



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

October 25, 1996

MEMORANDUM TO: Charles W. Hehl, Director  
Division of Nuclear Materials Safety  
Region I

FROM: Donald A. Cool, Director  
Division of Industrial and  
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSESSMENT OF APGEE CORPORATION'S  
PART I RESPONSE TO CONFIRMATORY ACTION LETTER  
1-96-007 AND SUPPLEMENT, DATED AUGUST 12, 1996

A meeting was held on August 15, 1996, between representatives of Apgee Corporation (Apgee) and Region I and HQ staff to allow Apgee to present the first part of its response, dated August 12, 1996, to a Confirmatory Action Letter (CAL) dated June 19, 1996, and supplement to the CAL dated July 22, 1996. In accordance with Apgee's letter dated July 19, 1996, the report addressed only model LB 7400 Series devices, LB 300 L/LP Series devices, and LB 300 ML/MLT Series devices. At the conclusion of the meeting, my staff committed to reviewing the report and providing a technical assessment of the significance of the items identified in the report to the Region I office. The attachment to this memorandum provides the assessment of the report and recommendations as to the actions to be taken in response to the issues raised in the report.

Also in accordance with the July 19, 1996, letter, Apgee provided the second part of its response, covering the remaining registered devices, in a report dated October 15, 1996. A conference call was held on October 22, 1996, between Region I and IMNS personnel concerning the October 15, 1996, report, and it was determined that the report did not constitute an acceptable response to the CAL and could not be reviewed in its present condition. As a result of the conference call, it was agreed that a letter would be sent from the region to Apgee indicating that the October 15, 1996, report was not acceptable and should be resubmitted in its entirety as a complete response to the CAL, and that the assessment of the August 12, 1996, report would also be provided to Apgee with the letter. A preliminary assessment of the October 15, 1996, report and a modified version of the attached assessment of the August 12, 1996, report were provided to the regional staff on October 23, 1996. A complete technical assessment of Apgee's second part of its response to the CAL will be performed when it is resubmitted in its entirety. In addition, as requested in a letter from Apgee dated October 18, 1996, a meeting will be scheduled between NRC and Apgee personnel to discuss these issues and Apgee's priorities as they relate to the review of the reports.

Apgee's August 12, 1996, report was structured to respond to the commitments made in the CAL and supplement to the CAL. Apgee described differences and clarifications, as compared to its registration certificates, it identified for devices distributed in the past and for the current designs of the manufacturer. For each difference identified, Apgee provided the following: 1) a description of the difference, 2) the reason for the change, 3) the reason it is believed to be different from the design listed in the registration certificate, 4) an assessment of the safety

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significance of the change, 5) Apgee's recommended corrective action, and 6) the current distribution status of the product. For each clarification, Apgee provided a description of the clarification, indicated why the clarification was being provided, and provided the proposed corrective action (e.g., update the registration certificate to include the clarification). During the August 15, 1996, meeting, Apgee indicated that they do not consider clarifications as "differences" or changes to the registration certificates, but rather items that are considered to be approved under the current registration certificate, but are inadequately or incorrectly described in the registration certificate.

Attached is the technical assessment of the differences and clarifications identified in the August 12, 1996, report. The assessment of each item has been arranged to follow the format of the report and includes: 1) a brief description of the identified item, 2) an assessment of the effect of the identified item, 3) an assessment of the safety significance of each identified item and of Apgee's indication of the item's safety significance, and 4) actions recommended to be taken by Apgee and NRC. The level of action recommended for each identified item has been structured to be commensurate with the item's level of safety significance.

