

(SP-97-044, June 1997, Other, Transportation)

DATED: JUNE 12, 1997

SIGNED BY: RICHARD L. BANGART
FOR PAUL H. LOHAUS

ALL AGREEMENT STATES
OHIO, OKLAHOMA, PENNSYLVANIA

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-97-044)

Your attention is invited to the enclosed correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION...

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....

OTHER INFORMATION..... XX CONFIRMATORY
ACTION LETTER TO
AMERSHAM
CORPORATION
CONCERNING
TRANSPORTATION
PACKAGE TESTING

Supplementary information: Enclosed for your information is a Confirmatory Action Letter sent to Amersham Corporation on June 10, 1997. The letter identifies NRC concerns with the adequacy of transportation package tests and Quality Assurance Program implementation under the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." It also identifies actions to be taken by Amersham which includes, as specified in item (3) on page 2, notification to all users of Amersham packages.

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

POINT OF CONTACT: Tom O'Brien
TELEPHONE: (301) 415-2308
FAX: (301) 415-3502
INTERNET: TJO@NRC.GOV

Paul H. Lohaus, Deputy Director
Office of State Programs

Enclosure:
As stated

DATED: JUNE 10, 1997

SIGNED BY: JOHN T. GREEVES
FOR CARL J. PAPERIELLO

CAL No. 97-7-005

Amersham Corporation
ATTN: Mr. William M. McDaniel
Facility Manager
40 North Avenue
Burlington, Massachusetts 01803

SUBJECT: CONFIRMATORY ACTION LETTER

Dear Mr. McDaniel:

On June 4-6, 1997, U.S. Nuclear Regulatory Commission staff conducted an inspection at Amersham Corporation, in Burlington, Massachusetts. Amersham Corporation has a Quality Assurance Program approved by the NRC under the provisions of Subpart H of 10 CFR Part 71 (Docket No. 71-0040). Amersham Corporation is also the holder of several NRC Certificates of Compliance for transportation packages. The inspection was related to testing under 10 CFR Part 71.

The inspection identified problems regarding testing performed for hypothetical accident conditions under 10 CFR Part 71.73, including: a) whether the steel puncture bar was properly mounted on the test pad; b) whether the condition of the drop test pad used for the tests constituted an essentially unyielding surface; c) whether free-drop tests were performed in the most damaging orientation; d) whether puncture tests were performed in the most damaging orientation; and, e) whether the test conditions and results were accurately and fully recorded, assessed, and reported to the NRC.

The problems we identified with the conduct of your test program call into question the adequacy of the tests performed in support of Amersham's transportation package designs. Further, we are concerned that the implementation of your Quality Assurance Program did not disclose those problems.

For the reasons stated above, and pursuant to telephone conversations between you and Dr. Susan Frant Shankman on June 9 and June 10, 1997, it is our understanding that you will take the following actions which will be completed by the dates specified:

- (1) Effective immediately, suspend fabrication of all NRC-certified transportation packagings, until you receive authorization to resume from the NRC.
- (2) For all Amersham packages that are certified by the NRC, justify why there are no immediate health and safety concerns regarding the continued use of the packages. This action will be completed and submitted to the NRC by June 16, 1997.
- (3) Prepare a notice to all users of Amersham packages notifying them of the following: a) the questions that were raised by NRC regarding the packages; b) that retesting will be performed; and, c) any administrative controls that the users should take prior to completion of Amersham's retesting. This notice will be issued by June 16, 1997.
- (4) Have an independent assessment performed of the drop test pad that was used in the testing program. The report from this independent assessment will be submitted to the NRC by June 16, 1997.
- (5) Prepare detailed test plans and procedures for the packagings that will be retested. Amersham will obtain the services of an independent testing expert to assure that the proposed testing, acceptance criteria, and post-test examinations will be in accordance with the requirements of 10 CFR Part 71. The name and qualifications of the expert will be sent to the NRC by June 16, 1997, for review and approval. The test plans and procedures will be developed and submitted to the NRC within 30 calendar days after NRC approval of the expert. Following submittal of the plan and procedures, Amersham will meet with the NRC to discuss the details of the testing. Retesting will not proceed without agreement from the NRC.
- (6) Conduct retesting of Type B transportation packages to demonstrate that the designs meet the requirements of 10 CFR Part 71. Models to be tested include the 660 series, 650 series, 650L, 702, 676, 680, 715, 920 and other appropriate packages. The retesting will be performed utilizing a puncture bar that is mounted on an essentially unyielding surface. Amersham will propose the priority for retesting these designs, considering such factors as number of existing units

and estimated frequency of shipments. A schedule of proposed testing, with dates, will be provided to the NRC upon completion of item number 5, above. Amersham will give NRC two days notice prior to each test. All testing will be completed by not later than six months from NRC approval of the test plan in item number 5, above.

- (7) Develop a plan to modify the Amersham Quality Assurance Program for Transportation to assure adequate packaging design and testing. This plan will be submitted to the NRC by June 23, 1997.
- (8) Preserve all packaging, components, specimens, and records from testing performed on NRC-certified package designs. Amersham will not perform any tests on or modifications to test specimens.

You will also:

- (1) Notify me immediately if your understanding differs from that set forth above;
- (2) Notify Mr. William Kane, Director, Spent Fuel Project Office, if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change; and
- (3) Notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other Certificate-holder actions; nor does it preclude NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information, so that it can be placed in the PDR without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Sincerely,

Carl J. Paperiello, Director
Office of Nuclear Material
Safety and Safeguards

W. McDaniel

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cc: R. Hallisey, State of Massachusetts
A. Roberts, Department of Transportation

Dockets 71-0040, 71-9029, 71-9033