

MISADMINISTRATION OF RADIATION TREATMENT

Purpose: To provide guidelines to:

1. define treatment variance and different levels of variance;
2. identify, report, and track radiation treatment variances in a timely manner;
3. identify person/committee responsible for implementation and compliance with this procedure; and,
4. comply with definitions of 102 and section 712 of the Louisiana Radiation Regulations (LAC 33:XV.102 and LAC 33:XV.712).

Policy:

1. It is the responsibility of each staff member to initiate this procedure immediately when a variance is identified.
2. It is the responsibility of the medical physicist to ensure compliance with this procedure.
3. The medical physician or manager will be notified of any possible misadministration immediately upon discovery.
4. The medical physicist will convene whenever a possible misadministration occurs.
 - a. The medical physicist will have the authority and responsibility to:
 - i. determine if a misadministration has occurred;
 - ii. notify the medical director of radiation oncology and RSO of any misadministration and the Louisiana Radiation Protection Division of any brachytherapy misadministration; and
 - iii. prepare a written report on the misadministration, as required by the Louisiana Radiation Regulations.
 - b. The Medical Physicist, RSO and Radiation Oncology Manager will document results and present findings to Radiation Safety Committee.
 - c. To establish a quorum for review of a misadministration, at least four members of the committee must be present, including the RSO, physicist, radiation oncology manager and one radiation oncologist.

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Radiation Oncology
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5. Treatment variance records include, but are not limited to, the following:
 - a. Variance Reports
 - b. Treatment Variance Report Evaluation and Follow-up
 - c. Possible Misadministration Follow-up Report
 - d. Documentation to correct the treatment course of the affected patient and to prevent recurrences of the event; and,
 - e. Documentation of the RSo and Radiation Safety Committee on action(s) taken and the effectiveness of these actions.
6. Treatment variance records are confidential peer review records and are not subject to disclosure (except when meeting the requirements for reporting misadministrations). Documentation pertaining to variances classified as misadministrations shall be maintained in the safety committee file.
7. Treatment Variance Report shall be reported immediately upon discovery.

Definitions:

1. **Written Prescription** - an order in writing for a specific patient, dated and signed by a radiation oncologist prior to the administration of radiation, containing the following information:
 - a. For external beam: the total dose, dose per fraction, treatment site, energy, and overall treatment period;
 - b. For conventional brachytherapy:
 - i. prior to insertion of sources: the radioisotope, number of sources, and source strengths; and
 - ii. after insertion of sources, but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).
2. **Treatment Variance** - a deviation from the radiation oncologist's intended treatment of a patient, which may result from, but are not limited to:
 - a. a machine or equipment malfunction;
 - b. an improperly written prescription;
 - c. the improper carrying out of a written prescription;
 - d. the improper carrying out of the radiation oncologist's instructions given during simulation;

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Radiation Oncology
Proc.19.1.9

- e. the improper carrying out of the radiation oncologist's instructions given during treatment; or,
 - f. not following standard procedure, whether the procedure is written accepted LSUHSC procedure.
3. **Minimal Treatment Variance** - treatment which is within specifications of the prescription. A brachytherapy or external beam treatment is considered to have minimal variance when the daily administered dose/volume differs from the prescribed dose/volume by less than 5%.
4. **Minor Treatment Variance** - a treatment which is not within specifications of the prescription or accepted day-to-day variance and may or may not require action to correct the treatment course of the affected patient; frequent occurrences may require further monitoring and evaluation to avoid or decrease their occurrence.

A minor treatment variance involves:

- a. the administration of external beam when:
 - i. the daily administered dose/volume differs from the prescribed dose/volume by $\geq 5\%$;
 - ii. the weekly administered dose/volume differs by $\geq 5\%$, but $\leq 15\%$ from the prescribed dose/volume;
 - iii. the total administered dose/volume differs from the prescribed dose/volume by $\geq 5\%$, but $\leq 10\%$; and,
 - iv. the monitor units delivered are documented incorrectly in the patient's treatment record.
 - b. the administration of brachytherapy when the administered dose/volume differs from the prescribed dose/volume by $\geq 5\%$, but $\leq 10\%$; and,
 - c. any variance which could be considered more serious than "minimal variance" but less serious than a recordable event.
5. **Recordable Event** - a variance that is unlikely to cause patient morbidity or affect tumor control outcome, but is likely to require corrections to the patient's treatment course.