The following is a summary of the assessment of the August 12, 1996, report:

- A substantial number of differences and clarifications identified in the report require additional detail in order to adequately assess the significance of the identified item and/or amend the registration certificate.
- Apgee did not identify the locations to where devices with differences have been distributed. In particular, Apgee did not identify locations where pneumatic actuators have been installed on model LB 7400 Series devices, as committed in the CAL supplement dated July 22, 1996.
- On a number of items, Apgee did not provide adequate justification to support its claims of no safety significance or safety improvement for identified differences.
- Several differences were identified by Apgee as safety improvements. For these items, Apgee only considered the effect on devices containing the difference. Apgee did not address whether changes were made due to actual or potential problems identified in the field, and whether devices in use without the change could present a safety hazard.
- Several items identified as clarifications should have been identified as differences since they represent actual changes in the design as approved in the registration certificate.
- A number of items identified have the potential to impair or prevent proper operation of the devices. These items should be given priority attention by regional and Apgee staff. In particular, the pneumatic actuator may have the potential to shear off the shutter shaft, completely preventing shutter operation.
- Several of Apgee's responses indicate that it may not be clear to Apgee that the CAL covers all differences in devices distributed as compared to the designs approved by NRC, not just changes the manufacturer indicates have been made to its designs in the past. These may be different since the manufacturer's original design may not be consistent with the design approved by NRC and may contain additional features or options.
- For several items, Apgee indicated that they are aware that a change has been made, and the change is not in accordance with its registration certificate, but Apgee indicated that they intend to continue distribution, in apparent violation of its license, or did not commit to cease distribution of devices with the changes.

Although Apgee's investigation seems to have been intended to meet the commitments in the CAL and supplement for model LB 7400 Series devices, LB 300 ML/MLT Series devices, and LB 300 L/LP Series devices, Apgee's discussion of many of the items identified lacked detail and supporting data, especially its discussion of safety significance. Apgee's identification of a history of distributions of unauthorized devices indicates a lack of control to ensure devices are distributed in accordance with its licenses and/or registration certificates. The preliminary assessment of Apgee's October 15, 1996, report also identified several instances where Apgee indicated that they intend to continue distribution of sources and devices that are not in accordance with its licenses or registration certificates. Apgee's continuing to distribute sources and devices that are not in accordance with its licenses or registration certificates indicates an apparent disregard for the requirements of its licenses and registration certificates, and NRC regulations.

Resolution of the issues raised in Apgee's reports, and the assessments of these reports, will likely require a coordinated response. If you have any questions or comments concerning the assessments of Apgee's reports, or require additional support or assistance, do not hesitate to call me at (301) 415-7197 or Mr. Douglas Broaddus at (301) 415-5847.

Attachment: As stated

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accordance with their licenses or registration certificates indicates an apparent disregard for the requirements of their licenses, registration certificates, and NRC regulations.

If you have any questions or comments concerning our assessment of Apgee's report, please call Mr. Douglas Broaddus at (301) 415-5847.

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### LB 7400 Series Devices:

#### **Differences:**

1. Distribution of alternate source model #2623-800 (VZ-1508/2) in place of the approved model P-2623-100 source.

**ASSESSMENT:** Construction of source model 2623-800 is essentially identical to model P-2623-100, except that model 2623-800 is 1.6 mm longer. Apgee provided a letter from EG&G Berthold that indicated that the shutter mechanism to source clearance is 3.4 mm using model 2623-800. However, a letter from Apgee dated July 5, 1994, indicated that this clearance was 3.5 mm using model P-2623-100. Since model 2623-800 is 1.6 mm longer than model P-2623-100, this statement is not consistent with the previous submittal. Based on the July 5, 1994, submittal, the clearance would be only 1.9 mm. In addition, the safety report for the VZ-1508/2 source provided in the report indicates a maximum activity of 20 GBq (540 mCi); the currently approved source has a maximum activity of 18.5 GBq (500 mCi). Apgee should determine if any devices were distributed with activities greater than 18.5 GBq (500 mCi).

**ACTION:** We will evaluate Apgee's request for amendment to the registration certificate for the addition of the new source model. To support this request, Apgee should address the issues noted above, especially the inconsistency of the stated clearances and the potential for interference with the shutter mechanism due to variations in the construction of the devices that could lessen or negate a 1.9 mm clearance, or due to wear or shifting of components during use. As alternative source models are available, Apgee should cease distribution of the source until sufficient information has been provided to NRC to perform an adequate safety evaluation of the source, and the source is approved for use in these devices. Apgee should also provide any additional information necessary to allow NRC to completely assess the safety significance of this change.

