Sterigenics.

J-5

MS-16

March 7, 2005

Ms. Judith Joustra
Security and Industrial Branch
Division of Nuclear Materials Safety
U. S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Reference: Renewal Application, Material License Number 29-20900-01
Docket Number 03022307

Dear Ms. Joustra:

In response to your letter of January 18, 2005, the following information addresses your questions.

1. Radiation safety training instructors will meet the specifications as described in NUREG-1556, Volume 6, Appendix G.

2. The source rack dimensions as specified in the renewal application are correct. The source rack was replaced in the summer of 2003 in order to improve the processing capabilities of the irradiator. The dimension of the source rack has little impact on the shielding calculations as previously submitted. With the same maximum activity spread over a slightly larger area, the calculated radiation levels should be lower than originally calculated. To verify, the same shielding calculations as previously submitted were repeated, changing only the dimensions of the source rack. The results show a lower calculated radiation level for all barriers, with the exception of the cell roof, which is marginally higher due to the new source rack being a few inches closer to the ceiling when the irradiator is operating, and the surface of the pool when the rack is in the stored position, again resulting from the source rack being marginally closer to the pool surface. The following table summarizes the comparison of the two sets of shielding calculations.

	mR/h with buildup	
Barrier	Old Rack	New Rack
A / D	0.06723	0.0656
B / C	0.0303	0.0280
E	0.000326	0.000316
F	0.000801	0.000746
Roof	1.046	1.069
Pool	0.001091	0.01526

3. The ventilation specifications as shown in the renewal application are correct. The ventilation system was replaced during the cell upgrades in the summer of 2003. The previous 20-inch duct was replaced with a 24-inch duct and the ventilation fan was replaced with one capable of providing 6,600 cfm ventilation to the cell area. Other than the increased duct size and fan

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capacity, no other changes were made in the ventilation system, i.e., the previous drawings and diagrams are still correct with the exception of the increased system capacity.

4. Area posting at the irradiator meets the requirements of 10 CFR 20.1902. Signs posted at the cell entrance are "Caution – Radioactive Material" and "Grave Danger – Very High Radiation Area."

5. The heat detector is a thermocouple-type detector that responds to elevated temperature in the cell and is tested by applying an external heat source, such as a heat gun, to the detector and noting alarm activation.

   The smoke detector may be either a photoelectric or an ionization detector system, depending on the availability, cost, and operability of the system. Both detectors are in use in different facilities throughout the company. Although the ionization detectors are more commonly in use and are currently installed in Salem, the company desires the flexibility to install either system, where the only difference is the actual type of detector used. The smoke detector is tested by generating an artificial smoke stream and directing it into the detector to test for alarm activation.

6. The reference to Section 13.B.1.1 should have been to section 9.B.1.1.

7. Sources are automatically returned to the shielded position when an electrical power failure lasts at least 10 seconds. As standard operating procedure, a calibrated and operable survey meter is always used upon entry to the cell, including during a power failure.

8. Enclosed is a copy of the standard operating procedure for (1) source loading and unloading operations, (2) repositioning sources within the rack, and (3) source cable replacement. The standard instructions for clearing a stuck source rack are included in the relevant emergency procedure, a copy of which is attached. Note that the specific actions to take in this situation will vary appreciably depending on the nature of the obstruction.

   There are no foreseeable circumstances under which a planned special exposure would occur, since the expected personnel dose from any of the non-routine operations is zero or near zero. Personnel performing non-routine operations will wear appropriate whole body personal dosimeters.

I trust that this will address the question raised in your letter. Should you need further information of clarification, please contact me at the address or phone number on this letterhead.

