

April 2, 1997

Docket Nos. 030-20043  
030-21228  
030-32518  
EA 96-246

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

Mr. G.M. (Bud) Smith, President  
Apgee Corporation and Berthold Systems, Inc.  
Hopewell Business and Industrial Park  
103 Corporation Drive  
Aliquippa, Pennsylvania 15001-4863

SUBJECT: NRC INSPECTION REPORT NOS. 030-20043/96-001, 030-21228/96-001,  
AND 030-32518/96-001; RESPONSES TO CONFIRMATORY ACTION  
LETTER DATED JUNE 19, 1996 AND SUPPLEMENT DATED JULY 22, 1996;  
AND PREDECISIONAL ENFORCEMENT CONFERENCE

Dear Mr. Smith:

This refers to the inspection conducted on June 11 through 13, 1996, at your Aliquippa, Pennsylvania facility and our subsequent review of devices that were not distributed in accordance with the conditions of the applicable registration certificates. In our letter dated August 2, 1996, we forwarded a copy of Inspection Report Nos. 030-20043/96-001, 030-21228/96-001, and 030-32518/96-001 concerning the inspection, and indicated that we were deferring NRC enforcement action until we reviewed your response to the Confirmatory Action Letter (CAL) dated June 19, 1996 and supplement to the CAL dated July 22, 1996. This CAL required you to review designs of devices and sealed sources distributed, identify deviations from the approved designs, evaluate the safety significance of each deviation and propose corrective actions. In response to the CAL, you submitted additional information in letters dated July 19 and 25, 1996, August 12 and 20, 1996, October 15, 1996, November 27, 1996, December 4, 1996 and December 20, 1996. We have completed our analysis of this information and our assessment of this information is included in Enclosure 1. This assessment is in addition to the assessment of your partial response to the CAL provided to you previously in a letter dated October 28, 1996.

Based on the results of the inspection and our review of the subsequent information provided by you, three apparent violations were identified and are being considered for escalated enforcement action, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. The apparent violations include the 1) distribution of devices not in accordance with the conditions of the registration certificate or for which a certificate of registration has not been issued; 2) failure to conduct audits on a quarterly basis; and 3) failure to distribute model LB 7400 series devices with manuals that include written instructions advising the customer not to lock the device in the open position. Since we are considering escalated enforcement, no Notice of Violation is presently being issued for these findings. In

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REGION I

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addition, please be advised that the number and characterization of apparent violations described in the inspection report and assessment of your responses to the CAL may change as a result of further NRC review. Please find enclosed an internal NRC technical analysis that summarizes the NRC findings of the issues identified as a result of our review of your submittals. We understand that a copy of this document was inappropriately provided to EG&G Berthold in Tennessee.

Further, we have a number of safety concerns regarding particular devices that have been distributed to specific and general licensees which do not meet the requirements contained in the applicable registration certificates. Accordingly, we are also considering action to order Apgee/Berthold Systems, Inc. to recall and or make modification to the following devices:

1. LB 7400 with alternative sources No. 2623-800 (VZ-1508/2) and No. 2623-700 (VZ-1486/3).
2. LB 7400 with pneumatic actuator
3. LB 7400 with carbon steel transport bolts
4. LB 300 IPD/L with modified source lengths and shield diameters
5. LB 300 IPD/L with new Amersham or Bebig sources
6. LB AS

In addition, our review of the information submitted in your letters revealed a number of areas where insufficient information was provided to determine the potential health and safety implication of modifications made to certain devices, or that appropriate corrective action has been proposed to correct the deviations. Please review the enclosed analysis detailing the additional information we require to continue our assessment.

A transcribed predecisional enforcement conference to discuss the apparent violations and the related issues discussed above, has been scheduled for April 24, 1997 at 2:00 p.m., at our King of Prussia, Pennsylvania office. The conference will be open to public observation. Directions to our office are enclosed with this letter. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to enable the NRC to make an enforcement decision, such as a common understanding of the facts, root causes, missed opportunities to identify the apparent violation sooner, corrective actions, significance of the issues and the need for lasting and effective corrective action. During the enforcement conference you should be prepared to discuss your plans for recalling the devices discussed above or provide an alternative plan for addressing our safety concerns. In addition, you should also be prepared to address the apparent inaccurate information in your written submittals dated August 12, November 27, and December 20, 1996. Specifically: (1) concerning Model LB 300 ML/MLT devices, your November submittal indicated that no devices containing the

G.M. (Bud) Smith  
Apgee Corporation

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new locking mechanism had been distributed, but your December submittal stated that a device was, in fact, distributed to U.S. Steel; (2) concerning Model LB 7400 devices, your August and November submittals stated that a limited number of Model VZ-1508/2 sources were distributed in these devices, but your December submittal indicated that several hundred devices containing Model VZ-1508/2 and VZ-1486/3 sources were distributed.

Finally, you should also provide, in writing, the additional information requested in the enclosed report or a schedule for providing this information promptly. In addition, this is an opportunity for you to point out any errors in our inspection report and technical analysis and for you to provide any information concerning your perspectives on 1) the severity of the violations, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

Sincerely,

ORIGINAL SIGNED BY:  
A. RANDOLPH BLOUGH

A. Randolph Blough, Director  
Division of Nuclear Materials Safety

Docket Nos. 030-20043  
030-21228  
030-32518  
License Nos. 37-21226-01  
37-21226-02G  
37-28697-01

G.M. (Bud) Smith  
Apgee Corporation

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cc w/encl 1:  
Commonwealth of Pennsylvania

Enclosures:

1. NRC technical review of Apgee's responses to CAL
2. NUREG 1600
3. Directions to Region I office
4. Excerpt from NRC Information Notice 96-28



G.M. (Bud) Smith  
Apgee Corporation

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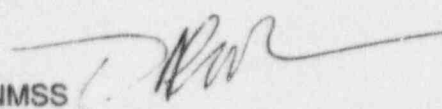


UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

March 10, 1997

37-21226-01

MEMORANDUM TO: A. Randolph Blough, 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  
ADDITIONAL RESPONSES, DATED NOVEMBER 27, 1996,  
DECEMBER 4, 1996, AND DECEMBER 20, 1996, TO  
CONFIRMATORY ACTION LETTER 1-96-007 AND  
SUPPLEMENT

A meeting was held on November 21, 1996, between representatives of Apgee Corporation (Apgee), EG&G Berthold in Oak Ridge, TN, the State of Tennessee (via phone conference), and Region I and HQ staff to address the issues raised in Apgee's Part I and II submittals, dated August 12, 1996, and October 15, 1996, to a Confirmatory Action Letter (CAL) dated June 19, 1996, and supplement to the CAL dated July 22, 1996. The Part I and II reports covered all devices distributed by Apgee and discussed identified differences between the designs of distributed devices and the designs approved in the registration certificates and clarifications to the registration certificates. A number of issues were discussed at the meeting including potential health and safety issues identified in the Part I and II reports and the lack of sufficient information and detail in the reports (especially the Part II report) to make an adequate evaluation of the issues identified. At the conclusion of the meeting, Apgee committed to addressing all outstanding issues discussed in the meeting in a written response within 30 days of the date of the meeting. To this end, Apgee submitted three separate reports dated November 27, 1996, December 4, 1996, and December 20, 1996.

We committed to reviewing the reports 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 technical assessment of the three additional reports submitted by Apgee and makes recommendations as to the actions to be taken in response to the issues raised in these reports, and in previous reports. The assessment has been arranged to follow the format of Apgee's Part I and II reports. This assessment includes: 1) a brief identification of the issues raised, 2) an assessment of Apgee's discussion of the issue, 3) an assessment of the safety significance of each issue, 4) recommendations as to potential citations of violations of NRC's regulations or Apgee's and Berthold's licenses, 5) recommendations as to the acceptability for continued use of devices or sources that do not conform to the registration certificate, 6) an assessment of the amendments to the registration certificate and licenses that would be necessary to bring the devices into compliance, and 7) additional outstanding issues or questions that should be addressed by Apgee. In cases where sufficient information has been provided to resolve an issue, the recommended course of action to close out the issue has been indicated.

The following is a summary of the assessment of Apgee's November 27, 1996, December 4, 1996, and December 20, 1996, submittals:

- A substantial number of instances of potential violations were identified. In all, over three hundred devices and sources have been distributed that do not conform to the approved designs, with the majority of these being model LB 7400 Series devices. In several cases, a single model device had multiple differences identified.
- For the following models, a significant percentage of the devices distributed, and in some cases all devices distributed, contain differences from the designs approved and described in the registration certificates: LB 7400 Series, LB 379 Series, LB 330 Series, LB 300 IP D/L Series, and the LB AS Series (all devices).
- For the following model devices, a health and safety concern (to varying degrees) continues to exist: LB 7400 Series, LB 300 IRL Series, LB 330 Series, LB 300 IP D/L Series, LB AS Series, and LB 6600 Series. The concern is based on statements made in the report or because insufficient information was provided to perform an adequate health and safety assessment. In some cases, the changes identified have the potential to impair or prevent proper operation of the device.
- For the following device models, it is recommended that certain of the devices that are not in conformance with the approved designs be removed from service pending resolution of health and safety concerns: LB 7400 Series, LB 300 IP D/L Series, LB AS Series, and LB 6600 Series.
- In several cases, Apgee did not adequately discuss the identified issue, provide sufficient information to perform a complete assessment of the issue, or justify its determination that the issue presents no health and safety concern.
- For several items, Apgee identified a change that had been made and indicated that the change was not in accordance with the registration certificate, but indicated that it is continuing to distribute the device (in apparent violation of its license). This indicates an apparent disregard by Apgee for the requirements of its licenses, registration certificates, and NRC regulations.
- Based on Apgee's identification of differences, all eleven registration certificates issued to Apgee would require amendment to accurately reflect the devices distributed and currently in the field. In cases where Apgee requested amendment to its registration certificates, the Sealed Source Safety Section will address any outstanding issues directly with Apgee and work to complete the amendments. See below for cases where Apgee did not request amendment to its registration certificates.
- It will be necessary and appropriate to discuss and coordinate a response to a number of the issues raised in Apgee's reports with State of Tennessee personnel. This is due to the fact that EG&G Berthold in TN has now become the manufacturer's US representative for Berthold devices and will be applying (and in some cases has already applied) to TN for registration certificates and service licenses for the devices.
- In several cases, Apgee deferred resolution (including amendment to the registration certificate) to EG&G Berthold in TN. This would leave a number of licensees (including general licensees) possessing and using Berthold devices in violation of their licenses -- until such time as EG&G Berthold in TN is issued a registration certificate for the devices or modifications to the devices are made -- since the licensees possess devices that are not in conformance with the approved design in the registration certificate. Apgee did not provide a commitment from EG&G Berthold in TN that it would resolve the deferred issues. Resolution of these issues will require coordination with the State of Tennessee.

