



December 8, 2015

Colleen C. 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: Amendment of U.S. NRC License 22-00057-61
3M Brookings Gamma Irradiator

Dear Ms. Casey:

3M Company would like to inform you of a recent organizational change affecting the information submitted to NRC with the renewal application dated 23 August 2013 for the subject license and to request an amendment to the subject license.

In September 2015, 3M reorganized its Medical Department so that Corporate Health Physics reports to the Occupational Medicine section instead of reporting directly to the Staff Vice President of the Medical Department. The 3M organizational chart and description of radiation safety program oversight were provided to NRC as Item No. 7 of Attachment 1 of the renewal application dated 23 August 2015. A revised Item No. 7 is attached to this correspondence incorporating the new organizational chart. Additions and changes are shown in highlighted text. Michael Lewandowski remains the Corporate Radiation Safety Officer with responsibility for oversight of the radiation safety program for the irradiator facilities in Brookings, SD.

3M would like to request the subject license be amended to remove William (Bill) Flynn as an Alternate Radiation Safety Officer from Condition 12B as Mr. Flynn has retired from active employment with 3M. William (Bill) Flynn was removed from the list of Alternate Radiation Safety Officers in Item No. 7.

3M would also like to request the subject license be amended regarding the commitments made in Item No. 8 of Attachment 1 of the renewal application dated 23 August 2013 regarding the initial and annual training of irradiator operators. In the renewal application 3M committed to Corporate Health Physics developing and providing initial and annual training for irradiator operators. The current size of the Corporate Health Physics staff makes this commitment impractical. 3M would like to

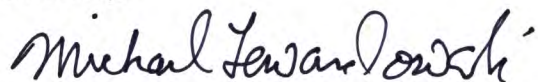
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amend the license commitments to additionally permit initial and annual training to be delivered by the irradiator facility RSO or Alternate RSO using materials developed by Corporate Health Physics and approved by the Corporate RSO. 3M would also like to amend the license to additionally permit initial and annual training to be developed and delivered by the irradiator manufacturer. A revised Item No. 8 is attached to this correspondence. Additions and changes are shown in highlighted text.

If you have any questions, please contact me at (651) 737-4452.

Sincerely,

A handwritten signature in black ink that reads "Michael Lewandowski". The signature is written in a cursive style with a large, prominent initial "M".

Michael A. Lewandowski, CHP®
3M Corporate Radiation Safety Officer

Attachment 1: Revised pages

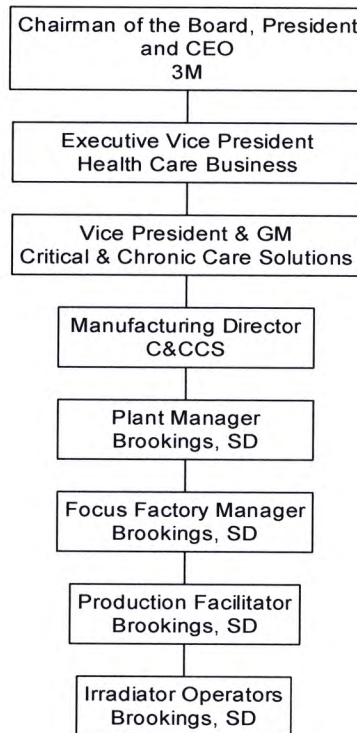
Item No. 7: Individual(s) Responsible for Radiation Safety Program

