

2. Table 2 to part 226 is amended by revising the following entries and footnote 2, and by removing the entry for "Ledge Point" under "Southeast

Alaska" and adding in its place the entry for "Gran Point", to read as follows:

* * * * *

TABLE 2 TO PART 226

State/region/site	Boundaries to—			
	Latitude	Longitude	Latitude	Longitude
Alaska:				
Central Aleutians:				
Seguam I:				
South ¹	52°19.5N	172°18.0W	52°15.0N	172°37.0W
Western Gulf of Alaska:				
Bird I ¹	54°40.5N	163°18.0W		
Central Gulf of Alaska:				
Ushagat I ¹	58°55.0N	152°22.0W		
Eastern Gulf of Alaska:				
Cape Fairweather	58°47.5N	137°56.3W		
Graves Rock	58°14.5N	136°45.5W		
Southeast Alaska:				
Biorka I	56°50.0N	135°34.0W		
Cape Addington	55°26.5N	133°49.5W		
Cape Cross	57°55.0N	136°34.0W		
Cape Ommaney	56°10.5N	134°42.5W		
Coronation I	55°56.0N	134°17.0W		
Gran Point	59°08.0N	135°14.5W		
Lull Point	57°18.5N	134°48.5W		

¹ Includes an associated 20 nm aquatic zone.

² Associated 20 nm aquatic zone lies entirely within one of the three special foraging areas.

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Proposed Rules

Federal Register

Vol. 59, No. 114

Wednesday, June 15, 1994

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 300

RIN 3206-AG06

Time-In-Grade Rule Eliminated

AGENCY: Office of Personnel Management.

ACTION: Proposed rulemaking.

SUMMARY: The Office of Personnel Management (OPM) is proposing to abolish the time-in-grade restriction on advancement to positions in the General Schedule. This proposal would implement recommendations of the President's National Performance Review and National Partnership Council. Abolishment of the restriction would eliminate the 1-year service requirement for promotions (but employees would have to meet qualification requirements).

DATES: Written comments will be considered if received no later than July 15, 1994.

ADDRESSES: Send or deliver written comments to Leonard R. Klein, Associate Director for Career Entry, Office of Personnel Management, room 6F08, 1900 E Street, NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Leota Shelkey Edwards on 202-606-0830 (FAX 202-606-2329).

SUPPLEMENTARY INFORMATION: Since the early 1950's, Federal employees in General Schedule positions at GS-5 and above have been required to serve at least 1 year in grade before being promoted. The restriction originated in statute with the "Whitten Amendment," a series of controls on expansion of the Federal work force during the Korean conflict. The intent of the restriction was to prevent excessively rapid promotions. Since expiration of the Whitten Amendment in 1978, OPM has continued the time-in-grade restriction in regulation but limited its application to General Schedule positions in the competitive service.

In its report *From Red Tape to Results: Creating a Government That Works Better & Costs Less*, the National Performance Review (NPR) recommended abolishing the time-in-grade restriction. The restriction can limit open competition by eliminating candidates who have the proven ability to perform the duties of higher grade positions, but have not served at least one year in lower graded Government positions.

The National Partnership Council, established by Executive Order 12871 of October 1, 1993, was responsible for developing legislative proposals for the President to implement the NPR recommendations. The Council, too, recommended abolishing the time-in-grade restriction (see *A Report to the President on Implementing Recommendations of the National Performance Review by the National Partnership Council, January 1994*). The Council further recommended that, as a condition of employment, the current time-in-grade requirement remain in effect for bargaining unit employees until the parties agree to modify it through either consensus or collective bargaining.

This document proposes to implement the NPR and Council recommendations and abolish the time-in-grade restriction. Eliminating the restriction would mean that employees' promotion eligibility will be based on their meeting qualification requirements. Also, agencies no longer would need OPM approval of training agreements that provide for consecutive accelerated promotions, as discussed in former Federal Personnel Manual subchapter 7, chapter 338 (provisionally retained through December 31, 1994, in the FPM Sunset Document.)

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it affects only certain Federal employees.

List of Subjects in 5 CFR Part 300

Government employees, Personnel Management Office.

Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM proposes to amend 5 CFR Part 300, as follows:

PART 300—EMPLOYMENT (GENERAL)

The authority citation for part 300 is revised to read as follows:

Authority: 5 U.S.C. secs. 552, 3301, 3302; E.O. 10577, 3 CFR, 1954-1958 Comp., page 218, unless otherwise noted.

Secs. 300.101 through 300.104 also issued under 5 U.S.C. secs. 7201, 7204, 7701; E.O. 11478, 3 CFR, 1966-1970 Comp., page 803.

Secs. 300.401 through 300.408 also issued under 5 U.S.C. secs. 1302(c), 2301, and 2302.

Secs. 300.501 through 300.507 also issued under 5 U.S.C. 1103(a)(5).

Subpart F—[Removal and Reserved]

2. In Part 300, Subpart F, consisting of §§ 300.601 through 300.606, is removed and reserved.

[FR Doc 94-14519 Filed 6-14-94; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Parts 1942, 1948, 1951, and 1980

RIN 0575-AB77

Loans and Grants to Rural Associations and Public Bodies

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to amend its regulations to increase the loan size threshold for requiring interim financing, clarify instructions governing the preparation of Community Program notes and bonds, modify the procedures for monitoring graduation of existing borrowers to other credit, clarify procedures for servicing loans to borrowers whose loans were sold in the 1987 Community Program Asset Sale, implement use of an applicant's Internal Revenue Service (IRS) Taxpayer Identification Number (TIN), and provide consistency in docket preparation through the use of a checklist. This action is necessary to reduce the burden on the public, comply with the OMB Circular A-129 and simplify procedures for the agency's field staff.

The intended effect of this change is to bring the agency in compliance with OMB Circular A-129, and to clarify and

simplify the agency regulations to provide better service to the public.

In the Food, Agriculture, Conservation and Trade Act of 1990, Congress transferred certain community and business programs administered by FmHA to the newly created Rural Development Administration (RDA). Until further notice, RDA programs continue to be administered under FmHA programs regulations.

DATES: Comments must be submitted on or before August 15, 1994.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Regulations Analysis and Control Branch, Farmers Home Administration, U.S. Department of Agriculture, room 6348, South Agriculture Building, 14th Street and Independence Avenue SW., Washington, DC 20250-0700. All written comments made pursuant to this notice will be available for public inspection during regular working hours at the above address.

FOR FURTHER INFORMATION CONTACT: Bill Barrett, Senior Loan Specialist, Community Facilities Division, Rural Development Administration, U.S. Department of Agriculture, room 6310, South Agriculture Building, 14th Street and Independence Avenue SW., Washington DC 20250-0700, telephone (202) 720-1498.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The reporting and recordkeeping requirements contained in these regulations have been submitted to the Office of Management and Budget for review under section 350(h) of the Paperwork Reduction Act of 1980. The public reporting burden for this collection of information is estimated to vary from 10 minutes to 15 hours per response, with an average of 2.47 hours per response including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, room 404-W, Attention: Desk Officer for Farmers Home Administration, Washington, DC, 20503.

Classification

We are issuing this proposed rule in conformance with Executive Order 12866, and we have determined that it is not a "significant regulatory action." Based on information compiled by the

Department, we have determined that this proposed rule: (1) Would have an effect on the economy of less than \$100 million; (2) would not adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (3) would not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (4) would not alter the budgetary impact of entitlements, grants, user fees, or loan programs or rights and obligations of recipients thereof; and (5) would not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or principles set forth in Executive Order 12866.

Intergovernmental Review

The programs/activities are listed in the Catalog of Federal Domestic Assistance under numbers 10.764, Resource Conservation and Development Loans; 10.760, Water and Waste Disposal Systems for Rural Communities; 10.770, Water and Waste Disposal Loans and Grants (Section 306C); 10.766, Community Facilities Loans; and 10.434, Nonprofit National Corporation Loan and Grant Program. The Section 601—Energy Impacted Area Development Assistance Program is not in the Catalog of Federal Domestic Assistance because it is not funded. All programs listed are subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. FmHA conducts intergovernmental consultation in the manner delineated in FmHA Instructions 1901-H and 1940-J.

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR Part 1940, Subpart G, "Environmental Program." FmHA has determined this action does not constitute a major Federal action significantly affecting the quality of human environment, and in accordance with the National Environmental Policy Act of 1969, Public Law 91-190, an Environmental Impact Statement is not required.

Compliance with Executive Order 12778

The regulation has been reviewed in light of Executive Order 12778 and meets the applicable standards provided in sections 2(a) and 2(b)(2) of that Order. Provisions within this part which are inconsistent with state law are controlling. All administrative remedies

pursuant to 7 CFR Part 1900 Subpart B must be exhausted prior to filing suit.

The Agency regulations require the use of interim construction financing for all Community Program loans of \$50,000 or more to encourage the participation of local lenders and to reduce the need for multiple draws of FmHA loan funds. Interim financing is not cost effective for very small loans and for those projects that have a short construction period due to the duplication of much of the financing costs for the two issues. The Agency proposes to raise the loan size threshold from \$50,000 to \$100,000 to reduce the burden on smaller issues, and give the State Director additional authority to waive the interim financing requirement for larger issues, projects with a construction period of 6 months or less, and under other circumstances when the cost is considered prohibitive.

1. The proposed changes will assist FmHA field employees, attorneys, and bond counsel in preparing promissory notes and bonds for Community Programs loans. The section of the regulations used by bond counsels and others in drafting debt instruments for Community Programs loans has been found to be incomplete, vague, or poorly organized.

2. FmHA proposes to amend its regulations to incorporate and require the use of Guide 28, "Community Programs Lender Contact Worksheet," of subpart A of part 1942 and exhibit D, "Community Programs Thorough Review Worksheet," of subpart F of part 1951 to strengthen the documentation on which loanmaking and graduation review decisions are made. FmHA regulations require that applicants who may be able to finance projects through commercial sources be referred to those sources. In addition, when it appears that a borrower can refinance its loan(s) (graduate), the borrower will be required to seek other financing. Exhibit D will provide a systematic method to evaluate each thorough review conducted during the graduation review process regarding the borrower's ability to refinance its loan(s). This action is needed to encourage stronger documentation on which decisions are made by FmHA during loanmaking and graduation reviews.

