



NRC INSPECTION PROCEDURE 87132 TRAINING

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Outline

- Background
- Overview – IP 87132 “Brachytherapy Programs”
- Changes to IP 87132
- Updated Appendix B: “Reviewing Licensee’s Implementation of Procedures for Permanent Brachytherapy Administrations”
- New Appendix C: “Use of Interim Enforcement Policy for Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)”
- Questions and Answers

Background

- NRC Inspection Manual Chapter 2800:
 - establishes the general policy for the Materials Inspection Program
 - describes a performance-based approach for inspecting
- IPs provide guidance for different program types. IP 87132 is for Brachytherapy Programs.
- IP 87132 training was previously conducted in 2012 following the last revision.
- New IP 87132 revision to reflect NRC Interim Enforcement Policy.

Background

- Medical regulations in 10 CFR 35 were revised in its entirety in 2002 (67 FR 20250).
- In 2008, a proposed rule was published amending Part 35 sections involving reporting and notification of MEs, as well as to clarify requirements for permanent implant brachytherapy. The ME criteria for permanent implant brachytherapy was changed from a dose-based to an activity-based criteria.
- Due to a large number of MEs reported in 2008, the staff re-evaluated the proposed rule.



Background

- In August of 2010, following rejection of the revised (re-proposed) rule, the Commission directed staff to work with ACMUI, broader stakeholders and medical community, and conduct public workshops to develop ME definitions for permanent implant brachytherapy. The staff also requested the ACMUI prepare a report on this subject.
- Based on ACMUI's recommendations and the knowledge gained at the workshops, staff developed the revised criteria for ME definitions in SECY-12-0053.

Background: SRM-SECY-12-0053

- Commission directed the staff to pursue rulemaking to modify the requirements in 10 CFR 35.3045 for medical event reporting to establish separate ME criteria for permanent implant brachytherapy in terms of total source strength administered (activity-based) rather than the dose delivered (dose-based).
- This would eliminate dose-based medical event reporting for the treatment site.
- Commission also directed the staff to develop an Interim Enforcement Policy (IEP) to allow for effective and objective criteria for medical event reporting for permanent implant brachytherapy until the rulemaking is finalized.

Background: Interim Enforcement Policy

- Bridges the gap to an activity-based (total source strength and exposure time) rule for the treatment site.
- Allows for use of enforcement discretion in medical event reporting violations under the current regulations in 10 CFR 35.3045 for treatments involving permanent implant brachytherapy.
- IEP was published in the Federal Register, then added to the NRC Enforcement Policy. Applies to NRC licensees. Agreement States may choose to use the same approach.
- IEP will remain in place until the implementation date of a final rule associated with the medical event reporting requirements.

Background

Interim Enforcement Policy

Total Source Strength & Exposure Time
 (TSS/ET) to determine ME to Tx site

Absorbed Dose to determine
 ME to Tx site

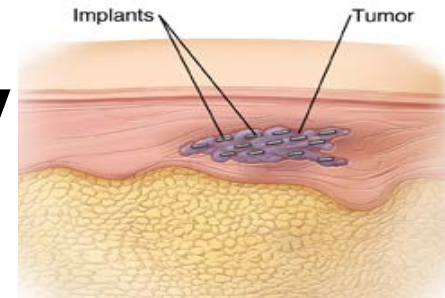
**Use Discretion for licensee using
 TSS/ET if:**

**Use discretion if Dose to Tx site is \geq
 120% of prescribed dose, if:**

1. Documented procedures specify TSS/ET as regulatory evaluation values for Tx site dose comparisons,
 [AND]
2. Licensee entered both the prescribed dose & delivered dose into the WD as TSS/ET,
 [AND]
3. Timely ME report based on TSS/ET Tx site dose comparison, if applicable

1. Licensee used absorbed dose for Tx site dose comparisons
 [AND]
2. Total dose for Tx site is expressed in WD as absorbed dose
 [AND]
3. Doses to normal tissues & structures did not exceed limits in 35.3045(a)(3)

IP 87132 “Brachytherapy Programs” Overview



- Provides inspection guidance and is applicable to all forms of brachytherapy (temporary and permanent implants, remote afterloaders, eye applicators and plaques, etc).
- Provides important inspection focus areas (performance expectations) to be used in evaluation of licensee performance in relation to permanent implant brachytherapy.
- Provides Appendices:
 - Appendix B discusses inspection actions for general assessment of the licensee's programs (discussions, review of records and procedures, observation of licensed activities).
 - Appendix C discusses case examples clarifying use of the IEP.