Radiation Safety Officer (RSO) Training and Experience

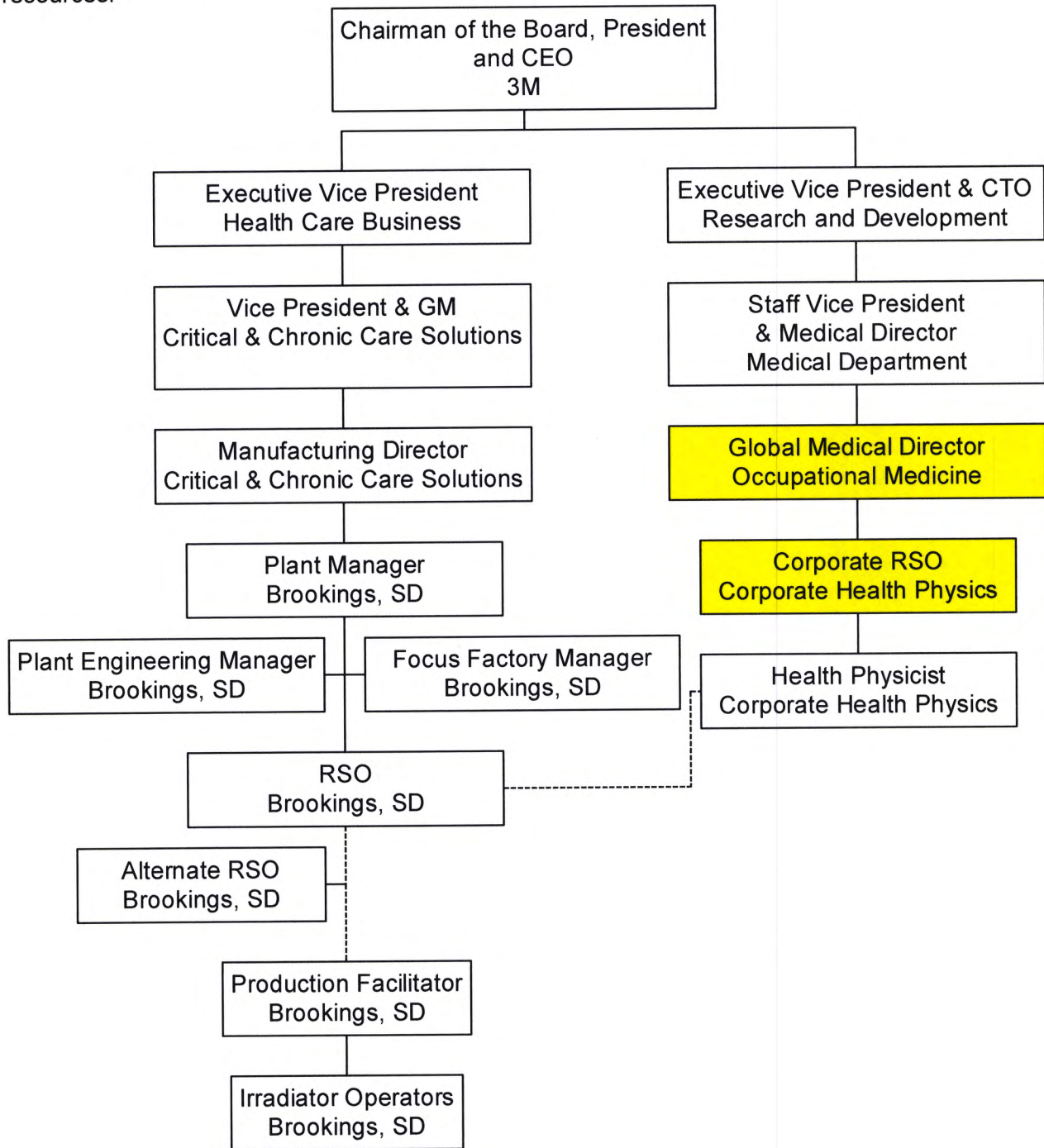
- The Radiation Safety Officer for this license is Kostas Kaounas (tenure starting in 8/31/2001 following USNRC approval). The Alternate Radiation Safety Officer for this license is Lindsay Wollman (tenure starting in 11/28/2011 following USNRC approval).

Responsibilities and Authorities

- The S8 & S10 organizational management structures are separated into two components; management of the operation of the irradiators and management of the radiation safety program. The following organizational chart summarizes the reporting structure for irradiator operations.



The radiation safety program management is illustrated by the following organizational chart which includes participation by 3M corporate radiation safety resources as well as plant resources.



