September 28, 1998

NOTE TO: NR-112-D-807-B

FROM: John W. Lubinski

CAL & CONVERTING THE REGISTRATION CERTIFICATE TO INACTIVE

NRC has evaluated the responses to the CAL and has determined that all issues are closed. Specifically, Apgee has indicated that no sources over 100 cm were distributed (except one used in a custom device registered by LA) and has indicated that the spec.fications for the ANSI flanges are identical to the DIN flanges. In addition, since the certificate is being converted to inactive, NRC has disregarded the Apgee's request to use longer sources in the devices.

Application detail June 4, 1987, regurant increal legtly & activities. The request for increased activity was withdown on June 17,1987. As indirected above, struce the resubtration was rejusted to be made inactive, and no sources of increased length well distributed, the application detail June 4, 1987, is considered withdown to being meinte in the file as it alls updated drawings of the source components.

Dec 20, '96 Att 6, 7, 8 / May 13, '97 Att. 14

Complete, make changes as noted & copy Attas

NO.: NR-0112-D-807-S DATE:

PAGE 1 OF 7

DEVICE TYPE: Level Measuring Device

MODEL: LB 300 IRL Series (Drawing 21257.000-000)

DISTRIBUTOR: Apgee Corporation Hopewell Business & Industrial Park 103 Corporation Drive Aliquippa, PA 15001

MANUFACTURER : EG&G Berthold Postfach 160 Calmbacher Strasse 22 D-7547 Wildbad I Germany

SEALED SOURCE MODEL DESIGNATION:

why the charge EG&G Berthold Model, Drawing. No.5 P-2608-100+4924 (Cobalt-60) ort P-2608-101 Amersham Duite Dwg. Amersham Buchler Model, Berthold Drawing No.SK 1208 (Cesium-137)

ISOTOPE:

Cobalt-60 Cesium-137 MAXIMUM ACTIVITY:

8 millicuries (0.296 GBq) 50 millicuries (1.85 GBg)

LEAK TEST FREQUENCY: 36 months

PRINCIPAL USE: (D) Gamma Gauges

CUSTOM DEVICE: YES X NO

<u>NO.</u>: NR-0112-D-807-S <u>DATE</u>:

PAGE 2 OF 7

DEVICE TYPE: Level Measuring Device

DESCRIPTION:

A Model LB 300 IRL Series device is used to measure the level of content of large vessels or pipes. Figure (a) of Attachment 1 of this safety evaluation shows a typical installation for an LB 300 IRL Series Device. Under the Apgee Corp. scheme of model numbers, the "LB 300 IRL Series" identifies a series of electronic systems; the "I" indicates that the source is mounted in a "dip tube"; i.e., immersed in a vessel but not in contact with the vessel's contents; the "R" indicates a rod source of radiation; that "L" identifies use for level measurements.

The device uses either a cobalt-60 rod source or a cesium-137 rod source. When the ac ce is in its "off" position, the rod source is contained in a steel encased, lead shielded housing. The housing is mounted on a "dip tube" that extends into the vessel. When the device is in its "on" position, the rod source is in the "dip tube." The dip tube is sealed so that the source does not come in contact with the contents of the vessel. The dip tube may enter the vessel from any direction; i.e., top, bottom, or sides.

For some installations, the housing is used to transfer the rod source into or out of the dip tube but does not remain mounted on the dip tube. For these installations, a plug or cover plate closes the dip tube and protects the rod source during use.

When the device is in its "on" position, radiation exits the dip tube and is reduced in intensity by the contents of the vessel before reaching a scintillation detector probe that is mounted on the external surface of the vessel.

The design of construction of the dip tube are performed by the manufacturer of the vessel or pipe. To insure the integrity of the dip tube, Apgee will review and approve its design to determine that adequate protection will be provided to the source at all times.

Post knoe?

<u>NO.</u>: NR-0112-D-807-S <u>DATE</u>:

PAGE 3 OF 7

DEVICE TYPE: Level Measuring Device

DESCRIPTION (cont.):

The housing serves as transport container, source transfer container, and storage container. Several housings are used in the LB 300 IRL Series of devices. Each cylindrical in shape, has lead shielding encased by steel, can accommodate a single rod source, has a means of positioning the rod source without exposing the operator to an unshielded source, and has a means of closing (lead plug or shutter) and securing the source storage tube. The housing uses either stiff wire or a steel rod to position the rod source as discussed below.

In some housings, the rod source is positioned by manipulating a stiff wire that is attached to the rod source. This wire is accessible upon removal of the locked cover (cap showed at the top of Figure (b) of Attachment 1). The stiff wire is connected to the rod source by use of a link that is crimped to the wire. The wire's link is attached to the rod source's link by a screw, lock washer, and nut.

A yellow marking band on the stiff wire is visible when the rod source is in its "off" position. This mark is made at the time of installation of the device by Berthold Systems, Inc., or other specific licensee. Safety instructions supplied by Apgee advise persons to determine that the source rod is in its storage position by both (a) visual check for the yellow marking band and (b) verification by the electronics of the system.

In some housings the rod source is manipulated by a handling rod which can be screwed into an internally treaded hole in the top of the rod source. The top of the rod source has a short steel pin which protrudes at 90° into a slot and prevents rotation of the source while the handling rod is being attached to, or removed from, the rod source. When the handling rod is not in use, it is stored on the side of the housing.

The manufacturer provides a cover plate for a closure of the end of the source dip tube when the housing is not mounted on a vessel. This plate is attached to the housing by fasteners.

The cobalt-60 rod-shaped source has a stainless steel capsule with external dimensions of approximately 7 millimeters (0.28")in diameter and ranging from a few centimeters to 100 centimeters (39.4") in length. The capsule has a minimum wall thickness of 1 millimeter (0.04") and is sealed by argon gas arc welding. The cobalt-60 is in the form of wire made of a cobalt-nickel alloy.

<u>NO.</u>: NR-0112-D-807-S <u>DATE</u>:

PAGE 4 OF 7

DEVICE TYPE: Level Measuring Device

DESCRIPTION (Cont.):

The cesium-137 rod-shaped source has an outer stainless steel capsule and a minimum wall thickness of 1 mm (0.04") and is sealed by argon gas arc welding. The cesium-137 is in the form of cesium glass or ceramic bead within welded stainless steel inner capsules. Spacers may be used in the rod source to distribute the inner capsule throughout the length of the source. The source is approximately 7 millimeters (0.28") in diameter and ranges in length from a few to 100 centimeters (39.4").

LABELING:

The manufacturer/distributor states that each source housing will be labeled in accordance with the requirements of 10 CFR 20.1901.

These labels are made of aluminum or stainless steel and are riveted in place or are made of mylar and secured in place with an adhesive.

Additionally, with regard to installation on vessels or tanks where there is accessibility into the vessel or tank, a caution sign with the statement "Radiation Area - Check to insure that the shutter is closed before entering" to be placed at any logical access point.

DIAGRAMS:

See Attachment 1: (a) Sketch of installed device; (b) Drawing of housing Drawing 21257.000-000.

CONDITIONS OF NORMAL USE:

The system is designed for the measurement of the level of the contents of large vessels or pipes.

The device might encounter a variety of industrial environments; however, because of characteristics inherent to scintillation detector systems, particularly with respect to temperature and

<u>NO.</u>: NR-0112-D-807-S <u>DATE</u>:

PAGE 5 OF 7

DEVICE TYPE: Level Measuring Device

CONDITIONS OF NORMAL USE (cont.):

vibration, environmental stresses on radiological protection features of the device should be well within the protective capabilities of those features. The manufacturer's operating instructions that accompany the device state -20° to 50°C (-4 to 122°F) for the scintillation counter.

Multiple barriers (seals) between the radioactive material and the exterior of the device housing and dip tube provide protection against corrosive abrasive airborne material.

As related by the manufacturer, European experience has shown that the design of the Berthold equipment has been such as to be unaffected by normal use in industrial environments.

Written radiation safety instructions are provided to users.

PROTOTYPE TESTING:

Apgee Corporation did not supply prototype test results regarding mechanical operation (e.g., no specific data on life cycle testing of the shutter mechanism). In lieu of such submission, Apgee Corporation states "the continued use of these devices in Europe over a 10 year period in industrial environments without operational problems causing radiation exposures in excess of acceptable levels indicates to us that prototype testing at this time is not necessary - units are considered field tested."

The rod sources have been evaluated and each has achieved classification of ISO/C65444 (same as ANSI N542-1977). The housings-satisfy the standards set forth in IAEA and German (mou), transport standards for Type A packaging and are used in the U.S. under the provisions of 49 CFR 173.415(d).

EXTERNAL RADIATION LEVELS:

The manufacturer states that radiation levels at 30 centimeters (11.8") and at 1 meter (39.4") from accessible surfaces of vessels containing installed devices with the source inserted in its dip tube would not exceed 5.0 mR/hr (50μ Sv/hr) and 1.0 mR/hr (10μ Sv/hr), respectively.

<u>NO.</u>: NR-0112-D-807-S <u>DATE</u>:

PAGE 6 OF 7

DEVICE TYPE: Level Measuring Device

EXTERNAL RADIATION LEVELS (cont.):

Apgee Corporation states that with the source inserted in its housing maximum radiation levels would be: 100 mR/hr (1 mSv/hr) at the surface of the housing, 5 mR/hr (50μ Sv/hr) at 30 cm (11.8"), 2.5 mR/hr (25μ Sv/hr) at 60 centimeters (23.6"), and 1 mR/hr (10μ Sv/hr) at 1 meter (39.4").

QUALITY ASSURANCE AND CONTROL:

The manufacturer/distributor performs inspection and testing on each device to assure that labeling and other radiation protection features are in accordance with specifications and drawings. Each source prior to installation is also tested for leakage/contamination and assayed for source strength. A copy of the "Quality Assurance and Control Program" is on file with the NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

• This device shall be used by persons specifically licensed by the NRC or an Agreement State.

intervels not to exceed

- The device shall be leak tested at 3 years intervals using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- Handling, storage, use, transfer and disposal: To be determined by the licensing authority.
- This registration sheet and the information contained within the references shall not be changed without written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Since the effective date of this document, the Berthold Model LB 300 IRL Series gauges are not current products distributed by Apgee or Berthold. However, Apgee has indicated that Bertholds will handle repairs, servicing, and disposals of these devices.

Based on our review of the information and test data contained in the references cited below, we continue to conclude that the Model LB 300 IRL Series device is acceptable for licensing

<u>NO.</u>: NR-0112-D-807-S <u>DATE</u>:

PAGE 7 OF 7

DEVICE TYPE: Level Measuring Device

SAFETY ANALYSIS SUMMARY (Cont.):

purposes. Furthermore, we continue to conclude that the device would be expected to maintain its containment integrity for normal conditions of use and for accident conditions which might occur during the uses specified in this certificate.

REFERENCE:

ISSUING AGENCY:

The following supporting documents for the Model LB 300 IRL Series Level Measuring Device are hereby incorporated by reference and are made a part of this registration document:

- Berthold Systems, Inc. application dated May 24, 1984, as revised June 20, 1984.
- Berthold Systems, Inc. letters dated September 27, 1984, October 29, 1984, November 15, 1984, November 23, 1984, February 13, 1985, February 28, 1985, March 20, 1985, April 9, 1985, April 25, 1985, May 2, 1985, May 9, 1985, and August 29, 1988, with attachments thereto.
- Berthold Systems, Inc., letters dated March 4, 1985, with transmittal letter dated March 22, 1985.
- Apgee letters dated August 8, 1991, September 28, 1991, October 2, 1991, August 12, 1996, November 27, 1996, December 20, 1996, May 13, 1997, June 4, 1997, June 16, 1997, June 17, 1997, December 5, 1997, and December 18, (FAX) 1997, with enclosures thereto.

U. S. NUCLEAR REGULATORY	COMMISSION
DATE :	REVIEWER: John W. Lubinski
DATE :	CONCURRENCE:

April 14, 1999

G.M. Smith, Jr. Apgee Corporation 103 Corporation Drive Aliquippa, PA 15001

Dear Mr. Smith:

Based on the information submitted in your letter dated December 5, 1997, and subsequent letters, with enclosures thereto, we have transferred the following registration certificates to inactive status. The registration numbers of the certificates have been changed as indicated in the table.

Old Certificate Number	New Certificate Number	Model Number
NR-112-D-104-B	NR-112-D-804-B	LB 378
NR-112-D-112-B	NR-112-D-805-B	LB-BW Series
NR-112-D-106-B	NR-112-D-806-B	LB 300 L and LP Series
NR-112-D-107-S	NR-112-D-807-S	LB 300 IRL Series
NR-112-D-101-B	NR-112-D-808-B	LB 379

Please review the registration certificates (copies enclosed) in their entirety and notify us immediately if there are any errors or omissions.

If you have any questions, please contact me at (301) 415-7868 or Mr. Douglas Broaddus at (301) 415-5847.

Sincerely,

John W/Lubinski, Mechanical Engineer Materials Safety and Inspection Branch Division of Industrial and Medical Nuclear Safety Office of Nuclear Material Safety And Safeguards

Enclosure: As stated

cc w/encl: Skimberle	y, LFDCB			
Distribution:				
IMNS r/f	NE01			
97-44	97-76	97-43	97-77	97-42
(NR-112-D-807-S)	(NR-112-D-8	О5-В) (NR-112-D-	806-B) (NR-112-D-804-	B) (NR-112-D-808-B)

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<u>NO.</u>: NR-0112-D-807-S <u>DATE</u>: APR 14 1999 <u>PAGE 1 OF 8</u>

DEVICE TYPE: Level Measuring Device

MODEL: LB 300 IRL Series (Drawing 21257.000-000)

DISTRIBUTOR: Apgee Corporation Hopewell Business & Industrial Park 103 Corporation Drive Aliquippa, PA 15001

MANUFACTURER: EG&G Berthold Postfach 160 Calmbacher Strasse 22 D-7547 Wildbad I Germany

SEALED SOURCE MODEL DESIGNATION:

EG&G Berthold Model, Drawing. Nos. P-2608=100-101 and P-2608-101 (Cobalt-60)

Amersham Buchler Model, Berthold Drawing No. SK 1208 (Cesium-137)

ISOTOPE:	MAXIMUM ACTIVITY:			
Cobalt-60	8 millicuries (0.296 GBg)			
Cesium-137	50 millicuries (1.85 GBg,			

LEAK TEST FREQUENCY: 36 months

PRINCIPAL USE: (D) Gamma Gauges

CUSTOM DEVICE: YES X NO

9904270115 9pm

NO.: NR-0112-D-807-S DATE: APR 14 1999

PAGE 2 OF 8

DEVICE TYPE: Level Measuring Device

DESCRIPTION:

A Model LB 300 IRL Series device is used to measure the level of content of large vessels or pipes. Figure (a) of Attachment 1 of this safety evaluation shows a typical installation for an LB 300 IRL Series Device. Under the manufacturer's scheme of model numbers, the "LB 300 IRL Series" identifies a series of electronic systems: the "I" indicates that the source is mounted in a dip tube, i.e., immersed in a vessel but not in contact with the vessel's contents; the "R" indicates a rod source of radiation; that "L" identifies use for level measurements.

The device uses either a cobalt-60 rod source or a cesium-137 rod source. When the device is in its "off" position, the rod source is contained in a steel encased, lead shielded housing. The housing is mounted on a dip tube that extends into the vessel. When the device is in its "on" position, the rod source is in the dip tube. The dip tube is sealed so that the source does not come in contact with the contents of the vessel. The dip tube may enter the vessel from any direction, i.e., top, bottom, or sides.

For some installations, the housing is used to transfer the rod source into or out of the dip tube but does not remain mounted on the dip tube. For these installations, a plug or cover plate closes the dip tube and protects the rod source during use.

When the device is in its "on" position, radiation exits the dip tube and is reduced in intensity by the contents of the vessel before reaching a scintillation detector probe that is mounted on the external surface of the vessel.

The design of construction of the dip tube were performed by the manufacturer of the vessel or pipe. To insure the integrity of the dip tube, Apgee reviewed and approved its design, prior to initial distribution, to determine that adequate protection is provided to the source at all times.

The housing serves as a transport container, source transfer container, and storage container. Several housings are used in the LB 300 IRL Series of devices. Each cylindrical in shape, has

NO.: NR-0112-D-807-S DATE: APR 14 1999

PAGE 3 OF 8

DEVICE TYPE: Level Measuring Device

DESCRIPTION (Cont.):

lead shielding encased by steel, can accommodate a single rod source, has a means of positioning the rod source without exposing the operator to an unshielded source, and has a means of closing (lead plug or shutter) and securing the source storage tube. The housing uses either stiff wire or a steel rod to position the rod source as discussed below.

In some housings, the rod source is positioned by manipulating a stiff wire that is attached to the rod source. This wire is accessible upon removal of the locked cover (cap shown at the top of Figure (b) of Attachment 1). The stiff wire is connected to the rod source by use of a link that is crimped to the wire. The wire's link is attached to the rod source's link by a screw, lock washer, and nut.

A yellow marking band on the stiff wire is visible when the rod source is in its "off" position. This mark is made at the time of installation of the device by Berthold Systems, Inc., or other specific licensee. Safety instructions supplied by Apgee advise persons to determine that the source rod is in its storage position by both (a) visual check for the yellow marking band and (b) verification by the electronics of the system.

In some housings the rod source is manipulated by a handling rod which can be screwed into an internally treaded hole in the top of the rod source. The top of the rod source has a short steel pin which protrudes at 90° into a slot and prevents rotation of the source while the handling rod is being attached to, or removed from, the rod source. When the handling rod is not in use, it is stored on the side of the housing.

The manufacturer provides a cover plate for a closure of the end of the source dip tube when the housing is not mounted on a vessel. This plate is attached to the housing by fasteners.

The cobalt-60 rod-shaped source has a stainless steel capsule with external dimensions of approximately 7 millimeters (0.28") in diameter and ranging from a few centimeters to 100 centimeters (39.4") in length. The capsule has a minimum wall thickness of

<u>NO.</u>: NR-0112-D-807-S <u>DATE</u>: APR 14 1999 <u>PAGE 4 OF 8</u>

DEVICE TYPE: Level Measuring Device

DESCRIPTION (Cont.):

1 millimeter (0.04") and is sealed by argon gas arc welding. The cobalt-60 is in the form of wire made of a cobalt-nickel alloy.

The cesium-137 rod-shaped source has an outer stainless steel capsule and a minimum wall thickness of 1 mm (0.04") and is sealed by argon gas arc welding. The cesium-137 is in the form of cesium glass or ceramic bead within welded stainless steel inner capsules. Spacers may be used in the rod source to distribute the inner capsule throughout the length of the source. The source is approximately 7 millimeters (0.28") in diameter and ranges in length from a few to 100 centimeters (39.4").

LABELING:

Apgee states that each source housing is labeled in accordance with the requirements of 10 CFR 20.1901. These labels are made of aluminum or stainless steel and are riveted in place or are made of mylar and secured in place with an adhesive.

Additionally, with regard to installation on vessels or tanks where there is accessibility into the vessel or tank, a caution sign with the statement "Radiation Area - Check to insure that the shutter is closed before entering" is placed at any logical access point.

DIAGRAMS:

See Attachment 1: (a) Sketch of installed device (b) Housing Drawing 21257.000-000

CONDITIONS OF NORMAL USE:

The system is designed for the measurement of the level of the contents of large vessels or pipes.

NO.: NR-0112-D-807-S DATE: APR 14 1999

PAGE 5 OF 8

DEVICE TYPE: Level Measuring Device

CONDITIONS OF NORMAL USE (Cont.):

The device might encounter a variety of industrial environments; however, because of characteristics inherent to scintillation detector systems, particularly with respect to temperature and vibration, environmental stresses on radiological protection features of the device should be well within the protective capabilities of those features. The manufacturer's operating instructions that accompany the device state -20° to 50° C (-4 to 122° F) for the scintillation counter.

Multiple barriers (seals) between the radioactive material and the exterior of the device housing and dip tube provide protection against corrosive abrasive airborne material.

As related by the manufacturer, European experience has shown that the design of the equipment has been such as to be unaffected by normal use in industrial environments.

Written radiation safety instructions are provided to users.

PROTOTYPE TESTING:

Apgee Corporation did not supply prototype test results regarding mechanical operation (e.g., no specific data on life cycle testing of the shutter mechanism). In lieu of such submission, Apgee Corporation states "the continued use of these devices in Europe over a 10 year period in industrial environments without operational problems causing radiation exposures in excess of acceptable levels indicates to us that prototype testing at this time is not necessary - units are considered field tested."

The rod sources have been evaluated and each has achieved an ISO classification of C65444.

NO.: NR-0112-D-807-S DATE: APR 14 1899

PAGE 6 OF 8

DEVICE TYPE: Level Measuring Device

EXTERNAL RADIATION LEVELS:

The manufacturer states that radiation levels at 30 centimeters (11.8") and at 1 meter (39.4") from accessible surfaces of vessels containing installed devices with the source inserted in its dip tube would not exceed 5.0 mR/hr (50μ Sv/hr) and 1.0 mR/hr (10μ Sv/hr), respectively.