**SAFETY SIGNIFICANCE:** We agree with Apgee's statement that an increased ISO Classification is a safety improvement. However, change in the construction of a sealed source is considered a safety significance change.

2. Distribution of model LB 7400 series devices constructed of stainless steel rather than the approved cast iron.

**ASSESSMENT:** Apgee did not provide detailed design information concerning the stainless steel housing. Apgee committed to providing this information.

**ACTION:** We will evaluate Apgee's request for amendment to add stainless steel housings to the registration certificate when Apgee provides the information indicated in the report. Apgee should cease distribution of devices with stainless steel housings and provide sufficient information concerning the changes in the design and construction of devices with stainless steel housings to justify the claim that this change has no safety significance, and for NRC to perform an adequate assessment of the safety significance of this change and perform a safety evaluation to support Apgee's amendment request. In addition, Apgee should indicate if the use of stainless steel in place of cast iron for the housing was necessitated by environmental or other conditions of use, and evaluate how these environmental or other conditions of use could adversely effect the functionality of other components of the device.



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**SAFETY SIGNIFICANCE:** Insufficient information was provided by Apgee to adequately assess the safety significance of this change. Although stainless steel is generally regarded as a more resilient material than cast iron, a change in the materials of construction of the primary containment housing of a device is considered a safety significant change. The ability of a stainless steel housing to provide equivalent or greater protection in the device's intended conditions of use is dependent on a variety of factors, such as the thickness of the stainless steel housing and dimensional variations of internal components to accommodate a housing of a different thickness.

3. Pneumatic actuator installed on devices.

**ASSESSMENT:** A pneumatic actuator replaces the shutter positioning handle with an pneumatically controlled automatic positioning mechanism. Apgee provided insufficient information concerning the design, construction, prototype testing, and installation of the pneumatic actuators for NRC to perform an adequate assessment of the safety significance of this change, and to justify their claim that this change has no safety significance. In addition, Apgee did not indicate if the construction of installed pneumatic actuators was the same for all installations. Apgee did not identify all locations where pneumatic actuators are installed as committed to in the supplement to the CAL dated July 22, 1996. Apgee indicated in the report that the difference is not considered a change to the device by them because the devices have always been manufactured by EG&G Berthold with pneumatic actuators as an option.

**ACTION:** We will evaluate Apgee's request for amendment to add pneumatic actuators to the registration certificate when an amendment request is submitted by Apgee. Apgee should cease distribution of devices containing automatic actuators and provide sufficient design, construction, and prototype testing data for each type automatic actuator installed on these devices for NRC to determine the safety significance of the use of the actuator and justify the claim that automatic actuators installed on these devices have no safety significance. Apgee should provide the locations for all installations of pneumatic actuators as indicated in the supplement to the CAL dated July 22, 1996. Furthermore, if Apgee wishes to have the use of a pneumatic actuator added to the registration certificate for these devices, Apgee should submit an amendment request that contains sufficient information for NRC to perform an adequate safety evaluation of the use of the actuator with these devices. A letter requesting this type information was sent to Apgee on July 21, 1994; but the information was never provided. In addition, a previous letter from Apgee indicated that both pneumatic and electro-mechanical actuators could be used on these devices. Apgee should indicate if other types of shutter positioning mechanisms, including electro-mechanical actuators, have ever been distributed, and provide the above information for these units, as well.

**SAFETY SIGNIFICANCE:** Insufficient information was provided by Apgee to adequately assess the safety significance of this change. However, a review of a previous request to approve the use of automatic actuators for these devices and a report from the State of Alabama, indicating that an automatic actuator installed on an LB 7400 Series device likely contributed to the failure of a shutter shaft on the device where the shaft was sheared off by a twisting force, indicate that the use of automatic actuators has a high safety significance and may cause an unsafe situation where proper shutter operation may be impaired or prevented. In addition, a modification to the method of operation of a shutter mechanism would be considered a safety significant change.

