



January 20, 2010

Colleen C. Casey  
Material Licensing Branch  
Division of Nuclear Material Safety  
U.S. Nuclear Regulatory Commission, Region III  
2443 Warrenville Road  
Suite 210  
Lisle, Illinois 60532-4352

Subject: License # 22-00057-61, Control # 318560

Dear Ms. Casey:

Thank you for your review of our October 9, 2009 license amendment request. This letter constitutes a follow-up response to your request for additional information (dated 12/7/2009 and faxed to 3M on 12/16/2009). Throughout this letter and attachments we refer to specific procedure names and numbers. However, we reserve the right to change procedure names and numbers and modify procedure content so long as they continue to meet the same criteria as those described here.

**Group Responsibilities**

The first paragraph of your additional information request asks about the responsibilities of the various 3M entities. In reply, at the present time, 3M irradiates four flammable liquid formulations at the Brookings facility. These four formulations are used in 23 specific products.

All changes to these products are controlled by a single process described in a standard operating procedure, SOP-LAB-05-000020. Changes are tracked and communicated using a computer database program Change Management Record (CMR). Responsibility for developing, implementing and maintaining the procedure and database reside with the Quality Assurance/Quality Systems group in the Health Care business. The computer database has undergone validation testing for compliance with FDA Medical Device QSR (21 CFR 820).

All product changes originate in a St. Paul-based laboratory where a specific Product Engineer is assigned "ownership" of each product. "Ownership" means that the Product Engineer is responsible for product changes – including formulation changes. No formulation change can occur to a particular product without the involvement of the Product Engineer who "owns" the product. Currently, two Product Engineers own the 23 products irradiated at Brookings.

**RECEIVED JAN 22 2010**

The Product Engineer's organization is responsible for training on SOP-LAB-05-000020 (per FDA requirements), the formal process that requires:

- involvement of the Product Engineer in every product change (including formulation changes),
- notification of the Brookings Sterilization Engineer (BSE) of any formulation changes, and
- receipt of notification from the BSE to the Product Engineer of completion of required tasks by the BSE before the formulation change can be implemented.

The BSE's organization is responsible for developing, implementing, maintaining, training and testing on the formal processes that assure:

- new and modified formulations are identified,
- Lower Flammability Limits (LFL) are determined,
- Small Quantity Volume (SQV) calculations are documented and compared to license restrictions,
- tote loadings are in compliance with license restrictions and
- new worst-case SQV products are not irradiated until a license amendment is received.

3M Corporate Health Physics (CHP) is responsible for testing, and auditing activities to confirm that the Product Engineer's and BSE's organizations comply with license requirements.

Attachment 6 presents a listing of the groups involved and their specific responsibilities. Attachments 2 – 5 include specific listings of audits and tests of the formal processes.

### **Process Overview**

The second paragraph of your additional information request asks about looking at the "forest" that covers all the "trees." To this end, Attachment 1 was created for your review. At the top of the flow diagram, modification of an existing formulation is initiated by a Product Engineer. Clear, explicit details regarding change are provided in Attachment 2. The change is initiated by completing an entry into an electronic system. The entry form specifically demands a response to the question whether the change involves a flammable liquid that is sterilized in the gamma irradiator. Identifying the formulation change as requiring a flammability analysis generates an e-mail notification of the proposed change to the BSE.

The middle of the flow diagram describes the Brookings Sterilization Engineer (BSE) determining the LFL, performing a Small Quantity Volume (SQV) analysis (consisting of SQV calculations) and a license review analysis (consisting of comparisons of the SQV calculations to the worst-case SQV and license restrictions). Clear, explicit details regarding these activities are provided in Attachments 3 & 4.

The next box of the flow diagram describes the BSE performing a tote loading analysis (consisting of creating a tote loading diagram), which must be completed before product can be irradiated. If the new tote loading is more restrictive it is implemented immediately to ensure that the changed formulation will be loaded properly. Clear, explicit details regarding the tote loading analysis are provided in Attachment 5.

The last box of the flow diagram describes the BSE making an entry into the electronic system controlling product changes stating that required activities are complete. Only after that entry is made is the Product Engineer able to complete the process of changing the formulation.

