**3M Corporate Health Physics**
**Bldg 220-06-W-08**
**St. Paul, MN 55144**

# Fax

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| **To:** | Colleen Carol Casey | **From:** | Frederick B. Entwistle |
| **Fax:** | 630-515-1078 | **Fax:** | 651-736-2285 |
| **Phone:** | 630-829-9841 | **Phone:** | 651-736-0740 |
| | Number of pages including cover page: | 18 | |
| **Date:** | October 9, 2009 | | |
| **Subject:** | License Amendment Request License #: 22-00057-61 | | |

**Comments:** Please call me at the above number if you have any questions.

Frederick B. Entwistle, Certified Health Physicist®
Manager, 3M Corporate Health Physics

**3M Corporate Health Physics**

**3M Center, Building 0220-06-W-08**
**St. Paul, MN 55144-1000**
**651 736 0498 Office**
**651 736 2285 Fax**

October 9, 2009

Colleen Carol Casey
Materials 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 Amendment Request, License #: 22-00057-61

Dear Ms. Casey:

This letter constitutes a license amendment request regarding the irradiation of more than small quantities of flammable formulations in the S8 & S10 irradiators. A Formulation is a specific mixture of chemicals that is used in a variety of different products irradiated in S8 & S10. Therefore, it's more appropriate to refer to the formulation name rather than product names.

The contents provided herein update previous information sent to your Office. Specifically, the letters dated: 3/31/03 (S8 license renewal) and 5/8/08 (S10 amendment request). Since the Small Quantity Volume calculations are based on the example in NUREG-1556, Vol. 6, Appendix F, page F-2, and the calculations using the ventilation system are similar to our 5/08/08 request (which was accepted by the NRC), a review of this letter should be simple and straight-forward.

3M asks for an **expedited** review of this letter. Specifically, we are asking for your review to be completed within one week of receipt. The formulations in question are integral to 3M business - amounting to over $150,000 of lost sales per day while we cannot irradiate these formulations. The products on hold pending the NRC's review of this letter are used in hospitals for surgical site wound care. They represent a key component of hospital infection prevention and skin damage reduction programs. These products are the only wound barrier films available which are supported by extensive clinical data showing that they allow continuous visualization and monitoring of wound sites. As such, they are considered critical to wound care management and are unique in functionality. Supply disruption to hospitals throughout the US could potentially increase patient risk due to the lack of a comparable replacement product available for hospitals to purchase and use. In addition to this potential patient risk, the lost sales to 3M has the potential of causing permanent damage to our business operations.

On our part, if there's anything we can do to help you expedite a decision, please let us know.

We are asking for the following license amendment requests:

- A new worst-case Formulation has been identified for the S8 irradiator. The name of this formulation is Formulation #2 (41-4202-4610-4). The Small Quantity Volume value for this formulation is 6.2 liters. We request authorization to irradiate more than small quantities of this formulation in the S8 irradiator. We commit to limiting the total volume per tote of this formulation to 6.2 liters (i.e. the Small Quantity Volume). There are 48 totes in the S8 irradiator.

- Presently, there are three other formulations that are to be used in S8. These are identified below and in Attachment 4. The Small Quantity Volume values have also been provided. In the future, these formulations may be modified or removed and other formulations may be added. We request authorization to irradiate more than small quantities of these formulations in the S8 irradiator as long as they don't comprise a new worst-case formulation. For these formulations, we commit to limiting the total volume per tote to the respective formulation-specific Small Quantity Volume.

- A new worst-case Formulation has been identified for the S10 irradiator. The name of this formulation is Formulation #2 (41-4202-4610-4) The Small Quantity Volume value for this formulation is 24.1 liters. We request authorization to irradiate more than small quantities of this formulation in the S10 irradiator. We commit to limiting the total volume per tote of this formulation to 24.1 liters (i.e. the Small Quantity Volume). There are 22 totes in the S10 irradiator.

