and reimbursable travel. In addition, recent congressional action may result in additional salary increases of 3.0 percent in 1997. Although the program's operating reserves were adequate to cover the January 7, 1996, salary increase, this will not be the case for 1997 salary increases, and a fee increase is needed.

The grading program fees need to be increased to cover the costs associated with maintaining adequate levels of service during shifting production patterns within the dairy industry. The industry changes include plant consolidations, geographical shifts of dairy production areas, and changes in the types of dairy products being manufactured and offered for inspection and grading services. To minimize the necessary fee increase, the Department has initiated cost-reduction efforts which include the reduction of staff and program overhead.

Proposed Changes

This rule proposes the following changes in the regulations implementing the dairy inspection and grading program:

1. Increase the hourly fee for nonresident services from $48.00 to $52.00 for services performed between 6:00 a.m. and 6:00 p.m. The nonresident hourly rate is charged to users who request an inspector or grader for particular dates and amounts of time to perform specific grading and inspection activities. These users of nonresident services are charged for the amount of time required to perform the task and undertake related travel plus travel costs.

2. Increase the hourly fee for continuous resident services from $43.00 to $47.00. The resident hourly rate is charged to those who are using grading and inspection services performed by an inspector or grader assigned to a plant on a continuous, year-round resident basis.

Timing of Fee Increase

It is contemplated that the proposed fee increases would be implemented on an expedited basis in order to minimize the period of revenue shortfall. Accordingly, it is anticipated that the fee increases, if adopted, would become effective upon publication, or very soon after publication, of the final rule in the Federal Register and that delaying the effective date of the final rule until 30 days after publication in the Federal Register would not occur. An approximate effective date would be January 5, 1997.

All written submissions made pursuant to this notice will be made available for public inspection in the Dairy Division during regular business hours.

List of Subjects in 7 CFR Part 58

Dairy products, Food grades and standards, Food labeling, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, it is proposed that 7 CFR Part 58 be amended as follows:

PART 58—GRADING AND INSPECTION, GENERAL SPECIFICATIONS FOR APPROVED PLANTS AND STANDARDS FOR GRADES OF DAIRY PRODUCTS

1. The authority citation for Part 58 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

Subpart A—[Amended]

2. In subpart A, § 58.43 is revised to read as follows:

§ 58.43 Fees for inspection, grading, and sampling.

Except as otherwise provided in §§ 58.38 through 58.46, charges shall be made for inspection, grading, and sampling service at the hourly rate of $52.00 for service performed between 6:00 a.m. and 6:00 p.m. and $57.20 for service performed between 6:00 p.m. and 6:00 a.m., for the time required to perform the service calculated to the nearest 15-minute period, including the time required for preparation of certificates and reports and the travel time of the inspector or grader in connection with the performance of the service. A minimum charge of one-half hour shall be made for service pursuant to each request or certificate issued.

3. Section 58.45 is revised to read as follows:

§ 58.45 Fees for continuous resident services.

Irrespective of the fees and charges provided in §§ 58.39 and 58.43, charges for the inspector(s) and grader(s) assigned to a continuous resident program shall be made at the rate of $47.00 per hour for services performed during the assigned tour of duty. Charges for service performed in excess of the assigned tour of duty shall be made at a rate of 1½ times the rate stated in this section.

Dated: November 6, 1996.

Lon Hatamiya,

Administrator.

[FR Doc. 96–29106 Filed 11–13–96; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 33

RIN 3150—AF54

Specific Domestic Licenses of Broad Scope for Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is considering amending its regulations governing specific licenses of broad scope for byproduct material to clarify the regulatory and health and safety basis of current licensing practices and to provide licensees with the flexibility to make certain types of changes to their radiation safety programs. Currently, the regulations do not contain a clear description of the duties and responsibilities of management, the Radiation Safety Officer (RSO) or the Radiation Safety Committee (RSC). In addition to various ongoing staff efforts regarding the possible need for clarification of requirements for broad scope licensees, consideration of changes to the regulations was also a recommendation of the Incident Investigation Team reviewing a recent incident involving ingestion of phosphorus-32 at a broad scope facility. The NRC is evaluating, for possible codification in its regulations, existing regulations and appropriate requirements derived from prior guidance and license standard review plans with reference to: management oversight of broad-scope licensed programs; the role of the RSO; the responsibilities of the RSC; supervision; the qualifications of the authorized user; the use of audits and inventory requirements; and security and control of licensed material. The NRC is seeking comments and suggestions on possible revisions.

DATES: Comment period expires February 12, 1997. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Send written comments and suggestions to: Secretary, Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Docketing and Service Branch. Hand-deliver comments to: 11555 Rockville Pike, Rockville, MD, between 7:45 a.m. and 4:15 p.m., Federal workdays.