Apgee Corporation states that with the source inserted in its housing maximum radiation levels would be: 100 mR/hr (1 mSv/hr) at the surface of the housing, 5 mR/hr (50μ Sv/hr) at 30 cm (11.8"), 2.5 mR/hr (25μ Sv/hr) at 60 centimeters (23.6"), and 1 mR/hr (10μ Sv/hr) at 1 meter (39.4").

QUALITY ASSURANCE AND CONTROL:

The manufacturer/distributor performed inspection and testing on each device to assure that labeling and other radiation protection features are in accordance with specifications and drawings. Each source, prior to installation, was also tested for leakage/contamination and assayed for source strength. A copy of the quality assurance and control program is on file with the NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device may be used by specific licensees of NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- The device shall be leak tested at intervals not to exceed 36 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

NO .: NR-0112-D-807-S DATE: APR 14 1999

PAGE 7 OF 8

DEVICE TYPE: Level Measuring Device

SAFETY ANALYSIS SUMMARY:

Since the effective date of this document, the Apgee Model LB 300 IRL Series gauges are not current products distributed by Apgee or Berthold System, Inc. However, Apgee has indicated that Berthold System, Inc. will handle repairs, servicing, and disposals of these devices.

Based on our review of the information and test data contained in the references cited below, we continue to conclude that the Model LB 300 IRL Series device is acceptable for licensing purposes. Furthermore, we continue to conclude that the device would be expected to maintain its containment integrity for normal conditions of use and for accident conditions which might occur during the uses specified in this certificate.

NO.: NR-0112-D-807-S DATE: APR 1 4 1999 PAGE 8 OF 8

DEVICE TYPE: Level Measuring Device

REFERENCE:

The following supporting documents for the Model LB 300 IRL Series Level Measuring Device are hereby incorporated by reference and are made a part of this registration document:

- Berthold Systems, Inc. application dated May 24, 1984, as revised June 20, 1984.
- Berthold Systems, Inc. letters dated September 27, 1984, October 29, 1984, November 15, 1984, November 23, 1984, February 13, 1985, February 28, 1985, March 20, 1985, April 9, 1985, April 25, 1985, May 2, 1985, May 9, 1985, and August 29, 1988, with attachments thereto.
- Berthold Systems, Inc., letters dated March 4, 1985, with transmittal letter dated March 22, 1985.
- Apgee letters dated August 8, 1991, September 28, 1991, . October 2, 1991, December 20, 1996, May 13, 1997, June 4, 1997, June 16, 1997, June 17, 1997, December 5, 1997, and December 18, 1997, with enclosures thereto.

ISSUING AGENCY:

U. S. NUCLEAR REGULATORY COMMISSION

DATE: APR 1 4 1999

REVIEWER:

John W. Lubinski

CONCURRENCE: /

DATE: APR 1 4 1999

Douglas A. Broaddus

NO.: NR-0112-D-807-S DATE: APR 14 1999

.

ATTACHMENT 1



Fig. (b)

April 14, 1999

G.M. Smith, Jr. Apgee Corporation 103 Corporation Drive Aliquippa, PA 15001

Dear Mr. Smith:

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Based on the information submitted in your letter dated December 5, 1997, and subsequent letters, with enclosures thereto, we have transferred the following registration certificates to inactive status. The registration numbers of the certificates have been changed as indicated in the table.

Old Certificate Number	New Certificate Number	Model Number
NR-112-D-104-B	NR-112-D-804-B	LB 378
NR-112-D-112-B	NR-112-D-805-B	LB-BW Series
NR-112-D-106-B	NR-12-D-806-B	LB 300 L and LP Series
NR-112-D-107-S	NR-112-D-807-S	LB 300 IRL Series
NR-112-D-101-B	NR-112-D-808-B	LB 379

Please review the registration certificates (copies enclosed) in their entirety and notify us immediately if there are any errors or omissions.

If you have any questions, please contact me at (301) 415-7868 or Mr. Douglas Broaddus at (301) 415-5847.

Sincerely,

John W/Lubinski, Mechanical Engineer Materials Safety and Inspection Branch Division of Industrial and Medical Nuclear Safety Office of Nuclear Material Safety And Safeguards

Enclosure: As stated

cc w/encl: Skimberle	y, LFDCB			
Distribution:				
IMNS r/f	NE01			
97-44	97-76	97-43	97-77	97-42
(NR-112-D-807-S)	(NR-112-D-8	05-B) (NR-112-D-	806-B) (NR-112-D-804-	B) (NR-112-D-808-B)

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NAME	JLubinski ⁰		
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P. 9204220112

<u>NO.</u>: NR-0112-D-807-S <u>DATE</u>: APR 14 1999 <u>PAGE 1 OF 8</u>

DEVICE TYPE: Level Measuring Device

MODEL: LB 300 IRL Series (Drawing 21257.000-000)

DISTRIBUTOR: Apgee Corporation Hopewell Business & Industrial Park 103 Corporation Drive Aliquippa, PA 15001

MANUFACTURER: EG&G Berthold Postfach 160 Calmbacher Strasse 22 D-7547 Wildbad I Germany

SEALED SOURCE MODEL DESIGNATION:

EG&G Berthold Model, Drawing. Nos. P-2608-100-101 and P-2608-101 (Cobalt-60)

Amersham Buchler Model, Berthold Drawing No. SK 1208 (Cesium-137)

ISOTOPE:	MAXIMUM ACTIVITY:			
Cobalt-60	8 millicuries (0.296 GBq)			
Cesium-137	50 millicuries (1.85 GBq)			

LEAK TEST FREQUENCY: 36 months

PRINCIPAL USE: (D) Gamma Gauges

CUSTOM DEVICE: YES X NO

24904270115 9pp

NO .: NR-0112-D-807-S DATE: APR 14 1989

PAGE 2 OF 8

DEVICE TYPE: Level Measuring Device

DESCRIPTION:

A Model LB 300 IRL Series device is used to measure the level of content of large vessels or pipes. Figure (a) of Attachment 1 of this safety evaluation shows a typical installation for an LB 300 IRL Series Device. Under the manufacturer's scheme of model numbers, the "LB 300 IRL Series" identifies a series of electronic systems: the "I" indicates that the source is mounted in a dip tube, i.e., immersed in a vessel but not in contact with the vessel's contents; the "R" indicates a rod source of radiation; that "L" identifies use for level measurements.

The device uses either a cobalt-60 rod source or a cesium-137 rod source. When the device is in its "off" position, the rod source is contained in a steel encased, lead shielded housing. The housing is mounted on a dip tube that extends into the vessel. When the device is in its "on" position, the rod source is in the dip tube. The dip tube is sealed so that the source does not come in contact with the contents of the vessel. The dip tube may enter the vessel from any direction, i.e., top, bottom, or sides.

For some installations, the housing is used to transfer the rod source into or out of the dip tube but does not remain mounted on the dip tube. For these installations, a plug or cover plate closes the dip tube and protects the rod source during use.

When the device is in its "on" position, radiation exits the dip tube and is reduced in intensity by the contents of the vessel before reaching a scintillation detector probe that is mounted on the external surface of the vessel.

The design of construction of the dip tube were performed by the manufacturer of the vessel or pipe. To insure the integrity of the dip tube, Apgee reviewed and approved its design, prior to initial distribution, to determine that adequate protection is provided to the source at all times.

The housing serves as a transport container, source transfer container, and storage container. Several housings are used in the LB 300 IRL Series of devices. Each cylindrical in shape, has

NO.: NR-0112-D-807-S DATE: APR 14 1999 PA

PAGE 3 OF 8

DEVICE TYPE: Level Measuring Device

DESCRIPTION (Cont.):

lead shielding encased by steel, can accommodate a single rod source, has a means of positioning the rod source without exposing the operator to an unshielded source, and has a means of closing (lead plug or shutter) and securing the source storage tube. The housing uses either stiff wire or a steel rod to position the rod source as discussed below.

In some housings, the rod source is positioned by manipulating a stiff wire that is attached to the rod source. This wire is accessible upon removal of the locked cover (cap shown at the top of Figure (b) of Attachment 1). The stiff wire is connected to the rod source by use of a link that is crimped to the wire. The wire's link is attached to the rod source's link by a screw, lock washer, and nut.

A yellow marking band on the stiff wire is visible when the rod source is in its "off" position. This mark is made at the time of installation of the device by Berthold Systems, Inc., or other specific licensee. Safety instructions supplied by Apgee advise persons to determine that the source rod is in its storage position by both (a) visual check for the yellow marking band and (b) verification by the electronics of the system.

In some housings the rod source is manipulated by a handling rod which can be screwed into an internally treaded hole in the top of the rod source. The top of the rod source has a short steel pin which protrudes at 90° into a slot and prevents rotation of the source while the handling rod is being attached to, or removed from, the rod source. When the handling rod is not in use, it is stored on the side of the housing.

The manufacturer provides a cover plate for a closure of the end of the source dip tube when the housing is not mounted on a vessel. This plate is attached to the housing by fasteners.

The coba!t-60 rod-shaped source has a stainless steel capsule with external dimensions of approximately 7 millimeters (0.28") in diameter and ranging from a few centimeters to 100 centimeters (39.4") in length. The capsule has a minimum wall thickness of

NO.: NR-0112-D-807-S DATE: APR 14 1999

PAGE 4 OF 8

DEVICE TYPE: Level Measuring Device

DESCRIPTION (Cont.):

1 millimeter (0.04") and is sealed by argon gas arc welding. The cobalt-60 is in the form of wire made of a cobalt-nickel alloy.

The cesium-137 rod-shaped source has an outer stainless steel capsule and a minimum wall thickness of 1 mm (0.04") and is sealed by argon gas arc welding. The cesium-137 is in the form of cesium glass or ceramic bead within welded stainless steel inner capsules. Spacers may be used in the rod source to distribute the inner capsule throughout the length of the source. The source is approximately 7 millimeters (0.28") in diameter and ranges in length from a few to 100 centimeters (39.4").

LABELING:

Apgee states that each source housing is labeled in accordance with the requirements of 10 CFR 20.1901. These labels are made of aluminum or stainless steel and are riveted in place or are made of mylar and secured in place with an adhesive.

Additionally, with regard to installation on vessels or tanks where there is accessibility into the vessel or tank, a caution sign with the statement "Radiation Area - Check to insure that the shutter is closed before entering" is placed at any logical access point.

DIAGRAMS:

See Attachment 1: (a) Sketch of installed device (b) Housing Drawing 21257.000-000

CONDITIONS OF NORMAL USE:

The system is designed for the measurement of the level of the contents of large vessels or pipes.

NO.: NR-0112-D-807-S DATE: APR 14 1999

PAGE 5 OF 8

DEVICE TYPE: Level Measuring Device

CONDITIONS OF NORMAL USE (Cont.):

The device might encounter a variety of industrial environments; however, because of characteristics inherent to scintillation detector systems, particularly with respect to temperature and vibration, environmental stresses on radiological protection features of the device should be well within the protective capabilities of those features. The manufacturer's operating instructions that accompany the device state -20° to 50° C (-4 to 122° F) for the scintillation counter.

Multiple barriers (seals) between the radioactive material and the exterior of the device housing and dip tube provide protection against corrosive abrasive airborne material.

As related by the manufacturer, European experience has shown that the design of the equipment has been such as to be unaffected by normal use in industrial environments.

Written radiation safety instructions are provided to users.

PROTOTYPE TESTING:

Apgee Corporation did not supply prototype test results regarding mechanical operation (e.g., no specific data on life cycle testing of the shutter mechanism). In lieu of such submission, Apgee Corporation states "the continued use of these devices in Europe over a 10 year period in industrial environments without operational problems causing radiation exposures in excess of acceptable levels indicates to us that prototype testing at this time is not necessary - units are considered field tested."

The rod sources have been evaluated and each has achieved an ISO classification of C65444.

NO.: NR-0112-D-807-S DATE: APR 14 1999

PAGE 6 OF 8

DEVICE TYPE: Level Measuring Device

EXTERNAL RADIATION LEVELS:

The manufacturer states that radiation levels at 30 centimeters (11.8") and at 1 meter (39.4") from accessible surfaces of vessels containing installed devices with the source inserted in its dip tube would not exceed 5.0 mR/hr (50μ Sv/hr) and 1.0 mR/hr (10μ Sv/hr), respectively.

Apgee Corporation states that with the source inserted in its housing maximum radiation levels would be: 100 mR/hr (1 mSv/hr) at the surface of the housing, 5 mR/hr (50μ Sv/hr) at 30 cm (11.8"), 2.5 mR/hr (25μ Sv/hr) at 60 centimeters (23.6"), and 1 mR/hr (10μ Sv/hr) at 1 meter (39.4").

QUALITY ASSURANCE AND CONTROL:

The manufacturer/distributor performed inspection and testing on each device to assure that labeling and other radiation protection features are in accordance with specifications and drawings. Each source, prior to installation, was also tested for leakage/contamination and assayed for source strength. A copy of the quality assurance and control program is on file with the NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device may be used by specific licensees of NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- The device shall be leak tested at intervals not to exceed 36 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

NO.: NR-0112-D-807-S DATE: APR 14 1999

PAGE 7 OF 8

DEVICE TYPE: Level Measuring Device

SAFETY ANALYSIS SUMMARY:

Since the effective date of this document, the Apgee Model LB 300 IRL Series gauges are not current products distributed by Apgee or Berthold System, Inc. However, Apgee has indicated that Berthold System, Inc. will handle repairs, servicing, and disposals of these devices.

Based on our review of the information and test data contained in the references cited below, we continue to conclude that the Model LB 300 IRL Series device is acceptable for licensing purposes. Furthermore, we continue to conclude that the device would be expected to maintain its containment integrity for normal conditions of use and for accident conditions which might occur during the uses specified in this certificate.

NO.: NR-0112-D-807-S DATE: APR 1 4 1999

PAGE 8 OF 8

DEVICE TYPE: Level Measuring Device

REFERENCE:

The following supporting documents for the Model LB 300 IRL Series Level Measuring Device are hereby incorporated by reference and are made a part of this registration document:

- Berthold Systems, Inc. application dated May 24, 1984, as revised June 20, 1984.
- Berthold Systems, Inc. letters dated September 27, 1984, October 29, 1984, November 15, 1984, November 23, 1984, February 13, 1985, February 28, 1985, March 20, 1985, April 9, 1985, April 25, 1985, May 2, 1985, May 9, 1985, and August 29, 1988, with attachments thereto.
- Berthold Systems, Inc., letters dated March 4, 1985, with transmittal letter dated March 22, 1985.
- ٠ Apgee letters dated August 8, 1991, September 28, 1991, October 2, 1991, December 20, 1996, May 13, 1997, June 4, 1997, June 16, 1997, June 17, 1997, December 5, 1997, and December 18, 1997, with enclosures thereto.

ISSUING AGENCY:

U. S. NUCLEAR REGULATORY COMMISSION

DATE: APR 1 4 1999

REVIEWER:

DATE: APR 1 4 1999

John W. Lubinski

CONCURRENCE :

Douglas A. Broaddus

NO.: NR-0112-D-807-S DATE: APR 14 1999

ATTACHMENT 1





Soptember 28, 1998

NOTE TO: NR-112-D-807-B

FROM: John W. Lubinski

CAL & CONVERTING THE REGISTRATION CERTIFICATE TO INACTIVE

NRC has evaluated the responses to the CAL and has determined that all issues are closed. Specifically, Apgee has indicated that no sources over 100 cm were distributed (except one used in a custom device registered by LA) and has indicated that the specifications for the ANSI flanges are identical to the DIN flanges. In addition, since the certificate is being converted to inactive, NRC has disregarded the Apgee's request to use longer sources in the devices.

Application dated June 4, 1997, requested increased source lengths and activities. The request for increased activities was withdrawn on June 17, 1997. As indicated above, since the registration was requested to be made inactive, and no sources at increase length were distributed, the application date June 4, 1997, is considered withdrawn. However, since this document provided updated drawings of source components, a copy of the document is being maintained in the file.

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Apgee Corporation

97-44

Hopewell Business & Industrial Park • 103 Corporation Drive • Aliquippa, Pennsylvania 15001 • Telephone: (412) 378-7877 • Fax: (412) 378-1926

June 17, 1997

Mr. Doug Broaddus Mechanical Engineer Sealed Source Safety Section Nuclear Safety, NMSS US Nuclear Regulatory Commission Washington, D.C. 20555

Dear Mr. Broaddus:

We had requested in our application for amendments dated June 4, 1997, that the following registration certificates have added the P-2608-100/101 source with longer lengths and higher activities. We have decided not to add the higher activity levels for these devices:

- 1. NR-112-D-106-B
- 2. NR-112-D-111-S
- 3. NR-112-D-107-S

Therefore, we are requesting only the longer lengths for these sources with the activity levels as per the current registration certificate.

If you have any questions, please call Mary Deppla at 412-378-1900 x3006.

Sincerely,

Sell

G.M. (Bud) Smith, Jr. President Apgee Corporation/ Berthold Systems, Inc.

cc: Mary Dedola Gus Norton John McGrath, NRC Region I

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Apgee Corporation

97-44

Hopewell Business & Industrial Park • 103 Corporation Drive • Aliquippa, Pennsylvania 15001 • Telephone: (412) 378-7877 • Fax: (412) 378-1926

June 16, 1997

Mr. Douglas Broaddus US Nuclear Regulatory Commission Office of Nuclear Material Safety and Safeguards Two White Flint North 11555 Rockville Pike Rockville, MD 20852-2738

Dear Mr. Broaddus:

Please be advised that all technical questions regarding the license amendments and clarifications submitted to your office on May 13, 1997, June 4, 1997 and June 5, 1997, should be directed to Mr. Martin (Gus) Norton at (423)483-2229 or fax (423) 481-2432. Mr. Norton will ensure that Berthold Systems, Inc./Apgee Corporation receives copies of all information submitted to the NRC and summaries of all phone conversations.

Questions or requests for additional information concerning licensing issues should be directed to Mary Dedola at Berthold Systems, Inc. at 412-378-1900 or fax 412-378-1926.

If you have any questions please contact me or Mary Dedola.

Sincerely.

G.M. (Bud) Smith, Jr. President Berthold Systems, Inc./ Apgee Corporation

 cc: Mr. Charlie Arnott (Tennessee Division of Radiological Health) Ms. Mary Dedola (Berthold Systems, Inc.) Mr. Charles Ferrin (Apgee Corporation) Ms. Jami Holbert (EG&G Berthold) Mr. Juergen Muthmann (EG&G Berthold) Mr. Martin Norton (EG&G Berthold)

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Apgee Corporation

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Iopewell Business & Industrial Park • 103 Corporation Drive • Aliquippa, Pennsylvania 15001 • Telephone: (412) 378-7877 • Fax: (412) 378-1926

December 5, 1997

Mr. Doug Broaddus Division of Industrial and Medical Nuclear Safety Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission Washington, D.C. 20555-0001

Subject: Transfer of various registration certificates to "In-Active" Status

Dear Mr. Broaddus:

Apgee requests the transfer of the following Registration Certificates to "In-Active" Status:

1	NR-112-D-101-B	•	In-fline Density Measuring Device (LB 379) Number of Devices Sold - 56 Estimate of Number of Devices still in use - 37
2.	NR-112-D-104-B	•	Continuous Sulphur Analyzer (LB 375) Number of Devices Sold - 63 Estimate of Number of Devices still in use - 52
-3.	NR-112-D-106-B		Level Measuring Device (LB 300 L) Number of Devices Sold - 266 Estimate of Number of Devices still in use - 243
14.	NR-112-D-107-S	-	Level Measuring Device (LB 300 IRL) Number of Devices Sold - 156 Estimate of Number of Devices still in use - 138
-5.	NR-112-D-108-B	-	Density/Level Measuring Device (LB 300 IPD/L) Number of Devices Sold - 87 Estimate of Number of Devices still in use - 85
<i>1</i> 6.	NR-112-D-109-B		Density/Level Measuring Device (LB 330) Number of Devices Sold - 134 Estimate of Number of Devices still in use - 25
7.	NR-112-D-112-B	•	Basis Weight Gauge (LB BW) Number of Devices Sold - 5 Estimate of Number of Devices still in use - 3

Berthold Systems, Inc. plans to continue to repair, service, wipe test, prepare for shipment for disposal and return for repair, survey, and retrieve, store and transfer these devices for return to EG&G Berthold or an authorized disposal site as per Berthold Systems, Inc. License # 37-21226-01. Apgee Corporation will only transfer these devices back to EG&G Berthold or Berthold Systems, Inc. for the above referenced services.

Appee will no longer transfer the above devices to Berthold Systems, Inc. for commercial distribution

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Apgee Corporation

Hopewell Business & Industrial Park • 103 Corporation Drive • Aliquippa, Pennsylvania 15001 • Telephone: (412) 378-7877 • Fax: (412) 378-1926

within the US.

