



CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU Cynthia Myers		DATE OF CONTACT 10/17/2019	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING	
E-MAIL ADDRESS cynthia.r.myers@dupont.com		TELEPHONE NUMBER (989) 636-4110		
ORGANIZATION DDP Specialty Electronic Materials US, Inc.		DOCKET NUMBER(S) 030-39163		
LICENSE NAME AND NUMBER(S) DDP Specialty Electronic Materials US, Inc. 21-35537-01		MAIL CONTROL NUMBER(S) NA		
SUBJECT Additional Information Required to Address Incoming NRC Inquiries				
<p>SUMMARY AND ACTION REQUIRED (IF ANY) This is a record of the conversation between Laura Cender and Cynthia Myers as a follow-up to the multiple inquiries that have been raised regarding material and locations authorized on the DDP Specialty Electronic Materials US, Inc. materials license.</p> <p>Please provide a response to each of the following items:</p> <ol style="list-style-type: none"> 1. SHD-30 Device with Modified Shutter <ol style="list-style-type: none"> a. Confirm device model, including if the device is really model SHD-30 or SHD, isotope, and activity. b. Provide a copy of the sealed source and device registry from the manufacturer for this device. c. Submit any documentation (emails, etc.) you have from the manufacturer regarding this modified shutter condition. d. Please clarify how long this condition has existed, or been known to this licensee. e. Please provide photos that show the current arrangement if available. f. Please confirm that if this wire were to fail, the shutter would move into the safe/closed position. g. Please describe the area where this gauge is used, and if workers are located in the surrounding area. h. Are you able to still perform the 6 month shutter checks required by Condition 16.A. of the license? 				
NAME OF PERSON DOCUMENTING CONVERSATION Laura Cender				
SIGNATURE <i>Laura B. Cender</i>			DATE OF SIGNATURE 10/17/2019	

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

DDP Specialty Electronic Materials US, Inc.
21-35537-01

MAIL CONTROL NUMBER(S)

NA

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

2. Leaking Nickel-63 source

- a. Please provide the facility, address, and license number for the location where the leaking Ni-63 source originated.
- b. Provide the date that the device was sent to the manufacturer.
- c. Provide the current location of the device/leaking source.
- d. Describe who packed the sealed sources for transport to the manufacturer? I.e. did the manufacturer send a representative to package the device or was it packaged by the license holder?
- e. Provide any leak test results, including before and after transportation of the source.
- f. Has a notification report been filed for the leaking source?
- g. Who was the responsible owner of the sealed source at the time leaking was discovered?

3. Ion Exchange Resins

- a. Please confirm that you understand that your current NRC license only permits NI-63 sealed sources for use in Agilent Technologies Model G2397 devices to be used at the Larkin Laboratory. The license does not permit receipt of radioactive ion exchange resin material. Regulated radioactive material cannot be received at a facility listed in Condition 10 of the license if the material is not authorized in Items 6-9 of the license.
- b. Please describe the systems that use these resins are used with at nuclear power plants and describe the potential that exists for the resins to become contaminated.
- c. Please describe the procedures that are in place to ensure radioactive resin material is not shipped to your facilities.
- d. Please confirm if these resins are shipped back to the power plants after the testing is performed or if the resins are disposed of onsite.

4.. Tritium Sealed Sources

- a. I understand from our conversation today that the devices you are interested intending to acquire are not custom sources and devices built by the manufacturer to your unique specifications. In this case, as the manufacturer has not submitted a sealed source and device registry for these devices the equivalent information to what would normally be listed in th registry must be provided by the device recipients. Attached is a list of the information that will be required to license these devices.