The proposed changes will provide a system for collecting and evaluating lending, applicant, and borrower data, and a basis for referring applicants and borrowers to other lending sources. The new Guides 28 and 29 of subpart A of part 1942 and Exhibit D of subpart F of part 1951 are available in any FmHA Office but are not published in the Federal Register.

The Office of Inspector General (OIG) Review of FmHA Graduation of Community Programs Loans to Commercial Lenders, dated June 22, 1989, found, in part, that State and District Office surveys of lender refinancing criteria were not always adequate. (Guide 28 will be used to record the lending criteria of commercial lenders and serve as a basis for applicant referrals to other sources of credit, as well as resource material for requesting a borrower to refinance.) The OIG report also found that inadequate or poorly documented graduation reviews were performed and recommended that a guide be developed to serve as a basis for making decisions.

3. OMB Circular A-129 requires Federal agencies to obtain the IRS TIN from all applicants to assist in debt collection. The Agency proposes to amend its regulations to require the use of the applicant's TIN as part of its case number.

4. In accordance with the loan sale agreements for the 1987 Community Programs Asset Sale, applicants whose loans were sold are required to obtain consent from the purchaser of the loans whenever additional financing is requested. The Agency proposes to incorporate the purchaser's requirements into its regulations to assist applicants and FmHA field offices in the orderly processing of such requests for consent. The proposed Guide 29 of subpart A of part 1942 will provide detailed and complete instructions to loan applicants and FmHA field offices to ensure the orderly processing of requests for consent.

5. Community Programs regulations currently include the use of Forms FmHA 1942-39, FmHA 1942-40, and Guide 15 of subpart A of part 1942 to assist in orderly project development, which have been found to be ineffective. FmHA proposes to replace Forms FmHA 1942-39, FmHA 1942-40, and Guide 15 with a comprehensive loan processing checklist. A general lack of consistency in docket preparation has been observed. The checklist will provide additional guidance to field offices and loan/grant applicants in orderly docket preparation and improve the consistency and quality of Community Programs loans. The revised Guide 15 of subpart A of part 1942 is not published in the Federal Register, but is available in any State and District Office.

List of Subjects

7 CFR Part 1942

Business and industry, Community facilities, Fire prevention, Loan

programs—housing and community development, Loan programs—natural resources, Reporting and recordkeeping requirements, Rural areas, Soil conservation, Waste treatment and disposal, Water supply.

7 CFR Part 1948

Coal, Community facilities, Loan programs—housing and community development, Reporting and recordkeeping requirements, Rural areas.

7 CFR Part 1951

Accounting, Agriculture, Community facilities, Credit, Housing, Loan programs—housing and community development, Low and moderate income housing, Reporting and recordkeeping requirements, Rural areas.

7 CFR Part 1980

Administrative practice and procedure, Business and industry, Community facilities, Credit, Loan programs—agriculture, loan programs—business, Loan programs—housing and community development, Low and moderate income housing, Reporting and recordkeeping requirements, Rural areas.

Therefore, Chapter XVIII, Title 7, Code of Federal Regulations is proposed to be amended as follows:

PART 1942—ASSOCIATIONS

1. The authority citation for part 1942 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989; 16 U.S.C. 1005; 7 CFR 2.23 and 2.70.

Subpart A—Community Facility Loans

2. Section 1942.2 is amended by revising paragraphs (a)(2)(i) and (c)(3) to read as follows:

§ 1942.2 Processing applications.

(a) * * *

(2) * * *

(i) State Directors should maintain files containing criteria from commercial lenders to be used in determining the preapplications which should be referred to those lenders. In order to provide a basis for such referrals, State and District Directors should maintain liaison with representatives of banks, bond dealers, financial consultants, and other lender representatives who are interested in financing Water and Waste and Community Facility projects. State Directors will contact lenders having potential statewide or multidistrict interest in Community Programs lending. District Directors will contact

lenders having a potential interest in Community Programs lending primarily within their District. Guide 28 (available in any State and District Office), or other locally developed worksheet containing similar information, will be used to document the contacts with commercial lenders. The State and District Directors will keep each other informed of lender criteria by forwarding copies of completed Guide 28 and/or worksheets to each other.

* * * * *

(c) * * *

(3) When an applicant is notified to proceed with an application, the District Director should arrange for a conference with the applicant to provide copies of appropriate appendices and forms; furnish guidance necessary for orderly application processing; and to initiate a processing checklist for establishing a time schedule for completing items. Guide 15 (available in any State or District Office) will be used by the State Director to develop a processing checklist that includes all applicable items in the guide and any other items that may be unique to the individual State. The checklist will be updated during the application conference based upon decisions reached with the applicant. The District Director will give the applicant a copy and explain the updating process. The original will be retained in the District Office official file and will be updated as the application is processed and the project develops to completion. A copy will be sent to the State Program Chief who is responsible for keeping the copy current. The District Director will arrange for additional conferences with the applicant as needs arise. The applicant's copy of the processing checklist should be updated during these meetings.

* * * * *

3. Section 1942.5 is amended by adding paragraph (d)(8) to read as follows:

§ 1942.5 Application review and approval.

* * * * *

(d) * * *

(8) The case number will be the applicant's or transferee's Internal Revenue Service TIN, preceded by State and county code numbers. Only one case number will be assigned to each applicant regardless of the number of loans or grants or number of separate facilities, unless an exception is authorized by the National Office. When an applicant has not received a TIN, the State Office will assign a temporary identification number. See the Forms Manual Insert for Form FmHA 1940-1

for specific instructions. Any temporary number assigned must be replaced with the TIN prior to loan or grant closing unless prior approval of the National Office is received.

4. Section 1942.17 is amended by adding paragraph (m)(8) and by amending the introductory text in paragraph (n)(3) by revising "\$50,000 to \$100,000" in the first sentence, by adding the words "(available in any State or District Office)" between the words "Guide 1a" and the comma in the second sentence, and by adding a new sentence after the first sentence, to read as follows:

§ 1942.17 Community facilities.

* * *

(m) * * *

(8) *Applicants indebted to the Community Programs Loan Trust 1987-A (Trust).* Applicants indebted to the Trust must obtain consent from the Trust prior to incurring additional debt. Guide 29 (available in any State or District Office) outlines the information normally required by the Trust.

* * *

(n) * * *

(3)

(3) * * * However, the State Director may authorize exceptions when the cost of issuance of both temporary and permanent debt instruments is considered prohibitive, or the planned construction period does not exceed 6 months. * * *

* * *

5. Section 1942.19 is revised to read as follows:

§ 1942.19 Information pertaining to preparation of notes or bonds and bond transcript documents for public body applicants.

(a) *General.* This section includes information for use by public body applicants in the preparation and issuances of evidence of debt (bonds, notes, or debt instruments, herein referred to as bonds) and other necessary loan documents.

(b) *Policies related to use of bond counsel.* The applicant is responsible for preparation of bonds and bond transcript documents. The applicant will obtain the services and opinion of recognized bond counsel experienced in municipal financing with respect to the validity of a bond issue, except as provided in paragraphs (b)(1) through (3) of this section. Bond counsel services may be obtained either directly or through the applicant's local counsel.

(1) *Issues of \$50,000 or less.* With prior approval of the FmHA State Director, the applicant may elect not to

use bond counsel. Such issues will be closed in accordance with the following:

(i) The applicant must recognize and accept the fact that application processing may require additional legal and administrative time;

(ii) It must be established that not using bond counsel will produce significant savings in total legal costs;

(iii) The local attorney must be able and experienced in handling this type of legal work;

(iv) The applicant must understand that it will likely have to obtain an opinion from bond counsel at its expenses if FmHA requires refinancing of its loan pursuant to statutory refinancing requirements;

(v) Bonds will be prepared in accordance with this regulation and conform as closely as possible to the preferred methods of preparation stated in paragraph (e) of this section; and

(vi) Specific closing instructions must be issued by OGC.

(2) *Issues of over \$50,000 to \$250,000.* The applicant may elect to use bond counsel only to issue a final opinion, and not to prepare the bond transcript and other documents, when the applicant, FmHA, and bond counsel agree in advance on the method of preparing the bond transcript documents. In such circumstances, the applicant will be responsible for preparation of the bond transcript.

(3) *Issues of over \$250,000 to \$500,000.* The applicant may elect not to use bond counsel in a straight note and mortgage situation if competitive bidding is not required for the sale unless a complicated financial situation exists. If there is a known backlog in the OGC Regional Office, FmHA will advise the applicant and suggest that using bond counsel may be more expeditious. If bond counsel is not used, the applicant must comply with paragraphs (b)(1)(iii) through (vi) of this section.

(c) *Bond transcript documents.* Any questions relating to FmHA requirements should be discussed with FmHA representatives. Bond counsel or local counsel, as appropriate, must furnish at least two complete sets of the following to the applicant, who will furnish one complete set to FmHA:

(1) Copies of all organization documents;

(2) Copies of general incumbency certificate;

(3) Certified copies of minutes or excerpts from all meetings of the governing body at which action was taken in connection with authorizing and issuing the bonds;

(4) Certified copies of documents evidencing that the applicant has complied fully with all statutory

requirements incident to calling and holding a bond election, if one is necessary.

(5) Certified copies of resolutions, ordinances, or other documents such as bond authorizing resolutions or ordinance and any resolution establishing rates and regulating use of the facility, if such documents are not included in the minutes furnished;

(6) Copies of the official Notice of Sale and the affidavit of publication of the Notice of Sale when State statute requires a public sale;

(7) Specimen bond, with any attached coupons;

(8) Attorney's no-litigation certificate;

(9) Certified copies of resolutions or other documents pertaining to the bond award;

(10) Any additional or supporting documents required by bond counsel;

(11) For loans involving multiple advances of FmHA loan funds, a preliminary approving opinion of bond counsel, or local counsel if no bond counsel is involved, if a final unqualified opinion cannot be obtained until all funds are advanced. The preliminary opinion for the entire issue shall be delivered at or before the time of the first advance of funds. It will state that the applicant has the legal authority to issue the bonds, construct, operate and maintain the facility, and repay the loan, subject only to changes during the advance of funds, such as litigation resulting from the failure to advance loan funds, and receipt of closing certificates; and

(12) Preliminary approving opinion, if any, and final unqualified approving opinion of bond counsel, or local counsel if no bond counsel is involved, including an opinion as to whether interest on bonds will be exempt from Federal and State income taxes. With approval of the Administrator, a final opinion may be qualified to the extent that litigation is pending relating to Indian claims that may affect title to land or validity of the obligation. It is permissible for such options to contain:

(i) Language referring to the last sentence of section 306(a)(1) or to section 309A(h) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1926(a)(1) or 1929a(h)); or

(ii) Language providing that, if the bonds are acquired by the Federal Government and sold on an insured basis from the Agriculture Credit Insurance Fund or the Rural Development Insurance Fund, interest on such bonds will be included in gross income for the purpose of Federal income tax statutes.