In Regulatory guide NUREG-1550, entitled "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations", Section 8.3 it states that the reviewer of this application must ensure that the background files for these registrations are complete and up-to-date with information pertaining to any changes made to these devices. In Apgee's responses to the Confirmatory Action letter dated June 19, 1996, Supplement dated July 22, 1996, and Pre-decisional Enforcement Conference complete documentation was submitted to the NRC for each of these devices. As it stands, Apgee is not aware of any further documentation needed to complete the NRC files.

Please note, due to the request for "In-Active" Status of the devices listed on the attached invoices that amount due will not be paid. Apgee requests that no fees be assessed after October 1, 1997, since no shipments of these devices have been made.

If there are any questions, please contact Mary Dedola @ 412-378-1900.

Sincerely.

G.M. (Bud) Smith, Jr. President Apgee/Berthold Systems, Inc.

Attachments:

Invoices for renewal of registration Certificates

	NR-112-D-101-B
•	NR-112-D-106-B
	NR-112-D-106-B
	NR-112-D-107-S
	NR-112-D-108-B
•	NR-112-D-109-B
	NR-112-D-112-B

cc: Mary Dedola Darlene Williamson U. S. NUCLEAR REGULATORY COMMISSION FY 98 Annual Materials Fee Invoice Period 10/1/1997 - 9/30/1998 10 CFR 171.16

Invoice Date 10/25/1997 License Anniversary Month

Invoice Numler AM0110-98

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10:12

APGEE CORPORATION ATTENTION: RADIATION SAFETY OFFICER 103 CORPORATION DRIVE HOPEWELL BUSINESS & IND PARK ALIQUIPPE PA 15001

***** Mark THIS COPY with any billing address changes *****

License/Approval/

Registration/	Code	Annual ree		
Certificate Number	AA905	Category(s)	Fe	e Amount
			====	
NR0112D101B	ANN	AC	\$	7,200.00
		TOTAL :	\$	7,200.00

TOTAL INVOICE: \$ 7,200.00

For terms and conditions see attached. Payment must be received within 30 days of the date of this invoice to avoid late charges. Questions: call 301/415-7554

===> To ensure accurate credit, return this copy of the <=== ===> invoice with your payment. Processing may be <=== ===> delayed if the invoice is not included. <===</pre>

> 11-18-97 INACTI IE DER WhIT

U. S. NUCLEAR REGULATORY COMMISSION FY 98 Annual Materials Fee Invoice Period 10/1/1997 - 9/30/1998 10 CFR 171.16

Invoice Date 10/25/1997 License Anniversary Month

Invoice Number AM0112-98

APGEE CORPORATION ATTENTION: RADIATION SAFETY OFFICER HOPEWELL BUSINESS & IND. PARK 103 CORPORATE DRIVE ALIQUIPPE PA 15001

***** Mark THIS COPY with any billing address changes *****

License/Approval/ Registration/ Certificate Number	Code AA905	Annual Fee Category(s)	Fee Amount
NR0112D104B	ANN	9A	\$ 7,200.00
		TOTAL	\$ 7,200,00

TOTAL INVOICE: \$ 7,200.00

If paid by Fedwire see attached Terms and Conditions. If paid by check, make check payable to the NRC (reference Invoice no.) and mail to: U.S. Nuclear Regulatory Commission <=== This PO Box address is License Fee & Accounts Receivable Branch <=== for receipt of payments P.O. Box 954514 <=== only. St. Louis, MO 63195-4514

For terms and conditions see attached. Payment must be received within 30 days of the date of this invoice to avoid late charges. Questions: call 301/415-7554

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U. S. NUCLEAR REGULATORY COMMISSION FY 98 Annual Materials Fee Invoice Period 10/1/1997 - 9/30/1998 10 CFR 171.16

Invoice Date 10/25/1997

License Anniversary Month October

Invoice Number

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APGEE CORPORATION ATTENTION: RADIATION SAFETY OFFICER HOPEWELL BUSINESS & IND. PARK 103 CORPORATE DRIVE PA 15001 ALIOUIPPE

> **** Mark THIS COPY with any billing address changes *****

License/Approval/

Registration/	Coce	Annual Fee	
Certificate Number	AA905	Category (s)	Fee Amount
NR0112D106B	ANN	9A	\$ 7,200.00
		TOTAL :	\$ 7,200.00

TOTAL INVOICE: \$ 7,200.00

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U.S. Nuclear Regulatory Commission <=== This PO Box address is License Fee & Accounts Receivable Branch <=== for receipt of payments <=== only. P.O. Box 954514 St. Louis, MO 63195-4514

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License Anniversary Month Invoice Date Invoice Number -----------10/25/1997 October

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APGEE CORPORATION ATTENTION: RADIATION SAFETY OFFICER HOPEWELL BUSINESS & IND. PARK 103 CORPORATE DRIVE PA 15011 ALIQUIPPE

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License/Approval/

Registration/	Code	Annual Fee		
Certificate Number	AA905	Category(s)	Fe	e Amount

NR0112D107S	ANN	9A	\$	7,200.00
		TOTAL :	\$	7,200.00

TOTAL INVOICE: \$ 7,200.00

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If paid by Fedwire see attached Terms and Conditions. If paid by check, make check payable to the NRC (reference Invoice no.) and mail to: U.S. Nuclear. Regulatory Commission <=== This PO Box address is License Fee & Accounts Receivable Branch <=== for receipt of payments P.O. Box 954514 <=== only. St. Louis, MO 63195-4514

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Invoice Date 10/25/1997 License Anniversary Month

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APGEE CORPORATION ATTENTION: RADIATION SAFETY OFFICER HOPEWELL BUSINESS & IND. PARK 103 CORPORATE DRIVE ALIQUIPPE PA 15001

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License/Approval/

Registration/	Code	Annual Fee	
Certificate Number	AA905	Category (s)	Fee Amount

NR0112D108B	ANN	AG	\$ 7,200.00
		TOTAL :	\$ 7,200.00

TOTAL INVOICE: \$ 7,200.00

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St. Louis, MO 63195-4514

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===> delayed if the invoice is not included. <===</pre>

Invoice Date 10/25/1997 License Anniversary Month

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APGEE CORPORATION ATTENTION: RADIATION SAFETY OFFICER HOPEWELL BUSINESS & IND. PARK 103 CORPORATE DRIVE ALIQUIPPE PA 15001

***** Mark THIS COPY with any billing address changes *****

License/Approval/

Registration/	Code	Annual Fee		
Certificate Number	AA905	Category(s)	F€	ee Amount

NR0112D109B	ANN	AG	\$	7,200.00
		TOTAL :	\$	7,200.00

TOTAL INVOICE: \$ 7,200.00

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U.S. Nuclear, Regulatory Commission <=== This PO Box address is License Fee & Accounts Receivable Branch <=== for receipt of payments P.O. Box 954514 <=== only. St. Louis, MO 63195-4514

For terms and conditions see attached. Payment must be received within 30 days of the date of this invoice to avoid late charges. Questions: call 301/415-7554

===> To ensure accurate credit, return this copy of the <=== ===> invoice with your payment. Processing may be <=== ===> delayed if the invoice is not included. <===</pre>

10/25/1997

Invoice Date License Anniversary Month Invoice Number October

APGEE CORPORATION ATTENTION: RADIATION SAFETY OFFICER HOPEWELL BUSINESS & IND. PARK 103 CORPORATE DRIVE PA 15001 ALIQUIPPE

***** Mark THIS COPY with any billing address changes *****

License/Approval/ License/Approval/
Registration/CodeAnnual FeeCertificate NumberAA905Category(s)Fee AmountExample Figure ************ 9A \$ 7,200.00 ANN NR0112D112B ------------TOTAL: \$ 7,200.00

TOTAL INVOICE: \$ 7,200.00

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If paid by Fedwire see attached Terms and Conditions. If paid by check, make check payable to the NRC (reference Invoice no.) and mail to: U.S. Nuclear Regulatory Commission <=== This PO Box address is License Fee & Accounts Receivable Branch <=== for receipt of payments <=== only. P.O. Box 954514 St. Louis, MO 63195-4514

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> ****** PAYMENT COPY *****

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Apgee Corporation

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Hopewell Business & Industrial Park + 103 Corporation Drive + Aliquippa, Pennsylvania 15001 + Telephone: (412) 378-7877 + Fax: (412) 378-925

FAX TRANSMITTAL

Hopewell Business and Industrial Park 103 Corporation Drive Aliquippa, PA 15001-4863 Phone: 412-378-1900 Fax: 412-378-1926

Date: December 18, 1997 BSI Log #: <u>9269</u> Operator. <u>Max y</u> Fax Number: 301-415-5369

To: Mr. John Lubinski and Mr. Brian Smith - USNRC

From: Mary Dedola (X3006)

Subject: Keeping the LB 300 IRL and LB 300 L device registrations "Active"

Dear Mr. Lubinski and Mr. Smith:

As per the conversation between Mary Dedola of BSI and Mr. Smith of the NRC, in our December 5, 1997 letter, we had asked that the LB 300 IRL and the LB 300 L registration Certificates # NR-112-D-107-S and # NR-112-D-106-B be transferred to "In-active" status. We have found that one of each of these devices is in our Backlog to be shipped by the end of January 1998. Therefore, we are requesting that these registration certificates be held "active" until February 1, 1998, allowing us to make these shipments.

Apgee understands that, by your conversation with Mary Dedola, this afternoon, on February 1, 1998 the registration certificates will be transferred to "In-Active" status and distribution will be prohibited.

Sincerely,

10.

G.M. (Bud) Smith, Jr. President Apgee Corporation

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IMOB/RCES



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I

475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 11, 1997

MEMORANDUM TO:

General 2900

James Lieberman, Director Office of Enforcement

Regional Administrator

Hubert J. Miller

Region I

FROM:

Willerh

SUBJECT:

PROPOSED CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY) (APGEE CORPORATION)

Attached for your review and concurrence is a Confirmatory Order involving Apgee Corporation. A predecisional enforcement conference was held on April 24, 1997, in order to discuss apparent violations identified during an inspection conducted by the NRC. The three apparent violations involved: (1) distribution of devices which were not in compliance with the Sealed Source and Device (SSD) Registry Certificates; (2) failure to conduct quarterly audits; and (3) failure to provide instructions advising customers not to lock certain devices in the open position.

In a subsequent series of correspondence and review of information provided by the licensee, the NRC identified 42 areas of concern regarding 11 devices that are distributed by the licensee. Six of these concerns were discussed at the predecisional enforcement conference at which time, the licensee proposed corrective actions to address the specific concerns. At the conference, the licensee also committed to provide additional information regarding some of the remaining concerns within 30 days of the date of the conference.

With respect to the specific concerns discussed at the conference, the licensee committed to either: (1) submit a request to amend certain device registry certificates to address changes to the devices; (2) verify that certain devices are in compliance with the current registry certificates; and/or (3) bring the devices into compliance with the current registry certificates. Additional commitments will be sought as necessary following review of the additional information related to the remaining concerns.

A Confirmatory Order is proposed as discussed with you and Nader Mamish, of your staff, who was in attendance during the predecisional enforcement conference and during the caucus following the conference, to address the necessary corrective actions and the potential health and safety implications of the devices that are not in compliance with the current registry certificates.

PROPOSED ENFORCEMENT ACTION NOT FOR PUBLIC RELEASE WITHOUT APPROVAL OF THE DIRECTOR, OE

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Memorandum to James Lieberman

While the inspection that identified the apparent violations that are the basis for this action was conducted in June 1996, extensive NRC review of additional information provided by the licensee was required in order to assess the safety significance of the specific devices that were not in compliance with the SSD Registry Certificates. Therefore, timeliness for this case should be determined from March 10, 1997, which is the date that NMSS completed their review and provided the results of the Technical Assessment Request (TAR) to Region I.

Docket No. 030-32518 License No. 37-28697-01

Attachments:

- 1. Proposed Confirmatory Order (Effective Immediately)
- 2. Inspection Report
- NRC Letter to Licensee dated April 2, 1997
- 4. Licensee Presentation at the Predecisional Enforcement Conference
- 5. NRC Letter to Licensee dated May 8, 1997
- 6. Licensee Response, dated May 19, 1397, Agreeing to Commitments
- 7. Licensee Letter, dated May 23, 1997

cc w/Attachments:

- F. Davis, OGC
- D. Cool, NMSS
- B. Summers, OE
- D. Screnci, PAO-RI
- N. Sheehan, PAO-RI

The Regional Counsel has no legal objections to this Proposal Yes X No.

Memorandum to James Lieberman

While the inspection that identified the apparent violations that are the basis for this action was conducted in June 1996, extensive NRC review of additional information provided by the licensee was required in order to assess the safety significance of the specific devices that were not in compliance with the SSD Registry Certificates. Therefore, timeliness for this case should be determined from March 10, 1997, which is the date that NMSS completed their review and provided the results of the Technical Assessment Request (TAR) to Region I.

Docket No. 030-32518 License No. 37-28697-01

Attachments:

- 1. Proposed Confirmatory Order (Effective Immediately)
- 2. Inspection Report
- 3. NRC Letter to Licensee dated April 2, 1997
- 4. Licensee Presentation at the Predecisional Enforcement Conference
- 5. NRC Letter to Licensee dated May 8, 1997
- 6. Licensee Response, dated May 19, 1997, Agreeing to Commitments
- 7. Licensee Letter, dated May 23, 1997

cc w/Attachments:

- F. Davis, OGC
- D. Cool, NMSS
- B. Summers, OE
- D. Screnci, PAO-RI
- N. Sheehan, PAO-RI

The Regional Counsel has no legal objections to this Proposal Yes No

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EA No. 96-246

Mr. G. M. (Bud) Smith President Apgee Corporation 103 Corporation Drive Aliquippa, Pennsylvania 15001

SUBJECT: CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY) (NRC INSPECTION REPORT NOS. 030-20043/96-001, 030-21228/96-001, AND 030-32518/96-001)

Dear Mr. Smith:

The enclosed Confirmatory Order (Effective Immediately) is being issued to confirm commitments you made at a predecisional enforcement conference conducted in the Region I office on April 24, 1997, and during a subsequent telephone conversation on May 1, 1997. The Order requires that you either: (1) bring the devices that are not in compliance with the Sealed Source and Device (SSD) Registry Certificates into compliance by either obtaining an amendment to the registry certificates or take actions to modify the devices; (2) verify that the devices are in compliance with the current registry certificates; or (3) recall the devices. The Order also requires you to provide the NRC with: (1) a schedule for your quarterly audits; (2) written reports of the results of the audits; and (3) monthly reports describing the status of all the actions required by this Order.

In your letter dated May 19, 1997, you agreed to the issuance of the enclosed Order. In a subsequent telephone conversation on May 29, 1997, you agreed to an extension of the dates for the commitments established in the May 1, 1997 telephone conversation and reflected in the NRC's letter to you dated May 8, 1997. In recognition of the fact that you have already submitted amendment requests for several of the SSD Registry Certificates and completed distribution of the galvanized replacement bolts for the LB 7400 devices, your commitments to complete these actions are not reflected in the Order.

At the predecisional enforcement conference, you also agreed to provide the NRC the information on those gauges where NRC analysis had determined that the information was insufficient. Following review of this additional information, the conditions of the Order may need to be modified, in which case the NRC will contact you prior to issuance of a Modified Confirmatory Order.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Order shall be subject to criminal prosecution as set forth in that section. Violation of this Order also may subject the person to civil monetary penalty.

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Apgee Corporation

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, at (301) 415-2741.

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

Sincerely,

James Lieberman, Director Office of Enforcement

Docket No. 030-32518 License No. 37-28697-01

Enclosures: As Stated

cc w/encl: Commonwealth of Pennsylvania

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Apgee Corporation

DISTRIBUTION: PUBLIC SECY CA LCalian, EDO EJordan, DEDE JLieberman, OE HMiller, RI LChandler, OGC FDavis, OGC CPaperiello, NMSS DCool, NMSS **Enforcement Coordinators** RI, RII, RIII, RIV BBeecher, GPA/PA GCaputo, OI DBangart, OSP HBell, OIG DRoss, AEOD DScrenci, PAO-RI NSheehan, PAO-RI OE:Chron OE:EA DCS LAS: DNMS (RI) Nuclear Safety Information Center (NSIC) NUDOCS

OFFICE	RI:ORA	RI:DNMS	RI:ORA	RI:RAMA
NAME	TWalker/mjc	RBlough	BFewell 004	HMiller
DATE	06/8/97	06/ 6/97	06/9 /97	06/9 /97

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ENCLOSURE

UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of APGEE CORPORATION Aliquippa, Pennsylvania

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Docket No. 030-32518 License No. 37-28697-01 EA 96-246

CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY)

Apgee Corporation (Licensee) is the holder of NRC License No. 37-28697-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The license authorizes the possession and use of a variety of radionuclides incident to the loading of sealed sources into devices prior to transfer. Apgee Corporation is also the holder of Sealed Source and Device (SSD) Registry Certificates, NR-0112-D-102-B, NR-0112-D-111-S, NR-0112-D-106-B, NR-112-D-101-B, NR-0112-D-107-S, NR-0112-D-109-B, NR-112-D-108-B, NR-112-D-104-B, NR-0112-D-105-S and NR-112-D-112-B issued by the NRC pursuant to 10 CFR Part 32. The Licensee imports devices manufactured by EG&G Berthold in Germany, performs quality assurance checks, and transfers the devices to Berthold Systems, Inc. for distribution within the U.S. to specific and general licensees. The license was initially issued on September 30, 1991 and is due to expire on October 31, 2001. Most of the SSD Registration Certificates referenced above were originally issued on October 18, 1991. Registration Certificate NR-112-D-109-B was issued on February 16, 1994. Registration Certificates have no expiration date.

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On June 11-13, 1996, representatives from NRC Region I and the Office of Nuclear Materials Safety and Safeguards conducted a routine inspection of Apgee Corporation and Berthold Systems, Inc. in Aliquippa, Pennsylvania. The NRC identified three apparent violations of 10 CFR 32.210 (f)(1) and (2). The apparent violations involve the Licensee's failure to: (1) distribute devices in accordance with the conditions of the Sealed Source and Device (SSD) Certificates of Registration; (2) perform quarterly audits; and (3) distribute devices with manuals that include written instructions advising the customer not to lock the devices in the open position.

Due to the NRC's concern about the improper distribution of devices, the NRC issued a Confirmatory Action Letter (CAL) to the Licensee on June 19, 1996, requiring the Licensee to perform a comprehensive audit of every device currently being distributed by Apgee/Berthold in the United States, including a review of the current design for each model of each device, an evaluation of the safety significance for each deviation between the actual device distributed and the statements and representations contained in the applicable SSD Registration Certificate, and a proposal for corrective actions. The Licensee responded to the CAL in a letter dated July 19, 1996, confirming that some of the devices manufactured by EG&G Berthold and distributed by the licensee may deviate from the SSD Certificates of Registration.

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On July 22, 1996, the NRC issued a supplement to the CAL confirming that Apgee/Berthold: (1) would transfer only devices that meet the requirements of the SSD registrations and the conditions of each license; and (2) specifically address distribution of model LB 7400 series devices with automatic actuators installed at Ciba Geigy in McIntosh, Alabama, and at other customer locations, since this apparent deviation from the SSD Registry Certificate had been specifically identified in previous correspondence between the Licensee and the NRC.

The Licensee submitted its response to the CAL and Supplement in letters dated August 12 and October 15, 1996. In a letter to the Licensee dated October 28, 1996, the NRC reported its findings based on an analysis of the August 12, 1936 submittal and a preliminary review of the October 15, 1996 submittal. The NRC reported that a significant amount of information was needed before the NRC could complete its assessment of the safety significance of the identified deviations. The NRC then asked that the Licensee to completely address each identified deviation and provide complete supporting data. On November 21, 1996, a meeting was held with the Licensee at NRC Headquarters in Rockville, MD to clarify the information necessary to fully respond to NRC's request. On November 27 and December 20, 1996, the Licensee submitted the requested information.

NRC provided its analysis of the Licensee's additional submittels in a letter to the Licensee dated April 2, 1997. The NRC analysis identified 42 areas of concern regarding 11 devices. A number of these concerns constituted apparent violations. There were also a number of areas where additional information was still required. The NRC letter indicated that action was being considered to order the licensee to recall or make modifications to certain devices based

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on safety concerns involving the following devices: (1) LB 7400 with alternate sources; (2) LB 7400 with pneumatic actuator; (3) LB 7400 with carbon steel transport bolts; (4) LB 300 IPD/L with modified source lengths; (5) LB 300 IPD/L with new Amersham or Bebig sources; and (6) LB AS.

A predecisional enforcement conference was conducted with the Licensee at the NRC Region I office on April 24, 1997, to discuss the apparent violations and the concerns identified in the NRC analysis. During the enforcement conference, the Licensee indicated that organizational weaknesses in their program led to the problems. The Licensee also acknowledged that audits of the manufacturing process performed by the Licensee were not thorough.

