

June 23, 2014

Elizabeth Ullrich, Senior Health Physicist
Commercial, Industrial, R&D and Academic Branch
Division of Nuclear Materials Safety
US NRC Region I Office
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

Subject: Widetronix Response to NRC Questions in Email Dated April 17, 2014

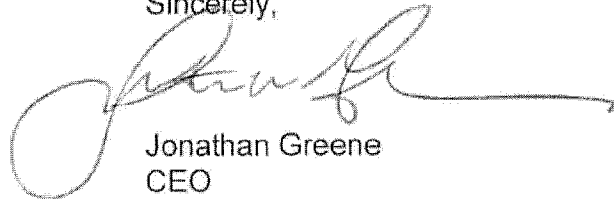
Re: NRC License No. 31-35133-01
Docket No. 030-38719
Control No. 583285

Dear Ms. Ullrich,

Thank you for your consideration of Widetronix's license request to demonstrate our betavoltaic power sources at temporary job sites where the NRC maintains jurisdiction. We have taken the time to respond to all the questions you raised regarding our license application. If the responses are sufficient for you to issue us a license, we would like to request an advanced copy of the license to review before it is issued to ensure that it suits our purposes.

If you additional information, please contact Mr. Samuel Portnoff by phone at (607) 330-4752 or by email to sportnoff@widetronix.com.

Sincerely,



Jonathan Greene
CEO

Widetrnix Response to NRC Questions in Email Dated April 17, 2014

NRC License No. 31-35133-01

Docket No. 030-38719

Control No. 583285

1. Item 5 of you application states that the material is in the form of sealed sources or plated foils, however, you did not provide the manufacturer or model number of the sealed sources in accordance with 10 CFR 30.32(g). In addition, Item 10.11 states that the sealed sources or plated foils are not registered. As required by 10 CFR 30.32(g)(1), identify the manufacturer and model number as registered with the NRC pursuant to 10 CFR 32.210, or provide the information identified in 10 CFR 32.210(c) for the sealed sources or foils you are requesting for the license.

Widetrnix Response – Widetrnix is licensed for plated foils and unspecified sealed sources under NY License C5379, however we have no sealed sources in our inventory and thus have no model/serial number information to provide. The listing of unspecified sealed sources is for future use with the requirement under our NY license that registered sealed sources may be possessed. The NY requirement for the possession of registered sealed sources in the future will also apply to this NRC license.

The plated foils are the primary subject of this NRC license application. These foils are integrated with a betavoltaic device and then are packaged in a hermetically sealed semiconductor package. The hermeticity of these packages has been tested and they maintain their seal in accordance with ISO 9978 6.1.2. In addition, the betavoltaic packages have been wipe monitored over time, dating back to October 2012, and have maintained radiation levels below our leak test limits (i.e. below our historical Minimum Detectable Activity of approx. 40 dpm or 1.8×10^{-5} microcurie).

2. Item 5 of your application lists the maximum possession limit for all sealed sources or plated foils for each radionuclide. Please specify the maximum quantity of material in any given sealed source or plated foil, and the maximum total of material needed for possession of all sealed sources or plated foils, for each radionuclide.

Widetrnix Response – For clarification, the information in Item 5 applies only to those sealed sources or plated foils that are in Widetrnix's possession when visiting customer sites in NRC jurisdiction locations. The limit in Item 5 does not apply to Widetrnix's total possession of RAM at its home facility in NY State or to possession while at customer sites under the jurisdiction of NY State.

Widetrnix is requesting Tritium (H-3) at up to 0.25 curies per foil, up to 2.5 curies per packaged betavoltaic, or any combination of plated foils and/or sealed sources up to a total of 20 curies for use at customer sites in NRC jurisdiction locations.

Widetrnix is requesting Nickel-63 (Ni-63) at up to 0.04 curies per foil, up to 0.4 curies per packaged betavoltaic, or any combination of plated foils and/or sealed sources up to a total of 20 curies for use at customer sites in NRC jurisdiction locations.

