UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

August 28, 2001

Tom Zunino
Agilent Technologies.
2850 Centerville Road
Wilmington, DE 19808

RE: Amendment to Agilent Technologies registration certificates

Dear Mr. Zunino:

This is in reference to your letter dated March 5, 2001, and March 9, 2001, letters, regarding amendment to Agilent Technologies registration certificates. In order to complete our review, we need the following information.

1. Your March 5 letter informs us that Agilent has not been conducting two tests during fabrication as specified in the registration certificate commitments. Please indicate when this practice started, and report the total number of ECDs involved.

2. Please provide full corporate name and address for all source manufacturers.

3. Verify that the changes, described in item 3 of your letter dated March 5, to the metal label attached to the ECD constitute only an addition to the information currently on the label, and that you are not removing any information from the label that was previously specified.

4. In reviewing the background information for your products, we discovered that we can not locate a copy of Hewlett-Packard's September 9, 1980, letter referenced in registration certificate NR-0348-D-106-B. Please provide a full copy, including any attachments.

5. What is the purpose of the "analysis of a standard pesticide sample"? We need this information to determine whether this test is necessary.

6. As a certificate holder for a custom source, via the NR-0348-D-106-S and NR-0348-D-109-S certificates, you are responsible for ensuring that all commitments made regarding the design of the source are carried out. You requested that the "measurement of the ionization current" test be transferred to the source manufacturer. It is our understanding that the "measurement of the ionization current" is used to verify the activity of the cells. Please confirm or provide corrected information regarding the purpose of the test. In addition, if the test is used to confirm activity, please provide details regarding how this will be incorporated into your QA program's oversight of the manufacturer in order to ensure that no device exceeds the allowable activity. Regarding the NR-0348-D-111-S certificate, explain how Agilent ensures that all ECDs are distributed with the correct activity if this test is not performed by Agilent.

7. Your March 9 letter requests a change to "A careful visual inspection of new cells per documented sampling scheme." Please specify the scheme, and describe the visual inspection, or provide the test procedure.

8 Your March 9 letter requested a reduction in the visual inspection of the plated surface of the ECDs, from 100% of the units to a sampling plan. Please confirm that the wipe and leak tests will still be performed on every cell.

9. Your March 5 letter informed us that Agilent is now ISO 9001 registered. Please indicate whether this is to the American or British standard. If you are indicating that you have begun manufacturing and distributing under this registration, please provide a copy of the ISO registration, and provide a listing of the sealed source and device registration certificates for which the ISO 9001 registered QA program applies. Please note that this would mean that you must continue to manufacture and distribute under the an ISO 9001 registration, and change to that commitment would require an amendment to all registration certificates listed.

10 During our review, we noted that the QA plan in the file is dated October 3, 1990. Please indicate whether this is still a current version. If there is a more recent version, please provide a copy along with a list of items that have changed.

11. Although your March 5 letter also lists your four inactive certificates, we do not see any requested changes to these certificates. Please verify that there are no changes requested, or identify the changes requested for your inactive certificates so that we may continue our review.

Please submit the requested information within 30 calendar days of the date of this letter. If you have any questions, please contact me at (301) 415-5868 or John Jankovich at (301) 415-7904.

Sincerely,

/RA/

Michele Burgess, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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