Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§30.21	Radioactive drug: Capsules containing carbon-14 urea for ``in vivo'' diagnostic use for humans.		B	**New Section:** (a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from the regulations in this part and part 35 of this chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 mCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, 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 pursuant to part 35 of this chapter. (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 pursuant to Sec. 32.21 of this chapter.			

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				(d) Nothing in this section relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.			
§32.21	Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for ``in vivo'' diagnostic use for humans to persons exempt from licensing; Requirements for a license		NRC	**New Section:** (a) An application for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing 37 kBq (1mCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for ``in vivo'' diagnostic use, to persons exempt from licensing under Sec. 30.21 of this chapter or the equivalent regulations of an Agreement State will be approved if: (1) The applicant satisfies the general requirements specified in Sec. 30.33 of this chapter, provided that the requirements of Sec. 30.33(a)(2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;			

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				(2) The applicant meets the requirements under Sec. 32.72(a)(2) of this part; (3) The applicant provides evidence that each capsule contains 37 kBq (1 mCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process); (4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being; (5) The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and (6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures. (b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.			

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§32.21a	Same: Conditions of license.		NRC	**New Section:** (a) The immediate container of the capsule(s) must bear a durable, legible label which: (1) Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and (2) Bears the words “Radioactive Material." (b) In addition to the labeling information required by paragraph (a) of this section, the label affixed to the immediate container, or an accompanying brochure also must: (1) State that the contents are exempt from NRC or Agreement State licensing requirements; and (2) Bear the words ”Radioactive Material”. For “In Vivo" Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured for Commercial Distribution. This Material May Be Disposed of in Ordinary Trash."			