eV Products, a Division of II-VI, Inc.

ENCLOSURE

We are in the process of reviewing your application for the Model CPC-48 thickness gauge using a Cd-109 source. In order to continue our review, we need the following information:

1. Please clarify the Cd-109 source classification:
   a. For the Isotope Product Corp. XFB-3 source, the registration certificate CA-406-S-112-S stated on the page 3 of 6 that the classification of XFB-3 is 32232. However, on page 4 of 6, it is 33232.
   b. For Amersham Corp. CUC.D1 source, the registration certificate IL-136-S-165-U stated that the classification of CUC.D1 is 44344.
   c. The registration certificate MD-1003-S-102-G for CPC-48 stated that the source has a classification as 77C66435.
   d. Your application stated that the source has 77C33222 on page 3.
   e. ANSI 43.6-1997 requires a classification of 43232 for gamma gauges with source in the device.

2. Please clarify the CUC.D1 capsule. The registration certificate IL-136-S-165-U stated that the capsule type is X130/5. However, your application stated it is X130/8.

3. On page 4, please explain how and what type of material is likely to accumulate on the surface of Cd-109 source. Please describe the operating circumstances that are inducive for the accumulation of surface material.

4. On pages 4 and 5, please provide an estimate of the dose to a worker who operates the device and removes material accumulations. Please also address the yearly exposure rate by estimating occupational exposures during normal use as well as cleaning. Please provide your calculations by delineating your assumptions such as the number of times the device would typically need cleaning, and assuming how long the cleaning would take.

5. On page 5, please provide the environmental ranges in quantitative terms for temperature, pressure, vibration, corrosion for normal use. Please address how the device is likely to maintain its radiation protection properties in the explosion scenarios that you referred to. Please also address other feasible accident conditions, such as fire, or dropping the device from its operational position when mounting or dismounting.

6. On page 5, please provide the locations and material for tamper-resistant hardware or assembly method for the source. Please provide engineering drawings to illustrate the tamper proof nature of the assembly.

7. On page 6, please provide the rationale for working life of 20 years which is equivalent to approximately 15 half lives (one half life is 464 days). The registration certificate MD-1003-S-102-G shows that the working life is 10 years.

8. Enclosure 7 did not provide the complete set of engineering drawings for the mechanical components. For example, Drawing No. 52886 shows the source assembly, but did not

provide the engineering drawings for five parts. Please provide the complete set of engineering drawings with dimensions and materials to be used.

9. On page 8, please provide the appropriate filtration, relief values, operating pressures, and reliability data for the pneumatic cylinder to be used. Please provide engineering drawings for the pneumatic system. In addition, please provide a full description of the operation of the pneumatic system including reliability data for the pneumatic components as well as information including, but not limited to, reliability data on the internal spring.

10. On page 8, please provide the color for light-emitting diode (LED) for open and closed shutter positions. Can the LED be visible from all directions?

11. On page 9, please revise the label in accordance with 10 CFR 51(a)(3)(i) to provide the instructions and precautions, and change the content complying with 10 CFR 32.51(a)(iii)(3). Also, please specify the actual activity in the label, not the nominal value.

12. On pages 11 through 13. Regarding prototype testing, please indicate the duration of how long the devices have been in use at the locations which you described. Please present the actual operating hours and the number of work cycles.

13. On page 12, please provide the ranges for shock and vibration tests performed for pipe coating application.

14. On page 12, please provide the specifics for four tests performed for paint booth test.

15. On page 13, please provide the conditions for automotive paint measurement application.

16. On page 15, please clarify the meaning of the abbreviation ":R/hour."

17. On page 15, your application stated that the maximum exposure rate occurs at 5 cm from the unshielded end of the gauge (800 mR/hour) for Condition # 4. However, Enclosure 11 shows it 3150 mR/hr. Please clarify this discrepancy.

18. On page 15, your application stated that the maximum exposure rate occurs at 5 cm from the unshielded end of the gauge (3.95 mR/hour) for Condition # 3. However, Enclosure 11 shows it 1850 mR/hr. Please clarify this discrepancy.