Information to be supplied regarding licensing of a custom device:

1. Device Manufacturer and Distributor
 - a. Provide the name of the device manufacturer and distributor.
 - b. Include the name and function of any other companies involved in the manufacture and distribution of the device.
2. Model Number, Sealed Source or Device Type, and Principal Use Code
 - a. State the model number designation for the custom device.
 - b. State the radionuclides requested and the maximum activity of any isotope to be used.
 - c. Provide the Sealed Source and Device Registration number for the sealed source requested.
 - d. Provide the maximum time interval to be permitted between leak tests and who will perform the analysis.
3. Conditions of Use
 - a. Describe the location of use.
 - b. Describe the types of users of the device, and the occasions when individuals may in close proximity to the custom device and the frequency of these occasions.
 - c. Evaluate the likely environmental conditions that the gauge will be subjected to during normal use and likely accident conditions during use, handling, storage and transportation.
 - i. Consider corrosion, vibration, impact, flooding, excessive high or low temperatures or thermal cycling, exposure to moisture, etc.
 - d. Provide the estimated working life of the device.
4. Construction of the Product
 - a. Describe the construction aspects of the product, including components of the product, materials of construction, dimensions, assembly methods, source containment and shielding, and operation of the product and its safety features.
 - b. Provide a brief written description that includes the following information
 - Overall operation of the product
 - Identification of primary components and safety features
 - Type of installation, including method of attachment to its mounting if installed in a fixed location and the means of relocation if portable
 - Primary construction materials used for the product's structure and integrity and for its safety features
 - Accessibility of the radiation beam during use
 - Means of providing containment, radiation safety, and shielding of the radiation source, including shutters or other movable shielding
 - Location and operation of on/off or shielded/exposed indicators
 - Identification of other design features that protect the product from abuse or tampering
 - c. Design and construction data should be sufficient to allow the reviewer to fully understand the construction and operation of the product and its components and safety features and to evaluate the products safety and integrity.
 - d. Drawings of safety-related parts and components should (1) be fully dimensioned with tolerances, (2) include identification of the safety-related parts, (3) indicate the materials of construction or refer to a materials specification sheet or list, (4) indicate fabrication and assembly methods, and (5) include a drawing number and revision date

or number. Parts related to safety include those parts or components that provide primary containment, safety, and shielding of the radioactive material or sealed source.

- e. Applicants should also provide drawings and descriptions of nonsafety-related components and parts that contribute to the product's safety or integrity or both. These drawings should include sufficient descriptive information to determine how the components contribute to the safety and/or integrity of the product, how the component is integrated with other components of the product, and whether the non-safety related components could degrade the effectiveness or usefulness of safety related components.
- f. The applicant should describe all special design features that protect the product from abuse, control the hazard from direct or scattered radiation, and discourage unauthorized access to the source. The application should address accessibility of the radiation beam during use, including the size of openings or air gaps that could allow any part of a human body to enter the radiation beam, and any protective measures, additional guards, or installation requirements designed to prevent accessibility of the radiation beam during use.

5. Prototype Testing

- a. An applicant must provide information that verifies that the product design will maintain its integrity when subjected to conditions of normal use and likely accidents that could occur during use, maintenance, storage, handling, and transportation. This could be in the form of one or a combination of the following:
 - i. Actual testing of a device prototype.
 - ii. Performance of an engineering evaluation that consists of a systematic analysis of the products design and materials to determine the products ability to maintain its integrity when subjected to likely accident conditions.
 - iii. An analysis of the operational history of the device model.
 - iv. Comparison to a similar device that has been reviewed and registered.

6. Labeling

- a. Provide a description of the labeling of the custom device and sealed source, including the information contained on the label, materials of construction for the label, and the location where the label is attached.

7. Radiation Profiles

- a. Provide the maximum radiation levels around the product when it contains the maximum allowable quantity of each nuclide or combination of nuclides. Include the maximum radiation levels on the product surface, at 5 cm, 30 cm, and 100 cm from the custom device.
- b. Provide radiation levels when the device is in the open and closed positions.

8. Quality Assurance and Quality Control

- a. Provide details of the QA program that will be implemented to ensure the product is manufactured and distributed as described.

9. Installation, Servicing and Instructions to Users

- a. Describe who will perform the device installation, and performing non-routine maintenance activities with the custom device.
- b. Describe the training that will be provided to the authorized users of the custom device.
- c. Provide copies of operational, maintenance, and emergency procedures that will be used.