Changes to IP 87132

- Section 03.02(h), “Medical Events” updated
- Appendix B updated, “Reviewing Licensees’ Implementation of Procedures for Permanent Implant Brachytherapy Administrations”
- Appendix C updated with new focus and name, “Use of Interim Enforcement Policy for Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)”

Section 03.02(f), “Written Directives”

- No substantive changes to this section of IP 87132.
- Retains reference to Appendix B – “Reviewing Licensees’ Implementation of Procedures for Permanent Implant Brachytherapy Administrations.
- Appendix B was reorganized and will be reviewed later in this presentation.

WRITTEN DIRECTIVE			
Name: _____		SS#: _____	
DOB: _____		Diagnosis: _____	
PATIENT IDENTIFICATION			
PT. Name Announced _____		Spelling of Name _____	
Birth Date _____		SS# _____	
Wrist Band _____		Other _____	
PREGNANCY / BREAST FEEDING STATUS			
Negative pregnancy confirmed by: _____ PG Test _____ LMP _____ N/A			
Breast Feeding: _____ Yes _____ No _____ N/A			
DESIRED PROCEDURE			
_____ ⁸⁹ Sr Therapy for palliation of osseous mets. pain			
_____ ¹⁵³ Sm Therapy for palliation of osseous mets. pain			
_____ ³² P (Sodium) Therapy for polycythemia vera			
_____ ¹³¹ Iodine Whole Body Scan			
_____ ¹³¹ Iodine Substernal Thyroid Scan			
_____ ¹³¹ Iodine Therapy for Hyperthyroidism			
_____ ¹³¹ Iodine Therapy for Thyroid Cancer			
_____ ⁹⁰ Y Zevalin Therapy for Non-Hodgkin's Lymphoma			
Other: _____			
RADIOPHARMACEUTICAL (Circle One)			
⁸⁹ Sr Chloride		¹⁵³ Samarium	
Sodium ³² P		¹³¹ I Sodium Iodide	
⁹⁰ Yttrium Ibritumomab Tiuxetan (Zevalin)		Other: _____	
Prescribed Dose: _____		Route: _____	
Signature of Authorized User: _____		Date: _____	
Administered Dose: _____		By: _____ Date: _____	
Witness: _____		Date: _____	

Section 03.02(h), “Medical Events”

Major content remains the same:

- Assess the licensee’s ability to effectively identify and respond to different types of medical events through interviews with selected staff and a review of selected records.
- Verify that licensee staff is aware of what constitutes a medical event and what the reporting procedures are within their organization:
 - to which individual should they report a medical event or treatments that may have resulted in a medical event, and
 - the individual responsible for reporting medical events to the regulatory agency.

Section 03.02(h), “Medical Events”

Updated with information from the IEP on use of enforcement discretion:

- Enforcement discretion may be used to not cite a violation for failure to use a dose-based calculation if:
 - Total source strength and exposure time are used to evaluate the existence of a medical event AND the criteria in the IEP are met
- Enforcement discretion may be used to not cite a violation for failure to report a medical event if:
 - Absorbed dose is used to evaluate the existence of a medical event, the total dose to the treatment site equaled or exceeded 120 percent of the prescribed dose AND the criteria in the IEP are met.

Appendix B

“Reviewing Licensees’ Implementation of Procedures for Implant Brachytherapy Administrations”

- Appendix was reorganized. Inspection activities were prioritized to those that the inspector should always attempt to perform and those that may be added if time and circumstances allow.
- It is typically not possible for inspectors to observe brachytherapy treatment activities.
- In order to observe a surgical procedure, some licensees require:
 - Advance approval, including consent of the patient.
 - Signed non-disclosure agreement.
 - Special training to enter a sterile environment.



Appendix B

- Perform general program assessment to show that licensee performance is adequate to ensure public health and safety. Otherwise, conduct a more thorough review if specific performance expectations are not met.
- Focus on determining whether the identified weakness resulted in a safety issue.
- Focus on safety.
- Focus on whether there is a program in place to provide high confidence that each administration is in accordance with the written directive.



