

March 8, 1983

Nicholas Lembares
Chairman, Legislative Committee
American Association of Physicists in Medicine
c/o Christ Hospital, Radiation Oncology Dept.
4440 W. 95th Street
Oak Lawn, Illinois 60453

Dear Mr. Lembares:

I enclose for your information a copy of a notice published in the Federal Register (48 Fed. Reg. 2115) concerning a final rule on teletherapy room radiation monitors which has been promulgated by the Nuclear Regulatory Commission. Your organization, through Dr. Hubbard, had expressed an interest in this rulemaking and earlier NRC orders to teletherapy licensees on this subject.

I trust this information will be useful to you.

Sincerely,



Stephen G. Burns
Counsel to NRC Staff

Enclosure: As stated

cc:
Dr. Lincoln B. Hubbard
Box 367
Hines, Illinois 60141
bcc: A. Rocklein, RES

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Rules and Regulations

Federal Register

Vol. 48, No. 12

Tuesday, January 18, 1983

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 213

Excepted Service

AGENCY: Office of Personnel Management.

ACTION: Final rule; technical amendment.

SUMMARY: The Office of Personnel Management (OPM) is issuing a technical amendment to the Schedule A excepted appointing authority for the Presidential Management Intern Program to implement changes made by Executive Order 12364, The Presidential Management Intern Program, dated May 24, 1982. This amendment provides for an extension of Presidential Management Intern appointments for an additional year and removes superfluous language from the basic appointing authority.

EFFECTIVE DATE: January 18, 1983.

FOR FURTHER INFORMATION CONTACT: William Bohling, 202-632-6000.

SUPPLEMENTARY INFORMATION: Executive Order 12364 replaced Executive Order 12008 of the same title, issued August 25, 1977, as the basic authority for the Presidential Management Intern Program. The new order changed the absolute 2-year limit for Intern appointments by providing for extension, with OPM approval, for additional year. Interns may, however, still be converted to competitive status after completing at least 2 years of excepted service.

The Schedule A appointing authority provides that requirements for conversion will be published in the Federal Personnel Manual. However, the authority also included a summary of those requirements. As that summary was superfluous and was less informative

than the instructions in the Federal Personnel Manual, it has been deleted. Agencies will find the requirements for conversion of Presidential Management Interns to competitive appointments in chapter 315 of the Federal Personnel Manual.

The Director finds that good cause exists to waive the general notice of proposed rulemaking and to make this amendment effective in less than 30 days. The regulation is being made effective immediately because it does not change the substance of the regulation issued July 2, 1982, but merely updates its provision to reflect and implement Executive Order 12364, which is already in effect.

E.O. 12291, Federal Regulation

OPM has determined that this is not a major rule as defined under Section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it pertains solely to conditions for appointment of certain employees by Federal agencies.

List of Subjects in 5 CFR Part 213

Government employees.

Office of Personnel Management,
Donald J. Devine,
Director.

PART 213—[AMENDED]

Accordingly, the Office of Personnel Management is amending 5 CFR Part 213 by revising § 213.3102(ii) to read as follows:

§ 213.3102 Entire executive civil service

(ii) Positions of Presidential Intern, GS-9 and 11, in the Presidential Management Intern Program. Initial appointments must be made at the GS-9 level. No one may serve under this authority for more than 2 years, unless extended with OPM approval for up to one additional year. Upon completion of 2 years of satisfactory service under this authority, the employee may qualify for conversion to competitive appointment under the provisions of Executive Order 12364, in accordance with the provisions of § 315.708 of this chapter and

requirements published in the Federal Personnel Manual.

(5 U.S.C. 3301, 3302; EP 12364, 47 FR 22831)
(FR Doc. 83-1214 Filed 1-17-83; 845 am)
BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 225 and 226

Vegetable Protein Products; Used in Child Nutrition Programs

Correction

In FR Doc. 83-522, on page 775, in the issue of Friday, January 7, 1983, make the following corrections:

1. On page 781, third column, paragraph (b)(1), line 4, remove the quotation marks.

2. On page 782, first column, correct the table, item 7 to read: "Vitamin B₁₂ (micrograms)..... .1".

BILLING CODE 1505-01-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

Teletherapy Room Radiation Monitors and Inspection and Servicing of Teletherapy Source Exposure Mechanisms

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations applicable to NRC teletherapy licensees. The intent of these amendments is to ensure prior warning to the operator in the event of a malfunction of a teletherapy source exposure mechanism and to ensure adequate inspection and servicing of the teletherapy machine. The amendments require:

1. The installation of radiation monitors in teletherapy rooms;
2. The use of portable survey instruments or audible alarm personal dosimeters whenever the permanent radiation monitors are inoperable; and
3. The inspection and servicing of all teletherapy units to assure proper

functioning of the source exposure mechanism, during source replacement or at intervals not to exceed five years, whichever comes first.

EFFECTIVE DATE: March 4, 1983.