(d) *Interim construction financing from commercial sources for loans of*

\$100,000 or more. When funds can be borrowed from commercial sources on an interim basis at reasonable interest rates, such interim financing will be obtained so as to preclude the necessity for multiple advances of FmHA funds. The State Director may authorize exceptions when:

(1) The cost of issuance of both temporary and permanent debt instruments is considered prohibitive; or

(2) The planned construction period does not exceed 6 months.

(e) *Permanent instruments for FmHA loans.* FmHA loans will be evidenced by an instrument determined legally permissible and in accordance with the following order of preference:

(1) *First preference—Form FmHA 440-22.* Refer to paragraph (e)(2) of this section for methods of various frequency payment calculations.

(2) *Second preference—single instruments with amortized installments.* A single instrument providing for amortized installments which follows Form FmHA 440-22 as closely as possible. The full amount of the loan must show on the face of the instrument, and there must be provisions for entering the date and amount of each advance on the reverse or an attachment. When principal payments are deferred, the instrument will show that "interest only" is due on interest-only installment dates, rather than specific dollar amounts. The payment period including the "interest only" installment cannot exceed 40 years, the useful life of the facility, or State statute of limitations, whichever occurs first. The amortized installment, computed as follows, will be shown as due on installment dates thereafter.

(i) *Monthly payments.* Multiply by twelve the number of years between the due date of the last interest-only installment and the final installment to determine the number of monthly payments. When there are no interest-only installments, multiply by twelve the number of years over which the loan is amortized. Then multiply the loan amount by the amortization factor and round to the next higher dollar:

Example of Computation of Monthly Payment:

Date of Loan Closing.....	7-5-1986
Loan Amount.....	\$100,000.00
Interest Rate.....	5%
Amortization Period.....	40 years
Interest Only.....	7-5-1987 and 7-5-1988
Installments.....	
First Regular Installment.....	7-5-1989
Final Installment.....	7-5-2026
Computation: $2026-1988 \div 12 = 456$	
monthly payments	
$\$100,000.00 \times .00491 = \$491.00$ monthly	
payment due	

(ii) *Semiannual payments.* Multiply by two the number of years between the due date of the last interest-only installment and the due date of the final installment to determine the correct number of semiannual periods. When there are no interest-only installments, multiply by two the number of years over which the loan is amortized. Then multiply the loan amount by the applicable amortization factor:

Example:

Date of Loan Closing.....	7-5-1986
Loan Amount.....	\$100,000.00
Interest Rate.....	5%
Amortization Period.....	40 years
Interest Only Installments.....	7-5-1987 and 7-5-1988
First Regular Installment.....	7-5-1989
Final Installment.....	7-5-2026
Computation: $2026-1988 \div 2 = 76$	
semiannual periods	
$\$100,000.00 \times .02952 = \$2,952.00$ semiannual	
payment due	

(iii) *Annual payments.* Subtract the due date of the last interest-only installment from the due date of the final installment to determine the number of annual payments. When there are no interest-only installments, the number of annual payments will equal the number of years over which the loan is amortized. Then multiply the loan amount by the applicable amortization factor and round to the next higher dollar:

Example:

Date of Loan Closing.....	7-5-1986
Loan Amount.....	\$100,000.00
Interest Rate.....	5%
Amortization Period.....	40 years
Interest Only Installments.....	7-5-1987 and 7-5-1988
First Regular Installment.....	7-5-1989
Final Installment.....	7-5-2026
Computation: $2026-1988 \div 38$ annual	
payments	
$\$100,000.00 \times .05929 = \$5,929.00$ annual	
payment due	

(3) *Third preference—single instrument with installments of principal plus interest.* If a single instrument with amortized installments is not legally permissible, use a single instrument providing for installments of principal plus interest accrued on the principal balance. For bonds with semiannual interest and annual principal, the interest is calculated by multiplying the principal balance times the interest rate and dividing this figure by two. Principal installments are to be scheduled so that total combined interest and principal payments closely approximate amortized payments.

(i) The repayment terms concerning interest-only installments described in paragraph (e)(2) of this section apply.

(ii) The instrument shall contain in substance provisions indicating:

(A) Principal maturities and due dates;

(B) Regular payments shall be applied first to interest due through the next principal and interest installment due date and then to principal due in chronological order stipulated in the bond; and

(C) Payments on delinquent accounts will be applied in the following sequence:

(1) Billed delinquent interest;
 (2) Past due interest installments;
 (3) Past due principal installments;
 (4) Interest installment due; and
 (5) Principal installment due.
 (4) *Fourth preference—serial bonds with installments of principal plus interest.* If instruments described under the first, second, and third preferences are not legally permissible, use serial bonds with a bond or bonds delivered in the amount of each advance. Bonds will be numbered consecutively and delivered in chronological order. Such bonds will conform to the minimum requirements of paragraph (h) of this section. Provisions for application of payments will be the same as those set forth in paragraph (e)(3)(ii) (B) and (C) of this section.

(5) *Coupon bonds.* Coupon bonds will not be used unless required by State statute. Such bonds will conform to the minimum requirements of paragraph (h) of this section. Provisions for application of payments will be the same as those set forth in paragraph (e)(3)(ii) (B) and (C) of this section.

(i) To compute the value of each coupon when the bond denomination is consistent:

(A) Multiply the amount of the loan or advance by the interest rate and divide the product by 365 days to determine the daily accrual factor;

(B) Multiply the daily accrual factor by the number of days from the date of advance or last installment date to the next installment date; and

(C) Divide the interest computed in paragraph (e)(5)(i)(B) of this section by the number of bonds securing the advance to determine the individual coupon amount.

(ii) To compute the value of each coupon when the bond denomination varies:

(A) Multiply the denomination of the bond by the interest rate and divide the product by 365 days; and

(B) Multiply the daily accrual factor by the number of days from the date of advance or last installment date to the next installment due date; to determine the individual coupon amount.

(f) *Multiple advances of FmHA funds using permanent instruments.* Where interim financing from commercial

sources is not used, FmHA loan proceeds will be disbursed on an "as needed by borrower" basis in amounts not to exceed the amount needed during the 30-day periods.

(g) Multiple advances of FmHA funds using temporary debt instruments.

When none of the instruments described in paragraph (e) of this section are legally permissible or practical, a bond anticipation note or similar temporary debt instrument may be used. The debt instrument will provide for multiple advances of FmHA loan funds and will be for the full amount of the FmHA loan. The instrument will be prepared by bond counsel, or local counsel if bond counsel is not involved, and approved by the State Director and OGC. At the same time FmHA delivers the last advance, the borrower will deliver the permanent bond instrument and the canceled temporary instrument will be returned to the borrower. The approved debt instrument will show at least the following:

(1) The date from which each advance will bear interest;

(2) The interest rate as determined by § 1942.17(f)(1) of this subpart;

(3) A payment schedule providing for interest on outstanding principal at least annually; and

(4) A maturity date which shall be no earlier than the anticipated issuance date of the permanent instrument(s) and no longer than the 40-year statutory limit.

(h) Minimum bond specifications. The provisions of this paragraph are minimum specifications only and must be followed to the extent legally permissible.

(1) **Type and denominations.** Bond resolutions or ordinances will provide that the instrument(s) be either a bond representing the total amount of the indebtedness or serial bonds in denominations customarily accepted in municipal financing (ordinarily in multiples of not less than \$1,000). Single bonds may provide for repayment of principal plus interest or amortized installments. Amortized installments are preferred by FmHA.

(2) **Bond registration.** Bonds will contain provisions permitting registration for both principal and interest. Bonds purchased by FmHA will be registered in the name of "United States of America, Farmers Home Administration," and will remain so registered at all times while the bonds are held or insured by the Government. The FmHA address for registration purposes will be that of the Finance Office.

(3) **Size and quality.** Size of bonds and coupons should conform to standard

practice. Paper must be of sufficient quality to prevent deterioration through ordinary handling over the life of the loan.

(4) **Date of bond.** Bonds will normally be dated as of the day of delivery. However, the borrower may use another date if approved by FmHA. Bonds may or may not be delivered at the same time funds are delivered; however, loan closing is the date of delivery of the bonds or the date of delivery of the first bond when utilizing serial bonds, regardless of the date of delivery of the funds. The date of delivery will be stated in the bond if different from the date of the bond. In all cases, interest will accrue from the date of delivery of the funds.

(5) **Payment date.** Loan payments will be scheduled to coincide with income availability and be in accordance with State law.

(i) If income is available monthly, monthly payments will be required unless precluded by State law. If income is available quarterly or otherwise more frequently than annually, payments must be scheduled on such basis. However, if State law only permits principal plus interest (P&I) type bonds, annual or semiannual payments will be used.

(ii) The payment schedule will be enumerated in the evidence of debt, or if that is not feasible, in a supplemental agreement.

(iii) Unless infeasible, the first payment will be scheduled one full month, or other period as appropriate, from the date of loan closing or any deferment period. Due dates falling on the 29th, 30th, or 31st day of the month will be avoided. When principal payments are deferred, interest-only payments will be scheduled at least annually.

(6) **Extra payments.** Extra payments are derived from the sale of basic chattel or real estate security, refund of unused loan funds, cash proceeds of property insurance as provided in § 1806.5(b) of this chapter (paragraph V.B. of FmHA Instruction 426.1), and similar actions which reduce the value of basic security. At the option of the borrower, regularly facility revenue may also be used as extra payments when regular payments are current. Unless otherwise established in the note or bond, extra payments will be applied as follows:

(i) For loans with amortized debt instruments, extra payments will be applied first to interest accrued through the date of receipt of the payment and second to principal last to become due.