Cender, Laura

To: Cender, Laura
Subject: RE: RE: RE: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

From: Cender, Laura
Sent: Thursday, October 17, 2019 3:34 PM
To: Myers, Cynthia R <cynthia.r.myers@dupont.com>
Subject: RE: RE: RE: RE: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

Hello Cindy,

Attached is a record of our conversation this afternoon detailing the additional information required for each topic we discussed. Also attached is the outline of information required to license the tritium devices that do not have a sealed source and device registry through the manufacturer.

As there are some potential safety concerns associated with the SHD-30 device with the modified shutter and with the leaking Ni-63 source I do request that you submit a signed and dated response addressing those items by no later than Friday Nov. 1, 2019. If additional time is needed to gather information or to address certain requested items please feel free to let me know.

If you have any questions in the meantime please feel free to reach out to me at 630-829-9712 or send me an email.

Thank you,
Laura

Laura Cender
U.S. Nuclear Regulatory Commission
Materials Licensing Branch
E-mail: Laura.Cender@nrc.gov
Phone: (630) 829-9712

From: Myers, Cynthia R <cynthia.r.myers@dupont.com>
Sent: Thursday, October 17, 2019 10:56 AM
To: Cender, Laura <Laura.Cender@nrc.gov>
Subject: [External_Sender] RE: RE: RE: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

Wonderful! Thank you. I will call you then.

Cindy

From: Cender, Laura [<mailto:Laura.Cender@nrc.gov>]
Sent: Thursday, October 17, 2019 11:50 AM
To: Myers, Cynthia R <cynthia.r.myers@dupont.com>
Subject: [EXTERNAL] RE: RE: RE: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

Sure, that will work for me. You can call me at 630-829-9712 when you are ready.

Thank you,
Laura

From: Myers, Cynthia R <cynthia.r.myers@dupont.com>
Sent: Thursday, October 17, 2019 10:45 AM
To: Cender, Laura <Laura.Cender@nrc.gov>
Subject: [External_Sender] RE: RE: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

Laura,
Would 3:30 be a good time for you?

Cindy

From: Cender, Laura [<mailto:Laura.Cender@nrc.gov>]
Sent: Thursday, October 17, 2019 11:43 AM
To: Myers, Cynthia R <cynthia.r.myers@dupont.com>
Subject: [EXTERNAL] RE: RE: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

Hello Cindy,

Thank you for your patience. I have looked further into each item we have discussed and I am ready to set up a phone call to discuss what we need to move forward. I am available this afternoon after 3:00 Eastern, or any time tomorrow.

Please let me know when you are available, and we can also schedule for next week if necessary.

Thank you,
Laura

Laura Cender
U.S. Nuclear Regulatory Commission
Materials Licensing Branch
E-mail: Laura.Cender@nrc.gov
Phone: (630) 829-9712

From: Cender, Laura
Sent: Thursday, October 10, 2019 3:21 PM
To: Myers, Cynthia R <cynthia.r.myers@dupont.com>
Subject: RE: RE: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

Thank you Cindy, I appreciate your prompt response. I am still working with a few individuals to determine the information that we will need to move forward with each item that you have brought to my attention. To move forward we will likely need another phone conversation and I will reach out to you next week to set up a time.

Respectfully,
Laura Cender

Laura Cender

U.S. Nuclear Regulatory Commission
Materials Licensing Branch
E-mail: Laura.Cender@nrc.gov
Phone: (630) 829-9712

From: Myers, Cynthia R <cynthia.r.myers@dupont.com>

Sent: Thursday, October 10, 2019 11:41 AM

To: Cender, Laura <Laura.Cender@nrc.gov>

Subject: [External_Sender] RE: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

Ms. Cender,

Thank you for your phone discussion regarding my concerns. I have numbered them for clarity.