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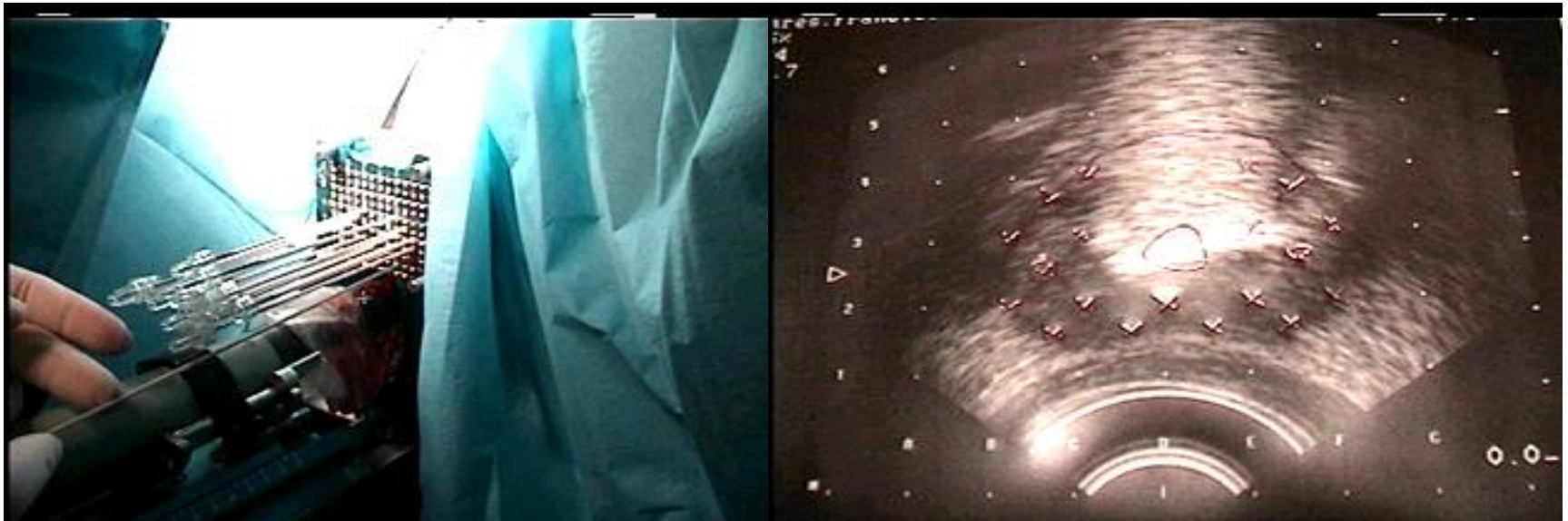
Appendix B

- The inspector should always attempt to review:
 - Description of permanent implant brachytherapy program, including the method(s) used for treatment planning and treatment administration, and the roles and responsibilities of each member of the treatment team.



Appendix B

- The inspector should always attempt to review:
 - Method used to verify that the target is accurately identified and sources are accurately positioned.



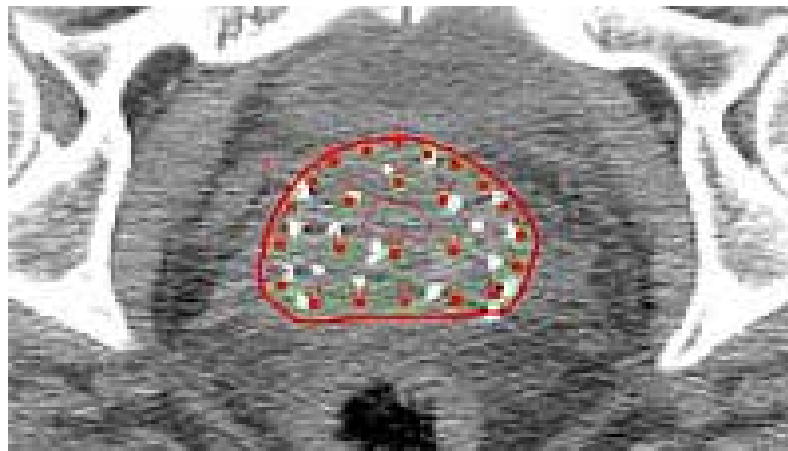
Appendix B

- The inspector should always attempt to review:
 - A sampling of recent written directives. Confirm that written directives include all required information, including pre-implantation and post-implantation sections.

