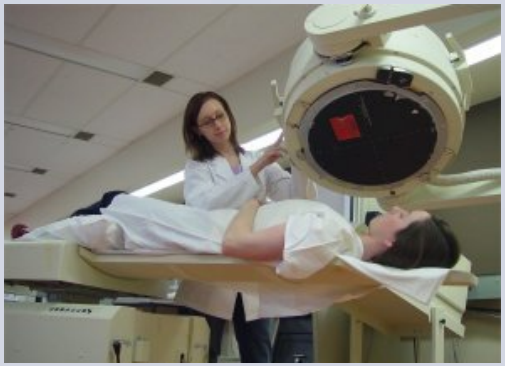
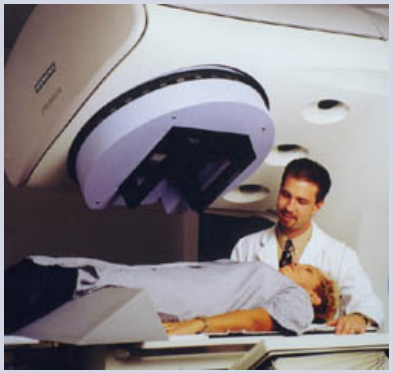
Written Directives

In any medical administration, a written directive is required communicating and documenting the physician's treatment plan or intent for that individual patient.

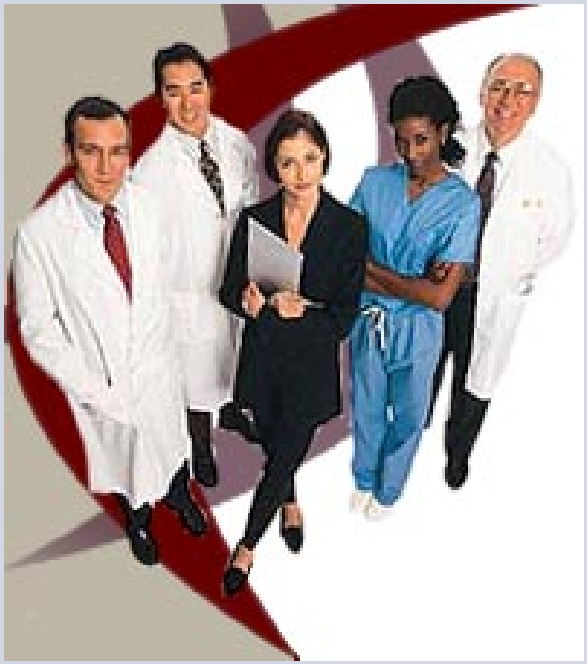
- Before the administration of radiation for therapeutic purposes a written directive must be signed and dated by an authorized user.

- The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments.





- A number of individuals may be involved in the delivery process. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process.



- 10 CFR 35.27(c) holds licensees responsible for omissions or commissions of it's supervised individuals and in meeting that requirement, many licensees establish a policy for all supervised individuals to request clarification, as needed, about instructions, including procedures requiring a written directive (WD).

For each modality, the licensee shall develop procedures for WDs to meet the objectives of 10 CFR 35.40 and 35.41 (as applicable to the type of medical use), outlined below:

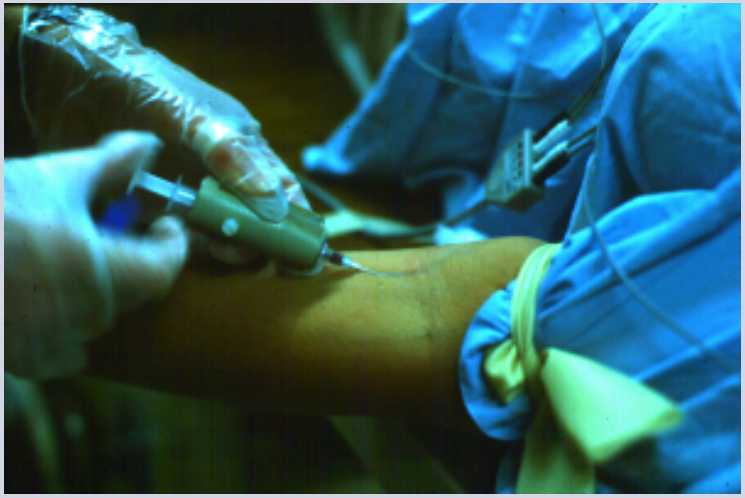
- Have an authorized user prepare, date, and sign a written directive prior to the administration,
- Verify the patient's or human research subject's identity prior to each administration,
- Verify that the specific details of the administration are in accordance with the written directive and the treatment plan,
- Check both manual and computer-generated dose calculations,
- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices, and
- Record the radiopharmaceutical dosage or radiation dose actually administered.

