Steve Sisolak
Governor

Richard Whitley, MS
Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

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Lisa Sherych
Administrator

Ihsan Azzam,
Ph.D., M.D.
Chief Medical Officer

Theresa Clark, Deputy Director
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
And Safeguards
U.S. Nuclear Regulatory Commission
T8-E18
Washington, D.C. 20555-0001

Dear Theresa Clark:

Nevada has adopted 10 CFR 35 by reference and our radioactive material licensees are required to report medical events per 10 CFR 35.3045 and 35.3047. In order for an event to qualify as a medical event it must meet the 5 rem threshold.

We would like to add the enclosed license condition to our medical use licenses, which requires licensees to report to us the same events listed in 10 CFR 35.3045 and 35.3047 when they are below the 5 rem threshold. In this license condition, we are referring to the events that are below the 5 rem threshold as a "misadministration". This is an additional reporting requirement above what 10 CFR 35 requires.

Is it acceptable to the NRC for us to add this condition to our medical licenses? Will this condition cause any compatibility issues?

If you have any questions, please feel free to contact me at 702-486-3017 or by email jfollette@health.nv.gov.

Sincerely,

John Follette

John Follette
Manager, Radiation Control Program

Enclosures:
As stated

cc: Karen Beckley, Bureau Chief
Division of Public and Behavioral Health

14. The licensee shall report to RCP all events listed in this license condition. The licensee shall also report to RCP their evaluation of an event, which involves an administration of radioactive material, that has been determined not to be a medical event, as defined in 10 CFR 35.3045 or a reportable dose to an embryo/fetus or nursing child, as defined in 10 CFR 35.3047. When reporting a misadministration or an evaluation of an event, the licensee shall comply with the reporting requirements specified in NAC 459.551.

    The licensee shall report the following events as a misadministration to the RCP:

    A. Any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in—

        (1) The total dose delivered differs from the prescribed dose by 20 percent or more;

        (2) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range;

        (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

        (4) An administration of a wrong radioactive drug containing radioactive material;

        (5) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

        (6) An administration of a dose or dosage to the wrong individual or human research subject;

        (7) An administration of a dose or dosage delivered by the wrong mode of treatment;

        (8) A leaking sealed source; or

        (9) A dose to the skin or an organ or tissue other than the treatment site that exceeds 50 percent 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 site).

    B. Any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

    C. Any dose to an embryo/fetus that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

D. Any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

Below is NAC 459.551, referenced above.

NAC 459.551 Notification and report of medical misadministration; maintenance of record of medical misadministration. (NRS 459.201)

1. A registrant for a radiation machine, including, without limitation, a therapeutic X-ray system, shall:

(a) Notify the Division by telephone not later than the next calendar day after the discovery of a medical misadministration; and

(b) Submit a written report to the Division within 15 days after the discovery of the medical misadministration. The written report must include, without limitation:

(1) The name of the registrant;
(2) The name of the prescribing physician;
(3) A brief description of the medical misadministration;
(4) An explanation as to why the medical misadministration occurred;
(5) The effect, if any, on the person who received the administration of radiation;
(6) The actions, if any, that have been taken or are planned to be taken to prevent reoccurrence; and
(7) Certification that the registrant notified the person who is the subject of the medical misadministration of the medical misadministration as required by subsection 3 or notified that person's responsible relative or guardian as authorized by subsection 5 or, if such notification was not provided, the reason why the notification was not provided.

2. The report submitted pursuant to subsection 1 must not contain the name of the person who is the subject of the medical misadministration or any information that could lead to identification of the person.

3. Except as otherwise provided in this subsection and subsections 4 and 5, the registrant shall, not later than 24 hours after discovery of the medical misadministration, provide notification of the medical misadministration to the referring physician and to the person who is the subject of the medical misadministration unless the referring physician personally informs the registrant that:

(a) He or she will inform the person; or
(b) Based on medical judgment, notifying the person would be harmful.

4. The registrant is not required to notify the person who is the subject of the medical misadministration without first consulting the referring physician. If the referring physician or the person who is the subject of the medical misadministration cannot be reached within 24 hours after discovery of the medical misadministration, the registrant shall notify the person as soon as possible thereafter. The registrant may not delay any appropriate medical care for the person, including any necessary remedial care as a result of the medical misadministration, because of any delay in notification.

5. To meet the requirements of this section, the notification of the person who is the subject of the medical misadministration may be made instead to that person's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the person, or the appropriate responsible relative or guardian, that a written description of the medical misadministration can be obtained from the registrant upon request. The registrant shall provide such a written description if so requested.

6. Aside from the notification requirement, nothing in this section affects any rights or duties of registrants and physicians in relation to each other, to persons affected by the medical

misadministration or to the responsible relatives or guardians of a person affected by the medical misadministration.

7. The registrant shall:

(a) Make and retain for not less than 3 years a record of each medical misadministration reported pursuant to this section. The record must include, without limitation:

(1) The information required to be included in the written report submitted to the Division pursuant to subparagraphs (1) to (6), inclusive, of paragraph (b) of subsection 1;

(2) The name and social security number or other identification number, if one has been assigned, of the person who is the subject of the medical misadministration; and

(3) A statement indicating whether the registrant notified the person who is the subject of the medical misadministration of the medical misadministration or notified that person's responsible relative or guardian of the medical misadministration and, if not, whether the failure to notify such persons was based on the guidance of the referring physician.

(b) Provide a copy of the record of the medical misadministration to the referring physician, if other than the registrant, not later than 15 days after the discovery of the medical misadministration.

8. As used in this section, "medical misadministration" means:

(a) An event that is the result of an intervention of a patient or human research subject in which the administration of radiation from a radiation machine results in or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician; or

(b) Any event, other than an event that is the result of intervention of a patient or human research subject, in which the administration of radiation from a radiation machine results in:

(1) An administration of a dose to the wrong person, using the wrong mode of treatment or at the wrong treatment site; or

(2) The calculated total dose administered differing from the total prescribed dose by 20 percent or more.