The foils have a range of activity levels and are placed in a device in a mix of configurations to achieve a desired betavoltaic power output. Since we will not know future customer needs, our original application only listed maximum amounts.

3. Item 6 of you application requests authorization to take the licensed material in the form of power sources to temporary job sites for demonstrate their operability and effectiveness. Although Item 10 of you application includes many areas that are related to the use at temporary job sites, additional information is required as follows:

a. Item 9 states that licensed materials will remain under the direct control of an authorized Widetrnix employee at all times at temporary job sites, and will not be left unattended at any time. Confirm if conditions might exist for secured storage at temporary job sites, in the event of the authorized worker taking a lunch break or other interruption, and provide appropriate procedures.

Widetrnix Response – Widetrnix will maintain control of the betavoltaic while demonstrating the device at a temporary job site. In the event of the authorized Widetrnix worker taking lunch break or other interruption, the device(s) will be stored in a locked container and secured to an immovable object at the customer facility by chain or wire cable of sufficient thickness to prevent casual breakage. Widetrnix personnel will keep control of the keys/combinations to the locks.

b. Item 10.7.7 states that a physical inventory will be performed at 6-month intervals. However, there is no item that describes your procedures for tracking licensed materials that are shipped to temporary job sites, and returned to the facilities. Typically, licensees that use materials at temporary job sites maintain a record of the material that was taken to the temporary job site, identifying it by serial number and the date and name of the individual responsible for the material at the temporary job site, and the date that the item was returned to storage. Confirm that you will develop procedures that track licensed materials that are in use at temporary job sites.

Widetrnix Response – Widetrnix confirms that, under our NY State license, our existing inventory procedure requires that we log the location of all foils and/or sources. An entry is made to indicate the shipping to a customer site (with foil, source, and/or device serial numbers and the date) and an entry is made when the RAM is returned to Widetrnix's NY facility. In addition, Widetrnix maintains copies of shipping papers in accordance with DOT regulations that also assist in providing traceability of RAM.

c. Your procedures should include a means to ensure that the temporary job site is free of residual contamination from the sources used during your demonstration activities

with the licensed materials. If you are not planning to perform surveys at the temporary job site, as indicated in Item 10.4.2.3 of your application, provide an alternate means of determining that facilities are free of contamination, or a justification including data, demonstrating that surveys are not required.

Widetrnix Response – In accordance with DOT regulations, Widetrnix performs a contamination check of all packages leaving a customer's site prior to shipment. The package contamination check also includes a wipe test of the betavoltaic devices before placement inside the shipping package. To perform this test when betavoltaic devices are ready to be shipped back to Widetrnix's NY facility, Widetrnix travels with a portable liquid scintillation counter, calibration standard(s) for H-3 and/or Ni-63, and other needed supplies. The Widetrnix operational removable contamination limit is 100 dpm/100 cm² and a wipe of the devices that is below this limit is proof that the customer's site is free of contamination from the betavoltaic packages.

4. Item 7 of your application states that the Radiation Safety Officer is Jeffrey Leavey. Mr. Leavey is currently the Radiation Safety of a Broad Scope program at Penn State University in University Park, PA.

a. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

Widetrnix Response – Mr. Leavey has no other commitments as RSO with other licensees beyond Penn State University and Widetrnix. Mr. Leavey is available continuously via telephone, email etc. Mr. Leavey is physically at Widetrnix regularly once per month to perform survey and other regulatory duties and is available at other times to visit as needed. Mr. Leavey typically spends 4 – 5 hours per month at the Widetrnix facility.

b. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

Widetrnix Response – Mr. Samuel Portnoff is the Widetrnix on-site representative with continuous access to Mr. Leavey via telephone, email, etc. Mr. Portnoff has been with Widetrnix since the start of RAM usage and has assisted Mr. Leavey with the development of the radiation safety program.

c. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

Widetrnix Response – Mr. Leavey's overall availability is described in the responses to 4a and 4b above. The NRC will need to specify Mr. Leavey's response time to what facility.