Therapeutic Dose or Dosage of a Radionuclide

The following policies and procedures should be established:

An authorized users must prepare, date, and sign a written directive prior to the administration of any dose or dosage. This is required by 10 CFR 35.40.

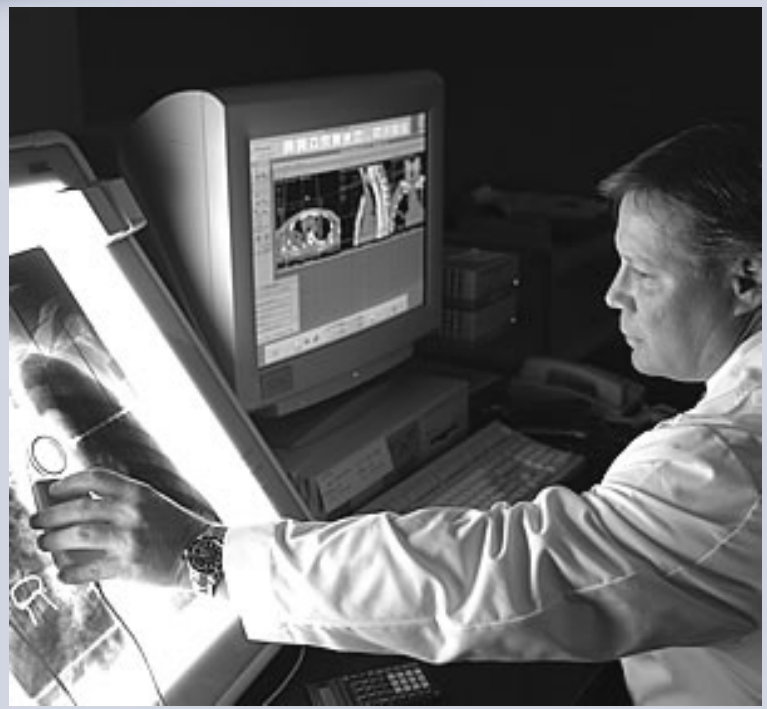
Prior to administering a dose or dosage, the patient's or human research subject's identity will be verified as the individual named in the written documents. Examples of patient identity verification include the patient's ID bracelet, hospital ID card, driver's license or social security card.



Before administering the dose or dosage, the specific details of the administration will be verified in accordance with the written directive or treatment plan.

- All components of the written document (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the written document.

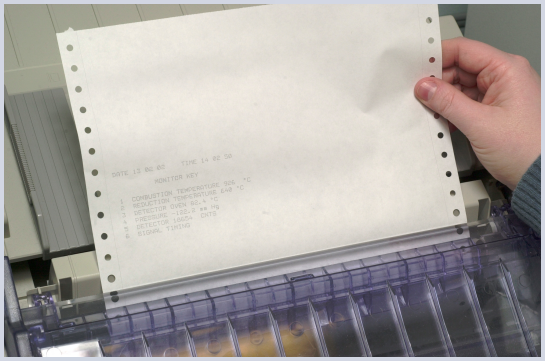
- Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded vials or sealed sources, or using clearly marked storage locations.



- The verification will be performed by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist) preferably other than the individual who prepared the dose or dosage or the treatment plan.