#### **Identified Weaknesses and Their Correction**

CHP and laboratory personnel identified as a weakness that Product Engineers were not specifically required, in a formal procedure, to:

- notify a Brookings Sterilization Engineer (BSE) when changes were made to a product containing a liquid to be irradiated at Brookings and
- have confirmation from the BSE that the proposed flammable liquid was authorized under the NRC license before proceeding with the change.

These weaknesses were corrected in September 2009, by adding the requirement to SOP-LAB-05-000020 for Product Engineers to notify the BSE and obtain a confirmatory response. 3M is committed to routinely audit these activities (see Attachments 2 – 5 for specific listings of audits and tests).

CHP and Brookings personnel identified several weaknesses at the Brookings facility consisting of a lack of formal procedures to:

- require the BSE to complete and document Small Quantity Volume (SQV) calculations for every flammable liquid to be irradiated,
- obtain accurate Lower Flammability Limit data on flammable liquids,
- compare a product's SQV to the worst-case SQV authorized by the US NRC,
- ensure tote loadings meet license restrictions, and
- ensure the correct tote loading diagram is used when a modified formulation arrives at Brookings.

In September 2009, standard operating procedures were created to address these weaknesses at the Brookings facility. These procedures include: STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R. These documents have been updated to precisely and clearly require compliance with the commitments provided in our letter to the US NRC (dated 10/9/2009, Attachment 3). 3M is committed to routinely audit these activities (see Attachments 2 – 5 for specific listings of audits and tests).

### **Training and Testing**

Product Engineers are required to have detailed knowledge of the product change procedure SOP-LAB-05-000020, including specific knowledge of the requirement in SOP-LAB-05-000020 to notify a BSE of any change to a flammable liquid product that is gamma sterilized in Brookings. This training is provided by laboratory management when an individual is assigned as Product Engineer. CHP will test this quarterly by:

- contacting the laboratory to confirm who are the Product Engineers with ownership of the sterilized flammable liquids,
- determining whether the requirements in SOP-LAB-05-000020 regarding flammable liquids to be irradiated at Brookings have changed
- if either Product Engineers or procedures have changed, determining that the Product Engineers have been trained on the formulation change process in SOP-LAB-05-000020, and
- confirming the Product Engineers' knowledge of the specific requirements given above.

Failures of this test of training will result in notification by CHP of laboratory and executive management of the failure with a response required on the cause of the failure and corrective action taken. No changes to formulations will be made until the corrective action is complete.

Initial validation testing was conducted on the CMR computer database that controls the change process. The database is now in frequent use in tracking and controlling the many product changes in the Health Care business. It should be noted that the system fails to safety, as the process halts and no change is made if notification of the intended change is not conveyed from the Product Engineer to the BSE and the BSE's response is not conveyed back.

The BSE Supervisor provides initial training and written testing of BSEs, the Radiation Safety Officer, and Alternate Radiation Safety Officers on their understanding and familiarity with STER-ASSESS-05-127360, Brookings SOP 81 Supplement R, and Brookings SOP 82 Supplement R. A passing rate of 90% is required on the test. Incorrect test responses will be discussed with the test participant. A participant scoring less than 90% will retrain on the missed subjects and then retake the test before the training and test is declared completed. Individuals may not perform activities related to flammability assessment until training and testing is successfully completed.

On an annual basis, CHP will review STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R to confirm that appropriate formal procedures addressing evaluation of flammable liquids are present. Failure to maintain these procedures will result in notification by CHP of Brookings and executive management of the failure with a response required on the cause of the failure and corrective action taken. No changes to formulations will be made until the corrective action is complete.

Colleen C. Casey  
Page 5  
January 20, 2010

**Auditing**

CHP is the organization responsible for conducting the audits presented in Attachments 2 - 5.

**Corrected Small Quantity Volume Calculation**

In Item 2. of your December 16, 2009 communication you referred to an error identified in Attachment 1 & 2 of our earlier letter dated 10/09/2009. Attachment 7 contains corrected copies of Small Quantity Volume (SQV) calculations in that letter.

If you have any further questions, please contact Nick Bates at 651-737-1019.

