



October 20, 2009

Geoffrey M. Warren  
Materials Inspection Branch  
Division of Nuclear Material Safety  
U.S. Nuclear Regulatory Commission, Region III  
2443 Warrenville Road  
Suite 210  
Lisle, Illinois 60532-4352

Subject: Flammable Product Report for License # 22-00057-61

Dear Mr. Warren:

This letter constitutes a follow-up report to our telephone conversation of September 17, 2009. Specifically, it relates to our discovery that certain products - having Small Quantity Volumes (as defined in NUREG-1556, Vol. 6, page F-1) less than those provided in license amendment requests (letters dated, 3/31/03 – for S8 and 5/8/08 – for S10) – were irradiated at the Brookings facility.

Attachment 1 is a brief chronology of the events pertaining to our discovery.

Attachment 2 is list of immediate actions implemented as a result of our discovery.

Attachment 3 provides the underlying cause.

Attachment 4 is a list of actions taken to prevent recurrence.

Attachment 5 is a list of new license commitments regarding the processing of flammable formulations. These commitments were also sent to the Materials Licensing Branch in a license amendment request letter dated, October 9, 2009.

If you have any comments regarding this communication, please direct them to Nick Bates at 651-737-1019.

Sincerely,

Frederick B. Entwistle, Certified Health Physicist<sup>®</sup>  
Manager, 3M Corporate Health Physics

Enclosures:

RECEIVED OCT 23 2009

## Attachment 1 Chronology

- 1986 – Irradiation of flammable materials authorized for S8.
- 2003 – S8 authorization renewed during license renewal.
- 2008 – Irradiation of flammable materials authorized for S10.
- 2009 – Brookings' sterilization engineering group begins comprehensive review of flammable product irradiation.
- 2009 - August 31:
  - Two products processed in S8 were discovered to have Small Quantity Volumes **less** than the license restriction of 14.6 liters. Namely:
    1. Input Number: 44-0052-0471-2  
**Product Description:** Nexcare™ No Sting Liquid Bandages, Spray Catalogue # 118-03
    2. Input Number: 44-0042-8834-4  
**Product Description:** 118-03 No Sting Liquid Bandage Spray
  - A Brookings Sterilization Engineer promptly directed the Irradiator Scheduler to stop irradiation of the two products at S8.
  - Following discussions between the Brookings Site RSO and Corporate Health Physics a decision was made to stop irradiation of all flammable products in S8.
  - The last flammable product irradiated at S8 occurred on August 31, 2009.
  - Flammable product processing continued at the S10 irradiator (as it was believed that those items had Small Quantity Volume values that met the license restriction of 36 liters).
- Brookings initiated an investigation to identify the underlying cause and appropriate corrective actions (August 31 – October 9, 2009).
- Brookings continued the process of documenting Small Quantity Volume calculations and obtaining information regarding S8 & S10 flammable product processing (August 31 – October 9, 2009).
- September 17, 2009
  - The 3M Corporate Radiation Safety Officer (Fred Entwistle) and the Brookings Site Radiation Safety Officer (Kostas Kaounas) spoke with Geoffrey Warren, (NRC Region III inspector for the 3M Brookings facility).
  - A summary of the recent findings by the Brookings staff was provided. Specifically, that irradiation of flammable liquids in the S8 irradiator had not been done in full compliance with the commitments under the subject license.
  - It was communicated to Mr. Warren that 3M took immediate action to halt irradiation of those products in S8.
  - It was communicated to Mr. Warren that 3M had the intention to correct the underlying issue of Brookings failing to receive communications that flammable formulation changes had taken place. These changes caused product Small Quantity Volume values to fall below the S8 restriction in the license.
  - 3M noted that there were no adverse consequences from irradiation of these products and that there was no significant increase in hazard.