A recordable event involves:

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Radiation Oncology
Proc.19.1.9

- a. the administration of radiation therapy without a written prescription (verbal orders are allowed in emergency cases, provided that a radiation oncologist signs the orders within 24 hours or before the next treatment);
 - b. the administration of external beam when:
 - i. the calculated weekly administered dose/volume differs from the weekly prescribed dose/volume by $> 15\%$;
 - ii. the calculated total administered dose/volume differs from the total prescribed dose/volume by $> 10\%$, but $< 20\%$;
 - iii. the wrong beam type, photon vs. electron, is used (This classification is used at the radiation oncologist's discretion.);
 - iv. the wrong beam energy is used (This classification is used at the radiation oncologist's discretion.); or
 - v. the monitor units delivered are not documented in the patient's chart.
 - c. the administration of brachytherapy when:
 - i. the calculated administered dose/volume differs from the prescribed dose/volume by more than 10% ; and,
 - ii. the treatment delivered is not recorded in the patient's treatment record.
6. **Misadministration** - a variance which is likely to require corrections to the patient's treatment course and may cause patient morbidity or affect tumor control outcome; must be reported to the RSO immediately upon discovery.

A misadministration involves:

- a. treatment of the wrong patient;
- b. treatment of the wrong site;
- c. the administration of external beam when:
 - i. the wrong beam type or energy is used and the Medical Physicist feels that the treatment differed significantly from the intent of the radiation oncologist;

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- ii. the treatment consists of three or fewer fractions and the calculated total administered dose differs from the prescribed dose by more than 10% of the total prescribed dose;
 - iii. the calculated weekly administered dose is 30% greater than the weekly prescribed dose; and,
 - iv. the calculated total administered dose differs from the total prescribed dose by more than 20%.
- d. the administration of a brachytherapy radiation dose when:
- i. the wrong radioisotope is used;
 - ii. a leaking sealed source is used;
 - iii. for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; and,
 - iv. the calculated administered dose differs from the prescribed dose by more than 20%.
7. **Notable Event** - any occurrence which a staff member feels should be reported to the Medical Physicist.

Procedure:

1. When a treatment variance is identified, the person identifying the variance will notify a physicist immediately, and
 - a. if the variance is identified during a patient's treatment and an adjustment can be made in the balance of the treatment, the physicist will instruct the therapist as to the corrections to be made before continuing the treatment;
 - b. if a variance is identified by a therapist during a weekend or holiday treatment, the therapist will notify the radiation oncologist of the variance (If immediate action is required, the therapist will beep a physicist for assistance in the corrective action.); and
 - c. if radiation oncologist determines that no immediate corrective action is required, the therapist will notify the physicist of the variance on the first working day after discovery.
2. A physicist will make an initial categorization of the variance, in consultation with the radiation oncologist if necessary.

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3. The physicist will make a formal quantification of the variance and will document corrective action, if any, in the patient's treatment record.
4. If the variance is **minimal or minor (but not notable)**:
 - a. The physicist will:
 - i. document the variance on the green chart checking monitoring form in the physics section of the patient's chart;
 - ii. if instructed by the radiation oncologist, modify subsequent treatments to adjust for the variance;
 - iii. take any action necessary to prevent recurrence; and
 - iv. pull the patient chart for documentation.
 - b. The radiation oncology manager will:
 - i. collect and review monitoring forms which document minimal and minor variances;
 - ii. maintain a record of all minimal and minor variances for statistical purposes;
 - iii. prepare a statistical report of minimal and minor variances to present to the ROS staff meeting at least quarterly;
 - iv. assure staff education and training
 - v. maintain radiation safety QA reports.
5. If the variance is a **notable event**, a **recordable event**, or a **misadministration**:
 - a. the physicist will ask the person most knowledgeable about the variance to describe the variance on a Treatment Variance Report and be signed and dated;
 - b. the manager will log the variance on the variance tracking log;
 - c. the report will be forwarded to physicist for review and quantification of the variance; and
 - d. the report will be forwarded to the RSO for review.
 - e. the report will be forwarded to the radiation safety committee for review and comments