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4. Carbon steel bolts used without a galvanized surface treatment.

**ASSESSMENT:** Bolts are used for transportation purposes and to hold the shutter handle in the open position. Carbon steel bolts without a galvanized surface treatment may corrode during use. Apgee provided insufficient information to perform an adequate assessment of the safety significance of this change. Apgee's proposed action for future shipments seems appropriate. Apgee's statement that no action will be taken to correct current devices in the field whose bolts are not galvanized was not supported or justified.

**ACTION:** We will evaluate Apgee's request for amendment to the registration certificate to include stainless steel as a material for the bolt. To support this request, Apgee should indicate the type of stainless steel to be used and indicate if there will be any other design changes for the bolt. Apgee should provide justification as to why bolts installed in devices in the field that are not galvanized should not be replaced with galvanized bolts.

**SAFETY SIGNIFICANCE:** Corroded bolts could prevent proper operation and closing of the shutter mechanism. Apgee's report indicated that bolts have become frozen in the past and have required replacement. A frozen bolt that prevents proper shutter operation is considered a safety significant issue and should be addressed.

5. Installation of an additional "L" shaped locking mechanism.

**ASSESSMENT:** Apgee indicated that the "L" shaped locking mechanism is a customer required option that allows additional safety for workers working in and around tanks. If installed properly, the mechanism would not interfere with the normal operation of the device. The mechanism would be installed over the hole where the transport bolt is installed. Apgee did not discuss the effect this mechanism would have on the use of the transport bolt. A letter from NRC to Apgee dated July 21, 1994, responding to a previous request for this type mechanism, requested information necessary to perform a safety evaluation on the mechanism. No additional information on this mechanism was ever received and the action was voided.

**ACTION:** We will evaluate Apgee's request for amendment to the registration certificate to include the additional locking mechanism. Apgee should cease distribution of devices containing this additional locking mechanism and provide additional design information on the mechanism sufficient for NRC to perform an adequate safety evaluation; including minimum clearances when operated, any potential adverse effects on the operation of the device due to the use of the mechanism, how installation of the mechanism would effect use of the transport bolt, prototype testing, and installation requirements and checks.

**SAFETY SIGNIFICANCE:** Any interference of this mechanism with shutter operation should be identified by Apgee or BSI during initial installation and operation verification and could be corrected prior to distribution of the device. The mechanism could only interfere with shutter operation when the shutter was nearly in the fully off position. The mechanism would provide an additional level of safety for persons working inside tanks onto which the device is installed. Although modifications to the shutter mechanism are considered safety significant, any adverse effects caused by this mechanism should be minimal and easily identified by the user and could be corrected without causing a significant safety hazard.

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### Clarifications:

6. & 7. Change in the labeling to include complete manufacturers name.

**ASSESSMENT:** Change is consistent with our labeling policy.

**ACTION:** We will amend the registration certificate to include this change.

**SAFETY SIGNIFICANCE:** None.

Note: During the discussion of Clarification 6 and 7, Apgee requested additional clarification as to if specifically licensed devices should contain labeling that also identifies Apgee, such as is currently included with the LB 300 L/LP Series devices. Adding this type labeling to all specifically licensed device would be an appropriate and consistent with our policy for labeling of devices. In addition, while researching this issue, a letter dated July 5, 1994, from Apgee was identified that contains a commitment that labeling of devices will be updated to include labeling similar to that on the LB 300 L/LP Series devices. This would seem to indicate that Apgee has already made this commitment.

8. Registration certificate incorrectly states the material of the shutter mechanism as stainless steel rather than brass.

**ASSESSMENT:** Background information on file with NRC has confirmed that this clarification is correct.

**ACTION:** We will correct the registration certificate.

**SAFETY SIGNIFICANCE:** None

9. Protective cap installed on some devices to provide added protection to the ON/OFF mechanism.

**ASSESSMENT:** Protective cap covers the shutter positioning handle and has been indicated to be necessary in certain environments to provide additional protection for the ON/OFF mechanism. The cap is also intended to keep the ON/OFF mechanism clean in dirty environment. The report did not indicate the environments for which the use of the cap would be considered necessary to ensure proper operation.