Sincerely,



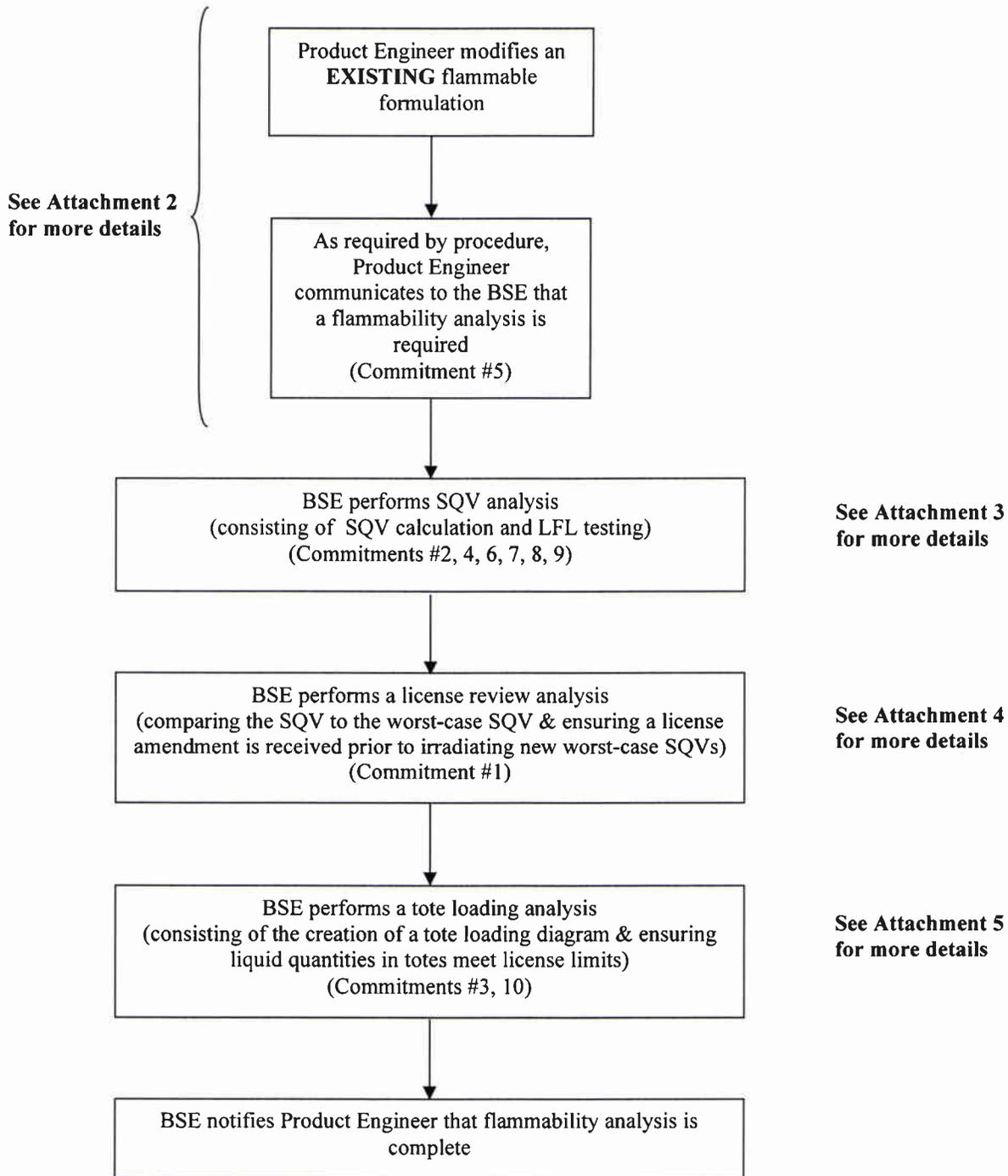
Frederick B. Entwistle, CHP<sup>®</sup>  
Manager, 3M Corporate Health Physics

**Attachments:**

- 1: Process Overview
- 2: Brookings Notification of a Modified Formulation
- 3: Brookings Sterilization Engineer (BSE) Performs a Small Quantity Volume (SQV) Analysis
- 4: Brookings Sterilization Engineer (BSE) Performs a License Review Analysis
- 5: Brookings Sterilization Engineer (BSE) Performs a Tote Loading Analysis
- 6: Roles and Responsibilities
- 7: Corrected Small Quantity Volume (SQV) Calculations Previously Submitted to the US NRC (dated 10/9/2009, Attachments 1 & 2).