Sincerely,

Mark A. Smith, CHP
Vice-President, Radiation Services

cc: S. Ferraro

Sterigenics GAMMA Medical Division **Radiation Safety Work Instruction**		PROCEDURE NUMBER MDGA-RS-008 EFFECTIVE DATE 07/30/04 REVISION NUMBER 1 APPROVED BY Dorothy M. Friesen
PAGE 1 OF 3	TITLE: SOURCE LOADING & UNLOADING	APPROVED BY Mark A. Smith

I. SCOPE

This procedure defines the general process for loading or unloading sources into or out
$@ of a Sterigenics gamma irradiator. More detailed information regarding individual actions and the organization of the operations is contained in the Cask Quality Program Instruction Manual.

II. PERFORMED BY

$ A. The facility Radiation Safety Officer (RSO) or any individual designated by the RSO shall be responsible for the overall management of source loading and unloading operations. At least one person per shift, who must remain onsite throughout the shift while any loading or unloading operations are being performed, shall be designated by the RSO to manage all radiation safety aspects of the loading or unloading operations. If the RSO is physically present
@ at all times, this function may be performed by the RSO.

$@ B. Individuals shall be designated by the RSO to perform specific tasks or to work on task-oriented teams (e.g., for activities on the truck, inside the cell, on the roof, etc.) during source loading or unloading.

C. The corporate team of individuals with training and expertise in source loading operations should be called upon as necessary to supplement local personnel or
$@ provide expertise not available at the facility. The Corporate RSO will coordinate involvement of this team.

III. EQUIPMENT REQUIRED

The Quality Instruction Manual from the Cask Quality Program contains specific checklists of equipment that is required for each type of transportation cask that may be used.

IV. INTERNAL REFERENCE

Cask Quality Program Instruction Manual
MDGA-RS-006, *Pool Water Tests*
MDGA-RS-007, *Cell Survey*
MDGA-RS-010, *Source Inventory & Control*
MDGA-RS-014, *Ozone Measurement*

MDGA-RS-017, *Source Manipulation*
PP-MDGA-014, *Radiation Safety Training*
Emergency Operating Procedures Manual
Planning Checklist

V. TRAINING REQUIREMENTS

$@ A. The RSO or individual designated by the RSO for either overall management of the operations or for managing the radiation safety aspects of the operations on a shift (i.e., individuals listed in Section II.A. above) shall have at least the following training:

$

- RSO-level radiation safety training

@

- Training in preparing transportation documents
- Training as required for source loading or unloading team members, as described below

B. Other individuals participating on the source loading or unloading team shall have at least the following training:

- Basic-level radiation safety training
- Procedure-specific training and experience in source loading operations, including source manipulation, transportation cask handling, survey meter operation and reading, and other areas pertinent to the particular individual's involvement in the operations
- Emergency procedure training
- HAZMAT training as defined in the Department of Transportation regulations at 49 CFR 172.704
- Operational briefing for the specific loading or unloading operation as described below.

C. Individuals being trained in source manipulation, loading, or unloading procedures may be allowed to participate in operations without the required procedure-specific experience, provided that their activities are under the direct supervision and in the physical presence of an appropriately trained individual.

VI. PROCEDURE

A. Approximately six to eight weeks prior to a source loading or unloading, or as soon as possible if that length of time is not available, the facility RSO and Facility General/Operations Manager shall coordinate with the Corporate RSO for expected operations and logistics. A planning checklist should be prepared and completed, as appropriate to the scope of operations, to ensure that all aspects of the loading or unloading will be covered, the necessary equipment, supplies, and personnel are available, and all involved individuals are provided with the appropriate level of training.

B. Conduct and document a safety meeting with all personnel involved with the loading prior to starting the loading process. This meeting should include designated hard hat areas, radiation areas, crane safety, designation of the Radiation Protection Officer for the project and each shift, and a review of applicable cask and emergency procedure.

C. Contact regulatory agencies (federal, state, or local government) either as required by the facility Radioactive Materials License or as a courtesy notification.

D. Follow and complete all necessary forms in the applicable Cask Quality Program Instruction. Checklists have been developed to describe the specific process for loading or unloading sources from each type of approved transportation cask. Source manipulation activities shall follow MDGA-RS-017.