With regard to the six issues of particular safety concern to the NRC, the Licensee indicated that they planned to either: (1) submit a request to amend certain SSD Registry Certificates to address changes to the devices; (2) verify that certain devices are in compliance with the current Registry Certificates; and/or (3) bring the devices into compliance with the current Registry Certificates. In the case of the LB 7400 with pneumatic actuator, the only device in the field had already been modified to comply with the Registry Certificate. The Licensee also indicated that there were no immediate safety concerns with any of the devices that were currently in the field. The NRC also raised concerns about the LB 330 Belt Scale device and indicated that additional information was needed with regard to the increased diameter source capsules and spacers contained in the device.

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By letter dated May 8, 1997, the NRC described to the Licensee the NRC's understanding of the commitments the Licensee plans to implement. The Licensee subsequently consented to the issuance of this Order in accordance with the conditions described in Section IV below, by a waiver signed on May 19, 1997. On May 29, 1997, in a telephone conversation between John McGrath, USNRC Region I, and G. M. Smith, Apgee Corporation, at N'AC's request a slight relaxation in the implementation dates was agreed upon. The Licensee agreed that this Order is to be effective upon issuance and to waive its rights to a hearing in the matter of this Order only. Implementation of these commitments will provice assurance that sufficient resources will be applied to the Licensee's quality assurance program to ensure that the devices are operated as designed and reviewed by the NRC to protect the health and safety of the public.

I find that the Licensee's commitments as set forth in Section IV, are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health and safety require that the Licensee's commitments be confirmed by this Order. Based on the above, and the Licensee's consent, this Order is immediately effective upon issuance.

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Accordingly, pursuant to sections 8: 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, that:

- A. With respect to the LB 7400 devices with alternative sources, within seven months of the date of the Order, Apgee shall:
 - receive approval from the NRC by obtaining an amended SSD Registry Certificate to allow for the longer source capsules and, once NRC approval is obtained, complete the replacement of the source holders in the devices to conform to the amended Registry Certificate; or
 - 2. recall the devices; or
 - 3. bring the devices into compliance with the current SSD Registry Certificate.
- B. With respect to the LB 7400 devices with carbon steel transport bolts, within seven months of the date of this Order, Apgee shall obtain confirmation (e.g., written, telephone, visual verification, etc.) that all possessors/users of the gauges have replaced the non-galvanized bolts with the supplied/authorized galvanized replacement bolts as instructed.

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- C. With respect to the LB 300 IPD/L devices with modified source housing lengths, shield diameters and other changes previously identified by Apgee, by July 31, 1997, Apgee shall:
 - 1. complete a field inspection of all generally licensed gauges; and
 - notify the NRC immediately of any identified deviations from the SSD Registry Certificate.
- D. With respect to the LB 300 IPD/L devices with new Amersham or Bebig sources, within seven months of the date of the Order, Apgee shall:
 - receive approval from the NRC by obtaining an amended SSD Registry Certificate to allow for the new sources and any other changes to the device that have been identified as not being in accordance with the Registry Certificate; or
 - 2. recall the devices; or
 - 3. bring the devices into compliance with the current SSD Registry Certificate.
- E. With respect to the LB AS devices, Apgee shall:

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- 1. by July 31, 1997, recall the devices; or
- 2. by June 30, 1997, provide the NRC with technical justification as to the safety of the devices and as to why they should remain in the public domain. If the NRC determines that the technical justification is inadequate, Apgee shall recall all devices within 15 days of the NRC's notification or by July 31, 1997, whichever is longer.
- F. With respect to the LB 330 Belt Scale devices with increased diameter of the source capsule and spacers in the source rod, within seven months of the date of the Order, Apgee shall:
 - receive approval from the NRC by obtaining an amended SSD Registry Certificate to allow for the 7mm diameter source and spacers and other changes to the devices; or
 - 2. recall the devices; or
 - 3. bring the devices into compliance with the current SSD Registry Certificate.
- G. Apgee shall provide, in writing, the following information to the Director, Division of Nuclear Materials Safety, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406:

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 Within 30 days of the date of the Order, the schedule for performance of the required quarterly audits. The NRC shall be notified at least 30 days in advance of any change of the scheduled audit dates.

- 2. Within 30 days after the completion of each audit, for a period of one year from the date of the Order, a report describing the results of the quarterly audits. In cases where the audit identifies deficiencies in which devices do not comply with the Registry Certificate, the report shall include a description of corrective action planned to ensure that commitments or requirements are met, a schedule for completion of the corrective action, and a basis as to why the NRC should not take further enforcement action for the continued failure to comply with NRC requirements.
- Monthly status reports that include the status of all actions required by this Order.
- H. If, for any reason, a date specified in the above conditions cannot be met, Apgee shall contact, in writing, Mr. A. Randolph Blough, Director, Division of Nuclear Materials Safety, at the address in Provision G above.

The Regional Administrator, Region I, may relax or rescind, in writing, any of the above conditions upon a showing by the Licensee of good cause.

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Any person adversely affected by this Confirmatory Order, other than the Licensee, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, and include a statement of good cause for the extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region 1, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

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In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director Office of Enforcement

Dated at Rockville, Maryland this day of June, 1997

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ATTACHMENT 2

AUG 2 1996

Docket No. 030-32518

License No. 37-28697-01

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

SUBJECT: ROUTINE INSPECTION NO. 030-32518/96-001

9904270038 300.

Dear Mr. Smith:

On June 11-13, 1996, Douglas Broaddus, of the Office of Nuclear Material Safety and Safeguards, and John McGrath and Kathleen Dolce of this office, conducted a safety inspection at the above address of, activities authorized by the above listed NRC license. Areas examined during the inspection are identified in the enclosed inspection report. Within these areas, the inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements, as described in the enclosed inspection report. However, we are deferring NRC enforcement action until we have reviewed your response to the Confirmatory Action Letter (Ch_{-}) dated June 19, 1996, and, accordingly, no Notice of Violation is being issued at this time. After reviewing your response to the CAL, the NRC will determine the appropriate enforcement action necessary to ensure compliance with NRC regulatory requirements.

In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and enclosure will be placed in the Public Document Room (PDR).

Attachment (4)

G. M. Smith Apgee Corporation

Distribution w/encl: PUBLIC Nuclear Safety Information Center (NSIC) Region I Docket Room (w/concurrences) J. Lieberman, OE N. Mamish, OE R. Weisman, OGC L. Camper, NMSS S. Baggett, NMSS D. Broaddus, NMSS D. J. Holody, RI J. McGrath, RI K. Dolce, RI

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ATTACHMENT 2

AUG 2 1996

Docket No. 030-32518

License No. 37-28697-01

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

SUBJECT: ROUTINE INSPECTION NO. 030-32518/96-001

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Dear Mr. Smith:

On June 11-13, 1996, Bouglas Broaddus, of the Office of Nuclear Material Safety and Safeguards, and John McGrath and Kathleen Dolce of this office, conducted a safety inspection at the above address of, activities authorized by the above listed NRC license. Areas examined during the inspection are identified in the enclosed inspection report. Within these areas, the inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements, as described in the enclosed inspection report. However, we are deferring NRC enforcement action until we have reviewed your response to the Confirmatory Action Letter (CA_{-}) dated June 19, 1996, and, accordingly, no Notice of Violation is being issued at this time. After reviewing your response to the CAL, the NRC will determine the appropriate enforcement action necessary to ensure compliance with NRC regulatory requirements.

In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and enclosure will be placed in the Public Document Room (PDR).

G. M. Smith Apgee Corporation

Your cooperation with us is appreciated.

Sincerely,

Charles W. Hehl, Director Division of Nuclear Materials Safety

Docket No. 030-32518 License No. 37-28697-01

Enclosure: Inspection Report No. 030-32518/96-001

cc w/enclosure: Charles Ferrin, Radiation Safety Officer Commonwealth of Pennsylvania G. M. Smith Apgee Corporation

Distribution w/encl: PUBLIC Nuclear Safety Information Center (NSIC) Region I Docket Room (w/concurrences) J. Lieberman, OE N. Mamish, OE R. Weisman, OGC L. Camper, NMSS S. Baggett, NMSS D. Broaddus, NMSS D. J. Holody, RI J. McGrath, RI K. Dolce, RI

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U.S. NUCLEAR REGULATORY COMMISSION **REGION I**

INSPECTION REPORT

Report No. 030-32518/96-001

03214 Program Codes

Docket No. 030-32518

License Nos. 37-28697-01

Priority 3 Category E

Apgee Corporation Licensee: 103 Corporation Drive Aliquippa, Pennsylvania 15001

Facility Name: Apgee Corporation

Inspection At: 103 Corporation Drive Aliquippa, Pennsylvania 15001

Inspection Conducted: June 11-13, 1996

Inspector:

Douglas Broaddus, Mechanical Engineer

Dolce, Health Physicist

Inspector:

Inspector:

John My Raths John McGrath, Senior Health Physicist

Approved By:

Francis M. Costello, Chief

Nuclear Materials Safety Branch 3 Division of Nuclear Materials Safety

8/1/96 date

5/1/96 date

Inspection Summary: Routine, unannounced inspection conducted on June 11-13, 1996. (Inspection Report No. 030-32518/96-001).

<u>Areas Inspected</u>: Organization, Leak Testing, Sealed Source and Device Inventory, Receipt and Transfer of Radioactive Material, Sealed Source and Device Certificates of Registration, and Gauge Fabrication Materials.

Results: Three apparent violations were identified:

- Distribution of devices not in accordance with the conditions of the registration certificate or for which a certificate of registration has not been issued is an apparent violation of License Condition 12 of License No. 37-28697-01 and 10 CFR 32.210(f)(1) and (2). (Summarized in Table 1)
- 2. Failure to conduct audits on a quarterly frequency is an apparent violation of 10 CFR 32.210(f)(1) (Section 6 of this report).
- 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 is an apparent violation 10 CFR 32.210(f)(1) and License Condition 12 of License No. 37-28697-01 (Section 6 of this report).

DETAILS

1. Persons Contacted

*G.M. (Bud) Smith, President *Whit Little, VP Finance *Charles Ferrin, VP for Technology and Radiation Safety Officer (RSO) *Mary Dedola, Engineering Service Manager and Assistant RSO (ARSO) Todd Wuchevich, Senior Service Engineer Bill Gerber, Senior Development Engineer

Paul Heyl, Shipping/receiving personnel (shipper)

*Francis M. Costello, Branch Chief, USNRC Region I (via telephone call)

*Indicates presence at exit interview

2. Organization

Apgee Corporation (Apgee) is authorized to possess, inspect, and transfer radioactive material (10 curies each of Co-60, Kr-85, Sr-90, Cs-137, Am-241, and Cm-244) in the form of sealed sources and devices containing these sealed sources. Apgee transfers these sealed sources and devices containing sealed sources in the United States to Berthold Systems, Inc. (BSI), of Aliquippa, Pennsylvania.

Apgee and BSI occupy the same physical space. Apgee attempts to segregate its radioactive material inventory from BSI's inventory. During the inspection, Apgee's radioactive material and BSI's radioactive material were located in the same controlled area, but were divided by concrete block partitions. Within the controlled area, no other differentiation was made for Apgee's and BSI's inventory.

Apgee utilizes BSI employees for everyday activities. BSI's shipping/receiving personnel (shipper) accepts radioactive material for Apgee and is responsible for the segregation of the material.

3. Leak Testing

The NRC inspector took five leak test samples of Apgee's sealed sources. Two sources were Am-241 and three were Cs-137. The samples were taken using tongs and a dry Whatman filter. The sample results indicate that none of the sources were leaking (i.e., activity of the sample was less than 0.005 microcurie).

The licensee sends leak test samples to either BSI or Applied Health Physics, Inc. (AHP) of Bethel Park, Pennsylvania. BSI has instrumentation to analyze for the presence of Co-60 and Cs-137, and was shown during Inspection No. 030-20043/96-001 and 030-21228/96-001 to be capable of detecting activities of 0.005 microcuries or less. AHP's instrumentation is reported by the licensee to be capable of analyzing for Am-241 to the required minimum detectable activity.

No violations of regulatory requirements were identified.

4. Sealed Source and Device Inventory

Apgee's sealed source inventory includes four rod sources (two are Am-241 and two are Cs-137) and 11 Cs-137 point sources. All sources were accounted for during the inspection.

Apgee's inventory of devices (shields) included a box of assorted LB 7400 series devices. A number of devices in this box contained a secondary key locking mechanism attached to the shutter handle in addition to the currently approved plunger type key lock. This additional lock is not an approved configuration for these devices. This box also included a number of LB 7400 series devices with an "L" shaped bracket bolted to the shutter handle and another bracket bolted to the housing body. The licensee's RSO explained that when aligned, a padlock is inserted through these brackets to act as an additional locking mechanism. These brackets are also not an approved configuration for these devices.

In a nearby, smaller box there were several other LB 7400 series devices that had been modified from the currently approved design. The shutter handle of these devices contained a cutout through which a wire cable and adapter c uld be threaded. The cab e and adapter are intended to be attached to the source holder, which would then be threaded through the source housing and lowered into the process material to provide a direct measurement. The RSO indicated that these type devices are approved and widely used in Germany, but have not been approved for use in the United States.

The two boxes were located adjacent to a box of LB 7400 series devices which were stated by the RSO to be in full compliance with the current certificate of registration for these devices and that could be distributed.

The inspector expressed concern that the proximity of these unapproved devices to the box of approved devices, the similarity of the devices, and unrestricted access to these devices by BSI personnel, provides a potential for distribution of the unapproved devices to customers. Interviews with BSI's field service engineers indicated that devices are routinely installed (i.e., distributed) with the additional "L" shaped locking mechanism described above.

5. Receipt and Transfer of Radioactive Material

Apgee is authorized to receive sealed sources and source housings from the original manufacturer in Germany. Apgee transfers, in the United States, sealed sources and devices containing sealed sources only to BSI. Apgee also transfers sealed sources and devices to the original manufacturer in Germany, but the licensee's RSO indicated that this occurs infrequently. No other transfers of radioactive material occur.

6. Sealed Source and Device Certificates of Registration

Prior to approval for use, sealed sources and devices containing sealed sources are required to undergo a safety evaluation by the NRC or an Agreement State. Apgee has eleven Sealed Source and Device Certificates of Registration for sealed sources and source housings issued by the NRC and one issued by the State of Louisiana summarizing the safety evaluation performed and the approvals and limitations of the devices.

10 CFR 32.210(f)(1) and (2) require, in part, that persons submitting a request for evaluation and registration of safety information about the product shall distribute the product in accordance with the statements and representations, including quality control program, contained in the request and in accordance with the conditions of the registration certificate.

License Condition 12 of License No. 37-28697-01 requires that only sealed sources and devices which have been evaluated by the Nuclear Regulatory Commission or an Agreement State, and for which the certificate of registration described in 10 CFR 32.210 has been issued, may be distributed to persons a thorized by the Commission or an Agreement State.

A review of devices distributed from Apgee to BSI, interviews of service personnel, and visits to customer sites revealed the following distributions of devices to BSI that were not in accordance with a certificate of registration and/or for which NRC or an Agreement State has not performed a safety evaluation and found the device to be acceptable for licensing:

Apgee's RSO indicated that BSI distributed Model LB 7400 series devices containing transport bolts since 1988 and Apgee continued to distribute these devices containing transport bolts to BSI after October 1991. Apgee received certificates of registration for these devices in October 1991. Apgee's registration certificates (NR-112-D-102-B and NR-112-D-103-B) for Model LB 7400 series devices did not include approval of a transport bolt until July 21, 1994. Therefore, devices distributed from Apgee to BSI between October 1991 and July 21, 1994, and containing transport bolts were not in compliance with the certificates of registration for Model LB 7400 series devices.

Apgee's RSO indicated that Model LB 7400 series devices in BSI's inventory, transferred from Apgee to BSI, contained a transport bolt constructed from carbon steel and these bolts did not contain a galvanized surface treatment. Apgee's letter dated July 5, 1994, submitted in support of device registration NR-0112-D-102-B specifies that transport bolts are constructed from "St 37-2k" steel with a galvanized surface treatment. Transport bolts constructed from carbon steel without a galvanized surface treatment are not in compliance with the certificate of registration for the Model LB 7400 series devices.

Apgee's ARSO provided drawings that indicate that two Model LB 300 ML/MLT devices were distributed to BSI with a detent assembly. A letter to BSI dated July 2, 1985, from NRC specified, in part, that drawing numbers #21225 and #21199 would be used to designate the approved configurations of these devices with manual and automatic control. Apgee committed to abiding by all commitments made by BSI for these devices when Apgee requested the certificates of registration be transferred to Apgee in September 1991. These drawings and registration certificate NR-0112-D-111-S for Model LB 300 ML/MLT devices do not include a detent assembly.

The field engineers and the licensee's RSO stated that most LB 7400 series devices distributed within the last two years have included a protective cap installed on the source housing over the shutter handle. The installation of the protective cap is not included in registration certificate NR-0112-D-102-B as an approved configuration for the Model LB 7400 series devices.

Distribution of devices to BSI, such as the examples described above, which have not been evaluated by the NRC or an Agreement State and for which a certificate of registration described in 10 CFR 32.210 has not been issued is an apparent violation of License Condition 12 of License No. 37-28697-01 and 10 CFR 32.210(f)(1) and (2).

In order to verify that received devices meet the design criteria of their respective registration certificate, the shipping/receiving personnel (shipper) perform a visual check of the device and the shipping documents for model identification. The licensee's RSO indicated that if the shipper identifies any changes, he is instructed to bring this to the attention of the RSO. The shipper verified that if he saw a device that he wasn't familiar with, he would seek out the ARSO. However, when the inspectors asked about the box of unregistered devices, the shipper was not certain whether these devices were in accordance with the registration certificates.

Apgee relies on the original manufacturer to determine what device designs (drawings) conform to the registration certificates. The licensee's RSO indicated that the original manufacturer has been provided a copy of the device registrations, and has been asked to only ship devices meeting the criteria in the certificates. The RSO and/or ARSO check the drawing number of the received device against the drawing number identified by the original manufacturer as conforming to the registration certificate. During the inspection, the licensee informed the inspectors that the original manufacturer may make modifications to the device or drawing without changing the drawing number. Other than the visual and drawing number checks indicated above, Apgee relies on the original manufacturer's Quality Assurance and Control program to determine if the devices transferred to Apgee or drop-shipped to customers in the United States meet the conditions of the NRC registration certificates.

Apgee's quality control program is referenced in all 11 certificates of registration. As part of Apgee's quality control program, Apgee committed in a letter dated October 2, 1991, to, on at least a quarterly basis, perform audits of the original manufacturer to assure that the devices and sources are manufactured as described in the certificates of registration. Audits were performed on May 3, 1996, October 29, 1995, July 18, 1995, December 8, 1994, September 1, 1994, and March 10, 1994; time periods that exceed quarterly.

10 CFR 32.210(f)(1) requires, in part, that persons submitting a request for evaluation and registration of safety information about the product shall distribute the product in accordance with the statements and representations, including quality control program, contained in the request.

Audits not performed on at least quarterly intervals is an apparent violation of 10 CFR 32.210(f)(1).

The inspectors reviewed the instructions provided to users of model LB 7400 series devices. Page 53 of the June 1994, revision of the Operating Manual for the LB 7400 series devices taken from the licensee's stock included instructions clearly informing the user to lock the device in the OPEN position during use. As of June 12, 1996, the licensee was continuing to supply the June 1994 revision of the manual with LB 7400 series devices. The licensee indicated that the June 1994 revision of the manual i. the current version and that the manual does not contain additional instructions to not lock the device in the OPEN position.

10 CFR 32.210(c) requires, in part, that a request for review of a sealed source or device must include sufficient information about ... operating and safety instructions, and its potential hazards of the device, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. A letter dated July 5, 1994, submitted in support of the application for registration of the LB 7400 series devices, requires, in part, that written instructions advising the customer not to lock the device in the OPEN position be provided in the user's manual with the device. 10 CFR 32.210(f)(1) requires, in part, that persons submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with the statements and representations ... contained in the request. In addition, License Condition 12 of License No. 37-28697-01 requires only sealed sources and devices which have been evaluated by the Nuclear Regulatory Commission or an Agreement State and for which the certificate of registration described in 10 CFR 32.210 has been issued may be distributed to persons authorized by the Commission or an Agreement State.

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 is an apparent violation 10 CFR 32.210(f)(1) and License Condition 12 of License No. 37-28697-01.

7. Gauge Fabrication Materials

Throughout the applications for Berthold devices, references are made to steel and stainless steel as two different materials. In addition, the drawings provided from the German manufacturer of Berthold devices also distinguishes between the use of steel and stainless steel. The two German words that were translated by BSI as meaning stainless steel are *Edelstahl* and *Nichtr. Stahl*. In addition, several drawings also referred to stainless steel by its material specification code, such as Nr. 1.4301. The German word for common steel was translated by BSI as *Stahl* and also specified by its material specification, such as St 37-2k on a number of drawings. The applications for the devices, originally submitted by BSI, consistently translated and referred to steel where the drawings contained the German equivalent and specified stainless steel where the drawings contained the German equivalent word or material specification.