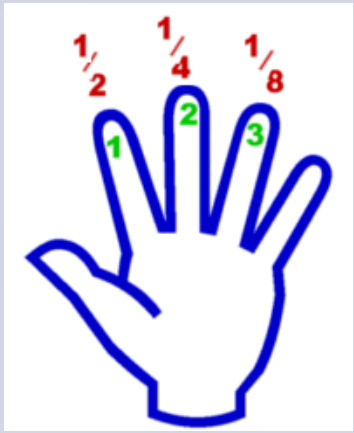
All workers will be instructed to seek guidance if they do not understand how to carry out the written directive. Specifically, workers should stop and ask if they have any questions about what to do or how it should be done, prior to administration, rather than continuing a procedure when there is any doubt.

Dose calculations will be checked before administering the prescribed therapy dose. An authorized user or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations.



The responsibilities and conditions of supervision are contained in 10 CFR 35.27. Suggested methods for checking the calculations include the following:

1. Computer-generated dose calculations will be checked by examining the computer printout to verify that correct input data for the patient were used in the calculations (e.g., source strength and positions).
2. The computer-generated dose calculations for input into the therapy console will be checked to verify correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times)



Manual dose calculations will be checked for:

a. Arithmetic errors,

b. Appropriate transfer of data from the WD, treatment plan, tables and graphs,

c. Appropriate use of nomograms (when applicable), and

d. Appropriate use of all pertinent data in the calculations

- If possible, a therapy dose will be manually calculated to a single key point and the results compared to the computer generated dose calculations.

- If the manual dose calculations are performed using computer-generated outputs (or vice versa), particular emphasis should be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual).

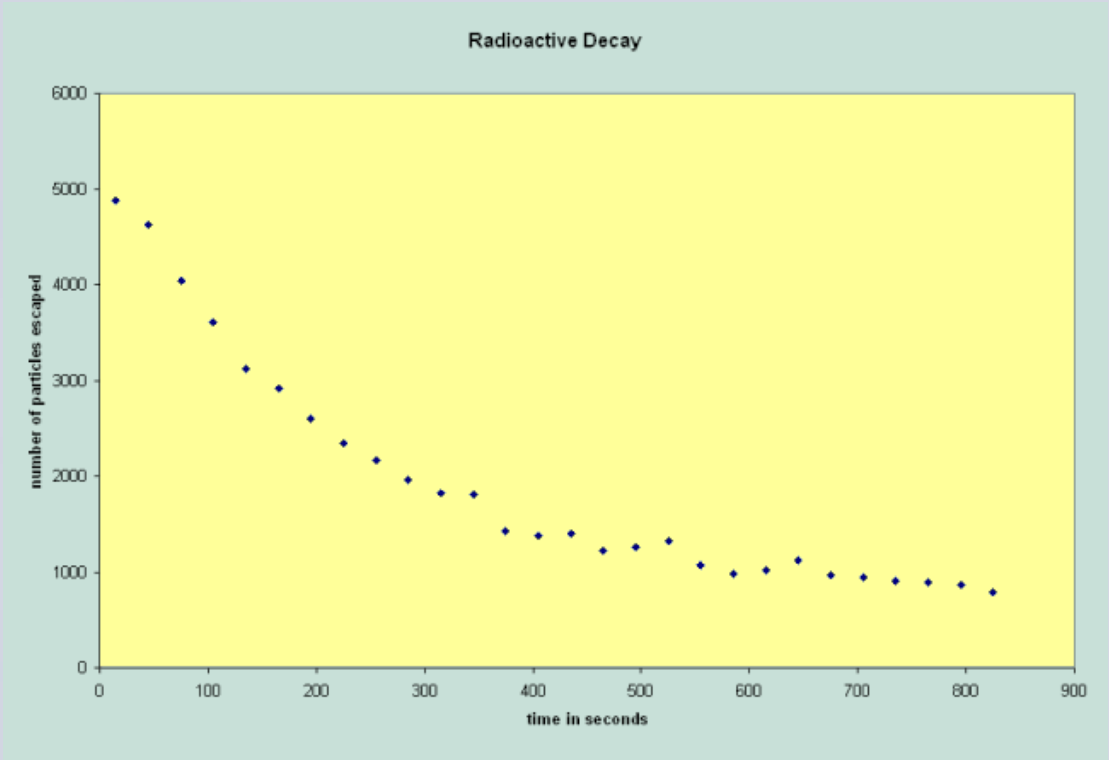
- After insertion of permanent implant brachytherapy sources, an AU will promptly record the actual number of radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that will be used for dose calculations.