- Based on statements made in Apgee's reports and discussions with Apgee personnel, it is unlikely that Apgee would be able to obtain sufficient additional information from the manufacturer of the devices or EG&G Berthold in TN to address some of the remaining open issues. This is due primarily to the manufacturer no longer considering Apgee as an authorized distributor of Berthold devices. This potential should be considered when determining appropriate actions to take.

The last two items above indicate a concern that in some cases neither Apgee nor EG&G Berthold in TN may assume responsibility to correct devices, or their respective registration certificates, currently in the field that do not meet the approved design in the registration certificate or that Apgee will never be able to provide sufficient information to address the remaining open issues. There are several options available to resolve these issues: 1) Advise Apgee that it is fully responsible for the distributions of devices and sources that are not in accordance with the approved designs and, therefore, must bring all devices and sources in the field into conformance with the approved designs, or submit applications for the design changes, 2) Defer the issue of bringing the devices into conformance or submitting an application for the design changes to EG&G Berthold in TN and the State of Tennessee (this would require a commitment from EG&G Berthold to do this), and 3) Issue Orders to all users of these devices to immediately cease use of the device and either dispose of the device or submit an application for a custom review. Throughout the attachment to this memorandum, an effort has been made to indicate the appropriate course of action in these situations. However, in cases where it is unclear as to the most appropriate course of action, it is recommended that the options above be attempted in the order they are presented.

As with the previous assessments, resolution of the issues raised will likely require a coordinated response. If you have any questions or comments concerning the assessments of Apgee's reports or the recommendations made in the attachment, 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



Review of Apgee's submittal of additional responses dated November 27, 1996, and December 20, 1996, to the CAL dated June 19, 1996 and supplement to the CAL dated July 22, 1996.

#### **General considerations:**

- Each issue is treated separately and the conclusions and recommendations of one issue should not be construed to contradict or over-ride another.
- Only issues that are currently outstanding have been addressed in this report.
- The potential violations listed in this assessment are recommend, but are not to be construed as definitive or all inclusive.
- The recommendations for continued use are based on the level of the potential health and safety risk to users who possess and use the devices.

#### **Detailed Review:**

**Model:** LB 7400 Series Devices:

**Device Type:** Density and level gamma gauge.

**Registration certificate:** NR-0112-D-102-B

**Licenses:** 37-21226-01

37-28697-01

37-21226-02G

#### **Issues Identified:**

1. Distribution of alternate source model #2623-800 (VZ-1508/2) in place of the approved model P-2623-100 source. Also, Apgee identified two additional differences: distribution of devices containing Co-60 source model #2623-700 (VZ-1486/3) and distribution of devices with an alternate source holder installed without prior safety review and approval.

#### **Findings:**

- Several hundred model LB 7400 Series devices were distributed containing model VZ-1508/2 or VZ-1486/3 sources between 1992 and 1996.
- Design and construction of source model #2623-700 (VZ-1486/3) is essentially identical to model #2623-800 (VZ-1508/2), except for the isotope. In particular, the overall length of source model #2623-700 (VZ-1486/3) is also 1.6 mm greater than the currently approved sources.
- An analysis of the clearance of the new source models was provided by the manufacturer. The manufacturer's indicated minimum acceptable clearance value is 1.8 mm. The analysis indicated that there is insufficient clearance between the shutter mechanism and source capsule to ensure proper operation. The analysis further indicated that in the worst case condition, the minimum clearance would be -1.4 mm (an interference fit). To increase the clearance, manufacturing personnel were instructed to shorten the length of the source holder by 2 mm. This would provide a minimum clearance of 0.6 mm. However, shortened source holders were not provided with the devices distributed in the US with the new source models. Therefore, devices distributed in the US with



the new sources have the potential to have as little clearance as -1.4 mm, and all will have clearances below the manufacturer's minimum acceptable level.

The analysis provided by the manufacturer also indicated that a functional test, required to be performed by Apgee and BSI prior to distribution to users, and periodic shutter operation checks performed by users would identify any clearance fit problems. In addition, the manufacturer claims that all devices are installed in an orientation (beam flat or pointing down) such that wear of the shutter mechanism would increase the clearance after installation. However, there is no requirement that these devices be installed in this orientation. The manufacturer concluded that since no problems have been reported and the potential for the clearances to increase in the future is minimal, there is no safety hazard associated with the use of these devices.

The analysis provided by the manufacturer included an action plan for Apgee, intended to identify any clearance fit problems and provide replacement (shortened) source holders for the devices that are identified as having a clearance fit problem. The action plan also called for the replacement of source holders with the shortened versions for all model LB 7445 devices containing the new source models, regardless if a problem is or is not identified. This is due to these devices having a maximum possible clearance of 0.1 mm.

- Apgee did not indicate if they plan to perform the action plan contained in the manufacturer's analysis. Therefore, Apgee should indicate the specific actions they plan to take to correct this situation. Their options include: 1) recall of all devices containing the new sources; 2) amending the certificate to add the shortened source holder as an approved variation and retrofitting all devices containing the new sources with the shortened source holder; or 3) replacing the new sources with an approved source. Option 2) would require Apgee to provide a means for license reviewers and service personnel to distinguish between devices containing the shortened source holder and those that do not, so that new sources are not inadvertently installed into a device containing an original length source holder.
- Apgee did not indicate if devices containing model VZ-1508/2 and VZ-1486/3 source were distributed to both specific and general licensees.
- Apgee indicated that no model VZ-1508/2 sources were distributed in model LB 7400 Series devices containing greater than 500 mCi.

**Potential Safety Hazards:**

- The information provided by Apgee indicates a potential for a health and safety risk due to the use of model LB 7400 Series devices containing model VZ-1508/2 or VZ-1486/3 sources. The risk is an increased potential for the shutter mechanism to bind or to cause damage to the source capsule as a result of there being insufficient clearance (especially with an interference fit) between the shutter mechanism and the source capsule.
- The fact that the manufacturer has recommended that all model LB 7445 devices containing the new sources be retrofitted with the shortened source holder length seems to contradict its claim that there is no health and safety risk.

**Potential Violations:**

- Distribution of model LB 7400 Series devices with model VZ-1508/2 or VZ-1486/3 sources is not in conformance with registration certificate NR-0112-D-

102-B. It is recommended that this be considered a violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, License Condition 12 of License No. 37-28697-01, and, if distributed to general licensees, 10 CFR 32.51(a) and License Condition 11 of License No. 37-21226-02G.

**Required Amendments:**

- Distribution of model LB 7400 Series devices containing model VZ-1508/2 or VZ-1486/3 sources or a shortened source holder requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-102-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-102-B for this change.
- Apgee and BSI have deferred amendment to the registration certificate to EG&G Berthold in TN.

**Recommendations for continued use:**

- A review of model VZ-1508/2 and VZ-1486/3 sources installed in model LB 7400 Series devices indicates that this combination would likely not be authorized for distribution and use without additional limitations or conditions of use. This is due to the lack of sufficient clearance between the source and shutter as specified by the manufacturer (1.8 mm minimum) and the lack of a means to ensure the new sources are not installed in devices containing the original length source holders.
- Users of model LB7400 series devices containing model VZ-1508/2 or VZ-1486/3 sources, especially model LB7445 devices, should cease use of these devices until such time as Apgee demonstrates that there is sufficient clearance in the devices to ensure continued safe operation. This may be accomplished by Apgee submitting and executing an appropriate action plan for modification of these devices such that sufficient clearance is assured (either in accordance with the approved design or with the modified design, if approved) and for submission of an application for the evaluation and registration of the the modified version of these devices (shorter source holder and alternative sources) if Apgee wishes this design be authorized for use. If neither Apgee nor EG&G Berthold commit to performing modifications to these devices that would ensure the proper clearances and to submitting an application for safety review and registration of these devices containing the alternate sources, consideration should be given to issuing a Order for the immediate recall of these devices.

**Additional Questions:**

- Apgee should indicate if devices containing model VZ-1508/2 and VZ-1486/3 source were distributed to both specific and general licensees.
- Apgee should indicate if they plan to perform the action plan contained in the manufacturer's analysis, or if not, provide their proposed plan of action to bring users of these devices into conformance. As amending the registration certificate has not been requested, this would seem to require correcting devices in the field or issuing a recall.

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

**Findings:**

- Fifteen LB 7400 Series devices have been distributed that were constructed with a stainless steel outer housing rather than the approved cast iron outer housing during the period December 1989 to November 1995.
- Apgee indicated that the change was not necessitated by environmental factors, but rather by sanitary requirements in certain industries.
- Apgee did not indicate if devices containing a stainless steel outer housing were distributed to both specific and general licensees.

**Potential Safety Hazards:**

- The information provided by Apgee indicates no immediate health and safety risk due to the use of model LB 7400 Series devices constructed with a stainless steel outer housing.

**Potential Violations:**

- Distribution of model LB 7400 Series devices with a stainless steel outer housing is not in conformance with registration certificate NR-0112-D-102-B. This is a violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, License Condition 12 of License No. 37-28697-01, and, if distributed to general licensees, 10 CFR 32.51(a) and License Condition 11 of License No. 37-21226-02G.

**Required Amendments:**

- Distribution of model LB 7400 Series devices with a stainless steel outer housing requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-102-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-102-B for this change.
- Apgee and BSI have deferred resolution of this issue (including amendment to the registration certificate) to EG&G Berthold in TN.
- If neither Apgee nor EG&G Berthold in TN request and receive a registration certificate indicating approval for distribution and use of these devices, the current possessors/users of the devices should be required to apply for a custom evaluation.

**Recommendations for continued use:**

- A cursory review of the design data submitted by Apgee for the model LB 7400 Series devices constructed with stainless steel outer housings indicates that this material change would likely be authorized for distribution and use.
- Licensees possessing model LB 7400 Series devices should be allowed to continue to use the devices while pending review and issuance of a registration certificate. Apgee indicated that EG&G Berthold in TN would do this.

**Additional Questions:**

- Apgee should indicate if devices containing a stainless steel outer housing were distributed to both specific and general licensees.

