



CONVERSATION RECORD

04/26/2013

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

Christopher P. Leamon, Ph.D., Radiation Safety Officer, Vice President of R&D

DATE OF CONTACT

04/24/2013

TYPE OF CONVERSATION

☐ E-MAIL☒ TELEPHONE☐ INCOMING☒ OUTGOING

E-MAIL ADDRESS

chrisleamon@endocyte.com

TELEPHONE NUMBER

(765) 807-0607

ORGANIZATION

Endocyte Incorporated

DOCKET NUMBER(S)

030-35228

LICENSE NUMBER(S)

13-32212-01

CONTROL NUMBER(S)

580044

SUBJECT

Our review of your amendment request letter dated February 14, 2013

SUMMARY

We have reviewed your amendment request and find that we are unable to continue this action until we have received additional information regarding the following:

The submitted facility diagram is limited to an annotated architectural rendering of current approved and additional proposed radioactive materials use areas. Refer to NUREG 1556, Volume 7, pp. 8-19 to 8-20, for facility information needed to add an area of use. See <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/sr1556v7.pdf> for the guidance document. Diagrams should describe facilities, per Appendix K, pp. K-1 to K-2, of the referenced document, and animal facilities, per Appendix H, pages H-1 to H-2, of the referenced document.

As discussed by telephone, please resubmit your request, including a revised facility diagram. The diagram should include room numbers and be drawn to a specified scale, or dimensions should otherwise be indicated. The diagram should be free of superfluous architectural markings. Identify any storage, fume hoods, waste, or other special use areas. In particular, highlight animal handling areas, such as bedding, housing, and other contamination control aspects of the facility. Finally, note access control to the lab and waste area and outline uses of rooms/corridors above, below, and adjacent to the lab and waste area.

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ACTION REQUIRED (IF ANY)

We have requested that the licensee resubmit its request, attached to a signed, dated cover letter and referencing Control No. 580044, as listed at the top of this memo. The response should include a revised facility diagram as noted above.

Submit requested information within 10 days of our conversation. Call us as soon as possible if you will need additional response time. Please FAX your response to my attention at (630) 515-1078, or scan your response and send to me via email, as a pdf file.

We expect to receive your written response on or before May 4, 2013.

Please direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.

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NAME OF PERSON DOCUMENTING CONVERSATION

Sara A.B. Forster, Materials Licensing Branch, Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532

SIGNATURE

04/26/2013

Forster, Sara

From: Forster, Sara
Sent: Friday, April 26, 2013 8:18 AM
To: 'chrisleamon@endocyte.com'
Subject: Amendment Request, Endocyte, Inc., License No. 13-32212-01, C/N 580044
Attachments: 03620.580044.13-32212-01 telecon signed.pdf

Dear Mr. Leamon:

As we discussed by telephone, I have attached a summary of additional information needed to complete the request. Please note that we have requested a written response by May 4, 2013; please let me know as soon as possible if you are unable to meet this timeline. As noted in the attached record, you may wish to refer to NRC's Research and Development guidance, in preparing your response. This volume may be found at the NRC website:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/sr1556v7.pdf>.

Do not hesitate to call me if you have any questions regarding this message. I look forward to receiving your response.

Sincerely yours,

Sara A. B. Forster, Health Physicist Licensing Reviewer

U.S. Nuclear Regulatory Commission - Region III

Division of Nuclear Materials Safety

2443 Warrenville Rd. - Ste. 210

Lisle, IL 60532-4352

sara.forster@nrc.gov

Direct: (630) 829-9892

