

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 MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

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 was initially issued on September 30, 1991, and is due to expire on October 31, 2001. The license authorizes the possession and use of a variety of radionuclides incident to the loading of sealed sources into devices prior to transfer. These devices are described in Sealed Source and Device (SSD) Registry Certificates, NR-0112-D-101-B, NR-0112-D-102-B, NR-0112-D-104-B, NR-0112-D-105-S, NR-0112-D-106-B, NR-0112-D-107-S, NR-0112-D-108-B, NR-0112-D-109-B, NR-0112-D-110-B, NR-0112-D-111-B, and NR-0112-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. Most of the SSD Registration Certificates referenced above were originally issued on October 18, 1991. Registration Certificate NR-0112-102-B was issued on April 26, 1996, Registration Certificate NR-0112-106-B was issued on October 1, 1992, and Registration Certificate NR-0112-D-109-B was issued on February 16, 1994. Registration Certificates have no expiration date.

II

On June 11-13, 1996, during an inspection of Apgee Corporation and Berthold Systems, Inc., at their Aliquippa, Pennsylvania facility, certain apparent violations involving improper distribution of sources and devices were identified, as described in Inspection Report Nos. 030-20043/96-001, 030-21228/96-001 and 030-32518/96-001. As a result, a Confirmatory Action Letter (CAL) was issued to the Licensee on June 19, 1996, requiring the Licensee to perform a comprehensive audit of every device and its contained source currently being distributed and distributed in the past. In its response to the CAL dated July 19, 1996, the Licensee confirmed that some of the devices manufactured by EG&G Berthold and distributed by the Licensee may have deviated from the SSD Certificates of Registration.

On July 22, 1996, the NRC issued a supplement to the CAL. The Licensee submitted further responses to the CAL and Supplement by letters dated August 12, and October 15, 1996. By letter dated October 28, 1996, the NRC requested that the Licensee provide additional information in order that the Commission could complete its assessment of the safety significance of the identified deviations. This information was submitted by the Licensee on November 27, December 4, and December 20, 1996.

By letter dated April 2, 1997, the NRC informed the Licensee that it had completed its analysis of the information submitted by the Licensee. The

letter informed the Licensee that, based upon the results of the inspection and the NRC's review of the information provided, three apparent violations were identified, including: (1) distribution of devices not in accordance with the conditions of the registration certificate or for which a certificate of registration had 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.

In an enclosure to its April 2, 1997 letter, the NRC identified 42 areas of concern regarding 11 types of devices and a number of areas for which additional information was still required. The NRC expressed safety concerns in its April 2, 1997, letter regarding the following devices, which were apparently distributed without conforming to the requirements of the applicable registration certificate: (1) LB 7400 devices with alternate sources; (2) LB 7400 devices with pneumatic actuator; (3) LB 7400 devices with carbon steel transport bolts; (4) LB 300 IPD/L devices with modified source housing lengths; (5) LB 300 IPD/L devices with new Amersham or Bebig sources; and (6) all LB AS devices.

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 its 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 it 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. In addition, the Licensee agreed to provide the NRC information on those gauges where NRC analysis had determined that the information was insufficient.

III

By letter dated May 8, 1997, the NRC documented its understanding of the commitments agreed to by the licensee. The letter informed the Licensee that the NRC had determined that public health and safety required these commitments be confirmed by a Confirmatory Order Modifying License (Order), and that these commitments would be incorporated into an Order following the Licensee's written consent to them. The letter also informed the Licensee that if it consented to the issuance of this Order, it would be waiving its right to request a hearing on all or any part of the Order, and the letter requested the Licensee to sign a Hearing Waiver indicating that it agreed to

such commitments and consented to the issuance of this Order. On May 19, 1997, the licensee consented to issuing this Order with the commitments, as described in Section IV below, by signing a Hearing Waiver. On May 29, 1997, in a telephone conversation between John McGrath, USNRC Region I, and G. M. Smith; Apgee Corporation, at NRC's request, agreed to an extension of the dates for the commitments identified in paragraphs "C" and "E" of this Order. Implementation of these commitments will provide enhanced assurance that sufficient resources will be applied to the Licensee's quality assurance program, and that distributed devices will comply with their SSD Registry Certificate and NRC requirements.

I find that the Licensee's commitments as set forth in Section IV of this Order 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.

IV

Accordingly, pursuant to sections 81, 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 LICENSE NO. 37-28697-01 IS MODIFIED AS FOLLOWS:

- A. With respect to the LB 7400 devices with alternative sources, within seven months of the date of this Order, Apgee shall:
1. if an amended SSD Registry Certificate is issued to allow for the longer source capsules, 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.
- 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
 2. 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 this Order, Apgee shall:
1. if an amended SSD Registry Certificate is issued 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, complete any actions needed to ensure the devices conform to the amended 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:
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 the later date.
- 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 this Order, Apgee shall:
1. if an amended SSD Registry Certificate is issued to allow for the 7mm diameter source and spacers and other changes to the devices, complete any actions needed to ensure the devices conform to the amended Registry Certificate; 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:

1. Within 30 days of the date of this 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 this 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.
 3. 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.

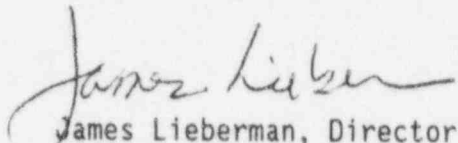
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Any person adversely affected by this Confirmatory Order, other than the Licensee, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for 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 I, 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.

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 26th day of June, 1997

June 26, 1997

Apgee Corporation

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