### Attachment 1: Process Overview

**Notes:** BSE = Brookings Sterilization Engineer  
SQV = Small Quantity Volume



## Attachment 2: Brookings Notification of a Modified Formulation

(The names of the procedures given in this document may change in the future)

**Step 1:** 3M Product Engineer identifies a need to change an existing formulation.

**Responsible person(s):** Product Engineer.

**NOTE:** Presently, 23 flammable liquid products (existing formulations) are gamma irradiated at Brookings. Two Product Engineers are assigned the lead responsibility for these products. These two Product Engineers are involved in every change made to the products they own.

**What documents/procedures control the actions in this step?:** SOP-LAB-05-000020.

**NOTE:** The only path for making a change to one of the 23 flammable liquid products (existing formulations) that are gamma irradiated at Brookings is through the use of SOP-LAB-05-000020.

**How are the responsible person(s) trained on the actions in this step?:** Product Engineer is trained in the use of SOP-LAB-05-000020 by detailed review and study of the document.

**Tests:**

- On a quarterly basis, CHP will confirm that the current list of all existing products and all Product Engineers assigned to those products is correct.
- On a quarterly basis, CHP will confirm that the requirements regarding flammable liquids to be irradiated at Brookings in SOP-LAB-05-000020 have not changed .
- On a quarterly basis, CHP will confirm that SOP-LAB-05-000020 is the only procedure that is used to make a product change to one of the existing products.
- On a quarterly basis, CHP will confirm that if Product Engineers or procedures have changed, that training on SOP-LAB-05-000020 has been completed.

**Audits:** On a quarterly basis, CHP will ask each Product Engineer if any formulation changes have occurred to the products they own.

**Step 2:** 3M Product Engineer notifies the BSE that a flammability analysis is required. **This step corresponds to Commitment #5 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** Product Engineer.

**What documents/procedures control the actions in this step?:** SOP-LAB-05-000020.

**How are the responsible person(s) trained on the actions in this step?:** Product Engineer is trained in the use of SOP-LAB-05-000020 by detailed review and study of the document.

**Tests:** None

**Audits:** On a quarterly basis, if formulation changes have been made, CHP will audit all product modifications to the existing products to determine if the Product Engineer did communicate with a BSE.

### **Attachment 3: Brookings Sterilization Engineer (BSE) Performs a Small Quantity Volume (SQV) Analysis**

(The names of the procedures given in this document may change in the future)

**Step 1:** On receipt of notification from the Product Engineer that a flammability analysis is required, the BSE uses Brookings SOP 81 Supplement R, Brookings SOP 82 Supplement R and STER-ASSESS-05-127360 to complete the remaining steps in Attachment 3.

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** Brookings SOP 81 Supplement R, Brookings SOP 82 Supplement R, STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor. The Brookings Site RSO and ARSOs (as listed on the license) will also receive this training and testing by the BSE Supervisor.

**Tests:** None

**Audits:** On an annual basis, CHP will review initial training information and training/testing records.

**Step 2:** The BSE verifies that the volume of flammable liquid per individual article is restricted to a maximum of 30 milliliters. **This step corresponds to Commitment #2 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately.

**Step 3:** The BSE verifies that the total flammable liquid in each box will be limited by the appropriate Packing Group (as specified in 49 CFR 173.121). **This step corresponds to Commitment #4 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately.

**Attachment 3 (continued)**

**Step 4:** The BSE verifies that Lower Flammability Limit (LFL) values for the formulation are obtained from an independent testing laboratory. **This step corresponds to Commitment #8 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately.

**Step 5:** The BSE calculates the Small Quantity Volume (SQV) for the formulation. **This step corresponds to Commitment #6 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately.