FOR FURTHER INFORMATION CONTACT: Mr. Alan K. Roeklein, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301-443-5970).

SUPPLEMENTARY INFORMATION: In May 1980, the Office of Nuclear Material Safety and Safeguards issued orders to all NRC teletherapy licensees requiring the installation of teletherapy room radiation monitors and the use of portable radiation survey meters when the installed monitors are inoperable. In 1972 the NRC established a standard teletherapy license condition requiring inspection and servicing of all teletherapy machines to assure proper functioning of the source exposure mechanisms at time of source replacement or every five years, whichever comes first, and requiring that a record of the inspection and servicing be kept on file for review by the Commission's Office of Inspection and Enforcement. These actions were intended to provide early warning of, and to help prevent, potentially serious over-exposures of teletherapy operators and patients in the event that the source exposure mechanism failed.

The radioactive sources contained in teletherapy units produce radiation fields on the order of hundreds of rads per minute in areas accessible to patients and operators. An undetected exposed source could result in overexposures of patients or operating personnel in a short period of time. Teletherapy units are designed with reliable source handling components. In spite of careful design the NRC is aware of some teletherapy equipment malfunctions that had the potential for causing serious overexposures. Although no overexposures involving serious injury have occurred, the rule changes described in the summary are intended to provide greater assurance that teletherapy equipment malfunctions do not occur and that they will be detected before a serious injury can occur.

It is the Commission's intent to codify the previously described orders and license condition, as modified herein, so that they are uniformly applicable to existing licensees and new applicants. A copy of this final rule notice will be sent to all current teletherapy licensees with a cover letter calling the licensees' attention to the matters outlined below.

With regard to the May 7, 1980 orders requiring the installation of radiation monitors, licensees are advised that the

orders are hereby rescinded. Most teletherapy licenses now include a license condition that incorporates the provisions of the May 7, 1980 orders. Licensees are advised that the NRC considers the final rule to supersede these license conditions as well. Specifically the rule differs from the previous orders in that it will permit the use of a back-up power supply other than a battery and will also permit the use of audible alarm personal dosimeters as well as portable survey meters if the radiation monitor is inoperable. Licensees are referred to Regulatory Guide 8.28, "Audible Alarm Dosimeters," for guidance concerning the use and limitations of audible alarm personal dosimeters.

Some licensees requested relief from the 1972 license condition requiring five-year inspection and servicing of their units. The NRC staff considered these requests on a case-by-case basis and many of the requests have been granted in the form of a license condition modifying the time interval. It is intended that the license conditions already granted will take precedence over the rule when it becomes effective.

The rule includes a provision to this effect in § 35.26.

Licensees are advised that if, after the rule change is published and becomes effective, there are unusual circumstances, they may request a specific exemption under 10 CFR 30.11. These requests will be considered on a case-by-case basis as a request to amend a license and must be accompanied by the appropriate fee required by 10 CFR 170.31.

Comment Analysis

On April 28, 1982, the Nuclear Regulatory Commission published for comment in the Federal Register (47 FR 18131) proposed amendments to 10 CFR Part 35 of its regulations. Six letters of public comment were received. One letter opposed the rule and five proposed minor changes. As a result of analysis of the public comments received and further staff discussions, two changes have been made in the amendments as proposed.

—Proposed § 35.25.(b) required that the visible indicator of high radiation levels must be located so as to be observable by a person entering the room and during operation of the unit. Several commenters observed and the staff has confirmed that most teletherapy treatment facilities are designed with a maze to prevent exposure of the operator during treatment. In many cases this design would require a separate television camera and receiver system in order to

observe the visible indicator on the radiation monitor during treatment. This paragraph has been revised to require that the visible indicator be observable by a person entering the treatment room only.

—Proposed § 35.25(e) required that if a radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a portable survey instrument to monitor for any malfunction of the source exposure mechanism that may have resulted in an exposed or partially exposed source. It was suggested that audible alarm personal dosimeters would be an acceptable alternative to a portable survey instrument. The staff agreed that, if checked daily before use, available audible alarm personal dosimeters would provide adequate warning of an exposed source if the fixed monitor were inoperable. This paragraph has been revised to permit use of an audible alarm personal dosimeter.

Other substantive comments received on the proposed rule were:

—A statement that inspection of the source exposure mechanism is redundant in view of the requirement for monitoring equipment. This comment is rejected for the reason that inspection is intended to prevent malfunctions, while the radiation monitor can only provide warning that a malfunction has occurred;

—A suggestion that teletherapy units should be equipped with improved timing devices to minimize the chances of exposure timing errors. Although the staff recognizes the merit of improved exposure timing devices the staff does not believe that the comment is within the scope of this rulemaking procedure. However, this comment is under consideration for inclusion in a regulatory guide for teletherapy licensing.