5. Item 9 of your application did not describe the instrumentation that you will use to perform contamination and leak test surveys. Please provide a description of the equipment that you will use.

Widetronix Response – Widetronix uses a Triathler portable liquid scintillation counter (LSC) manufactured by Hidex (see <http://www.hidex.com/media/8046/triathler2009.pdf>) for analyzing samples collected when a worker is performing surveys and leak tests. Widetronix also possesses at least one (1) pancake GM meter for general lab checks.

6. Please describe your instrument calibration procedures and the frequency of instrument calibration. If your instruments will be calibrated by the instrument manufacturer or a person specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State for instrument calibration, you only need to specify the name of the firm and the license number that authorizes the firm to perform calibration services, and the calibration frequency. If you intend to calibrate your own instruments, please submit your calibration procedures including calibration frequency. Appendix M of NUREG-1556, Volume 7 contains calibration procedures acceptable to the Commission and may be helpful to you in developing your response.

Widetronix Response – The Triathler LSC is calibrated before each use using NIST or vendor traceable H-3 and Ni-63 standards when wipes are counted. LSC efficiency is simply: $\text{Eff} = (\text{Standard CPM}) / (\text{Standard DPM})$ and $\text{Wipe DPM} = (\text{Wipe CPM} - \text{Background}) / \text{Eff}$. The H-3 efficiency is approximately 40% and the Ni-63 efficiency is approximately 50%. Widetronix will travel with H-3 and/or Ni-63 standards to calibrate the LSC prior to measuring wipes. At customer sites the LSC is considered functional if the H-3 and/or Ni-63 LSC standards when counted provide the correct historical efficiencies. The Triathler has been shipped to several customer sites and has a proven record of being fully functional in the field without the use of standards.

The Widetronix GM meter(s) are calibrated by Radiation Safety and Control Services under New Hampshire license 381R. These meters are calibrated annually.

7. Please provide your leak test procedures. Appendix R of NUREG-1556, Volume 7 contains model leak test procedures and may be helpful to you in developing your response. If you select to have another person perform the leak test, please submit the name of the person and the license under which they are authorized to perform this activity.

Widetronix Response – Widetronix currently has no registered sealed sources in inventory. All of the current betavoltaic packages are considered to be and treated as unsealed RAM as described and detailed above. However, before these packages would be taken to NRC jurisdiction for demonstration they would be leak tested in house following Chapter 10 of Widetronix's procedure manual approved under our NY state license. A copy of this procedure is in Attachment 1 and the leak test record form is shown in Attachment 2.

Attachment 1 – Widetronix Procedures Manual Chapter 10

NYS DOH Required Surveys and Sealed Source Leak Tests

Two types of surveys are required at Widetronix: the after-use check survey and the NYS DOH required monthly contamination survey. In addition, sealed sources require leak tests every six months.

After Use Check Survey

The after use check survey is required when radioactive material use is completed, or at the end of the day when work continues into the next day. This check consists of a wipe survey for Ni-63 and H-3, and/or GM meter scan for Pm-147.

A record of this check is not required to be kept but provides information to the user whether additional clean up is necessary or not.

NYS DOH Required Survey

CR 38.22(e) (or Part 16.10.a.3) specifies monthly (or more frequent) surveys where unsealed radioactive materials are used. The survey consists of a GM meter scan of the use area for Pm-147 and a wipe test for Ni-63, H-3, and Pm-147. Completed survey forms will be review by the RSO and maintained for inspection by the DOH.

Survey Technique

The method for performing wipe tests will be sensitive enough to detect 100 dpm/100 cm² for beta/gamma emitters (Minimum Detectable Activity or MDA).

To perform a wipe test:

1. Obtain a monthly survey form and a wipe location map of the area(s) to be tested.
2. Use a piece of 2.5 cm filter paper (or similar) dry or moistened slightly with water.
3. Wipe the area to be tested with a big "S" curve motion using moderate pressure. The diameter of the filter paper over the path length of a large "S" shape will give about 100 cm² coverage.
4. Placed the wipe in a scintillation vial, "dirty side" up. This increases the efficiency, especially for H-3.
5. Add approximately 5 ml of scintillation fluid and count.