**Step 6:** The BSE gives the SQV calculation to the Brookings Site RSO for review and approval.

**Responsible person(s):** BSE, RSO.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor. The Brookings Site RSO and ARSOs (as listed in the license) will also receive this training and testing by the BSE Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** None

**Step 7:** The Brookings Site RSO reviews and, if acceptable, approves the SQV calculation. **This step corresponds to Commitment #7 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** BSE, RSO.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor. The Brookings Site RSO and ARSOs (as listed in the license) will also receive this training and testing by the BSE Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately.

**Attachment 3 (continued)**

**Step 8:** The BSE maintains a record of the SQV calculation and supporting documentation. **This step corresponds to Commitment #9 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether documentation is maintained.

## Attachment 4: Brookings Sterilization Engineer (BSE) Performs a License Review Analysis

(The names of the procedures given in this document may change in the future)

**Step 1:** The Brookings Sterilization Engineer (BSE) compares the Small Quantity Volume (SQV) calculation to the worst-case SQV submitted to the US NRC.

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately and documented.

**Step 2:** If the new SQV is a new worst-case SQV, a license amendment is required. The BSE does not allow irradiation of the formulation until a license amendment is received. **This step corresponds to Commitment #1 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately and documented.

**Step 3:** If the new SQV is a new worst-case SQV, then the BSE communicates to Corporate Health Physics (CHP) that a license amendment is required.

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately and documented.

**Attachment 5: Brookings Sterilization Engineer (BSE) Performs a Tote Loading Analysis**

**Step 1:** BSE has determined that the irradiation is authorized (i.e., SQV is not a new worst-case **OR** for a new worst-case SQV a license amendment has been obtained).

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360 contains this requirement.

**Audits:** None

**Step 2:** The Brookings Sterilization Engineer (BSE) updates Brookings SOP 81 Supplement R and SOP 82 Supplement R with the Small Quantity Volume (SQV) for the given Product containing flammable liquid (using the Stock Number or SKU #).

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** STER-ASSESS-05-127360, Brookings SOP 81 Supplement R, Brookings SOP 82 Supplement R.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that STER-ASSESS-05-127360, Brookings SOP 81 Supplement R, Brookings SOP 82 Supplement R contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately and documented.

**Step 3:** The BSE ensures that the calculated maximum number of cartons per tote does not exceed one SQV per tote. **This step corresponds to Commitment #3 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** Brookings SOP 81 Supplement R, Brookings SOP 82 Supplement R.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that Brookings SOP 81 Supplement R, Brookings SOP 82 Supplement R contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately and documented.

**Attachment 5 (continued)**

**Step 4:** The BSE updates Brookings SOP 81 Supplement R and SOP 82 Supplement R with the maximum number of cartons allowed per tote for the given Product (using the Stock Number or SKU #).

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** Brookings SOP 81 Supplement R, Brookings SOP82 Supplement R.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that Brookings SOP 81 Supplement R, Brookings SOP 82 Supplement R contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately and documented.

**Step 5:** The BSE creates a tote loading diagram for the given Product (using the Stock Number or SKU #). **This step corresponds to Commitment #10 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

**Responsible person(s):** BSE.

**What documents/procedures control the actions in this step?:** Brookings SOP 81 Supplement R, Brookings SOP 82 Supplement R.

**How are the responsible person(s) trained on the actions in this step?:** BSE receives initial training and testing by his/her Supervisor.

**Tests:** On an annual basis, CHP will verify that Brookings SOP 81 Supplement R, Brookings SOP 82 Supplement R contains this requirement.

**Audits:** On a quarterly basis, if any formulation changes have occurred, CHP will determine whether this activity was performed accurately and documented.

## Attachment 6: Roles and Responsibilities

(The names of the procedures given in this document may change in the future)

### Radiation Safety Officer (RSO) Responsibilities

- Reviews and approves Small Quantity Volume (SQV) calculations. **This corresponds to Commitment #7 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**
- Arranges Corporate Health Physics (CHP) audits/tests with a CHP Staff member.
- Completes initial training on STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R.
- Maintains familiarity with STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R.