- **RSO:** responsible for day-to-day implementation of the radiation safety program including:
 - implementation and maintenance of the radiation safety program
 - verifying the adequacy of radiation safety training provided to personnel

- advising the Plant Manager, Focus Factory Manager, and CHP of any deficiencies or necessary changes to the radiation safety program
- maintaining records required by 10 CFR 36.81
- **Alternate RSO:** assumes responsibilities of the RSO in the absence of the RSO
- The VP & General Manager has the responsibility for compliance with NRC rules and requirements. Authority to achieve compliance through administration of the radiation safety program is delegated to the Brookings Plant Manager. The roles of personnel involved in this process are clarified below.
 - **Plant Manager:** responsible for overall safety of the irradiators
 - **Plant Engineering Manager:** assumes responsibilities of the Plant Manager relative to safety of the irradiators in the absence of the Plant Manager
 - **Focus Factory Manager:** provides management oversight for irradiator operations
 - **Production Facilitator:** assist the Irradiator Operators in complying with the radiation safety program through:
 - training personnel in the operation of the irradiator
 - notifying the RSO of any radiation safety related or regulatory compliance issues
 - In addition, the Production Facilitator must adhere to the radiation safety program and is directly accountable for Irradiator Operator actions relative to regulatory compliance.
 - **Irradiator Operators:** responsible for complying with the requirements of the radiation safety program and notifying the Production Facilitator and the RSO if any radiation safety related problem or regulatory compliance issue is identified.

Corporate Health Physics is the section of the 3M Medical Department with responsibility related to the management of the 3M corporate radiation safety program. These responsibilities were established by the 3M Corporate Management Committee in 1959 and include:

- establishing and auditing a radiation safety program wherever ionizing radiation sources are used with 3M
- serving as a central coordination group for 3M's licensing and registration activities for these radiation sources

Overall responsibility for oversight of the corporate radiation safety program, including responsibility for oversight of the radiation safety program for the S-8 & S-10 irradiators, has been delegated to the Corporate Radiation Safety Officer. Specific responsibilities related to the irradiators include:

- process and maintain the NRC material license
- notify the state of South Dakota of changes in the radioactive material inventory in the irradiators
- develop and maintain detailed radiation safety procedures
- develop and maintain a radiation safety record keeping system
- develop personnel radiation safety training
- establish a formal CHP quarterly audit program to assure that the irradiators are operated in accordance with the established radiation safety program and applicable provisions of Title 10 of the Code of Federal Regulations
- report audit results and any necessary recommendations to appropriate management representatives
- assist the Brookings RSO in fulfilling his responsibilities as needed

Stop Work Authority

The RSO, Production Facilitator, and Irradiator Operators have the authority to stop work at the irradiators during any situation when conditions deteriorate such that it is likely that someone may become exposed to harmful levels of ionizing radiation or in situations that may lead to violations of federal regulations. Any individual who terminates work under these conditions is responsible for notifying the Production Facilitator, RSO, Focus Factory Manager, and Plant Manager immediately. Members of the Brookings plant management team retain the authority to stop work in any part of the facility in accordance with established plant policies and procedures.

Item No. 8: Individuals Working In Or Frequenting Restricted Areas**Initial Training for Irradiator Operators**

- Before using licensed material, irradiator operators have successfully completed one of the training courses described in Criteria in the section entitled "Initial Training and Experience for Irradiator Operators" in NUREG-1556, Vol. 6, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR 36 Irradiator Licenses,' dated January 1999.

This training includes classroom instruction and hands-on training under the supervision of an individual who meets the requirements for unsupervised operation under 10 CFR 36.51(a). The classroom instruction lasts approximately 40 hours although some of that time (up to 50%) may be self-study from written materials. The topics covered in classroom instruction include:

Radiation Safety

- external radiation and radioactive contamination
- internal and external radiation exposure
- biological effects of radiation
- units of radiation dose
- types and relative hazards of radioactive material possessed
- ALARA concept
- use of time, distance, and shielding to minimize exposure
- proper use of survey meters and dosimeters