- Regulatory reporting requirements were reviewed with Mr. Warren and it was agreed that there appeared to be none that applied to this situation.
- A follow-up phone call from Mr. Warren and Colleen Casey (NRC Region III Licensing) was received by Mr. Entwistle. In the call, the NRC requested the submission of a written report.
- September 18, 2009
  - The Brookings facility received information from 3M Product Services in St. Paul which indicated that the Lower Flammability Limit values (LFL) used in Small Quantity Volume calculations may be incorrect.
  - It was decided to stop irradiation of flammable products in S10 since incorrect LFL values would lead to incorrect Small Quantity Volumes.
- September 21, 2009 - Revised 3M SOP-LAB-05-000020 pre-released (effective October 1, 2009).
- September 22, 2009 - Brookings determined that all products currently awaiting irradiation at S8 & S10 were made from one of four common flammable formulations. A Formulation is a specific mixture of chemicals.
- September 23, 2009 - Samples of the four flammable formulations were sent to an outside company for LFL testing.
- October 5, 2009 - 3M IMS SOP 81, Supplement R & SOP 82, Supplement R revised.
- October 6, 2009 – LFL testing results received by 3M
- October 9, 2009 – A license amendment letter was sent to the NRC with information regarding new worst-case flammable formulations to be irradiated at S8 & S10. The letter was based on new Small Quantity Volume calculations using the LFL testing results.
- October 10, 2009 – Start-up processing of **less** than a Small Quantity Volume of flammable formulations in S10 (less than one Small Quantity Volume in the entire irradiator chamber).

## **Attachment 2**

### **Immediate Actions that were Implemented as a Result of our Discovery**

- Suspension of flammable product processing at S8 on 8/31/09 upon discovery that two products have Small Quantity Volumes less than the licensed value.
- Suspension of flammable product processing at S10 on 9/18/09 upon identification that LFL values used to calculate Small Quantity Volumes may be incorrect.
- Communications between 3M and the NRC to self-disclose the deviations from license restrictions.
- Submission of flammable formulation samples for LFL testing.
- New calculations of Small Quantity Volumes of flammable formulations completed and compared to license restrictions.
- Investigation to identify root causes of deviations from license restrictions.
- Investigation of LFL data used in Small Quantity Volume calculations.

### **Attachment 3**

#### **Underlying Cause**

- There was no formal process to notify the irradiator facility of changes in the “recipe” of the flammable formulations used for all products irradiated in S8 & S10 and in providing the necessary data (including accurate LFL data) for calculating Small Quantity Volumes.

## **Attachment 4**

### **Actions Taken to Prevent Recurrence**

The following procedural changes have been implemented to address the preliminary causes. They have been reviewed with the Brookings Sterilization Engineers, Sterilization Engineering Manager, Radiation Safety Officer, Alternate Radiation Safety Officer and the Plant Manager.

- 3M SOP-LAB-05-000020 was updated:
  - This is a procedure which describes the change control process for all commercialized products managed by 3M Infection Prevention Division and 3M Skin & Wound Care Division.
  - The procedure now states that if a product or component (i.e. flammable formulation) is a liquid that requires irradiation, a Flammability Analysis (i.e. Small Quantity Volume calculation) is required to be completed by a Brookings Sterilization Engineer.
  - This procedure applies to all commercial products managed by 3M Infection Prevention Division and 3M Skin & Wound Care Division.
- 3M Brookings STER-ASSESS-05-12730 was created:
  - This document was created to describe the procedure for completing a Flammability Analysis (i.e. Small Quantity Volume calculation).
  - The document requires the submission to an outside LFL testing laboratory of samples from all flammable formulations to be irradiated.
  - A Small Quantity Volume calculation template is provided which must be used for all calculations.
  - The results of the Small Quantity Volume calculation is to be used to determine the quantity of flammable liquid that may be added per tote for each irradiator to assure that license restrictions are not violated.
  - The document provides a table containing a current listing of all the flammable formulations that are processed at S8 & S10 and all the products (via SKU# stock numbers) that are made from those flammable formulations.
  - The document is reviewed and approved by the Brookings Site RSO and management.
- Brookings IMS SOP 81, Supplement R (for S8) was updated:
  - This document is referenced when products containing flammable formulations are required to be loaded into a tote at S8.
  - The document contains a table with the same product listing as in the STER-ASSESS-05-127360 document.
  - The table contains products (via SKU # stock numbers), product-specific Small Quantity Volume calculations (based on the flammable formulation in the product), the volume of liquid contained in each carton, and the number of cartons allowed per tote as to assure that license restrictions are not violated.
  - A flammable product cannot be loaded into a tote unless it appears in the table.
  - The document provides the worst-case Small Quantity Volume values presently in the license.
  - The document specifically states that if the Small Quantity Volume value in the table is smaller than the worst-case license value, irradiation is not authorized until the issuance of a license amendment.