E. Prior to shipment of empty or full casks, Corporate Quality Assurance, the Corporate RSO, or an individual designated by one of the above shall approve all shipping paperwork and related transportation documentation.

F. All records concerning the source loading or unloading will be maintained on file at the facility until the facility is decommissioned.

G. Upon completion of source loading or unloading, perform the following as applicable:

1. A cell survey in accordance with MDGA-RS-007, if sources were added to the irradiator racks;

2. Pool water tests in accordance with MDGA-RS-006;

3. Ozone level measurements in accordance with MDGA-RS-014, if the total activity in the source racks is increased; and

4. Source inventory update as specified in MDGA-RS-010.

Sterigenics GAMMA Medical Division	PROCEDURE NUMBER MDGA-RS-017
	EFFECTIVE DATE 07/30/04
Radiation Safety Work Instruction	REVISION NUMBER 1
	APPROVED BY Dorothy M. Friesen
PAGE 1 OF 3 — TITLE: SOURCE MANIPULATION	APPROVED BY Mark A. Shaffer

I. SCOPE

This procedure delineates steps for underwater removal of sealed sources from casks and loading of these sealed sources into modules for placement in source racks. An inverse process is used when sealed sources are downloaded from modules and placed in casks.

II. PERFORMED BY

$@ Facility Radiation Safety Officer (RSO), individual designated by the RSO for this function, or individuals with appropriate training as described in Section IV

III. EQUIPMENT REQUIRED

Source Handling Tools
Module Holder and Modules
Calibrated Survey Meters
Basket for Containing Sources
Underwater Camera and Camera Holder
Underwater Lighting

IV. TRAINING REQUIREMENTS

$@ Individuals directing or supervising source manipulation operations shall have completed the training requirements at the RSO level. Individuals involved in source manipulation operations (i.e., source handlers) shall have completed the training requirements for source loading operations, which includes a radiation safety training course at the Basic level or higher, hazard recognition and evaluation appropriate to the activity (i.e., HAZMAT training as defined in the Department of Transportation and Occupational Safety and Health Administration regulations), and task-specific training in source handling. Individuals may be involved in these operations for training purposes, provided they work only under the direct supervision and in the physical presence of an appropriately trained individual.

V. INTERNAL REFERENCE

MDGA-RS-015. *Source Hoists Lockout*

VI. PROCEDURE

A. Personnel involved with source manipulation must wear a whole body dosimeter, either a TLD badge, film badge, or digital dosimeter.

B. Continuously monitor radiation levels in the work area and above the pool with a calibrated survey instrument, preferably a survey instrument with an audible signal or alarm.

C. All tooling must be fully ventilated, i.e. filled with water, before handling sources, modules, or baskets. Radiation levels at the user's end of the tool must be checked with a calibrated survey meter to ensure ventilation of the tool.

D. Source Manipulation and Handling

The following steps describe the process for loading modules or adding sources to the source racks. If sources are being unloaded from the racks, the same process is involved in reverse (e.g., sources are removed from modules and placed in baskets).

1. Follow the instructions included in MDGA-RS-015, Source Hoists Lockout, prior to source manipulation.

2. Place the module holder, if one is being used, in the storage pool. A loading shelf may be used to reduce the depth at which source manipulation must be done. The shelf if used, must be 10 feet or more below the pool water surface.

3. Using appropriate tooling, unlatch the source rack clamps, if present, to allow removal and replacement of the module holders.

4. Using appropriate tooling, remove the source basket from the cask that is positioned on the bottom of the pool, if applicable. In some instances the source basket may already be removed from the cask and is being stored on the bottom of the pool.

5. Place the basket on the load shelf or on the bottom of the pool where sources can be retrieved easily.

6. With appropriate tooling, retrieve a predetermined module from a source rack or storage area and place in the module holder or on the load shelf. Record the module number, which is located on the front hook area of the module.