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6. If the variance is a **notable event** or a **recordable event**:
 - a. the medical physicist, radiation oncology manager, and the radiation oncologist will review the report, make the final categorization of the variance, confirm that the appropriate actions have been taken and sign the report;
 - b. the medical physicist will abstract and file the report in the radiation safety files;
 - c. the medical physicist will present the abstracted report to the Radiation Safety Committee at its next quarterly meeting;
 - d. the Radiation Safety Committee will review the facts regarding the notable or recordable event, including the cause(s), and may recommend and assign responsibility for actions to prevent the occurrence of similar events in the future;
 - e. the abstracted report will be reviewed radiation safety officer

7. If the variance is a **possible misadministration**,
 - a. the medical physicist and the radiation oncology manager will notify the medical director immediately.
 - b. the medical physicist will appoint at least one person who is knowledgeable of the variance to present the circumstances of the deviation to the group and provide a written statement;
 - c. the committee will review the facts and decide if the variance should be classified as a misadministration;
 - d. if the circumstances of the variance are not such that a decision is incisive, the committee may choose to judge an event a misadministration if the event:
 - i. significantly increases the probability of causing undue severe acute morbidity;
 - ii. significantly increases the risk of late morbidity;
 - iii. significantly reduces the chance of local control in a curative case;
 - iv. significantly compromises palliative care in a palliative case; or,

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- v. creates an unintended and substantial financial expense to the patient.
8. If the variance is not classified as a misadministration by the medical physicist.
 - a. the committee will complete the Treatment Variance Report form and forward the the radiation safety officer and radiation safety committee chairman.
 - b. the manager may recommend and assign responsibility for actions to prevent the occurrence of similar events in the future;
 - c. the reports are abstracted and filed in the radiation safety files;
9. If the variance is an **external beam misadministration**, it will be treated as a recordable event until the Radiation Protection Division of the State Department of Environmental Quality (LARPD) includes reporting requirements for linear accelerators.
10. If the variance is a **brachytherapy misadministration**:
 - a. upon the medical physicist , the physicist and manager will verbally report the misadministration to the medical director, hospital administrator, RSO, and to the LARPD within 24 hours (LAC 33:XV.712.A.1.);
 - b. the prescribing radiation oncologist will report the event to the patient's referring physician (LAC 33.XV.712.A.3.);
 - c. if the referring physician decides it is in the best interest of the patient, he or the radiation oncologist will notify the patient or his/her authorized representative no later than 24 hours after the discovery of the event (LAC 33:XV.712.A.3.);
 - d. in consultation with the prescribing radiation oncologist, the medical physicist and manager will recommend actions to correct the treatment course of the affected patient and to prevent the occurrence of similar misadministrations;
 - e. the physcist and manager will complete the Treatment Variance and radiation safety committee follow-up reports and prepare a written report to be submitted to the RSO, the LARPD and the involved patient (if notified) within 15 days of the discovery of the misadministration. The report will include all information required by paragraph 712.A.2 and A.4 of the Louisiana Radiation Regulations;
 - f. Quality Management will review the facts regarding the misadministration, including the cause(s), and may also recommend and

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Radiation Oncology
Proc.19.1.9

assign responsibility for actions to prevent the occurrence of similar events in the future; and,

- g. written reports of the misadministration will be retained in the Radiation Safety files for at least five years LAC 33:XV.712.B.).

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