- The document requires that during the preparation of a tote loading diagram, the table listing of the maximum number of cartons per tote for a given product must be examined to verify compliance with license restrictions.
- Tote loading diagrams are reviewed and approved by a Sterilization Engineer.
- Brookings IMS SOP 82, Supplement R (for S10) was updated:
  - This document is referenced when products containing flammable formulations are required to be loaded into a tote at S10.
  - The document contains a table with the same product listing as in the STER-ASSESS-05-127360 document.
  - The table contains products (via SKU # stock numbers), product-specific Small Quantity Volume calculations (based on the flammable formulation in the product), the volume of liquid contained in each carton, and the number of cartons allowed per tote as to assure that license restrictions are not violated.
  - A flammable product cannot be loaded into a tote unless it appears in the table.
  - The document provides the worst-case Small Quantity Volume values presently in the license.
  - The document specifically states that if the Small Quantity Volume value in the table is smaller than the worst-case license value, irradiation is not authorized until the issuance of a license amendment.
  - The document requires that during the preparation of a tote loading diagram, the table listing of the maximum number of cartons per tote for a given product must be examined to verify compliance with license restrictions.

In addition, a request has been made to revise the license conditions pertaining to the processing of flammable formulations (NRC license amendment letter dated, October 9, 2009). This request includes the specific commitments as shown in Attachment 5.

**Attachment 5**  
**New List of License Commitments Regarding the Processing of Flammable Formulations in S8 & S10**

**These commitments pertain equally to S8 & S10**

**Commitment #1:** New worst-case formulations require a license amendment prior to irradiation.

**Commitment #2:** The volume of flammable liquid per individual article for any formulation will be restricted to a maximum value of 30 milliliters.

**Commitment #3:** The volume of flammable liquid per tote for any formulation will be restricted to the Small Quantity Volume of that formulation.

**Commitment #4:** The total flammable liquid in each box will be limited by the appropriate Packing Group (as specified in 49 CFR 173.121).

**Commitment #5:** All flammable formulations will be identified:

- existing formulations
- new formulations
- changed formulations in existing products
- changed quantities in existing product packages

**Commitment #6:** Small Quantity Volume calculations will be documented for every formulation:

- existing formulations
- new formulations
- changed formulations in existing products

**Commitment #7:** Small Quantity Volume calculation results will be reviewed and approved by the Brookings Site RSO prior to irradiation of any products containing flammable formulations.

**Commitment #8:** Lower Flammability Limit (LFL) values for every formulation will be obtained from testing using an independent laboratory:

- existing formulations
- new formulations
- changed formulations in existing products

**Commitment #9:** Documentation will be maintained for every irradiated formulation.

**Commitment #10:** Product and formulation-specific tote loading diagrams will be created to assure that no more than a Small Quantity Volume is placed in each tote.

**Commitment #11:** Written procedures will be maintained to implement Commitments #1 - #10.

**Commitment #12:** Evaluation of Commitments #1 - #11 will be done quarterly through audits performed by the Brookings RSO or by Corporate Health Physics. The audit will include verification of:

- adequacy of product-specific tote limitations to assure that no more than a Small Quantity Volume per tote is irradiated.
- adequacy of Small Quantity Volume calculation documentation
- adequacy of procedures to implement the commitments

3M General Offices  
3M Center Bldg. 220-6W-08  
St. Paul, MN 55144-1000  
Frederick B. Entwistle



7003 3110 0004 8229 9339

**3M**



HASLER **\$6.49**  
OCT 20 2009  
US POSTAGE  
FIRST CLASS  
MAILED FROM 55144  
011A0413001854

First Class Mail

Geoffrey M. Warren  
Materials Inspection Branch  
Division of Nuclear Material Safety  
U.S. Nuclear Regulatory Commission, Region III  
2443 Warrenville Road  
Suite 210  
Lisle, Illinois 60532-4352