7. With appropriate tooling, remove a source from the using the underwater camera or appropriate magnifying optics confirm that source serial number agrees with the vendor's source identification manifest. Place the source into the designated module and if applicable into the defined position in the module. Record the source serial number with the module identification number in which it was placed.

8. Repeat step 7 until the module is loaded to its prescribed number of sources.

9. Using appropriate tooling, place the loaded module into the predetermined location in the source rack. Record the position in the source rack where the module was placed.

10. Repeat steps 6 - 9 until all modules have been loaded into the source racks.

11. Upon completion of the source manipulation close the source rack clamps to lock down the modules, where applicable.

12. Update the facility Source Inventory by entering the location of each module number, the source serial numbers contained in each module and the certified source activity for each source. Print the updated report and place in the facility Source Inventory.

Sterigenics GAMMA Medical Division	PROCEDURE NUMBER MDGA-OPS-034
	EFFECTIVE DATE 07/30/04
Operations Work Instruction	REVISION NUMBER 1
	APPROVED BY Dorothy M. Friman
PAGE 1 OF 5 — TITLE: SOURCE CABLE REPLACEMENT & RACK HEIGHT MEASURE	APPROVED BY [signature]

I. SCOPE

The following provides methods for verification of source rack position and source rack cable replacement.

II. FREQUENCY

$@ Source Cable Replacement - as deemed necessary by the RSO
Source Rack Position - isotope addition or removal or as deemed necessary by Operations Management

III. PERFORMED BY

$@ RSO, maintenance personnel or designee

IV. INTERNAL REFERENCE

MDGA-VAL-008, *Dose Mapping: Initial Product Qualification (Medical)*

V. MATERIAL REQUIREMENTS

- Two each 3/8 inch (3/16 inch for mini-cells), 7 x 19, 304 stainless steel strand core cables, with a stainless steel marine eye end swag fitting on one end. Request test certificate or material specifications from cable supplier. Cables to be of sufficient length to complete installation.
- Four each source rack positioning devices (McMaster Carr # 9545K36 rubber stopper)
- Spare 3/8 (3/16 inch for mini-cells) inch stainless steel thimbles and U-bolt cable clamps.
- Isotope handling pole with hook on the end.

VI. PROCEDURE

Prior to using this procedure for measuring or adjusting source rack height, Mini-Cell facilities must contact Corporate Engineering for any exceptions or additional parts to be employed during the execution of this exercise.

A. Discretionary Source Rack Height Verification and Source Rack Height Verification During Isotope Load or Unload

When verifying source rack height during isotope loading or unloading, steps VI.A.1 - VI.A 4. must be performed, 3 times with the measurements averaged, prior to and after the isotope loading/unloading activity.

1. Enter the radiation cell and place one source rack positioning device on each source guide cable at water level.

2. Set the safety system and raise the source racks to the full up position.

3. Immediately lower the source racks to down position.

4. Enter the radiation cell and measure and record the dimension from ceiling to the bottom of the source rack positioning device at each source guide cable. Compare the measurements to the applicable engineering drawing listed below which specifies source rack height with the center line of the irradiation container. Record the averaged measurements on the applicable engineering drawing. Copies of engineering drawings may be obtained from the Corporate Engineering department upon request.

5. With the isotope handling pole, measure and record the measurement of each side of each rack relative to the top of the water. A minimum ten foot shield is required.

6. The center line of the source plane should be 4" above the center line of the irradiation container within plus or minus 1". The source rack should be level to within 1" over the length of the source rack. For a mini-cell, the vertical centerline of the source plane should be at the vertical centerline of the two level tote box.

7. If it is discovered that the source rack height does not meet the requirements listed in VI.A.4 and VI.A 6., during isotope removal or loading, the racks should be adjusted to the correct height at that time and the requirements for dose mapping be followed as required in MDGA-VAL-008. Adjust the source racks by repositioning the appropriate limit switch. Repeat steps VI.A.1 - VI.A.5 until source rack position meets the specification.