The information submitted by BSI in support of the safety evaluation for the model LB 300 ML/MLT devices refers only to steel as the material of construction of the outer and inner shell of the source housing. Reference to stainless steel as the material of construction for the source housing was not specifically included in this information. In addition, a letter to BSI dated July 2, 1985, from NRC specified, in part, that drawing numbers (#21225) and (#21199) would be used to designate the approved configurations of these devices with manual and automatic control. These drawings do not include references to stainless steel, but drawing 21225.000-000 specifies the radiation channel is constructed from St-Blech.

Based on the translations provided by BSI, the consistent reference to steel and stainless steel as different materials of construction, and the specification in the application that the model LB 300 ML/MLT devices are constructed of steel, these devices do not appear to have been evaluated as constructed from stainless steel and thus the staff's belief is that the certificate of registration for the mocel LB 300 ML/MLT devices authorizes distribution of these devices manufactured only from steel. The evaluation of model LB 300 ML/MLT devices constructed from steel is supported by Apgee's application for amendment to the certificate of registration for this device dated December 12, 1994. This application provided a listing of the proposed changes for these devices and indicated that the material of construction was proposed to be changed to stainless steel 1.4301. The change was indicated to be intended to improve durability of the devices.

The licensee confirmed that the devices had been previously manufactured from steel and not stainless steel and that the devices were changed to stainless steel because stainless steel would be more resilient to the harsh conditions these devices are subjected to during use and would make the devices safer. Although a change to stainless steel was identified in the December 12, 1994, amendment request, the licensee indicated during the inspection that they felt that a change from steel to stainless steel did not require an amendment to the registration certificate.

During a review of the licensee's inventory of returned devices, a number of model LB 300 ML/MLT devices were observed constructed of steel and stainless steel. The steel devices were severely corroded while the stainless steel devices were not. The inspector expressed concern that the construction of these devices has been changed and NRC has not been able to evaluate the purpose for this change. The statements made by the licensee concerning the change to stainless steel for durability purposes and the corroded devices in the licensee's returned inventory indicate that the devices in use and not constructed of stainless steel may not be sufficiently durable to withstand the intended conditions of use.

Model LB 300 ML/MLT devices may not have been evaluated by NRC as being constructed from stainless steel. The inspectors informed the licensee that all changes to the information submitted in support of the safety evaluation of the device and that would have an impact on the safe use of the device must be provided to NRC for consideration of safety significance and for NRC evaluation.

8. Exit Interview

The results of the inspection were discussed with the individuals identified in Paragraph 1 at the conclusion of the inspection.
TABLE 1	SUMMARY OF APPARENT DIFFERENCES E TRANSFERRED TO BERTHOLD SYSTEMS,	BETWEEN THE DEVICE BEING INC. AND THE DEVICE REGISTERED	
Device Model No.	Device Registration	Apparent Difference	
LB 7400 series	Certificate of Registration No. NR-112-D-102-B Devices with transpo bolts distributed pr transport bolts bein approved on July 21,		
LB 7400 series	Certificate of Registration No. NR-112-D-102-B	Devices containing transport holts constructed of carbon steel without a galvanized surface treatment rather than being constructed from St 37-2K with a galvanized surface treatment.	
LB 300 ML/MLT	Certificate of Registration No. NR-112-D-111-S	Devices constructed with a detent pin assembly.	
LB 7400 series	Certificate of Registration No. NR-112-D-102-B	Devices constructed with a protective cap.	



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415 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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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:

- 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
- 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 c ir 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

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,

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

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

Distribution w/encl (1):

PUBLIC Nuclear Safety Information Center (NSIC) Region I Docket Room (w/concurrences) H. Thompson, DEDR W. Axelson, RI C. Paperiello, NMSS J. Lieberman, OE D. Cool, NMSS A. Nicosia, OGC L. Davis, OGC J. Fewell, RI D. Holody, RI T. Walker, RI PAO, RI (2) C. Gordon, RI

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

37-21226-01

March 10, 1997

MEMORANDUM TO:

A. Randolph Blough, Director Division of Nuclear Materials Safety Region I

FROM:

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 issue 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.

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Attachment (6)

A. Blough

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 Sualed 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.

A. Blough

 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 abie 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:

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 1. 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 (\/Z-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 maximu 1 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-C2G.

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 submitting 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 clearance; and to submitting an application for safety review and registration of these devices containing the alternate sources, consideration should be given to issuing a Odrer 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.

Distribution of model LB 7400 series devices constructed of stainless steel rather than 2 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 other 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:

1

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

Pneumatic accuator installed on devices. 3.

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

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-gaivanized 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 licens ses, 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.

necommendatic.is 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.

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

Findings:

9

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.

Alternative plunge lock installed on devices. 10.

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 alternativo 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 documer ation (and the registration certificate) accurately reflect the basic design of these devices.

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

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.

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

Findings:

- Five 80 mm shields were distributed to Rapublic 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 i: 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.

Installation of a new locking mechanism that will not allow the device's shutter 9 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.

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

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 amondment. 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.
- Stainless steel construction of the source housings rather that carbon steel. 11.

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.
- Spring-loaded detent, not authorized in the registration certificate, has been installed on 12. 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 '/iolations:

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:

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

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.

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

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.

Fecommendations for continued use:

None.

Additional Questions:

None.

Addition of a 270 mm diameter shield. 3.

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

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:

I not request amendment to registration certificate NR-0112-D-106-B to
 ource as an approved model.

Second ferred this issue (including amendment of the registration certificate) to
 E March Forthold in TN.

Recommended ons for continued use:

N.

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:

Flanges are welded on two sides instead of one 1.

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 revices 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.
- Clarification of maximum activity and distribution of alternate source 2

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 rathe: 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, 37-21225-02G, 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 sequested amendment to registration certificate NR-0112-. D-101-B for this change.
- Apgee and BSI have not defe red 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.

A ditional 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?
- Different ISO classification for source. 3.

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:

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

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 p. ior 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.
- 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 curscry 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.
- The maximum allowable length of the source should be increased from 100 cm to 2 150 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
- 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
- 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 greator 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:

Increased diameter of source encapsulation 1.

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 cources.
- 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 conditions 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, 37-21226-01G, 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 e 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.
- Modify wording in registration certificate to reflect the use of 7 mm diameter sealed 3. 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.

Include drawing of new size source. 4.

See issues 1 and 3 above.

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

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 I vistration ertificate 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-112-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 lengt.
- 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 cor sem 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-198-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-112-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) shoul I provide a commitment from EG&G indicating their action plan for addressing this issue.
- Include two new sources Amersham (same as in LB 7400 series) and Bebig models. 2.

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: LBAS 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
- drawing 21241.000-SK is indicated to be only a preliminary sketch.
- & 3.

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 posses 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 posses 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 ...nd an action plan for addressing this issue.
- Use of alternate source models AMC.D3, AMC.16, and AMC.17. 2.

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.

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.

 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.

 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:

Use Amersham design of source capsule X2 (#3A11001) instead of the approved 1. 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 wald 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.

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

Findings:

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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 37-28597-01. 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.

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

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.

New stainless steel nameplate. 4.

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:

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.

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.

Nuclear Regulatory Commission Pre-decisional Enforcement Conference Presentation	by Apgee Corporation	Attachment 4	
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Agenda

- I. Opening Remarks
- II. Overview of Relationship Between BSI/Apgee and EG&G
- III. Concerns Regarding Potential Inaccurate Information
- IV. Extent-of-Condition Analysis
- V. Root Cause Analysis
- VI. Apparent Violations/ Specific Device Issues
- VII. Summary of Safety Implications
- VIII. Corrective Actions
- IX. Closing Remarks

Opening Remarks

- We Have Consistently Implemented a "Safety First" Philosophy
- We Continue To Work Together To Address All Identified Concerns
- We Have Acted In "Good Faith"
- Apgee Acknowledges That Certain Weaknesses Occurred
- Prompt and Extensive Corrective Actions Have Been and Continue To Be Taken
- We Are Committed To "Doing It Right"

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NRC Concerns Regarding Potential Inaccurate Information	 Two apparent instances: (1) November & December 1996 submittals differ regarding whether Model LB 300 ML/MLT devices were distributed with new locking mechanism; and (2) August & November 1996 submittals differ from December 1996 submittal regarding whether a "limited number" of Model LB 7400 devices were distributed with Model VZ-1508/2 sources 	 Neither Apgee nor EG&G Knowingly Provided Inaccurate Information 	Different Information Occurred Because:	 Difficulties in Extracting Data/Information Our Desire To Promptly Address NRC's Concorns Certain Notification Process Weaknesses Existed (within each organization and between both organizations) 	Positive Aspects:	 We were not satisfied with "skin deep" look at issues We continue to pro-actively look for other issues Comprehensive evaluations to date have not identified any safety concerns or evidence of a programmatic breakdown in quality programs
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Extent-Of-Condition Analysis

- Scope of Review (included document review and personnel interviews)
- 100% Review of Design Drawings (Including Change Orders)
- Looked at Date of Change, Why Change Made, Who Made Change and Whether Distributed in U.S.
- Review began with original registration
- Reviewed Engineering Change Procedure
- Evaluated Customer Experience Records Worldwide
- We Have Confidence That Scope of Issues Are Bounded

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Root Causes

- Different Regulatory Approach Utilized in Germany 3y Manufacturer
- Audits Performed By Apgee Needed To Be More Focused and Thorough
- Communications Weaknesses Existed
- In both directions between Apgee and EG&G and within companies
- Language Differences Contributed
- Expectations Were That No Design Changes Would Occur (i.e., Product Line Historically Stable)
- The Causes Were Multi-Faceted and Problems Developed Incrementally, Over Time
- However, The Focus Was Always on Safety
- Problems Did Not Result From Incompetence or Willful Disregard e

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Apparent Violation No. 1

- "Distribution of devices not in accordance with the conditions of the registration certificate or for which a certificate of registration has not been issues"
- Root Causes Are Consistent With the Overall Root Causes

Apparent Violation No. 2

- "Failure to conduct audits on a quarterly basis"
- Root Cause: Performed Audits on a Quarterly Basis
 - Audit Documentation Weak
- Audit Focus Required Enhancement

Apparent Violation No. 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"
- When originally identified, page change made; upon reprint of manual, page change not included and this was not recognized by Apgee
- Root Cause: Isolated, Human Error

Discussion of Specific Device Issues In 4/2/97 NRC Letter

- LB 7400 with alternate sources (approximately 200)
- Current field data indicates no binding
- Notification within two weeks to all affectedlicensecs' Safety Officers to test device and report results
- December 20, 1996, Attachment No. 23, submittal which provided drawings of shorter Apgee will apply for amended registration for shorter source holder consistent with source holder
- Trained service engineer will replace with shorter source holder, mark each new holder for identification purposes, and train licensee
 - Replacement of source holder entails minimal handling and does not require source disposal
 - Proposed start date is May 1997 (contingent on NRC)
 - Monthly status reports will be made to NRC
- 7400 with pneumatic actuator (one device)
- The actuator was removed by replacing shield
 - Actuator being returned to EG&G

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 Discussion of Specific Device Isrues In 4/2/97 NRC Letter LB 7400 with carbon steel transport bolts 750 of 1272 galvanized bolts replaced, remainder scheduled for replacement by end of May 1997 and will be reported to NRC Touring normal service, check will be made for installation of correct bolt LB 300 IPD/L with modified source lengths and shield diameters LB 300 IPD/L with modified source lengths and shield diameters We believe that all devices contain 100 mm shields and 30 mCi sources (<i>i.e.</i>, within registration) We believe that all devices contain 100 mm shields and 30 mCi sources (<i>i.e.</i>, within registration) To show that doses are below regulatory requirements General licenses: 7 customers - 10 devices Field inspections within 60 days will verify dose rates and that shields and sources are within registration Timpections identify deviations from registration, NRC will be informed and appropriate remedial steps will be provided Monthly status reports will be provided 	
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 Discussion of Specific Devi LB 300 IPD/I, with new Amersham or Beb Four devices one (General Licensee Licensees) with Bebig sources Registration does not authorize use of No safety concern because sources an Request for revised registration will b LB AS Worst Case" radiation safety evaluat "Worst Case" radiation safety evaluat Tibration, Fire, Temperature, Shutter facility In-field inspection to be performed an performed Apgee will apply for amended registra
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Discussion of Specific Device Issues In 4/2/97 NRC Letter

LB 330 Belt Scale

- Issues: (1) will increased diameter of rod source create a safety concern; and (2) what is the purpose of spacers?
 - source (i.e., registration already authorizes other isotopes); and (2) a request for revised Rod source diameter: (1) current registration technically bounds use of 7 mm Am-241 registration will be submitted
 - Spacers: (1) used to assure repeatability of measurement; (2) no safety impact; and (3) request for revised registration will address this matter

Summary of Safety Implications

Key Activities

- Exhaustive Review & Corrective Actions Taken or In Progress
- Customer Experience Data -- For Every Product
- Pre-distribution inspection and Testing
- Installation Testing
- Customer Testing Every Six Months
 - No Reports of Problems
- Customer Training Provides Additional Confidence In Experience Data
 - All Apgee Engineers Are Qualified RSOs
 - Verification Testing For Certain Devices
- Engineering Analyses of Devices With Non-conforming Registrations Meet National and International Health and Safety Standards

Bottom Line

- No Apparent Health and Safety Implications
- All Regulatory Issues Are Being Actively Pursued To Resolution

Summary of Corrective Actions

- Formerly Distributed Devices
- Apgee and EG&G Performed Extensive Evaluations of Design/Manufacturing Documents, Design/Maufacturing Change Process
- Reviewed Customer Experience Worldwide
- EG&G Currently Verifying Configuration Control Activities
- Apgee Will Provide New LB 386 Manuals to Every Customer and Make Conforming Changes Made to Other Manuals
 - Reference Actions Discussed For Specific Devices
- Future Distribution of Devices
- U.S. Based General Manager for EG&G
- Germany Based RSO Trained in U.S. Regulations
- Apgee Audit Procedure In Current QA Manual (Developed Consistent With RG 6.9) Will Be Used To Audit EG&G
 - EG&G Instituted a Strict Policy of No Design Changes
- EG&G Instituted Requirement That U.S. General Manager Musi Approve Any Proposed Design Change and Initiate Any Required Registration Change With Apgee
 - Implementation of Notice Protocols Between Apgee and EG&G

 Apgee and EG&G Strong Business - Within NRC Business - Within NRC We Are Committed to a " We Have and Are Taking We Have and Are Town NRC
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May 08, 1997

EA 96-246

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

Dear Mr. Smith:

This letter is in reference to the predecisional enforcement conference with you, members of your staff, and employees of EG&G Berthold, US Operations, on April 24, 1997, and to the follow-up telephone conversation between you and Mr. Francis M. Costello of my staff on May 1, 1997.

At the conference, you provided specific information as to the corrective actions taken or planned to address the NRC's concerns as stated in the NRC's letter to you, dated April 2, 1997, and in response to the apparent violations listed in Inspection Report Nos. 030-20043/96-001, 030-21228/96-001, and 030-32518/96-001 forwarded with NRC's letter dated August 2, 1996. Specifically, you indicated, in part, that you had completed corrective actions for the one LB 7400 device with the pneumatic actuator by removing the actuator and replacing the shield. In addition, you agreed to provide the NRC, within 30 days of the date of the conference, the information on those gauges where NRC analysis had determined that the information was insufficient. Our April 2, 1997 letter to you enclosed a March 10, 1997 NRC memorandum that described the additional information we need regarding these gauges.

Based on these conversations, we understand that you agree to the commitments identified below. The NRC has determined that public health and safety require that the commitments be confirmed by a Confirmatory Order Modifying License (Order). Therefore, we intend to incorporate these commitments into an Order following your written consent to them. Further, following review of the additional information that you agreed to provide us, the conditions of the Order may need to be modified, in which case the NRC will contact you prior to issuance of a Modified Confirmatory Order.

- A. With respect to the LB 7400 devices with alternative sources, within seven months of the date of the Order, Apgee shall perform one of the following:
 - Submit a request, by May 31, 1997, for amendment of the device registration sheet to allow for the longer source capsules, receive approval from the NRC by obtaining an amended registration, and, once NRC approval is obtained, complete the replacement of the source holders in the devices to conform to the amended registration;

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- 2. Recall the devices; or
- Bring the devices into compliance with the current device registration sheet.
- B. With respect to the LB 7400 devices with carbon steel transport bolts, Apgee shall:
 - 1. By May 31, 1997, complete the distribution of the remaining galvanized replacement bolts for the device; and
 - Within seven months of the date of this Order, obtain confirmation (e.g., written, telephone, visual verification, etc.) that all possessors/users of the gauges have replaced non-galvanized bolts with the supplied/authorized replacement bolts as instructed.
- C. With respect to the LB 300 IPD/L devices with modified source housing lengths, shield diameters and other changes previously identified by Apgee, within two months of the date of this Order, Apgee shall:
 - 1. Complete a field inspection of all generally licensed gauges; and
 - Notify the NRC immediately of any identified deviations from the device registration sheet.
- D. With respect to the LB 300 IPD/L devices with new Amersham or Bebig sources, within seven months of the date of the Order, Apgee shall perform one of the following:
 - Submit a request, by May 31, 1997, for amendment of the device registration sheet for the new sources and any other changes to the device that have been identified as not being in accordance with the registration certificate, and receive approval from the NRC by obtaining an amended registration;
 - 2. Recall the devices; or
 - Bring the devices into compliance with the current device registration sheet.
- E. With respect to the LB AS devices, Apgee shall either:
 - 1. Within two months of the date of the Order, recall the devices; or

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- 2. Within 30 days of the date of the Order, provide the NRC with technical justification as to the safety of the devices and as to why they should remain in the public domain. If the NRC determines that the technical justification is inadequate, Apgee shall recall all devices within 15 days of the NRC's notification or within two months of the date of the Order, whichever is longer.
- F. With respect to the LB 330 Belt Scale devices with increased diameter of the source capsule and spacers in the source rod, within seven months of the date of the Order, Apgee shall perform one of the following:
 - Submit a request, by May 31, 1997, for amendment of the device registration sheet for the 7mm diameter source and spacers and other changes to the devices, and receive approval from the NRC by obtaining an amended registration;
 - 2 Recall the devices; or
 - Bring the devices into compliance with the current device registration sheet.
- G. Apgee shall provide, in writing, the following information to the Director, Division of Nuclear Materials Safety, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406:
 - Within 30 days of the date of the Order, the schedule for performance of the required quarterly audits. The NRC shall be notified at least 30 days in advance of any change of the scheduled audit dates.
 - 2. Within 30 days after the completion of each audit, for a period of one year from the date of the Order, a report describing the results of the quarterly audits. In cases where the audit identifies deficiencies in which devices do not comply with the certificate of registration, the report shall include a description of corrective action planned to ensure that commitments or requirements are met, a schedule for completion of the corrective action, and a basis as to why the NRC should not take further enforcement action for the continued failure to comply with NRC requirements.
 - Monthly status reports that include the status of all actions required by this Order.
- H. If, for any reason, a date specified in the above conditions cannot be met, Apgee shall contact, in writing, Mr. A. Randolph Blough, Director, Division of Nuclear Materials Safety, at the address in Provision G above.

If you consent to issuance of the Order confirming the above commitments, you are waiving your right to request a hearing on all or any part of the Order. In addition, you must sign the Hearing Waiver (enclosed) indicating that you agree to such commitments and are consenting to the issuance of the Confirmatory Order. Please return the signed Hearing Waiver within ten business days from the date of this letter to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738. In addition, please provide a copy of your written consent to Mr. A. Randolph Blough, Director, Division of Nuclear Materials Safety, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406. After receiving your written consent, the NRC will issue the aforementioned Order.

Questions concerning this letter should be addressed to Mr. Blough at (610) 337-5281.

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

Sincerely,

Original Signed by: W.L. Axelson

Hubert J. Miller Regional Administrator

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

Enclosure: As stated

cc w/encl: Commonwealth of Pennsylvania State of Tennessee

DISTRIBUTION: PUBLIC SECY CA JCallan, EDO EJordan, DEDO JLieberman, OE LChandler, OGC JGoldberg, OGC CPaperiello, NMSS DCool, NMSS **Enforcement Coordinators** RII, RIII and RIV BBeecher, GPA/PA DBangart, OSP HBell, OIG GCaputo, Ol DRoss, AEOD DScrenci, PAO-RI NSheehan, PAO-RI OE:EA (2) DCS LAT: DNMS (RI) Nuclear Safety Information Center (NSIC) NUDOCS

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see attached concurrences

RI/ES	RIDNMS	RI/RC	NMSS	OE	RI/RA
TWalker	RBlough	BFewe	SBaggett	JLieberman	HMMer tu
5/1 /97	5/ /97	5/1/197	5/ /97	5/ /97	5/7/97

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DISTRIBUTION: PUBLIC SECY CA JCallan, EDO EJordan, DEDO JLieberman, OE LChandler, OGC JGoldberg, OGC CPaperiello, NMSS DCooi, NMSS Enforcement Coordinators RII, RIII and RIV BBeecher, GPA/PA DBangart, OSP HBell. OIG GCaputo, OI DRoss, AEOD DScrenci, PAO-RI NSheehan, PAO-RI OE:EA (2) DCS LAT: DNMS (RI) Nuclear Safety Information Center (NSIC) NUDOCS

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HEARING WAIVER

Apgee Corporation and Berthold Systems, Inc. (Apgee/BSI), hereby agrees to comply with the commitments described in the NRC's letter dated May 08, 1997, and agrees to the incorporation of these commitments into a Confirmatory Order Modifying License that will be effective upon issuance. I recognize that by signing below, Apgee/BSI consents to the issuance of a Confirmatory Order Modifying License with the commitments described on Pages 1 through 3 of the NRC's letter dated May 08, 1997, and, by doing so, pursuant to 10 CFR 2.202(d), Apgee/BSI waives the right to request a hearing on all or any part of the Order.

