



**REPORTING GUIDELINE:**  
**EXAMPLE FORMAT FOR THERAPY MEDICAL EVENTS**

The use of therapeutic radiation machines in Michigan is subject to registration conditions pursuant to R 333.5039(2). For therapy machines, the Department sets registration conditions requiring a therapy medical events be reported in writing within 30 days of the date of its discovery. A therapy medical event is defined as any event, except one that results from patient intervention, in which the administration of therapeutic radiation:

- (1) Results in the total dose delivered differing from the prescribed dose by 20% or more; or
- (2) Results in any single delivered fraction of a fractionated treatment exceeding the prescribed dose by 50% or more; or
- (3) Involves the wrong patient, wrong treatment modality, or wrong treatment site.

At a minimum, the reporting of a therapy medical event shall contain the elements listed below. Each item should be on a separate line or should constitute a separate paragraph(s).

1. The date this report is prepared.
2. The facility name and address (as it appears on the registration certificate).
3. The facility registration number and registration number of the therapy machine involved.
4. The date the therapy medical event occurred.
5. The date of discovery of the therapy medical event.
6. The name of the prescribing physician.
7. A brief narrative description of the event and its cause.
8. The effect, if any, on the individual(s) who received the administered dose.
9. A narrative detailing the corrective action taken or planned to prevent a recurrence.
10. Certification that the registrant notified the individual (or the individual's responsible relative or guardian). If this notification has not occurred, justification shall be provided.
11. The name and signature of the individual preparing the report.

The report should not contain the name of the affected individual(s) or any other information that could lead to the identification of the individual.

The medical event report can be submitted to the Department by any one of the following methods:

Mailed to: MIOSHA/Radiation Safety Section  
Michigan Department of Licensing and Regulatory Affairs  
525 West Allegan Street  
P.O. Box 30643  
Lansing, Michigan 48909-8143

E-mailed to: [rssinfo@michigan.gov](mailto:rssinfo@michigan.gov)

Faxed to: (517) 763-0131

If additional information is needed contact the Lansing office of the Radiation Safety Section at (517) 284-7820 or the Detroit district office at (313) 456-4660.