(ii) For loans with debt instruments with P&I installments, the extra

payment will be applied to the final unpaid principal installment.

(iii) For borrowers with more than one loan, the extra payment will be applied to the account secured by the lowest priority of lien on the property from which the extra payment was obtained. Any balance will be applied to other FmHA loans secured by the property from which the extra payment was obtained.

(iv) For assessment bonds, see paragraph (h)(13) of this section.

(7) **Place of payment.** Payments on bonds purchased by FmHA are to be submitted to the FmHA District Office. The District Office will process payments in accordance with part 1951, subpart B, of this chapter.

(8) **Redemptions.** Bonds will normally contain customary redemption provisions. However, no premium will be charged for early redemption on any bonds held by the Government.

(9) **Additional revenue bonds.** Parity bonds may be issued to complete the project. Otherwise, parity bonds may not be issued unless acceptable documentation is provided establishing that net revenues for the fiscal year following the year in which such bonds are to be issued will be at least 120 percent of the average annual debt service requirements on all bonds outstanding, including the newly-issued bonds. For purposes of this section, net revenues are, unless otherwise defined by State statute, gross revenues less essential operation and maintenance expenses. This limitation may be waived or modified by the written consent of bondholders representing 75 percent of the then-outstanding principal indebtedness. Junior and subordinate bonds may be issued in accordance with the loan agreement.

(10) **Scheduling of FmHA payments when joint financing is involved.** When FmHA participates with another lender in joint financing of the project, the FmHA principal and interest payments should approximate amortized installments.

(11) **Precautions.** The following types of provisions in debt instruments should be avoided:

(i) Provisions for the holder to manually post each payment to the instrument;

(ii) Provisions for returning the permanent or temporary debt instrument to the borrower in order that it, rather than FmHA, may post the date and amount of each advance or repayment on the instrument; or

(iii) Provisions that amend covenants contained in Forms FmHA 1942-47 or FmHA 1942-9.

(12) *Defeasance provisions in loan or bond resolutions.* When a bond issue is defeased, a new issue is sold which supersedes the contractual provisions of the prior issue, including the refinancing requirement and any lien on revenues. Since defeasance in effect precludes FmHA from requiring graduation before the final maturity date, it represents a violation of the statutory refinancing requirement; therefore, it is disallowed. No loan shall include a provision of defeasance.

(13) *Assessment bonds.* When security includes special assessment to be collected over the life of the loan, the instrument should address the method of applying any payments made before they are due. It may be desirable for such payments to be distributed over remaining payments due, rather than to be applied in accordance with normal procedures governing extra payments, so that the account does not become delinquent.

(14) *Multiple debt instruments.* The following will be adhered to when preparing debt instruments:

(i) When more than one loan type is used in financing a project, each type of loan will be evidenced by a separate debt instrument or series of debt instruments;

(ii) Loans obligated in different fiscal years and those obligated with different terms in the same fiscal year will be evidenced by separate debt instruments;

(iii) Loans obligated in for the same loan type in the same fiscal year with the same terms may be combined in the same debt instrument;

(iv) Loans obligated in the same fiscal year with different interest rates that can be closed at the same interest rate may be combined in the same debt instrument.

(i) *Bidding by FmHA.* Bonds offered for public sale shall be offered in accordance with State law and in such a manner to encourage public bidding. FmHA will not submit a bid at the advertised sale unless required by state law nor will reference to FmHA's rates and terms be included. If no acceptable bid is received, FmHA will negotiate the purchase of the bonds.

Subpart C—Fire and Rescue Loans

6. Section 1942.111 is amended by revising paragraph (b) to read as follows:

§ 1942.111 Applicant eligibility.

(b) *Credit elsewhere determination.* District Directors should maintain files with criteria from commercial lenders to be used in determining the preapplications which should be

referred to those lenders. If credit elsewhere is indicated, the District Director should inform the applicant and recommend that they apply to commercial sources for financing. In order to provide a basis for such referrals, District Directors should maintain liaison with representatives of banks, bond dealers, financial consultants, and other lender representatives who are interested in receiving applicant referrals. State Directors will contact lenders having a potential statewide or multidistrict interest in Community Programs lending. District Directors will contact lenders having a potential interest in Community Programs lending primarily within their District. Guide 28 (available in any State or District Office) or locally developed worksheet containing similar information will be used to document the contacts with commercial lenders. The State Director and District Director will keep each other informed of lender criteria by forwarding copies of completed Guide 28 and/or worksheets to each other.

Subpart I—Resource Conservation and Development (RCD) Loans and Watershed (WS) Loans and Watershed Advances

7. Section 1942.419 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 1942.419 Approval, closing, and cancellation.

(a) Approval and closing actions will be taken in accordance with the applicable provisions of FmHA regulations including part 1901, subpart A, of this chapter and §§ 1942.5, 1942.6, 1942.7, 1942.8, and 1942.12, of subpart A of this part, and the following:

PART 1948—RURAL DEVELOPMENT

8. The authority citation for part 1948 is revised to read as follows:

Authority: 7 U.S.C. 1989; 7 CFR 2.23 and 2.70.

Subpart B—Section 601 Energy Impacted Area Development Assistance Program

9. Section 1948.92 is amended by removing paragraphs (d) through (g) and revising paragraph (c) to read as follows:

§ 1948.92 Grant approval and fund obligation.

(c) Grants must be approved and obligated in accordance with § 1942.5(d) of this chapter.

§ 1948.94 [Amended]

10. Section 1948.94 (b) is amended in the second sentence by revising the reference "FmHA Instruction 402.1 (available in any FmHA Office)" to part 1902, subpart A, of this chapter".

PART 1951—SERVICING AND COLLECTIONS

11. The authority citation for part 1951 is revised to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 1480; 7 CFR 2.23 and 2.70.

Subpart E—Servicing of Community and Insured Business Programs Loans and Grants

12. Subsection 1951.230 (c)(3) is amended by revising the last sentence to read as follows:

§ 1951.230 Transfer of security and assumption of loans.

(c) * * *

(3) * * * If applicable, 1942.19 (h)(14) of this chapter will govern the preparation of any new debt instruments required.

Subpart F—Analyzing Credit Needs and Graduation of Borrowers

13. Section 1951.261 is amended by revising the fourth and fifth sentences of the introductory text of paragraph (c), and by adding two new sentences at the end of paragraph (e)(5) to read as follows:

§ 1951.261 Graduation of FmHA borrowers to other sources of credit.

(c) * * * (The servicing official, in lieu of writing a narrative for all programs, may use Exhibit A for Farmer Program loans, Exhibit B for Rural Housing loans, and Guide 28 (available in any State or District Office) for Community Programs loans.) For Community Programs, the servicing official will request the assistance of the State Director pursuant to § 1942.2(a)(2)(i) of this chapter. * * *

(e) * * *

(5) * * * Exhibit D "Community Programs Thorough Review Worksheet" (available in any State or District Office) will be completed for each Community Programs borrower for whom a thorough review is conducted. The original will be placed in the borrower's file and a copy will be forwarded to the State Director for each borrower recommended for graduation.

PART 1980—GENERAL

14. The authority citation for part 1980 is revised to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1989; 42 U.S.C. 1480; Pub. L. 100-387, 102 Stat 924; Pub. L. 101-82, 103 Stat 564 (7 U.S.C. 1421 Note); 7 CFR 2.23 and 2.70.

Subpart A—General

15. Section 1890.12 is revised to read as follows:

§ 1980.12 Case and identification (ID) numbers.

(a) *Case number.* The case number will be the proposed borrower's or transferee's Social Security or Internal Revenue Service (IRS) Taxpayer Identification Number (TIN), whichever is appropriate, preceded by State and County code numbers. The County Supervisor will provide the lender with these numbers, except for Business and Industry and Community Programs cases where the State Director or District Director, respectively, will provide them. Only one case number will be assigned to each borrower regardless of the number of loans or grants or number of separate facilities, unless an exception is authorized by the National Office.

(1) If such party is an individual, his or her Social Security number will be used. If such party is husband and wife, the Social Security number of either one, as designated by the spouses, will be used.

(2) If such party is a legal entity, its TIN will be used.

(b) *Temporary ID numbers.* When a proposed borrower has not received a TIN, the State Office will assign a temporary ID number. See the Forms Manual Insert for Form FmHA 1940-3, "Request for Obligation of Funds," for specific instructions. Any temporary ID number assigned must be replaced with the TIN prior to issuing the Loan Note Guarantee unless prior approval of the National Office is received.

(c) *ID number of lender and holder.* The lender's and holder's IRS TIN will be used as its ID number in correspondence and FmHA forms relating to the guarantee.

Subpart I—Community Programs Guaranteed Loans

16. Section 1980.856 is amended by adding paragraph (i) to read as follows:

§ 1980.856 Conditions precedent to issuance of the Loan Note Guarantee (Form FmHA 449-34).

* * * * *

(i) *Proposed borrowers indebted to the Community Program Loan Trust 1987-*

A (Trust). Proposed borrowers indebted to the Trust must obtain consent from the Trust prior to incurring additional debt. Guide 29 (available in any State or District Office) outlines the information normally required by the Trust.

Dated: December 9, 1993.

Bob J. Nash,

Under Secretary, Small Community and Rural Development.

[FR Doc. 94-13743 Filed 6-14-94; 8:45 am]

BILLING CODE 3410-07-M

NUCLEAR REGULATORY COMMISSION**10 CFR Parts 20 and 35**

RIN 3150-AE41

Criteria for the Release of Patients Administered Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations concerning the criteria for the release of patients administered radioactive material. The new criteria for patient release would be dose-based rather than activity-based and would be consistent with the recommendations of the International Commission on Radiological Protection (ICRP). The proposed rule would require the licensee to maintain a record for 3 years if the quantity of radioactive material is likely to result in an annual total effective dose equivalent to an individual exposed to the patient that exceeds 1 millisievert (0.1 rem) from a single administration. The proposed rule responds to two petitions for rulemaking regarding the criteria for release of patients administered radioactive material.

DATES: The comment period expires August 29, 1994. Comments received after this date will be considered if it is practicable to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attn: Docketing and Service Branch.

Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland between 7:45 a.m. and 4:15 p.m. Federal workdays.