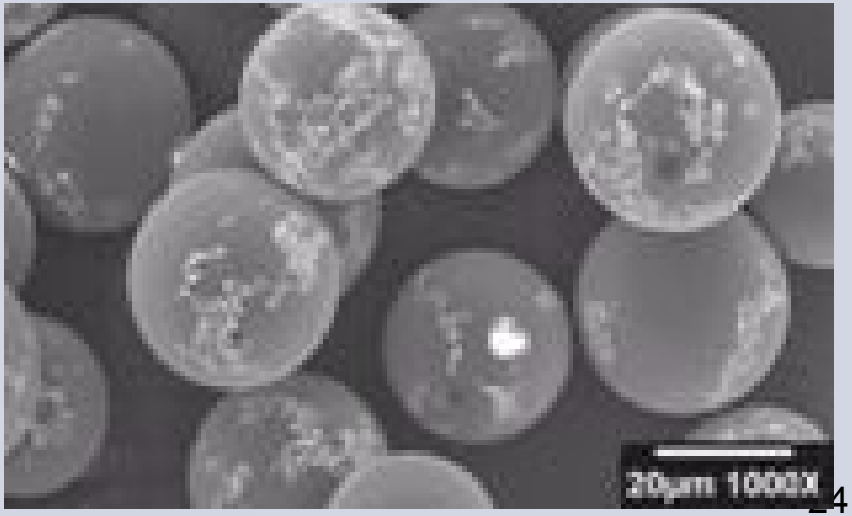
- Acceptance testing shall be performed before the first ***use*** of a treatment planning or dose calculating computer program for therapy dose calculations.

Each treatment planning or dose calculating computer program will be assessed based the intended uses of the software and the consequent requirements for accuracy, reproducibility and documentation.

- Acceptance testing will also be considered after each source replacement or when spot-check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration, corrected mathematically for radioactive decay.



- For Y-90 microspheres (SIR-Spheres and Theraspheres) , "prescribed dose" means the total dose documented in the written directive.

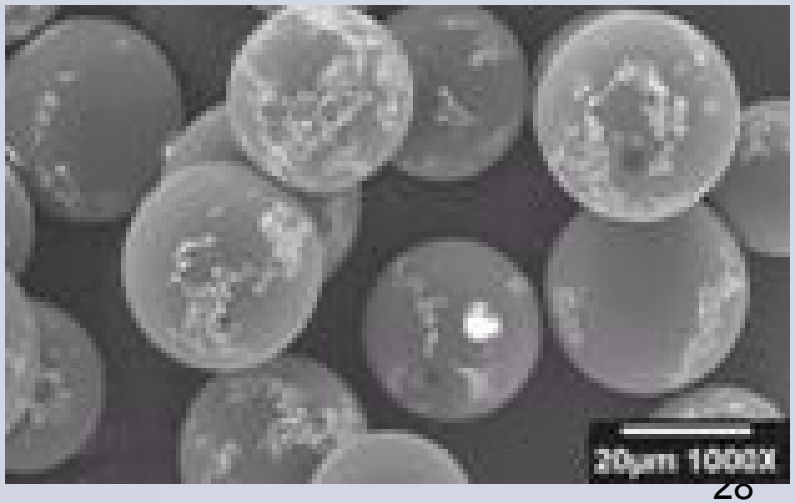


- The written directive should include before implantation:
  - the treatment site, the radionuclide (including the chemical/physical form Y-90 micro spheres), and dose.
- Also in the written directive after implantation but before completion of the procedure:
  - the radionuclide (including the chemical/physical form Y -90 microspheres, treatment site and the total dose.

- When the authorized user uses the medical end point of stasis to determine when to terminate implantation of the microspheres The written directive should include:
  - dose delivered when stasis occurred and when the implantation was terminated.

