OCT 2 8 1996

Docket Nos.
030-20043
030-21228
030-32518

License Nos.
37-21226-01
37-21226-02G
37-28697-01

G.M. (Bud) Smith, Jr., President
Apgee Corporation
Hopewell Business and Industrial Park
101 Corporation Drive
Aliquippa, Pennsylvania 15001-4863

Dear Mr. Smith:

This is in reference to your letters dated August 12, 1996 and October 15, 1996, which were in partial response to our Confirmatory Action Letter dated June 19, 1996 and Supplement to Confirmatory Action Letter dated July 22, 1996.

With regard to your August 12, 1996 response, we have performed a preliminary review of this information. Our analysis is enclosed. As you can see from this analysis, there is a significant amount of information needed before we can complete our assessment and make the necessary revisions to the device registrations.

A cursory review of your October 15, 1996 letter identified significant deficiencies which render the report unreviewable. The primary deficiencies are 1) the absence of engineering drawings referenced in the report (indicated to require up to six additional weeks to provide), 2) the submittal of an untranslated technical report, written in German, included as an attachment to the report, 3) a lack of detail in the discussion of items identified in the report, especially safety significance, sufficient for NRC to assess the significance of the items and/or perform a safety evaluation in support of requests to amend the registration certificates. It should be noted that no identification of which items would require amendment to the registration certificates were made. In addition, the report contained several references to the past and continuing distribution of sealed sources that have not been authorized and/or are in excess of the authorized maximum contained activity. Appropriate justification as to why distribution of these apparently unauthorized sources should continue was not provided.

Based on the above, we do not consider your October 15, 1996 submittal as an adequate response to the Confirmatory Action Letter. Therefore, Apgee should resubmit the report in its entirety, completely addressing each identified item and providing complete supporting (translated) data. In addition, Apgee should commit to providing the complete resubmittal no later than November 26, 1996 (six weeks, as indicated in the report).

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In your October 18, 1996 letter to us, you indicated a desire to meet with the NRC to discuss the urgency in resolving these issues. We are entirely amenable to a meeting in order to facilitate resolution of these issues. At that meeting, you should be prepared to address the issues raised in the attached analysis. Although we have not as yet performed a preliminary review of the information in your October 15 letter, our attachment should give you an idea of the types of issues which concern us, and you should be prepared to address similar issues on the gauges addressed in your October 15 letter.

For those devices that you are continuing to ship, i.e. the LB 300 ML and MLT, LB 300 IRL, LB 330, LB 6600 and LB BW, you should also be prepared to provide your specific justification for continued distribution in compliance with our July 22, 1996 Supplement to Confirmatory Action Letter No. 1-96-007 which states that you will transfer only devices that meet the requirements of the sealed source and device registrations and the conditions of your licenses.

Thank you for your cooperation in this matter.

Sincerely,

Original Signed By:
Charles W. Hehl

Charles W. Hehl, Director
Division of Nuclear Materials Safety

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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 he 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: To support Apgee's request for amendment to the registration certificate for the addition of the new source model, 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. Apgee should also address the above items to allow NRC to completely assess the safety significance of this change.
   SAFETY SIGNIFICANCE: Insufficient information was provided by Apgee to adequately assess the safety significance of this 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: Apgee should provide the information indicated in the report to support their request for amendment to add stainless steel housings to the registration certificate . Apgee should provide sufficient information concerning the changes in the design and construction of devices with stainless steel housings for NRC to perform an adequate assessment of the safety significance of this change, justify their claim that this change has no safety significance, 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
   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 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: If Apgee wishes to have the use of a pneumatic actuator added to the registration certificate for these devices, Apgee should submit an amendment application 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. Apgee should provide design, construction, and prototype testing data for each type automatic actuator installed on these devices sufficient 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. A previous letter from Apgee indicated that both pneumatic and electro-mechanical actuators could be used on these devices. Apgee should indicate if other type of shutter positioning mechanisms, including electro-mechanical actuators, were ever 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 indicates 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.

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 during use. 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: To support Apgee's request for amendment to the registration certificate to include stainless steel as a material for the bolt, 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 of the mechanism. Prior to Apgee's August 12, 1996, report, additional information on this mechanism was not provided and the action was voided.
ACTION: Apgee should provide additional information on the mechanism sufficient for NRC to perform an adequate safety evaluation, to support their request for amendment to the registration certificate to include the additional locking mechanism. This should include 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.