Examine comments received, the environmental assessment and finding of no significant impact, and the regulatory analysis at: The NRC Public

Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Obtain single copies of the environmental assessment and finding of no significant impact and the regulatory analysis (NUREG-1492) from: Jayne McCausland, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 415-6219.

Obtain single copies of the draft regulatory guide, "Release of Patients Administered Radioactive Material," which is related to this rulemaking, by writing to: Distribution and Mail Services Section, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT:

Stewart Schneider, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6225.

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I. Background

Each year in the United States, radioactive pharmaceuticals or radioactive implants are administered to approximately 8 to 9 million patients for the diagnosis or treatment of disease (hereinafter this group will be referred to as patient(s)). These patients can expose others around them to radiation until the radioactive material has been excreted from their bodies or has decayed away. As discussed below, most of these exposures would be much less than 1 millisievert (0.1 rem) total effective dose equivalent per year.

NRC's current patient release criteria in 10 CFR 35.75, "Release of patients containing radiopharmaceuticals or permanent implants," are as follows:

"(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either: (1)

The measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter; or (2) The activity in the patient is less than 30 millicuries; (b) A licensee may not authorize release from confinement for medical care of any patient administered a permanent implant until the measured dose rate is less than 5 millirems per hour at a distance of one meter."

On May 21, 1991 (56 FR 23360), the NRC published a final rule that amended 10 CFR part 20, "Standards for Protection Against Radiation." The rule contained limits on the radiation dose for members of the public in 10 CFR 20.1301. However, when 10 CFR part 20 was issued, there was no discussion in the supplementary information on whether or how the provisions of 10 CFR 20.1301 were intended to apply to the release of patients, thereby creating the need to address this issue.

To determine the potential number of patients that could be affected by this issue, the NRC performed a screening analysis to determine how many patients administered radioactive materials could cause the exposure of an individual to a dose exceeding 1 millisievert (0.1 rem) total effective dose equivalent in a year if there were no restrictions on patient release. The screening analysis indicated that none of the diagnostic administrations were likely to result in a dose to an individual exposed to the patient exceeding 1 millisievert (0.1 rem), except for a few diagnostic procedures using iodine-131. The therapeutic administrations that the screening analysis indicated needed consideration were: (1) The treatment of hyperthyroidism with iodine-131 (50,000 per year); (2) the treatment of thyroid cancer with iodine-131 (10,000 per year); and (3) the treatment of a variety of cancers (e.g., prostate cancer) with the permanent implantation of iodine-125 seeds (2,000 per year). Other radionuclides may also warrant consideration. For example, doses to individuals exposed to a patient administered yttrium-90 and gold-198 for therapy might result in radiation exposures exceeding 1 millisievert (0.1 rem) to individuals exposed to the patient. However, these radionuclides are seldom used. In addition, procedures involving radiolabeled antibodies might result in doses exceeding 1 millisievert (0.1 rem), although no such procedures using byproduct material are yet approved for routine use. (For further information see the regulatory analysis for the proposed rule. Single copies of the draft regulatory analysis are available as indicated in the ADDRESSES heading.)

II. Petitions for Rulemaking

Because some licensees were uncertain about what effect the revised 10 CFR part 20 would have on patient release criteria, two petitions were received on the issue.

On June 12, 1991 (56 FR 26945), the NRC published in the *Federal Register* a notice of receipt of, and request for comment on, a petition for rulemaking (PRM-20-20) from Dr. Carol S. Marcus. In addition, Dr. Marcus submitted a letter dated June 12, 1992, further characterizing her position. Dr. Marcus requested that the NRC amend the revised 10 CFR part 20 and 10 CFR part 35 to—

(1) Raise the annual radiation dose limit in 10 CFR 20.1301(a) for individuals exposed to radiation from patients receiving radiopharmaceuticals for diagnosis or therapy from 1 millisievert (0.1 rem) to 5 millisieverts (0.5 rem).

(2) Amend 10 CFR 35.75(a)(2) to retain the 1,110-megabecquerel (30-millicurie) limit for iodine-131, but provide an activity limit for other radionuclides consistent with the calculational methodology employed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."

(3) Delete 10 CFR 20.1301(d) which requires licensees to comply with provisions of Environmental Protection Agency's environmental regulations in 40 CFR part 190 in addition to complying with the requirements of 10 CFR part 20.

On March 9, 1992 (57 FR 8282), the NRC published a notice of receipt and request for comment in the *Federal Register* on another petition for rulemaking (PRM-35-10) on patient release criteria from the American College of Nuclear Medicine (ACNM). On May 18, 1992 (57 FR 21043), the NRC published in the *Federal Register* notice of an amendment submitted by the ACNM to its original petition (PRM-35-10A). In addition, the ACNM submitted two letters dated September 24, 1991, and October 8, 1991, on the issues in their petition. The ACNM requested (considering the contents of all four letters) that the NRC revise 10 CFR part 35 to—

* National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37 (October 1, 1970). (Available for sale from the NCRP, 7910 Woodmont Avenue, suite 800, Bethesda, MD 20814-3095.)

(1) Adopt a dose limit of 5 millisieverts (0.5 rem) for individuals exposed to patients who have been administered radiopharmaceuticals.

(2) Permit licensees to authorize release from hospitalization any patient administered a radiopharmaceutical regardless of the activity in the patient by defining "confinement" to include not only confinement in a hospital, but also confinement in a private residence.

Because the petitions submitted by Dr. Marcus and the ACNM both address the patient release criteria set forth in 10 CFR 35.75, the NRC has decided to resolve both petitions with this single rulemaking. The proposed actions, if adopted in final form, would constitute the partial granting of these petitions as set forth in this notice. All other portions of petitions PRM-20-20 and PRM-35-10 would be denied.

III. Public Comments Received on the Petitions

There were 140 comment letters received on PRM-20-20 and 88 comment letters on PRM-35-10 and PRM-35-10A. Commenters represented hospitals and clinics, professional associations, citizens' groups, Agreement States and Government agencies, State radiation advisory boards, universities, consulting firms, public utilities, a utility association, and a labor union. The majority of the commenters were physicians who expressed concerns primarily related to the cost of hospitalization. Other commenters included health and medical physicists, pharmacists, nuclear medicine technicians, professors, and one former nuclear medicine patient. Overall, the majority of all comments supported a dose limit of 5 millisieverts (0.5 rem) for individuals exposed to patients released with radioactive material.

IV. Coordination with NRC Agreement States

The NRC conducted a public workshop with representatives of the Agreement States on July 15 and 16, 1992, to discuss a variety of medical issues, including the proposals for amending 10 CFR parts 20 and 35. The workshop was held in Atlanta, Georgia. Twenty-one of the Agreement States were represented, as well as a representative from the City of New York. The major recommendations on the rule provided by the representatives may be summarized as follows:

(1) Revise 10 CFR part 20 to exclude doses to individuals exposed to patients released under 10 CFR 35.75.

(2) In 10 CFR 35.75, retain the dose rate limit of 0.05 millisievert (5

millirems) per hour at a distance of 1 meter and add a dose limit of 5 millisieverts (0.5 rem) in 1 year for individuals exposed to patients.

(3) Retain the current 1,110-megabecquerel (30-millicurie) activity limit for iodine-131 but provide activity limits for other radionuclides based on the recommendations of NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."

(4) Do not define "confinement" in 10 CFR part 35 because the present wording gives regulatory agencies the prerogative to confine patients by means other than hospitalization.

(5) Require that written instructions on how to maintain doses to other individuals as low as reasonably achievable be given to the released patient and any individual likely to spend significant time in close proximity with the patient.

The NRC staff presented a status report on the requirements of the proposed rule to the Agreement States at another public meeting in October 1993, in Tempe, Arizona. The Agreement States were generally supportive of the approach in this proposed rule. Transcripts of both meetings have been placed in and are available for examination at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

In addition, in July 1993, the NRC requested the Agreement States to provide comments on a previous version of the proposed rule. Of those responding, 14 Agreement States were generally supportive of the approach in this proposed rule, one was in opposition, and one was uncertain of its support without further study. The Agreement State that opposed the annual dose limit of 5 millisieverts (0.5 rem) (total effective dose equivalent) believed that instructions on how to maintain doses as low as reasonably achievable to household members and other individuals would not be followed, radioactive contamination would be a problem, and permanent implants could dislodge.

V. Coordination With the Advisory Committee on Medical Uses of Isotopes

The NRC staff presented their suggestions for a proposed rule to the Advisory Committee on Medical Uses of Isotopes (ACMUI) during a public meeting held in Rockville, Maryland, on October 22 and 23, 1992. The ACMUI is an advisory body established to advise the NRC staff on matters that involve the administration of radioactive material and radiation from radioactive material.

The major ACMUI recommendations on the proposed rule were to—

(1) Add a dose limit of 5 millisieverts (0.5 rem) in 1 year for individuals exposed to a patient released with radionuclides.

(2) Retain both the 1,110-megabecquerel (30-millicurie) activity limit and the maximum dose rate of 0.05 millisieverts (5 millirems) per hour for patient release in 10 CFR 35.75 because they are a simple means to show compliance without assumptions or calculations.

(3) Develop a regulatory guide that includes a set of standardized calculations with factors (e.g., occupancy factor) for licensees to determine compliance with patient release criteria on an individual basis. Provide tables of acceptable release activities that are radionuclide specific, based on exposure at 1 meter for routine patient releases, with built-in safety factors to avoid doses to individuals near the 5-millisievert (0.5-rem) limit.

(4) Require that written instructions on how to maintain doses to other individuals as low as reasonably achievable be provided to the patient upon release from confinement.

The NRC staff presented status reports on the requirements of the proposed rule to the ACMUI at two other public meetings in May 1993, in Bethesda, Maryland, and in November 1993, in Reston, Virginia. The ACMUI was generally supportive of the approach in this proposed rule. Transcripts of all meetings have been placed in and are available for examination at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

VI. Issues and Their Resolution

There are seven issues that arise in responding to the two petitions. These issues and their resolution are discussed below.

Issue 1: Should the limits in 10 CFR 35.75 or in 20.1301(a) govern patient release? The petitioners requested an annual dose limit of 5 millisieverts (0.5 rem) for individuals exposed to radiation from a released patient.

