

ASSESSMENT OF FEDERAL REGULATIONS  
AND POLICIES ON FAMILY

AGENCY: Nuclear Regulatory Commission

TITLE OF ACTION 10 CFR Parts 20, 32, and 35, Medical Use of Byproduct Material

UPCOMING ACTION Final Rule

RIN: 3150-AF74

ESTIMATED DATE OF  
ISSUANCE: September 2000

STATUTORY OR  
JUDICIAL DEADLINE: None

DESCRIPTION OF ACTION:

This final rule is a comprehensive revision of 10 CFR Part 35, "Medical Use of Byproduct Material." It relaxes certain prescriptive requirements in the current 10 CFR Part 35 with respect to Radiation Safety Committees, quality management programs, training and experience, reporting and recordkeeping, and other requirements currently covered by both 10 CFR Part 35 and 10 CFR Part 20.

At the same time that it revises Part 35, the final rule also amends the regulations in 10 CFR Part 20, "Standards for protection against radiation," § 20.1301, in response to a Petition for Rulemaking (PRM-20-24) dated April 7, 1996, from the University of Cincinnati. PRM-20-24 requests NRC to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to 5 mSv (0.5 rem) of radiation exposure per year, rather than the current limit of 1 mSv (0.1 rem) in 10 CFR 20.1301.

POTENTIAL EFFECT ON FAMILIES:

The majority of the regulations promulgated in this rule do not pertain to families and are not likely to result in any of the impacts outlined in the seven assessment factors below. However, the estimated cost savings to NRC licensees from the new requirements, as compared to the current requirements, is approximately eight million dollars annually. This cost savings provides a general societal benefit, and may translate into lower costs for families that purchase health care insurance, or who have a member in need of medical services that use NRC-licensed material. In addition, the final rule contains three provisions that can benefit families in certain case-specific instances, as discussed below.

## ASSESSMENT:

1. The action strengthens or erodes the stability of the family and, particularly, the marital commitment.

The final rule can strengthen the stability of the family by expanding the circumstances and the time allowed for family members and others to visit a patient confined to a medical institution while undergoing radiation therapy using NRC-licensed material. Previously, visitors were subject to the dose limit for members of the general public, which is 1 mSv (0.1 rem). The final rule amends 10 CFR 20.1301 to permit visitors to receive up to 5 mSv (0.5 rem) if permitted by the physician authorized user.

The final rule can strengthen the stability of the family by permitting a patient with a temporary implant containing byproduct material to return to the family rather than remain hospitalized. Release from the medical institution is subject to certain radiation dose limitations for family members and others. The provision that allows a medical institution to release a patient with a temporary implant is 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material." Before this final rule, § 35.75 was entitled, "Release of individuals containing radiopharmaceuticals or permanent implants." It did not permit the release of a patient with a temporary implant.

2. The action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children.

See comments under Assessment Factor No. 1. Because the final rule expands the circumstances and the time allowed for visits to a child confined to a medical institution while undergoing radiation therapy using NRC-licensed material, the final rule can strengthen parental ability to nurture a child in this case-specific instance.

In addition, the final rule may allow a child with a temporary implant containing byproduct material to be released from the medical institution and return to the family, in which case the ability of the family to nurture the child is strengthened.

3. The action helps the family perform its functions, or substitutes government activity for the function.

Section 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child," establishes the criteria for reporting the radiation dose received by an embryo/fetus or nursing child incidental to the diagnosis or treatment of the mother. If a report is required, the licensee must notify the referring physician and pregnant individual or mother unless the referring physician informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. In addition, the licensee must provide the referring physician with a copy of the record of the event and have a written description of the event available for the mother, or the mother's or child's responsible relative or guardian. This provision will provide both the referring

physician and the mother with information needed to make health care decisions in this sensitive area.

4. The action increases or decreases disposable income or poverty of families and children.

See second comment under Assessment Factor No. 1. The final rule can result in shorter hospital stays for patients being treated with a temporary implant containing byproduct material. Under this case-specific instance, healthcare costs would be lower, and there may be less travel and meal expense for family members who would otherwise have to make visits to the patient at the medical institution.

Additionally, as noted above, there is an estimated cost savings of approximately eight million dollars annually to NRC licensees from the final rule, as compared to the current requirements. This cost savings provides a general societal benefit, and could lower costs incrementally for families that purchase health care insurance, or who have a member in need of medical services that use NRC-licensed material.

5. The proposed benefits of the action justify the financial impact on the family.

This action will not have a negative financial impact on the family.

6. The action may be carried out by State or local government or by the family.

This assessment factor is not relevant to the final rule.

7. The action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

This assessment factor is not relevant to the final rule.

#### NEGATIVE EFFECTS:

The NRC has determined that this action will not negatively affect family well-being.

RECORD OF COMPLIANCE WITH  
"ASSESSMENT OF FEDERAL REGULATION AND POLICIES ON FAMILIES"

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The requirements of the Act apply to this action because the action may affect family well-being.

Signed \_\_\_\_\_

Dated: \_\_\_\_\_