G.M. (Bud) Smith, President Apgee Corporation and Berthold Systems, Inc. Aliquippa, Pennsylvania Date
16103375269 P.02

ATTACHMENT 6

APGEE CORPORATION

Hopewell Business Park * 103 Corporate Drive * Aliquippa, PA 15001 * Tel. (412) 378-1900, fax. 1926

TO

May 19, 1997

Mr. Hubert J. Miller Regional Administrator U.S. Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406-1415

Dear Mr. Miller,

I refer to your letter of May 8, 1997. We wish to provide the NRC with two pieces of information.

PARAGRAPH G: Quarterly Audits.

Please be advised that Apgee is scheduling its next quarterly audit on or after June 18th but before June 27th, 1997, this audit to take place at the EG&G Berthold facility in Wildbad, Germany. Our Charles Ferrin will conduct the audit. If a more specific date is required, please let me or Mr. Ferrin know.

HEARING WAIVER is attached, I understand this wording agreed to by your regional counsel, Bradley Fewell.

BERTHOLD SYSTEMS, INC. APGEE CORPORATION

22.

G.M. (Bud) Smith, Jr. President

Attachment: Hearing Waiver

cc: Mary Dedola Charlie Ferrin Mike Fox At EG&G: Gus Norton Neil Sullivan

9404260236 2m

HEARING WAIVER

Apgee Corporation and Berthold Systems. Inc. (Apgee/BS!), hereby agrees to comply with the commitments as described paragraphs "A" through "H" on pages 1 through 3 of the NRC's letter dated May 8, 1997 (the "Commitments"), a copy of which is attached and agrees to the incorporation of the Commitments into a Confirmatory Order Modifying License that will be effective upon issuance. I recognize that by signing below, Apgee/BSI consents to the issuance of a Confirmatory Order Modifying License with the Commitments and, by doing so, pursuant to 10 CFR 2.202(d), Apgee/BSI waives the right to request a hearing on all or any part of the Order.

The Commitments are being undertaken voluntarily. This agreement to waive hearing and accept and comply with Confirmatory Order is not an admission or statement against interest of any kind, or a waiver or estoppel with respect to any defense (except the waiver of a hearing with respect to an order adopting the entry of the Commitments). Apgee/BSI does not adopt and will not be bound by any statements, findings, historical summary or similar provisions that also may be included or incorporated in the Confirmatory Order, other than the Commitments.

G. M. (Eud) Smith, President

Date

G. M. (Bud) Smith, President Apgee Corporation and Berthold Systems, Inc. Aliguippa, Pennsylvania

CC: Mary Dedola Charlie Ferrin Mike Fox Neil Sullivan

HEARING WAIVER

Apgee Corporation and Berthold Systems, Inc. (Apgee/BSI), hereby agrees to comply with the commitments as described paragraphs "A" through "H" on pages 1 through 3 of the NRC's letter dated May 8, 1997 (the "Commitments"), a copy of which is attached and agrees to the incorporation of the Commitments into a Confirmatory Order Modifying License that will be effective upon issuance. I recognize that by signing below, Apgee/BSI consents to the issuance of a Confirmatory Order Modifying License with the Commitments and, by doing so, pursuant to 10 CFR 2.202(d), Apgee/BSI waives the right to request a hearing on all or any part of the Order.

The Commitments are being undertaken voluntarily. This agreement to waive hearing and accept and comply with Confirmatory Order is not an admission or statement against interest of any kind, or a waiver or estoppel with respect to any defense (except the waiver of a hearing with respect to an order adopting the entry of the Commitments). Apgee/BSI does not adopt and will not be bound by any statements. findings, historical summary or similar provisions that also may be included or incorporated in the Confirmatory Order, other than the Commitments.

G. M. (Bud) Smith, President

Date

G. M. (Bud) Smith, President Apgee Corporation and Berthold Systems, Inc. Aliquippa, Pennsylvania

CC: Mary Dedola Charlie Ferrin Mike Fox Neil Sullivan

BSI LOG NO. , OPERATOR SEND TO TELEFAX NO. 610 337 5269 PAGE NUMBER _ OF 3

BSI INSTRUMENTS

Process Control Instruments

Hopewell Business Fark 101 Corporation Drive Aliguippa, PA 15001-4863 Telephone: (412) 376-1900 Telefax: (412) 378-1325

May 18, 1997

HUBERT J. MILLER To: REGIONAL ADMINSTRATOR NRC REGION I

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The attached letter is transmitted, and will also be delivered by mail.

Sincerely yours,

G.M. Smith, Jr. APGEE CORPORATION

Hopewell Business & Industrial Park * 103 Corporation Drive * Aliquippa, Pennsylvania 15001 * Telephone: (412) 378-7877 * Fax: (412) 378-1926

May 23, 1997

Mr. Hubert J. Miller Regional Administrator United States Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406

Dear Mr. Miller:

This letter is in response to the order sent to my attention dated May 8, 1997. As per the order the following lists the items chosen to complete the safety evaluation and the continued use of these devices in the field:

- A. With respect to the LB 7400 devices with alternale sources:
- Please see ATTACHMENT #1, the amendment for the addition of source model #2623-800 (VZ-1508/2) Cs-137, source model #2623-700 (VZ-1486/3) Co-60 and the addition of revised source holder design to provide sufficient clearance for the VZ-1508/2 and VZ-1486/3 sources in Registration #NR-0112-D-102-B
- B. With respect to the LB 7400 devices with carbon steel transport bolts, Apgee shall:
- By May 31, 1997, complete the distribution of the remaining galvanized replacement bolts for the device.

Distribution of the galvanized bolts was completed on May 26, 1997.

- Confirmation of the replacement of these bolts by our customers, will be completed within 7 months of the date of this order.
- C. With respect to the LB 300 IPD/L devices with modified source housing lengths, shield diameters and other changes previously identified by Apgee, within two months of the date of this Order, Apgee shall:
- 1. Complete a field inspection of all generally licensed gauges.

The scheduling of this visitations are in progress.

Notify the NRC immediately of any identified deviations from the device registration sheet.

Please see ATTACHMENT #2 of this letter. This listing shows the diameters of the shields that are out in the field. Where the listing refers to transport shield, the sources only were replaced.

Please see ATTACHMENT #3 for a complete amendment to the registration certificate for these devices. Please note that these shields are being sent for prototype testing. The test results will be submitted to the NRC upon completion.

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- D With respect to the LB 300 IPD/L devices with new Amersham or Bebig sources, within seven months of the date of the order, Apgee shall perform one of the following
- Submit a request, by May 31, 1997, for the amendment of the device registration sheet for the new sources and any other changes to the device that have been identified as not being in accordance with the registration certificate, and receive approval from the NRC by obtaining an amended registration;

Please see ATTACHMENT #3 for a complete amendment to the registration certificate for these devices. Please note that these shields are being sent for prototype testing. The test results will be submitted to the NRC upon completion.

- E. With respect to the LB AS devices, Apgee shall either:
- Within 30 days of the date of the Order, (not yet received) provide the NRC with Technical justification as to the safety of the devices and as to why they should remain in the public domain.

Please see ATTACHMENT #4 for a complete amendment to the registration certificate to all the new design of the LB AS devices. Please not that ATTACHMENT #5 show the shutter and temperature test results for these devices. The complete prototype testing package will be sent upon completion by the independent testing laboratory conducting the tests.

- F. With respect to the LB 330 belt scale devices with increased diameter of the source capsule and spacers in the source rod, within seven months of the date of the Order, Apgee shall perform on the of the following:
- Submit a request, by May 31, 1997, for the amendment of the device registration sheet for the 7mm diameter source and spacers and other changes to the devices, and receive approval from the NRC by obtaining an amended registration;

Please see ATTACHMENT #6 for a complete amendment to the registration certificate adding the 7 mm source capsules and spacers to this device.

- G. Apgee shall provide, in writing the following information to the Director, Division of Nuclear Materials Safety, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406:
- Within 30 days of the date of the Order, the schedule for performance of the required quarterly audits. The NRC shall be notified at least 30 days in advance of any change of the scheduled audit dates.

Please see ATTACHMENT #7, for the letter sent to Mr. A. Randolph Blough, Director, listing the scheduled dates for thenext four quarterly audits. September, December and March dates are tentative, and will be confirmed in the monthly reports to follow.

- Within 30 days after these audits a complete report describing the audit results will be submitted to the NRC. All details subject to condition G.2. of the order will be specified.
- 3. By the 15th of each month a status report of all actions will be sent to the NRC.

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H. If for any reason the dates listed above cannot be met, Apgee will contact, Mr. A. Randolph Blough, Director, Division of Nuclear Materials Safety, Region I, in writing.

If there are any questions, please contact me or Mary Dedola.

Sincerely,

.

G.M. (Bud) Smith, Jr. President Apgee Corporation/ Berthold Systems, Inc.

Attachments.

- 1. Amendment to LB 7400 series registration #NR-0112-D-102-B
- 2. List of LB 300 IPD/L Customers with shielding diameters
- 3. Amendment to LB 300 IPD/L registration #NR-0112-D-108-B
- 4. Amendment to LB AS registration #NR-0112-D-110-B
- 5. LB AS shutter and temperature test results
- 6. Amendment to LB 330 registration #NR-0112-D-109-B
- 7. Letter to Randolph Blough with tentative audit schedule
- cc: Doug Broaddus Mary Dedoia Charles Ferrin Gus Norton Mike Fox

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December 20, 1996

Mr. Charles Hehl, Director Division of Nuclear Materials Safety US Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406-1415

Subject: Response to Confirmatory Action Letter dated June 19, 1996 and Supplement to Confirmatory Action Letter dated July 22, 1996.

Re-Submittal of the October 15, 1996 letter sent to the NRC.

Dear Mr. Hehl:

As per the request of the Confirmatory Action Letter dated June 19, 1996, a comprehensive audit was performed on all registrations, including source housings and sources containing byproduct material, manufactured by Labortorium Prof. Dr. Berthold GmbH & Co. KG (referred to as Labe) and distributed in the United States, by APGEE Corporation and Berthold Systems, Inc. (referred to as BSI).

The following three registrations were reported on August 12, 1996, November 27, 1996 and December 4, 1996. Unless commented on otherwise in this report please refer to the above referenced letters for our response for these devices:

1. LB 7400 Series - NRC Registration #NR-112-D-102-B

2. LB 300 ML or MLT - NRC Registration #NR-112-D-111-S

3. LB 300 L and LP - NRC Registration #NR-112-D-106-B

This report provides a comprehensive report on the remaining devices and all open issues from the above letters:

Section I: LB 379 - NRC Registration #NR-112-D-101-B

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Section II:	LB 300 IRL	- NRC Registration #NR-112-D-107-S
Section III:	LB 330	- NRC Registration #NR-112-D-109-B
Section IV:	LB IPD/L	- NRC Registration #NR-112-D-108-B
Section V:	LB AS	- NRC Registration #NR-112-D-110-B
Section VI:	LB 375	- NRC Registration #NR-112-D-104-B
Section VII:	LB 6600	- NRC Registration #NR-112-D-105-S
Section VIII	LB BW	- NRC Registration #NR-112-D-112-B

The audit as conducted by the appropriate staff of Labe and EG&G, included:

- A review of the current design, including engineering drawing(s) for each model of each device currently being distributed, and of drawings supplied from the NRC files were also reviewed;
- A comparison of every device distributed (including devices distributed from Germany) with the design approved in the applicable SSD Certificate of Registration;
- Identification of any potential deviation between the actual device distributed and the statement and representations contained in the applicable SSD Certificate of Registration, and identification of items appropriate for clarification;
- Evaluation of the safety significance of each potential deviation;
- 5. Proposed corrective action.

Where indicated, shipments are being withheld pending resolution of issues identified. Otherwise, devices continue to be distributed in response to customer requirements.

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SECTION I: LB 379

Engineering Change Orders (ECO)

- 1. Difference Identified: ECO # 9504002 dated 4-6-95:
 - a. Change made: Flanges that hold the device in the product line are welded on two sides instead of one.
 - b. Reason for change: APGEE has been made aware that four devices with single welds experienced flange weld cracks under conditions of severe vibration. See letter from EG&G Berthold. (ATTACHMENT #1)
 - c. Issue: Change in weld specifications is not on file with the NRC.
 - d. Safety significance: None. See attached letter. (ATTACHMENT #1)
 - e. Action: Please see ATTACHMENT #1 for the actions taken by EG&G for correction of this problem. ATTACHMENT #2 is a copy of the drawing of the two weld for the LB 379 shield.

Please see ATTACHMENT #3 for a copy of the fax sent to each customer for evaluation of the units distributed in the US. This fax has been distributed with a response date of December 31, 1996. If a problem is reported, the device will be replaced with a double welded flange device.

A copy of the customer listing was given in ATTACHMENT #2 of the December 4, 1996 letter.

- f. Distribution status: Shipments of all LB 379 devices have been stopped pending issue resolution.
- 2. Clarification: The Am-241 point source can go up to 300 MCI. Our registration has the maximum activity of 100. Also, the 100 MCI source drawing on file is different from the 30 MCI and 300 MCI sources.

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APGEE does not request an addition of the 300 mCi source to the registration certificate.

Please note that APGEE Corporation has not distributed sources higher than the 100 mCi limit in the registration certificate. Also, all 30 mCi sources distributed by APGEE have been returned, therefore the only sources in the field are:

X91 - 100 MCI- AMC.16

Please note that the P-2642-100 drawing listed int the registration certificate shows the X91 capsule. No change was made to the source. Please see ATTACHMENT # 4 and #5. For consistency of the registrations, EG&G would like the Am-241 source listed as above in the registration ceruficate.

3. Clarification: Page 4 of 9 paragraph 8, ISO classification has changed to C64644.

These sources have a higher ISO Classification. The Higher Classification was given to the sources within the source holder. The sources ther selves were not tested alone for this classification. The construction of the sources were not changed. The testing for the higher ISO classification was performed with the source within the device. The source, itself was not tested.

It is noted that device housing is constructed of stainless steel.

SECTION II: LE 300 IRL

Drawings on file with the NRC:

- 1. Dwg # 21256.000-000
- 2. Dwg # 21257.000-000
- 3. Dwg # 21288.000-000
- 4. Dwg # 21204.500-000
- 5. Dwg # 21323.000-000

 Clarification: The Co-60 and Cs-137 rod sources should be changed to those with new ISO classification as in the LB 300 L series devices. Drawing numbers should be corrected using the LB 300 L source drawings

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numbers, also. The Co-60 sources were not changed, only tested for the higher ISO Classification. The Cs-137 sources are shown in ATTACHMENT #6.

- 2. Clarification: Paragraphs 5 and 6 of Page 3 of 7: Source lengths can go up to 130 cm. Drawing #21257.000-000 on file with the NRC, shows lengths of the sources as 1500 mm (150 cm) but the text says lengths go from a few cm to 100 cm. Please add the 1500mm length to the registration certificate.
- 3. Clarification: On Page 5 of 7 paragraph 2 ISO Classification has changed as those in the LB 300 L registration.
- 4. Clarification:: Added ANSI flanges to shield for use in the US market. (300 lb/square inch.) Drawing number changed due to flange change. New Dwg # 21288.200 and 300. Two flanges added 3" and 4" flange. (Type 80). Please see ATTACHMENT #7 and #8.
- Clarification: Source Encapsulation material was changed to a higher grade of stainless steel due to the higher ISO Classification sources used. This change is for the Cs-137 rod sources, please see ATTACHMENT #6. The Co-60 Food sources were not changed but re-tested for the higher ISO Classification.
 - Note: This is the same standardization change on rod sources that was listed in the LB 300 L registration review in the August 12th letter.

SECTION III: LB 330

A general set of drawings for this device are included in ATTACHMENT #9.

- 1. ECO #140887 dated 8-24-87
 - a. Difference identified: Diameter of source encapsulation was changed to the same as the LB 300 L series (7mm instead of 6mm) for the Co-60 and Cs-137 Rod sources. Please see ATTACHMENTS #1 and #11 for the drawings of these sources.
 - b. Reason for change: Standardization of rod sources within Labe.

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- c. Issue: Registration states diameter of the source encapsulation to be 6mm.
- d. Safety Significance: Safety improvement due to higher ISO Classification for sources used in these devices.
- e. Action: This is the same change to a higher ISO classification that was submitted in the August 15, 1996 letter. Please add the revised drawings in ATTACHMENTS #10 and #11 to the registration certificate.
- f. Distribution status: Shipments have not been stopped.
- 2. ECO #9111015 dated 11/14/91
- a. Differences identified: formalized addition of plastic spacers on the body of the source capsule.
- b. Reason for change: The spacers stabilize the measuring path under vibration conditions.
- c. Issue: These spacers are not shown on the drawings presently on file with the NRC.
- d. Safety Significance: None noted, activities of the sources within shields have not changed.
- e. Action: Please add the new drawings as shown in ATTACHMENT #10 and #11 to the registration certificate.

Differences identified are as submitted in 3,4,&5 below. NO ECO are available to identify differences in the wording:

3. Clarification: Page 3 of 10, Paragraph 2, should be modified to delete the phrase "except for small diameter". The rod sources are the same as in the LB 300 L. Please use the following wording:

> "The cobalt-60 rod sources consist of irradiated cobalt-nickel wire wrapped around an rod-shaped core and enclosed within a stainless steel capsule. Capsules measure approximately 7 mm in diameter and can range from 10 to 170 centimeters in length. Each capsule has a minimum wall thickness of 1 mm and is sealed by argon gas arc welding.

The cesium-137 rod sources contain cesium-137 in the form of cesium

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glass or ceramic beads within welded, stainless steel capsules. These capsules are additional enclosed within the outer stainless steel capsule. Spacers may be used to distribute the inner capsules throughout the length of the source. Sources measure approximately 7 mm in diameter, range in length from 10 to 170 centimeter, have a minimum wall thickness of 1 mm and are sealed by argon gas arc welding."

- 4. Difference: Drawing #201 is a schematic showing principles and #202 shows the dimensions of the source. Drawing P2651-202 must be updated because it shows the wrong diameter (6mm instead of 7). Current version not on file with NRC. Please see ATTACHMENT #11 fcr these drawings.
- 5. Difference: Labe has modified the shutter mechanism from 180 degrees to a 90 degree shutter rotation because 90 degree shutter rotation is mandatory for production of this shield for the Swedish authorities, so Labe must standardize on one type. The 90 degree rotation give a smaller angle of exposure when turning the mechanism on or off.

There are two devices with the 90 degree rotational shutter that were distributed in the US. These devices will be modified by APGEE to the 180 degree shutter rotation, as per the request of EG&G. The customer is:

Western Sugar Billings 3020 State Ave. Billings, MT 59107

Two Cs-137 Rod sources serial #84-1-96 and 86-1-96.

APGEE will complete the modification by January 31, 1997.

APGEE will not distribute these devices until they are registered with the State of Tennessee, therefore no request for registration amendment for the 90 degree rotational shutter is necessary.

Section IV: LB 300 IPD/L

1. ENGINEERING CHANGE ORDERS:

NO ENGINEERING CHANGE ORDERS ARE AVAILABLE FOR DRAWINGS CURRENTLY ON FILE WITH THE NRC.

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The drawings on file with the NRC show old types of shields with fixed dimensions for the insertion of the source. Various lengths are needed for application purposes. In order to standardized Labe made new drawings that show a range of shielding length. The design of the shields was standardize and 10 insertion lengths were defined - 320mm to 680mm. At the same time the diameter for the shieldings were standardized to, 75mm, 100mm 125mm and 200mm. The NRC drawings show diameters of 100 and 130mm. Please see ATTACHMENT #12 for a copy of the current drawings for these devices.

The shutter operation was standardized to that shown in Drawings #21224.000-000. With this design the source is pulled away from the opening and not pushed away. The guiding tube for the push rod is used for the ease of manufacture, it makes it easier to get the source into the shield for the source manufacturing department.

APGEE does not request the addition of these drawings to the registration certificate. These drawings will be added by EG&G with the State of Tennessee.

2 Clarification: The P-2623-100 drawing must be replaced with the Amersham drawings as in the LB 7400 series registration update. Using the Amersham drawing numbers. Please see ATTACHMENT #13 for a copy of the Amersham drawings. The Bebig point sources are also used as a standard for point sources in Labe. Please see ATTACHMENT #14 for the source drawings and registrations certificates.

APGEE does not request the addition of these drawings to the registration certificate. These drawings will be added by EG&G with the State of Tennessee.