**ACTION:** We will evaluate Apgee's request to add the cap to the registration certificate. Distribution of devices containing protective caps should be allowed to continue. Apgee should describe in greater detail the conditions under which the protective cap would be considered necessary. In addition, Apgee should address if these conditions are outside the normal operating conditions for these devices and if any devices in the field that are subjected to these conditions do not have a protective cap. Apgee should address the need to retrofit devices in use under these conditions that do not have protective caps.

**SAFETY SIGNIFICANCE:** The addition of the cap would provide additional protection to the ON/OFF mechanism. Only safety significance would be if devices currently in use need the protective cap to ensure proper operation.

10. Alternative plunge lock installed on devices.

**ASSESSMENT:** Alternative lock performs an equivalent function to the currently approved lock. The operation of this alternative lock is not significantly different to the operation of the current lock design. The difference is that the locking mechanism of the current design is integral to the plunge lock whereas the new design uses a plunge lock



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that is held in the locked position by an external pad lock. Although the registration certificate generically mentions a plunge lock, a change in the operation of the locking mechanism would need to be evaluated for safety significance and the need for an amendment to the registration certificate.

**ACTION:** We will evaluate Apgee's request to add this alternative lock to the registration certificate. Apgee should commit to the same requirements placed on the currently approved locking mechanism, such as providing instructions to not lock the device in the open position. Distribution of this alternate locking mechanism should be allowed to continue.

**SAFETY SIGNIFICANCE:** None, since operation of the locking mechanism is essentially the same as the currently approved design.

### Model LB 300 ML/MLT:

**Differences:** None identified.

### **Clarifications:**

- 1., 6., & 7. Devices manufactured using tungsten do not have a "second steel cylinder."  
**ASSESSMENT:** Apgee claims the intent of the original application to use tungsten as an alternative to lead shielding was that a second steel cylinder was not required and that all devices of this type have been manufactured in this manner. The registration certificate and information on file with NRC are unclear on this point. However, because these devices have always been manufactured in this manner, it is reasonable to assume that the original application intended to indicate that the devices were manufactured without a second steel cylinder.  
**ACTION:** We will correct the registration certificate to indicate the lack of a second steel cylinder with tungsten shielding. Distribution of devices containing tungsten shielding without a second steel cylinder should be allowed to continue.  
**SAFETY SIGNIFICANCE:** None. Tungsten is sufficiently resilient to not require a second steel cylinder to ensure proper operation and containment.
2. Description of the construction of the Co-60 rod source is incorrect.  
**ASSESSMENT:** Apgee did not indicate if the description of the rod source is incorrect because the construction has been changed or if NRC's interpretation of the drawings on file is incorrect.  
**ACTION:** Apgee should clarify why the wording is incorrect and clarify if the current drawings on file with NRC for the rod source are current and correct. We will update the registration certificate based on Apgee's response to the above issue.  
**SAFETY SIGNIFICANCE:** None, if construction of source has not been changed.
3. & 8. Description of the construction of the Cs-137 rod source should be updated to be consistent with other registration certificates.  
**ASSESSMENT:** Current description is incomplete and not up-to-date because the certificate has not been amended for over 10 years.  
**ACTION:** We will update the description of the rod source in the registration certificate.  
**SAFETY SIGNIFICANCE:** None; only a clarification to the wording of the certificate.

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4. Request to authorize use of an alternate rod source (VZ-1501/1).

**ASSESSMENT:** Construction of the alternate rod source is similar to the currently approved rod source model. However, the information provided is insufficient to perform a complete safety evaluation of the new rod source.

**ACTION:** We will evaluate Apgee's request to amend the registration certificate to add the new source model. Apgee should provide sufficient information concerning the design, construction, and prototype testing of the sealed source for NRC to perform an adequate safety evaluation and demonstrate that the new source will perform equivalently to the currently approved source. Distribution of devices containing these sources should not be authorized until they are found acceptable for use in the devices.