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 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 that 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 environments. The report did not indicate the environments for which the use of the cap would be considered necessary to ensure proper operation.
ACTION: To support Apgee's request to amend the registration certificate to add the protective cap, Apgee should describe in greater detail the conditions under which the protective cap would be considered necessary and should address if these conditions are outside the normal operating conditions for these devices. In addition, Apgee should indicate if any devices in the field are currently subjected to these conditions and do not have a protective cap, and should address the need to retrofit devices in use under these conditions that do not have protective caps installed.
SAFETY SIGNIFICANCE: The addition of the cap would provide additional protection to the ON/OFF mechanism. There is a safety significance 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 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: To support 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 (e.g., providing instructions to not lock the device in the open position, etc.).
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.
SAFETY SIGNIFICANCE: None. Tungsten is sufficiently resilient to not require a second steel cylinder to ensure proper operation and containment under normal operations.

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/or not correct.
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.

4. Request to authorize use of a 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: To support 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.
SAFETY SIGNIFICANCE: None. Apgee claims that 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.

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. 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 NUDOCS 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. The information requested in this letter was not provided and the action was voided.
ACTION: Apgee did not request in the report amendment to the registration certificate to add the 80mm device. If Apgee wishes to register the 80mm shield, Apgee should request amendment to the registration certificate and provide sufficient information (i.e. design, construction, prototype testing, etc.) for NRC to perform a safety evaluation. Apgee may refer to the January 17, 1995, letter when preparing to provide information for the 80mm shield. In addition, Apgee should identify all locations where these devices have been distributed and provide sufficient information concerning the design and safety significance of the distributed devices and their installed sources for NRC to make an adequate assessment of the safety significance of these 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.
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 mechanisms, claims that the current locking mechanisms will prevent locking of the shield unless the shield is in the closed

position. Apgee's description of the change seems to indicate that the current locking mechanisms will allow locking of the shutter mechanism in a position other than closed.

ACTION: To support 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 new locking mechanism, sufficient for NRC to perform an adequate safety evaluation. In addition, Apgee should address if the current locking mechanisms allow locking of the shield in any position other than in the fully closed position, and Apgee's corrective action if this is the case.

SAFETY SIGNIFICANCE: Insufficient information to assess safety significance of the change. However, there is no immediate safety significance with the new mechanism since Apgee claims that 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 approved 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. Apgee should assess the need to amend the registration certificate based on 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 that 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 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 (e.g., non-corrosive environments only, etc.). 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.

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 the 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 information adequate for NRC to perform an assessment of this change. In addition, if Apgee wishes to amend the registration certificate to include this mechanism, Apgee should request amendment to the registration certificate and provide sufficient information for NRC to perform a safety evaluation on this mechanism.

SAFETY SIGNIFICANCE: The addition of mechanisms that effect the operation of the shutter mechanism is considered safety significant as they 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: To support 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.
   SAFETY SIGNIFICANCE: Changes to the specifications of protective coatings would be considered a safety significant change. However, selection of an appropriate polyurothane 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: Apgee should submit an application for amendment to the registration certificate, as committed to in the report. To support this application, Apgee should provide complete design and construction 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: A change in the attachment of a component that provides structural integrity to the device would be considered safety significant. However, insufficient information was provided to assess the safety significance of this change. If devices have not been distributed with the change, there would be no current safety significance.

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 diameter. A 270mm diameter shield is not currently approved in the registration certificate and Apgee did not provide design, construction, and radiation profile information for this new shield specification. Apgee did not indicate if devices with a 270mm diameter shield have been distributed.

ACTION: To support a request for amendment to the registration certificate to add a 270mm shield diameter, 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 shield diameters greater than the currently approved 254mm have been distributed.
SAFETY SIGNIFICANCE: A change in the diameter of the shielding of a device would be considered safety significant. However, insufficient information was provided to assess the safety significance of this change. If no devices with shield diameters greater than 254mm have been distributed, there would be no current safety significance.

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 which indicates that these sources have never been distributed and will not be distributed pending issue resolution.
ACTION: To support 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 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. Apgee should also provide sufficient information to allow NRC to completely assess the safety significance of this change.
SAFETY SIGNIFICANCE: Insufficient information was provided to assess the safety significance of the use of this new source.