Supporting Comments

The majority of commenters favored a dose limit of 5 millisieverts (0.5 rem) per year for individuals exposed to released patients rather than the 1 millisievert (0.1 rem) in 10 CFR 20.1301(a). The representatives from Agreement States who attended the public meeting held in Atlanta, Georgia, on July 15 and 16, 1992, and the ACMUI public workshop held in October 1992 in Rockville, Maryland, also favored the 5-millisievert (0.5-rem) limit. Some

commenters stated that a dose limit of 5 millisieverts (0.5 rem) per year for individuals exposed to a patient is in line with the recommendations of the ICRP and the NCRP.

Some commenters believed that the 5-millisievert (0.5-rem) limit is beneficial to both the patient and the family because patients are able to return home earlier than would be permitted if a 1-millisievert (0.1-rem) limit were used. One commenter believed that the case could be made that no limit should be applied to the patient's family, just maintain doses as low as reasonably achievable, because there is a benefit to the family from the patient's being home. A physician commented that many patients come from homes in which no member of the family is under the age of 30, and therefore, contended that there was less risk from radiation exposure. Other comments in favor included: (1) Hospitalization can be a distressing experience for many cancer patients; (2) patients can develop hospital acquired infections if kept in the hospital too long; and (3) confining patients in a hospital until the release criteria are met increases the dose to hospital personnel and other patients.

Controlling the cost of medical care was one of the most cited reasons in favor of the 5-millisievert (0.5-rem) limit. Concern was expressed that the costs to all parties involved (i.e., patients, hospitals, insurance companies, etc.) would dramatically rise if a 1-millisievert (0.1-rem) limit were used. Commenters said a 1-millisievert (0.1-rem) limit would require longer periods of hospitalization, that many outpatients would become inpatients, and that this would be extremely expensive.

Comments from nuclear power utilities supported the 5-millisievert (0.5-rem) limit requested by PRM-20-20. These commenters stated further that if the limit for annual dose to the public exposed to patients were 5 millisieverts (0.5 rem), then the dose limit should be 5 millisieverts (0.5 rem) for all exposures to the public, including those from nuclear power plants, because no demonstrable health effects have been observed at chronic exposure levels of 5 millisieverts (0.5 rem).

Opposing Comments

A citizens' group commented that any amount of radiation, no matter how small, carries a risk to the recipient. Thus, decisions that affect the public health should be made strictly on the basis of health, not economic considerations. A second citizens' group expressed similar concerns.

A few commenters stated that the licensee already has the requested relief because the Commission has made provision in 10 CFR 20.1301(c) for approval of a licensee's request to increase the annual dose limit to 5 millisieverts (0.5 rem) for individuals exposed to a patient.

Response

The NRC has determined that patient release should be governed by 10 CFR 35.75, not 10 CFR 20.1301(a). 10 CFR 35.75 of the NRC's regulations adopted in 1986 (51 FR 36932; October 16, 1986) prohibits an NRC licensee from authorizing patient release until the measured dose rate from the patient is less than 0.05 millisievert (5 millirem) per hour at 1 meter or the activity in the patient is less than 1,110 megabecquerels (30 millicuries). 10 CFR 20.1301(a) of the revised standards for protection against radiation, adopted in 1991 (56 FR 23360; May 21, 1991), requires a licensee to limit the radiation dose of any individual member of the public from licensed activities to less than 0.1 rem (1 millisievert) (total effective dose equivalent) in a year.

The NRC's view that 10 CFR 35.75 governs patient release represents a reasonable interpretation of the Commission's regulations on this subject. As a general rule, requirements in 10 CFR part 35 are "in addition to," rather than "in substitution for," compliance with other NRC requirements including 10 CFR part 20. However, in this case, the dose limit of 10 CFR 20.1301(a), if it were interpreted to apply to patient release, could require a licensee to continue confinement of a patient whose release would be permitted under 10 CFR 35.75. The NRC will not adopt this interpretation because that would make 10 CFR 35.75 essentially meaningless.

When the NRC proposed 10 CFR 35.75 (50 FR 30627; July 25, 1985), it said, "The Commission believes that either limit (i.e., 30 millicuries of activity or the 6 milliroentgen per hour exposure rate at 1 meter) provides an adequate measure of safety for the general public and that further reductions in public exposure are not reasonably achievable considering the cost and potential for detrimental effect from an unnecessarily long hospital confinement." Further, when it approved 10 CFR 35.75 in final form, the NRC again said, "The NRC believes that a 30-millicurie release limit provides an adequate measure of public health and safety." See 51 FR 36932. The NRC's conclusion was based on an independent NRC public health and safety judgement that is specific to

patient release. This conclusion was neither tied to nor designed to implement the more general considerations in the 10 CFR part 20 dose limits that had already been proposed when the conclusion of adequacy was reached.

The NRC maintains that the public health and safety judgement specific to patient release in 10 CFR part 35 should prevail over the more general 10 CFR part 20. The criterion in the proposed 10 CFR part 35, 5 millisieverts (0.5 rem) total effective dose equivalent per year, excluding background or any occupational exposure, is consistent with: The Commission's provision in 10 CFR 20.1301(c) for authorizing a licensee to operate up to this limit for limited periods of time; the recommendations of the International Commission on Radiological Protection (ICRP) in ICRP Publication 60,² "1990 Recommendations of the International Commission on Radiological Protection;" and the recommendations of the National Council on Radiation Protection and Measurements (NCRP) in NCRP Report No. 116,³ "Limitation of Exposure to Ionizing Radiation." Each of these provides a basis for allowing individuals to receive annual doses up to 5 millisieverts (0.5 rem) under certain circumstances. Both the ICRP and NCRP recommend that an individual be allowed to receive a dose up to 5 millisieverts (0.5 rem) in a given year in situations where exposure to radiation is not expected to result in doses above 1 millisievert (0.1 rem) per year for long periods of time, as would be the case for doses from released patients. The recommendations of the ICRP and NCRP are based on their findings that annual exposures in excess of 1 millisievert (0.1 rem) to a small group of people, provided that they do not occur often to the same group, need not be regarded as especially hazardous. Therapeutic treatments with radioactive materials are limited to a relatively small proportion of the population and are not often repeated for the same patient.

Although the NRC adopted 10 CFR 20.1301(a) after 10 CFR 35.75, it did not intend to supersede 10 CFR 35.75. There is no indication in the associated statements of consideration or response to comments that NRC intended to

supersede 10 CFR 35.75 criteria when 10 CFR part 20 was amended. Because the NRC finalized 10 CFR 35.75 after proposing revisions to 10 CFR part 20 in 1986, the NRC's silence should indicate that it did not intend the revised standards for protection against radiation to supersede either 10 CFR 35.75 or the NRC's underlying adequacy judgement.

As reflected in the above discussion, the NRC's finding of adequacy with respect to patient release criteria does not apply to or set a precedent for the operations of nuclear power plants. The basis for the limit for patient release is justified by the considerations that specifically apply to patient release.

To codify the policy regarding the issue of the applicability of 10 CFR 20.1301 to patient release, the NRC is proposing to amend 10 CFR 20.1301(a)(1) to explicitly exclude doses to individuals exposed to released patients. In addition, 10 CFR 20.1301(a)(2) would be amended by adding the words "exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 35.75" to make it clear that the limit on dose in unrestricted areas does not include dose contributions from patients administered radioactive material and released in accordance with 10 CFR 35.75.

Issue 2: Should the patient release criteria in 10 CFR 35.75 be expressed as a dose-based limit instead of being expressed in terms of activity retained in the patient and dose rate at 1 meter from the patient?

Supporting Comments

While the choice of a dose-based vs. an activity-based limit was not presented as an issue in the petitions, many commenters supported a dose-based limit of 5 millisieverts (0.5 rem), although those same commenters also generally supported retaining an activity limit.

Some commenters and the ACNM discussed the inadequacy of the current activity-based limit in 10 CFR part 35 to deal with new techniques such as the use of radiolabeled antibodies.

Supporting Comments

PRM-20-20 requested that patients given 1,110 megabecquerels (30 millicuries) of iodine-131, or more, be hospitalized and released in accordance with the guidelines of NCRP Report No. 37, and that the maximum activity that a patient can be released with for a specific nuclide be consistent with the calculations methodology of NCRP Report No. 37. Many commenters and

² International Commission on Radiological Protection (ICRP). "1990 Recommendations of the International Commission on Radiological Protection," ICRP Publication No. 60 (November 1990). Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.

³ National Council on Radiation Protection and Measurements, "Limitation of Exposure to Ionizing Radiation," NCRP Report No. 116 (March 31, 1993). Available for sale from the NCRP, 7910 Woodmont Avenue, suite 800, Bethesda, MD 20814-3095.

representatives from the Agreement States that attended the public workshop held in Atlanta, Georgia, on July 15 and 16, 1992, also agreed with this request.

Opposing Comments

No comments opposing the methodology in NCRP Report No. 37 were received.

Response

The NRC agrees that the calculational methodology of NCRP Report No. 37 can be used to calculate external doses from patients. Although NCRP Report No. 37 is dated, it still contains an appropriate method to calculate the integrated dose at 1 meter from a patient following administration of certain radionuclides. This methodology is modified in the draft regulatory guide to calculate activities to meet the 5-millisievert (0.5-rem) (total effective dose equivalent) limit.

Opposing Comments

Several commenters, as well as representatives from the Agreement States and the ACMUI, noted that the 1,110-megabecquerel (30-millicurie) activity limit is a simple method to demonstrate compliance with NRC regulations and should be retained.

PRM-20-20 requested that the NRC specify an activity for each specific radionuclide consistent with the calculational methodology of NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."

Response

The NRC's primary concern is the public's health and safety. Doses are a measure of degree of protection, whereas activity of different radionuclides is not related in any consistent way to the level of protection. For this reason, the NRC proposes to establish a dose limit as the only patient release criterion in 10 CFR 35.75. The proposed dose limit is 5 millisieverts (0.5 rem) total effective dose equivalent in a year. This dose limit is consistent with the underlying risk basis of the current 10 CFR 35.75 (50 FR 30627), the recommendations of the ICRP, and the provisions in 10 CFR 20.1301(e), pertaining to temporary situations in which there is requisite justification for a dose limit higher than 1 millisievert (0.1 rem).

