

NOTICE OF INTENT

Department of Environmental Quality
Office of Environmental Assessment

Medical Events Occurring from X-Rays
(LAC 33:XV.102, 613, 615, 915, and 917) (RP038)

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary gives notice that rulemaking procedures have been initiated to amend the Radiation Protection regulations, LAC 33:XV.102, 613, 615, 915, and 917 (Log #RP038).

This rule adds new sections to the radiation regulations for medical events occurring as a result of the misadministration of X-rays to human beings in the healing arts. LAC 33:XV.613 and 915 are being added to mirror the changes adopted for radioactive materials in LAC 33:XV.712, for notifications of medical events involving the use of X-rays. LAC 33:XV.615 and 917 are being added to mirror the changes adopted for radioactive materials in LAC 33:XV.710, for notifications for embryos/fetuses of medical events involving the use of X-rays. In June 2004, the department adopted new regulations for medical use of radioactive materials in order to mirror the new federal regulations. The definition for misadministration was eliminated and a new definition for medical event was adopted. The new definition was taken verbatim from the NRC rule, which does not include misadministrations occurring from X-rays. The department regulates diagnostic X-ray energies and linear accelerators in LAC 33:XV.Chapters 6 and 9, while the NRC does not. Additionally, new federal reporting requirements were also adopted regarding dose to an embryo/fetus. These new requirements need to be adopted with regard to X-rays as well, for both diagnostic and therapeutic X-ray energies. The basis and rationale for this rule are to modify the adopted federal regulation definition of medical event for misadministrations of radioactive material and reporting requirements for a dose to an embryo/fetus to include not only radioactive material but also X-ray radiation, which is not regulated by the NRC but is regulated by the department.

This proposed rule meets an exception listed in R.S. 30:2019(D)(2) and R.S. 49:953(G)(3); therefore, no report regarding environmental/health benefits and social/economic costs is required. This proposed rule has no known impact on family formation, stability, and autonomy as described in R.S. 49:972.

A public hearing will be held on March 29, 2005, at 1:30 p.m. in the Galvez Building, Oliver Pollock Conference Room C111, 602 N. Fifth Street, Baton Rouge, LA 70802. Interested persons are invited to attend and submit oral comments on the proposed amendments. Should individuals with a disability need an accommodation in order to participate, contact Judith A. Schuerman, Ph.D., at the address given below or at (225) 219-3550. Free parking is available across the street in the Galvez parking garage when the parking ticket is validated by department personnel at the hearing.

All interested persons are invited to submit written comments on the proposed regulation. Persons commenting should reference this proposed regulation by RP038. Such comments must be received no later than April 5, 2005, at 4:30 p.m., and should be sent to Judith A. Schuerman, Ph.D., Office of Environmental Assessment, Regulation Development Section, Box 4314, Baton Rouge, LA 70821-4314 or to FAX (225) 219-3582 or by e-mail to judith.schuerman@la.gov. Copies of this proposed regulation can be purchased by contacting the DEQ Public Records Center at (225) 219-3168. Check or money order is required in advance for each copy of RP038. This regulation is available on the Internet at <http://www.deq.louisiana.gov/planning/regs/index.htm>.

This proposed regulation is available for inspection at the following DEQ office locations from 8 a.m. until 4:30 p.m.: 602 N. Fifth Street, Baton Rouge, LA 70802; 1823 Highway 546, West Monroe, LA 71292; State Office Building, 1525 Fairfield Avenue, Shreveport, LA 71101; 1301 Gadwall Street, Lake Charles, LA 70615; 201 Evans Road, Building 4, Suite 420, New Orleans, LA 70123; 111 New Center Drive, Lafayette, LA 70508; 110 Barataria Street, Lockport, LA 70374.

Wilbert F. Jordan, Jr.
Assistant Secretary

Title 33

ENVIRONMENTAL QUALITY

Part XV. Radiation Protection

Chapter 1. General Provisions

§102. Definitions and Abbreviations

As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain chapter may be found in that chapter.

* * *

Medical Event—an event that meets the criteria in LAC 33:XV.613.A, 712.A., or 915.A.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), LR 19:1421 (November 1993), LR 20:650 (June 1994), LR 22:967 (October 1996), LR 24:2089 (November 1998), repromulgated LR 24:2242 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2563 (November 2000), LR 26:2767 (December 2000), LR 30:1171, 1188 (June 2004), amended by the Office of Environmental Assessment, LR 31:44 (January 2005), LR 31:**.

Chapter 6. X-Rays in the Healing Arts

§613. Notifications, Reports, and Records of Medical Events

A. A registrant shall report any medical event, except for an event that results from patient intervention, in which the administration of radiation involves the wrong patient, a procedure different than that which was authorized by the licensed practitioner of the healing arts, or a body site different from that which was authorized and intended to be exposed by the authorized X-ray procedure.

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

C. All reports, notifications, and records shall be in accordance with LAC 33:XV.712.C, D, and F.

D. Aside from the notification requirement, nothing in this Section affects any rights or duties of registrants and physicians in relation to each other, the individual, or the individual's responsible relatives or guardians.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2104 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality,
Office of Environmental Assessment, LR 31:**.

§615. Report and Notification of a Dose to an Embryo/Fetus

A. A registrant shall report any dose to an embryo/fetus in excess of 50 mSv (5 rem) dose equivalent that is a result of a diagnostic X-ray procedure, in accordance with LAC 33:XV.710.A and C-F.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2104 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality,
Office of Environmental Assessment, LR 31:**.