3. Pneumatic actuator installed on devices.

**Findings:**

- Eleven LB 7400 Series devices have been distributed that were constructed with a pneumatic actuator for shutter control between January 1988 and August 1994.
- Devices containing a pneumatic actuator for shutter control were distributed to both specific and general licensees.
- Apgee indicated that all but one user of model LB 7400 series devices containing pneumatic actuators has ceased use of the actuators and have had their devices converted to manual shutter operation. The remaining user is a general licensee, USX Mining in Cumberland, PA.
- Apgee provided verification that the pneumatic actuators were permanently removed from the devices (except for USX Mining).

**Potential Safety Hazards:**

- The information provided by the State of Alabama concerning the use of pneumatic actuators by one of their licensees indicates an increased level of health and safety risk due to the excessive force the pneumatic actuator can exert on the shutter shaft of model LB 7400 Series devices.
- USX Mining indicates that their model LB 7400 series device has been in use with the automatic actuator since 1988 with no safety related problems with the automatic actuator.

**Potential Violations:**

- Distribution of model LB 7400 Series devices with a pneumatic actuator is not in conformance with registration certificate NR-0112-D-102-B. This is a violation of 10 CFR 32.210(f)(1) and (2), 10 CFR 32.51(a), License Condition 12 of License No. 37-21226-01, License Condition 11 of License No. 37-21226-02G, and License Condition 12 of License No. 37-28697-01.

**Required Amendments:**

- Distribution of model LB 7400 Series devices with a pneumatic actuator requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-102-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-102-B for this change.
- Apgee and BSI have not deferred resolution of this issue to EG&G Berthold in TN.

**Recommendations for continued use:**

- A review of the design and use history of the model LB 7400 Series devices distributed with pneumatic actuators indicates that these devices would likely not be authorized for distribution and use.
- As no safety evaluation has been performed for model LB 7400 series devices containing an automatic actuator and because of the potential for the actuator to shear the shutter shaft, USX Mining should cease use of the device with the pneumatic actuator or supply sufficient information concerning the design and use of the device to perform a custom licensing evaluation. This would require USX Mining apply for, and be issued, a custom registration certificate and a specific license.



**Additional Questions:**

- None.

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

**Findings:**

- Numerous LB 7400 Series devices have been distributed since as early as 1988 containing a transport bolt constructed from carbon steel without a galvanized surface treatment.
- Devices containing a non-galvanized transport bolt were distributed to both specific and general licensees.
- Apgee has requested that stainless steel bolts be authorized for use instead of galvanized carbon steel bolts.

**Potential Safety Hazards:**

- The information provided by Apgee concerning the use of non-galvanized bolts indicates an increased level of health and safety risk due to possible sticking of the shutters in the open position. Apgee indicated that the use of galvanized or stainless steel bolts would significantly reduce this risk.

**Potential Violations:**

- Distribution of model LB 7400 Series devices with a non-galvanized transport bolt is not in conformance with registration certificate NR-0112-D-102-B. This is a violation of 10 CFR 32.210(f)(1) and (2), 10 CFR 32.51(a), License Condition 12 of License No. 37-21226-01, License Condition 11 of License No. 37-21226-02G and License Condition 12 of License No. 37-28697-01.

**Required Amendments:**

- Distribution of model LB 7400 Series devices with a stainless steel transport bolt requires a safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-102-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01.
- Apgee and BSI have requested amendment to registration certificate NR-0112-D-102-B for this change.
- Apgee and BSI have not deferred resolution of this issue to EG&G Berthold in TN. Apgee and BSI are working to replace all non-galvanized bolts with either galvanized bolts or stainless steel bolts.
- Pending a fee issue resolution, registration certificate NR-0112-D-102-B will be amended to include the use of a stainless steel transport bolt.

**Recommendations for continued use:**

- A review of the design of the stainless steel bolt and the model LB 7400 series devices indicates that this request would be approved and distribution and use would be authorized.
- It is recommended that Apgee be allowed to replace non-galvanized transport bolts with either galvanized carbon steel or stainless steel transport bolts while the certificate is being amended.

**Additional Questions:**

- Updates as to the status of the notification/replacement program should be provided on a routine basis and at completion. Apgee should indicate who will provide these updates (Apgee or EG&G?).



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

**Findings:**

- Nine LB 7400 Series devices have been distributed with an additional "L" shaped locking mechanism from October 1992 to February 1996.
- Apgee did not indicate if devices containing an additional "L" shaped locking mechanism were distributed to both specific and general licensees.
- Apgee provided an additional installation requirement check that has been added to ensure proper operation of shutter when the "L" shaped locking mechanism is installed.

**Potential Safety Hazards:**

- The information provided by Apgee indicates that there is not an immediate health and safety risk due to the use of the additional "L" shaped locking mechanism with model LB 7400 Series devices.

**Potential Violations:**

- Distribution of model LB 7400 Series devices with an additional "L" shaped locking mechanism is not in conformance with registration certificate NR-0112-D-102-B. This is a violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, and License Condition 12 of License No. 37-28697-01, and, if distributed to general licensees, 10 CFR 32.51(a) and License Condition 11 of License No. 37-21226-02G.

**Required Amendments:**

- Distribution of model LB 7400 Series devices with an additional "L" shaped locking mechanism requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-102-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendments have been issued.
- Apgee has requested amendment to registration certificate NR-0112-D-102-B for this change.
- Apgee has not deferred resolution of this issue to EG&G Berthold in TN.
- Pending a fee issue resolution, the SSSS will evaluate Apgee's request for amendment to registration certificate NR-0112-D-102-B to include the use of an additional "L" shaped locking mechanism with these devices.

**Recommendations for continued use:**

- A cursory review of the design of the additional "L" shaped locking mechanism and the model LB 7400 series devices indicates that this option would likely be approved and distribution and use would likely be authorized.
- It is recommended that licensees possessing these devices be allowed to continue using them while the certificate is being amended.

**Additional Questions:**

- Apgee should indicate if devices containing an additional "L" shaped locking mechanism were distributed to both specific and general licensees.
- Apgee should provide an action plan for ensuring all current users of devices containing the "L" shaped locking mechanism these devices are provided the additional installation requirement procedure and request that all users perform the procedure and verify proper operation of the shutter mechanism. Apgee should also indicate the steps and corrective action to be taken if users indicate improper operation.

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

**Findings:**

- Apgee indicated that the protective cap is not required for proper operation in any environment and that it is provided to users who request additional protection of the shutter handle and labeling from dirt or process material that may make them difficult to observe.

**Potential Safety Hazards:**

None.

**Potential Violations:**

- Distribution of model LB 7400 Series devices with protective caps is considered to be in compliance with registration certificate NR-0112-D-102-B and not a violation of any regulation or license condition.

**Required Amendments:**

- Addition of the protective cap to the registration certificate can be performed as an administrative amendment. No safety evaluation is required.

**Recommendations for continued use:**

- Apgee may distribute protective caps for use with these devices without the need for additional authorization.
- Licensees possessing devices containing the protective cap should be allowed to continue to use the devices while the certificate is being updated.

**Additional Questions:**

None.

10. Alternative plunge lock installed on devices.

**Findings:**

- Apgee indicated that the alternative plunge lock is essentially identical in function to the current design contained in the background files for the model LB 7400 Series devices. This information gives a general description of a plunge lock and provides a general drawing of a representative plunge lock. The design of the alternative plunge lock is in conformance with the general description provided for the plunge lock.
- Apgee has committed to all previous requirements for the current plunge lock and has committed to providing instructions to users of the alternative plunge lock equivalent to the currently provided instructions.

**Potential Safety Hazards:**

None.

**Potential Violations:**

- Distribution of model LB 7400 Series devices with an alternative plunge lock is considered to be in compliance with registration certificate NR-0112-D-102-B and not a violation of any regulation or license condition.

**Required Amendments:**

- Addition of the alternative plunge lock to the registration certificate can be performed as an administrative amendment. No safety evaluation is required.

**Recommendations for continued use:**

- Apgee may distribute devices containing the alternative plunge lock without the need for additional authorization.

- Licensees possessing devices containing this alternative plunge lock should be allowed to continue to use the devices while the certificate is being updated.

**Additional Questions:**

- Apgee should ensure current users of devices containing these alternative plunge locks are provided appropriate instructions and information equivalent to the instructions and information provided with the presently authorized lock.

**Model:** Model LB 300 ML/MLT  
**Device Type:** Mold level control for the steel industry  
**Registration certificate:** NR-0112-D-111-S  
**Licenses:** 37-21226-01  
37-28697-01

**Issues Identified:**

**General Issue:**

It is recognized that the size of individual model LB 300 ML/MLT devices and other components (such as flanges) may vary from one installation to another. However, it is important that the basic design of the device, necessary to provide adequate health and safety and containment of the material under normal use conditions, be reviewed and approved prior to distribution. Therefore, Apgee (or EG&G, if appropriate) should ensure that the basic (current) design of the model LB 300 ML/MLT, including all options, is on file with the appropriate regulatory authority (NRC or TN) and has been reviewed and approved. To this end, Apgee (or EG&G) should review the documentation submitted to NRC (or TN) and determine if this documentation (and the registration certificate) accurately reflect the basic design of these devices.

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

**Findings:**

- Apgee provided a clarifying statement that no model VZ-1501/1 sources have ever been distributed in model LB 300 ML/MLT devices.

**Potential Safety Hazards:**

None.

**Potential Violations:**

- Since no sources were distributed, there is no violation of regulations or license conditions.

**Required Amendments:**

- Apgee did not request amendment to registration certificate NR-0112-D-111-S to add this source as an approved model.
- Apgee deferred this issue (including amendment of the registration certificate) to EG&G Berthold in TN.

**Recommendations for continued use:**

None distributed.

**Additional Questions:**

None.

5. Distribution of an 80 mm shield. Certificate authorizes a minimum diameter of 100 mm.

**Findings:**

- Five 80 mm shields were distributed to Republic Engineered Steel in Canton, OH. Shipping documentation indicates the devices were shipped on or about December 26, 1995.
- Apgee claims that the design and construction of the 80 mm shield is essentially identical to the greater diameter shields approved on the registration certificate,

except that the diameter has been reduced.

**Potential Safety Hazards:**

- The information provided by Apgee, and its claim that the devices are essentially identical to larger diameter devices in the field, indicates that there is not an immediate health and safety risk due to the use of the distributed 80 mm model LB 300 ML shields.

**Potential Violations:**

- Distribution of model LB 300 ML/MLT devices with diameters less than 100 mm is not in conformance with registration certificate NR-0112-D-111-S. This is a violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, and License Condition 12 of License No. 37-28697-01.