Unlike the current 10 CFR 35.75, the proposed 10 CFR 35.75 does not specify an activity or dose rate for authorizing patient release. The 1,110-megabecquerel (30-millicurie)

requirement was not retained because the doses from a released patient are different for different radionuclides that have the same activity. Likewise, a release criterion based on dose rate from the patient is not a uniform indicator of dose because the total dose depends on the effective half-life of the radioactive material in the body of the patient and other factors, which will differ for different materials.

In most cases, the dose received by an individual exposed to the patient will be from external exposure. However, in the case of a breast-feeding mother, the infant could be exposed following ingestion of breast milk. In this case, the 5-millisievert (0.5-rem) limit applies to the infant as the individual likely to receive the highest exposure.

To help licensees easily determine if they may authorize the release of a patient, a draft regulatory guide, published concurrently with this proposed rule, contains a table that specifies the activity of commonly used radionuclides with which a patient can be released in compliance with the proposed dose limit. The table in the draft guide provides a simple method to demonstrate compliance that assumes no biological elimination of the radioactive material. For example, in the case of iodine-131, the value specified is 1,200 megabecquerels (33 millicuries). The draft regulatory guide also offers guidance for the licensee who chooses to calculate activities at which patient release may be authorized based upon case specific information. Single copies of the draft regulatory guide are available as indicated in the ADDRESSES heading.

The 0.05 millisievert (5 millirems) per hour at 1 meter dose rate limit was not retained in the regulation because, in essence, consideration of the dose rate is included in calculating the activity for each of the radionuclides specified in the draft regulatory guide. In addition, the draft regulatory guide now relates the dose rate with the release criteria in the proposed 10 CFR 35.75.

Newer techniques, such as the therapeutic use of radiolabeled antibodies, involve the administration of perhaps as much as several gigabecquerels (hundreds of millicuries). These newer techniques require that a patient remain under the control of the licensee for a much longer period of time before the current release criteria can be met. By changing the basis for the release of patients in the proposed rule to an annual dose limit, the activity or resulting dose rate are no longer the only limiting factors upon which a patient release is based. Under the proposed rule, the dose would be

the determining criteria, irrespective of the amount of radioactive material administered or the potential pathways of exposure of individuals as a result of contact with the patient. This is particularly important for proper control of some types of materials, such as strong beta emitters, which do not pose a large external dose hazard. In these cases, dose through inhalation or ingestion of contamination could be significant pathways and must be accounted for in a calculation for compliance. To demonstrate compliance with the proposed rule in this situation, the optional calculational method described in the draft regulatory guide could be used, potentially resulting in an earlier patient release than would otherwise have been allowed, while still providing the specified level of protection.

Issue 3. Should the calculational methodology in NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," be an acceptable means to demonstrate compliance with the proposed rule?

Issue 4. Should, as the ACNM requested, the word "confinement" be defined to include confinement in a private residence?

Supporting Comments

The ACNM petitions stated that 10 CFR 35.75 seems to mandate hospitalization as the only place of confinement for patients receiving radiopharmaceutical therapy for compliance with 10 CFR 35.75. The ACNM petitions also stated that 10 CFR 35.75 overlooks the merits of a necessary option, temporary home confinement, for outpatient radiopharmaceutical therapy at levels exceeding 1,110 megabecquerels (30 millicuries). This petition further stated that patients containing quantities up to 14,800 megabecquerels (400 millicuries) of iodine-131 could be confined in a private residence, as justified by published scientific papers that contend that home confinement of such patients would not adversely affect public health and safety.

Another commenter supported home confinement because it would greatly improve patient comfort while reducing medical expenditures by a considerable amount, and that this can be accomplished without any significant risk to the public. Some commenters believed that patients confined at home with as much as 14,800 megabecquerels (400 millicuries) of iodine-131 would not create a safety hazard to the public if simple precautions were followed.

Several commenters believed that they had been told by the NRC that the use of the term confinement in 10 CFR 35.75 provided for a nonhospital option.

A couple of commenters suggested that if a patient is medically capable of self-care, informed and cooperative, release in amounts greater than 1,110 megabecquerels (30 millicuries) is sensible.

Opposing Comments

The Conference of Radiation Control Program Directors (CRCPD) commented that confinement should not be defined in 10 CFR part 35 because the present wording already provides the option to confine patients by means other than hospitalization.

An Agreement State representative remarked that it is not realistic to believe that a person will go home and lock themselves in a room for two to three days with limited contact with family and friends. Another Agreement State representative maintained it is difficult to control actions of an ambulatory patient and difficult to ensure that the patient has remained in confinement. This commenter also noted that the ACNM definition does not address transportation to a confined area in a private residence that would prohibit a patient from using public transportation.

A former radiopharmaceutical therapy patient opposed the changing of the existing requirements. He said that cutting hospital costs by releasing highly radioactive patients may afford short-term economic benefits for health care providers but it carries serious health and safety risks to the family and the public. He also indicated that some people would have a difficult time following the extensive advice that is given as to the precautions to be taken on returning home.

Some commenters expressed the belief that release from a hospital with activities as high as 14,800 megabecquerels (400 millicuries) of iodine-131 is dangerous to public health and safety.

Response

The NRC has decided that the term "confinement" should be deleted from the proposed revision to 10 CFR 35.75. Instead, the proposed rule language now uses the phrase "licensee control." The NRC believes that the phrase "licensee control" more clearly reflects the NRC's intent.

The phrase "licensee control" refers to the ability of the licensee to demonstrate that it can control doses to other individuals from the patient, as well as the spread of radioactive

material. The licensee maintains control both from the location of patients and by the actions the licensee takes to control doses. Although licensee control does not necessarily restrict a patient to a hospital, the location of the patient must be listed as a place of use on the license or a license amendment must be issued pursuant to 10 CFR 35.13(e). Additional choices would be available (e.g., hospices or nursing homes) as long as the licensee can demonstrate that it can control doses to other individuals as well as the spread of radioactive material.

The NRC believes that there is a distinct difference between a patient being "confined" in a hospital and "confined" in a home. In hospital confinement, the licensee has control over access to the patient as well as having trained personnel and instrumentation available for making radiation measurements not typically available at the patient's home. In addition, while under licensee control, a licensee has control over the dose by limiting the amount of time that individuals are in close proximity to the patient. Therefore, as a general practice, the NRC does not want licensees to use a patient's home for the purpose of confining the patient.

Issue 5. Should 10 CFR 20.1301(d) require compliance with Environmental Protection Agency (EPA) regulations? PRM-20-20 stated that compliance with the EPA's Clean Air Act air effluent standards would cost medical facilities \$100,000,000 per year, which would be added to national health care costs.

Supporting Comments

Most comments from physicians and medical associations expressed concern over redundant NRC and EPA regulations contained in 40 CFR 61 resulting from the EPA's limitation on air effluent from NRC-licensed facilities.

Opposing Comments

No opposing comments were received.

Response

The EPA regulations referenced in 10 CFR 20.1301(d) are contained in 40 CFR part 190, which deals only with doses and airborne emissions from uranium fuel cycle facilities. 40 CFR part 190 does not apply to hospitals or to the release of patients. Furthermore, 10 CFR 20.1301(d) does not incorporate the EPA's Clean Air Act standards in 40 CFR part 61 that apply to hospitals. The NRC is separately pursuing actions with the EPA to minimize the impact of dual regulation under the Clean Air Act.

Because the reference to EPA regulations in 10 CFR 20.1301(d) has nothing to do with the patient release issue and has no impact on the petitioner, the NRC will not grant this request of the petitioner.

Issue 6. Should the regulations require that patients, upon release, receive written instructions on how to maintain doses to other individuals as low as reasonably achievable?

Supporting Comments

PRM-20-20 recommended education of the patient and the care provider. Some commenters supported written instructions for the patient upon release. Representatives from the Agreement States who attended the public workshop held in Atlanta, Georgia, on July 15 and 16, 1992, and the ACMUI public workshop held in October 1992 in Rockville, Maryland, also agreed with this concept.

Opposing Comments

A physician stated that instructions regarding patient activities significantly increase apprehension needlessly.

Response

The NRC agrees that written instructions on how to maintain doses as low as reasonably achievable to people exposed to released patients should be provided. These written instructions would specify what actions should or should not be taken by the released patients and by the individuals potentially exposed. In fact, written instructions are already required under 10 CFR 35.315(a)(6) and 35.415(a)(5). Under the proposed 10 CFR 35.75(b), when the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem) from a single administration, the licensee would be required to provide written instructions to the patient on how to maintain doses as low as reasonably achievable to household members and other individuals. If the dose to any individual exposed to the patient is not likely to exceed 1 millisievert (0.1 rem), instructions are not required but the physician could give any instructions that he or she considers desirable.

Written instructions provide an available reference after the patient's release, if questions regarding patient care arise. Written instructions reduce the chance of misunderstanding the licensee's instructions as verbal instructions may not be properly conveyed to persons not present at the time of release. The NRC also believes that providing written instructions will

help relieve apprehensions of the patient, primary care-giver, and family.

The draft regulatory guide published concurrently with this proposed rule includes recommended contents of the written instructions. The instructions should be specific to the type of treatment given, such as radioiodine for hyperthyroidism or thyroid carcinoma, or permanent implants; and may include additional information regarding individual situations. The instructions should include a contact and phone number in case the patient has any questions. Written instructions should include, as appropriate: (1) maintaining distance from individuals, including sleeping arrangements and the need to avoid public transportation; (2) the need to stop breast-feeding if appropriate; (3) avoidance of public places (such as grocery stores, shopping centers, theaters, restaurants, and sporting events); (4) hygiene; and (5) the length of time precautions should be taken. Not all of these precautions are necessary for every patient; therefore, patients should be given specific instructions that are applicable to their situation.

Issue 7. Should records of patients released containing radioactive materials be required?

Although the issue of records did not arise in the petitions or the comments on the petitions, proposed 10 CFR 35.75(b) would require the licensee to maintain a record of the basis for the patient's release and the calculations performed to determine the total effective dose equivalent if an individual is likely to receive a dose in excess of 1 millisievert (0.1 rem) in a year from a single administration. It is anticipated that this requirement will be met by either a notation, such as a reference to the Regulatory Guide, or calculation(s) to be retained in the patient's file. This record would provide a basis for assuring that the maximum dose to an individual exposed to the patient is below 5 millisieverts (0.5 rem) for any single administration. This record also provides the basis for ensuring that doses from multiple administrations greater than 1 millisievert (0.1 rem) each do not total more than 5 millisieverts (0.5 rem) in any year.

