



**RECEIVED
05/05/2020**

May 5, 2020

Kimberly D. Daniel
*Radiation Safety Officer &
Acting Environmental Coordinator*
National Center for Toxicological Research
Regulatory Compliance & Risk Management
U.S. Food and Drug Administration
Tel: 870-543-7640
Mobile: 870-718-3858
E-Mail: Kimberly.Daniel@fda.hhs.gov

**Mail Control Number: 618953
Docket Number : 3008559
License Number : 03-15093-01
Licensee Name : Department of Health and Human
Services**

Ms. Carol Hill
U.S. Nuclear Regulatory Commission
Region IV
1600 East Lamar Blvd.
Arlington, Texas 76011-4511

Ms. Hill:

I respectfully request that NCTR be changed back to a Broad Scope Type B License. In 2017, NCTR requested NRC license renewal. Our intent was to continue under the same NRC Broad Scope Type B License, that we have operated under for over 20 years. However, I believe, the description of our program was misinterpreted as a request for a Broad Scope Type A License rather than renewal of the Broad Scope Type B License.

Please be assured that NCTR continues to operate in the conservative manner described in our Radiation Safety Program Document, nothing has changed, our Radiation Safety Committee continues to meet quarterly. However, given these uncertain times, and the fact that our radioisotope use in research at NCTR has sharply declined over the years, I feel it is in NCTR's best interest to continue operating under the same Broad Scope Type B license type it has in the past rather than to become more restrictive.

Respectfully,

Kimberly D. Daniel

From: [Torres, Roberto](#)
To: [Hill, Carol](#)
Subject: FW: RE: Broad Scope B changed to A by mistake.
Date: Tuesday, May 05, 2020 4:53:24 PM
Attachments: [2020-05-05-CorrectLicRenewalBack2TypeB.pdf](#)
[image001.png](#)
[image003.png](#)
Importance: High

Carol:

Assign this amendment to me. The amendment request is publicly available.

From: Daniel, Kimberly D <Kimberly.Daniel@fda.hhs.gov>
Sent: Tuesday, May 05, 2020 4:45 PM
To: Hill, Carol <Carol.Hill@nrc.gov>
Cc: Torres, Roberto <RobertoJ.Torres@nrc.gov>
Subject: [External_Sender] RE: Broad Scope B changed to A by mistake.
Importance: High

Ms. Hill,

Please find the attached letter requesting that our NRC License be changed back to Broad Scope Type B. NCTR has held a Broad Scope Type B License for over 20 years, and when we requested license renewal in 2017, our intent was to continue under Broad Scope Type B License. I believe due to the description of our program, the assumption was made that we were requesting a Broad Scope Type A License rather than the renewal of the Broad Scope Type B License we held for well over 20 years. I respectfully request that NCTR be changed back to a Broad Scope Type B License.

Kim Daniel

Radiation Safety Officer & Environmental Coordination

Regulatory Compliance & Risk Management

National Center for Toxicological Research

U.S. Food and Drug Administration

Tel: 870-543-7640

Mobile: 870-718-3858

Mobile: 501-200-2537

E-Mail: Kimberly.Daniel@fda.hhs.gov



From: Torres, Roberto <RobertoJ.Torres@nrc.gov>
Sent: Friday, March 27, 2020 4:09 PM
To: Daniel, Kimberly D <Kimberly.Daniel@fda.hhs.gov>
Subject: RE: Broad Scope B changed to A by mistake.

Ms. Daniel:

I just read your email and reviewed the renewal. We received the renewal that contained

language indicating the desire for a Type A Broad Scope even though the renewal did not specifically state "Type A". As a result we sent a request for additional information to confirm the expanded authorization being requested and a response was received confirming the addition of the Type A license condition to the license. Unfortunately I cannot self-initiate a licensing action and will need a letter to change the license back to Type B. The letter can be signed by you as RSO and you can send the letter (in pdf format) to our licensing assistant carol.hill@nrc.gov.

If you believe that myself or any other NRC inspector were derelict in their duties you can report the occurrence directly to my supervisor: heather.gepford@nrc.gov.

Thank you for your understanding.

Roberto J. Torres
Senior Health Physicist
U.S. NRC Region IV

From: Daniel, Kimberly D <Kimberly.Daniel@fda.hhs.gov>
Sent: Friday, March 13, 2020 4:54 PM
To: Torres, Roberto <RobertoJ.Torres@nrc.gov>
Subject: [External_Sender] Broad Scope B changed to A by mistake.
Importance: High

Mr. Torres,

Thank you for clearing up the questions I had in determining whether a piece of equipment had a generally licensed source, or if I was supposed to conduct periodic leak checks. I have made the appropriate mental and physical notes to myself to help me remember when similar questions arise in the future.

You also answered a question I had concerning our Broad Scope Type B material license having been converted to a Broad Scope Type A material license, even though we did not officially or specifically ask for it to be changed and did not intend for it to be changed. You stated that based on the verbiage in our renewal it was assumed by NRC we wanted a broad scope A license, based on verbiage in our request. We requested to renew our existing NRC -Broad Scope Type B License. Just because we disclosed information about our Radiation Safety Program and our program is more conservative than what it is required to be based on the Broad Scope Type B License requirements, doesn't mean we wanted to change from Type B to Type A. We have operated under Broad Scope type B License for over 20 years, with a conservative radiation safety program, that is more restrictive than required by Broad Scope type B material license and previous renewals didn't result in NRC changing our License type.

