ENCLOSURE 2

Response to USNRC Comments

Document 2

1. **Please clarify the Cd-109 source classification:**

   1. **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.**

      Isotope Product Laboratories has issued a revision to registration certificate CA-406-S-112-S to resolve this inconsistency. In addition, the XFB-3 capsule has undergone more rigorous testing, which has resulted in its reclassification (in accordance with ANSI Standard N43.6-1997) to 43333.

   2. **For Amersham Corp. CUC.D1 source, the registration certificate IL-136-S-165-U stated that the classification of CUC.D1 is 44344.**

      Amersham Corp. has revised its registration certificate IL-136-S-211-S to include the CUC.D1 device. The registration shows that the capsule has been tested to a classification of 64344, in accordance with ANSI Standard N542-1977 (the predecessor standard to ANSI N 43.6-1997). This classification is remains unchanged per ANSI N 43.6-1997.

   3. **The registration certificate MD-1003-S-102-G for CPC-48 stated that the source has a classification as 77C66435.**

      The classification contained in certificate MD-1003-S-102-G is based on ANSI Standard N542-1977. In accordance with Table 4 of ANSI N43.6-1997, the appropriate classification for a Cadmium-109 source should be 33222 (beta gauges and sources for low-energy gamma gauges or x-ray fluorescence analysis).

   4. **Your application stated that the source has 77C33222 on page 3.**

      Since Cadmium-109 is a low-energy gamma emitter, the appropriate classification per Table 4 of ANSI N43.6-1997 is 33222 (see response to Item # 1.3, above). Since the sources to be used in the CPC-48 are both classified using a more rigorous testing protocol, the 33222 classification is highly conservative (i.e., the conditions the two source capsule designs were proven to withstand are much more restrictive than the testing required for the device).

   5. **ANSI 43.6-1997 requires a classification of 43232 for gamma gauges with source in the device.**

      See response to Item # 1.4, above.

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.**

The CPC-48 gauge will utilize the X130/8 capsule for the CUC.D1 source. The revision to registration certificate IL-136-S-211-S includes the X130/8 capsule.

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.**

Any material accumulation would occur on the aluminized polyester film that covers the open end of the source housing. Such accumulation would be the result of materials being transferred to the device (due to its close proximity to the surface being monitored) or of environmental conditions (e.g., high levels of moisture and/or airborne particulates) in the vicinity of the device. Significant accumulations of material would be readily apparent by the loss of gauge efficiency, with confirmation easily achieved by visual inspection.

The only way that material could accumulate on the surface of the source itself would be in the event of a tear in the aluminized polyester film. Such an event would constitute a failure of the CPC-48 device. This type of failure would be evident by a change in gauge efficiency, and would be readily confirmed by a visually inspection of the gauge. In accordance with operator instructions, the failure of the aluminized polyester film would result in the operator removing the gauge from service and returning it to eV Products or an eV Products-authorized representative for repair. The User Safety Instructions for the device have been revised to stress that no attempt should be made to remove any material accumulation from the surface of the source itself.

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.**

The shielding of the CPC-48 and the proximity of the surface that the gauge is monitoring will prevent an operator from being exposed to significant amounts of radiation. In its normal operating mode, the CPC-48 is attached to another device (e.g., a robot arm) that moves it to within 1.9 centimeters (0.75 inches) of the surface to be measured before the shutter opens. The other likely operating mode for the CPC-48 is its attachment to a crawler device that travels along pipes (again bringing the gauge within 1.9 centimeters of the pipe's surface before the shutter opens). In both of these operating modes, standard industrial safety practice keeps personnel away from where the device is operating. This practice will help to maintain personnel exposure from the CPC-48's operation to as low as reasonably achievable (ALARA) levels.

