Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation—Part 3. Licensing of Sources of Radiation.

28-35-178j. General license for use of radioactive material for certain in vivo clinical or laboratory testing.

(a) Except as provided in subsections (b) and (c), each person shall be exempt from the license requirements in part 3 and part 6 of these regulations if the person receives, possesses, uses, transfers, owns, or acquires any capsules containing 37 kBq (1 μCi) of carbon-14 urea, allowing for nominal variation that may occur during the manufacturing process for in vivo diagnostic use for humans.

(b) Before using the capsules specified in subsection (a) for research involving human subjects, each person shall apply and shall be considered for approval for a specific license. Each person shall be required to have a specific license before engaging in the research specified in this subsection.

(c) Before manufacturing, preparing, processing, producing, packaging, repackaging, or transferring the capsules specified in subsection (a) for commercial distribution, each person shall apply and shall be considered for approval for a specific license. Each person shall be required to have a specific license before performing any of the actions specified in this subsection.

(d) Nothing in this regulation shall exempt any person from applicable FDA requirements, other federal requirements, and state requirements governing receipt, administration, and use of drugs.

(Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended March 18, 2011.)

***** Authenticated Kansas Administrative Regulation *****