

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-32518/96-001

Program Codes 03214

Docket No. 030-32518

License Nos. 37-28697-01

Priority 3

Category E

Licensee: Apgee Corporation
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: *Francis M. Costello*
Douglas Broadus, Mechanical Engineer

8/2/96
date

Inspector: *Kathleen Dolce*
Kathleen Dolce, Health Physicist

8/1/96
date

Inspector: *John McGrath*
John McGrath, Senior Health Physicist

8/1/96
date

Approved By: *Francis M. Costello*
Francis M. Costello, Chief
Nuclear Materials Safety Branch 3
Division of Nuclear Materials Safety

8/1/96
date

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

Areas Inspected: 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:

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 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 could be threaded. The cable 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 authorized 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 is 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 model 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 BETWEEN THE DEVICE BEING TRANSFERRED TO BERNHOLD SYSTEMS, 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 transport bolts distributed prior to transport bolts being approved on July 21, 1994.
LB 7400 series	Certificate of Registration No. NR-112-D-102-B	Devices containing transport bolts 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.