- Presently, there are three other formulations that are to be used in S10. These are identified below and in Attachment 4. The Small Quantity Volume values are also provided. In the future, these formulations may be modified or removed and other formulations may be added. We request authorization to irradiate more than small quantities of these formulations in the S10 irradiator as long as they don't comprise a new worst-case formulation. For these formulations, we commit to limiting the total volume per tote to the respective formulation-specific Small Quantity Volume.

These license amendment requests can be summarized in the following table:

| | **Formulation #1** | **Formulation #2 (worst case)** | **Formulation #3** | **Formulation #4** | **Any Future Formulation** |
|---|---|---|---|---|---|
| | Small Quantity Volume & Maximum Volume Allowed per Tote | Small Quantity Volume & Maximum Volume Allowed per Tote | Small Quantity Volume & Maximum Volume Allowed per Tote | Small Quantity Volume & Maximum Volume Allowed per Tote | Maximum Volume Allowed per Tote |
| S8 Irradiator | 9.2 liters | 6.2 liters | 6.8 liters | 7.3 liters | Limited to the formulation-specific Small Quantity Volume provided it is greater than 6.2 liters |
| S10 Irradiator | 35.5 liters | 24.1 liters | 26.2 liters | 28.2 liters | Limited to the formulation-specific Small Quantity Volume provided it is greater than 24.1 liters |

The S8 Small Quantity Volume calculation for Formulation #2 (41-4202-4610-4) is provided in Attachment 1. The calculation methodology follows the example in NUREG-1556, Vol. 6, Appendix F, page F-2. The calculation result differs from that provided previously to the NRC (dated, 3/31/03). The difference is primarily because of the addition of isooctane which results in a smaller Lower Flammability Limit (LFL).

Attachment 2 is the same as Attachment 1 – but applied to the S10 irradiator. The calculation result differs from that provided previously to the NRC (dated, 5/8/08). The difference is because Formulation #2 (41-4202-4610-4) has a Lower Flammability Limit (LFL) that is smaller than the Product used in that submission.

The Small Quantity Volume calculations for Formulations #1, 3, & 4 are not provided in this letter since they don't represent worst-case examples. These calculations are available for inspection.

A new list of license commitments regarding the processing of flammable formulations is provided in Attachment 3.

A current table of flammable formulations to be processed in the S8 & S10 irradiators is provided in Attachment 4. Please note that this table is subject to change – formulations may be added or deleted in accordance with our business needs. The table does not imply any commitments that should be applied under the subject license.

Attachment 5 provides 3M's rationale for allowing greater than small quantities of flammable formulations within the S8 irradiator chamber. It is the same rationale used in our 5/08/08 submission to the NRC (which was accepted) – but applied to the S8 irradiator. The only differences are the use of the new worst-case Formulation #2 (41-4202-4610-4) and several S8-specific parameters (ventilation rate, etc). Essentially, the rationale comes down to a single observation:

- there doesn't appear to be any physical mechanism that could cause the destruction of enough totes (and the vaporization of the protected flammable liquid-containing packages within them) to produce a vaporization rate large enough relative to the ventilation rate to produce an explosive environment within the irradiation room.

Attachment 6 is the same as Attachment 5 – but applied to the S10 irradiator. It is the same rationale used in our 5/08/08 submission to the NRC (which was accepted). The only difference from that submission is the use of the new worst-case Formulation #2 (41-4202-4610-4).

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

Sincerely,

Mike Lewandowski for

Frederick B. Entwistle, Certified Health Physicist ®
Manager, 3M Corporate Health Physics

Enclosures: Attachment 1 S8 New Worst-Case Formulation Small Quantity Volume Calculation
Attachment 2 S10 New Worst-Case Formulation Small Quantity Volume Calculation
Attachment 3 License Commitments Regarding the Processing of Flammable Formulations in S8 & S10
Attachment 4 A Current Table of Flammable Formulations to be Processed in S8 & S10
Attachment 5 Rationale for Allowing Greater Than Small Quantities of Flammable Formulations to be Irradiated in S8
Attachment 6 Rationale for Allowing Greater Than Small Quantities of Flammable Formulations to be Irradiated in S10