FOR FURTHER INFORMATION CONTACT: Patricia K. Holahan, Ph.D., Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–8125, e-mail PKH@NRC.GOV.

SUPPLEMENTARY INFORMATION:

I. Background

The regulations for specific licenses of broad scope for byproduct material are codified in 10 CFR Part 33. This part was initially published on June 26, 1965, and became effective on August 8, 1965. Its provisions are applicable to licenses for multiple quantities and types of byproduct material. There are three types of broad scope licenses, currently described in Part 33, that authorize the receipt, acquisition, ownership, possession, use, transfer, and import of byproduct material for purposes authorized by the Atomic Energy Act, as amended. A ''Type A specific license of broad scope'' usually authorizes quantities in the multicurie range for radionuclides with a range of atomic numbers. The possession limit for a ''Type B specific license of broad scope'' for a single radionuclide is the quantity specified in Column I of Schedule A to Part 33. If two or more radionuclides are possessed, a sum of the ratios test is performed to determine possession quantities. Similarly, the possession limit for a ''Type C specific license of broad scope'' for a single radionuclide is the quantity specified in Column II of Schedule A to Part 33. In general, the possession limits are progressively smaller as the Type changes from A to B to C.

Each type of specific license of broad scope has a condition regarding individuals who may use or directly supervise other individuals who use byproduct material. Material possessed under a Type A specific license of broad scope may only be used by, or under the direct supervision of, individuals approved by the licensee's RSC. Material possessed under a Type B specific license of broad scope may only be used by, or under the direct supervision of, individuals approved by the licensee's RSO. Material possessed under a Type C specific license of broad scope may only be used by, or under the direct supervision of, individuals who satisfy the education and training requirements specified in 10 CFR 33.15.

In practice, Part 33 reduces the administrative burden for both licensees and the Commission without reducing safety standards or lessening the licensing requirements for training, experience, facilities, and equipment. Both the NRC and the licensee benefit from the reduction in license amendments that might otherwise be needed to change authorized radionuclides, quantities, or names of individuals who may use, or supervise the use of, byproduct material. The provisions of Part 33 recognize that certain licensees, who conduct varied and large-scale activities with licensed material under oversight by persons with extensive training and experience in radiation safety, do not require the same degree of regulatory oversight as do licensees who perform similar or less complex activities with licensed material, but have less comprehensive radiation safety programs. Part 33 does not prescribe requirements for a radiation safety program to meet the specific needs of the licensed facility and activities. Rather, broad scope licensees develop an application addressing general requirements specified for each type of specific license of broad scope and submit this program description for the NRC to review. The commitments made by the license applicant, upon approval by the NRC, become conditions of the license by reference.

The NRC has issued guidance for preparation of applications of broad scope (Regulatory Guide 10.5, ''Applications for Licenses of Broad Scope'') to provide acceptable methods to ensure that licensed activities will be conducted in a safe manner. In the approximately 30 years since Part 33 was issued, this guidance was revised to address many issues that are not explicitly set forth in the regulation. For example:

(1) There is no requirement for management oversight of the radiation program, including audits and specification of the responsibilities and duties of the RSC or the RSO;

(2) There are no requirements in Part 33 for inventory and accountability of byproduct material in use;

(3) Although these licensees may approve users and new uses of byproduct material, there is no provision to permit a specific licensee to make certain types of changes to the radiation program as described in the application (such as changing dosimetry vendors) without an amendment of the conditions of the license; and

(4) There is no requirement specifying either a single location of use or multiple locations of use. Government agencies and corporations with similar operations at multiple locations have sought to reduce their administrative burden and regulatory costs by centralizing their radiation safety functions and consolidating multiple single site licenses.

The NRC is considering the need to codify, as requirements, some of the licensing guidance and practices, to provide a clearer regulatory basis for evaluating whether to issue or deny licenses of broad scope and provide a clear regulatory framework within which licensees must operate.

In 1993, an internal senior management review of NRC's existing medical use regulatory program, considered needed improvements in the medical licensing and inspection programs. Additionally, the review determined that many of the significant problems identified in medical programs are a consequence of licensee management and RSO failures. The report recommended that current NRC requirements and guidance on the responsibilities of RSOs, at all materials facilities, should be examined with consideration given to a performance-based rule. Draft NUREG–1516, [1] ''Management of Radioactive Material Safety Programs at Medical Facilities,'' was published in January 1995 for comment, in part to address this recommendation. This report describes a systematic approach for effectively managing radiation safety programs at medical facilities. It should be noted that other types of broad scope facilities such as manufacturers and research and development facilities are also being considered in this process.

