

RSO Refresher

Course Objective:

- This session will provide a refresher of RSO requirements and responsibilities under both regulatory and accrediting bodies. It will span radiation oncology, nuclear medicine and radiology as well as the expanding charges of the Radiation Safety Committee.
- In most hospitals the RSO is a physician authorized user who relies heavily on the consultant medical physicist to supply guidance and analytic assessment to ensure regulatory compliance. Often the Medical Physicist may be asked to address radiation safety issues outside their normal scope of practice.
- This session will attempt to provide a broad overview of the typical RSO responsibilities and Radiation Safety Program content applied to clinical environments. The evolving and expanding practice issues for the consulting Medical Physicist will also be addressed.

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RSO Refresher

Course Objective:

- provide a broad overview of RSO responsibilities,
- identify the Regulatory requirements applicable to a medical radiation protection program,
- discuss the expanding scope of the Radiation Safety Committees responsibilities under both regulatory and accrediting organization.
- and address the expanding radiation safety responsibly for the consulting medical physicist.

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RADIATION PROTECTION IN A CLINICAL SETTING: REGULATIONS AND RECOMMENDATIONS

- Radiation Protection in a Medical Institution:
 - The Radiation Safety Officer-RSO
 - The Radiation Safety Committee
 - Radiation Protection an ALARA
 - Standards for Protection Against Ionizing Radiation
 - State and Federal Regulatory Requirements
 - The Facility Radiation Safety Program
- Licensing a Medical Facility for Use of Radioactive Materials
 - State and Federal Guidelines
- Equipment, Instrumentation, and Radiation Safety
 - Radionuclides and Radiopharmaceuticals
 - Sealed Source therapies / Unsealed Source Therapies
 - Instrumentation and Equipment
 - QC and Calibrations
 - Waste Management
- Patient Dosimetry in Diagnostic Imaging-
 - Radiology and Molecular Imaging
- National Source Tracking
- Medical Events and the Medical Physicist
- Structural Shielding
- Medical/Radiological Emergency Response Plan
- Radiation Control Program Inspections
 - State and Federal Regulatory Agencies
- Radiation Exposure Risk Evaluations



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§ 20.1101 Radiation Protection Programs.

- (a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See § 20.2102 for recordkeeping requirements relating to these programs.)
- (b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).
- (c) The licensee shall periodically (**at least annually**) review the radiation protection program content and implementation.

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RSO Appointment

- A licensee's management shall appoint a Radiation Safety Officer, **who agrees, in writing**, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

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RSO Authority

A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to-

- (1) Identify radiation safety problems;
- (2) Initiate, recommend, or provide corrective actions;
- (3) Stop unsafe operations; and,
- (4) Verify implementation of corrective actions.

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A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing

- Activities involving licensed material that the RSO considers unsafe are stopped;
- Ensure radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate (s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;

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A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing

- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals and records of the results of such monitoring are maintained;
- Licensed material is properly secured;

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A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing

- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to NRC, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the radiation protection program are performed at least annually and documented;

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A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing

- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

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Radiation Safety Committee (RSC)

§ 35.24 Authority and responsibilities for the radiation protection program.

- Licensees that are authorized for two or more different types of uses of byproduct material shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

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RSC Agenda

- Review of minutes from previous meeting (correction, additions or deletions).
- Unfinished Business (open items from previous meetings)
- Standing Reports - Quarterly
 - ALARA Review of Dosimetry Reports - Last Quarter (RSO)
 - ALARA Review of Bioassay Measurements - Last Quarter (RSO)
 - Review of Incidents Since Last Meeting (RSO)
 - Medical Events (RSO or Technologist)
 - Spills or Accidental Exposures (RSO or Technologist)
- Quarterly Review of Quality Assurance (RSO or Medical Physicist)
 - Nuclear Medicine
 - Diagnostic Radiology
 - Mammography Reproducibility & Linearity
 - Radiation Oncology
 - CT Dose Tracking
 - Fluoro Dose Tracking
 - Major Repair Tracking
- Review of NRC Notices, Circulars and Regulatory Guides (RSO or Medical Physicist)
- Review of Authorized Users (NRC or State notification required within 30 days)