## Attachment 1

S8 New Worst-Case Formulation Small Quantity Volume Calculation

HMDS = Hexamethyldisiloxane (CAS #107-46-0, $C_6H_{18}OSi_2$)
P97A = Permethyl 97A (also called Isooctane or 2,3,4-Trimethylpentane) (CAS #540-84-1, $C_8H_{18}$)

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 $m^3$/mole at 30°C
Density of air = 1.165 kg/$m^3$ at 30°C
Density of water = 0.9956 kg/liter at 30°C

Room volume = 101.8 $m^3$

Vapor density of volatile components relative to air
= {[(molar weight of HMDS x percent HMDS) + (molar weight of P97A x percent P97A)]} / (percent HMDS + percent P97A) / (molar gas volume constant / density of air)
= {[(0.16238 kg/mole x 84%) + (0.11423 kg/mole x 9%)] / 93%} / (0.0249 $m^3$/mole x 1.165 kg/$m^3$)}
= {[0.13640 + 0.01028 kg/mole] / 0.93} / (0.02901 kg/mole)}
= 5.437

Volume of volatile vapor in the room at LFL
= LEL x Volume of the room
= 0.7% x 101.8 $m^2$
= 0.713 $m^3$

Weight of volatile vapor in the room at LFL
= Volume of vapor at LEL x Density of air x vapor density relative to air
= 0.713 $m^3$ x 1.165 kg/$m^3$ x 5.437
= 4.516 kg

Volume of volatile liquid in the room at LFL
= Weight of volatile vapor / (specific gravity of liquid x density of water)
= 4.516 kg / (0.78 x 0.9956 kg/liter)
= 5.815 liters

Volume of liquid (volatile and non-volatile) in the room at LFL
= Volume of volatile liquid / total percent volatile liquid in the solution
= 5.815 liters / (84% + 9%)
= 6.253 liters
**= 6.2 liters**

**Attachment 2**

S10 New Worst-Case Formulation Small Quantity Volume Calculation

HMDS = Hexamethyldisiloxane (CAS #107-46-0, $C_6H_{18}OSi_2$)
P97A = Permethyl 97A (also called Isooctane or 2,3,4-Trimethylpentane) (CAS #540-84-1, $C_8H_{18}$)

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 $m^3$/mole at 30°C
Density of air = 1.165 kg/$m^3$ at 30°C
Density of water = 0.9956 kg/liter at 30°C

Room volume = 393.1 $m^3$

Vapor density of volatile components relative to air
= {[(molar weight of HMDS x percent HMDS) + (molar weight of P97A x percent P97A)]} / (percent HMDS + percent P97A) / (molar gas volume constant / density of air)
= {[(0.16238 kg/mole x 84%) + (0.11423 kg/mole x 9%)] / 93%} / (0.0249 $m^3$/mole x 1.165 kg/$m^3$)}
= {[0.13640 + 0.01028 kg/mole] / 0.93} / (0.02901 kg/mole)}
= 5.437

Volume of volatile vapor in the room at LFL
= LEL x Volume of the room
= 0.7% x 393.1 $m^2$
= 2.752 $m^3$

Weight of volatile vapor in the room at LFL
= Volume of vapor at LEL x Density of air x vapor density relative to air
= 2.752 $m^3$ x 1.165 kg/$m^3$ x 5.437
= 17.432 kg

Volume of volatile liquid in the room at LFL
= Weight of volatile vapor / (specific gravity of the liquid x density of water)
= 17.432 kg / (0.78 x 0.9956 kg/liter)
= 22.448 liters

Volume of liquid (volatile and non-volatile) in the room at LFL
= Volume of volatile liquid / total percent volatile liquid in the solution
= 22.448 liters / (84% + 9%)
= 24.138 liters
= **24.1 liters**

**Attachment 3**
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

**Attachment 4**

A Current Table of Flammable Formulations to be Processed in S8 & S10

| Formulation Number | Bulk Solution Stock Number | S8 Calculated Small Quantity Volume (liters) | S10 Calculated Small Quantity Volume (liters) |
|---|---|---|---|
| 1 | 41-4202-3239-3 | 9.2 | 35.5 |
| 2* | 41-4202-4610-4* | 6.2* | 24.1* |
| 3 | 41-4202-3238-5 | 6.8 | 26.2 |
| 4 | 41-4202-4611-2 | 7.3 | 28.2 |

* Formula #2 is the new worst-case formulation to be processed in the S8 & S10 irradiators. Small Quantity Volumes for Formulation #1, 3, 4 were calculated in the same manner as #2 (Attachments 1, 2). Since they are not worst-case examples, the calculations for these other formulations are not presented.