WRITTEN DIRECTIVE			
Name: _____	SS#: _____		
DOB: _____	Diagnosis: _____		
PATIENT IDENTIFICATION			
_____ Pt. Name Announced _____	Spelling of Name _____	ID Card _____	
_____ Birth Date _____	SS# _____	Wrist Band _____	Other _____
PREGNANCY / BREAST FEEDING STATUS			
Negative pregnancy confirmed by: _____ PG Test _____ LMP _____ N/A			
Breast Feeding: _____ Yes _____ No _____ N/A			
DESIRED PROCEDURE			
_____ ⁸⁹ Sr Therapy for palliation of osseous mets. pain			
_____ ¹⁵³ Sm Therapy for palliation of osseous mets. pain			
_____ ³² P (Sodium) Therapy for polycythemia vera			
_____ ¹³¹ Iodine Whole Body Scan			
_____ ¹³¹ Iodine Substernal Thyroid Scan			
_____ ¹³¹ Iodine Therapy for Hyperthyroidism			
_____ ¹³¹ Iodine Therapy for Thyroid Cancer			
_____ ⁹⁰ Y Zevalin Therapy for Non-Hodgkin's Lymphoma			
Other: _____			
RADIOPHARMACEUTICAL (Circle One)			
⁸⁹ Sr Chloride	¹⁵³ Samarium	Sodium ³² P	¹³¹ I Sodium Iodide
⁹⁰ Yttrium Ibritumomab Tiuxetan (Zevalin)		Other: _____	
Prescribed Dose: _____		Route: _____	
Signature of Authorized User: _____		Date: _____	
Administered Dose: _____		By: _____	Date: _____
Witness: _____		Date: _____	

Appendix B

- The inspector should always attempt to review:
 - Method used to verify that the treatment was administered in accordance with the written directive and, if applicable, the treatment plan. Include review of a sampling of recent records.
 - Licensee staff's knowledge of NRC medical event reporting requirements and ability to recognize medical events, including consideration of both the treatment site and other organs and tissues.



Appendix B

- The inspector may also review:



- Source ordering, verification of source strength and loading pattern, and source calibration.
- If computerized treatment planning is used, acceptance testing and calculation double-checks.
- Method used to verify patient identity.
- Method used to demonstrate compliance with patient release requirements.
- Response to unusual circumstances such as equipment malfunctions, unavailability of personnel, atypical patient anatomy, or unexpected imaging results.

Appendix C

“Use of the Interim Enforcement Policy for Permanent Implant Brachytherapy Medical Event Reporting 35.3045)”

- Clarifies use of the IEP through supplemental Qs and As containing hypothetical cases and examples.
- Does not replace official inspection guidance in IP 87132.
- Applies to all permanent implants (not just prostate).
- Licensee programs are not required to “fit” the sample cases.
- Sample cases do not represent all possible applications of the IEP.

Appendix C, Question 1

Must the prescribed dose in the written directive (WD) be expressed in units of dose, or may the licensee also express the prescribed dose in units of total strength and exposure time?

WRITTEN DIRECTIVE			
Name: _____		SS#: _____	
DOB: _____		Diagnosis: _____	
PATIENT IDENTIFICATION			
_____ Pt. Name Announced _____ Spelling of Name		_____ ID Card	
_____ Birth Date _____ SS#		_____ Wrist Band _____ Other _____	
PREGNANCY / BREAST FEEDING STATUS			
Negative pregnancy confirmed by: _____ PG Test _____ LMP _____ N/A			
Breast Feeding: _____ Yes _____ No _____ N/A			
DESIRED PROCEDURE			
_____ ⁹⁰ Sr Therapy for palliation of osseous mets. pain			
_____ ¹⁵³ Sm Therapy for palliation of osseous mets. pain			
_____ ³² P (Sodium) Therapy for polycythemia vera			
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_____ ¹³¹ Iodine Therapy for Thyroid Cancer			
_____ ⁹⁰ Y Zevalin Therapy for Non-Hodgkin's Lymphoma			
Other: _____			
RADIOPHARMACEUTICAL (Circle One)			
⁹⁰ Sr Chloride	¹⁵³ Samarium	Sodium ³² P	¹³¹ I Sodium Iodide
⁹⁰ Yttrium Ibritumomab Tiuxetan (Zevalin)		Other: _____	
Prescribed Dose: _____		Route: _____	
Signature of Authorized User: _____		Date: _____	
Administered Dose: _____		By: _____ Date: _____	
Witness: _____		Date: _____	

Appendix C, Answer 1

Per the definition of “prescribed dose” in 10 CFR 35.2, the licensee may express the dose as described in the WD in terms of either (1) dose or (2) total source strength and exposure time.

However, 10 CFR 35.3045(a)(1) requires that a licensee report as a medical event an administration involving a dose that differs from the prescribed dose by specified values in units of Sv or rem.

