

From: david_bennett@agilent.com
To: [Ullrich, Elizabeth](mailto:Ullrich.Elizabeth)
Cc: esmeralda_anaya@agilent.com; david_bennett@agilent.com
Subject: [External_Sender] FW: your request for an exemption
Date: Monday, May 04, 2020 4:05:16 PM
Attachments: [image001.png](#)
[4-7-2020-NMSS COVID-19 Response Letter to Licensees.pdf](#)
[NRC-01 License.pdf](#)
[Part 30 Material Licensee Generic Exemptions.pdf](#)
[Untitled1.pdf](#)

Hi Betsy,

I hope I have answered your questions below correctly as I wasn't quite sure about the last one. Please let me know if you have any questions. I've also attached a copy of the current license and an exemption request letter in case you wish to have one.

I'm also going to send a separate request for temporary exemption for a biennial audit of our radioactive source supplier which is part of our QA program due to current travel restrictions.

Thanks,
Dave

From: Ullrich, Elizabeth <Elizabeth.Ullrich@nrc.gov>
Sent: Friday, May 01, 2020 2:00 PM
To: BENNETT,DAVID S (Agilent USA) <david_bennett@agilent.com>
Subject: your request for an exemption

David,

Your email was forwarded to Region I as a request for an exemption. At the time we discussed your issue (March 19), the NRC was not considering exemption requests. The attached letter dated April 7 is the first official document on the issue.

In order to complete your exemption request, I need you to:

- List the license condition that you are requesting an exemption from. List the condition number, and subpart if applicable. (As we discussed, if your sources are considered to be in storage, then you may not need an exemption from the leak test requirement, but you would have to leak test them prior to the next use if they are outside of the usual leak test period.) **Conditions 14.A. and Condition 15. As the chemists using the devices that require wipe and inventory are required to work from home, I would request that the ECDs under their control be considered as being in storage. No one can use their ECDs in their absence.**
 - If you require an exemption from commitments made in a letter listed on your license, provide the commitment and the date of the letter. **N/A**
 - If you require an exemption from a regulation, cite the specific regulation **10 CFR 30.34, section copied below from Part 30 Material Licensee Generic Exemptions (attached). Additionally, our SS&D (NR-0348-D-111-B), under LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE REQUIRES, requires 6 month wipe tests.**
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- Describe the actions you have taken to ensure that licensed materials are secured while you are restricted from access. **Licensed materials are maintained in electronic, access controlled labs in a building requiring electronic, access controlled badges.**

You may respond with this information directly to me by email. If you need to call me, best to send an email with a number where you can be reached. I am working from home.

Thanks,
Betsy

Betsy Ullrich, Senior Health Physicist
USNRC Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406
610-337-5040 (office)
240-704-4575 (cell)
Elizabeth.ullrich@nrc.gov

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Agilent Technologies, Inc.</p> <p>2. 2850 Centerville Road Wilmington, Delaware 19808</p>	<p>In accordance with the letter dated February 3, 2016,</p> <p>3. License number 07-28762-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date February 28, 2023</p> <hr/> <p>5. Docket No. 030-32792 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Nickel 63</p>	<p>7. Chemical and/or physical form</p> <p>A. Plated Foils (U.S. Radium Model LAB 508-1 and LAB 508-3)</p> <p>B. Foils and Plated Sources (Isotope Products Laboratories custom plated sources; DuPont Merck Pharmaceutical custom plated sources; AEA Technology custom plated sources; Eckert & Ziegler Isotope Products (formerly QSA Global) Model NBCD; Eckert & Ziegler Isotope Products Model NER-004P; or Bristol-Myers Squibb Medical Imaging (formerly DuPont Merck Pharmaceutical) Model NER-004P)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 4 curies and no single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State</p> <p>B. 100 curies and no single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State</p>
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9. Authorized use:

A. and B. Receipt of returned devices for disposal.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
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030-32792

Amendment No. 21

- B. Research and development as defined in 10 CFR 30.4; testing, production, and assembly of detector cells; demonstration of use of detector cells; and for distribution in detector cells to persons authorized to receive the licensed material pursuant to terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or any Agreement State.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Little Falls Center, 2850 Centerville Road, Wilmington, Delaware.
11. A. Licensed material shall be used by, or under the supervision and in the physical presence of, individuals who have received the training described in the letter dated October 31, 2013, and September 5, 2012.
- B. The Radiation Safety Officer for this license is David S. Bennett.
12. The licensee shall not use licensed material in or on human beings.
13. This license does not authorize distribution to persons licensed pursuant to 10 CFR 32.72 or 32.74; to persons exempt from licensing; or to general licensees.
14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- C. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- D. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

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- E. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- F. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
15. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Letter dated September 5, 2012 (ML12271A213)
- B. Letter dated January 22, 2013 (ML12291A842)
- C. Letter dated October 31, 2013 (ML13324A143)
- D. Letter dated September 9, 2015 (ML15273A391)
- E. Letter dated September 9, 2015 (ML15273A389)
- F. Letter dated February 3, 2016 (ML16053A461)