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RSC Agenda

- Standing Reports - Semi-Annual
 - ALARA Semi-Annual Review of Contamination & Exposure Levels (RSO)
 - Semi-Annual Review of Radiation Safety Program (Medical Physicist)
- Standing Reports - Annual
 - Annual/Programmatic Review of The Program (RSO)
 - Annual Review of Written Directives
 - Annual Review of Part 21 Program
 - Annual Review of Emergency Response
 - Annual Review of Lead Apron Testing and Tracking
 - Annual Review of Training Program (General & Department Specific)
- New Business
- Next Scheduled Meeting

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Nuclear Medicine Requirements

- Patient Dose Records §35.63
- Decay in Storage - §35.92
- Sealed Source Inventory
- Sealed Source Leak Test
- Dose Calibrator Geometry
- Dose Calibrator Constancy
- Dose Calibrator Linearity
- Dose Calibrator Accuracy
- Receipt

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Patient Dose Records §35.63 (3 year retention)

1. Name or abbreviation of the radiopharmaceutical
2. Lot number and expiration date
3. Radionuclide
4. Patient name and ID number, if any
5. Prescribed dosage
6. Activity of dose at time of measurement (or notation that activity is less than 10 uCi)
7. Date and time of measurement
8. Initials of individual making record

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Decay in Storage - §35.92 (3 year retention)

1. Date of disposal
2. Date the material was placed in storage
3. Radionuclide disposed
4. Survey meter used
5. Background level
6. Exposure rate from material
7. Name of individual who performed disposal

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Sealed Source Inventory (5 year retention)

1. Model number and serial number
2. Radionuclide
3. Nominal activity
4. Location of source
5. Quarterly or semi-annual.

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Sealed Source Leak Test (5 year retention)



1. Model number and serial number, if any
2. Radionuclide
3. Estimated activity of source
4. Measured activity of test sample in uCi
5. Description of method used to measure the sample

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Sealed Source Leak Test MDA



- $MDA = 2.72/t_{gross} + 3.30[R_{bkg}/t_{bkg} [1 + t_{bkg}/t_{gross}]]^{1/2}$
- $Rs < Lc$ reported as $Rs + 1.65[R_{gross}/t_{gross} + R_{bkg}/t_{bkg}]^{1/2}$
- $Rs > Lc$ reported as $Rs + 1.96[R_{gross}/t_{gross} + R_{bkg}/t_{bkg}]^{1/2}$
- where $Lc = 1.65[cts_{bkg}/t_{bkg}^2 [1 + t_{bkg}/t_{gross}]]^{1/2}$

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Dose Calibrator Geometry ANSI (retained as long as the dose calibrator is in use)



1. Model and serial number
2. Configuration of source
3. Activity measured for each volume
4. Date of test
5. Initials of individual performing check

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Dose Calibrator Constancy ANSI (3 year retention)



1. Model and serial number
 2. Radionuclide of check source
 3. Date of check
 4. Activity measured
 5. Initials of individual performing check
 6. Primary source must be at least 50 uCi
- Note: record of signatures and initials.*

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Dose Calibrator Linearity ANSI (3 year retention)



1. Model and serial number of DCAL
2. Calculated values
3. Measured values
4. Date of test
5. Largest dose to 30 uCi.
6. Initials of individual performing check

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Dose Calibrator Accuracy ANSI (3 year retention)



1. Model and serial number of dose calibrator
2. Model and serial number of each source
3. Radionuclide and activity of each source
4. Date of test
5. Results of test
6. Initials of individual performing check

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Repair or Relocation of DCAL

- If DCAL is repaired or relocated perform:
 - Geometry
 - Linearity
 - Accuracy
- This will also apply to any loaner DCAL obtained during repair.
- Type H - DOT Shipping Requirements.