- 3. Clarification: The sources have a better ISO Classification. Please see the LB 7400 series devices. Please see ATTACHMENTS #13 and #14.
- 4. Clarification: Page 3 of 10 paragraph 3, the source description must be updated to the new sources as submitted for the LB 7400 series devices in the August 15, 1996 letter and shown in ATTACHMENTS #13 and #14.

Safety significance of the above: All shieldings are adjusted by the manufacturer for best performance. The push rod which holds the source is adjusted at the operating side to the maximum activity in the open position. The adjustment range is +or-10 mm so that the a source which is 1.8mm longer is easily adjusted for.

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Therefore, there are no safety concerns or effects and the Bebig sources are interchangeable with the Amersham Buchler sources.

APGEE has distributed one of the longer Amersham point sources , Drawing #1508/2 in the US in a LB 300 IPD/L. This device was distributed to:

American Xyrofin Co. RT 84 & 3 Mile Road Thomson, IL

RSO: Jerry Gravert Phone: 815-259-3311

S/N: 2974-11-95

Three of the Bebig sources were distributed by APGEE in these gauges to:

FMC Westvaco Road Green River, WY 82955

RSO: Gary Bayles Phone: 307-875-2580

S/N: 2977-11-95,2980-11-95 and 2983-11-95 Cs-137 30 mCi sources.

Distribution status: Shipments stopped.

These sources will be added by EG&G to the registration certificates through Tennessee. APGEe does not request addition of these sources to the present registration.

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Section V: LB AS

ENGINEERING CHANGE ORDERS:

NO ENGINEERING CHANGE ORDERS ARE AVAILABLE FOR DRAWINGS CURRENTLY ON FILE WITH THE NRC.

- 1. The drawing provided APGEE by the NRC SK 623- is not on file with Labe.
- Drawing #21241.000-SK, on file with the NRC, is a preliminary sketch (indicated by SK for German "Skizze"=sketch) of the device finalized in Drawing #21360.000-000. This drawing is shown in ATTACHMENT #15.

Comparing the drawing in the NRC registration the current #21360.000-000 shows that the shutter as well as the mounting bracket are the same. The collimator is wider and the lid of the radiation window is stronger as shown in Drawing #21360.000-000.

ATTACHMENT #15 includes the drawing #21241.000-000. a device with this drawing number was also shipped.

Please see ATTACHMENT #16 for a list of customer sites and a break-down of devices shipped for the LB AS devices.

 The sources used are those used in the In-Line Density but the ISO Classification is lower because the sources with higher ISO Classification were tested inside the Inline device:

> X11 - 30 MCI- AMC. D3 (ATTACHMENT #17) X91 - 100 MCI- AMC.16 (ATTACHMENT #4) X92 - 300 MCI-AMC.17 (ATTACHMENT #18)

Drawings on file with NRC are obsolete. Actual drawing is 21360.000-000. This is what has been shipped. The drawing number that is on file is Drawing # 21226.000-000. The only way we can get this drawing made is for spare parts - replacement. They would like this device be registered as being shipped in # 21360.000-000. Please see ATTACHMENT #15 for a copy of the new drawings.

Safety significance of the above: None, these devices have been in the field in Europe and the US for the passed 10 years with no problems noted.

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Distribution status: Shipments stopped pending issue resolution.

APGEE does not request addition of the devices to the registration certificate. The devices are being submitted by EG&G to the State of Tennessee.

Section VI: LB 375

There have been manufacturing changes made in these devices which cause differences from the registration certificate. None of the newly manufactured designs have been shipped to the US. APGEE will not distribute these new designs until they are registered with the State of Tennessee by EG&G Berthold.

- 1. Difference identified: ECO # 9309033 dated 9-15-93:
 - a. Changes made: The source is now fitted into a stainless steel holder with overall dimensions of 105 mm by 30mm by 34mm" Dwg # 15136.160-002.(Not cylindrical shaped but square shaped now). The source is put into holder
 Dwg # 2672.102-001 (IPL) then secured in place in the device by screw Dwg #2672.101-001. For Amersham sources use Dwg # 2672.101.002 for the source holder. This is due to the difference between the Amersham and IPL sources

Two padlocks were placed on the source holder. One to make sure the source is not removed from the holder and the other to ensure the holder is not removed from the device. These additions were due to transportation requirements of the German Regulatory Authorities.

Based upon the audit performed by Gus Norton of EG&G and Labe, APGEE has been advised that "the units installed in the USA are within registration. In view of this, we will not need to provide drawings for the LB 375."

- b. Reason for change: Continuous product improvement due to ISO 9000 classification. The source holder was designed to hold the two different sources used in the device. Only Amersham sources were used previously.
- c. Issue: The source holder has been redesigned and the drawings on file with the

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NRC are no longer valid.

- d. Safety Significance: None, the change was not made because of a problem and the new design was not distributed by APGEE and will not be distributed by APGEE until registered by EG&G with the State of Tennessee.
- e. Action: No action required.
- 2. Difference identified: ECO # 9508007 Dated 10-11-95:
 - a. Change made: The source holder used to be welded to the supporting plate and now it is bolted on and additionally secured with padlock and plastic seal

Based upon the audit performed by Gus Norton of EG&G and Labe, APGEE has been advised that, "the units installed in the USA are within registration. In view of this, we will not need to provide drawings for the LB 375."

- b. Reason for change: If the source needs to be changed or leak tested in a device that is using steam heating, the customer cannot remove the source from device without removing the entire holder.
- c. Issue: Change in design is not on file with the NRC.
- d. Safety Significance: None, the change was not made because of a problem and the new design was not distributed by APGEE and will not be distributed by APGEE until registered by EG&G with the State of Tennessee.

e. Action: No action is needed.

- 3. Difference identified: ECO # 9310053 dated 12-21-93:
 - a. Change made: Optional use of a polyethylene shield in front of 300 MCI source

Based upon the audit performed by Gus Norton of EG&G and Labe, APGEE has been advised that "the units installed in the USA are within registration. In view of this, we will not need to provide drawings for the LB 375."

b. Reason for change: Customer wanted to reduce the radiation levels when putting

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in the 300 MCI source.

- NOTE: The limits given in the registration and approved, are still valid without the shielding. There was no problem with the radiation doses to workers, this shielding was given as a option due to a customer request NOT BECAUSE A PROBLEM occurred.
- c. Issue: The shield addition is not listed in the registration.
- d. Safety significance: None, the change was not made because of a problem and the new design was not distributed by APGEE and will not be distributed by APGEE until registered by EG&G with the State of Tennessee.
- e. Action: No action required.
- 4. Difference identified: ECO # 9505022 dated 8-14-95:
 - a. Change made: As an option, the polyethylene shield can be placed on the back side of the rack to shield the 300 MCI source.

Based upon the audit performed by Gus Norton of EG&G and Labe, APGEE was advised that "the units installed in the USA are within registration. In view of this, we will not need to provide drawings for the LB 375."

- b. Reason for change: Request from customers that have the rack near walkways. NOTE: The limits given in the registration and approved, are still valid without the shielding. There was no problem with the radiation doses to workers. This shielding was given as a option due to a customer request NOT BECAUSE A PROBLEM occurred.
- c. issue This shield is not a part of the present registration.
- d. Safety significance: None, the change was not made because of a problem and the new design was not distributed by APGEE and will not be distributed by APGEE until registered by EG&G with the State of Tennessee.
- e. Action: No action needed.

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- Clarification: PAGE 1 of 9, states Americium-244, typing mistake should be Am-241.
- 6. Clarification: Dwg #15136.101 25 mm replaces Dwg #15136.000-000 in registration.

 Clarification: Instead of the Drawing #P2657-100.000 the Amersham drawing for this source should be used. Please replace #P2657-100.00 with the Amersham equivalent - X1314. Please see ATTACHMENT #19.

- 8. Clarification: The Cs-137 should have same text as LB 7400 series as given in the August 12, 1996 letter.
- 9. Clarification: Am/Be source should have same text as in the LB 6600 series registration as follows:

The 300 mCi americium-241:Be source ((Dwg # 3A11001) is a doubly encapsulated (stainless steel) source. the radioactive material consists of americium oxide-beryllium powder which is compressed into tablet form and placed in the inner capsule. Both stainless steel capsules are sealed by argon arc welding. Berthold's manufacturer for the Berthold Drawing #P 2611-100 source provided evidence of an ISO classification of C64544 and IAEA special form designation.

Please see ATTACHMENTS #20 for Dwg #3A11001.

- 10. Clarification: Paragraph 3 of Page 2 of 9 Please add that the Be window is attached to the stainless steel chamber.
- 11. Clarification: Bracket holding the source and the scintillation counter is now in a fixed position cannot rotate as before. The Rotating device was needed for calibration with the old analog systems. With new electronics this system was not needed.
- 12. Clarification: The manufacturer put a titanium foil over the Be window. One customer had problems with particles in the product damaging the BE window. Labe put the titanium foil cover as a standard feature.

Shipments of LB 375 devices have been stopped. There are a few of the registered design devices available if a shipment is necessary before the submission of the new design to the State of Tennessee.

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APGEE does not request an amendment to the present registration certificate to add these changes, the changes will be added by EG&G with the State of Tennessee.

Section VII: LB 5600

1. Difference identified: Source drawing number is incorrect and Am-241:Be not Am-244. Drawing number to be used : Dwg # 3A11001, please see ATTACHMENT #20.

Safety Significance: None, source construction is the same but the source drawing number is no longer a Berthold drawing number.

2. Clarification: The LB 6600 series devices

abe terminology:	LB 6666-1	100 MCI
	LB 6666-2	300 MCI
	LB 6669-1	100 MCI
	LB 6669-2	300 MCI

- 3. Clarification: Larger holes were used in the plate where the source holder was mounted. During manufacture, problems mounting source holder into tube due to tolerances being too tight. Position of source is unchanged. Assembly is easier and faster. NO SAFETY ISSUE. Please see ATTACHMENT #21 for a copy of the drawings for the LB 6600 series devices.
- 4. Clarification: Changed the nameplate from plastic to stainless steel, USA requirement

Distribution: Shipments have not been stopped.

Section Vill: LB BW

- 1. Clarification: Add capsule numbers to source model designation in registration. Please see page 1 of 9 of registrations sheet.
- 2. Clarification: Page 2 of 9 last paragraph Kr.-85 not 90.
- 3. Clarification: Replaced piston from pneumatic actuator Piston was discontinued by vendor and replaced therefore Labe

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needed to replace because couldn't buy the old type. No change in mechanical dimensions. The replacement was offered by the vendor with equal performance specifications for the device. Size, mounting features and forces are equal to the oldy cylinder. There were no changes to the Basis Weight device design die to the new cylinder.

Please see ATTACHMENT #22 for a copy of the drawings for the basis weight devices. No changes were made on these devices since the registration certificate was approved.

OPEN ISSUES INVOLVING THE FOLLOWING LETTERS AND THE NOVEMBER 21, 1996 MEETING:

October 28, 1996 December 3, 1996

December 3, 1996 -

Model LB 7400 series Devices

1. Please see ATTACHMENT #23. This attachment is a copy of the analysis performed on the tolerances and clearances within the LB 7400 series devices using the new source model VZ-1508/2 and VZ-1486/3.

Please see ATTACHMENT #24 for a copy of VZ-1486/3.

It was first noted that the source change in the LB 7400 series devices concerned only the Cs-137 sources. In further in further investigation is was found that the Co-60 pont sources were also changed.

A copy of the customer list for the Cs-137 VZ-1508/2 sources was sent with the November 27, 1996 letter. Please see ATTACHMENT #25 for a copy of the customer listing for the Co-60 sources Drawing # VZ-1486/3 and the Cs-137 VZ/1508/2 sources not provided in the November 27, 1996 letter.

Please see Section 3.0 Action Plan of ATTACHMENT #23, for the corrective action being taken.

The new source holder and sources will be part of the new registration in the State of Tennessee by EG&G Berthold. Therefore an addition of these sources to the

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present registration is not necessary.

APGEE has stopped shipment of these sources within the LB 7400 series devices under the NRC Registration.

Please note: These sources have been in the field since 1992 and no problems have been noted by APGEE/BERTHOLD.

 Please see ATTACHMENT#26 for a copy of the testing performed on the LB 7400 stainless steel shields and a copy of a letter concerning these shields from EG&G Beithold.

Drawings and reasons for construction of these devices were sent with the November 27, 1996 letter.

- Action: APGEE does not request the addition of these devices to the present registration. EG&G will add these devices to the registrations with the State of Tennessee. Please add these shields to the registration certificate.
- 3. Please see ATTACHMENTS #27 and #28 for statements from the customers whose actuators were removed.

ATTACHMENT #29 is a letter from Mr. Douglas Montgomery of USX Mining who is still using the actuator on his gauge. As shown in Mr. Montgomery's letter the actuator opens and closes six times a day, 340 days a year since 1988 with no problems noted.

Please see ATTACHMENT #30 for a copy of drawings sent by Labe for the pneumatic actuator on the LB 7400 series devices.

APGEE does NOT request the addition of the pneumatic actuator to the registration certificate.

- 4. The action plan for the LB 7400 non-galvanized bolt customers was provided in the November 27, 1996 letter.
- 5. The Drawings of the "L" shaped locking mechanism showing that the mechanism does not interfere with the proper operation of the LB 7400 series shields were provided in the November 27, 1996 letter.

Action: Please add the "L" shaped locking bracket to the registration certificate.

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6.-8. No response needed.

 The clarifying statement that the protective cap is not necessary under certain environments to ensure proper operation was made in the November 27, 1996 letter.

Action: Please add the protective cap to the registration certificate.

 Please see ATTACHMENT #31, this shows the instructions that will be faxed to each of the "plunger' lock customers by January 31, 1997 and be given to each new customer of this device.

Action: Please add the "plunger" lock to the registration certificate.

Model LB 300 ML/MLT devices:

- 1-3. No comment needed.
- 4. This statement was made in the November 27, 1996 letter.
- 5. This clarification and copy of drawings were sent in the November 27, 1996 letter.
- In the November 27, 1996 letter it was stated that the new locking mechanism Drawing number 21260.101-000 was not distributed by APGEE. In further review, one of these mechanisms was sent to:

USS Steel Gary Works 1 North Buchanan Gary, Indiana 46402

S/N # 316 2-93

This design was made to facilitate the design of the top plate for the US Gary shield.

A copy of Drawing #21260.101-000 is shown in ATTACHMENT #32. This new design and the current design of this locking mechanism will not allow locking of the shutter in a position other than fully shielded.

Action: Please add this locking mechanism to the registration certificate.

10. Clarification of the tools used to open and close theses devices was provided in the November 27, 1996 letter.

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- The reasons for use of stainless steel were provided in the November 27, 1996 letter, and a copy of the letter submitted in 1983 was included as an Attachment #10 of the November 27, 1996 letter.
- 12. The complete design and construction data for the detent pin was provided with the November 27, 1996 letter. Also in this letter, a statement was made of its historical use in these devices.

LB 300 L/LP Series Devices:

- 1. Clarification of the paint used on these devices and a copy of the specifications for this paint was provided in the November 27, 1996 letter.
- 2. A clarifying statement that devices containing the modified top plate were not distributed was made in the November 27, 1996 letter.
- 3. A copy of the complete design and construction data for the 270mm shield was provided in the November 27, 1996 letter.

Please see ATTACHMENT #33 of this letter for a copy of the invoice from the manufacturer for these devices.

4. A clarifying statement that no VZ-1501/1 source was distributed was made in the November 27, 1996 letter.

LB 379 Devices:

Please see ATTACHMENT #3. This is the notification that has been sent to each of the LB 379 customers on the list provided in the December 6, 1996 letter.

- As shown on the customer listing of the LB 379 devices provided in the December 6, 1996 letter, no sources were distributed with activities in excess of the 100 m/ci limit.
- 3. The higher classification for these devices was obtained by testing of the sources within the devices. Construction of the devices and/or sources was not changed.

Action: Shipments of the LB 379 devices have been stopped.

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In your letter of December 3 (page 6), you asked that we discuss a number of general issues. here is our response:

1. Upgraded Quality Assurance:

APGEE will continue to import and distribute Berthold devices in accordance with its NRC license through December 31, 1996, and will continue doing so during 1997 to the extent necessary for EG&G Instruments to obtain the necessary approvals from Tennessee regulatory authorities.

So long as APGEE imports and distributes Berthold devices, it and Labe will insure that only design-approved registered devices and sources are distributed, by following these additional procedures:

- Labe Upgrades: All future proposed changes to registered devices will be approved by:
 - a) the responsible design engineer
 - b) Labe's division manager
 - c) Labe's R&D manager
 - d) the general manager of EG&G Berthold USA

A revised procedure which implements these new approvals will be in place on January, 1997 and constitute an amendment to the ISO 9001 certification of EG&G Berthold. It shall be the responsibility of the QA manager of EG&G Berthold to ensure that the revised procedures are followed. This will provide the vehicle for notification of the licensing/registration authority of intended changes to existing registrations.

- b. APGEE Upgrades: Quarterly audits will continue, but be conducted between APGEE and Labe Radiation Safety Officers. Focus of these audits will be on shields and sources planned for production and/or shipment the following quarter. Next audit will be scheduled for 1st quarter, 1997.
- 2. Berthold device registrations with APGEE.

Regarding currently installed devices, it is the intention of EG&G Berthold that these devices are correctly registered with the NRC, and is providing APGEE with drawings

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and other information toward this end.

Regarding future device installations, APGEE will continue to hold device registrations and distribute these devices until EG&G Berthold USA has registered these devices with the State of Tennessee, as soon after January 1, 1997 as practical. Thereafter, APGEE intends to request termination of all Berthold registrations, subject of the approval and guidance of the NRC and alteration of Berthold Systems' license to distribute (on a non-exclusive basis) EG&G Berthold-registered devices.

3. Planned APGEE Activities.

A number of agreements have been entered between APGEE, Beithold Systems and EG&G Berthold, which support existing and future Berthold device holders of relevance here:

- a) Current users of Berthold devices may continue to obtain authorized service from Berthold Systems or APGEE Corporation. Users may also contact EG&G Berthold USA, for service as this capability is developed and properly licensed.
- b) Berthold Systems will continue distributing Berthold devices, on a non-exclusive basis.
- c) APGEE Corporation plans to make shields. As first step, APGEE will produce licensed Berthold shields in accordance with individual device registrations. Thereafter, APGEE expects to register additional shields of Labe and/or its own design, and manufacture these shields as approved.

4. Answers to all Questions.

In the body of the report, we have specified those changes that we have asked to be made in applicable registrations. Beyond that and to the best of my knowledge, this letter addresses all open issues and items. Please let me or Mary Dedola know if and as you need additional information.

As provided in 10CFR Part 2.7090(b), we request that certain information be withheld in who from public disclosure on the ground that it contains confidential commercial information. the reason for this request is that we currently hold this information in confidence and require all employees to do so. Release of such information could substantially harm our competitive position since it guides competitors to our customers.

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Information to be so withheld are identified separately in the Attachments. As appropriate, each has been marked "Confidential".

Sincerely yours,

APGE CORPORATION

G.M. (Bud) Smith, Jr. President

cc: Rainer Baule, E.G.&G Berthold Charlie Ferrin, Radiation Safety Officer Mary Dedola, Radiation Safety Officer Neil Sullivan, E.G.&G (Wellesley, MA.) David Watkins, EG&G Berthold, Radiation Safety Officer Gus Norton, EG&G Berthold Mike Fox, Gefsky & Lehman

ATTACHMENT:	#1	-	Letter from EG&G for LB 379
For NRC only	#2	-	LB 379 Drawing
	#3	-	Fax to LB 379 customers
	#4	-	Drawing #3A11056
	#5	-	Drawing # 2642-100
	#6	-	Drawing #VZ-1501/1
	#7		Drawing #21288.200-000
	#8	-	Drawing #21288.000-000
	#9	-	Drawing Package for the LB 330
	#10	-	Drawings of the Cs-137 Rod source for the LB 330
	#11	-	Drawings of the Co-60 Rod source for the LB 330
	#12	-	Drawing Package for the LB 300 IPD/L
	#13		Drawing #VZ-1508/2
	#14	-	Drawing and registration certificate for the Bebig sources
	#15		Drawing Package for the LB AS
	#16	-	Customer Listing for the LB AS devices (Confidential)

- #17 Drawing #3A11089
- #18 Drawing #3A11061
- #19 Drawing #3A61927
- #20 Drawing #3A11001
- #21 Drawing Package for the LB 6600
- #22 Drawing Package for the LB BW
- #23 Analysis of Tolerances and Clearances for the LB 7400 series devices
- #24 Drawing #VZ-1486/3
- #25 Customer listings for the VZ-1508/2 and VZ-1486/3 drawings (Confidential)
- #26 Tests performed on the LB 7400 series stainless steel device
- #27 Letter form Mead (Boise Cascade)
- #28 Letter from Ciba Geigy
- #29 Letter form USX Mining
- #30 Drawing of the Pneumatic actuator
- #31 Instructions to be sent for the "Plunger Lock"
- #32 Drawing #21260.101-000
- #33 Invoice for the LB 270mm shields

de

Apgee Corporation

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May 13, 1997

Mr. A. Randolph Blough, Director Division of Nuclear Materials Safety United States Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406-1415

Dear Mr. Blough:

This letter is in response to your letter dated April 2, 1997, the memorandum to you from Mr. Donald Cool, dated March 10, 1997 and our meeting in King of Prussia on April 24, 1997. We have chosen to follow the format set in Mr. Cool's letter. If there are any questions please contact Mary Dedola @ (412) 378-1900.