**Required Amendments:**

- Distribution of model LB 300 ML/MLT devices with diameters less than 100 mm requires prior safety evaluation (10 CFR 32.210), approval, and amendment to registration certificate NR-0112-D-111-S and License numbers 37-21226-01 and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendments have been issued.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-111-S for this change.
- Apgee and BSI have not deferred resolution of this issue to EG&G Berthold in TN.
- If neither Apgee nor EG&G Berthold request and receive approval of an 80 mm design (same as already distributed), either Republic Engineered Steel should be required to request a custom licensing evaluation of the continued use of these devices or Apgee should be required to submit an action plan to bring Republic Engineered Steel into compliance with their license.

**Recommendations for continued use:**

- A cursory review of the design of the 80 mm diameter shield indicates that this option would likely be approved and distribution and use would likely be authorized.
- Republic Engineered Steel should be allowed to continue to use the devices pending performance of a complete safety evaluation and issuance of a registration certificate for the device.
- The shipping documentation provided by Apgee indicates that the source installed in the 80 mm diameter device was 1.6 mCi Co-60 and that this gave external radiation levels less than 100 mR/hr at the surface of the device. The use of the existing 80 mm devices should be limited to 1.6 mCi Co-60 until such time as the 80 mm diameter device is reviewed and approved, including the use of other isotopes and/or greater activities.

**Additional Questions:**

- Apgee has not requested amendment to their registration certificate to add the 80 mm design. If neither Apgee nor EG&G Berthold (TN) request amendment to the registration certificate to add the 80 mm shield, Apgee should provide an action plan to bring Republic Engineered Steel into compliance for their devices.
- The primary issues for this device would be the maximum activity requested in the device and the external radiation levels with this activity level, and the ability of a smaller diameter device to survive the harsh conditions of use and provide appropriate protection to the source.



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.

**Findings:**

- Apgee previously indicated that no devices have been distributed, or plan to be distributed by Apgee/BSI, with the new locking mechanism. However, Apgee's December 20, 1996, letter identified one model LB 300 ML device that contained this new locking mechanism that was distributed to USS Steel in Gary, Indiana.

**Potential Safety Hazards:**

- The information provided by Apgee indicates that there is likely not an immediate health and safety risk due to the use of the distributed model LB 300 ML shield with the new locking mechanism. However, it could not be determined from the information provided whether the new locking mechanism would provide the safety feature whereby the shutter must be in the closed position prior to being moved (lifted), as the currently approved mechanism does. If the new mechanism does not provide this safety feature, there is a higher potential for users to move (lift) the device with the shutter in the open position. Apgee claims the design and construction of the new locking mechanism provides equivalent operability to approved models currently in use in the field.

**Potential Violations:**

- Distribution of model LB 300 ML/MLT devices with the new locking mechanism is not in conformance with registration certificate NR-0112-D-111-S. This is a violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, and License Condition 12 of License No. 37-28697-01.

**Required Amendments:**

- Distribution of model LB 300 ML/MLT devices with the new locking mechanism requires prior safety evaluation (10 CFR 32.210), approval, and amendment to registration certificate NR-0112-D-111-S and License numbers 37-21226-01 and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendments have been issued.
- Apgee requested amendment to registration certificate NR-0112-D-111-S to add this new locking mechanism.
- Apgee did not defer this issue to EG&G Berthold in TN.
- Pending a fee issue resolution, the SSSS will evaluate Apgee's request for amendment to registration certificate NR-0112-D-111-S to include the use of an the additional locking mechanism with these devices.

**Recommendations for continued use:**

- Insufficient information was provided concerning the new locking mechanism to perform an adequate safety review and determine the adequacy for its continued use.
- USS Steel should cease use of the device pending amendment to the registration certificate or provide a temporary procedure to ensure the locking mechanism operates properly (i.e., does not allow the device's shutter mechanism to be locked unless it is in the closed position) and that the device's shutter is always in the closed position before the device is moved.

**Additional Questions:**

- Additional questions concerning the design of this additional locking mechanism will be handled during the amendment process. However, Apgee should provide complete design drawings of the mechanism (including how it is attached to the

device) and describe fully its operation. In addition, the current locking mechanism is designed such that the shutter mechanism would be required to be in the fully shielded position prior to installing or removing the device from the mold. Apgee should indicate if the new locking mechanism would also provide this safety feature.

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

**Findings:**

- Apgee provided a definition of what is considered a "special key."

**Potential Safety Hazards:**

- None.

**Potential Violations:**

- As this is only a clarification of the wording, there is no violation of regulations or license conditions.

**Required Amendments:**

- Apgee provided additional clarifying wording to be included in the registration certificate concerning the "special key."
- Addition of the clarifying wording to the registration certificate can be performed as an administrative amendment. No safety evaluation is required.

**Recommendations for continued use:**

- None.

**Additional Questions:**

- Apgee should provide this clarifying wording to all users of these devices and should commit to including this wording in the instructions provided to users upon distribution of the device.

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

**Findings:**

- Numerous model LB 300 ML/MLT devices have been distributed constructed with an outer housing of stainless steel. Since as early as 1988, all model LB 300 ML/MLT devices have been constructed this way.
- Apgee indicated that only the outer housing was changed to stainless steel and the inner housing remained as carbon steel.

**Potential Safety Hazards:**

- The information provided by Apgee indicates no increased level of health and safety risk due to the use of a stainless steel outer housings rather than a carbon steel housing, or vice versa. Apgee claims that the stainless steel design would provide greater corrosion protection and claims that no safety related problems have occurred as a result of the stainless steel housing.

**Potential Violations:**

- Model LB 300 ML/MLT devices constructed with an outer housing of stainless steel is not clearly indicated in the original (and subsequent) application for approval of this device. Based on Apgee's statement that these devices have been constructed with a stainless steel outer housing since 1988, the prior approval of a similar device for Swank Metacon that contained a stainless steel outer housing (used, in part, as the basis for the approval of the LB 300 ML devices), and the ambiguity of the information in the background file for these

devices, it is recommended that distribution of model LB 300 ML/MLT devices by Apgee or BSI with an outer housing of stainless steel not be considered a violation of any regulations or license conditions.

**Required Amendments:**

- Pending a fee issue resolution, registration certificate NR-0112-D-111-S will be amended to include the use of a stainless steel outer housing.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-111-S for this change as they believe the design is included in the current approval.
- Apgee and BSI have not deferred resolution of this issue to EG&G Berthold in TN.

**Recommendations for continued use:**

- A review of the design of the stainless steel outer housing of the model LB 300 ML/MLT devices indicates that this design would likely be approved and distribution and use authorized.
- It is recommended that Apgee/BSI be allowed to continue to distribute model LB 300 ML/MLT devices with stainless steel outer housings in accordance with the information supplied.

**Additional Questions:**

- None.

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

**Findings:**

- Numerous model LB 300 ML/MLT devices have been distributed containing a spring-loaded detent.
- Apgee indicated that for all practical purposes, a spring-loaded detent has been installed in these devices since their introduction.

**Potential Safety Hazards:**

- The information provided by Apgee indicates no increased level of health and safety risk due to the use of a spring-loaded detent. Apgee claims that this design would provide greater safety and functionality as it would ensure the shutter is held in the correct position when open and claims that no safety related problems have occurred as a result of the spring-loaded detent.

**Potential Violations:**

- Model LB 300 ML/MLT devices containing a spring-loaded detent is not clearly indicated in the original (and subsequent) application for approval of this device. Based on Apgee's statement that these devices have contained a spring-loaded detent since as early as 1980, the prior approval of a similar device for Swank Metacon that contained a spring-loaded detent (used, in part, as the basis for the approval of the LB 300 ML devices), and the ambiguity of the information in the background file for these devices, it is recommended that distribution of model LB 300 ML/MLT devices by Apgee or BSI containing a spring-loaded detent not be considered a violation of any regulations or license conditions.

**Required Amendments:**

- Pending a fee issue resolution, registration certificate NR-0112-D-111-S will be amended to include the use of a spring-loaded detent.
- Apgee and BSI have not requested amendment to registration certificate NR-

0112-D-111-S for this change as they believe the design is already included in the registration certificate.

- Apgee and BSI have not deferred resolution of this issue to EG&G Berthold in TN.

**Recommendations for continued use:**

- A review of the design of the spring-loaded detent of the model LB 300 ML/MLT devices indicates that this design would likely be approved and distribution and use authorized.
- It is recommended that Apgee/BSI be allowed to continue to distribute model LB 300 ML/MLT devices containing the spring-loaded detent in accordance with the information supplied.

**Additional Questions:**

- None.

**Model:** LB 300 L and LP Devices  
**Device Type:** Tank fill level control gamma gauges.  
**Registration certificate:** NR-0112-D-106-B  
**Licenses:** 37-21226-01  
37-28697-01  
37-21226-02G

**Issues Identified:**

1. Change of paint on these devices from epoxy to polyurethane based.

**Findings:**

- Apgee indicated that all devices constructed after 1992 were painted with the new paint.
- Devices with the new paint applied have been distributed to specific and general licensees.
- Apgee confirmed that paint is included for corrosion protection.
- Apgee claims that the new paint provides equivalent corrosion protection as the previous paint.
- Apgee did not provide design specifications for the paint sufficient to demonstrate its corrosion protection qualities.

**Potential Safety Hazards:**

- The information provided by Apgee indicates that there is not an immediate health and safety risk due to the use of the new paint.

**Potential Violations:**

- Distribution of model LB 300 L/LP devices with a paint that does not meet or exceed the specifications contained in registration certificate NR-0112-D-106-B is a violation of 10 CFR 32.210(f)(1), 10 CFR 32.51(a), License Condition 12 of License No. 37-21226-01, License Condition 11 of License No. 37-21226-02G, and License Condition 12 of License No. 37-28697-01.
- If Apgee provides paint specifications that demonstrate that the new paint provides equivalent corrosion protection to the previously approved paint, distribution of these devices with the new specification should not be considered a violation of any regulations or license conditions.

**Required Amendments:**

- Distribution of model LB 300 L/LP devices with an alternate paint specification requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-106-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendments have been issued.
- Apgee has requested amendment to registration certificate NR-0112-D-111-S for this change.
- Apgee has not deferred resolution of this issue to EG&G Berthold in TN.

**Recommendations for continued use:**

- Licensees possessing devices containing the new paint should be allowed to continue using the devices pending amendment to the registration certificate.