The dose equivalent rate measurements made around the CPC-48 (see Section 6.0 and Enclosure 12 of the application) support this assertion. Condition # 6 (the shutter open, the RO-20 window open, and a thickness test plate installed) represents the normal conditions of CPC-48 operation. The User Safety Instructions for the CPC-48 (see Enclosure 5 of the application) prescribe that operators remain a minimum of five feet from the gauge. Even if operators remain at a distance of one meter from the open end of an operating gauge, however, Enclosure 12 shows that he or she would be exposed to an exposure rate of less than 100 microroengtens per hour (μR/hour).

If an operator remains in the vicinity of the CPC-48 window without a surface in front of the gauge (the most conservative condition), the exposure rates are still acceptably low. Enclosure 12, Condition # 4 (the shutter open, the RO-20 window open, and the open end of the gauge exposed) shows that the maximum exposure rate at a distance of one meter is 2.35 mR/hour. At a distance of five feet (the prescribed distance for operators), the exposure rate would be below 1.0 mR/hour. This exposure rate is below the standard for unrestricted areas specified in 10 CFR 20, §20.1301(a)(2).

The dose assessment for normal operations assumes that personnel are allowed to stand in close proximity to the device during its operation (a conservative assumption). The exposure environment would correspond to Condition # 5 (for deep dose equivalent) and Condition # 6 (for shallow dose equivalent) in Enclosure 12. Two exposure conditions are possible: an individual standing adjacent to the device as it takes a measurement, and an individual standing in the trajectory of the beam on the opposite side of the surface being measured.

The first exposure condition corresponds to measurement angles from the beam centerline greater than zero degrees. Considering the deep dose equivalent (Condition #5), the individual would receive less than 2 mrem/hour no matter how close he/she stood to the device. Beyond 30 centimeters (12 inches), there is no measurable deep exposure rate. For the shallow dose equivalent (Condition # 6), the individual would receive less than 2 mR/hour if they stood 13 centimeters (5.1 inches) from the device. Beyond 50 centimeters (20 inches), there is no measurable shallow exposure rate.

The second exposure condition corresponds to Condition # 5 (for deep dose equivalent) and Condition # 6 (for shallow dose equivalent) with a measurement angle of zero degrees from beam centerline. An individual standing 6 centimeters from the source would receive less than 2 mR/hour. If the individual stood more than 100 centimeters (39 inches) from the device, there would be no measurable exposure rate.

For a typical measurement, the shutter is open for two seconds. Using a conservatively high duty cycle of one measurement per minute for a forty hour week, 52 weeks per year, the shutter would be open for a total of 69.3 hours in a year. Assuming that an individual stands one foot away from the device throughout the year, the doses that he or she would receive are as follows:

Receptor Location	Deep Dose (mR/year)	Shallow Dose (mR/year)
Adjacent to Device	7	21
Opposite Measurement	28	28

These values are acceptably low for members of the general public.

Radiation exposures to the extremities that might result from the cleaning the CPC-48 have also been estimated. During cleaning operations, the operator will approach the gauge from the bottom or the side. The cleaning procedure delineated in Enclosure 5 requires the use of a cotton swab or similar tool to allow cleaning of the CPC-48's aluminized polyester window surface while maintaining separation between it and the operator's hand. Cleaning typically takes less than five minutes to perform, and is performed once per month. The exposure period for the operator over the course of a year is therefore one hour (5 minutes/cleaning x 1 cleaning/month x 12 months/year) or less.

To determine the dose to the operator's fingers in performing the cleaning, two computer codes were utilized. The VARSKIN code[1] was utilized to determine whether the internal conversion electrons emitted by Cadmium-109 make a significant contribution to extremity dose. When the data on Cadmium-109 are used as input to the code, however, the results show that there is no measurable contribution of these electrons to the extremity dose.

To assess the gamma dose, the computer code Microshield 5.01[2] was utilized. The geometry used for normal cleaning operations assumes that the operator cleans the aluminized polyester surface with a six-inch-long cotton swab, which is held at a thirty-degree angle to the aluminized polyester surface. When this geometry is used as input to the code, Microshield predicts an exposure rate at the operator's fingers from Cadmium-109 radiation of 238.6 mR/hour. Over a year's period, the dose to the operator's fingers would therefore be 238.6 mrem.