**SAFETY SIGNIFICANCE:** None. No sources of this type have been distributed. However, Apgee must address the above items to allow NRC to completely assess the safety significance of this change prior to distribution of the source.
5. Distribution of an 80mm shield that was not authorized by license and that was not listed on a registration certificate.

**ASSESSMENT:** Apgee claims that the distribution of the 80mm shield was verbally authorized by the NRC. This indicates a lack of understanding, on Apgee's part, of the regulations and requirements of a license. Verbal authorization is not sufficient to authorize distribution of radioactive material, and must be confirmed in writing or by license amendment, as appropriate. Apgee did not discuss the safety significance of the change to a 80mm shield and did not provide information concerning the 80mm shield and the installed source sufficient for NRC to perform an adequate assessment. Searches of our records and NUDOS found no record of the verbal authorization or a letter dated February 2, 1995, from Apgee or BSI to NRC. A previous letter to Apgee dated January 17, 1995, responding to a request by Apgee to register an 80mm version of these devices, requested additional information concerning the device. No response to this letter was received and the action was voided.

**ACTION:** Apgee did not request in the report amendment to the registration certificate to add the 80mm device. Apgee should cease all distribution of 80mm devices, identify all locations where these devices have been distributed, provide sufficient information concerning the design and safety significance of the 80mm shield and the installed source for NRC to make an adequate assessment, and provide complete design, construction, prototype testing data, etc., for NRC to perform a safety evaluation if Apgee wishes to register the 80mm shield. Apgee may refer to the January 17, 1995, letter when preparing to provide information for the 80mm shield. Regional licensing staff should ensure Apgee is aware of the limitations and authorizations of its license as relates to distribution of devices.

**SAFETY SIGNIFICANCE:** Insufficient information was provided to perform an adequate assessment of the safety significance of the distribution of 80mm devices. However, the distribution of any device that has not been evaluated by NRC is considered safety significant. In addition, a smaller diameter shield would be expected to have greater external radiation levels, possibly above the maximum levels indicated in the registration certificate.
9. Installation of a new locking mechanism that will not allow the device's shutter mechanism to be locked unless it is in the closed position.

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**ASSESSMENT:** Drawing #21260.101-000, indicated as showing the locking mechanism, was not provided in the attachments, so a complete assessment could not be made. However, information on file with NRC, supplied in support of the currently approved devices and locking mechanism, indicates that the it will prevent locking of the shield unless the shield is in the closed position. Apgee's description of the change indicates that the current locking mechanism will allow locking of the shutter mechanism in a position other than closed.

**ACTION:** We will evaluate Apgee's request for amendment to the registration certificate for the addition of the new locking mechanism. Apgee should provide complete design and operational information on the locking mechanism, sufficient for NRC to perform an adequate safety evaluation. Apgee should address if the current locking mechanism allows locking of the shield in any position other than in the fully closed position, and Apgee's corrective action if this is the case. Distribution of devices containing this new locking mechanism should not be authorized until it is found acceptable for use with these devices.

**SAFETY SIGNIFICANCE:** Insufficient information to assess safety significance of the change. However, there is no immediate safety significance with the new mechanism since none of the devices have been distributed with the new mechanism. Conversely, the potential of the currently approved mechanism to allow locking of the devices in any position other than in the fully closed position is a highly safety significant issue because persons working around the gauge could receive significant doses if the device is locked in the open position and removed from its use location.

10. Apgee defines the term "special key" in the registration certificate as a wrench.

**ASSESSMENT:** Current information on file with NRC and the registration certificate indicate that the device's shutter may be operated by a wrench, or "special key" provided by the manufacturer. However, there is no current description in the background information as to what is considered a "special key." Apgee's definition as to "special key" meaning wrench is inconsistent with the background information since a wrench would not operate some of the past designs (i.e., designs of some of the devices include circular disks for operating the shutter mechanism).