**Additional Questions:**

- Apgee should provide design specifications for the paint sufficient to demonstrate



its corrosion protection qualities, and should demonstrate that the paint provides equivalent or better corrosion protection as the currently approved paint for the device's intended conditions of use.

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

**Findings:**

- Apgee indicated that no devices have been distributed, or plan to be distributed by Apgee/BSI, with the new top plate.

**Potential Safety Hazards:**

None.

**Potential Violations:**

- Since no devices with the new top plate were distributed, there is no violation of regulations or license conditions.

**Required Amendments:**

- Apgee did not request amendment to registration certificate NR-0112-D-106-B to add this new top plate.
- Apgee deferred this issue (including amendment of the registration certificate) to EG&G Berthold in TN.

**Recommendations for continued use:**

None.

**Additional Questions:**

None.

3. Addition of a 270 mm diameter shield.

**Findings:**

- Three 270 mm LB 300 L shields were distributed to Grant Chemical in Zachary, LA. Apgee did not indicate the date this shipment was made as requested during the November 21, 1996, meeting.
- Apgee did not indicate if Grant Chemical received these devices under a specific or the general license.

**Potential Safety Hazards:**

- The information provided by Apgee indicates that there is not an immediate health and safety risk due to the use of the distributed 270 mm model LB 300 L shields. Apgee claims the design and construction of the 270 mm device is identical to approved models currently in use in the field, but with smaller diameters, and that the activity of the source installed in the 270 mm device was less than the maximum activity authorized in the 254 mm device.

**Potential Violations:**

- Distribution of model LB 300 L devices with diameters greater than 254 mm is not in conformance with registration certificate NR-0112-D-106-B. This is a violation of 10 CFR 32.210(f)(1) and (2) and/or 10 CFR 32.51(a), License Condition 12 of License No. 37-21226-01, License Condition 12 of License No. 37-28697-01, and/or License Condition 11 of License No. 37-21226-02G.

**Required Amendments:**

- Distribution of model LB 300 L devices with diameters greater than 270 mm requires prior safety evaluation (10 CFR 32.210 and/or 32.51), approval, and amendment to registration certificate NR-0112-D-106-B and License numbers

37-21226-01, 37-28697-01, and/or 37-21226-02G. No prior safety evaluation has been performed, no approval has been granted, and no amendments have been issued.

- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-106-B for this change.
- Apgee and BSI have not deferred resolution of this issue to EG&G Berthold in TN.
- If neither Apgee nor EG&G Berthold in TN request and receive a registration certificate for the 270 mm design (as already distributed), either Grant Chemical should be required to request a custom licensing evaluation for the continued use of these devices or Apgee should be required to submit an action plan to bring Grant Chemical into compliance with their license.

**Recommendations for continued use:**

- A cursory review of the design of the 270 mm diameter shield indicates that this option would likely be approved and distribution and use would likely be authorized.
- Grant Chemical should be allowed to continue to use the devices pending performance of a complete safety evaluation and issuance of a registration certificate indicating approval for use of the 270 mm device.
- The use of the existing 270 mm devices should be limited to the isotope and maximum activity authorized for use in a 254 mm device (500 mCi, Co-60) until such time as the 270 mm diameter device is reviewed and approved, including the use of other isotopes and/or greater activities.
- The State of Louisiana should be provided a copy of this report. If neither Apgee nor EG&G Berthold request and receive approval of an 270 mm design (same as already distributed), the State should consider the need to require Grant Chemical to request a custom licensing evaluation for the continued use of these devices.

**Additional Questions:**

- Apgee has not requested amendment to their registration certificate to add the 270 mm design. If neither Apgee nor EG&G Berthold (TN) request amendment to the registration certificate to add the 270 mm shield, Apgee should provide an action plan to bring Grant Chemical into compliance for their devices.
- The primary issues for this device would be the maximum activity requested in the device and the external radiation levels with this activity level, and the possibility of additional damage to the device from a drop during use due to the additional weight of the device.

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

**Findings:**

- Apgee provided a clarifying statement that no model VZ-1501/1 sources have ever been distributed in model LB 300 P/LP devices.

**Potential Safety Hazards:**

None.

**Potential Violations:**

- Since no sources were distributed, there is no violation of regulations or license conditions.

**Required Amendments:**

- Apgee did not request amendment to registration certificate NR-0112-D-106-B to add this source as an approved model.
- Apgee deferred this issue (including amendment of the registration certificate) to EG&G Berthold in TN.

**Recommendations for continued use:**

None.

**Additional Questions:**

None.

**Model:** LB 379

**Device Type:** In-line Density Measuring Device

**Registration Certificate:** NR-112-D-101-B

**Licenses:** 37-21226-01

37-28697-01

37-21226-02G

**Issues Identified:**

1. Flanges are welded on two sides instead of one

**Findings:**

- Apgee indicated that four devices installed outside the US have experienced weld cracks and/or failure in the flange that is used to mount the device to the pipe under conditions of severe vibration. To fix this potential problem, the manufacturer indicated that two welds will be used with the flange versus the current single weld.
- The engineering study performed on the welds indicates that the manufacturing process is faulty and that the weld specification was not followed. This faulty process caused cracks to develop at the time of manufacture, and the situation was worsened by the high vibration at the installation site.
- Apgee did not indicate if the customer listing provided included all possessors of model LB 379 devices or only those customers affected by the faulty weld process. In addition, Apgee did not indicate if both general and specific licensees were affected by this issue.
- The flange is used for device mounting and does not contribute to the containment or primary shielding of the sealed source.
- The device does not have a shutter. Failure of the flange such that the device came loose from its mounting could expose the primary beam of radiation from the source and cause the device to drop. The device does not have a shutter or safety mechanism to shield the source in this condition. In addition, a drop could cause additional damage to the device and possible loss of containment. Potential doses due to a loss of containment or shielding would not be expected to be high.
- Apgee provided an action plan to determine if devices in the field may have cracks in the weld region. Apgee has proposed that devices that contain cracks should be replaced with a double welded device.
- Background information for this device indicates that these devices are not expected to be subjected to severe vibration due to the limitations of the scintillation detector. However, Apgee indicated that the failures occurred only in cases of severe vibration. Apgee did not indicate if the vibration was considered to be outside the normal use conditions of the device.

**Potential Safety Hazards:**

- The information provided by Apgee indicates no immediate health and safety risk due to the use of model LB 379 devices with a single or double weld.

**Potential Violations:**

- None, since no devices were distributed.

**Required amendments:**

- Distribution of model LB 379 Series devices containing the second weld requires



prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-101-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.

- Apgee has not requested amendment to registration certificate NR-0112-D-101-B for this change.
- Apgee has not deferred resolution of this issue (including amendment to the registration certificate) to EG&G Berthold in TN.

**Recommendations for continued use:**

- A cursory review of the second weld on model LB 379 device indicates that this would likely be authorized for distribution and use.
- Any users who are determined to be potentially subject to the faulty weld process should inspect their welds for cracks.
- Users should not install these devices in vibration conditions greater than those recommended by the manufacturer as maximum levels.

**Additional Questions:**

- Apgee should indicate the customers potentially affected by the faulty weld process and whether they are general or specific licensees.
- Apgee should determine if any devices are installed in a high vibration condition that is outside of the normal use conditions for these devices. Apgee should specify what is considered the maximum permissible vibration level.
- Apgee should provide periodic updates as to the responses received from the user checks of the welds.
- If Apgee wishes to replace devices with faulty welds with a double welded device, Apgee should request amendment to the registration certificate for this option.

2. Clarification of maximum activity and distribution of alternate source

**Findings:**

- Apgee indicated that no model LB 379 devices were or are intended to be distributed containing greater than 100 mCi.
- The design of the 30 mCi sources that have been distributed in the past is different than the approved source listed in the certificate. Apgee did not indicate what the differences were. All 30 mCi sources have been taken out of service.
- Apgee did not indicate if sources not in conformance with the registration certificate were distributed to both specific and general licensees.
- The drawing provided by Apgee for the X.91 capsule is essentially similar to the AMC.16 and the P-2642-100 source models except that it is TIG welded rather than Argon Gas Arc welded.

**Potential Safety Hazards:**

- The information provided by Apgee indicates no immediate health and safety risk due to the use of source model AMC.16 or model X.91 capsules in model LB 379 devices.

**Potential Violations:**

- Distribution of model LB 379 devices with a source model that is not in conformance with the design listed in registration certificate NR-0112-D-101-B is in violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No.

37-21226-01, License Condition 12 of License No. 37-28697-01, and, if distributed to general licensees, 10 CFR 32.51(a) and License Condition 11 of License No. 37-21226-02G.

- The design of the AMC.16 is essentially identical to the approved model P-2642-100 source and would meet the design criteria of this model. Both the P-2642-100 source and the AMC.16 are manufactured by Amersham and are based on the X.91 capsule design. Based on this, it is recommended that distribution of model LB 379 devices containing model AMC.16 sources not be considered in violation of regulations or license conditions.
- The determination of other potential violations will be based on Apgee's identification of the design of the 30 mCi sources that were distributed.

**Required amendments:**

- Distribution of model LB 379 devices containing model AMC.16 sources requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-101-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee and BSI have requested amendment to registration certificate NR-0112-D-101-B for this change.
- Apgee and BSI have not deferred resolution of this issue (including amendment to the registration certificate) to EG&G Berthold in TN.
- Pending a fee issue resolution, the SSSS will evaluate Apgee's request for amendment to registration certificate NR-0112-D-101-B to add the AMC.16 source capsule and the X.91 capsule.

**Recommendations for continued use:**

- A cursory review of source model AMC.16 and capsule X.91 to be used in model LB 379 devices indicates that this would likely be authorized for distribution and use.

**Additional Questions:**

- When and how many 30 mCi sources, that are not in conformance with the registration certificate, were distributed?
- Is the X.91 source capsule with a TIG weld currently registered in the US?
- Submittal implies that only AMC.16 sources remain in service. Were any X.91 source capsules with a TIG weld distributed?
- Were source models not in conformance with the registration certificate distributed to general and specific licensees?

3. Different ISO classification for source.

Apgee indicated that the source installed in its source housing has been tested and received a higher ISO classification. However, the source itself was not retested. The registration certificate currently indicates only the source classification, which was not indicated to have changed. In addition, the source classification listed in the model LB 379 device registration certificate is consistent with the classification listed on Amersham's registration certificate for the model AMC.16. Therefore, the registration certificate for the device will not be amended to include the higher ISO classification.