Note: As indicated in our cover letter, a Formulation is a specific mixture of chemicals that is used in a variety of different products irradiated in S8 & S10.

**Attachment 5**

Rationale for Allowing Greater Than Small Quantities of Flammable Formulations to be Irradiated in S8

In 1986 3M requested and was authorized to irradiate products containing greater than small quantities of flammable material in the S8 irradiator. We seek to continue this authorization with the new worst-case Formulation #2 (41-4202-4610-4).

**STEP 1:** NRC Requirement For Applicants Requesting Authorization To Irradiate More Than A Small Quantity Of Flammable Material

NUREG-1556 Vol. 6 Appendix F, page F-3 (bottom) requires the applicant to "Describe why a single failure is unlikely to cause immobilization of the product being irradiated with the simultaneous inability to return the sources to the shielded position."

**ANSWER FOR STEP 1:**

There is no one single failure that would cause immobilization of the product being irradiated, with the simultaneous inability to return the sources to the shielded position.

- PRODUCT IMMOBILIZATION: Product may become immobilized in the source pass due to a conveying system drive fault, a conveying system mechanical fault or a tote jam. Occurrence of any of the above scenarios would cause the source to return to the storage pool. The source rack is protected by a stainless steel shroud and the totes are conveyed on rollers with guides on both sides of the tote. Each tote is surrounded either by other totes or by the conveying frame making it impossible for the tote to come in contact with the source rack.

- STUCK SOURCES: The sources may become stuck due to a compressed air source sequence valve failure or a guide cable failure. If the source rack becomes stuck due to a sequence valve failure, the source rack can be returned to the storage pool by manipulating the source rack hoist air regulator(s) in the Penthouse on the roof above the storage pool (under the RSO's direction). If the source rack becomes stuck due to a catastrophic failure to one of the guide cables, the source rack hoist system will lower the source rack to the storage pool using the remaining guide cable. A preventive maintenance program is in place to inspect and replace the source guide and source hoist cables at intervals recommended by the manufacturer. The maintenance program also monitors and adjusts tension to the guide cables per the manufacturer's recommendation.

- VENTILATION SYSTEM: The ventilation system consists of one exhaust fan. The ventilation system exhaust fan is interlocked to the irradiator control console. If the exhaust fan fails, the source rack are automatically returned to the storage pool.

**NOTE**: If multiple irreversible failures occur (e.g. the sources become stuck, the conveyor system jams, and/or the ventilation system fails), the product-filled totes will not be removed from the radiation room. The RSO will initiate the source rack water deluge system. 3M will notify the irradiator manufacturer and request immediate on-site support. The RSO will turn on the water flow to the pipes serving the sprinkler system above the product-filled totes when a smoke and/or heat detector alarm occurs. The totes containing products will remain in the radiation room until the rack(s) is lowered or until the irradiator manufacturer devises a plan to operate the conveyor system. USNRC approval will be required if safety system bypassing is required to control the conveyor system.

**STEP 2:** NRC Requirement For Applicants Requesting Authorization To Irradiate More Than A Small Quantity Of Flammable Material

NUREG-1556 Vol. 6 Appendix F, page F-3 (bottom) requires the applicant to "describe why the ventilation system will prevent the concentration of vapor in air from exceeding the lower flammable limit in a significant volume of the room if the product is immobilized and the sources cannot be returned to the shielded position."

**ANSWER FOR STEP 2:**

**NOTE:** If multiple irreversible failures occur (e.g. the sources become stuck, the conveyor system jams, and/or the ventilation system fails), the product-filled totes will not be removed from the radiation room. The RSO will initiate the source rack water deluge system. 3M will notify the irradiator manufacturer and request immediate on-site support. The RSO will turn on the water flow to the pipes serving the sprinkler system above the product-filled totes when a smoke and/or heat detector alarm occurs. The totes containing products will remain in the radiation room until the rack(s) is lowered or until the irradiator manufacturer devises a plan to operate the conveyor system. USNRC approval will be required if safety system bypassing is required to control the conveyor system.