For the U.S. Nuclear Regulatory Commission

Date March 7, 2016

By

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Commercial, Industrial, R&D and Academic Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406
Monday, March 7, 2016 10:51:16

Material Licensee Generic Exemptions During the Emergency Caused by the COVID-19 Pandemic

04/13/2020

Regulation	Description of Exemption	Safety Basis (Open)	Safety Basis (Closed)	Exemption Language
		10 CFR 30.34 Terms and conditions of licenses		
10 CFR 30.34	The requirement in License Condition [number] to perform a physical inventory every 6 months;	This exemption is relatively short compared to the required 6-month interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required 6-month interval. Additionally, the extension of inventory time does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not using these instruments.	From the date of issuance of this letter for a period of 90 days, the licensee is exempt from the requirement in license condition [number] to perform a physical inventory of licensed material every 6 months. Inventories shall be completed within 30 days following the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to perform leak testing every 6 months or at the frequency specified in the SSD; <i>Note: The leak testing requirements specified in the SSD range from 6 months to 3 years.</i>	This exemption is relatively short compared to the required leak testing interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required leak testing interval. Additionally, the extension of the leak test time does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not using these sources.	From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempt from the requirement in license condition [number] to perform leak tests every 6 months. The licensee shall perform the required leak tests within 30 days of the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to perform surveys <i>Note: for companies who are still operating, make</i>	This exemption is relatively short compared to the required survey interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety	This exemption is relatively short compared to the required survey interval. Additionally, the extension of survey time does not constitute a significant increase in risk to public health and safety, because the licensee suspended	From the date of this letter for a period of 90 days, the licensee is temporarily exempt from the survey time interval required by license condition [number] . The licensee shall perform the required surveys within 7 days

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	<i>sure that this exemption is needed</i>		operations and is not using these instruments.	of the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to exchange dosimetry	This exemption is relatively short compared to the required dosimetry exchange interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required dosimetry exchange interval. Additionally, the extension of dosimetry exchange time does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not using equipment that would lead to accumulated dose.	From the date of this letter for a period of 90 days, the licensee is temporarily exempt from the dosimetry exchange requirement in license condition [number] . The licensee shall make the required dosimetry exchanges within 7 days of the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to provide radiation safety refresher training at intervals not to exceed 12 months	This exemption is relatively short compared to the required refresher training interval. The NRC notes that the licensee must continue to provide initial radiation safety training to each radiation worker. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required refresher training interval. Additionally, the extension of time between training does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not acting under the authority of its license.	From the date of issuance of this letter until for a period of 90 days, the licensee is temporarily exempted from the refresher training frequency requirement in license condition [number] . The licensee shall provide the required refresher training within 90 days of the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to perform instrument calibration	This exemption is relatively short compared to the required calibration interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required calibration interval. Additionally, the extension of time between instrument calibrations does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not using the instruments for which calibration is required.	From the date of this letter for a period of 90 days, the licensee is temporarily exempt from the calibration time interval requirement in license condition [number] . The licensee shall perform the required calibration within 7 days of the expiration of this exemption.

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10 CFR 30.34	<p>The requirement in License Condition [number] to hold Radiation Safety Committee meetings at intervals not to exceed [X] months;</p> <p><i>Note: this exemption should only be used for licensees that have suspended licensed activities.</i></p>	[Do not issue this exemption for companies that are still acting under the authority of their licenses]	The extension of time between Radiation Safety Committee meetings does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not acting under the authority of its license.	From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempted from the requirement in license condition [number] to perform Radiation Safety Committee meetings at intervals not to exceed [X] months. The licensee shall hold the required meeting within 30 days of the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to complete an annual program review at intervals not to exceed 12 months;	This exemption is relatively short compared to the required annual program review interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required annual program review interval. Additionally, the extension of time between annual program reviews does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not acting under the authority of its license.	From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempted from the requirement in license condition [number] to perform an annual program review at intervals not to exceed 12 months. The licensee shall perform the annual program review within 90 days of the expiration of this exemption.



Agilent Technologies

2850 Centerville Road
Wilmington, DE 19808

May 1, 2020

Director
U.S. NRC Region 1
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

Ref.: Request for Exemption From Certain Licensed Activities License 07-28762-01

Dear Director,

This is a formal follow-up to an e-mail exchange I had with Betsy Ulrich of the Region 1 office on March 19, 2020. On that date, I requested direction regarding our license requirement for performing six-month wipes and inventory (lines 14.A and 15 of the license referenced above) as both were scheduled during the month of March. Most of the employees needed to perform both the wipe and inventory have been and continue to be required to work from home until COVID-19 restrictions have been lifted by the Governor of the State of Delaware. As the radioactive devices covered by the license are not being used during the restriction, Ms Ulrich directed that we could postpone both wipes and inventory for those devices until the restrictions were lifted. A copy of the e-mail is available upon request.

Please let me know if you have any question regarding this issue

Sincerely,

David S. Bennett
RSO
302-636-8262
david_bennett@agilent.com