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Receipt (NUREG-1556)

(3 years from transfers or disposal)

1. Name of organization shipping material
2. Radionuclides received and activity
3. Results of monitoring done and instrument used (background level)
4. Initials of individual performing monitoring

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Pet/CT Requirements

- Same as nuclear medicine for Dose Calibrator, etc.
- If mobile survey prior to moving may be required by DOT.
- While the tech's may be shielded from patient and CT the outside of the truck may not be especially above 7'.

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Routine Surveys

- Package Receipt – contamination
- Daily Survey End of Use – exposure
- Weekly Exposure
- Weekly Contamination
- DOT Return LQ Shipments
- Decay-in-Storage
- Patient Monitoring/Room Survey

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MDA / Instrument MDL

- $MDA = 2.72/t_{gross} + 3.30[R_{bkg}/t_{bkg} [1 + t_{bkg}/t_{gross}]]^{1/2}$
- $Rs < Lc$ reported as $Rs + 1.65[R_{gross}/t_{gross} + R_{bkg}/t_{bkg}]^{1/2}$
- $Rs > Lc$ reported as $Rs + 1.96[R_{gross}/t_{gross} + R_{bkg}/t_{bkg}]^{1/2}$
- where $Lc = 1.65[cts_{bkg}/t_{bkg}^2 [1 + t_{bkg}/t_{gross}]]^{1/2}$

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QA Testing NaI Well

- Accuracy
- Constancy
- Resolution (FWHM)
- Linearity (Eu-153)
- Chi-Square
- MDA

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Nuclear Medicine Therapy

- **Strontium (⁸⁹Sr)** bone metastase.
- **Iodine (¹³¹I)** with hyperthyroidism and thyroid cancer
- **Yttrium (⁹⁰Y) Zevalin** refractory Lymphoma.
- **Phosphorus (³²P)** overproduction of red blood cells
- **Samarium (¹⁵³Sm)** bone metastases
- **Radium (²²³Ra)** Xofigo bone metastases

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Instruction for Care of Patients Receiving I-131 §35.75 (3 years retention)

1. List of individuals receiving instructions
2. Description of instructions
3. Date of instruction
4. Name of individual who gave instruction

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Room Survey at I-131 Administration §35.315 (3 years retention)

1. Time and date of survey
2. A plan of area or list of points measured
3. Measured dose rates in mR/hr (< 2 mrem/hr unrestricted areas)
4. Instrument used for survey
5. Name of individual who made survey

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Records of the release of individuals §35.2075 (retain for 3 years)

- (a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 35.75, if the total effective dose equivalent is calculated by--
- (1) Using the retained activity rather than the activity administered;
 - (2) Using an occupancy factor less than 0.25 at 1 meter;
 - (3) Using the biological or effective half-life; or
 - (4) Considering the shielding by tissue.
- (b) A licensee shall retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

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Room Clearance Survey I-131 §35.315 (3 years retention)

1. Time and date of survey
2. A plan of area or list of points measured
3. Measured removable contamination levels (<200 dpm/100 cm²)
4. Instrument used for survey
5. Name of individual who made survey

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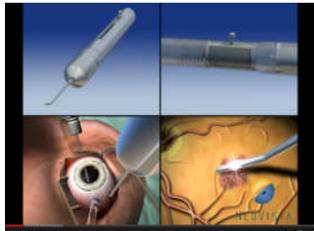
Personnel Monitoring TJC & State or NRC

- Timeliness of returned badges
- On averaging missed badges.
- The Meter Report or exposure at other employers.
- Declared pregnant workers.
 - Second badge
 - Exposure prior to badging

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NeoVista EpiRad 90TM Ophthalmic System

The Epi-Rad90 Ophthalmic System™. An epiretinal radiation delivery device developed to treat wet ARMD.



