



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 19, 2020

EA-20-074

Mr. David S. Bennett
Radiation Safety Officer
Agilent Technologies, Inc.
2850 Centerville Road
Wilmington, DE 19808

SUBJECT: TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY
COMMISSION REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS*
32.210(f) AND EXERCISE OF ENFORCEMENT DISCRETION

Dear Mr. Bennett:

By e-mail dated May 6, 2020, (Agencywide Documents Access and Management System [ADAMS] Accession No. ML20129J872), Agilent Technologies, Inc. (Agilent), requested an exemption from Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210(f). Specifically, Agilent requests an exemption from the provision in its Sealed Sources and Devices Registration Certificate No. NR-0348-D-111-B that Agilent audit the plated source supplier every 2 years.

In its request, Agilent stated that due to the COVID-19 public health emergency (PHE) it was unable to perform a biennial audit of its source supplier due to PHE travel restrictions and limitations.

The exemption provision in 10 CFR 30.11(a) states:

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

The U.S. Nuclear Regulatory Commission (NRC) staff reviewed the request in accordance with 10 CFR 30.11(a) and finds that the criteria contained therein are met. The regulation from which Agilent is requesting exemption is 10 CFR 32.210(f).

The regulation in 10 CFR 30.11(a) authorizes granting of exemptions specific to Part 32. The NRC staff has determined that the granting of the requested exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. The NRC staff, therefore, finds that the granting of the requested exemption is authorized by law.

The NRC staff has also determined that the requested exemption allowing Agilent to postpone the biennial audit of its source supplier is acceptable because the 90-day period of the

exemption is short compared to the biennial audit period and does not constitute a significant increase in risk to public health and safety. In addition, the NRC notes that Agilent's source supplier maintains its own quality control program.

The NRC also notes that, absent the requested exemption, the licensee may be required to take actions that may be contrary to guidance on preventing the spread of the virus that causes COVID-19. Therefore, the NRC staff finds that the requested exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.

Based on the above findings, the NRC grants the following exemption for the specified period of time:

From the date of issuance of this letter for a period of 90 days, the licensee is exempt from the requirement to perform its biennial audit of its source supplier. The biennial audit shall be completed within 30 days following the expiration of this exemption.

In addition, by failing to perform the biennial audit by April 30, 2020, and by not receiving prior approval for an exemption from that requirement prior to the due date, Agilent is in apparent violation of 10 CFR 32.210(f). Section 3.5 of the NRC's Enforcement Policy (ADAMS Accession No. ML19352E921), states, in part, that the NRC may refrain from issuing a Notice of Violation based on the merits of the case after considering the guidance in the Policy and such factors as the age of the violation, the significance of the violation, and other relevant circumstances. Further, the NRC may "refrain from issuing enforcement action for violations resulting from matters not within a licensee's control." The NRC staff acknowledges that Agilent has experienced restrictions and limitations due to the COVID-19 PHE, limiting its ability to perform the audit by the due date. This impact is the result of state-issued restrictions on social distancing, including impacts on air travel, and thus is not fully within the licensee's control. Therefore, I have been authorized, after consulting with the Director, Office of Enforcement, to exercise enforcement discretion and not issue a violation in accordance with Section 3.5 of the Policy for violations involving special circumstances. Specifically, the NRC is exercising its discretion to forgo taking enforcement action against Agilent for its violation of 10 CFR 32.210(f), provided that the audit is completed no later than 120 days from the date of issuance of this letter.

An environmental assessment for this action is not required, because the exemption is categorically excluded under 10 CFR 51.22(c)(25)(vi)(C), and, according to 10 CFR 51.10(d), the exercise of enforcement discretion is not subject to Section 102(2) of the National Environmental Policy Act. In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

If you have questions, please contact Tomas Herrera at Tomas.Herrera@nrc.gov or 301-415-7138.

Sincerely,

David W. Alley, Branch Chief
Material Safety and Tribal Liaison Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Materials Safety
and Safeguards

Sealed Source and
Device Registration No. NR-0348-D-111-B

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DATE: May 19, 2020

ADAMS Accession No.: ML20133L537

***via e-mail**

OFFICE	NMSS/MSST	OGC	OGC	OE	NMSS/MSST
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DATE	5/8/20	5/18/20	5/18/20	5/19/20	5/19/20

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