**ACTION:** In order to clarify this issue, Apgee should describe all methods that have been or are currently recommended by Apgee and/or BSI -- or for which users have been instructed -- to operate the shutter mechanism. In addition, Apgee should indicate if any users have been instructed in the past to operate the shutter mechanism in a method that is no longer recommended, and develop a plan for providing the appropriate instructions to those users. We will assess the need to amend the registration certificate based on Apgee's submission of the current methods recommended to operate the shutter.

**SAFETY SIGNIFICANCE:** Users should be aware of the recommendations of the manufacturer or distributor of the product for operating the devices properly in order to ensure safe operation.

11. Stainless steel construction of the source housings rather than carbon steel.

**ASSESSMENT:** Apgee indicated that these devices have been manufactured from stainless steel and carbon steel and believes both materials are approved in the registration certificate under the broad category of "steel." Apgee provided two reasons

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for why they believe stainless steel is an approved material of construction: 1) Stainless steel is a member of the steel family; and 2) Drawing #21211.000 identifies stainless steel as the material of construction for these devices. However, drawing #21211.000 is not one of the original drawings referred to in Apgee's and BSI's applications for registration of these devices (letter dated July 2, 1985, referred to drawings #21225 and #21199), and drawing #21211.000 only indicates a top plate and bolt as constructed from stainless steel, but not the cylindrical housing. Neither drawings #21225 or #21199 indicate stainless steel as a material of construction. NRC recognizes that stainless steel is a member of the steel "family." However, as indicated in our inspection reports to Apgee and BSI, the information on file with the NRC, used as the basis for the approval of the devices, indicates that the devices were intended to be manufactured from carbon steel rather than stainless steel. Apgee did not respond to many of the specific issues raised in the inspection report concerning this subject.

**ACTION:** If Apgee intends to distribute these devices manufactured from various materials in the steel "family," Apgee should provide specific information concerning the materials to be used (steel type or classification) and which components will be constructed from the materials. If Apgee wishes a range of materials to be authorized, Apgee should identify the range and specify the criteria that will be used to decide when a particular material will be used, or provide other equivalent information that demonstrates that the materials within the range are sufficient for their intended conditions of use. In addition, Apgee should address why the construction of these devices was changed from carbon steel to stainless steel (i.e., indicate if these devices are used under any environmental conditions that would require a more corrosion resistant material), and determine the need to replace or repair devices in the field constructed from carbon steel or limit their conditions of use to non-corrosive environments. As these devices seem to have been constructed of stainless steel for many years and NRC previously registered a similar device constructed of stainless steel for Swank Metacon, we will consider this clarification as a request for amendment to the registration certificate to clarify the intended construction of the devices, pending Apgee's providing the information above. Distribution of the devices constructed of stainless steel should be allowed to continue.

**SAFETY SIGNIFICANCE:** A change in the material of construction of the primary containment of the shielding and shutter mechanism of a device is considered safety significant. Based on the intended environments of these devices, a change from carbon steel to stainless steel as a material of construction would, in general, be considered a design improvement. However, insufficient information was provided concerning the types of stainless steels used to perform a complete assessment of the safety significance of this change.

12. Spring-loaded detent, not authorized in the registration certificate, has been installed on these devices for over ten years.

**ASSESSMENT:** Apgee did not provide design information concerning the spring-loaded mechanism nor provided a description of its purpose, but, rather, indicated that each is constructed to suit the customer's specific installation. NRC has no information on file concerning the use of a spring-loaded mechanism.

**ACTION:** Apgee should provide a complete description of the detent mechanism including its intended use, design, construction, prototype testing, and other pertinent



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information adequate for NRC to perform an assessment of this change. In addition, if Apgee intends to continue to distribute these devices with this mechanism, Apgee should provide sufficient information for NRC to perform a safety evaluation, and request an amendment to the registration certificate. Distribution of devices containing a detent mechanism should not be authorized until it is found to be acceptable for use with these devices.

**SAFETY SIGNIFICANCE:** The addition of mechanisms that effect the operation of the shutter mechanism would be considered safety significant as this could interfere with proper shutter operation. However, Apgee provided insufficient information to perform an adequate assessment of the safety significance of this change.

