

NOTICE OF INTENT

Department of Environmental Quality
Office of the Secretary
Legal Division

Exemptions from Licensing, General Licenses and Distribution of Byproduct Material: Licensing
& Reporting Requirements
(LAC 33:XV.304 and 328) (RP052ft)

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.304 and 328 (Log #RP052ft).

This rule is identical to federal regulations found in 10 CFR 30, which are applicable in Louisiana. For more information regarding the federal requirement, contact the Regulation Development Section at (225) 219-3985 or Box 4302, Baton Rouge, LA 70821-4302. No fiscal or economic impact will result from the rule. This rule will be promulgated in accordance with the procedures in R.S. 49:953(F)(3) and (4).

This rule will update the state regulations to be compatible with the changes in the federal regulations. This Rule addressess exemptions from licensing, general licenses and licensing and reporting for the distribution of byproduct material. The changes in the state regulations are federal category B & C requirements for the State of Louisiana to remain an NRC Agreement State. The basis and rationale for this rule is to mirror the federal regulations and maintain an adequate Agreement State program. This 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 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 August 29, 2012, at 1:30 p.m. in the Galvez Building, Oliver Pollock Conference Room, 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 Deidra Johnson at the address given below or at (225) 219-3985. Two hours of free parking are allowed in the Galvez Garage with a validated parking ticket.

All interested persons are invited to submit written comments on the proposed regulation. Persons commenting should reference this proposed regulation by RP052ft. Such comments must be received no later than August 29, 2012, at 4:30 p.m., and should be sent to Deidra Johnson, Attorney Supervisor, Office of the Secretary, Legal Division, Box 4302, Baton Rouge, LA 70821-4302 or to FAX (225) 219-4068 or by e-mail to deidra.johnson@la.gov. The comment

period for this rule ends on the same date as the public hearing. 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 RP052ft. This regulation is available on the Internet at www.deq.louisiana.gov/portal/tabid/1669/default.aspx.

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; 111 New Center Drive, Lafayette, LA 70508; 110 Barataria Street, Lockport, LA 70374; 201 Evans Road, Bldg. 4, Suite 420, New Orleans, LA 70123.

Herman Robinson, CPM
Executive Counsel

Title 33

ENVIRONMENTAL QUALITY

Part XV. Radiation Protection

Chapter 3. Licensing of Radioactive Material

Subchapter A. Exemptions

§304. Radioactive Material Other Than Source Material

A. – C.1.b. ...

c. Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007.

d. ...

e. Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007.

1.f. – 3.c. ...

~~4. Resins Containing Scandium-46, Designed for Sand Consolidation in Oil Wells. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing scandium-46 that are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the administrative authority or any other agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those contained in 10 CFR 32.16 and 32.17. This exemption does not authorize the manufacture of any resins containing scandium-46.~~

54. Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use for Humans

a. Except as provided in Subparagraphs C.54.b and c of this Section, any person is exempt from the requirements for a license set forth in these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37

kBq (1 μ Ci) carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing process), for "in vivo" diagnostic use for humans.

b. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license in accordance with LAC 33:XV.Chapters 3 and 7.

c. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license in accordance with LAC 33:XV.328.K.

d. Nothing in this Section relieves persons from complying with applicable FDA, other federal, and state requirements governing receipt, administration, and use of drugs.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.1.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), LR 24:2091 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 27:1226 (August 2001), amended by the Office of the Secretary, Legal Affairs Division, LR 38:**.

§328. Special Requirements for Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material

A. – J.4. ...

K. License Requirements for the Manufacture, Preparation, or Transfer for Commercial Distribution of Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use in Humans

1. An application for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing 37 kBq (1 μ Ci) carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing process) for "in vivo" diagnostic use, to persons exempt from licensing under LAC 33:XV.304.C.54 will be approved if:

K.1.a. – M.4.g. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.1.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), LR 24:2092 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2569 (November 2000), LR 26:2768 (December 2000), LR 27:1228 (August 2001), LR 30:1664 (August 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2526 (October 2005), LR 33:2179 (October 2007), LR 36:1771 (August 2010), LR 38:**.