In August of 2007, The Nuclear Regulatory Commission (NRC) amended its regulations to include jurisdiction over discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. This provided a regulatory framework by which to license and regulate byproduct material in accordance with the new, expanded definition. The amended regulations impacted numerous existing NRC information collections. The NRC packaged all the impacted information collections under the amended regulations and submitted it to OMB as a new information collection, which OMB approved and assigned control number 3150-0203. NRC is submitting this “no material or nonsubstantive change to a currently approved collection” to move the approved information collection burden covered under part 32 in this collection to the NRC existing approved collection for Part 32, 3150-0001.

One of the areas of existing Nuclear Regulatory Commission (NRC) regulations revised was Part 32 of which the information collection is covered by the currently approved information collection 3150-0001. The amended sections of Part 32 covered in 3150-0203 are outlined below.

Section 32.72(a)(4) requires that an applicant for a license pursuant to Section 32.72 satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The universe of licensees affected by this regulation is increased by an estimated 22 NRC licensees and 88 new Agreement State licensees.

Section 32.72(b)(5) applies to licensees that are licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution. These licensees are required to provide the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the State pharmacy licensure or registration. The universe of licensees affected by this regulation is increased by an estimated 22 NRC licensees and 88 new Agreement State licensees.

Section 32.72(c) requires that a licensee that possesses and uses instrumentation to measure radioactivity of radioactive drugs, pursuant to Section 32.72, shall have procedures for use of the instrumentation. The licensees may use procedures provided by the manufacturer of the instrumentation. There is an annualized one-time implementation burden for an estimated 22 NRC licensees and 88 new Agreement State licensees.

Section 32.74(a)(2)(viii) requires that persons licensed pursuant to Section 32.74 label the source or device with instructions for handling and storing the source or device from the radiation safety standpoint. The universe of licensees affected by this regulation is increased by an estimated 3 NRC licensees and 12 new Agreement State licensees.