The following calculation shows that the S8 ventilation system is able to prevent the lower flammable limit from being exceeded as long as Formulation #2 (41-4202-4610-4) does not leak or escape into the air with a constant release rate greater than 5.5 liters/minute. Since individual articles would contain no more than 30 milliliters of flammable liquid, this amounts to the entire contents of 183 articles leaking every minute. The Small Quantity Volume value for Formulation #2 is 6.2 liters. Based on the definition of a Small Quantity Volume value, up to 6.2 liters total of Formulation #2 can be released into the irradiator chamber when the ventilation system is off or not considered. If more than 6.2 liters is released, however, then the release rate becomes the limiting factor. If more than 6.2 liters is released, but at a release rate of less than 5.5 liters/minute then the ventilation system prevents the lower flammable limit from being exceeded. If the release rate were greater, then the limit would be exceeded. **In either case, if the source rack fails to return to the pool with the simultaneous failure of the conveyor system to index totes out of the radiation chamber, the water deluge sprinkler systems would be initiated over the source racks for fire suppression purposes.**

Assuming a constant release rate of Formulation #2 (41-4202-4610-4) vapor inside the radiation room, the change in concentration of Formulation #2 (41-4202-4610-4) vapor inside the room with respect to time is given by:

$dC/dt = (R/V)\ e^{-(f/V)t}$

where:
C is the Formulation #2 (41-4202-4610-4) concentration in air (Formulation #2 (41-4202-4610-4) in $m^3$/air volume in $m^3$)
R is the release rate of Formulation #2 (41-4202-4610-4) vapor in $m^3$/minute
V is the air volume of the radiation room in $m^3$, and
f is the ventilation system flow rate in $m^3$/minute

The term (R/V) has the same units as dC/dt. The exponential term is due to the ventilation system. The ventilation system causes the change in concentration (dC/dt) to be reduced with respect to time. Overall, the exponential term is unitless. You can see that (f/V) has the units 1/minute. When multiplied by t in minutes, the overall exponential term becomes unitless.

Using Calculus, integrating the expression dC/dt with respect to time from 0 to t' gives:

$C = (R/V)/\text{-}(f/V)\ [e^{-(f/V)t}]$ evaluated from 0 to t'

$C = (R/V)/\text{-}(f/V)\ [(e^{-(f/V)t'} - e^{-0}]$

Carrying the negative thru: $C = (R/V)/(f/V)\ [-e^{-(f/V)t'} + e^{-0}] = (R/V)/(f/V)[e^{-0} - e^{-(f/V)t'}]$

$C = (R/V)/(f/V)[1-e^{-(f/V)t'}]$, since $e^{-0} = 1$

The concentration builds up to a maximum at t = infinity. Therefore,

$C = (R/V)/(f/V)[1-e^{-(f/V)(\infty)}] = (R/V)/(f/V)[1-0]$, since $e^{-\infty} = 0$

The maximum relative concentration inside the radiation room is given by:

$C_{max} = (R/V)/(f/V) = R/(Vf/V) = R/f$

$(C_{max})\ (f) = R = (0.007)(96.35\ m^3/\text{minute}) = 0.674\ m^3/\text{minute}$

Therefore, Formulation #2 (41-4202-4610-4) vapor released at any rate less than 0.674 $m^3$/minute results in the maximum concentration not exceeding the lower flammable limit.