The maximum dose that an operator might receive assumes that he or she cleans the aluminized polyester surface by making direct contact with his or her fingers. It should be emphasized that this is **not** a recommended practice and represents an extremely conservative situation. If this geometry is used as input to the code, Microshield predicts the dose to the fingers to be 49.1 R/hour. If an operator used this method of cleaning over a year's period, the dose to the fingers would be 49.1 rem. This dose, even though it represents an extremely conservative situation, complies with the extremity dose limits specified in 10 CFR 20, §20.1201(a)(2)(ii).

In summary, the dose that would be received by operators in the vicinity of the CPC-48 during its normal operations is below criteria established for unrestricted areas. Doses

1 NUREG/CR-5873, "VARSKIN MOD 2 and SADDE MOD 2: Computer Codes for Assessing Skin Dose from Skin Contamination," dated December, 1992

2 Microshield 5.01, Grove Engineering, 1996.

received during cleaning operations are acceptably low and, even in the most conservative situations, will comply with occupational dose limits to the extremities.

5. **On page 5, please provide the environmental ranges in quantitative terms for temperature, pressure, vibration, and 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.**

The CPC-48 gauge can be used out-of-doors safely, but, due to the internal electronics, it is recommended the unit be used in a non-precipitating environment to provide reliable measurement data. The recommended operating temperature ranges from 0 degrees C to 55 degrees C. Performance of the gauge is not affected by normal changes in humidity or barometric pressure. Dust and paint spray accumulating on the front window may degrade the measurement quality but will not degrade the automatic safety shutter operation.

The gauge is designed for use as a process control device in the finishing stages of a manufacturing operation. The intended use of the CPC-48 is in a paint application environment where it is permanently attached to a fixed measuring stand or a suitable actuator to reach the painted part's measurement points (see the new Enclosure 6 in the CPC-48 application for a typical installation). As such, the window end of the device will be accessible to plant personnel only during maintenance periods while the automatic shutter is in closed position.

The device is suitable for operation in a paint booth and operates as a "Intrinsically Safe and Non-Incendive System". This characteristic has been evaluated and approved by CSA to Class I, Group D standards for Process Control Equipment for Hazardous Locations. The effects of fire or explosions resulting from other devices may affect the CPC-48's performance; however, the radiation source integrity is assured by the testing performed on the gauge's sealed source required for it to meet its ANSI N43.6 classification.

The sealed source is attached to a mounting post using a stainless steel holder clip and thus becomes an integral part of the device. In this configuration, it is protected from external forces during an accident by the CPC-48 housing.

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.**

The locations, material specifications, and assembly instructions for tamper-resistant hardware are shown in the complete set of engineering drawings attached to the revised application (see Enclosure 8 of the application).

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.**

The electrical and mechanical parts of the CPC-48 gauge have a twenty-year working lifetime. The Cadmium-109 source strength decays to unacceptably weak emissions levels at a much faster rate, however. The recommended replacement frequency for the Cadmium-109 source is once every two years. The user's manual requires that the gauge be returned to eV Products or an eV Products-authorized representative for leak testing on a six-month frequency. The source would be changed out during one of these maintenance cycles.

While the source is being replaced, a new main return spring will also be installed. The replacement of the main return spring will ensure that its probability of failure during CPC-48 operation is extremely small (see also the response to Item # 23).

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.**

A complete set of engineering drawings is included in Enclosure 8 of the revised application.

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.**

The CPC-48 gauge is equipped with a pneumatically-operated fail-safe shutter mechanism. The system operates from standard shop air system at approximately 60-psi air pressure. The shop air system is connected to the CPC-48 through a pressure regulator, which ensures that the air pressure delivered to the CPC-48 is in an acceptable range. A steady supply of air is required to OPEN the shutter mechanism and expose the source. The shutter is spring-loaded and will close automatically when the air supply is removed. The shutter air is controlled by the measurement programmable controller using a solenoid air valve located near the shutter (see drawings in the new Enclosure 6 of the Application). A red light, located on top of the CPC-48 gauge, illuminates to indicate the open status of

the shutter. Removal of shop air or electrical power to the gauge closes and secures the shutter in a closed position.