**Model:** LB 300 IRL  
**Device Type:** Level Measuring Device  
**Registration Certificate:** NR-112-D-107-S  
**Licenses:** 37-21226-01  
37-28697-01

**Issues Identified:**

1. New Cs-137 source and new ISO classification for both Cs-137 and Co-60 sources

**Findings:**

- Apgee did not indicate if any of the new model VZ-1501/1 sources were ever distributed. Previous statements indicated that no devices were distributed with these sources. However, the statements in the December 20, 1996, letter seem to indicate that these sources were distributed in model LB 300 IRL devices.
- Apgee did not provide adequate data to demonstrate that the sources have been tested to a higher ISO classification (only classification numbers were provided and these were in German and very hard to read).
- Apgee did not provide complete design data for the new source model VZ-1501/1.
- Apgee claims that the model VZ-1501/1 is essentially similar to the previously approved source model and that the construction of the Co-60 rod source model has not changed, only the ISO classification has changed.

**Potential Safety Hazards:**

- The information provided by Apgee indicates no immediate health and safety risk due to the use of model LB 300 IRL devices with model VZ-1501/1 sources.

**Potential Violations:**

- Distribution of model LB 300 IRL devices containing model VZ-1501/1 sources is not in conformance with registration certificate NR-112-D-107-S. This would be in violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, and License Condition 12 of License No. 37-28697-01.
- If no model VZ-1501/1 sources were distributed, there is no violation.

**Required amendments:**

- Distribution of model LB 300 IRL devices containing model VZ-1501/1 sources requires prior safety evaluation (10 CFR 32.210), approval, and amendment to registration certificate NR-112-D-107-S and License numbers 37-21226-01 and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee previously indicated that it did not wish to have the certificates amended to add the new Cs-137 source model VZ-1501/1. However, the statements in the December 20, 1996, letter seem to indicate that Apgee wishes to have the NR-112-D-107-S certificate amended to add the new source model.
- Apgee and BSI have not deferred resolution of this issue (including amendment to the registration certificate) to EG&G Berthold in TN.
- The new ISO classification cannot be added to the registration certificate until Apgee provides adequate demonstration that the sources have been tested to, and received, the new ISO classification.

**Recommendations for continued use:**

- A cursory review of source model VZ-1501/1 to be used in model LB 300 IRL

devices indicates that this would likely be authorized for distribution and use.

**Additional Questions:**

- Apgee should indicate if they wish to have the VZ-1501/1 source model and the new ISO classification added to the certificate. If so, Apgee should provide complete information on the design of the VZ-1501/1 source model and the ISO classification testing.
- Apgee should indicate if any of these devices were ever distributed with model VZ-1501/1 sources installed.

2. The maximum allowable length of the source should be increased from 100 cm to 150 cm.

**Findings:**

- Apgee believes the certificate authorizes source lengths up to 150 cm based on the attachment to the certificate. This is incorrect. The attachment shows the source housing with a length of 160 cm, the shielding with a length of 150 cm and no indication as to the length of the source (except that it is less than the shielding length). The text of the certificate and drawings submitted for the sources indicate a maximum length of 100 cm. There is no data on file that indicates source lengths greater than 100 cm. The drawing included with Apgee's December 20, 1996, submittal also indicates a maximum source length of 100 cm.
- Apgee did not provide additional prototype testing data for source lengths greater than 100 cm.
- Apgee did not indicate if source lengths greater than 100 cm were ever distributed.
- Apgee's submittal dated October 15, 1996, indicated a request for a maximum source length of 130 cm rather than 150 cm.

**Potential Safety Hazards:**

- Insufficient information was provided to determine the ability of sources with lengths greater than 100 cm to provide adequate containment and safety when subjected to the devices intended use conditions.

**Potential Violations:**

- Distribution of source lengths greater than 100 cm is not in conformance with registration certificate NR-112-D-107-S. This would be in violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, and License Condition 12 of License No. 37-28697-01.
- If no source lengths greater than 100 cm were distributed, there is no violation.

**Required amendments:**

- Distribution of source lengths greater than 100 cm requires prior safety evaluation (10 CFR 32.210), approval, and amendment to registration certificate NR-0112-D-107-S and License numbers 37-21226-01 and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- The certificate will not be amended based on the information provided.

**Recommendations for continued use:**

- No source lengths greater than 100 cm should be in use.
- Insufficient information was provided to determine the acceptability of use of source lengths greater than 100 cm.



**Additional Questions:**

- Apgee should indicate if source lengths greater than 100 cm were ever distributed and provide the locations where they were distributed.
- If Apgee wishes to have source lengths greater than 100 cm authorized, it should provide complete design, use, and prototype testing (ISO, ANSI, etc.) data to support a safety analysis for the sources in their intended use conditions.
- Apgee should clarify if it is requesting a maximum source length of 130 cm or 150 cm.

3. Different ISO source classification

See item 1. above.

4. New ANSI flanges installed on shield.

**Findings:**

- Apgee did not indicate if any devices were distributed with the new flanges.
- Apgee did not provide complete design data for the devices with the new flanges or the reason for the new flanges.
- Apgee did not provide an indication of the health and safety implications of the use of the device with the new flanges.
- Apgee indicated that the new flanges are a clarification rather than a change in the design of the device, but provided no justification for this claim.
- Flanges are used for stability and mounting during the loading and unloading of the source to or from the vessel to be measured.

**Potential Safety Hazards:**

- Insufficient information was provided to determine the health and safety implications of the new flanges. Apgee did not address this issue.

**Potential Violations:**

- Distribution of model LB 300 IRL devices with flanges that are not in accordance with the approved designs would be considered in violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, and License Condition 12 of License No. 37-28697-01.

**Required amendments:**

- Insufficient information was provided to determine if the new flanges require an amendment to the registration certificate.
- Apgee did not request amendment to the registration certificate.

**Recommendations for continued use:**

- Insufficient information was provided to determine the acceptability for use of the new flanges.

**Additional Questions:**

- Apgee should indicate if any of these devices were ever distributed with the new flanges.
- Apgee should provide the reason and justification for why the new flanges are not considered a change to the approved design.
- Apgee should indicate if they wish to amend the registration certificate to include the new flanges.
- Apgee should provide an analysis as to the health and safety implications of the new flanges (i.e., changes in device operation, changes in external radiation

levels during use due to the repositioning of the flanges, etc.).

5. New Cs-137 source which includes a higher grade stainless steel

See item 1. above.

**Model:** LB 330  
**Device Type:** Belt Weigher  
**Registration Certificate:** NR-112-D-109-B  
**Licenses:** 37-21226-01  
37-28697-01  
37-21226-02G

**Issues Identified:**

1. Increased diameter of source encapsulation

**Findings:**

- Apgee indicates that the diameter of the source was increased from 6mm to 7mm in 1987 to be consistent with other devices.
- Apgee referred to its August 15, 1996 letter for a higher ISO classification for these sources. No reference to a higher ISO classification for these sources could be found in that letter.
- Apgee continues to distribute these sources.
- Apgee did not indicate if the design of the device was required to be changed to accommodate the larger diameter sources.
- Additional drawings were provided that seem to indicate that additional changes to the device have been made in the past, but no discussion of this was provided.

**Potential Safety Hazards:**

- Insufficient information was provided to determine the potential health and safety applications of the use of larger diameter sources. Potential issues may be interference with the operation of the shutter mechanism due to the larger diameter and a reduced ability of the source to withstand the intended condition of use due to the reduction in strength (in certain conditions) of the source an increase in diameter would cause.

**Potential Violations:**

- Distribution of model LB 330 devices containing modifications to the approved design or containing source models with diameters in excess of 6mm is not in conformance with registration certificate NR-0112-D-109-B. This is in violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, License Condition 12 of License No. 37-28697-01, and, if distributed to general licensees, 10 CFR 32.51(a) and License Condition 11 of License No. 37-21226-02G.
- Apgee's indication that it continues to distribute a source that it has identified as not in conformance with the design approved in the registration certificate indicates a potential willful disregard for the requirements of its license and NRC's regulations.

**Required amendments:**

- An increase in source diameter from 6 mm to 7 mm requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-109-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee has requested amendment to registration certificate NR-112-D-109-B to add the 7 mm diameter source.

**Recommendations for continued use:**

- Insufficient information was provided to determine the adequacy for continued use of model LB 330 devices with 7 mm diameter sources and the compatibility of the larger diameter with the device. However, the information provided indicates that if the 7 mm diameter sources are found to be compatible with the devices, they would likely be authorized for distribution and use.

**Additional Questions:**

- Apgee should indicate the number of sources with larger diameters that were distributed, the locations to where they were distributed, and whether they were distributed to both specific and general licensees.
- Apgee should immediately provide sufficient information to demonstrate that the increase in diameter of the source would not cause a health and safety risk. If Apgee is not able to provide this demonstration, Apgee should provide an action plan to remove these sources from use.
- Apgee should provide a description of any changes in the device design necessary to accommodate the larger diameter source (mounting configuration, increase in diameter of the source holder shaft, changes to external radiation levels, etc.), and a clear demonstration of the increase in the ISO classification discussed in the report.
- Apgee should indicate the reasons why it continues to distribute sources that it has identified as not in conformance with the approved design.
- Apgee should discuss any other changes that have been made to the device design and the potential safety implications of these changes.

**2. Spacers added to source rod.****Findings:**

- Apgee indicated that spacers are used to stabilize the source rod under vibration conditions.
- Apgee did not indicate the reason it is necessary to stabilize the source rod in vibration conditions.
- Apgee did not indicate if the addition of spacers requires modification to the device design.
- Apgee did not indicate the potential health and safety implications of the use (or lack of use) of source rod spacers.
- Apgee did not indicate if devices were distributed containing the spacers, or if it continues to distribute devices containing spacers.

**Potential Safety Hazards:**

- Insufficient information was provided to determine the potential health and safety applications of the use (or lack of) source rod spacers. Potential issues may be interference with the operation of the shutter mechanism due to the spacers and an integrity problem with the sources in vibration conditions.

**Potential Violations:**

- Distribution of model LB 330 devices containing modifications to the approved design or containing source rod spacers is not in conformance with registration certificate NR-0112-D-109-B. This is in violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, License Condition 12 of License No. 37-28697-01, and, if distributed to general licensees, 10 CFR 32.51(a) and License Condition 11 of License No. 37-21226-02G.



- If Apgee indicates it is continuing to distribute devices with the spacers, this would indicate a potential willful disregard for the requirements of its license and NRC's regulations.