The volume of liquid Formulation #2 (41-4202-4610-4) that must be released to produce a vapor release rate of 0.674 $m^3$/min is found by:

Vapor density of Formulation #2 (41-4202-4610-4) relative to air: 5.437 (see Attachment 1)

Density of dry air at 30 C and standard pressure: 1.165 kg/m$^3$
Volume release rate of Formulation #2 (41-4202-4610-4) vapor: 0.674 m$^3$/min
Weight release rate of Formulation #2 (41-4202-4610-4) vapor volume: (0.674 m$^3$/min)(1.165 kg/m$^3$)(5.437) = 4.269 kg/min
Density of water at 30 C and standard pressure: 0.9956 kg/liter
Specific gravity of Formulation #2 (See Attachment 1): 0.78
Density of Formulation #2: 0.78 x 0.9956 kg/liter = 0.7766 kg/liter
Volume release rate of Formulation #2: (4.269 kg/min)/(0.7766 kg/liter) = 5.5 liters/min

Apart from overheating due to prolonged exposures to the source rack, there doesn't appear to be any other mechanism that could lead to the release of flammable vapor into the air. Possible mechanisms include falling objects and pneumatically driven pushers indexing the totes around the source. Falling objects, such as portions of the concrete ceiling, are an unlikely scenario since objects heavy enough to crush the packages in the totes would also interfere with movement of the totes on the conveyor system. This would automatically initiate irradiator shutdown and return the source racks to the storage pool. Operator resolution of the problem would be required at which time leaking packages would be removed from the irradiator. The electrically driven pushers used to index the totes around the source is also an unlikely scenario. The small amount of force used by the pushers during indexing precludes the possibility, in the event of a stuck tote, of the system causing one tote to crush into another. None of these conditions (falling objects, electric pushers) are likely to interfere with the operation of the source rack, which is protected from damage by a stainless steel shroud (according to the requirements of Title 10 CFR Part 36.35).

**STEP 3:** NRC Requirement For Applicants Requesting Authorization To Irradiate More Than A Small Quantity Of Flammable Material

NUREG-1556 Vol. 6 Appendix F, page F-3 (bottom) further requires the applicant to "provide a procedure to return the source to the shielded position and remove the product from the radiation room if the ventilation system fails. The procedure should also identify the means to detect ventilation system failure."

**ANSWER FOR STEP 3:**

The ventilation system exhaust fans are interlocked to the irradiator control console. If the exhaust fan fails, the source rack is automatically returned to the source storage pool. The totes may then be indexed out of the radiation room if it's deemed necessary. In the event of a ventilation system failure, an alarm activates both at the control console and at the 3M Brookings Security desk.

**Attachment 6**

Rationale for Allowing Greater Than Small Quantities of Flammable Formulations to be Irradiated in S10

In 2008 3M requested and was authorized to irradiate products containing greater than small quantities of flammable material in the S10 irradiator. We seek to continue this authorization with the new worst-case Formulation #2.

**STEP 1:** NRC Requirement For Applicants Requesting Authorization To Irradiate More Than A Small Quantity Of Flammable Material

NUREG-1556 Vol. 6 Appendix F, page F-3 (bottom) requires the applicant to "Describe why a single failure is unlikely to cause immobilization of the product being irradiated with the simultaneous inability to return the sources to the shielded position."

**ANSWER FOR STEP 1:**

There is no one single failure that would cause immobilization of the product being irradiated, with the simultaneous inability to return the sources to the shielded position.

- PRODUCT IMMOBILIZATION: Product may become immobilized in the source pass due to a conveying system drive fault, a conveying system mechanical fault or a tote jam. Occurrence of any of the above scenarios would cause the source to return to the storage pool. The source rack(s) is protected by a stainless steel shroud and the totes are conveyed on rails with ball bearing guides on both sides of the tote. Each tote is surrounded either by other totes or by the conveying frame making it impossible for the tote to come in contact with the source rack(s).

- STUCK SOURCES: The sources may become stuck due to a compressed air source sequence valve failure or a guide cable failure. If the source rack(s) becomes stuck due to a sequence valve failure, the source rack(s) can be returned to the storage pool by manipulating the source rack(s) hoist air regulator(s) in the 3rd Floor Mechanical Room (under the RSO's direction). If the source rack(s) becomes stuck due to a catastrophic failure to one of the guide cables, the source rack(s) hoist system will lower the source rack(s) to the storage pool using the remaining guide cable. A preventive maintenance program is in place to inspect and replace the source guide and source hoist cables at intervals recommended by the manufacturer. The maintenance program also monitors and adjusts tension to the guide cables per the manufacturer's recommendation.