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

I. Issue Identified:

 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.

Recommendations for continued use and Additional Questions:

- A. Apgee will submit a complete amendment to the registration certificate adding the alternate sources and the appropriate modification needed to ensure that there is sufficient clearance in the devices to ensure continued safe operation by May 31, 1997.
- B. Please see ATTACHMENT #1 for a listing of the customer locations of the devices containing the model VZ-1508/2 and VZ-1486/3 sources. This list includes the types of licensees these devices were purchased under.
- C. Action Plan: Once approval of the amendment referred to in item 1A, above. Apgee will:
- a. Notify each customer listed in ATTACHMENT #1 by fax, please see ATTACHMENT #2, to check the shutter mechanism on each device for binding or rubbing.
- b. Ask the customer to respond by returning page two of the fax in ATTACHMENT #2, indicating by serial number the devices checked and the outcome.

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- Once approved ,Apgeeand/or EG&G Berthold will begin the site visits correcting each of the devices starting with those devices showing potential problems, moving next to all generally licensed devices and finally completing the visits with the Specifically licensed customers.
- d Appee will complete this action plan within 7 months of the date of the order.
- e. On a monthly basis Apgee will inform the NRC of the progress made on the project.
- f. Upon completion of the Action Plan, the NRC will receive a letter detailing the closing of the action.

II. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A. Please see ATTACHMENT #3 for a listing of the locations of the stainless steel LB 7400 series shields. This listing includes the types of licenses under which the gauges were purchased.
- B. Apgee would like to add these devices to the registration certificate. A copy of the amendment application will be submitted in the May 30, 1997 submission to the NRC.

III. Issue Identified:

3. Pneumatic actuator installed on devices.

Recommendations for continued use and Additional Questions:

A. USX Mining (the only user) was contacted and chose to have the shield with pneumatic actuator removed from their facility. Please see ATTACHMENT #4 for a copy of the service report for the removal of this device. The device was sent back to Apgee Corporation for shipment to EG&G Berthold Germany.

IV. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A. Apgee asks the NRC to state the fee required for addition of the stainless steel transportation bolt to the registration certificate.
- B. Apgee has notified each of the LB 7400 series customers as listed in the December 4, 1996 letter to the NRC. Apgee/Berthold Systems, Inc. has delivered 750 of the 1272 bolts required for replacement. The additional 522 galvanized/stainless steel bolts will be distributed by May 31, 1997.
- C. Within 7 months from the date of the order signed sent to Bud Smith from Hubert J. Miller dated May 7, 1997, all customers listed in the December 4, 1997 letter to the NRC will be contacted and their confirmation of the bolt replacement will be documented.
- D. On a monthly basis the NRC will receive a status report of this action from Apgee.
- E. Upon completion of this action the NRC will receive a final letter to close-out this action from Apgee.

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V. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A. Apgee asks the NRC to state the fee required for addition of the "L" shaped locking mechanism to the registration certificate.
- B. Please see ATTACHMENT #5 for a listing of the "L" shaped bracket customers. This list includes the licenses under which the device was purchased.
- C. Each customer in ATTACHMENT #5 will be notified by fax shown in ATTACHMENT #6 stating the installation procedures for the "L" shaped brackets. Customers will be asked to fax back the second page of this fax for verification of proper operation of the shutter mechanism. This notification will be completed by June 30, 1997.
- D. If a problem is found with any of the above listed devices, a service engineer will be sent to site for correction to the problem. The action for the devices with problems will be completed by August 30, 1997
- E. On a monthly basis the NRC will be notified of the status of the action.
- F. Upon completion of the action a letter will be sent to the NRC to close-off the action. This letter will be submitted by September 15, 1997.

VI. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. Apgee asks the NRC to state the fee required for addition of the protective cap to the registration certificate.

VII. Issue Identified:

10. Alternative plunge lock installed on devices.

Recommendations for continued use and Additional Questions:

A. Please see ATTACHMENT #7 for a copy of the faxes sent to the customers of the alternative plunge lock.

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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

I. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. None. This rod source has never been used

II. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A EG&G Berthold is manufacturing an 80 mm diameter shield for testing purposes to show the ability of this diameter shield to survive the harsh conditions of use and provide appropriate protection to the source.
- B. An amendment to the registration certificate, to add the 80 mm diameter shields, will be submitted within 30 days from May 24, 1997 with test results added no later thatn 90 days from the date of this letter.

III. Issue Identified:

 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.

Recommendations for continued use and Additional Questions:

A The locking mechanism as provided in Drawing # 21260 101-000 (a copy of the drawing was given as ATTACHMENT #32 in the December 20, 1997 letter to the NRC) will not allow the shutter mechanism to be locked unless in the "CLOSED" position. As shown in the drawing the locking mechanism cannot be placed onto the shield until the arrow is pointing in the "CLOSED" position. Please see ATTACHMENT #7 for the section of the drawing showing the locking mechanism and how it is installed.

The devices are mounted externally, therefore they are not moved in and out of the mold. The devices are locked in the "Closed" position when not being used.

In further researching this locking mechanism. Apgee recently found that these shields were manufactured for US Steel Gary in 1982 with a diameter of 356 mm. This diameter is larger than allowed in the present registration sheet. The source strengths in these shields are 1.6 mCi of Co-60, well below the permissible strength allowed for the smaller shield diameters listed in the registration

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certificate. The shields were manufactured to meet the standards of the US Steel Gary Plant, below 2 mRem/hr on the surface of the shield. Therefore, there is no radiation safety issues surrounding these shields.

US Steel Gary will cease use of the large shield over the next year. Thereafter, each of these devices will be disposed of by Berthold Systems, inc. and/or EG&G Berthold.

B. Due to the fact that US Steel Gary is disposing of these devices. Apgee would like to defer the addition of this locking mechanism to EG&G Berthold through TN with their application for the LB 300 ML/MLT registration.

IV. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A. Please see ATTACHMENT #8 for a copy of the fax to be sent to all LB 300 ML/MLT customers clarifying the term "shecial key". This fax will be sent by June 30, 1997, with completion by August 31, 1997.
- B. Apgee with on a monthly basis report progress of the action plan to the NRC.
- C. Upon completion the NRC will receive a letter to Close-out the action plan, by September 30, 1997.

V. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. Apgee asks the NRC to state the fee required for addition of the stainless steel construction, along with the carbon steel construction, to the registration certificate.

VI. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. Apgee asks the NRC to state the fee required for addition of the Spring-loaded detent to the registration certificate.

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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

I. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A. Please see ATTACHMENT #9 for a comparison of the specifications between the old and new paint used on the LB 300 LP devices. The two pages attached to the comparison shows the corrosion protection qualities of the new paint (Mankeiwitz - Alexit Decklack L 401).
- B. Apgee asks the NRC to state the fee required for addition of the "new paint" to the registration certificate.

II. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. None

III. Issue Identified:

3. Addition of a 270 mm diameter shield.

Recommendations for continued use and Additional Questions:

A. In first researching, Apgee reported in error, the distribution of 270 mm diameter shields to Grant Chemical in Zachary, LA. Upon further research, it was found that the distributed devices were in fact 200 mm in diameter. To clarify the discrepancy, Apgee sent a service engineer to Grant to measure the devices. The engineer found the device to measure 200 mm in diameter.

In light of this finding Apgee states that no devices above the allowable 254 mm diameter shields were distributed in the US. Therefore, all questions and recommendations for continued use need no further attention.

IV. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. None.
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Model: LB 379 Device Type: In-line Density Measuring Device Registration Certificate: NR-0112-D-101-B Licenses: 37-21226-01 37-28697-01 37-21226-02G

I. Issue Identified:

1. Flanges are welded on two sides instead of one.

Recommendations for continued use and Additional Questions:

A. The customers listed in the December 20, 1996 letter to the NRC are the LB 379 customers whose units are of one weld. ATTACHMENT #10 re-lists the customers and locations of the one weld devices with the addition of the license under which the device was purchased. These customers were are asked to check their devices using the fax shown in Attachment #3 of the December 20, 1997 letter.

Of the listed customers seven have not yet returned their copies of the completed faxes. The others who have responded noted that there has been not problems with the welds in the under conditions of installation in their plant.

- B. Apgee will close-out the remaining 7 customers by July 31, 1997 by phoning each of the 7 customers and personally request a faxed response to the issue.
- C. Apgee will submit to the NRC by August 15, 1997 a final letter closing this matter.
- D. An amendment to the registration certificate for the two-welded devices will be submitted in the May 30,1997 submission to the NRC.

II. Issue Identified:

2. Clarification of maximum activity and distribution of alternate source

Recommendations for continued use and Additional Questions:

- A. The only difference in the past and presently distributed Am-241 sources for the LB 379 is the TIG weld versus the argonac weld.
- B. The X.91 capsule has been distributed in the use of these gauges as per the registration certificate drawing #2642-100 shows. Please see ATTACHMENTS #11 AND #12.
- C. As a clarification, the X.91 capsule has an NRC Model No. of AMC.16. Therefore, the X.91 and the AMC.16 are one in the same. The X.91 capsule is listed in the Amersham catalog, please see ATTACHMENT #13. Please see ATTACHMENT #20, the X.91 capsule is listed in this drawing.

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D. Apgee asks the NRC to state the fee required for addition of the X.91, AMC 16 capsule with the TIG weld, to the registration certificate.

III. Issue Identified:

3. Different ISO Classification for source.

Recommendations for continued use and Additional Questions:

A. None

Model: LB 300 IRL Device Type: Level Measuring Device Registration Certificate: NR-0112-D-107-S Licenses: 37-21226-01 37-28697-01

I. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A. Apgee would like to defer the addition of the VZ-1501/1 source model to EG&G Berthold through their registration application with the State of Tennessee.
- B. The VZ-1501/1 sources were never distributed in the LB 300 IRL devices.

II. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A. Apgee has distributed only one source length that is over 100 cm. This source is 106 0 cm delivered to the Olin Corporation in Lake Charles. LA. Olin Corporation has a special registration certificate with the State of Louisiana for these devices.
- B. Due to the fact that Apgee distributed no other over length sources. Apgee would like to defer the addition of the longer source lengths to EG&G through their registration application with the State of Tennessee.

III. Issue Identified:

3. Different ISO source classification.

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Recommendations for continued use and Additional Questions:

A. Apgee would like to defer the addition of the different ISO classification of the new sources to EG&G through the State of Tennessee.

IV. Issue Identified:

4. New ANSI flanges installed on Shield.

Recommendations for continued use and Additional Questions:

- A. All devices shipped to the US have the ANSI flanges.
- B. There is no health and safety implications in using the ANSI flanges due to the fact that their specifications are equivalent to the DIN flanges.
- C. Please see ATTACHMENT #14 for a customer and license listing of the devices distributed in the US.
- D. The ANSI flapges were added to these devices in order to mate with the installations in the US where ANSI is the standard.
- E. Apgee would like to add these flanges to the registration certificate. A complete application for amendment will be submitted in the May 31, 1997 submission.

V. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. Apgee would like to defer the addition of these sources to EG&G through their registration application with the State of Tennessee.

Model: LB 330 Device Type: Belt Weigher Registration Certificate: NR-0112-D-109-B Licenses: 37-21226-01 37-28697-01 37-21226-02G

I. Issue Identified:

1. Increased diameter of sour Je encapsulation.

Recommendations for continued use and Additional Questions:

- A. Apgee will submit a complete application for amendment for the increased diameter sources by May 31, 1997.
- B. Please see ATTACHMENT #15 for a list of customer locations of the 7 mm diameter sources. This list also includes the license under which the devices were purchased.

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- C. As stated in the April 24, 1997 meeting with the NRC, the 7 mm diameter Am-241 sources have been approved for use in the Belt Weigher systems. Therefore, the use of the 7 mm diameter Cs-137 and Co-60 sources in these devices will not cause any health or safety risks and were judged to be in registration. Once this interpretation was found to be a problem in the April 2, 1997 letter to Bud Smith, distribution of these devices was stopped.
- D. There were no changes to the design of these devices to accommodate the increase in diameter due to the fact the 7 mm diameter Am-241 sources in relies of the devices.

II. Issue Identified:

1. Spacers added to source rod.

Recommendations for continued use and Additional Questions:

- A. Apgee will submit a complete application for amendment for the addition of the spacers by May 31, 1997.
- B. The spacers have always been used in all belt weigt or systems to stabilize the measuring path for calibration purposes.
- C. The list shown in ATTACHMENT #15 is also the list of customer locations and licenses where the spacers are located.
- D. A full amendment will be submitted by May 31, 1997. answering the remaining questions of this section.

III. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. All sources distributed by Apgee/Berthold Systems, Inc. are 7 mm diameter sources.

IV. Issue Identified:

4. Include drawing of new size source

Recommendations for continued use and Additional Questions:

A New size source will be added in the amendment application to be submitted by May 31, 1997.

V. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. Apgee has modified the 90 degree shutter mechanism at Western Sugar in Billings. MT to a 180 degree rotating. The devices had not yet been installed, they were still in their crate. This was the only customer.

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B. Western Sugar had purchased these devices under a General License.

Model: LB 300 IPD/L Device Type: Density/Level Measuring Device Registration Certificate: NR-0112-D-108-B Licenses: 37-21226-01 37-28697-01 37-21226-02G

I. Issue Identified:

1. Modified source insertion lengths and shielding diameters.

Recommendations for continued use and Additional Questions:

A. Please see ATTACHMENT #16 for a customer listing and location of the LB 300 IPD/L devices distributed. Included in this listing is the diameter of the shielding.

oppee will submit hy May 31, 1997, a complete amendment to the registration certificate to add the various size sheildings in the field.

- C. A LB 300 IPD/L has been sent to an independent testing laboratory for testing purposes. No problems have been noted with any devices in the installed base.
- D Apgee is in the process of inspected each of the generally licensed devices in the field and will complete this process within two months of the date of the order as per the letter to Bud Smith dated May 7, 1997.
- E. Please see ATTACHMENT #17 for a copy of the radiation levels for these devices

II. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. These two new sources will be added to the registration certificate in the May 31, 1997 amendment to the registration certificate as listed in 1A above.

III. Issue Identified:

3. Higher ISO source classification

Recommendations for continued use and Additional Questions:

A. The addition of the higher ISO classification for the sources used in these devices will be handles in the amendment to the registration certificate on the May 31, 1997.

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IV. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. The wording correction will be handled in the amendment to the registration certificate on May 31. 1997.

Model: LB AS Device Type: Coal Fines Analyzer Gauge Registration Certificate: NR-0112-D-110-B Licenses: 37-21226-01 37-28697-01 37-21226-02G

I. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A. Please see ATTACHMENT #18 for a copy of the customer listing for these devices, including the license in which they were purchased.
- B. Apgee will within 30 days of the order provide justification that the devices are safe and should stay in the public domain.

II. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. For clarification purposes, please see ATTACHMENT #19 and #20.

The sources listed in the registration certificate are P2627-100 and P2642-100. On these drawings the use the Amersham X.92 (NRC Model # AMC.17) and X.91 (NRC Model # AMC.16) capsules are noted. Therefore, the distribution of these source capsules are not in violation of the registration certificate. EG&G Berthold would like to standardize on using the source model and capsule numbers to identify these sources instead of an in-house drawing number.

- B. The Amc.16 and AMC.17 sources were distributed in the LB AS shields. The AMC D3 have not been distributed.
- C. Apgee requests the addition of the AMC.16, AMC.17 and AMC.03 to the registration certificate.

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Model: LB 375 Device Type: Continuous Sulphur Analyzer Registration Certificate: NR-0112-D-104-B Licenses: 37-21226-01 37-28697-01 37-21226-02G

I. Issue Identified:

1.-4. A number of changes were identified for these devices. However, Apgee indicates that it has not distributed any device containing the changes. All changes have been made by the manufacturer, but have not been included in any of the devices provided by 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.

Recommendations for continued use and Additional Questions:

A. None

II. Issue Identified:

5. Typo in registration certificate

Recommendations for continued use and Additional Questions:

A. Typo will be corrected

III. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. Drawing 1536.101-25mm is a subset of 1536.000-000. The reason for the replacement is that drawing #1536.000-000 contains 25mm and 50 mm measurement chambers and drawing # 1536.101-000 is a 25 mm chamber only. This was done to ease drawing number management at the factory. Please see ATTACHMENT #21

IV. Issue Identified:

7 Use Amersham design of the source capsule (x131-4) it stead of #P2657-100 000

Recommendations for continued use and Additional Questions:

A. The SSSS will add the new drawing number and capsule to the sheet when other corrections are made.

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V. Issue Identified:

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

Recommendations for continued use and Additional Questions:

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

VI. Issue Identified:

 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.

Recommendations for continued use and Additional Questions:

A. Handled in the LB 6600 review, please see below

VII. Issue Identified:

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

Recommendations for continued use and Additional Questions:

A. The Beryllium window and titanium foil are associated with the detection system (scintillation counter) of the device only. They have nothing to do with the source and shield. They provide a barrier between the product in the pipe and the proportional counter. The physics of the measurement requires a thin membrane between the detector and the material in the pipe, yet the membrane must withstand the pressure of the product in the pipe. The device shield and source is not affected by the presence or absence of the titanium foil or Beryllium window. Therefore, there is no need for retrofit of these devices for their uses. Please see ATTACHMENT #21.

VIII. Issue Identified:

11. Device modified to no longer rotate

Recommendations for continued use and Additional Questions:

A. Please see ATTACHMENT #21.

IX. Issue Identified:

12. Titanium foil added to Be window

Recommendations for continued use and Additional Questions:

A. Flease see issue identified VII. above. Please see ATTACHMENT #21.

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Model: LB 6600 Device Type: Moisture Detector - Bunker Probe Registration Certificate: NR-0112-D-105-S Licenses: 37-21226-01 37-28697-01

I. Isisue Identified:

1. Use of 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.

Recommendations for continued use and Additional Questions:

A. Apgee asks the NRC to state the fee required to add this source capsule to the registration certificate.

II. Issue Identified:

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

Recommendations for continued use and Additional Questions:

- A. No sources distributed had an activity greater than 100 mCi.
- III. Issue Identified:
- 3. New drawings for source holder larger hole for mounting.

Recommendations for continued use and Additional Questions:

- A. Please see ATTACHMENT #22.
- IV. Issue Identified:
- 4. New stainless steel nameplate

Recommendations for continued use and Additional Questions:

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

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Model: LB BW Device Type: Basis Weight Gauge Registration Certificate: NR-0112-D-112-B Licenses: 37-21226-01 37-28697-01 37-21226-02G

I. Issue Identified:

1. Add capsule numbers to the registration certificate.

Recommendations for continued use and Additional Questions:

A. Certificate will not be changed.

li. Issue Identified:

3. New piston used for the automatic actuator

Recommendations for continued use and Additional Questions:

A. Please see ATTACHMENT #23 for a copy of the new piston identification data. The new piston used is the piston used to replace the old version that was discontinued.

This completes the submission as required, the first monthly report will be submitted by June 15, 1997. If there are any questions, please contact Mary Dedola or myself at (412)378-1900.

Sincerely.

2n m

G.M. (Bud) Smith President Apgee Corporation/Berthold Systems. Inc.

- Attachments (including listing)
- cc: Charles Ferrin, Apgee Mary Dedola, Berthold Systems, Inc. Gus Norton, EG&G Berthold

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ATTACHMENTS

- #1 List of VZ-1508/2 and VZ-1486/3 customers
- #2 Fax to customers whose deviced contain the VZ-1508/2 and VZ-1486/3 sources
- #3 LB 7400 series Stainless Steel Customers
- #4 Service Report from USX Mining LB 7400 series Phuematic Actuator Removal
- #5 LB 7400 series "L" shaped bracket customers
- #6 Fax to "L" shaped bracket customers
- #7 Fax to Plunger Locking Mechanism customers
- #8 Fax to LB 300 ML/MLT "Special Key" customers
- #9 Comparison of "old" and "nes" point for the LB 300 LP devices
- #10 LB 379 One-Weld Customer List
- #11 Source drawing #2642-100
- #12 Source drawing #3A11056 and back-up
- #13 Amersham catalog listing for the X.91 and X.92 capsules
- #14 LB 300 IRL customer list
- #15 LB 330 customer list
- #16 LB 300 IPD/L customer list
- #17 LB 300 IPD/L Radiation surveys
- #18 LB AS customer list
- #19 Source drawing #P2627-100
- #20 Source drawing #P2642-100
- #21 LB 375 Be and Titanium Fc1 data
- #22 LB 6500 "new" source holder drawings
- #23 LB BW "new" piston specifications