I am writing you to make absolutely certain that in order for me to get our license type corrected back to the way it has been for over 20 years, I have to send an official request for amendment, that specifically requests our license be converted back to type B, even though, we never asked it to be changed in the first place?

When we initially renewed our license, I don't think there was a problem, I believe we were initially

renewed as Broad Scope Type B. I believe the NRC inspector that came out raised questions about the language in our program being more restrictive than what was required by our license. I did not realize that by writing NRC as I was advised by the inspector that the end result would be our NRC License being changed from Broad Scope B to Broad Scope A, if I had understood that is what I was being directed to do, I would explained to the inspector that we know we are operating more conservatively than we are required to and that we want to keep things as they were.

Again, please forgive me, I really do not want to be a pain, or cause problems... But are you sure you can't correct the license type back to type B like it has always been, without official amendments since, technically it wasn't supposed to be changed to A in the first place? I will do this if necessary, just seems like red-tape that wasn't supposed to exist in the first place.

Respectfully,

Kim Daniel

*Radiation Safety Officer &
Acting Environmental Coordinator*

**National Center for Toxicological Research
Regulatory Compliance & Risk Management
U.S. Food and Drug Administration**

Tel: 870-543-7640

Mobile: 870-718-3858

Mobile: 501-200-2537

E-Mail: Kimberly.Daniel@fda.hhs.gov





ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Kimberly D. Daniel
Radiation Safety Officer
Department of Health and Human Services
Food and Drug Administration
National Center for Toxicological Research
3900 NCTR Road, HFT-2
Jefferson, AR 72079

Date

05/20/2020

License Number(s)

03-15093-01

Mail Control Number(s)

618953

Licensing and/or Technical Reviewer or Branch

C. Hill

This is to acknowledge receipt of your: Letter and/or Application Dated: 05/05/2020

The initial processing, which included an administrative review, has been performed.

Amendment Termination New License Renewal

There were no administrative omissions identified during our initial review.

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

The following administrative omissions have been identified:

[Empty box for administrative omissions]

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

**Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140**

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 03610
Status Code: Pending Amendment
Fee Category: 3L
Exp. Date: 10/31/2032
Fee Comments: 3E ADDED 8/13/92
Decom Fin Assur Reqd: Y

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: Department of Health and Human Services
Received Date: 05/05/2020
Docket Number: 3008559
Mail Control Number: 618953
License Number: 03-15093-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____

Agency: NRC

WBL WORKSHEET

DOCKET NUMBER: 3008559 LICENSE NUMBER: 03-15093-01 STATUS: Pending Amendment

MAIL CONTROL NUMBER: 618953 RECEIPT DATE: 05/05/2020 ACTION TYPE: Amendment

DUE DATE: 08/03/2020 INST. CODE: 15093 LICENSE REGION: Region 4

LICENSE TYPE: 30 ENTITY TYPE: G LICENSE GROUP: Academic

ISSUE DATE: ORIGINAL DATE: 06/13/1988 EXPIRATION DATE: 10/31/2032

DECOMMISSIONING CATEGORY: Group 2 LAST ISSUE DATE:

LICENSEE NAME: Department of Health and Human Services DECOM FIN ASSUR REQD: Y
SUBM: Y

MAILING ADDRESS LINE1: 3900 NCTR Road CONT PLAN REQD: N APPRV: N

MAILING ADDRESS LINE 2: HFT-2

CITY: Jefferson STATE: AR ZIP: 72079

CONTACT PERSON: PREFIX: Ms. FIRST NAME: Kimberly MIDDLE INITIAL: D.

LAST NAME: Daniel SUFFIX:

JOB TITLE: Radiation Safety Officer PHONE: 870-543-7640 FAX: EMAIL: kimberly.daniel@fda.hhs

BILLING ADDRESS LINE 1: 3900 NCTR Road

BILLING ADDRESS LINE 2: HFT-2

CITY: Jefferson STATE: Arkansas ZIP: 72079

BILLING CONTACT PERSON: FIRST NAME: MIDDLE INITIAL: LAST NAME:

PHONE: EMAIL: FAX:

PRIMARY PGM CODE: 03610 SECONDARY PGM CODE:

INSPECTION REGION: Region 4 PRIORITY: 3

RSO: PREFIX: FIRST NAME: Kimberly MIDDLE INITIAL: D. LAST NAME Daniel

SUFFIX: RSO JOB TITLE: Radiation Safety Officer

RSO PHONE: 870-543-7640 RSO FAX: 870-543-7635 RSO EMAIL: kimberly.daniel@fda.hhs.gov

STATES WHERE USE IS AUTHORIZED: 1
0- ALL LISTED STATES
1- SAME AS STATE IN ADDRESS
2- ALL STATES
3- NON-AGREEMENT-STATES

AUTHORIZED STATES (USE ONLY IF ABOVE IS ZERO):