Chapter 9. Radiation Safety Requirements for Particle Accelerators

Subchapter B. Radiation Safety Requirements for the Use of Particle Accelerators

§915. Notifications, Reports, and Records of Medical Events

A. A registrant shall report any medical event, except for an event that results from patient intervention, in which the administration of radiation results in one or more of the events described in LAC 33:XV.712.A or involves the wrong patient, wrong treatment site, or wrong mode of treatment.

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

C. All reports, notifications, and records shall be in accordance with LAC 33:XV.712.C, D, and F.

D. Aside from the notification requirement, nothing in this Section affects any rights or duties of registrants and physicians in relation to each other, the individual, or the individual's responsible relatives or guardians.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2104 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality,
Office of Environmental Assessment, LR 31:**.

§917. Report and Notification of a Dose to an Embryo/Fetus

A. A registrant shall report any dose to an embryo/fetus in excess of 50 mSv (5 rem) dose equivalent that is a result of a therapeutic X-ray procedure, in accordance with LAC 33:XV.710.A and C-F.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2104 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality,
Office of Environmental Assessment, LR 31:**.

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

LOG #: RP038

Person

Preparing

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Return

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Rule

Title: Medical Events Occurring from
X-rays (LAC 33:XV.102, 613, 615, 915,
917)

Date Rule

Takes Effect: Upon promulgation**SUMMARY**

(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There are no expected implementation costs or savings to state or local governmental units as a result of the proposed rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There is no estimated effect on revenue collections of state or local governmental units by the proposed rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

There are no estimated costs and/or economic benefits to directly affected persons or non-governmental groups by the proposed rule.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There is no estimated effect on competition or employment by the proposed rule.

Signature of Agency Head or Designee

Legislative Fiscal Officer or Designee

Wilbert F. Jordan, Jr., Assistant Secretary
Typed Name and Title of Agency Head or Designee

Date of Signature

Date of Signature

LFO 03/09/2001

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

The following information is requested in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

This rule adds new sections to Chapters 6 and 9 of LAC 33:XV (LAC 33:XV.613, 615, 915 and 917), and modifies the definition of "medical event" in Chapter 1 to reference the new sections in Chapters 6 and 9 on medical events occurring as a result of the misadministration of X-rays to human beings in the healing arts. Sections 613 and 915 are being added to Chapters 6 and 9, respectively, to mirror, for the medical use of X-rays, the changes recently adopted in LAC 33:XV.712 for notifications of "medical events" (previously "misadministrations") involving application of radioactive materials. Sections 615 and 917 are being added to Chapters 6 and 9 to mirror the changes adopted in LAC 33:XV.710 for such notifications for embryos/fetuses.

- B. Summarize the circumstances which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

In June 2004, LDEQ adopted new regulations for medical use of radioactive materials in order to mirror new federal regulations. In doing so, the definition of "misadministration" was eliminated and a new definition of "medical event" was adopted in its place. The new definition was taken verbatim from the NRC rule, which does not address misadministrations occurring from X-rays. New reporting requirements were also adopted from the new federal rule regarding doses of radioactive materials to an embryo/fetus. These new notification/reporting requirements now need to be adopted with regard to X-rays as well, for both diagnostic and therapeutic X-ray energies.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session
(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

No increase in expenditure of funds is expected as a result of the proposed rule.

- 2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

- (a) _____ Yes. If yes, attach documentation.
(b) _____ No. If no, provide justification as to why this rule change should be published at this time.

This question is not applicable.

FISCAL AND ECONOMIC IMPACT STATEMENT

WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

| COSTS | FY 04-05 | FY 05-06 | FY 06-07 |
|-----------------------------------|----------|----------|----------|
| PERSONAL SERVICES _____ | | | |
| OPERATING EXPENSES _____ | | | |
| PROFESSIONAL SERVICES _____ | | | |
| OTHER CHARGES _____ | | | |
| EQUIPMENT _____ | | | |
| TOTAL | -0- | -0- | -0- |
| MAJOR REPAIR & CONSTR. | | | |
| POSITIONS (#) | -0- | -0- | -0- |

2. Provide a narrative explanation of the costs or savings shown in "A.1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The proposed rule should not result in any increase or decrease in costs to implement the proposed action.

3. Sources of funding for implementing the proposed rule or rule change.

| SOURCE | FY 04-05 | FY 05-06 | FY 06-07 |
|-----------------------------|----------|----------|----------|
| STATE GENERAL FUND _____ | | | |
| AGENCY SELF-GENERATED _____ | | | |
| DEDICATED _____ | | | |
| FEDERAL FUNDS _____ | | | |
| OTHER (Specify) _____ | | | |
| TOTAL | -0- | -0- | -0- |

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The agency has sufficient funds to implement the proposed rule.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

There will be no impact on local governmental units.

2. Indicate the sources of funding of the local governmental unit which will be affected by these costs or savings.

This does not apply.

FISCAL AND ECONOMIC IMPACT STATEMENT

WORKSHEET

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

| REVENUE INCREASE/DECREASE | FY 04-05 | FY 05-06 | FY 06-07 |
|-----------------------------|------------|------------|------------|
| STATE GENERAL FUND _____ | | | |
| AGENCY SELF-GENERATED _____ | | | |
| RESTRICTED FUNDS* _____ | | | |
| FEDERAL FUNDS _____ | | | |
| LOCAL FUNDS _____ | | | |
| TOTAL | -0- | -0- | -0- |

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

This does not apply.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS

A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

There will be no costs and/or economic benefits to directly affected persons or non-governmental groups.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

This does not apply.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

There will be no impact on competition or employment in the public or private sector from the proposed action.