The 1-millisievert (0.1-rem) threshold for recordkeeping is based on the public dose limit of 1 millisievert (0.1 rem) specified in 10 CFR part 20. This threshold would not result in an undue recordkeeping burden for the majority of diagnostic administrations because these administrations are well below 1-millisievert (0.1-rem). Based on the regulatory analysis, the majority of

administrations requiring records involve iodine-131 therapeutic administrations and a few diagnostic procedures using iodine-131. Recordkeeping would affect less than one percent of all administrations. (For further information, see the regulatory analysis for the proposed rule. Single copies of the draft regulatory analysis are available as indicated in the ADDRESSES heading.)

The proposed record retention period of 3 years is consistent with similar recordkeeping requirements in 10 CFR parts 20 and 35.

VII. Summary of the Proposed Changes

This section summarizes the regulation changes that are being proposed. The NRC proposes to amend 10 CFR 20.1301(a)(1) to specifically state that the dose to individual members of the public from a licensed operation does not include doses received by individuals exposed to patients who were released by the licensed operation under the provisions of 10 CFR 35.75. This is not a substantive change but clarifies the NRC policy that patient release is governed by 10 CFR 35.75, not 10 CFR 20.1301, as discussed above under Issue 1.

The NRC proposes to amend 10 CFR 20.1301(a)(2) to specifically state that the limit on dose in unrestricted areas does not include dose contributions from patients administered radioactive material and released in accordance with 10 CFR 35.75. The purpose of this change is to clarify that licensees are not required to control areas, such as a waiting room, simply because of the presence of a patient released pursuant to 10 CFR 35.75. If a patient is not required to be confined pursuant to 10 CFR 35.75, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a patient to 0.02 millisievert (2 millirem) in any one hour. Patient waiting rooms or hospital rooms need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75.

The NRC proposes to adopt a new 10 CFR 35.75(a) to change the patient release criteria from 30 millicuries of activity in a patient or a dose rate of 5 millirem per hour at 1 meter from a patient to a dose limit of 5 millisieverts (0.5 rem) in any one year, excluding background or any occupational exposure, to an individual from exposure to a released patient. The reasons for this change were discussed above under Issue 2. In brief, a dose-based limit provides a single limit that can be used to provide an equivalent level of risks from all radionuclides.

Also, the proposed changes are supported by the recommendations of the ICRP and NCRP that an individual can be allowed to receive an annual dose up to 5 millisieverts (0.5 rem) in temporary situations where exposure to radiation is not expected to result in doses above 1 millisievert (0.1 rem) for long periods of time.

Doses among individuals who may come in contact with a released patient are highly variable and reflect the crucial, but difficult to define, parameters of time, distance, and shielding. Although all members of society have the potential for exposure to a released patient, based on time and distance considerations, it is reasonable to conclude that for the overwhelming majority of released patients, the maximally exposed individual is likely to be one who is aware of the patient's condition such as the primary care-giver, a family member, or any other individual who spends significant time close to the patient.

The NRC proposes to adopt a new 10 CFR 35.75(b)(1) to require that the licensee provide released patients with written instructions on how to maintain as low as reasonably achievable doses to other individuals if the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem) in any one year. A requirement for written instructions for certain patients was already contained in 10 CFR 35.315(a)(6) and 35.415(a)(5). The proposed requirement would add approximately 50,000 patients per year who are administered iodine-131 for the treatment of hyperthyroidism. The purpose of the written instructions is to maintain as low as reasonably achievable doses to individuals exposed to patients, as discussed in more detail under Issue 6.

The NRC proposes to revise 10 CFR 35.75(b)(2) to require that licensees maintain a record of the basis for the patient's release for three years. These records must include the calculations performed to determine the total effective dose equivalent of the individual likely to receive the highest dose if the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem) in a year from a single administration. It is anticipated that this requirement will be met by either a notation, such as a reference to the applicable regulatory guide or calculation(s) to be retained in the patient's file. The major purpose of the change is to provide the basis for controlling the dose to individuals exposed to a patient who may receive

more than one administration in a year, as discussed above under Issue 7.

Finally, the NRC proposes to amend its requirements on written instructions in 10 CFR 35.315(a)(6) and 35.415(a)(5). These regulations already required written instructions in certain cases, but the phrase "if required by § 35.75(b)" was added. The purpose of this change was to ensure internal consistency within 10 CFR part 35 on when written instructions must be provided.

VIII. Consistency with 1979 Medical Policy Statement

On February 9, 1979 (44 FR 8242), the NRC published a Statement of General Policy on the Regulation of the Medical Uses of Radioisotopes. The first statement of this policy states that, "The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public." The proposed rule is consistent with this statement because its purpose is to provide for the safety of individuals exposed to patients who are administered radioactive materials.

The second statement of the policy states that, "The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate." This statement is not relevant to the proposed rule because the proposed rule does not affect the safety of patients themselves but affects the safety of individuals exposed to patients.

The third statement of the policy states that, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The proposed rule is consistent with this statement because it places no requirements on the administration of radioactive materials to patients and because the release of patients administered radioactive materials has long been considered a matter of regulatory concern rather than solely a matter of medical judgement.

Thus, the proposed rule is considered to be consistent with the 1979 medical policy statement.

IX. Issue of Compatibility for Agreement States

The NRC believes that the proposed modifications to 10 CFR 20.1301(a) and 10 CFR 35.75 should be Division 1 and 2 items of compatibility, respectively, because the patient release criteria required by the rule are the minimum requirements necessary to ensure adequate protection of public health and

safety. However, representatives of the Agreement States who attended the public workshop held in Atlanta, Georgia, on July 15 and 16, 1992, have recommended that the proposed changes to 10 CFR part 35 should not be a matter of compatibility (i.e., Division 3) for the Agreement States. In addition, two Agreement States in their written comments on the draft rule reviewed in July 1993 addressed the issue of patient release under 10 CFR part 35 as a Division 3 matter. Under Division 2 status, the Agreement States must address the changes and may adopt more stringent requirements, but may not adopt less stringent provisions.

X. Finding of No Significant Environmental Impact: Availability

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR part 51, that the proposed amendments, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required. The proposed amendment would clarify the pertinent regulatory language to reflect explicitly the relationship between 10 CFR part 20 and part 35 with respect to release of patients, and revise the release criteria for patients receiving radioactive material for medical use from an activity-based standard to a dose basis. Because the risk basis of the current regulation remains unchanged, it is expected that there would be no significant change in radiation dose to the public as a result of the revised regulation.

The draft environmental assessment and finding of no significant impact on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft environmental assessment and the finding of no significant impact are available as indicated in the **FOR FURTHER INFORMATION CONTACT** heading.

XI. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The public reporting burden for this collection of information is estimated to

average 0.42 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-3019 (3150-0010), Office of Management and Budget, Washington, DC 20503.

XII. Regulatory Analysis

The NRC has prepared a regulatory analysis (NUREG-1492) for the proposed amendment. The analysis examines the benefits and impacts considered by the NRC. The regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies are available as indicated under the **FOR FURTHER INFORMATION CONTACT** heading.

XIII. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that, if adopted, this proposed rule would not have a significant economic impact on a substantial number of small entities. As a result of the revised regulation, the impact would not be significant because the revised regulation basically represents a continuation of current practice.

The NRC is seeking public comment on the initial regulatory flexibility certification. The NRC is particularly seeking comment from small entities as defined under the NRC's size standards published on November 6, 1991 (56 FR 56672), as to how the regulations will affect them and how the regulations may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety. Any small entity subject to this regulation who determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should offer comments that specifically discuss the following items:

(a) The licensee's size and how the proposed regulation would result in a significant economic burden or whether the resources necessary to implement this amendment could be more effectively used in other ways to

optimize public health and safety, as compared to the economic burden on a larger licensee;

(b) How the proposed regulation could be modified to take into account the licensee's differing needs or capabilities;

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation were modified as suggested by the licensee;

(d) How the proposed regulation, as modified, could more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group; and

(e) How the proposed regulation, as modified, would still adequately protect the public health and safety.

The comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555. ATTN: Docketing and Service Branch. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

XIV. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed rule, because these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

XV. List of Subjects

10 CFR part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting and recording requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR part 35

Byproduct material, Criminal penalty, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR parts 20 and 35.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for part 20 is revised to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (U.S.C. 5841, 5842, 5846).

2. In § 20.1301, paragraph (a) is revised to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) Each licensee shall conduct operations so that—

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003 and from patients administered radioactive material and released in accordance with § 35.75; and

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 35.75, does not exceed 0.002 rem (0.02 mSv) in any one hour.

* * *

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

3. The authority citation for part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 68 Stat. 1242, as amended (42 U.S.C. 5841).

4. In § 35.8, paragraph (b) is revised to read as follows:

§ 35.8 Information collection requirements: OMB approval.

* * *

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.13, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.75, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

* * *

5. Section 35.75 is revised to read as follows:

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

(a) A licensee may authorize release from licensee control any patient administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to an individual from exposure to the released patient is not likely to exceed 5 millisieverts (0.5 rem) in any one year.

(b) If the total effective dose equivalent to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem) in a year from a single administration, upon release the licensee shall:

(1) Provide the patient with written instructions on how to maintain doses to other individuals as low as reasonably achievable; and

(2) Maintain, for three years, a record of the released patient and the calculated total effective dose equivalent to the individual likely to receive the highest dose.

6. In § 35.315, paragraph (a)(6) is revised to read as follows:

§ 35.315 Safety precautions.

(a) * * *

(6) Provide the patient with radiation safety guidance, if required by § 35.75(b), that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient.

* * *

7. In § 35.415, paragraph (a)(5) is revised to read as follows:

§ 35.415 Safety precautions.

(a) * * *

(5) Provide the patient with radiation safety guidance, if required by § 35.75(b), that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

* * *

Dated at Rockville, MD, this 9th day of June, 1994.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Acting Secretary of the Commission.

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