**Required amendments:**

- The addition of spacers to the source rods requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-109-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee has requested amendment to registration certificate NR-112-D-109-B to add the spacers to the source rods.

**Recommendations for continued use:**

- Insufficient information was provided to determine the adequacy for continued use of these devices with the spacers. However, if Apgee indicates that the need to stabilize the device is based on measurement data only rather than for the integrity of the source, the spacers would likely be authorized for distribution and use.
- If Apgee indicates that the spacers are required due to problems with the integrity of the sources in vibration conditions, this change would likely be authorized for distribution and use. However, the continued use of devices not containing the spacers would be in question.

**Additional Questions:**

- Apgee should clearly indicate the reasons why spacers were added and indicate if they were added due to a safety concern with the use of the sources in vibration conditions.
- Apgee should indicate the number of devices distributed with the spacers, the locations to where they were distributed, and whether they were distributed to both specific and general licensees.
- Apgee should immediately provide sufficient information to demonstrate that the use (and lack) of the spacers will not cause a health and safety risk. If vibration was determined to be a concern with these devices, Apgee should provide any limiting vibration conditions of use. If Apgee is not able to provide these demonstrations, Apgee should provide an action plan to remove these sources from use.
- Apgee should provide a description of any changes in the device design necessary to accommodate the spacers.
- If Apgee indicates that it continues to distribute devices with spacers, it should indicate the reasons why it continues to distribute devices that it has identified as not in conformance with the approved design.

3. Modify wording in registration certificate to reflect the use of 7 mm diameter sealed sources.

The SSSS will consider the revised wording only after Apgee has provided complete information for the 7 mm sources (see response to issue 1.) and the 7 mm sources are approved. Proposed revised wording indicates that all devices that were distributed contained 7 mm diameter sources. Apgee should indicate if 6 mm diameter sources were also distributed.

4. Include drawing of new size source.

See issues 1 and 3 above.

5. Modification of shutter from 180 degree operation to 90 degree operation.

**Findings:**

- Two LB 330 devices were distributed to Western Sugar Billings in Billings, MT that were constructed to allow a 90 degree shutter operation rather than the approved 180 degree rotation.
- Apgee did not indicate if Western Sugar Billings received the device under a specific or general license.
- Apgee indicated that the change was made to meet Swedish requirements.
- Apgee indicated that the devices at Western Sugar Billings will be modified back to 180 degree operation by January 31, 1997, to bring Western Sugar Billings into conformance with the registration certificate.

**Potential Safety Hazards:**

- None if modification back to 180 degree shutter operation is done properly.

**Potential Violations:**

- Distribution of model LB 330 devices with a 90 degree shutter rotation is not in conformance with registration certificate NR-0112-D-109-B. This is in violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, License Condition 12 of License No. 37-28697-01, and, if Western Sugar Billings received the devices under the general license, 10 CFR 32.51(a) and License Condition 11 of License No. 37-21226-02G.

**Required Amendments:**

- Distribution of model LB 330 devices with a 90 degree shutter rotation requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to registration certificate NR-0112-D-109-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-109-B for this change.
- Apgee and BSI have deferred amendment to the registration certificate to add this option to EG&G Berthold in TN.

**Recommendations for continued use:**

- Western Sugar Billings should be allowed to continue to use the devices provided they are modified to be in conformance with registration certificate NR-0112-D-109-B.

**Additional Questions:**

- Apgee should provide verification that the devices have been modified to a 180 degree shutter operation.

**Model:** LB 300 IPD/L  
**Device Type:** Density/Level Measuring Device  
**Registration Certificate:** NR-112-D-108-B  
**Licenses:** 37-21226-01  
              37-28697-01  
              37-21226-02G

**Issues Identified:**

1. Modified source insertion lengths and shielding diameters.

**Findings:**

- Registration certificate NR-112-D-108-B contains two approved designs for model LB 300 IPD/L devices with fixed dimensions. Apgee indicates that these designs are outdated and that the dimensions of the new designs are variable between a specified range. Apgee indicated that a range of dimensions are needed for various applications.
- Apgee did not clearly indicate if any other size devices were distributed other than the two fixed dimension devices.
- One of the fixed length devices listed in the registration certificate is authorized to be distributed to general licensees and the other is authorized to be distributed only to specific licensees. Apgee did not indicate if devices that did not conform to the approved designs were distributed to both general and specific licensees.
- Apgee indicated that the new source models identified in the LB 7400 series discussion were also distributed with these devices.
- Apgee did not discuss the potential health and safety implications of the use of devices (by both specific and general licensees) with dimensional ranges outside those approved in the registration certificate.
- The basic design of the new devices is similar to the design approved in the registration certificate. However, numerous changes have been made that could effect the use and safety of the devices.
- Apgee indicated that the additional length (1.8 mm) of the new source (as described in the LB 7400 series discussion) is not a concern in these devices as there is sufficient clearance and adjustability in these devices to allow for the extra length.
- One of the designs indicates an automatic actuator. The use of automatic actuators is not listed as an authorized option in the registration certificate.

**Potential Safety Hazards:**

- Insufficient information was provided to determine the potential health and safety implications of the use by either specifically or generally licensed persons of devices that are not in accordance with the designs approved in the registration certificate. Of particular concern is the external radiation levels around the devices, the potential doses to persons working with or around the devices, and the potential of the automatic actuator to damage or shear the shutter shaft during use.

**Potential Violations:**

- Distribution of model LB 300 IPD/L devices with dimensional ranges other than those indicated in the registration certificate, with source models other than those in the registration certificate or with an automatic actuator is not in conformance

with registration certificate NR-0112-D-108-B. This is in violation of 10 CFR 32.210(f)(1) and (2), 10 CFR 32.51(a), License Condition 12 of License No. 37-21226-01, License Condition 11 of License No. 37-21226-02G and License Condition 12 of License No. 37-28697-01.

- There is a potential for a large number of instances of violations with these devices. Apgee seems to indicate that these changes have been in effect for a number of years. A wide range of devices not in conformance with the registration certificate may have been distributed to both specific and general licensees.

**Required amendments:**

- Distribution of model LB 300 IPD/L devices with dimensional ranges and sources models other than those listed in registration certificate NR-0112-D-108-B or with automatic actuators requires prior safety evaluation (10 CFR 32.210 and 10 CFR 32.51), approval, and amendment to the registration certificate and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- The changes identified indicate a complete redesign of these devices. This would require a complete re-evaluation of these devices as if they were a new product.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-108-B for this change.
- Apgee and BSI have deferred this issue (including amendment to the registration certificate) to EG&G Berthold in TN.

**Recommendations for continued use:**

- Users who received devices under the general license that are not in conformance with the design in registration certificate NR-0112-D-108-B should immediately cease use of the devices until such time as Apgee or EG&G Berthold in TN demonstrate that these devices can be safely used by persons not having training in radiological protection, as required in 10 CFR 32.51.
- Insufficient information was provided to determine the adequacy for continued use of these devices by persons specifically licensed.

**Additional Questions:**

- Apgee should indicate if devices that were not in conformance with the approved designs in the registration certificate were distributed to persons specifically and generally licensed. In addition, Apgee should identify the names and locations of customers who received these modified devices.
- For modified devices that were distributed, Apgee should either provide sufficient justification to demonstrate that the devices can be safely used by specific and/or general licensees, or provide an action plan for removal of these devices from use.
- If Apgee intends to defer resolution of this issue to EG&G Berthold in TN, Apgee (of EG&G) should provide a commitment from EG&G indicating their action plan for addressing this issue.

2. Include two new sources - Amersham (same as in LB 7400 series) and Bebig models.

See issue 1. above.



3. Higher ISO source classification.

See issue 1. above.

4. Modify wording in registration certificate to reflect the two new sources

See issue 1. above.

**Model:** LB AS

**Device Type:** Coal Fines Analyzer Gauge

**Registration Certificate:** NR-112-D-110-B

**Licenses:** 37-21226-01

37-28697-01

37-21226-02G

**Issues Identified:**

- 1., 2., Drawing SK 623 on file with the NRC is not on file with the manufacturer, and
- & 3. drawing 21241.000-SK is indicated to be only a preliminary sketch.

**Findings:**

- Registration certificate NR-112-D-110-B contains two approved designs for model LB AS devices. Apgee indicates that these designs were only preliminary sketches and have been replaced with the drawings of the final product designs. Apgee indicated that only minor changes were made between the approved (preliminary) designs and the distributed (final) designs.
- Apgee indicated that all twenty-three devices distributed were in accordance with the final product designs rather than the approved (preliminary) designs.
- The designs contained in the registration certificate are authorized to be distributed to both general and specific licensees. Apgee did not indicate if these devices were distributed to both general and specific licensees.
- Apgee indicated that the changes from the approved design to the distributed design are minor in nature and should not pose a health and safety risk to users of the devices (by both specific and general licensees).
- One of the designs indicates an automatic actuator. The use of automatic actuators is not listed as an authorized option in the registration certificate.

**Potential Safety Hazards:**

- Insufficient information was provided to determine the potential health and safety implications of the use of these devices by persons generally licensed and of the use of these devices with automatic actuators by persons specifically licensed. Of particular concern is the external radiation levels around the devices, the potential doses to persons working with or around the devices, and the potential of the automatic actuator to damage or shear the shutter shaft during use.

**Potential Violations:**

- Distribution of model LB AS device designs not in conformance with the designs contained in registration certificate NR-0112-D-108-B is in violation of 10 CFR 32.210(f)(1) and (2), 10 CFR 32.51(a), License Condition 12 of License No. 37-21226-01, License Condition 11 of License No. 37-21226-02G and License Condition 12 of License No. 37-28697-01.
- All devices distributed were not in accordance with the approved design. Every distribution of these devices should be considered an instance of these violations. The fact that no devices were ever distributed in accordance with the approved designs, that the drawing numbers contained in the registration certificate and the background files were only sketches, that the manufacturer was constructing the devices to a completely different set of manufacturing drawings and specifications, and that Apgee did not identify that the devices were not being constructed in accordance with the drawings referenced in the

registration certificates indicates a significant breakdown of Apgee's QA program and a lack of knowledge and understanding by Apgee of the approved designs.

**Required amendments:**

- The designs of the model LB AS referenced in registration certificate NR-0112-D-110-B do not reflect the design of any devices currently in use. The designs of the devices currently in use must be evaluated in accordance with 10 CFR 32.210 and/or 10 CFR 32.51. In addition, registration certificate NR-0112-D-110-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01 must be amended prior to any further distribution of these devices.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-110-B for this change.
- Apgee and BSI have deferred this issue (including amendment to the registration certificate) to EG&G Berthold in TN.

