



NEW YORK CITY DEPARTMENT OF  
HEALTH AND MENTAL HYGIENE  
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*Commissioner*

## ORH INFORMATION NOTICE 2009-03

### REPORTING AND RECORD KEEPING REQUIREMENTS FOR MEDICAL EVENTS INVOLVING RADIATION

Licensees and Certified Registrants are reminded of the requirements specified in Article 175 of the New York City Health Code for the reporting of medical events (formerly “misadministrations”) involving radiation. These requirements can be found in §175.02(a) (129) and § 175.07(e) which are enclosed. Several studies have reported error rates in radiation therapy treatment to be 0.17% to 0.18% of total treatments performed. These figures appear to be several orders of magnitude higher than what is being reported in New York City, indicating serious under reporting of these events.

As per the above sections of Article 175, reportable medical events involving radiation include:

Administration of radiation or radioactive material:

From the wrong source, (Beam Energy, Radionuclide);

To the wrong person

By the wrong route of administration, or to the wrong body part, other than ordered by the prescribing physician.

Administration of radioactive material:

In a radiopharmaceutical different from activity ordered by more than 10% (therapeutic dose) or 50% (diagnostic dose).

In the wrong dose from a brachytherapy source if error exceeds 10%;

Administration of external beam radiation:

If final total treatment dose differs from prescribed total treatment dose by more than 10%;

If the fractional treatment dose differs from the prescribed fractional treatment dose by more than 50%.

Reportable medical events shall be reported to the Department within 24 hours by telephone and a written report shall be sent to the Department within seven (7) ys.

Records of medical events involving radiation (reportable or not) must be maintained as per §175.07. ORH inspection staff have been instructed to thoroughly review these records during inspections of Licensee and Certified Registration facilities. Discrepancies will be discussed with radiation safety officers and facility management, and where violations are noted, civil penalties will be issued.

From Article 175 of the New York City Health Code

§175.02(a) (129)

(129) "Medical misadministration" means the administration of:

(i) a radiopharmaceutical, radiobiologic or radiation from a source other than the one ordered;

(ii) a radiopharmaceutical, radiobiologic or radiation to the wrong person;

(iii) a radiopharmaceutical, radiobiologic or radiation by a route of administration, or to a part of the body, other than that in the order of the prescribing physician;

(iv) an activity of a diagnostic radiopharmaceutical or radiobiologic differing from the prescribed activity by more than 50 percent;

(v) an activity of a therapeutic radiopharmaceutical or radiobiologic differing from the prescribed activity by more than 10 percent;

(vi) a therapeutic radiation dose from any source other than a radiopharmaceutical, radiobiologic or brachytherapy source such that errors in computation, calibration, time of exposure, treatment geometry or equipment malfunction result in a calculated total treatment dose differing from the final prescribed total treatment dose ordered by more than 10 percent;

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(vii) a therapeutic radiation dose from a brachytherapy source such that errors in computation, calibration, treatment time, source activity, source placement or equipment malfunction result in a calculated total treatment dose differing from the final total treatment dose ordered by more than 10 percent; or

(viii) a therapeutic radiation dose in any fraction of a fractionated treatment such that the administered dose in the individual treatment or fraction differs from the dose ordered for that individual treatment or fraction by more than 50 percent.

§175.07(e)

1) Diagnostic misadministrations.

(i) Records of misadministrations as defined in §175.02(a) (129) of this Code which involve diagnostic procedures and the corrective actions taken pursuant to §175.07(b) (1) (ix) shall be retained for three (3) years; and

(ii) if such a misadministration results in a dose to the patient exceeding 50 millisieverts (5 rem) to the whole body or 500 millisieverts (50 rem) to any individual organ, or involves the administration of iodine-125 or iodine-131 in the form of iodide in a quantity greater than 1 megabecquerel (30 microcuries), the licensee or registrant shall notify the Department in writing within fifteen (15) days and make and retain a record pursuant to §175.07(e)(3).

(2) Therapy misadministrations.

(i) When a misadministration described in §175.02(a)(129)(v), (vi) or (vii), in which the percentage of error is equal to or less than 20 percent is discovered, the licensee or registrant shall immediately investigate the cause and take corrective action; and

(A) the licensee or registrant shall make and retain a record of all therapy misadministrations described in §175.07(e) (2). The record shall contain all the information required by §175.07(e) (3) and shall be retained for six (6) years.

(ii) When a therapy misadministration described in §175.02(a) (129)(i), (ii), (iii) or (viii) is discovered, or when a misadministration described in §175.02(a)(129)(v), (vi) or (vii) is discovered in which the percentage of error is greater than 20 percent, the licensee or registrant shall notify the Department by telephone within 24 hours. The licensee or registrant shall also notify the referring physician of the affected patient and the patient of any therapy misadministration described herein, with the exception of the misadministration defined in §175.02(a) (129) (viii). When it is not medically advisable to give such information to the patient, the information shall be made available to the patient's responsible relative or guardian on the patient's behalf. These notifications must be made within 24 hours after the misadministration is discovered. If the referring physician, patient or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee or registrant shall notify them as soon as practicable. It is not required that the patient be notified without first consulting the referring physician; however, medical care for the patient shall not be delayed because of this.

(iii) Within seven (7) days after an initial therapy misadministration report, the licensee or registrant shall send a written report to the Department. The written report must contain the name of the licensee or registrant, the information required by §175.07(e) (3) and whether the licensee or registrant notified the patient or the patient's responsible relative or guardian. This reporting requirement may be satisfied by submitting to the Department a copy of the incident report filed with the New York State Department of Health pursuant to 10 NYCRR Part 405 provided, however, that such report contains all information required by this Code.

(3) Each licensee or registrant shall maintain a record of each reportable diagnostic misadministration and each therapy misadministration for six (6) years. The record shall contain the names of all individuals involved in the event (including the treating physician, allied health personnel, the patient and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a description of the event, the effect on the patient (including sequelae, prognosis and follow-up actions) and actions taken to prevent recurrence.

(4) Within seven (7) days after an initial therapy misadministration report made pursuant to §175.07(e) (2) (ii), the licensee or registrant shall provide the patient a written report, with a copy to the patient's referring physician. The report shall contain a brief description of the event, the effect on the patient including any change in the patient's health status which resulted from or could result from the misadministration, and recommendations for the appropriate course of treatment or follow-up. If it is not medically advisable to give such information to the patient, the report shall be made available to the patient's responsible relative or guardian on the patient's behalf. Such action shall be documented in the patient's treatment record.