—A suggestion that the permanently mounted radiation monitor should be equipped with an audible alarm. Requiring that the radiation monitor be equipped with an audible alarm was considered in the development of this rule. A decision has been made not to include the audible alarm provision. The staff believes that the cost of backfitting an audible alarm is not justified by the marginal increase in safety. Licensees may install an audible alarm in addition to a visible alarm if they so choose. Licensees desiring to use an audible alarm only may request a specific exemption under 10 CFR 30.11. These requests will be considered on a case-by-case basis as a request to amend the license and must be accompanied by the

appropriate fee required by 10 CFR 170.31.

Paperwork Reduction Act Statement

This rule was submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act (Pub. L. 96-511; 42 U.S.C. Ch. 15). The recordkeeping requirement contained in this regulation was approved by OMB. OMB approval No. 3150-0010.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 805(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

About 440 teletherapy licensees are regulated by the NRC. Fewer than 1% of these can qualify as small entities for the purposes of the Regulatory Flexibility Act applying the standards contained in 13 CFR Part 121, Small Business Size Standards. All but a few of the teletherapy licensees are hospitals and the Small Business Administration defines small hospitals as having fewer than 150 beds. A check on 104 of NRC teletherapy licensees showed that all of them had more than 150 beds.

The NRC believes that all teletherapy licensees have already installed monitoring equipment and have portable survey instruments available in compliance with the 1980 orders. The cost of an installed monitor and survey instrument is approximately one thousand to fifteen hundred dollars. The approximate cost of a teletherapy unit exceeds one hundred thousand dollars. Annual revenue generated by a teletherapy unit is on the order of 200,000 dollars.

Costs for the inspection, servicing, and recordkeeping will be proportional to the number of units owned by the licensee. An estimate of these costs is less than 500 dollars per year per teletherapy unit.

The Commission believes that the costs to licensees is small compared to the revenue generated by use of a teletherapy unit and that the gains in patient and operator protection will significantly outweigh the economic impact on licensees.

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting 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 adopting the following amendments to 10 CFR Part 35.

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 is revised to read as follows:

Authority: Secs. 81, 161, 182, 183, 88 Stat. 935, 948, 953, 954, as amended; (42 U.S.C. 2111, 2201, 2232, 2233); Section 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 88 Stat. 953, as amended (42 U.S.C. 2273); §§ 35.2, 35.14 (b), (e) and (f), 35.21(a), 35.22(a), 35.24, and 35.31 (b) and (c) are issued under sec. 181b, 88 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14(b)(5) (ii), (iii) and (v) 35.2, 35.27 and 35.31(d) are issued under sec. 181c, 88 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 35.25 [Redesignated as § 35.27]

2. The present § 35.25 is redesignated § 35.27.

3. A new § 35.25 is added to read as follows:

§ 35.25 Requirements to install a permanent radiation monitor in teletherapy rooms and to use portable survey instruments or audible alarm dosimeters.

(a) Each licensee authorized under § 35.13 to use teletherapy units for treating humans shall install a permanent radiation monitor in each teletherapy room for continuous monitoring of beam status.

(b) Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that may result in an exposed or partially exposed source. The visible indicator of high radiation levels must be located so as to be observable by a person entering the treatment room.

(c) Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the teletherapy unit. This emergency power supply may be a battery system.

(d) Each radiation monitor must be tested for proper operation each day before the teletherapy unit is used for treatment of patients.

(e) If a radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a properly operating portable survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may have resulted in an exposed or partially exposed source. Survey instruments or dosimeters must be tested daily before use.

4. A new § 35.26 is added to read as follows:

§ 35.26 Inspection and servicing of the source exposure mechanism; relief granted by certain license conditions.

(a) The licensee shall cause each teletherapy unit used to treat humans to be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) Inspection and servicing of the teletherapy unit shall be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) Amendments to teletherapy licenses in effect as of March 4, 1983, which extended the time interval for the inspection and servicing requirement of paragraph (a) of this section shall remain in effect and are not rescinded by this section.

5. In redesignated § 35.27 the introductory text and paragraph (a) are revised to read as follows (paragraphs (b) and (c) of redesignated § 35.27 are not changed):

§ 35.27 Records.

The licensee shall maintain, for inspection by the Commission, records of the measurements, tests, corrective actions, inspection and servicing of the teletherapy unit, and instrument calibrations made under §§ 35.21 through 35.26 and records of the licensee's evaluation of the qualified expert's training and experience made under § 35.24.

(a) The following records must be preserved for five years after completion of the full calibration or after inspection and servicing:

(1) Full calibration measurements reports made under § 35.21.

(2) Records of calibration of the instruments used to make these measurements under § 35.23.

(3) Records of inspection and servicing of the teletherapy unit under § 35.26.

Dated at Bethesda, Md., this 4th day of January 1983.

For the Nuclear Regulatory Commission.

William J. Dircks,
Executive Director for Operations.

[FR Doc. 83-1279 Filed 1-17-83; 8:48 am]
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