6. Include a blank and an appropriate calibrated standard(s) for determining efficiency. An H-3 standard is used for H-3, a C-14 standard is used to represent Pm-147, and Ni-63 is used for Ni-63.
7. Complete the survey form, convert CPM to DPM and record the count data on the form. Attach the LSC printout to the form. Complete the Minimum Detectable Activity (MDA, see Chapter 13) calculation and record on the survey form.
8. Contamination limits are in Chapter 6 and the back of the survey form.
9. Give the survey form to the RSO for review and sign-off. File the completed form.

LSC Calibration Standards for Use at Widetronix

C-14 will be used to represent Pm-147 because they have similar average energies: 49 keV for C-14 and 62 keV for Pm-147. Commercially available H-3 and C-14 standards will be used.

For Ni-63, a standard will be prepared in-house using a known activity Ni-63 solution placed in approximately 10 ml of LSC fluid. The standard will have a target activity of 2000 to 3000 dpm.

Sealed Source Leak Tests

Widetronix will perform its own leak tests on sealed source modules in Widetronix's possession (both in-house development designs and those listed in the NRC/State Sealed Source Registry) using the procedure below.

A leak test will be performed immediately after a module is fabricated (if fabricated in-house), immediately upon receipt (if received from an outside fabricator), and every 6 months thereafter for sealed sources and/or modules in Widetronix's possession.

1. Obtain a leak test check form, one for each module to be tested.
2. Use a piece of 2.5 cm filter paper (or similar) dry or moistened slightly with water. Alternatively, a swab may be used in place of filter paper.
3. Wipe the entire surface area of the module to be tested using moderate pressure.
4. Placed the wipe in a scintillation vial, "dirty side" up. This increases the efficiency, especially for H-3.
5. Add approximately 5 ml of scintillation fluid and count.
6. Include a blank and an appropriate calibrated standard(s) for determining efficiency. An H-3 standard is used for H-3, a C-14 standard is used to represent Pm-147, and Ni-63 is used for Ni-63.

7. Count the wipe for a sufficient length of time to ensure the minimum detectable activity (MDA, see Chapter 13) is below 0.001 microcurie. This may require a preliminary count to obtain the parameters necessary to determine the MDA.
8. Complete the survey form, convert CPM to microcuries and record the count data on the form. Attach the LSC printout to the form. Complete the Minimum Detectable Activity calculation and record on the survey form.
9. The leak test limit is 0.005 microcuries (185 Bq or 11,100 dpm) (Part 16.10(a)(4) or CR 38.22(f)). If any test exceeds this limit, immediately notify the RSO and place the source/module in a sealed container (e.g. zip-lock bag).
10. Give the survey form to the RSO for review and sign-off. File the completed form.

Attachment 2 – Widetronix Leak Test Record Form

SEALED SOURCE/MODULE LEAK TEST REPORT

1. License Holder: **Widetronix** License Number: **C5379**

Leak Test By: _____ Test Date: _____

2. Sealed Source/Module Identification

Source/Module Model:

Source/Module Serial:

3. LSC Efficiency

Source/Module Isotope (circle): H-3 Ni-63 Pm-147 Specify: _____

Efficiency (%):

4. Leak Test Results

Description	Leak Test Results			
	REQUIRED All Isotopes			
Instrument Type	LSC			OTHER
Units	gross cpm	NET dpm	NET µCi	
Background		----	----	
MDA	----			
Source / Module				

Attach LSC printout to this form.

Equation:

$$dpm = \frac{grosscpm - backgroundcpm}{efficiency(cpm/dpm)}$$

5. Leak Test Limits: 0.005 microcuries

6. RSO Review

RSO Signature: _____ Date: ____ / ____ / ____

7. Notes: