



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

February 3, 1995

ALL AGREEMENT STATES

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-95-022)

Your attention is invited to the attached correspondence which contains:

INCIDENT AND EVENT INFORMATION.....XX

PROGRAM MANAGEMENT INFORMATION.....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....

OTHER INFORMATION.....

Supplementary information:

Enclosed for your information is a letter dated January 27, 1995 to Apgee Corporation, an NRC licensed manufacturer of gauging devices for use by persons covered under the general license in 10 CFR 31.5, or the equivalent section of Agreement State regulations. Apgee notified the NRC of a possible defect reportable under 10 CFR Part 21 (Reporting of Defects & Non-Compliance).

This case involves the binding of shutter mechanisms in Apgee Corporation model LB 7400 series gauges (see SSD certificate NR-0112-D-102-B issued 7/20/94). In some situations, failure of the shutter mechanism was noted. Since the shutter mechanism is the only means of protecting the user from exposure to the radiation beam, shutter mechanism failure could lead to radiation exposures in excess of regulatory limits.

NRC is presently working with Apgee Corporation to modify their manufacturing process for future gauges and to notify current users regarding shutter mechanism failures discovered to date. We will keep you informed on developments in this case. We would appreciate hearing from you, if you become aware of any similar failures of these devices in your State.

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FEB -3 1995

If you have any questions regarding this correspondence, please contact me or the individual named below.

POINT OF CONTACT: Lloyd Bolling  
 TELEPHONE: (301) 504-2327  
 FAX: (301) 504-3502  
 INTERNET: LAB@NRC.GOV

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 Paul H. Lohaus, Deputy Director  
 Office of State Programs

Enclosure:  
 As stated

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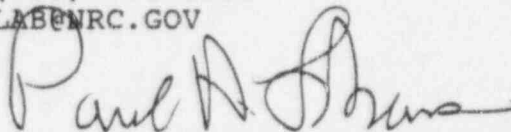
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A handwritten signature in dark ink, appearing to read "Paul H. Lohaus", is written over the printed name and title.

Paul H. Lohaus, Deputy Director  
Office of State Programs

Enclosure:  
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January 27, 1995

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

Dear Mr. Smith:

This letter is a follow-up to our meeting on January 17, 1995, concerning your notification of a possible defect under 10 CFR Part 21. During the meeting you identified the defect to be binding of shutter mechanisms in LB 7400 series devices, and in some situations, failure of the shutter to operate. This is of concern as the shutter mechanism is the only means of protection from the radiation beam for users of the device, especially for General Licensees. You stated that your investigation of the failures determined a buildup of corrosion products in the shutter caused expansion of the shutter walls and binding. The cause of the corrosion was indicated to be flux left between the lead and brass surfaces of the shutter following a brazing process. The flux, combined with moisture, caused corrosion to develop and swelling of the shutter cap.

Following the discussion of the cause of the failures, you presented your plan of action for rectifying the situation. You contend that this defect cannot be easily corrected by either the user or service personnel, and this requires that units exhibiting signs of failure must be replaced. The following is our understanding of the steps Apgee and Berthold will take or have taken to correct the defect and replace defective units in the field:

- EG&G Berthold in Germany has modified the brazing process to include cleaning, sand blasting, and testing steps to ensure no flux is left on the surrounding material.
- EG&G Berthold in Germany will begin serializing the LB 7400 Series source housings by stamping a serial number in the housing and will tie the serial number to a specific manufacturing history file. This will occur by the end of January 1995. Currently, Apgee serializes the devices by applying a label with the serial number, but the devices are not traceable to a specific manufacturing process or procedure performed in Germany. Please provide any changes to the current labeling provided by Apgee as a result of the serializing by EG&G Berthold in Germany.
- Confirm that bulletins were sent to all users (approximately 200) who possess devices (approximately 500) that may be affected by the defect, by January 20, 1995. The bulletin provides instructions to users for testing the device to determine if it is currently affected by the defect. At the meeting, your staff also committed to providing a list of the users to whom you would be sending these bulletins, by January 20, 1995.

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- Apgee will make follow-up phone calls to users who do not respond to the initial bulletin or whose response is not considered adequate.
- Apgee personnel will conduct site visits at user's facilities to test shutter mechanisms for users who are unable to properly evaluate the performance of their devices.
- Apgee will devise a plan to replace all defective devices in a timely manner and will provide instructions and recommendations to users who indicate that their device exhibits signs of failure.
- A follow-up letter will be sent to users if information, in addition to the above, needs to be disseminated.
- As defective devices are replaced, Apgee will analyze each to verify the failure, to document where the device was installed, and to record the environmental conditions to which the device was subjected. This analysis will be used to determine "high risk" industries and environments. The analysis will also be used to determine the priority and need to replace all devices used in a particular industrial application or environmental condition.
- Apgee will reevaluate the devices for limiting environmental conditions and make recommendations to NRC about whether limiting the environments of use for these devices is necessary and/or whether these devices should not be used in certain industrial applications in the future.
- Apgee will provide a schedule of implementation of the plan to NRC by January 27, 1995, and will provide additional information about the plan, as appropriate.
- Apgee will keep the NRC informed as to their progress with the steps outlined above.
- Mr. G.M. (Bud) Smith will be designated as the director and responsible officer for reporting purposes under 10 CFR Part 21.

Following the meeting on the shutter failure, we discussed several issues concerning the registration process and information necessary to perform a complete safety evaluation, with you and Mr. Gus Norton of EG&G Berthold in Germany. We hope this discussion was helpful and are willing to discuss this subject further with you and your staff or Mr. Norton, if needed. We would like to stress again the importance of submitting a complete and thorough engineering analysis if prototype testing is not to be submitted for demonstration of a device's ability to survive normal and abnormal likely conditions of use and environments. We also would be willing to talk directly to the design and production engineers at EG&G Berthold in Germany to discuss or clarify information necessary to complete a safety evaluation. However, all information submitted for review would still need to be submitted by Apgee.

If you disagree with our understanding of your plan, have any questions, or

Mr. G.M. Smith

-3-

January 26, 1995

would like to discuss any additional issues concerning the above information,  
please call me immediately at (301) 415-7273.

Sincerely,

Original Signed By:  
Steven L. Baggett

Steven L. Baggett, Section Chief  
Sealed Source Safety Section  
Source Containment and  
Devices Branch  
Division of Industrial and  
Medical Nuclear Safety, NMSS





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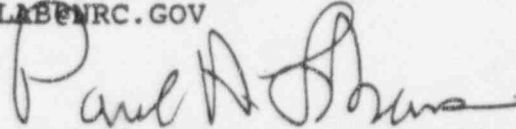
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