- VENTILATION SYSTEM: The ventilation system consists of two independent exhaust fans. The ventilation system exhaust fans are interlocked to the irradiator control console. If either of the exhaust fan fails, the source racks are automatically returned to the storage pool.

**NOTE:** If multiple irreversible failures occur (e.g. the sources become stuck, the conveyor system jams, and/or the ventilation system fails), the product-filled totes will not be removed from the radiation room. The RSO will initiate the source rack water deluge system. 3M will notify the irradiator manufacturer and request immediate on-site support. The RSO will turn on the water flow to the pipes serving the sprinkler system above the product-filled totes when a smoke and/or heat detector alarm occurs. The totes containing products will remain in the radiation room until the rack(s) is lowered or until the irradiator manufacturer devises a plan to operate the conveyor system. USNRC approval will be required if safety system bypassing is required to control the conveyor system. The sprinkler system above the product-filled totes will initiate when the RSO has opened the water flow to the pipes serving the sprinkler system and when the sprinkler head fusible links melt at temperatures in excess of approximately 286 degrees Fahrenheit.

**STEP 2:** NRC Requirement For Applicants Requesting Authorization To Irradiate More Than A Small Quantity Of Flammable Material

NUREG-1556 Vol. 6 Appendix F, page F-3 (bottom) requires the applicant to "describe why the ventilation system will prevent the concentration of vapor in air from exceeding the lower flammable limit in a significant volume of the room if the product is immobilized and the sources cannot be returned to the shielded position."

**ANSWER FOR STEP 2:**

NOTE: If multiple irreversible failures occur (e.g. the sources become stuck, the conveyor system jams, and/or the ventilation system fails), the product-filled totes will not be removed from the radiation room. The RSO will initiate the source rack water deluge system. 3M will notify the irradiator manufacturer and request immediate on-site support. The RSO will turn on the water flow to the pipes serving the sprinkler system above the product-filled totes when a smoke and/or heat detector alarm occurs. The totes containing products will remain in the radiation room until the rack(s) is lowered or until the irradiator manufacturer devises a plan to operate the conveyor system. USNRC approval will be required if safety system bypassing is required to control the conveyor system. The sprinkler system above the product-filled totes will initiate when the RSO has opened the water flow to the pipes serving the sprinkler system and when the sprinkler head fusible links melt at temperatures in excess of approximately 286 degrees Fahrenheit.

The following calculation shows that the S10 ventilation system is able to prevent the lower flammable limit from being exceeded as long as the Formulation #2 does not leak or escape into the air with a constant release rate greater than 6.5 liters/minute. Since individual articles would contain no more than 30 milliliters of flammable liquid, this amounts to the entire contents of 216 articles leaking every minute. The Small Quantity Volume value for Formulation #2 is 24.1 liters. Based on the definition of a Small Quantity Volume value, up to 24.1 liters total of Formulation #2 can be released into the irradiator chamber when the ventilation system is off or not considered. If more than 24.1 liters is released, however, then the release rate becomes the limiting factor. If more than 24.1 liters is released, but at a release rate of less than

6.5 liters/minute then the ventilation system prevents the lower flammable limit from being exceeded. If the release rate were greater, then the limit would be exceeded. **In either case, if the source rack fails to return to the pool with the simultaneous failure of the conveyor system to index totes out of the radiation chamber, the water deluge sprinkler systems would be initiated over the source racks for fire suppression purposes.**

Assuming a constant release rate of Formulation #2 vapor inside the radiation room, the change in concentration of Formulation #2 vapor inside the room with respect to time is given by:

$dC/dt = (R/V)\, e^{-(f/V)t}$

where:
C is the Formulation #2 concentration in air (Formulation #2 in $m^3$/air volume in $m^3$)
R is the release rate of Formulation #2 vapor in $m^3$/minute
V is the air volume of the radiation room in $m^3$, and
f is the ventilation system flow rate in $m^3$/minute

The term (R/V) has the same units as dC/dt. The exponential term is due to the ventilation system. The ventilation system causes the change in concentration (dC/dt) to be reduced with respect to time. Overall, the exponential term is unitless. You can see that (f/V) has the units 1/minute. When multiplied by t in minutes, the overall exponential term becomes unitless.