Appendix C, Answer 1 (cont'd)

IEP for total source strength and exposure time allows inspectors to exercise enforcement discretion:

- Applies to licensees using total source strength and exposure time to compare the treatment site delivered dose to the prescribed dose.
- FRN for the IEP noted that it is not necessary for the licensee to perform an assessment to compare the delivered dose to the prescribed dose, with both doses in units of Sv or rem.
- Applies only to ME determination for the treatment site.
- Does not apply if doses to other organs and tissues exceeded the criteria in 35.3045(a)(3).

Appendix C, Answer 1 (cont'd)

Enforcement discretion may be used if the following criteria are all met:

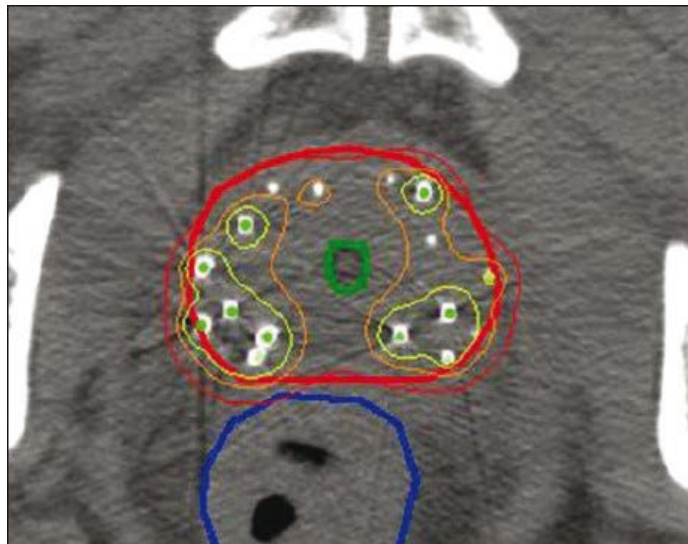
- Licensee's documented procedures under 10 CFR 35.41 specify total source strength and exposure time as the regulatory evaluation values
- Licensee entered both the prescribed and delivered dose into the WD as total source strength and exposure time
- Licensee timely reported any ME identified based on total source strength and exposure time

Case Number 1-1

- Licensee's written program called for comparison of total source strength and exposure time.
- Treatment plan was based on pre-treatment imaging performed six weeks earlier.
- AU signed pre-implantation WD for permanent implant of 75 sources of I-125, 0.5 mCi per source, 37.5 mCi total source strength.
- At time of implant, AU found that size of patient's prostate was smaller. AU implanted 65 sources and signed post-implantation WD for permanent implant of 65 sources of I-125, 0.5 mCi per source, 32.5 mCi total source strength.

Case Number 1-1 (cont'd)

- Dose calculations were performed based on a CT scan performed 30 days post-implant.
- Calculations showed that the dose to other organs and tissues did not exceed the ME criteria in 10 CFR 35.3045(a)(3).



Case Number 1-1 (cont'd)

Enforcement discretion may be used in this case:

- Licensee's documented procedures specified use of total source strength and exposure time for treatment site dose comparisons.
- AU entered the prescribed and delivered dose into the WD as total source strength and exposure time.
- No ME was identified:
 - Post-implant evaluation showed implanted source strength within 20% of the source strength in the WD.
 - Dose to other organs and tissues did not exceed ME criteria in 10 CFR 35.3045(a)(3).

Case Number 1-2

- Licensee's written program called for comparison of total source strength and exposure time.
- Sources ordered/implanted were each 0.43 mCi of I-125.
- Real-time planning calculations performed using source strength of 0.43 U (equivalent to 0.34 mCi).
- AU signed pre-implantation WD for permanent implant of 100 sources of I-125, 0.34 mCi per source, 34 mCi total source strength.
- AU implanted 100 sources and signed post-implantation WD for same values as pre-implantation WD.
- Staff identified error later and realized that 43 mCi was implanted instead of 34 mCi (26% variance from WD).

Case Number 1-2 (cont'd)

Enforcement discretion may not be used in this case:

- Source strength implanted into the treatment site differed from source strength in the WD by more than 20%.

Also:

- It is not necessary for the licensee to compare the delivered dose to the prescribed dose, with both doses in units of Sv or rem.
- It is not mandatory for the licensee to perform an assessment of dose to other organs and tissues.

Appendix C, Question 2

What relief can be provided to licensees from the requirement to report as a ME an administration in which the dose delivered to the treatment site differs from the prescribed dose by 20% or more?

Appendix C, Answer 2

Per 10 CFR 35.3045, if dose delivered to the treatment site differs from the prescribed dose by 20% or more, the licensee is required to report that instance as a ME.