The response to Item # 23 discusses the reliability of all components important to the operation of the shutter mechanism.

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?**

The LED for the shutter indicator is red (see Drawing No. EV001608). The LED housing has been placed in a prominent location on top of the CPC-48 (see drawing No. EV001591 for location). In this position, it can be seen for most angles, especially from the back (where the operator will most likely be standing) and the front (where the largest radiation field exists with the shutter open).

The LED cannot be easily seen from the bottom of the device, but there are no safety concerns associated with this lack of visibility. There is a redundant means for determining the status of the shutter (open vs. closed). Since the shutter is on the exterior of the device, its open location (20° from the gauge's central axis) is easy to detect from any direction where the gauge can be seen. The User Safety Instructions for the CPC-48 (Enclosure 5 of the application) contains drawings that show the open and closed locations for the shutter.

The prominent location of the LED and the easy-to-detect location of the shutter therefore provide an adequate means to alert personnel about the gauge's status.

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.**

A revised label is included in the revised application.

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.**

Expanded descriptions of the prototype tests have been included both in response to Items 14 and 15 and in the revised application for the CPC-48.

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

No specific measurements of shock or vibration were made as part of the prototype testing. The tests did, however, show that the shocks and vibration that are typical for the applications evaluated had no effect on either the CPC-48's operation or its physical integrity.

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

The specifics on the three tests conducted are as follows:

Shaw Pipe, Welland, ON.
This application involved a proof-of-concept evaluation during 3 days of production monitoring. The gauge was operating continuously during each ten-hour shift with product cycling at the rate of one pipe each 90 seconds.

The gauge was returned to the site on six additional occasions to conduct further production evaluation trials under similar production rate conditions. At the conclusion of each evaluation, the gauge was inspected for damaged components, effects of vibration, moisture, functionality of the shutter and the integrity of the source holder. No failures affecting the device safety were found.

EB Pipe Panama City, FL
The CPC-48 gauge was evaluated during additional pipe measurements made in a high-temperature environment. The gauge's operating environment was surveyed and found to be consistently at 380 degrees F during the trial. The trial lasted 5 days, with each day consisting of a ten-hour production shift with monitoring at a rate of one pipe per 120 seconds. The trial focused on evaluating the effects of high temperate and high humidity operation. The CPC-48 gauge, including the shutter, was inspected daily and at the conclusion of the test. No component failures were identified.

EUPEC Pipecoating, Mulhein AD Ruhr, Germany
EUPEC purchased a CPC-48 thickness gauge in August 2000 and took delivery of the system in September 2000. The unit was licensed by the German regulatory authorities and installed by S&G Technologies. The company uses the device for in-process verification of the thickness of the final layer of polyethylene applied to 42-inch diameter steel pipes. The device was inspected and serviced by S&G as part of the product warranty in November 2000. Several software modifications were implemented and a new 220 volt power supply was installed. However, no failures of the safety shutter mechanism were identified and no modifications were implemented.

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

The conditions for the three automobile paint measurement applications are as follows:

Behr Systems, Auburn Hills, MI
The CPC-48 was used to evaluate the effectiveness of four paint spray systems with each trial lasting 5 days. The trials were conducted in a typical automotive robotic paint booth equipped with full environmental controls (70 degrees F and 15% humidity). The gauge was used to measure production samples at a rate of one per 55 seconds. The ten-foot samples were measured in 10 to 12 locations as the conveyor moved the parts past the gauge. The CPC-48 gauge was inspected at the conclusion of each trial with no failures of the shutter or source holder mechanism observed.

