



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001
February 19, 2015

Agilent Technologies
ATTN: Mr. David Hoppy
EHS Manager, Eastern Region
2850 Centerville Road
Wilmington, DE 19808

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, AGILENT TECHNOLOGIES,
INC., AMENDMENT REQUEST DATED JANUARY 15, 2015

Dear Mr. Hoppy:

This letter is in response to your application dated January 15, 2015, requesting to register new ECD Models G4597A and G4598A into NR-0348-D-111-B. In reviewing your application, we find that additional information is required to complete our review. In the enclosure to this letter, we have summarized the issues not addressed in your application.

Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with reasoning as to why that is appropriate.

Please submit the requested information within 30 calendar days of the date of this letter. If we have not received complete information within 30 days, we will consider your amendment request as having been abandoned by you. This is without prejudice to the submission of a complete new amendment request.

If you have any questions, please contact me at Maria.Arribas-Colon@nrc.gov or (301) 415-6026.

Sincerely,

/RA/

Maria Arribas-Colon, Project Manager
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Materials Safety
and Safeguards

Enclosure: As stated

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NAME	Maria Arribas-Colon	Tomas Herrera	Hipolito Gonzalez	Maria Arribas-Colon
DATE	02/13/2015	02/18/2015	02/18/2015	02/19/2015

OFFICIAL RECORD COPY

Agilent Technologies, Inc. Amendment Request dated January 15, 2015
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Agilent Technologies, Inc. amendment request dated January 15, 2015, and determined that additional information is needed. In order to continue with our review, please address the issues listed below. This information is required by 10 CFR 32.210 and described in the relevant guidance document NUREG-1556 Volume 3 titled "Applications for Sealed Source and Device Evaluation and Registration."

General

1. Please confirm that Legacy Supply Chain Survives will not distribute the Models G4597A and G4598A.

Description/Construction

2. Please submit a full set of engineering drawings and a detailed description of the construction of both Models G4597A and G4598A. The information should be sufficient to allow the reviewer to fully understand the construction, operations of the product and its components and safety features and to allow the evaluation of the product's safety, security and integrity. The drawing provided in Attachment 3 is not sufficient to conduct a safety evaluation for Models G4597A and G4598A. Drawings of safety critical parts should be fully dimensioned with tolerances, include identification of the safety critical parts and components, indicate all the materials of construction or refer to a materials specification sheet or list, indicate the fabrication and assembly methods.
3. Please summarize all the differences between Model G4597A and Model G4598A.
4. Address the issue of potential corrosion of the components due to the compositions of gases to which the instrument will be exposed.
5. In your letter, you mentioned that the Models G4597A and Model G4598A are tamper-proofed with special screws; however you did not provide any specific details. Provide details about the tamper proofing measures.
6. Please provide all the Gas Chromatograph Systems in which the Models G4597A and G4598A will be used.

Labeling:

7. Please state the location of the label.

Conditions of Use:

8. Please provide statements indicating the conditions of use of Models G4597A and G4598A, with regard to maximum allowable temperature, vibration, shock, corrosion, during use, handling, storage, and transport.

Enclosure

9. Agilent Technologies letter dated September 14, 2006, from Keith Morgan to the NRC, stated that an ECD is a consumable product and has a typical life expectation between 5 and 10 years. In your application, you stated that the working life of the ECD is “over 10 years.” Please clarify if “10 years” should be used as the maximum working life for all the ECD Models listed in your Registration Certificate NR-0348-D-111-B, instead of “over 10 years”.

Prototype Testing

10. The prototype testing information provided in Attachment 4 refers to the “GC oven” used to conduct the elevated temperature test. Please clarify this term.
11. The prototype testing information provided in Attachment 4, references to “ECD” or “ECD cell.” Please clarify whether the complete ECD was tested or just the cell that contains the radioactive material. If only the Ni-63 cell was tested, please explain how these test results are relevant to Models G4597A and G4598A.
12. The impact test information provided in Attachment 4, stated the specific parts of the product that were impacted were the anode, inlet, and vent. Please explain the rationale in choosing these three locations.
13. On page 3 of your application, you stated that prototype ECDs were tested against ISO 2919, obtaining a classification of C42211. ISO 2919 states that to achieve a temperature classification of 4, the product must be tested to -40 °C (20 min) and +400 °C (1 h) and thermal shock to 20 °C. However, based on the prototype testing information provided in Attachment 4, it does not appear that the test was conducted with these parameters. Please clarify this discrepancy.
14. The information provided in Attachment 4 states that the prototype ECDs were subjected to thermal, pressure, and impact tests. The ECD Models currently registered in NR-0348-D-111-B were subjected to additional tests such as vibration and drop tests. Please explain the rationale why these tests were not conducted in the Models G4597A and G4598A prototypes.

Accompanying Documentation

15. Please state whether leak tests and radiation surveys will be provided to the user.
16. Page 20 of the “Installation, Servicing, and Instructions to Users” manual provided in Attachment 6, states that the “Customer maintenance of the ECD is limited to installation, radioactivity leak testing, thermal cleaning, and removal of the ECD.” On Page 4 of your letter you stated that the “Field Service Engineers (FSEs) are permitted to install and remove the ECD and are not permitted to perform wipe tests. These statements appear to be in contradiction, please provide clarification.
17. Please state the specific services (maintenance, repair, leak testing, radiation survey, etc.) Agilent Technologies will be providing for the ECDs.

18. The NRC Regions and Agreement States information in the “Installation, Servicing, and Instructions to Users” manual (Pages 71 to 73) is not up-to-date (e.g. NRC Regional addresses, Agreement States information missing from the list). Please also note that as of October 2003, all radioactive material functions in NRC Region II were transferred to Region I. Provide a copy of the final “Installation, Servicing, and Instructions to Users” manual that contains the up-to-date information.