10CFR35.1000
<http://pbadupws.nrc.gov/docs/ML0911/ML091140370.pdf>

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Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions

Radioactive seeds previously approved for the treatment of cancerous tumors, typically, iodine-125 and palladium-103 seeds between 200 – 300 µCi/seed are implanted into a breast lesion using a standard 18-gauge needle. These seeds are normally implanted within mammography or ultrasound suites and removed within surgical suites between 2 and 5 days post implantation

- Licensing Guidance
- General Instructions
- Safety Precautions and Instructions for Iodine-125 and Palladium-103 Seed Localization for Non-Palpable Lesions
- Suggested Revisions to Existing Iodine-125 and Palladium-103 Seed Localization Programs to Conform to this Licensing Guidance
- Procedures
- Records
- Reports
- Enforcement



<http://www.nrc.gov/materials/miau/med-use-toolkit/seed-localization.html>

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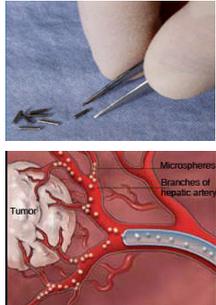
Brachytherapy Requirements

Low Dose Brachytherapy

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0400.html>

Intravascular Microsphere Therapy

<http://pbadupws.nrc.gov/docs/ML1217/ML12179A353.pdf>



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Brachytherapy Requirements

Manual Low Dose Brachytherapy

- RAM License Content
- The Authorized User
- The Authorized Medical Physicist
- Written Directives
- Medical Events
- Source Calibration
- Required Device QC
- Emergency Response Equipment
- Procedures
- Records
- Reports
- Enforcement



<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0400.html>

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Manual Low Dose Brachytherapy



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Intravascular Microsphere Therapy

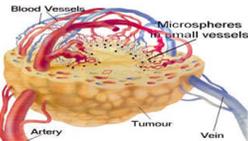
- RAM License Content
- The Authorized User
- The Authorized Medical Physicist
- Written Directives
- Source Calibration
- Inventory
- Patient Release
- Medical Events
- Source Calibration
- Emergency Response Equipment
- Procedures
- Records
- Reports
- Enforcement



<http://pbadupws.nrc.gov/docs/ML1217/ML12179A353.pdf>

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Intravascular Microsphere Therapy

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HDR Requirements

Medical Use Licensing of Byproduct Material: 10CFR35.600

- RAM License Content
- The Authorized User
- The Authorized Medical Physicist
- Written Directives
- Medical Events
- Source Calibration
- Required Device QC
- Emergency Response Equipment
- Procedures
- Records
- Reports
- Enforcement




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Specific Regulatory Requirements: HDR 10CFR35.643

- Pre-treatment spot checks
- Time and date of survey
- Electrical interlocks
- Source exposure indicator lights
- Radiation monitors used to indicate the source position
- Viewing and intercom systems
- Timer constancy
- Clock (date and time) in the unit's computer
- Simulated cycle of treatment

HDR Full Calibration:

- Output measured within +5% of expected
- Source positioning accuracy within +1 millimeter
- Source retraction with backup battery upon power failure
- Electrically assisted treatment room doors with power turned off
- Source guide tubes
- Timer accuracy and linearity over the range of use
- Length of the connectors
- Annual check of source guide tube and connector function



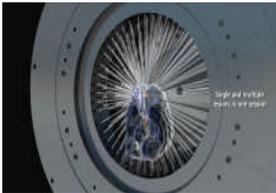
<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0600.html>

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Gamma Knife Requirements

~200 60Co sources (6000 Ci total initial activity)
Sources positioned and collimated to focus precisely at isocenter

- RAM License Content
- The Authorized User
- The Authorized Medical Physicist
- Written Directives
- Medical Events
- Source Calibration
- Required Device QC
- Emergency Response Equipment
- Procedures
- Records
- Reports
- Enforcement



<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/full-text.html#part035-0600>

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Gamma Knife Requirements 10CFR35.645

Periodic spot-checks for gamma stereotactic Radiosurgery Units.

(a) A licensee authorized to use a gamma stereotactic Radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic Radiosurgery facility and on each unit—Monthly, Before the first use of the unit on a given day; and after each source installation.