General Motors Truck Plant, Oshawa ON.
The CPC-48 gauge was collecting production data on the paint thickness variations of the GM truck body primer coat. The test was conducted in a typical automotive paint booth equipped with full environmental control system to maintain the conditions at 70 degrees F at 15% humidity. The production rate was one vehicle per 58 seconds with three measurements taken per vehicle. The gauge was fitted onto a robotic arm, which was in full control of the gauge positioning, the measurement cycle (including the shutter operation). The system was operated extensively in one- or two-day sessions over a four-month period and was inspected by the Canadian AECB as part of the nuclear regulatory licensing procedure. The CPC-48 gauge was inspected daily and the safety shutter was inspected and cycled as part of the normal startup procedure. No failures effecting the safe operation of the device were observed.

Daimler Chrysler Plant, Windsor, ON
The CPC-48 is being tested in an automotive paint measurement application, collecting production data on the paint thickness variations. Prior to deployment of the device, a videotape was developed on the device, its function, its safety features, and employee safety requirements. This videotape was shown to all plant employees before testing began. The device testing is ongoing, with S&G Technologies removing the device at the conclusion of each test series. The device is inspected each time it is returned to S&G Technologies. No failures affecting the safe operation of the device have been observed.

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

The units for the radiation readings have been corrected to be µR/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.

The radiation readings mentioned in the application are based on a survey performed on December 9, 1998, using an Eberline Model RO-20 that was calibrated on December 8, 1998. The data in Enclosure 11 will be replaced by the data from this survey. The maximum exposure rate mentioned in the text of the application (800 mR/hour) is correct.

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.

The correct reading at 4.5 cm. for Condition # 3 should be 500 mR/hour based on the data from the December 9, 1998 survey. The corrected paragraph will now read as follows:

The third set of measurements (Condition # 3) was made with the gauge shutter open and the instrument window closed. These measurements thus represent the deep dose equivalent around the gauge with the shutter open and the unshielded end of the gauge exposed. The maximum exposure rate occurs at 4.5 centimeters from the unshielded end of the gauge (500 mR/hour). At 100 centimeters and beyond, the exposure rate drops below the 2 mrem/hour standard for members of the general public stipulated in 10 CFR 20, §20.1301(a)(2).

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.

The corrected Enclosure 12 contains data on all six exposure conditions.

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

1. **Design conformity in accordance with information submitted in support of the application, including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, labeling;**
2. **Leak tests with techniques capable of detecting at least 0.005 mCi (185 Bq) of removable contamination;**
3. **Proper operation of all safety features;**
4. **Radiation levels do not exceed maximum stated in the application;**

5. **Correct labeling on device and inclusion of correct user manual/materials;**

6. **Tamper resistant hardware in the locations as described in the device application;**

7. **Overall device appearance;**

8. **Device safety features function properly; and**

9. **All units are checked.**

For every instrument that eV Products fabricates, quality assurance involves the application of four steps:

- The definition of quality for the instrument that is incorporated into its design documents (drawings, specifications, etc.)

- The level of quality that is proven through the prototype testing performed on the instrument.

- Prior to the start of instrument production, the documentation of design requirements in fabrication checklists for each component and subassembly and for final assembly, which the production workers complete for each unit as it is assembled.

- After final assembly, quality control for each production unit that involves a review of all completed checklists, an operability check of the instrument, the performance of radiation surveys, and a final inspection of the unit for conformance to design requirements.

For the CPC-48, documentation on the first two steps has been completed. Documentation for the latter two steps are in preparation, and will be submitted to the USNRC for review prior to the CPC-48 going into production.

With these steps in mind, the responses to the nine specific items are as follows:

1. The requirements of the CPC-48's design will be incorporated into the fabrication checklists for each step of its production. Production personnel will document that the checklists are followed by completing them as fabrication proceeds.

2. The leak testing of the Cd-109 sources will be a specification requirement for the source supplier, which will be checked upon receipt of the sources at eV Products. Given Cd-109's short half-life, sources will be procured on a "just-in-time" basis, so additional leak testing will not be required. Moreover, leak testing of the

completed CPC-48 will not be required, since the source is totally contained within the device.