### Alternate Radiation Safety Officer (ARSO) Responsibilities

- Reviews and approves SQV calculations in the RSO's absence.
- Arranges Corporate Health Physics (CHP) audits/tests with a CHP Staff member in the RSO's absence.
- Completes initial training on STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R.
- Maintains familiarity with STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R.

### Brookings Sterilization Engineer (BSE) Responsibilities

- Develops, updates and maintains STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R as appropriate.
- Completing initial training on STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R.
- Maintains familiarity and uses STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R.
- Verifies that the volume of flammable liquid per individual article is restricted to a maximum of 30 milliliters. **This corresponds to Commitment #2 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**
- Verifies that the total flammable liquid in each box will be limited by the appropriate Packing Group (as specified in 49 CFR 173.121). **This corresponds to Commitment #4 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**
- Verifies that Lower Flammability Limit (LFL) values for formulations are obtained from testing using an independent laboratory. **This corresponds to Commitment #8 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**
- Calculates the SQV for formulations. **This corresponds to Commitment #6 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**
- Compares SQV values to the worst-case SQV submitted to the US NRC.
- Does not allow the irradiation of new worst-case formulations until a license amendment is obtained. **This corresponds to Commitment #1 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**
- Initiates contact with CHP to request a license amendment.

## Attachment 6 (continued)

- Maintains contact with CHP to ensure Brookings is aware of when the license amendment is received.
- Maintains contact with the Product Engineer to ensure Brookings is aware of when a modified formulation is sent to Brookings.
- Maintains a record of SQV calculations and supporting documentation. **This corresponds to Commitment #9 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**
- Ensures that the maximum carton per tote determination calculates to no more than one SQV in a tote. **This corresponds to Commitment #3 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**
- Creates tote loading diagrams. **This corresponds to Commitment #10 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**

### BSE Supervisor Responsibilities

- Provides initial training to the BSE, RSO and ARSOs on STER-ASSESS-05-127360, SOP 81 Supplement R and SOP 82 Supplement R. CHP will audit as described in Attachments 2-5.
- Gives written test to BSE, RSO and ARSOs.

### Product Engineer Responsibilities

- Modifying existing flammable formulations for irradiation.
- Notifying the BSE of modified flammable formulations for irradiation. **This corresponds to Commitment #5 in 3M's letter to US NRC (dated 10/9/2009, Attachment 3).**
- Completing initial training on SOP-LAB-05-000020 by detailed review and study of the document.
- Maintains familiarity and correctly uses SOP-LAB-05-000020.

### Product Engineer Supervisor Responsibilities

- Ensures Product Engineers complete initial training on SOP-LAB-05-000020 by detailed review and study of the document.

### Quality Assurance/Quality Systems Engineer Responsibilities

- Develops, implements, updates and maintains SOP-LAB-05-000020 as appropriate.

### Corporate Health Physics (CHP) Responsibilities

- Conducts audits/tests. Publishes audit/test. Follows-up to ensure any Recommendations are closed-out. **This corresponds to Commitment #11 & #12 in 3M's letter to the US NRC (dated 10/9/2009, Attachment 3).**
- Maintains familiarity with, and conducts quarterly audits/reviews of STER-ASSESS-05-127360, Brookings SOP 81 Supplement R and Brookings SOP 82 Supplement R. **This corresponds to Commitment #11 & #12 in 3M's letter to the US NRC (dated 10/9/2009, Attachment 3).**
- Prepares and submits licensing requests and support documentation to the US NRC.
- Confirms that the Product Engineer is familiar with and understands SOP-LAB-05-000020.

**Attachment 7: Corrected Small Quantity Volume (SQV) Calculations Previously Submitted to the US NRC (dated 10/9/2009, Attachments 1 & 2).**

**Corrected Copy of Attachment 1 of 3M Letter to US NRC Dated 10/9/2009**  
S8 New Worst-Case Formulation Small Quantity Volume Calculation

HMDS = Hexamethyldisiloxane (CAS #107-46-0, C<sub>6</sub>H<sub>18</sub>OSi<sub>2</sub>)

P97A = Permethyl 97A (also called Isooctane or 2,3,4-Trimethylpentane) (CAS #540-84-1, C<sub>8</sub>H<sub>18</sub>)

Composition of Formula 2:

HMDS (volatile): 84% by weight

P97A (volatile): 9% by weight

Isoctyl acrylate polymer (non-volatile): 5% by weight

Polyphenylmethylsiloxane copolymer (non-volatile): 2% by weight

Total volatile components: 93%

Non-volatile components: 7% by weight

Physical and chemical properties:

Lower flammable limit (LFL) = 0.7% (from independent lab tests)

Flash point = -1.1 °C (30 °F) (from MSDS)

Specific gravity = 0.78 kg/liter (from MSDS)

Irradiator conditions:

Air temperature inside the chamber = 30 °C

Molar weight of HMDS = 0.16238 kg/mole

Molar weight of P97A = 0.11423 kg/mole

Molar gas volume constant = 0.0249 m<sup>3</sup>/mole at 30 °C

Density of air = 1.165 kg/m<sup>3</sup> at 30 °C

Density of water = 0.9956 kg/liter at 30 °C

Room volume = 101.8 m<sup>3</sup>

Vapor density of volatile components relative to air

$$= \frac{\{[(\text{molar weight of HMDS} \times \text{percent HMDS}) + (\text{molar weight of P97A} \times \text{percent P97A})]\}}{(\text{percent HMDS} + \text{percent P97A}) / (\text{molar gas volume constant} \times \text{density of air})}$$

$$= \frac{\{[(0.16238 \text{ kg/mole} \times 84\%) + (0.11423 \text{ kg/mole} \times 9\%)] / 93\% \}}{(0.0249 \text{ m}^3/\text{mole} \times 1.165 \text{ kg/m}^3)}$$

$$= \frac{\{[0.13640 + 0.01028 \text{ kg/mole}] / 0.93 \}}{(0.02901 \text{ kg/mole})}$$

$$= 5.437$$

Volume of volatile vapor in the room at LFL

$$= \text{LEL} \times \text{Volume of the room}$$

$$= 0.7\% \times 101.8 \text{ m}^3$$

$$= 0.713 \text{ m}^3$$

**Corrected Copy of Attachment 1 of 3M Letter to US NRC Dated 10/9/2009**  
S8 New Worst-Case Formulation Small Quantity Volume Calculation

Weight of volatile vapor in the room at LFL

$$\begin{aligned} &= \text{Volume of vapor at LEL} \times \text{Density of air} \times \text{vapor density relative to air} \\ &= 0.713 \text{ m}^3 \times 1.165 \text{ kg/m}^3 \times 5.437 \\ &= 4.516 \text{ kg} \end{aligned}$$

Volume of volatile liquid in the room at LFL

$$\begin{aligned} &= \text{Weight of volatile vapor} / (\text{specific gravity of liquid} \times \text{density of water}) \\ &= 4.516 \text{ kg} / (0.78 \times 0.9956 \text{ kg/liter}) \\ &= 5.815 \text{ liters} \end{aligned}$$

Volume of liquid (volatile and non-volatile) in the room at LFL

$$\begin{aligned} &= \text{Volume of volatile liquid} / \text{total percent volatile liquid in the solution} \\ &= 5.815 \text{ liters} / (84\% + 9\%) \\ &= 6.253 \text{ liters} \\ &= \mathbf{6.2 \text{ liters}} \end{aligned}$$

**Corrected Copy of Attachment 2 of 3M Letter to US NRC Dated 10/9/2009**  
S10 New Worst-Case Formulation Small Quantity Volume Calculation

HMDS = Hexamethyldisiloxane (CAS #107-46-0, C<sub>6</sub>H<sub>18</sub>OSi<sub>2</sub>)

P97A = Permethyl 97A (also called Isooctane or 2,3,4-Trimethylpentane) (CAS #540-84-1, C<sub>8</sub>H<sub>18</sub>)

Composition of Formula #2:

HMDS (volatile): 84% by weight

P97A (volatile): 9% by weight

Isoctyl acrylate polymer (non-volatile): 5% by weight

Polyphenylmethylsiloxane copolymer (non-volatile): 2% by weight

Total volatile components: 93%

Non-volatile components: 7% by weight

Physical and chemical properties:

Lower flammable limit (LFL) = 0.7% (from independent lab tests)