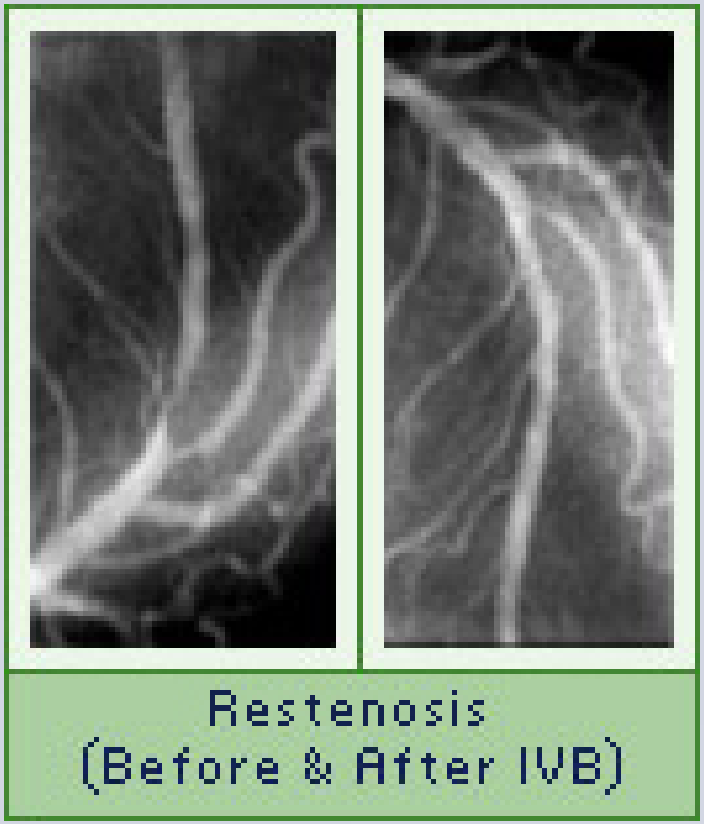
- The written directive should specify the maximum dose that would be acceptable for a specified site (or sites) outside the primary treatment site to which the microspheres could be shunted (such as the lung and gastrointestinal tract).

- Procedures for administrations requiring a written directive should, for Y-90 microsphere administrations, describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration to confirm that the administration is in accordance with the written directive.



- For Liquid Brachytherapy (Gliasite) procedures, a written directive should include the treatment site, the radionuclide (including the chemical/physical form, I-125 (Iotrex), and the dose.
- This written directive is entered in the patient record. After implantation but prior to completion of the procedure: the radionuclide including the chemical/physical form, I-125 (Iotrex), treatment site, and the total dose administered are entered in the patient record.

- For Intravascular brachytherapy (IVB) the written directive should, before treatment, specify treatment site, the radionuclide, and dose.



Restenosis
(Before & After IVB)

- If possible, a weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

Review of Administrations Requiring a Written Directive

- The licensee should consider establishing procedures to conduct periodic reviews of each applicable program area, e.g., radiopharmaceutical therapy, high-dose-rate brachytherapy, implant brachytherapy, teletherapy, gamma stereotactic radiosurgery and emerging technologies.

- The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery.

- In order to eliminate any bias in the sample, the patient cases to be reviewed should be selected randomly. If the number of errors in the sample does not exceed the acceptance number in the appropriate Sampling Table, the lot should be accepted.

- For each patient's case reviewed, the licensee shall determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan as applicable.
- For each patient case reviewed, the licensee should identify deviations from the WD, the cause of each deviation, and the action required to prevent recurrence.

- If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. The licensee or designee should regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

Medical Event

A medical event is an occurrence in which the administration of byproduct results in a dose that differs from the prescribed or intended dose by more than 5 rem effective dose equivalent or 50 rem to an organ or tissue, or dose to the skin and any one of the following:

- the total dose delivered differs from the prescribed dose by 20 percent or more;
- the total dose delivered falls outside the prescribed dosage range; or
- the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

Medical Event

A medical event is also an occurrence in which the dose that exceeds 5 rem effective dose equivalent, 50 rem to an organ or tissue, or dose to the skin due to:

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

Medical Event

Lastly, a medical event is also an occurrence in which the dose to the skin or an organ or tissue other than the treatment site exceeds 50 rem and 50 % or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment sit

Records of Medical Events

- The facility shall maintain a record of medical events for three years as required by 10 CFR 35.3045. The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical ever and shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after the discovery of the medical event, as required by 10 CFR 35.3045.

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