

Sara A.B. Forster
MATERIALS LICENSING BRANCH

TELECON & FAX TRANSMITTAL



TO: John Hartman, CFO, and
Milko Kermekchiev, Chief Scientist

COMPANY: DNA Polymerase Technology, Inc.

NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

PAGES: 2 TEL.: (314) 707-4919

FAX #: N/A

(630) 829-9892 FAX: (630) 515-1078

EMAIL: hartman@klentaq.com
milko@klentaq.com

CONVERSATION RECORD

TIME DATE
8:00 am April 9, 2013

NAME OF PERSON(S) CONTACTED	TELEPHONE NO.	ORGANIZATION
John Hartman, Chief Financial Officer	(314) 707-4919	DNA Polymerase Technology, Inc.
REPRESENTED PERSON or PERSONS		ORGANIZATION
Wayne M. Barnes, Ph.D., Radiation Safety Officer		DNA Polymerase Technology, Inc.
SUBJECT		
License No.: 24-32214-01		Control No.: 579332

SUMMARY

We have reviewed your requesting renewal application and find that we are unable to continue this action until we have received information regarding the following:

1. The application included Milko Kermekchiev, Ph.D., as an Authorized User (AU), but omitted Wayne M. Barnes, Ph.D., Brett Evans, B.S., and Katherine Rowlyk, M.A., from the list of AUs. Please confirm that Dr. Barnes, Mr. Evans, and Ms. Rowlyk should be deleted as AUs on the license.
In our phone conversation, Mr. Hartman indicated that the omissions were intended and correct. Accordingly, Dr. Barnes, Mr. Evans, and Ms. Rowlyk will be deleted from the referenced license's AU list. No additional information is required, regarding this item.
2. The application listed two new AUs – Zhian Zhang, Ph.D., and David Taylor, Ph.D. However, training and experience listed included neither work experience subsequent to 2006, nor documentation regarding their doctorate degrees. The NRC guidance document, NUREG 1556, Volume 7, page 8-17, outlines the minimum adequate training and experience required for a proposed AU.
Accordingly, please provide the following information for Drs. Zhang and Taylor, as available and/or applicable:
 - A. Copies of Ph.D. certificates, or, at a minimum, the date on which each Ph.D. was conferred, the conferring institutions, and the fields of study associated with the degrees.

- B. The date, location, and training provider, for each proposed AU's most recent radiation safety training in radiation protection principles, characteristics of ionizing radiation, units of radiation dose and quantities, and biological hazards of exposure to radiation.**
- C. Hands-on radioactive materials use experience, for each proposed AU, subsequent to the dates included in the application.**
3. The submitted facility diagrams are limited to the areas in which radioactive materials are used or stored. Refer to NUREG 1556, Volume 7, pages 8-19 to 8-20, for facility information that should be provided, in support of a license application.
As discussed by telephone, please provide additional facility information including access control to the lab and waste area; room numbers, as applicable; a description (or diagram) of where the exterior delivery door, the north stairwell, the lab, and the waste areas are located with respect to the building; and uses of rooms/corridors above, below, and adjacent to the lab and waste area.
4. On page 4 of the application, under, "10.6. Safe Use of Radionuclides and Emergency Procedures," you referenced attachment #4: DNA Polymerase Technology, Inc.'s Safe Use of Radionuclides and Emergency Procedures." Note that NUREG 1556, Volume 7, page 8-41, requires only that the applicant state that, "procedures for safe use, including security of materials, and emergencies have been developed, or will be developed before receipt of licensed material."
Please provide a statement in accordance with the guidance.
As we discussed, including the procedures outlined in Attachment 4 to your application is considered a commitment to adhere to those specific topics, such as the cost/benefit review noted on page 21 of the application.
If you wish to withdraw your commitment to adhere to the referenced procedures, please so state in your response to this correspondence.

We have requested that you submit the referenced items:

- Additional Training & Experience for Drs. Zhang & Taylor;
- Augmented Facility information; and
- Revised Safe Use commitments

– via facsimile, to (630) 515-1078. Please reference the Control No. 579332, as listed at the top of this memo. We expect to hear from you on or before April 23, 2013. **Include a signed, dated cover letter with your response.**

For future reference, please always include the name, phone number and fax number of at least one person whom we may contact for additional information when reviewing your licensing correspondence and requests.

Please submit the requested information within **14** days of this record. **Include reference control number 579332. Please FAX your response to my attention at (630) 515-1078.** You may also scan your response and send to me via email, as a pdf file.

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

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Sara A.B. Forster

Sara A.B. Forster 04/11/2013

Forster, Sara

From: Forster, Sara
Sent: Thursday, April 11, 2013 12:45 PM
To: 'hartman@klentaq.com'; 'milko@klentaq.com'
Subject: Renewal application, DNA Polymerase Technology, Inc., License No. 24-32214-01, C/N 579332
Attachments: 03620.579332.24-32214-01 telecon signed.pdf

Dear Mr. Hartman:

As we discussed by telephone, I have attached a summary of our April 9, 2013, phone conversation including additional information still needed in order to complete our review of the above referenced application. In that record, I referenced the Research and Development guidance, NUREG 1556, Vol. 7. Please note that 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 soon.

Sincerely yours,
Sara A. B. Forster, Health Physicist Licensing Reviewer
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