### LB 300 L and LP Devices:

#### **Differences:**

1. Change of paint on these devices.

**ASSESSMENT:** Background information for these devices specifies the paint to be applied. It is, therefore, appropriate for Apgee to notify NRC when a change to the paint is made. Apgee indicated that the change would not effect radiation levels of the device or the safety of the device. Paint was previously indicated to provide corrosion protection for these devices.

**ACTION:** We will evaluate Apgee's request for amendment to their registration certificate for these devices to add the new paint specifications. Apgee should address the ability of the new paint to provide corrosion protection of the devices equivalent to the previous paint for the device's intended conditions of use. In addition, Apgee may provide generic specifications for the paint/protective coating to preclude additional amendments in the future. Distribution of devices with the new paint specification should be allowed to continue.

**SAFETY SIGNIFICANCE:** Changes to the specifications of protective coatings would be considered safety significant. Selection of an appropriate polyurethane based paint could provide equivalent corrosion protection as an epoxy based paint and would not be considered a detrimental change.

2. Top plate of the shielding is threaded in place and welded nuts have been eliminated.

**ASSESSMENT:** Method of attachment of a plate that provides structural integrity to the device has been changed. Detailed drawings and descriptions of this change were not provided. Apgee did not indicate if devices with this change have been distributed.

**ACTION:** We will evaluate Apgee's request for amendment to the registration certificate when Apgee provides the application as committed to in the report. Apgee should provide complete information sufficient for NRC to perform a safety evaluation of the new method of attachment. Apgee should indicate if devices with the change have been distributed.

**SAFETY SIGNIFICANCE:** Insufficient information was provided to assess the safety significance of this change. However, Apgee did not indicate that devices have been distributed with the change, so there would be no immediate safety significance. A change in the attachment of a component that provides structural integrity to the device would be considered safety significant.



## ATTACHMENT

3. Addition of a 270mm diameter shield.

**ASSESSMENT:** Apgee identified certain information in the registration certificate that would need to be changed to specify that devices may be manufactured up to 270mm. However, Apgee did not provide design, construction, and radiation profile information for this new shield specification. Apgee did not indicate if devices with this specification have been distributed.

**ACTION:** We will evaluate this item as a request for amendment to the registration certificate. Apgee should provide design and construction information, in addition to that currently on file with NRC, sufficient to describe the new shield specification and to allow NRC to perform an adequate safety evaluation. In particular, Apgee should address external radiation level changes, additional prototype testing necessary to demonstrate the new shield's ability to operate in the intended conditions of use, and increased source activities. Apgee should indicate if devices with the change have been distributed.

**SAFETY SIGNIFICANCE:** Insufficient information was provided to assess the safety significance of the change. However, Apgee did not indicate that devices have been distributed with the change, so there would be no immediate safety significance. A change in the shielding diameter of the device would be considered safety significant.

4. Addition of new source (VZ-1501/1), as with the LB 300 ML/MLT devices.

**ASSESSMENT:** Apgee indicated that model LB 300 L/LP devices have been, and will continue to be, distributed with this new source. This seems to contradict item 4 of Apgee's discussion for LB 300 ML/MLT devices (see assessment of item number 4 for LB 300 ML/MLT devices above) which indicates that these sources have never been distributed and will not be distributed pending issue resolution.

**ACTION:** We will evaluate Apgee's request for amendment to the registration certificate to add the new source model. Apgee should clarify if this change is a redesignation of the drawing number as implied in this item or if the construction of the source has been changed as indicated in item 4 for the LB 300 ML/MLT devices. If the source construction has been changed, Apgee should cease distribution of these sources and supply the information requested in item 4 for the LB 300 ML/MLT devices so that NRC may perform a safety evaluation of these sources used with these devices. In addition, the Regional Office should consider the need for escalated enforcement for the continued distribution of sources not in accordance with Apgee's license.

**SAFETY SIGNIFICANCE:** Insufficient information was provided to assess the safety significance of the use of this new source. Apgee must address the above items to allow NRC to completely assess the safety significance of this change.