Nuclear Regulatory Commission

§ 35.10 Implementation.

by another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research—

(1) Obtain review and approval of the research from an “Institutional Review Board,” as defined and described in the Federal Policy; and

(2) Obtain “informed consent,” as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

(67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002)

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150–0010.

(b) The approved information collection requirements contained in this part appear in §§35.6, 35.12, 35.13, 35.14, 35.19, 35.21, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047 and 35.3067.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §35.12, NRC Form 313, including NRC Form 313A, which licensees may use to provide supplemental information, is approved under control number 3150–0120.

(2) [Reserved]