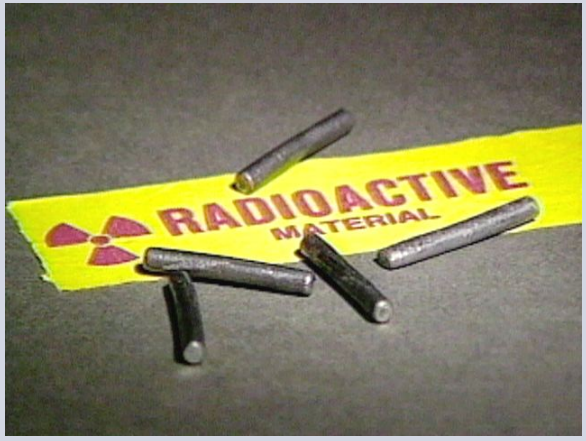

Treatment Directive,
Medical Events, and
Regulation Issues

Dose Prescription and Treatment Planning

Radium was the first radioisotope used extensively for therapeutic treatments. Clinicians typically prescribed the quantity of radium to be used in a Brachytherapy treatment and the length of time the radium would remain in place to deliver a certain dose to the tumor volume. This is the origin of the source-related prescription given in the units milligram hours (of radium).

Dose Prescription and Treatment Planning

As more and better sources became available for Brachytherapy treatments, doses were prescribed in terms of "equivalent" milligram hours (of radium), since almost all the relevant clinical experience of the past was tied to the use of radium.

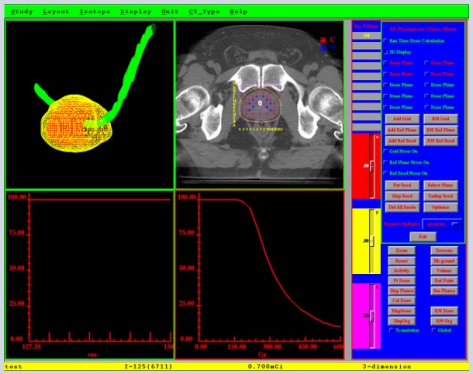


Dose Prescription and Treatment Planning

As dosimetry systems and quantities evolved, prescriptions moved away from total mgRa eq hours to actually computing the dose at a certain point, called the prescription point, in the implant. As dosimetry systems evolved further it became possible to prescribe the dose to a volume, rather than to a point. Even before the advent of computer.

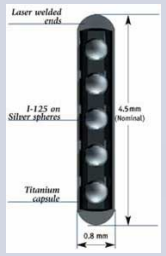
Dose Prescription and Treatment Planning

- With the availability of Brachytherapy computer planning systems it is possible to produce a desired dose distribution with a variety of sources in a variety of strengths and patterns.



Conclusions:

A Brachytherapy treatment plan is very dependent on the type and strength of sources used. Even the manufacturer will make a significant difference since five iodine-125 seeds from 5 different manufacturers will have five different gamma factors and five different radial distribution patterns, even if the source strength or activity is the same.



Conclusions:

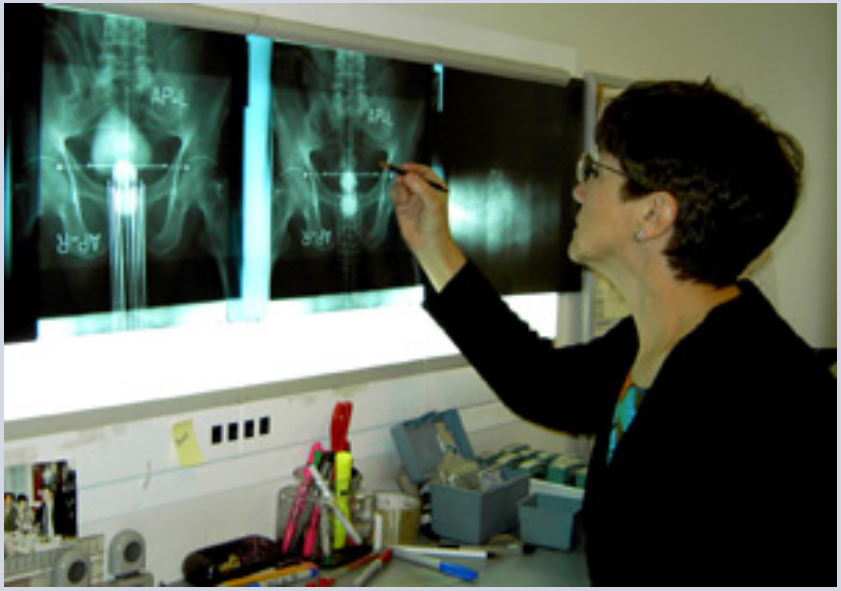
Since the dose at a certain point in the implant can be very different from the dose just a few millimeters away, the prescription point or the prescription volume is very critical. A prescription must very clearly state the exact point or volume where that prescription is defined.

Conclusions:

- The radiation produced by a Brachytherapy source decays continuously. The medical physicist must very carefully calculate the strength of the sources, based on the information provided by the vendor, for the time of the implant. In addition, the medical physicist must use some method or measurement to corroborate the information provided by the vendor.

Written Directives

- 10 CFR 35, section 40, describes the federal regulations concerning the prescription (or directive) from the authorized user.



Written Directives

- A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 MBq (**30 μCi**)

Written Directives

- If a delay in the treatment, in order to provide a written directive, would jeopardize the patient's health, an oral directive is acceptable but the information contained in the oral directive must be documented within 48 hours in writing in the patient's record.