$@ If it is discovered that the source rack height does not meet the requirements listed in VI.A.4 and VI.A.6 during a discretionary verification by Operations Management, then Corporate Operations Management in conjunction with the Facility General Manager, Operations Manager, and Quality Assurance Manager will perform and document an investigation and determine if the racks will be adjusted at that time or will not be adjusted until the next isotope loading or unloading. If the racks are adjusted at that time, then dose mapping requirements specified in MDGA-VAL-008 must be followed.

8. Once the source rack height is set, repeat step 1 through 4, three times to ensure accuracy of the measurement.

B. Cable Removal: Installation and Verification

Due to minor mechanical differences in our source systems, cable replacement instructions have been generalized. Perform any additional steps needed to facilitate safe cable replacement.

1. Verify the rack height prior to removing the source cables, follow section I.A. 1-6, repeating the measurement 3 times to ensure accuracy, average the three measurements, and in addition complete the following:

   a. Go to the cell top and note the approximate number of cable wraps on the source winch drum and/or the amount of cable clamped to the cable trolley.

   b. As a reference point, place tape on the cable near the trolley location (if applicable) or near the cable sheave housing and match the tape location on the hoist cable guide track (if applicable) or sheave housing.

   NOTE: If, while verifying the rack height prior to cable replacement, you find that the rack height no longer meets the specifications referenced in section VI.A.5. and VI.A.6., do not change the rack height to the drawing specification. Stop replacement activities and
$ contact the Facility General Manager, Operations Manager and
@ Quality Assurance Manager. The Facility General/Operations Manager should contact Corporate Engineering to determine if the facility will re-position the rack at that time and commence dose mapping as required in MDGA-VAL-008, or replace the cables at the current rack height and during the next isotope load or unload adjust the cables to the specified position.

2. Cable Removal and Installation

   a. Set the safety system and slack each source cable by powering the source winch motors down or by manually releasing the brakes.

   b. Enter the radiation cell and with the isotope pole remove the source cable hook assembly from each source rack.

   c. Go to cell top and remove the cable from the source winch drum or from the cable trolley. If applicable, remove any cable clamps and

thimbles from cable. Discard any damaged hardware.

d. Return to the radiation cell while having a helper hold the cable. Lower the cable through cell roof penetration.

e. Remove the cable hook assembly from the old cable swag fitting and set aside for reuse.

f. Stretch the new and old cable out on the floor to verify length of the new cable, as measured from the hook end. Place tape on the new cable at the same location of tape on the old cable.

g. Attach the cable hook assembly to new cable swag fitting.

h. Return to the cell top and have your helper push the cable from inside the cell to the cell top. NOTE: It may be necessary to temporarily move the lead shield on the roof penetration. Feed the cable through the lead shield, over the cable sheave, and under the positioning collar.

i. Pull the approximate amount of cable needed through the roof penetration to make a connection at the source winch drum or cable trolley.

j. Attach cable to source winch drum or cable trolley.

k. Return to the radiation cell and attach the cable hook assembly to source rack.

l. Repeat steps VI.B.2.d through VI.B.2.k for the remaining source rack.

m. Set the safety system and wrap each source cable around the drum by powering the source winch motors up with the source override controls.

n. Use the source override controls to bring the rack up to the down position switch. Use the tape on the cable to approximate the previous position or use the cable wraps on the source winch drum to match the previous cable wraps.

o. If applicable, attach the cable trolley to the source cable.

3. Post Source Cable Replacement Height Measurement Verification

After the source cables have been successfully replaced as specified in VI.B., the source rack height must again be verified. Repeat the steps defined in section VI.A.1. -VI.A.6, and verify that the source rack height is the same as it was prior to the cable replacement, +/- 1" to the averaged measurement. If the source rack height cannot be adjusted to within +/- 1" to the averaged rack height prior to the cable replacement, then dose mapping must commence as required in MDGA-VAL-008.

