



Michigan Department of Licensing and Regulatory Affairs
Radiation Safety Section



REPORTING GUIDELINE:
EXAMPLE FORMAT FOR REPORTABLE CT MEDICAL EVENTS

Rule 333.5715(2) requires that a written report of CT medical event be sent to the Michigan Department of Licensing and Regulatory Affairs, Radiation Safety Section within 15 days of discovery of any event. Rule 333.5715(5) requires that the registrant also provide notification of the CT medical event to the referring physician and the individual who is the subject of the event. The notification to the referring physician and the individual must be provided no later than 1 week after the discovery.

A CT medical event is an unintended event where a physician determines that actual damage has occurred to an organ or a physiological system of an individual due to or suspected to be due to exposure to diagnostic radiation from a CT scanner.

The CT medical event reporting format itemized below can meet the requirements of the Rules. Other formats which meet the requirements are also possible and acceptable.

Each item below should be on a separate line or should constitute a separate paragraph or paragraphs.

1. The registrant's name, address, facility registration number, and machine registration tag number as they appear on the registration certificate.
2. The name of the physician who determined a CT medical event occurred.
3. The dates of occurrence and discovery of the CT medical event.
4. A narrative description of the CT medical event.
5. The cause of the CT medical event.
6. The effect on the individual who received the exposure.
7. A narrative detailing corrective action taken or planned to prevent a recurrence.
8. Certification that the registrant notified the individual or the individual's responsible relative or guardian and, if not, why not.
9. The name and signature of the person preparing the report.

The report shall not contain the individual's name or any other information that could lead to the identification of the individual.

The registrant shall provide notification of the CT medical event to the referring physician and shall notify the individual who is the subject of the CT medical event no later than 1 week after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 1 week, the registrant should notify the individual as soon as possible thereafter. The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the CT medical event, because of any delay in notification. The notification of the individual who is the subject of the CT medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual or appropriate responsible relative or guardian that a written description of the CT medical event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

REPORTING GUIDELINE:
EXAMPLE FORMAT FOR REPORTABLE CT MEDICAL EVENTS

The CT 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

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.