Required Information for the Patient's Record

1. For any administration of quantities greater than 1.11 MBq (30 µCi) of sodium iodide 1-131: the dosage;
2. For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide 1-131: the radioactive drug, dosage, and route of administration;
3. For high dose-rate remote afterloading Brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
4. For all other Brachytherapy, the treatment site, the radionuclide, and the dose (before the implant); and the number of sources, total source strength and total exposure time (before the end of the implant).

Section 35.41 states that, for any administrations requiring a written directive:

1. The licensee shall develop, implement, and maintain written procedures to require that the patient's identity is verified before each administration and that each administration is in accordance with the written directive.
2. At a minimum, the licensee needs to check both manual and computer-generated dose calculations and verify that computer-generated dose calculations are correctly transferred to the treatment consoles.

Medical Event

If something untoward occurs during the administration of a Brachytherapy treatment, which is not due to any action taken by the patient (such as halting the treatment), the licensee must report the event to the licensing body if certain conditions are fulfilled. Section 35.3045 describes the circumstances that constitute a medical event.

Treatment Deviations, Regulations and Quality Management Issues

Definition of a Medical Event Involving Brachytherapy or Teletherapy (35.2)

A. A teletherapy radiation dose:

- 1. . Involving the wrong patient or human research subject, wrong mode of treatment, wrong energy or wrong treatment site; or
- 2. When treatment consists of 3 or less fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose;
- 3. When the weekly administered dose exceeds the weekly prescribed dose by more than 30%; or
- 4. When the total administered dose differs from the total prescribed dose by more than 20%

Treatment Deviations, Regulations and Quality Management Issues

Definition of a Medical Event Involving Brachytherapy or Teletherapy (35.2)

B. A brachytherapy radiation dose:

- Involving the wrong patient or human research subject, wrong radionuclide, or wrong treatment site (excluding migrated seeds);
- Involving a leaking sealed source;
- When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
- When the calculated administered dose differs from the prescribed dose by more than 20%.

Medical Event

A licensee shall report any event that results in :

- A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; AND
  - The total dose delivered differs from the prescribed dose by 20 % or more;
  - The total dosage delivered differs from the prescribed dosage by 20 % or more or falls outside the prescribed dosage range; or
  - The dose per fraction delivered differs from the prescribed dose for a single fraction, by 50 % or more.

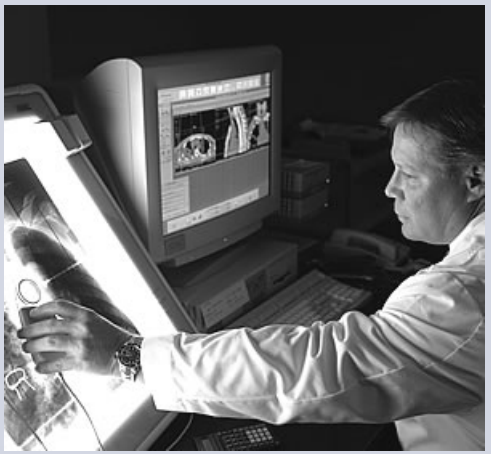
Medical Event

A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

- An administration of a wrong radioactive drug containing byproduct material;
- An administration of a radioactive drug containing byproduct material by the wrong route of administration;
- An administration of a dose or dosage to the wrong individual;
- An administration of a dose or dosage delivered by the wrong mode of treatment; or
- An administration of a dose or dosage delivered by a leaking sealed source.

Medical Event

The licensee shall report any event resulting from intervention of a patient in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.



Medical Event

- The licensee shall notify the NRC Operations Center (by telephone) no later than the next calendar day after discovery of the medical event, and submit a written report to the appropriate NRC Regional Office within 15 days after discovery of the medical event.

The written report must include:

The licensee's name,

The name of the prescribing physician,

A brief description of the event,

Why the event occurred,

The effect, if any, on the individual(s) who received the administration,

What actions, if any, have been taken or are planned to prevent a recurrence,

Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

Report Notification/Medical Event in 10 CFR 35

Section 3045	Contents
Report/notification of medical event excluding patient intervention) (1)	Dose differs from PD more than 0.05 Sv EDE, 0.5 Sv organ/tissue & SDE skin, *and,* TD delivered differs from PD by 20% *or* falls outside PD range; *or* single fraction delivered dose differs from single fraction PD +50%.
Report/notification of medical event (excluding patient intervention) (2)	Dose *exceeds* 0.05 Sv EDE, 0.5 Sv organ/tissue & SDE skin, *and,* TD from wrong: a) byproduct material; b) administration route; c) person; d) treatment mode; e) leaking source.

Report Notification/Medical Event in 10 CFR 35

Section 3045	Contents
Report/notification of medical event (excluding patient intervention) (3)	Excluding migrating permanent implant seeds, dose to skin/organ/tissue *other* than treatment site that *exceeds* 0.5 Sv organ/tissue *and* 50% of the dose expected from WD.
Report/notification of medical event (excluding patient intervention) (3) (b)	Report any patient interventions producing permanent physiological damage.
Report/notification of medical event (excluding patient intervention) (3) (c, d)	Notify NRC next calendar day after ME with written report in 15 days; notify referring MD & patient unless referring MD chooses not to for medical reasons; details of reports omitted here.

Report Notification/Medical Event in 10 CFR 35

Section 3045	Contents
Report/notification of medical event excluding patient intervention) (1)	Dose differs from PD more than 0.05 Sv EDE, 0.5 Sv organ/tissue & SDE skin, *and,* TD delivered differs from PD by 20% *or* falls outside PD range; *or* single fraction delivered dose differs from single fraction PD +50%.