August 1, 2001

| MEMORANDUM TO: | John Hickey, Chief<br>Materials Safety and Inspection Branch, DIMNS, NMSS                                       |
|----------------|---|
| THRU:          | John D. Kinneman, Chief / <b>RA by Francis Costello Acting For</b> /<br>Nuclear Materials Safety Branch 2, DNMS |
| FROM:          | Kathy Dolce Modes / <b>RA by Pamela Henderson Acting For</b> /<br>Health Physicist                              |
|                | John McGrath / <b>RA</b> /<br>Senior Health Physicist   |

SUBJECT: LEAK-TESTING OF NICKEL-63 SEALED SOURCES

This memorandum provides information concerning a number of recently reported leaking nickel-63 sources in excess of 0.005 microcuries. This may indicate the need for further review of the uses of nickel-63 sealed sources, or review of the requirements for leak-testing.

On May 31 and June 14, 2001, Region I inspected Agilent Technologies, Inc. (formerly Hewlett Packard) of Wilmington, Delaware to review, in part, nine Materials Licensee Event Reports (MLERs) which the licensee submitted since January 2000 concerning high levels of removable activity from nickel-63 sealed sources. The licensee manufactures and distributes gas chromatographs with electron capture detectors (ECDs). Each ECD contains 15 millicuries of nickel-63. The license defines high removable activity as any contamination in excess of 0.005 microcuries. The NRC requires that these sealed sources be leak-tested at intervals approved in the source/device registration, and that levels of contamination exceeding 0.005 microcuries be reported to the NRC. Reports of leaking sources are tracked in the Nuclear Materials Event Database (NMED).

During the period of January 2000 through June 2001, Agilent reported the following sources to have removable activity in excess of 0.005 microcuries:

| MLER-RI- | <u>Sources</u>                            |
|----------|---|
| 2000-22  | 3 ECDs (2 Model G1533A and 1 Model 19233) |
| 2000-23  | 5 ECDs (4 Model 19233 and 1 Model 19235)  |
| 2000-27  | 2 ECDs (Model 19233 and G1533A)           |
| 2000-28  | 3 ECDs (Model 19233)                      |
| 2000-32  | 1 ECD (Model 19233)                       |
| 2000-35  | 1 ECD (Model 19233)                       |
| 2000-36  | 1 ECD (Model G1533)                       |
| 2001-4   | 1 ECD (Model 19233)                       |
| 2001-6   | 2 ECDs (Model 19233)                      |

From 1994 through 1999, Agilent (Hewlett-Packard) reported only eight sources with contamination in excess of 0.005 microcuries: MLER-RI-94-2, 97-59, 98-3, 98-13, 98-29, 98-34,

## J. Hickey Materials Safety and Inspection Branch

99-8, and 99-17. The licensee did not identify the increase in the number of reports over the past 18 months, and did not further investigate this matter except to evaluate the leaking sources for degradation or corrosion. Although the licensee believed that most leakage was caused by customer abuse of the ECDs, the licensee did not ask customers about this matter.

As a result of the recent inspection, Agilent developed a High Wipes Matrix (Attachment 1). The licensee identified a total of 29 ECDs with high removable activity (19 reported to the NRC and 10 reported by customers outside the United States). This matrix clearly shows that there are more high wipes from Model 19233 and that the inlet is the location of the high removable activity. All but two of the sources were manufactured by Amersham (AEA). The licensee drafted a letter to AEA notifying them of this information because this may be a 10 CFR Part 21 defect. In addition, the licensee developed a Customer High Wipe Report Form (Attachment 2) to gather more information from the customer, and an ECD High Wipe Reporting Form (Attachment 3) to document this information and also to document the engineer's analysis of the degraded component.

During a recent inspection of a U.S. Army facility at the Aberdeen Proving Ground in Maryland, where 15 millicurie nickel-63 sealed sources are used in two chemical agent detectors, the Army reported that they recently identified contamination on the inside of two GID-3 devices. The GID-3 contains sealed sources manufactured by AEA Technology PLC (in England). The sealed source model numbers approved for this device are NBC, NBCD, or NBCQ8681. The contamination was found on the device drift tube and cell membrane.

The NRC's standard license condition for leak-testing of sealed sources requires that a report be filed with the NRC in accordance with 10 CFR 30.50(c)(2) if a leak test reveals the presence of 0.005 microcuries or more removable contamination. Certain sealed sources, including tritium sources, are not required to be leak-tested. Tritium sources are known to leak but are of low hazard; the Annual Limit on Intake (ALI) for tritium is 80 millicuries. A typical tritium foil used in portable gas chromatographs contains 100 millicuries of tritium, and temperature controls are required to ensure that the foil does not heat up to the point where tritium freely desorbs from the foil. Nickel-63 has an ALI of 70 millicuries, very similar to that of tritium, and the nickel-63 sources do not leak as readily as do tritium sources.

We recommend that the leak test requirement for nickel-63 sources be re-evaluated. The nickel-63 ECD and similar sources are of low hazard, similar to that of tritium sources. The time and effort to track the sources, schedule leak-testing, and maintain records of results can be burdensome in addition to the cost of the analysis of leak-tests themselves. In addition, when leakage is required to be reported, the NRC generally finds it unnecessary to take action beyond contacting the licensee to determine the extent of contamination, corrective action and root cause of the leaking source, if known. Findings indicate negligible consequences from these leaking sources. From a risk-informed viewpoint, the leak test requirement may not be justified. Alternately, the NRC should perform a review of all reported leaking nickel-63 sources in NMED to determine if a generic problem exists, including a specific review of the recent increase in reported leakage of the AEA nickel-63 sources.

If you have any questions regarding this matter, you may call Ms. Kathy Modes at (610) 337-5251 or Mr. John McGrath at (610) 337-5069.

Thank you for your time and consideration.

Attachments:

- 1. High Wipes Matrix
- 2. Customer High Wipe Report Form
- 3. ECD High Wipe Reporting Form

cc w/attachments:

- D. Collins, Region II
- C. Pederson, Region III
- D. Chamberlain, Region IV

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| DATE   | 08/01/01              | 08/01/01         |   | 08/01/01          | 08/ /01 | 08/ | /01 |  |

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