**Recommendations for continued use:**

- Users who received model LB AS devices under the general license should immediately cease use of the device until such time as Apgee or EG&G Berthold in TN demonstrate that these devices can be safely used by persons not having training in radiological protection, as required in 10 CFR 32.51.
- A cursory review of the new designs of the model LB AS device indicates that they would likely be authorized for distribution and use, with the exception of the use of an automatic actuator.
- Persons who possess devices under specific license (without automatic actuators) should be allowed to continue to use the devices pending approval and issuance of a registration certificate for the new designs.
- Users who possess devices with automatic actuators should cease use until this option is demonstrated to be safe for use and is approved.

**Additional Questions:**

- Apgee should identify which customers received these devices under the general license and those that received the devices with an automatic actuator.
- Apgee should either provide sufficient justification to demonstrate that the devices can be safely used by specific and/or general licensees, or provide an action plan for removal of these devices from use.
- If Apgee intends to defer resolution of this issue to EG&G Berthold in TN, EG&G (through Apgee) should provide a commitment indicating their intention to resolve this issue and an action plan for addressing this issue.

2. Use of alternate source models AMC.D3, AMC.16, and AMC.17.

**Findings:**

- It is unclear if alternate source models AMC.D3, AMC.16, and AMC.17 were distributed in model LB AS devices. This seems to be the implication.

**Potential Safety Hazards:**

- The information provided by Apgee indicates no immediate health and safety risk due to the use of source models AMC.D3, AMC.16, or AMC.17 in a model LB AS device.

**Potential Violations:**

- Distribution of model LB AS devices containing model AMC.D3, AMC.16, or AMC.17 sources is not in conformance with registration certificate NR-0112-D-110-B. This is in violation of 10 CFR 32.210(f)(1) and (2), 10 CFR 32.51(a),

License Condition 12 of License No. 37-21226-01, License Condition 11 of License No. 37-21226-02G and License Condition 12 of License No. 37-28697-01.

- These source models are similar to the designs of the approved model P-2627-100 and P-2642-100 sources. As indicated in the analysis of the model LB 379 device, the design of the AMC.16 is essentially identical to the model P-2642-100 source and would meet the design criteria of this model. The models AMC.D3 and AMC.17 are also similar to this design, however, the model AMC.D3 (registered as the model CTC.D2) has a diameter of 15 mm rather than 10.8 mm. Based on the similarity of designs of the sources to the approved sources, it is recommended that distribution of devices containing these sources be not considered in violation of any license conditions or regulations.

**Required amendments:**

- Distribution of model LB AS devices containing source models AMC.D3, AMC.16, and AMC.17 requires safety evaluation in accordance with 10 CFR 32.210 and 10 CFR 32.51, approval, and amendment to registration certificate NR-0112-D-110-B and License numbers 37-21226-01, 37-21226-02G, and 37-28697-01 prior to distribution and use.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-110-B for this change.
- Apgee and BSI have deferred this issue (including amendment to the registration certificate) to EG&G Berthold in TN.

**Recommendations for continued use:**

- A cursory review of source models AMC.D3, AMC.16, and AMC.17 to be used in model LB AS devices indicates that this would likely be authorized for distribution and use.

**Additional Questions:**

- These source models should be requested to be added to the registration certificate at the same time as the certificate is revised to reflect the correct device designs.

**Model:** LB 375

**Device Type:** Continuous Sulphur Analyzer

**Registration Certificate:** NR-112-D-104-B

**Licenses:** 37-21226-01

37-28697-01

37-21226-02G

**Issues Identified:**

1. - 4. A number of changes were identified for these devices. However, Apgee indicates that it has not distributed any devices containing the changes. All changes have been made by the manufacturer, but have not been included in any of the devices provided to Apgee for distribution. Updates to the registration certificate to include these changes have been deferred to EG&G Berthold in TN. For this reason, these changes are not being evaluated in this report.

5. Typo in registration certificate

Certificate will be amended to correct the typo.

6. Drawing #15136.101-25mm replaces #15136.000-000.

It is unclear whether this is identifying a typo in the certificate or if the drawing has been replaced with a new drawing. Apgee should explain clearly why this drawing has been replaced and provide a copy of the new drawing.

7. Use Amersham design of the source capsule (X131-4) instead of #P2657-100.000.

Source specifications are identical. It is not necessary to add the new drawing and capsule to the sheet. However, for consistency, the SSSS will add the new drawing number and capsule to the sheet when the other corrections are made.

8. Modify wording in registration certificate on the sealed sources to reflect the text in the LB 7400 registration certificate

Certificate will be amended with updated wording if approval of sources is granted for the LB 7400 series device.

9. Use Amersham design of source capsule X2 (#3A11001) instead of the approved drawing #P-2611-100 and modify wording in registration certificate to reflect the suggested text for the LB 6600 registration certificate, to be consistent.

See issues identified in the LB 6600 series device for the use of this source.

10. Clarification that there is a Be window on the stainless steel chamber.

Apgee should provide the design of the Be window for inclusion in the background file. Wording to certificate will be updated to include the Be window.



11. Device modified to no longer rotate.

Apgee should provide drawings that indicate the modifications necessary to keep the device from rotating. This change likely has no effect on the safety of the device.

12. Titanium foil added to beryllium window.

Apgee should provide drawings that indicate the attachment of the titanium foil to the Be window. The titanium was added to protect the Be window due to damage to the beryllium window from the product. Apgee should indicate if the device and/or source was adversely affected by this damage, and address the need to retrofit devices in the field to add the titanium foil?

**Model:** LB 6600

**Device Type:** Moisture Detector - Bunker Probe

**Registration Certificate:** NR-112-D-105-S

**Licenses:** 37-21226-01

37-28697-01

**Issues Identified:**

1. Use Amersham design of source capsule X2 (#3A11001) instead of the approved drawing #P-2611-100 and modify wording in registration certificate to reflect the different source model designation.

**Findings:**

- Amersham and Berthold drawings are essentially similar, except that the types of welds are different (TIG vs. Argon arc welding).
- Apgee provided ISO test data to demonstrate the classification of the source.

**Potential Safety Hazards:**

- The information provided by Apgee indicates no immediate health and safety risk due to the use of model X2 source capsules in model LB 6600 devices.

**Potential Violations:**

- Distribution of model LB 6600 devices with a source model that are not in conformance with the design listed in registration certificate NR-0112-D-105-S is in violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, and License Condition 12 of License No. 37-28697-01.
- The design of the X2 source capsule is essentially identical to the approved model P-2611-100 source and would meet the design criteria of this model except for the weld method. Both the P-2611-100 source and the X2 source capsules are manufactured by Amersham. Based on this, it is recommended that distribution of model LB 6600 devices containing model X2 source capsules not be considered in violation of regulations or license conditions.

**Required amendments:**

- Distribution of model LB 6600 devices containing model X2 source capsules requires prior safety evaluation (10 CFR 32.210), approval, and amendment to registration certificate NR-0112-D-105-S and License numbers 37-21226-01 and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee and BSI have requested amendment to registration certificate NR-0112-D-105-S for this change.
- Apgee and BSI have not deferred resolution of this issue (including amendment to the registration certificate) to EG&G Berthold in TN.
- Pending a fee issue resolution, the SSSS will evaluate Apgee's request for amendment to the registration certificate to add the X2 source capsule.

**Recommendations for continued use:**

- A cursory review of model X2 source capsule to be used in model LB 6600 devices indicates that this would likely be authorized for distribution and use.

**Additional Questions:**

- None.

2. Potential distribution of devices with source activity greater than 100 mCi?

**Findings:**

- Apgee was previously requested to clarify if model LB 6600 Series devices were distributed with activities greater than 100 mCi as this item implies. Apgee did not provide this information.

**Potential Safety Hazards:**

- Increased activities can cause increased external radiation levels. This concern is minimized since these devices are only authorized for use by persons specifically licensed.

**Potential Violations:**

- Distribution of model LB 6600 devices with activities greater than 100 mCi is not in conformance with the design listed in registration certificate NR-0112-D-105-S. This is in violation of 10 CFR 32.210(f)(1) and (2), License Condition 12 of License No. 37-21226-01, and License Condition 12 of License No. 37-28697-01.

**Required amendments:**

- Distribution of model LB 6600 devices with activities greater than 100 mCi requires prior safety evaluation (10 CFR 32.210), approval, and amendment to registration certificate NR-0112-D-105-S and License numbers 37-21226-01 and 37-28697-01. No prior safety evaluation has been performed, no approval has been granted, and no amendment has been issued.
- Apgee and BSI have not requested amendment to registration certificate NR-0112-D-105-S for increased activities.
- Apgee and BSI have not deferred resolution of this issue (including amendment to the registration certificate) to EG&G Berthold in TN.

**Recommendations for continued use:**

- Licensees possessing model LB 6600 Series devices with activities greater than 100 mCi should cease use of the devices until such time as they are evaluated for greater activities.

**Additional Questions:**

- Apgee should clarify if any model LB 6600 Series devices were distributed with activities greater than 100 mCi and provide the customer list of these users.
- If Apgee wishes activities greater than 100 mCi be authorized for use in model LB 6600 Series devices, Apgee should submit an application for amendment to the registration certificate for this change.

3. New drawings for source holder - larger hole for mounting.

It is unclear where this change has been made. Apgee should clearly identify which parts were affected by this change and the drawing numbers of the parts. It is likely that the change would not cause a health and safety concern.

A determination of potential violations and the need to amend the registration certificate will be made when Apgee provides the above identification.

4. New stainless steel nameplate.

The SSSS will update the registration certificate to reflect the material change.

**Model:** LB BW

**Device Type:** Basis Weight Gauge

**Registration Certificate:** NR-112-D-112-B

**Licenses:** 37-21226-01

37-28697-01

37-21226-02G

**Issues Identified:**

1. Add capsule numbers to the registration certificate.

For clarity purposes, the registration certificate lists the registered model numbers of the sources. Capsule numbers are not included unless the registered source model is the capsule number. Certificate will not be changed.

2. Typo on certificate: Kr-90 to Kr-85.

Certificate will be corrected to reflect the correct isotope.

3. New piston used for the automatic actuator.

Apgee should provide the new piston identification data or provide the generic specifications of the piston to allow for the determination of equivalency and to update the information in the background file. If the piston is determined to be equivalent to the previous piston, it is recommended that this not be considered in violation of regulations or license conditions.