Regulatory Requirements

- applicable regulations
- NRC dose limits
- license conditions, amendments, and renewals
- locations of use and storage of radioactive materials
- material control and accountability
- annual audit of radiation safety program
- transfer and disposal
- record keeping
- case histories of accidents or problems involving irradiators
- handling incidents
- recognizing and ensuring that radiation warning signs are visible and legible
- licensing and inspection by regulatory agencies
- need for complete and accurate information
- employee protection
- deliberate misconduct

Theory and Operation of Irradiators

- basic function of the irradiators
- radiation safety features of the irradiators
- operating and emergency procedures
- routine and non-routine maintenance
- lock-out procedures
- how an irradiator is designed to prevent contamination

A written test covering the material presented must be passed at a 70% rate in order to qualify each operator. The pass rate for regulatory requirements is established at 100%. Reviews of correct answers to missed questions are conducted immediately following the scoring of the test.

On-the-job training is done under the supervision of a qualified irradiator operator, consisting of supervised hands-on experience performing:

- Operating procedures which the individual is responsible for performing
- Test runs of emergency procedures which the individual is responsible for performing
- Routine maintenance (such as PMs – preventative maintenance procedures)
- Lock-out procedures.

Management ensures that potential RSOs and authorized operators are qualified to work independently with irradiators. This is demonstrated by written examination and by direct observations.

Training records are maintained in accordance with 10 CFR 36.81(b).

Annual Training Regarding Safety Reviews for Irradiator Operators

- Part of the annual safety review for each irradiator operator required by 10 CFR 36.51(d) is provided by a member of Corporate Health Physics, the RSO, the Alternate RSO, or a representative of the irradiator manufacturer in a classroom setting and includes the following topics as appropriate:
 - changes in operating and emergency procedures since the last safety review,
 - changes in regulations and license conditions since the last safety review,
 - reports on recent accidents, mistakes, or problems at similar irradiator facilities,
 - relevant results of operator evaluations performed under 10 CFR 36.51(e), and
 - relevant results of the facility's inspection and maintenance checks.

A review of any of the topics included in initial operator training may also be included as part of the annual safety review. A brief written test covering the material presented must be passed at a 70% rate in order to re-qualify each operator. The pass rate for regulatory requirements is established at 100%.

In addition to the classroom part of the safety review, each operator participates in a drill to practice an emergency or abnormal event procedure. Participation is defined in NUREG-1556, Vol. 6, dated January 1999 as performing, watching, or critiquing a drill. This drill is critiqued by the RSO, the Alternate RSO, or the Production Facilitator.

The final part of the annual safety review required by 10 CFR 36.51(e) is an individual evaluation of each operator's performance to assure that regulations, license conditions, and operating and emergency procedures are followed. These evaluations are performed by the RSO, the Alternate RSO, or the Production Facilitator. The results of these evaluations are immediately discussed with the operator including instructions to correct any mistakes made or to improve the operator's performance.

Training for Individuals Who Require Unescorted Access (including Training for Individuals Who Must Be Prepared to Respond to Alarms)

- Personnel who require access to the irradiators, including individuals trained to respond to alarms, are trained and tested on an annual basis in accordance with the requirements of 10 CFR 36.51(f) and (g). Following the guidance provided in NUREG-1556, Vol. 6, dated January 1999, the details of the training program are not contained in this document, rather the program is available for inspection.

Instructor Qualifications

Individuals providing classroom instruction and training to irradiator operators have at least a bachelor's degree in a physical or life science or engineering and advanced training in radiation safety. The classroom training for initial operator training as well as for the annual safety review is developed by Corporate Health Physics or the irradiator manufacturer. The training is delivered by a member of Corporate Health Physics, the RSO, the Alternate RSO, or a representative of the irradiator manufacturer. Training materials and tests developed by Corporate Health Physics are reviewed and approved by the Corporate RSO. Training for auxiliary personnel may be provided by a member of CHP, the RSO, the Alternate RSO, or the Production Facilitator. Individuals who provide instruction and evaluation of the hands-on portion of operator training are trained in accordance with the requirements of 10 CFR 36.51 and have sufficient experience to adequately evaluate the performance of the examinee.

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