

JUSTIFICATION FOR CHANGE IN AN OMB CLEARANCE PACKAGE
10 CFR PART 35
(3150-0010)

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 provides a regulatory framework by which to license and regulate byproduct material in accordance with the new, expanded definition. The amended regulations impacted numerous existing information collections. The NRC packaged all of the impacted information collections into one new information collection which OMB approved and assigned control number 3150-0203.

The clearance affecting this 83-C is 10 CFR Part 35, "Medical Use of Byproduct Material," which is currently covered under OMB Clearance 3150-0010. This regulation contains NRC's requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects.

The purpose of this 83-C is to transfer burden from OMB Clearance 3150-0203, "10 CFR Parts 20, 30, 31, 32, & 35, Requirements for Expanded Definition of Byproduct Material, Final Rule and NRC Forms 4, 5, 313, 314, & 664," to OMB Clearance 3150-0010, "Medical Use of Byproduct Material," which was contained in the final rule approved on 8/23/07. 10 CFR Part 35 regulations contain NRC's requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. Once the entire burden for 3150-0203 has been transferred to the correct clearances, we will submit an 83-D to discontinue 2150-0203. A total of 38,194 hours will be transferred to 3150-0010, resulting in a revised total burden of 1,025,958 hours.

Current Approved Burden for 3150-0010:

Number of Respondents:	8,751 respondents (1,862 NRC + 6,889 Agreement State)
Number of Responses:	259,332 responses (55,208 NRC + 204,124 Agreement State)
Total Burden Hours:	987,764 hrs (251,200 hrs NRC + 736,564 hrs Agreement State)

Total Burden Being Transferred from 3150-0203:

Number of Respondents:	123 respondents (28 NRC + 95 Agreement State)
Number of Responses:	2,062 responses (421 NRC + 1,641 Agreement State)
Total Burden Hours:	38,194 hrs (8,313 hrs NRC + 29,881 hrs Agreement State)

Total Revised Burden for 3150-0010:

Number of Respondents:	8,874 respondents (1,890 NRC + 6,984 Agreement State)
Number of Responses:	261,394 responses (55,629 NRC + 205,765 Agreement State)
Total Burden Hours:	1,025,958 hrs (259,513 hrs NRC + 766,445 hrs Agreement State)