REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart M: Reports

This new subpart contains all the reporting requirements necessary to implement the requirements in revised Part 35

- This subpart contains three reporting requirements:
  - 1) Report and notification of a medical event
    - Address patient intervention: Actions by the patient or human research subject, whether intentional or unintentional.
  - 2) Report and notification of a dose to an embryo/fetus or a nursing child
    - This is a new reporting requirement. NRC needs to submit an annual report to Congress of unscheduled incidents or events considered significant from the standpoint of public health and safety, e.g., abnormal occurrences
  - 3) Report of a leaking source

§35.3045 Report and notification of a medical event

- Any event must be reported, except patient intervention, if:

- 1) A dose from the prescribed dose or dose that would have resulted from the prescribed dosage differs by:
  - >5 rem (>0.05 Sv) effective dose equivalent, or
  - >50 rem (>0.5 Sv) to an organ or tissue, or
  - >50 rem (>0.5 Sv) shallow dose equivalent to the skin, AND

  - Total dose delivered differs from the prescribed dose by ≥20%,or
  - Total dosage delivered differs from the prescribed dosage by ≥20% or falls outside the prescribed dosage range, or
  - Fractionated dose delivered differs from the prescribed dose, for a single fraction, by ≥50%

§35.3045 Report and notification of a medical event (continuation)

- 2) A dose that exceeds 5 rem EDE, 50 rem organ or tissue, or 50 rem SDE to the skin from any of the following:
  - Administration of wrong radioactive drug containing byproduct material,
  - Administration of radioactive drug containing byproduct material by wrong route of administration,
  - Administration of dose or dosage to wrong individual or human research subject,
  - Administration of dose or dosage delivered by the wrong mode of treatment, or
  - A leaking sealed source

§35.3045 Report and notification of a medical event (continuation)

- 3) A dose to the skin or an organ or a tissue other than the treatment site that:
  - Exceeds by 50 rem (0.5 Sv) to an organ or tissue, 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 site)

§35.3045 Report and notification of a medical event (continuation)

- Licensees shall report any event resulting from patient intervention which results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician

- Notify NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event
- Submit a written report to the NRC Region within 15 days after discovery of the event

§35.3045 Report and notification of a medical event (continuation)

- Written report must include:
  - Licensee's name;
  - Name of prescribing physician;
  - Brief description of the event;
  - Why the event occurred;
  - Effect, if any, on the individuals(s);
  - Actions taken, if any, or are planned to prevent recurrence; and
  - Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not
- Report may not contain the individual's name or any other information that could lead to his/her identification

§35.3045 Report and notification of a medical event (continuation)

- Licensee is required to notify the referring physician and the individual no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful.
- Licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter.
- The licensee may not delay any medical care for the individual, as a result of the medical event, because of any delay in notification.
- Notification of the individual who is the subject of the medical event may be made instead to that individual's relative or guardian.

§35.3045 Report and notification of a medical event (continuation)

- If a verbal notification is made, the licensee shall inform the individual that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.
  - Note: Under the old rule licensees can provide the individual with a brief description of the event and possible consequences if they include a statement that the individual can also obtain a copy of the report that was submitted to the NRC from the licensee.
  - In the final rule licensees are not required to include a statement that a report was submitted to the NRC because knowledge of this might unduly alarm an individual with no added benefit. However, licensees are required to inform the individual that a written description of the event can be obtained from them upon request.

§35.3045 Report and notification of a medical event (continuation)

- A licensee shall:
- Annotate a copy of the report provided to the NRC with the:
  - Name of the individual; and
  - Social Security Number, or other identification number; and
- Provide a copy of the annotated report to the referring physician, if other than the licensee, within 15 days after discovery of the event

§35.3047 Records and notification of a dose to an embryo/fetus or a nursing child

- A licensee must report any administration of byproduct material, or radiation from byproduct material, to a pregnant female that results in a dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent unless the administration was specifically approved, in advance, by the authorized user
  - Note: Only unintended exposures are required to be reported to NRC

§35.3047 Records and notification of a dose to an embryo/fetus or a nursing child (continuation)

- A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast feeding individual that:
  - Is greater than 50 mSv (5 rem) total effective dose equivalent; or
  - Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician

§35.3047 Records and notification of a dose to an embryo/fetus or a nursing child (continuation)

- Notify NRC Operations Center, by telephone, no later than the next calendar day after the discovery
- Submit a written report to the NRC Regional Office within 15 days after discovery of the event

§35.3047 Records and notification of a dose to an embryo/fetus or a nursing child (continuation)

- Written report must include:
  - Licensee's name;
  - Name of prescribing physician;
  - Brief description of the event;
  - Why the event occurred;
  - Effect, if any, on the individuals(s);
  - Actions taken, if any, or are planned to prevent recurrence; and
  - Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not

- Report may not contain the individual's or child's name or any other information that could lead to the identification

§35.3047 Records and notification of a dose to an embryo/fetus or a nursing child (continuation)

- Licensee is required to notify the referring physician and the pregnant individual or mother no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful.
- Licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter.
- The licensee may not delay any medical care for the embryo/fetus or for the nursing child, as a result of the event, because of any delay in notification.
- Notification may be made to the mother's or child's responsible relative or guardian, when appropriate.

§35.3047 Records and notification of a dose to an embryo/fetus or a nursing child (continuation)

- If a verbal notification is made, the licensee shall inform the pregnant individual, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

§35.3047 Records and notification of a dose to an embryo/fetus or a nursing child (continuation)

- A licensee shall:
- Annotate a copy of the report provided to the NRC with the:
  - Name of the pregnant individual or nursing child; and
  - Social Security Number, or other identification number; and
- Provide a copy of the annotated report to the referring physician, if other than the licensee, within 15 days after discovery of the event

§35.3067 Records of a leaking source

- Licensee must file a report with the appropriate NRC Office and NMSS within 5 days if a leak test required by §35.67 reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination
- The report must contain:
  - Model number & serial number, if assigned, of the leaking source;
  - Radionuclide and its estimated activity;
  - Results of the test;
  - Date of the test; and
  - Action taken
  - Deleted: measured activity of each test sample expressed in μCi, a description of the method used to measure each test sample, and the signature of the RSO