(b) Each licensee is required to:

- Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.
- Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.
- Perform spot-checks to include verification to assure proper operation of—
 - Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 - Helmet micro-switches; and
 - Emergency timing circuits; and
 - Stereotactic frames and localizing devices (Trunnions).

(c) Determine:

- The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b). The difference between the measurement made and the anticipated output, expressed as a percentage of the anticipated output.

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Gamma Knife Requirements

(c)-continued- Determine:

- Source output as compared with the computer calculation;
- Timer accuracy and linearity over the range of use;
- On-off error and Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of—

- Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
- Source exposure indicator lights on the unit, on the control console, and in the facility;
- Viewing and intercom systems;
- Timer termination;
- Radiation monitors used to indicate room exposures; and
- Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in paragraph (c) that is not operating properly as soon as possible.

(f) If the results of the checks required in paragraph (d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645

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Leksell Gamma Knife® Perfexion™

10 CFR 35.1000 use

Although the Leksell Gamma Knife® Perfexion™ is a gamma stereotactic radiosurgery unit, it includes a number of engineering changes that make its components and operation significantly different from the gamma stereotactic radiosurgery units currently regulated in 10 CFR Part 35, Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units." As a result, the Perfexion™ is regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation From Byproduct Material."

1. Protective housing
2. Beam channels
3. Leksell coordinate frame
4. Brain target/isocenter
5. Patient positioning system
6. Radiation sources

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Adaptive Cobalt Therapy

The ViewRay™ system integrates full-time MR imaging, radiation therapy delivery, and software automation. Clinicians can see soft tissue, visualize and adjust dose, and gate therapy in real time; on live anatomy, without invasive markers or procedures, and without exposing the patient to the additional ionizing radiation.

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Adaptive Cobalt Therapy

ViewRay™ System for Radiation Therapy

Licensing Guidance: <http://fpbadupws.nrc.gov/docs/ML1317/ML13179A287.pdf>

- 10 CFR 35.1000 Use
- Licensing Guidance
- Sensitive Security Related Information-Increased Control Program
- Radionuclides, Form, Possession Limits, and Purpose of Use
- Facility Address and Description
- Posting Requirements
- Authorized Individuals
- Written Directive
- Specific Information on Radiation Safety Precautions and Instructions
- Published Protocols Accepted by Nationally Recognized Bodies
- Full Inspection and Service of the ViewRay™ Unit
- Procedures Required By 10 CFR 35.610, 35.642 and 35.645

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RSO Role in Emergency Planning: Radiological Events

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RSO Role in Emergency Planning: Radiological Events

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Emergency Planning: Resources

Radiation Emergency Assistance Center/Training Site (REAC/TS)
<http://www.orau.org/radiation-emergency-medicine/default.aspx>

Radiation Emergency Medical Management:
<http://www.remm.nlm.gov/toolsguidelines.htm>

IAEA Organization
<http://www-ns.iaea.org/tech-areas/emergency/preparedness.asp?l=1>

IAEA Joint Radiation Emergency Management Plan
<http://www-pub.iaea.org/MTCD/publications/PDF/jplan2004.pdf>

Health Physics Society: Medical Response Work Group
<http://hps.org/homeland/responsem.html>

Centers for Disease Control and Prevention
<http://emergency.cdc.gov/radiation/>

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RSO Resources

- NRC Regulations Title 10, Code of Federal Regulations: <http://www.nrc.gov/reading-rm/doc-collections/cfr/>
- Medical Uses Licensee Toolkit: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>
 - Includes Guidance for:
 - Regulations and Medical Policy Statement
 - Program Guidance
 - Inspection procedures
 - Licensing Guidance for 10 CFR 35.1000 sealed sources and devices
- Consolidated materials guidance is published in "Consolidated Guidance About Materials Licenses: (NUREG 1556) Program-Specific Guidance About Medical Use Licenses:
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>
- Frequently Asked Questions About Licensing Medical Uses of Byproduct Material Under Revised 10 CFR Part 35
<http://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html>

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Thank You

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