

July 31, 1997

MEMORANDUM FOR: Ross Chappell, Chief
Package Certification Section, SFPO

FROM: Christopher Brown, Materials Engineer
Package Certification Section, SFPO

SUBJECT: MEETING SUMMARY CONCERNING AMERSHAM'S TEST PLANS FOR THE
TYPE B Package

Attendees:

NRC

David Tiktinsky
Nancy Osgood
Bernie White
Li Yang
Chris Brown
Andrew Gaunt
Ross Chappell
Thomas Matula

Amersham

Khaja Afeef
Cathleen Roughan
Steven Grenier
William McDaniel

Packaging Technology

Gary L. Clark

Introduction

A meeting was held at the request of Amersham Corporation at Rockville, Maryland, on July 24, 1997, concerning Amersham's retesting program for their Type B packages. In particular, the meeting centered around retesting for the Model 660 and 650L radiography devices.

Discussion

1. The discussion focussed on Amersham's retesting program to demonstrate compliance with 10 CFR Part 71 including Amersham's revised standard operating procedures and work instructions that described development of package test plans.
2. Amersham presented test plans for hypothetical accident conditions for the Model 660 and 650L devices. In particular, detailed discussions centered around the orientation for drop testing the Model 660 and 650L. Models of the 660 and 650L were used to demonstrate the proposed drop testing orientations.

Docket Nos.: 71-9033, 71-9269, 71-0040

Attachments: Meeting Handouts

Distribution:

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Attendees w/o Attachment W. Kane CJHaughney SFShankman

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NAME	CLBrown	DHTiktinsky	NLOsgood	ERZiegler	CRChappell
DATE	7/31/97	7/31/97	7/31/97	7/ /97	7/31/97

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SENTINEL

PRODUCT TESTING AND EVALUATION

RESPONSIBLE PARTIES

Quality Assurance

Engineering

Regulatory Affairs

Quality Control

TEST STAGES

Test Planning

Test Plan Elements

Purpose, including the performance or regulatory requirements

System Failures of Interest

Material and Equipment List

Construction and Condition of the Test Specimens to Be Tested

Pass/Fail Criteria

Rationale and Justifications

Specific Test Instructions

Test Data to Be Collected at the Time of Test

SENTINEL

Review, Discussion, and Revision by Engineering, Regulatory Affairs, and Quality Assurance

Final Review and Approval by Engineering, Regulatory Affairs, and Quality Assurance

Test Preparation

Test Specimen Fabrication and Documentation

Gather and Check All Materials and Equipment

Test Execution

Recheck All Material and Equipment

Execute the Test in Accordance with the Test Plan.

Measure and Record Test Data During Test Cycle

Post-Test Assessment

Measure, Assess, and Document Condition of the Test Specimen after Each Test

Document Any Disassembly Steps Taken to Determine the Extent of Wear or Damage

Test Reporting

Analyze the Data and Document Conclusions

Circulate Test Report to Engineering, Quality Assurance, and Regulatory Affairs for Review and Approval

Retain All Test Plans, Data Sheets, Reports, Test Specimens, Photographs and Other Evidence of Testing

Amersham meeting

7/24/97

<u>Attendee</u>	<u>Company</u>	<u>Tel # / E mail</u>
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