Flash point = -1.1 °C (30 °F) (from MSDS)

Specific gravity = 0.78 (from MSDS)

Irradiator conditions:

Air temperature inside the chamber = 30 °C

Molar weight of HMDS = 0.16238 kg/mole

Molar weight of P97A = 0.11423 kg/mole

Molar gas volume constant = 0.0249 m<sup>3</sup>/mole at 30 °C

Density of air = 1.165 kg/m<sup>3</sup> at 30 °C

Density of water = 0.9956 kg/liter at 30 °C

Room volume = 393.1 m<sup>3</sup>

Vapor density of volatile components relative to air

$$= \{[(\text{molar weight of HMDS} \times \text{percent HMDS}) + (\text{molar weight of P97A} \times \text{percent P97A})] / (\text{percent HMDS} + \text{percent P97A}) / (\text{molar gas volume constant} \times \text{density of air})\}$$

$$= \{[(0.16238 \text{ kg/mole} \times 84\%) + (0.11423 \text{ kg/mole} \times 9\%) / 93\%] / (0.0249 \text{ m}^3/\text{mole} \times 1.165 \text{ kg/m}^3)\}$$

$$= \{[0.13640 + 0.01028 \text{ kg/mole}] / 0.93\} / (0.02901 \text{ kg/mole})\}$$

$$= 5.437$$

Volume of volatile vapor in the room at LFL

$$= \text{LEL} \times \text{Volume of the room}$$

$$= 0.7\% \times 393.1 \text{ m}^3$$

$$= 2.752 \text{ m}^3$$

**Corrected Copy of Attachment 2 of 3M Letter to US NRC Dated 10/9/2009**  
S10 New Worst-Case Formulation Small Quantity Volume Calculation

Weight of volatile vapor in the room at LFL

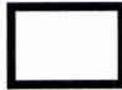
$$\begin{aligned} &= \text{Volume of vapor at LEL} \times \text{Density of air} \times \text{vapor density relative to air} \\ &= 2.752 \text{ m}^3 \times 1.165 \text{ kg/m}^3 \times 5.437 \\ &= 17.432 \text{ kg} \end{aligned}$$

Volume of volatile liquid in the room at LFL

$$\begin{aligned} &= \text{Weight of volatile vapor} / (\text{specific gravity of the liquid} \times \text{density of water}) \\ &= 17.432 \text{ kg} / (0.78 \times 0.9956 \text{ kg/liter}) \\ &= 22.448 \text{ liters} \end{aligned}$$

Volume of liquid (volatile and non-volatile) in the room at LFL

$$\begin{aligned} &= \text{Volume of volatile liquid} / \text{total percent volatile liquid in the solution} \\ &= 22.448 \text{ liters} / (84\% + 9\%) \\ &= 24.138 \text{ liters} \\ &= \mathbf{24.1 \text{ liters}} \end{aligned}$$



Package 1 of 1

Shipment #: 00240525



Desktop Shipping Request - ship.mmm.com

Traveler #: 00240525-001

Requested January 20, 2010 by US320699  
Printed on January 20, 2010 1:16 PM



**To:** COLLEEN C. CASEY  
US NRC, REGION III  
MATERIAL LICENSING BRANCH  
DIVISION OF NUCLEAR MATERIAL SAFETY  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE IL 60532-4352

Phone: 16517333902  
Email:

**From:** HARRIS, GLORIA M  
HARRIS, GLORIA M  
3M MAPLEWOOD 0220-06-W -08  
3M CENTER  
MAPLEWOOD MN 55144-1000

Phone: 16517333902  
Email: gmharris@MMM.COM

**Invoice:**

**Reference:**

**Service type:** UPS Next Day Air Saver® - Domestic

**Package type:**

**Est. Weight:** 1 LB

**Special Instructions:**

### INSTRUCTIONS

1. Please print a copy of this internal shipping label.  
If you are sending multiple pieces as one shipment, print one copy for each piece.  
You may also print an extra copy for your own records, if you wish.
2. Fold this label in half along the line above.
3. Attach this label to the envelope or box to be shipped, top half facing up.
4. Take this shipment to your local package drop for pickup.