Using Calculus, integrating the expression dC/dt with respect to time from 0 to t' gives:

$C = (R/V)/\text{-}(f/V)\ [e^{-(f/V)t}]$ evaluated from 0 to t'

$C = (R/V)/\text{-}(f/V)\ [(e^{-(f/V)t'} - e^{-0}]$

Carrying the negative thru: $C = (R/V)/(f/V)\ [-e^{-(f/V)t'} + e^{-0}] = (R/V)/(f/V)[e^{-0} - e^{-(f/V)t'}]$

$C = (R/V)/(f/V)[1-e^{-(f/V)t'}]$, since $e^{-0} = 1$

The concentration builds up to a maximum at t = infinity. Therefore,

$C = (R/V)/(f/V)[1-e^{-(f/V)(\infty)}] = (R/V)/(f/V)[1-0]$, since $e^{-\infty} = 0$

The maximum relative concentration inside the radiation room is given by:

$C_{max} = (R/V)/(f/V) = R/(Vf/V) = R/f$

$(C_{max})\ (f) = R = (0.007)(113.267\ m^3/\text{minute}) = 0.793\ m^3/\text{minute}$

Therefore, Formulation #2 vapor released at any rate less than 0.793 $m^3$/minute results in the maximum concentration not exceeding the lower flammable limit.

The volume of liquid Formulation #2 that must be released to produce a vapor release rate of 0.793 $m^3$/min is found by:

Vapor density of Formulation #2 relative to air: 5.437 (taken from Attachment 2)
Density of dry air at 30 C and standard pressure: 1.165 kg/$m^3$
Volume release rate of Formulation #2 vapor: 0.793 $m^3$/min
Weight release rate of Formulation #2 vapor volume: (0.793 $m^3$/min)( 1.165 kg/$m^3$)(5.437) = 5.02 kg/min
Density of water at 30 C and standard pressure: 0.9956 kg/liter
Specific gravity of Formulation #2 (taken from Attachment 2): 0.78
Density of Formulation #2: 0.78 x 0.9956 kg/liter = 0.7766 kg/liter
Volume release rate of Formulation #2: (5.02 kg/min)/(0.7766 kg/liter) = 6.5 liters/min

Apart from overheating due to prolonged exposures to the source rack, there doesn't appear to be any other mechanism that could lead to the release of flammable vapor into the air. Possible mechanisms include falling objects and electrically driven pushers indexing the totes around the source. Falling objects, such as portions of the concrete ceiling, are an unlikely scenario since objects heavy enough to crush the packages in the totes would also interfere with movement of the totes on the conveyor system. This would automatically initiate irradiator shutdown and return the source racks to the storage pool. Operator resolution of the problem would be required at which time leaking packages would be removed from the irradiator. The electrically driven pushers used to index the totes around the source is also an unlikely scenario. The small amount of force used by the pushers during indexing precludes the possibility, in the event of a stuck tote, of the system causing one tote to crush into another. None of these conditions (falling objects, electric pushers) are likely to interfere with the operation of the source rack, which is protected from damage by a stainless steel shroud (according to the requirements of Title 10 CFR Part 36.35).

**STEP 3:** NRC Requirement For Applicants Requesting Authorization To Irradiate More Than A Small Quantity Of Flammable Material

NUREG-1556 Vol. 6 Appendix F, page F-3 (bottom) further requires the applicant to "provide a procedure to return the source to the shielded position and remove the product from the radiation room if the ventilation system fails. The procedure should also identify the means to detect ventilation system failure."

**ANSWER FOR STEP 3:**

The ventilation system exhaust fans are interlocked to the irradiator control console. If any of the exhaust fans fail, the source racks are automatically returned to the source storage pool. The totes may then be indexed out of the radiation room if it's deemed necessary. In the event of a ventilation system failure, an alarm activates both at the control console and at the 3M Brookings Security desk.