19. On page 15, your application and the report "Design Analysis of the CPC-48 Thickness gauge for Radiation Safety," by Pettit Applied Technologies, Inc. did not provide the measurements for Conditions # 5 and 6, Please provide them.

20. On page 16, please provide a copy of your quality assurance program ensuring at least, prior to distribution, the following:

a. Design conformity in accordance with information submitted in support of the application, including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, labeling;
b. Leak tests with techniques capable of detecting at least 0.005 mCi (185 Bq) of removable contamination;
c. Proper operation of all safety features;
d. Radiation levels do not exceed maximum stated in the application;
e. Correct labeling on device and inclusion of correct user manual/materials;
f. Tamper resistant hardware in the locations as described in the device application;
g. Overall device appearance;
h. Device safety features function properly; and
i. All units are checked.

21. On page 4 of Enclosure 5, Sections 2, 3.a, and 3.b, please provide a up-to-date listing of regulatory authorities who license possession and use. You can find them in the NRC web site (http://www.hsrd.ornl.gov/nrc/home.html). In Section 3.c, please specify how the contaminated items should be shipped.

22. On page 6 of Enclosure 5, please make a correction: a copy of 10 CFR 31.5 must be supplied to the user, not obtained by user request, as required in 10 CFR 32.51(a).

23. Enclosure 9, Reliability Analysis of the CPC-48 Gauge

a. On page 3 (pages are not numbered), please provide the rationale that only ten components failures are considered. Why are the other possible failures not considered, such as electric fuses, springs, filter, lamps, etc?

b. On page 4 (pages are not numbered), ¶'s 13-14, the analysis used failure rate data for the ten critical components from the referenced textbooks, one of the texts is 28 years old. Textbooks provide usually generic information only. Please delineate how the generic data are applicable to each critical component of your design. Specifically, please describe the similarities and dissimilarities of your particular components to the textbook examples. For example, describe, starting with the first critical components, how the push button switch (Item 1, page 5, pages not numbered) of the Model CPC-48 gauge is similar to the switch in the text of Ref. 2. Please provide such a comparative analysis and demonstrate that the generic data are applicable for all ten critical components. You may also provide experimental data, or reliability factors from studies with machine elements similar to your particular design to support the into your reliability analysis.

c. On page 5 (pages are not numbered), ¶ 11, please provide references, manufacturer's data, or experimental evidence which would support your assumption that the failure rate is constant during the expected operational life of the device, i.e., 20 years. You may discuss why a higher rate in the initial (so called "burn-in") and final periods of life is not expected.

d. On pages 9-10 (pages are not numbered), you indicated a mean-time-between failures as 27.5 and 9.2 months respectively. Therefore, it can be reasonably assumed that an operator could find the gauge in the failed-open position. However, the User Safety Instructions, Appendix 5, page 4, do not provide instructions on what the operator should do to secure a failed-open gauge. You may want to make the safety instructions to be based on the list of critical components. Please add the proper instructions to the manual.

24. Please provide drawings which illustrate how the CPC-48 gauge is mounted to the painting machinery in typical applications. The drawing should show examples whether the devices are bolted in place, held in place by brackets, where the mounting surfaces are.

December 6, 2000

J. Bruce Glick, Division Manager
eV Products, a Division of II-VI, Inc.
373 Saxonburg Boulevard
Saxonburg, PA 16056

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON MODEL CPC-48

Dear Mr. Glick:

This letter is in response to your application dated October 27, 2000, requesting sealed source and device evaluation and registration of your CPC-48 thickness gauge. We are in the process of evaluating your request. In order to continue our evaluation, we need additional information attached in the Enclosure.

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

If you have any questions, please contact me at (301) 415-5787 or Dr. John Jankovich at (301) 415-7904.

Sincerely,

/RA/

Seung J. Lee, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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December 6, 2000

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Sincerely,

/RA/

Seung J. Lee, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated