PAGES: 3
(including this page)

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FROM: COLLEEN CAROL CASEY
(SENDER)

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

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MESSAGE

I will not be available Mon. afternoon, Oct. 6 but you can leave a voicemail message on my office phone, if you need to, and I'll get back to you Tues. Oct. 7.

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.

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CONVERSATION RECORD

|TIME

|DATE

ACTUALLY FAXED? YES.

October 5, 2008

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE Nos.

Terry Wade or

Zhongshan (John) Zhang, MSc., DABR, proposed AMP for
Oncology Hematology Associates of Southwest Indiana

573-406-5814

FAX: 812-485-5719

SUBJECT

License No.: PENDING

Control No.: 317483

SUMMARY

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At this time I was unable to approve your request to issue a new byproduct materials license for the use of certain diagnostic materials, sealed and unsealed, and an HDR remote afterloading brachytherapy device because the information provided in the above-referenced correspondence was insufficient to complete my review.

- 1. Your fax dated September 29, 2008, was still not entirely clear as to what you wanted to be licensed for in terms of sealed source diagnostic materials, Ge-68.**

The device name submitted "GE Discovery Ste" does not match up with the Sealed Source and Device Registry certifications. There is more than one "Discovery" CT/PET device that the Model No. A3429 can be used in. Please clarify the full model name for exactly which device you wish to be licensed for.

(I tried matching up your requested "per source" possession limit and I was still unable to determine which device you wanted.)

- 2. I noted that your fax was signed using only the first name of Ms. Wade. Please note that all correspondence to us must be signed using a complete first and last name.**

If you have any questions concerning this information above please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is (630) 515-1078.

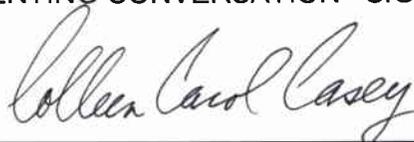
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