1. Please find enclosed an email chain regarding the addition of H-3 Tritium sources we discussed. I had believed I needed to add these sources to the license since the manufacturer did not have a distributors license and does not have an SSDR. I am not certain there was clarity of the new sources not having an SSDR in writing. Prior to finalizing our license, I spoke with Sara Forster via phone and she had indicated these new H-3 sources and our old H-3 sources were not required to be on our license and had been removed. In my July email linked above I was only asking for written documentation in case there was question in the future. Because they were not required to be on our license these sources have since been purchased but have not yet been delivered. All the information that I have on the new sources is enclosed in the email chain above.
2. On our license 9C the incorrect model was listed. The correct model is SHD-30. Please find enclosed the request to update our license. This is the sealed source I spoke with you about on the phone regarding the spring action pin that has been replaced with a piece of wire. We have reached out to the manufacturer for repair and the part we need is no longer being made. They have indicated that this wire being used to hold the shutter open still allows for the source to be isolated in the same manner as if the pin was there however they asked that we reach out to you so that you were aware. The source was manufactured in 1989 and is beyond its half-life but is functioning appropriately.
3. 6D of our license includes two Nickel-63 sealed sources. We now will only have one which will be at the 1382 location. There will not be a source at the Larkin Lab location.
4. The Larkin Lab location is at a separate address from our Michigan Operations location. They are performing testing on non-radioactive ion exchange resin bead samples that are received from nuclear power plants. They receive 250 ml to 1L samples and can receive up to 6 samples at one time. These resin beads are not in contact with radioactivity and would only be radioactive in the instance of a system failure. These samples go through extensive sampling before being released for testing even though no radiation is expected. The laboratory testing that we would like to do was performed at a different location outside of Michigan and they have never had a sample that was radioactive. However, some plants in some states require us to have a license in order to send us samples. In our lab these samples would be tested by first cleaning the sample by an acid or base wash and then performing physical properties tests on the resin beads. If we remove the sealed source from #3 from our license then they would no longer have a license covering their address.
5. I have also included documentation requesting address changes. Thank you.

I hope I have not missed anything. There is quite a lot to look at. Thank you so much for your help! I really appreciate it.

Cindy Myers

From: Myers, Cynthia R [<mailto:cynthia.r.myers@dupont.com>]

Sent: Wednesday, October 02, 2019 3:23 PM

To: Myers, Cynthia (C) <CRMyers@dow.com>

Subject: Fw: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

This email originated from outside of the organization.

From: Forster, Sara <Sara.Forster@nrc.gov>

Sent: Tuesday, September 24, 2019 12:18 PM

To: Myers, Cynthia R <cynthia.r.myers@dupont.com>

Subject: [EXTERNAL] RE: DDP Specialty Electronic Materials US, Inc., NRC License No. 21-35537-01, Dkt. No. 030-39163

Dear Ms. Myers:

I am following up on your inquiry from July 2019. From my review of the NRC's Web-Based Licensing system, we do not appear to have an open action for your license. Accordingly, to amend your license to add a new model gauge and sources, please send a signed and dated letter in support of that request. If the sources and devices are not included in the Sealed Source and Device Registry (SSDR), or if they will not be used in accordance with the SSDR, please include additional safety information with your request. Additional details must be sufficient for the NRC to confirm that the proposed use will not compromise the source integrity or shielding, or other components of the device critical to radiation safety.

In addition to this request, we are following up on the authorization for the use of Model SHLD-45 fixed gauging devices, as listed on Item No. 9.C. of your radioactive materials license. Could you please confirm that the model number as listed is correct? If so, please also provide a copy of the SSDR certificate from the manufacturer, for that device. If not, please provide a signed and dated letter requesting a revision to the model number, as listed on the license.

Sincerely yours,

Sara A. 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

Facsimile: (630) 515-1078



From: Myers, Cynthia R <cynthia.r.myers@dupont.com>

Sent: Thursday, July 25, 2019 11:02 AM

To: Forster, Sara <Sara.Forster@nrc.gov>

Subject: [External_Sender] License questions

Miss Forster,

I provided the above request to you for the addition of tritium sources to our license. These sources were not added to our license. I had requested addition due to the manufacturer not having a distributor license or a specific license. Can I please have verification in writing from you for future reference that these sources do not need to be listed on our license. Thank you so much.

Cindy Myers