However, the IEP allows inspectors to exercise enforcement discretion when the total dose to the treatment site equals or exceeds 120% of the prescribed dose.

This discretion applies only for licensees using absorbed dose to compare the treatment site delivered dose to the prescribed dose to determine if an ME has occurred.

Appendix C, Answer 2 (cont'd)

Enforcement discretion may be used if the following criteria are all met:

- Licensee used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose.
- Doses to normal tissues and structures did not exceed the dose limits for reporting medical events in 10 CFR 35.3045(a)(3).
- Total dose to the treatment site was expressed in the WD as absorbed dose.

Appendix C, Answer 2 (cont'd)

Enforcement discretion may not be used in the following circumstances:

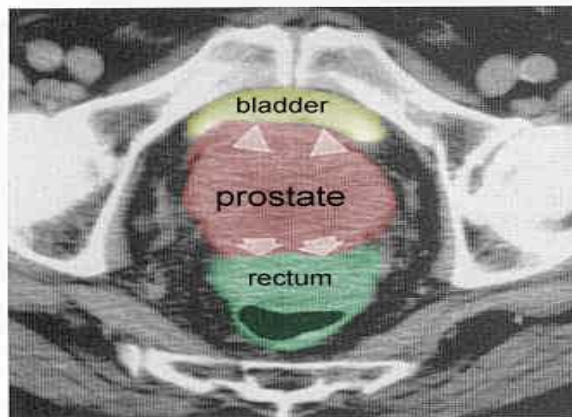
- Delivered dose to the treatment site is less than or equal to 80% of the prescribed dose.
- Licensee used total source strength and exposure time to compare dose delivered to the treatment site with the prescribed dose.

Case Number 2-1

- Licensee's written program called for comparison of absorbed dose. D90 (minimum dose to 90% of the treatment site) for dose delivered to treatment site was compared with prescribed dose in WD.
- AU signed a pre-implantation WD for a minimum dose of 145 Gy to be delivered to the entire treatment site.
- AU implanted sources and signed a post-implantation WD for a minimum of 145 Gy to the entire treatment site.

Case Number 2-1 (cont'd)

- Dose calculations were performed based on a CT scan performed 30 days post-implant.
- Calculations showed that:
 - D90 was 180 Gy (124% of the dose in the written directive).
 - The dose to other organs and tissues did not exceed the ME criteria in 10 CFR 35.3045(a)(3).



Case Number 2-1 (cont'd)

Enforcement discretion may be used in this case:

- Licensee's documented procedures specified use of absorbed dose as the regulatory evaluation value.
- Total dose to the treatment site was expressed in the WD as absorbed dose.
- Delivered dose to the treatment site was 124% of the prescribed dose.
- Dose to other organs and tissues did not exceed ME criteria in 10 CFR 35.3045(a)(3).

Case Number 2-2

- Licensee's written program called for comparison of absorbed dose. D90 for dose delivered to treatment site was compared with prescribed dose in WD.
- AU signed pre-implantation WD for 110 Gy and treatment plan was developed based on ultrasound images obtained five weeks before the implant date
- At time of implant, AU found that size of patient's prostate was significantly larger than expected.
- AU chose to implant 20% more sources than originally planned.
- AU signed a post-implantation WD for a minimum dose of 110 Gy to the prostate.

Case Number 2-2 (cont'd)

- Dose calculations were performed based on a CT scan performed 30 days post-implant.
- Calculations showed that:
 - D90 was 137 Gy (125% of the dose in the WD)
 - There was a bunching of sources in one section of the treatment site.
 - The dose to a volume of normal tissue outside the treatment site, near the bunched sources, exceeded the ME criteria in 10 CFR 35.3045(a)(3).

Case Number 2-2 (cont'd)

Enforcement discretion may not be used in this case.

- Delivered dose to the treatment site was 125% of the prescribed dose.
- Licensee's documented procedures specified use of absorbed dose as the regulatory evaluation value.
- Total dose to the treatment site was expressed in the WD as absorbed dose.

However

- Dose to other organs and tissues exceeded ME criteria in 10 CFR 35.3045(a)(3).

QUESTIONS?

Acronyms

- CFR – Code of Federal Regulations
- FR – *Federal Register*
- IEP – Interim Enforcement Policy
- IP – Inspection Procedure
- ME – Medical Event
- SRM – Staff Requirements Memorandum
- TSS/ET – Total Source Strength and Exposure Time
- Tx Site – Treatment Site
- WD – Written Directive