Sterigenics Emergency Operating Procedure		PROCEDURE NUMBER EOP-003 EFFECTIVE DATE 11/30/04 REVISION NUMBER 5 APPROVED BY K A Hoffman
PAGE 1 OF 3	TITLE: **STUCK SOURCE RACK**	APPROVED BY

I. SCOPE

A control or mechanical malfunction could result in a source rack becoming lodged in a partially or fully unshielded position. The probability of such an event is very low. This procedure outlines steps to take if such an event occurs.

II. HAZARD

Personnel overexposure to radiation
Overheating of product, potentially leading to fire in cell

III. PERFORMED BY

Initial Response: Shift Leader or System Operator
$ Advanced Response: Maintenance Manager and Radiation Safety Officer (RSO) or
@ Alternate RSO

IV. EQUIPMENT REQUIREMENTS

Ratchet Puller
Cable Cutter
Jam Hole Tooling

V. PROCEDURE

A. Determine Cause of Stuck Source - Initial Response

1. Examine PLC Monitor and printout for cause of stuck source rack.
$ 2. Notify the RSO, or designated alternate, who will notify the Corporate
@ RSO and ensure required notifications to regulatory agencies are made.
3. DO NOT ENTER CELL.
4. Inspect the source rack position visually while remaining outside the cell.
   a. Go to the cell roof, or, if available, view the roof via remote camera monitor.
   b. Check the location of the guide cable trolley.
5. Determine the nature of the mechanical problem, if any.
6. If there is no mechanical problem, skip ahead to section C.

B. Un-jam source rack according to the nature of the problem. This procedure is to
$@ be conducted only under authorization of the RSO - Advanced Response

1. Problem with Drive Cable in Roof Penetration
   a. Remove the lead rings that surround the drive cable on the cell roof.
      NOTE: Constraints on cable motion are most severe at this location.
   b. Monitor continuously the radiation levels around the cable penetration.
   c. Clear the cable jam.
   d. Release the motor brake to lower source rack manually.

2. Problem with Source Rack Guide Cables:
   a. Unbolt the guide cables on the cell roof to release tension.
   b. Release the motor brake to lower source rack manually.

3. Problem with Source Rack Hung Up on Source Cage, Carrier, or Product:
   a. Attach the ratchet puller to the drive cable trolley on top of the cell.
   b. Use the ratchet puller to raise the source rack.
   c. Remove jam-hole plugs on cell roof.
   d. Monitor continuously the radiation levels around the open jam hole.
   e. Insert long poles into hole to dislodge the item(s) interfering with source rack.
   f. Release the jam.
   g. Use the ratchet puller to lower the source rack manually.

4. Problem with Drive Cable on Cell Roof, between cable drive winch and cable trolley:
   a. Attach the ratchet puller to the cable trolley.
   b. Raise the source rack sufficiently to take the strain off the cable.
   c. Un-jam the cable.
   d. Use ratchet puller to lower source rack manually.

5. Problem with Drive Cable on Cell Roof, other than above:
   NOTE: This procedure is a last resort and must be authorized by the
$@ Corporate RSO.
   a. Clamp the cable drive between the guide cable trolley and source rack.
   b. Cut the cable between the winch and guide cable trolley using the cable cutter.
   c. Unclamp the cable.
   d. Use the ratchet puller to lower the source rack manually.
   e. Repeat steps a-d as necessary to lower rack to its fully shielded position.

C. Lower the source rack manually to its fully shielded position. This procedure is

$@ to be conducted only under authorization of the RSO - Advanced Response

1. Release the motor brake, or
2. Use ratchet puller as instructed in section B above.

D. Repair and retest system. This procedure is to be conducted only under
$@ authorization of the RSO - Advanced Response

1. Repair control or mechanical problems.
2. Replace cables if necessary.
3. Inspect source cables, guide cables, source racks.
4. Clear obstructions within the cell.
5. Perform safety system check.
6. Document the problem in the downtime log.
7. Investigate the cause of the stuck source rack.
8. Document all pertinent information regarding the incident.