3. Proper operation of all safety features will be tested at each step of the fabrication process, as well as at the final quality control step performed prior to shipment.

4. Radiation surveys of the completed instrument will be completed as a part of the final quality control step performed on each instrument.

5. The installation of the CPC-48's label will be included as an item on one of the fabrication checklists. Its presence and the manner in which it is attached to the device will be confirmed during the final quality control step performed prior to shipment. The final quality control step will also include confirmation that the appropriate manuals are included in the shipment.

6. The use of tamper-resistant hardware will be specified on all applicable fabrication checklists.

7. The overall device appearance will be evaluated during the final quality control step performed on each CPC-48 unit.

8. As mentioned in the response to specific item # 20.3, the proper function of device safety features will be tested as part of each fabrication step and confirmed during the final quality control step.

9. Through the use of the fabrication checklists and the final quality control step, all CPC-48 units will be thoroughly checked prior to shipment.

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.

A table will be added to Enclosure 5, listing all state radiological organizations, all NRC Regional Offices, and NRC Headquarters. Contaminated items will be shipped pursuant to U. S. Department of Transportation (DOT) regulations, under the advice/counsel of eV Products.

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).**

A complete copy of 10 CFR 31.5 is included in Enclosure 5.

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

1. **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?**

The reliability analysis has been modified to incorporate component-specific failure rates and cover all components that could adversely affect the shutter's performance. The revised reliability analysis, included in Enclosure 10 of the revised application, focuses on six components:

- The air cylinder that moves the shutter to its open position,
- The return spring,
- The shutter arms,
- The shaft on which the shutter arms pivot,
- The bearings that carry the load of the shutter's weight, and
- That air solenoid valve that supplies air to the air cylinder.

No other components of the CPC-48 were included in the reliability analysis, because their failure(s) either do not affect the shutter's operation (e.g., shutter indicator light, the radiation detector) or result in the automatic closure of the shutter (e.g., fuses, air hoses).

2. **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.

The failure rates used in the revised reliability analysis are component-specific values obtained from manufacturers. The Mean Time Between Failures (MTBF) calculated in the revised analysis is dominated by the failure rate quoted for the return spring. The spring manufacturer quoted a failure rate for the return spring of one in a million cycles. In conversations with the manufacturer, they agreed that its failure rate will be much lower than the value quoted. However, their predictive model doesn't provide data beyond the value of one in a million cycles. They were therefore unwilling to commit to a lower value.

The use of the quoted value for the return spring failure rate will result in a conservatively low estimate of the shutter's performance.

3. **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.**

eV Products is committed to the highly-reliable and safe operation of the CPC-48. The design of the device is such that any failure of a component will result in either a failure of the safety shutter to open or closure of the shutter (if it is open). eV Products provides extensive testing of the device at all stages of fabrication, from subassemblies to the finished gauge. This testing is designed to detect early component failures before the gauge is shipped. Finally, the reliability of the CPC-48 has been demonstrated in multiple prototype tests performed in actual field conditions.

The reliability analysis for the CPC-48 utilized highly conservative selections for the component failure rates (e.g., the use of the highly stressed failure rates for both the shaft and spring). For the return spring (whose reliability has the largest impact on the MTBF), the value selected is recognized by the manufacturer to be artificially conservative. Despite these selections, the revised MTBF was calculated to be over four years.

To address the quoted failure rate for the return spring, eV Products has committed to its replacement when the Cd-109 source is replaced. As stated in Section 2.3 of the revised application, the spring and the source will be replaced every two years.

The combination of a conservative design and extensive testing will help to identify early component failures before the CPC-48 goes into service. The use of a highly

conservative reliability analysis will bound the actual CPC-48, even when early failures are considered.

4. **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.**

   The User Safety Instructions have been modified to include detailed instructions on the steps to take in the event of a failed-open gauge.

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.**

    A new Enclosure 6 has been included in the application, which shows how the CPC-48 is mounted to a robotic arm.