Generally, the current program governing the regulation of specific licenses of broad scope for byproduct material has worked well to provide for public health and safety from these licensed activities. For the three-year period from 1993–96 there were only 38 events involving these licenses that resulted in some type of enforcement action. However, the majority of these events involved loss of control of the radioactive material, release of material in excess of the limits in 10 CFR 20, or contamination outside of the work area. These types of events, which could potentially result in doses to the public from radioactive material in unrestricted areas, are often the result of weak controls by either the RSO or RSC.

The NRC is currently developing a new materials licensing process. To proceed with the implementation of the new process, the NRC staff recommended certain actions for Commission approval. These included

[1] A free single copy of draft NUREG–1516 may be requested by those considering public comment by writing to the U.S. Nuclear Regulatory Commission, ATTN: Distribution and Mail Services Section, Room P–130A, Washington, DC 20555. A copy is also available for inspection and/or copying in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

the development of a standard license condition, for broad scope licensees, that is functionally equivalent to 10 CFR 50.59, for nuclear power reactor licensees. This would allow licensees to make certain types of changes to their program after review and approval by the RSC without the need for a specific license amendment, provided that the change does not alter radiation safety performance, but is only a change in the methods to achieve that performance. This process is now being considered as part of this advance notice of proposed rulemaking.

The possible need for clarification of requirements for broad scope licensees is also supported by two recent events, of a similar nature, involving phosphorus-32 (P–32) internal contamination of individuals at large biomedical research facilities. P–32 is widely used in research institutions, as are many other radionuclides. Although both of these events involved P–32, the inherent issues of control of licensed material and management of radiation safety programs extend to all facilities using licensed material. The NRC dispatched an Augmented Inspection Team to investigate the circumstances surrounding the first incident, and an Incident Investigation Team to investigate the contamination incident at the second facility. The teams found, among other things, that regulatory requirements and guidance for the application of security and control of relatively small quantities of unsealed byproduct material are inconsistent, and that the roles and responsibilities of RSOs, RSCs and management are not clearly specified.

Weak management oversight of the radiation protection program was also identified as a contributing factor in one of these internal contamination events. The licensee did not use a process of management review and self-assessment (audits) to look for weaknesses in its program, and to take appropriate remedial actions. Although Part 33 requires the establishment of an RSC and the appointment of an RSO, it does not provide broad scope licensees with a clear description of the duties and responsibilities of the RSO or the RSC. Therefore, the NRC is evaluating, for possible codification in Part 33, existing regulations and appropriate requirements derived from prior guidance and license standard review plans, with reference to: management oversight of broad scope licensed programs; the role of the RSO; the responsibilities of the RSC; supervision; the qualifications of the authorized user; the use of audits and inventory control; and security and control of licensed material.

II. Requests for Comments on General Considerations

The NRC has identified some areas, within Part 33, that could be modified or deleted, and is seeking comments on these as well as any other issues offered for consideration of this part. A major issue is whether the regulations should be performance-based or include some of the existing licensing guidance as specific requirements. A revised performance-based rule would clarify the objectives the licensee must include within its program, but details, as to one method acceptable to the NRC staff to meet those objectives, would continue to be provided in guidance documents, such as draft Regulatory Guide DG–0005, ''Applications for Licenses of Broad Scope'' (second proposed Revision 2 to Regulatory Guide 10.5) issued for public comment on October 1994.

The purpose of describing these preliminary issues and posing certain questions is to illustrate aspects of NRC's evaluation of Part 33 to date, and to request public comment on the completeness of this evaluation and whether the proposed changes pose any serious implementation problems. Commenters are invited to make additional suggestions. In addition to specific questions, draft rule language is provided, for comment, that reflects many of the identified issues.

1. Should the Responsibilities of Licensee Management for the Radiation Safety Program Be Specified in Part 33?

The team reviewing one of the internal contamination incidents identified weak management oversight of the Radiation Protection Program. The licensee did not use a process of management review and self-assessment (audits) to look for weaknesses in its program and to take appropriate remedial actions. Draft NUREG–1516, ''Management of Radioactive Material Safety Programs at Medical Facilities,'' discusses the importance of the role of an institution's executive management including selecting the RSO, determining adequate resources for the program, using contractual services, conducting audits, and establishing the roles of authorized users and supervised individuals. Draft Regulatory Guide DG–0005, ''Applications for Licenses of Broad Scope'' (second proposed Revision 2 to Regulatory Guide 10.5) recommends that a license application for a Type A license of broad scope include an organization chart depicting the management structure, reporting paths, and flow of authority. NRC is soliciting comment on the mechanism for, and extent to which, requirements defining management responsibilities for oversight of radiation safety programs should be included in Part 33.

2. Should the NRC Incorporate Requirements for the Duties and Responsibilities of the RSO and the RSC?

Part 33 provides broad scope licensees with neither a detailed description of the duties and responsibilities of the RSO or of the RSC nor with specific qualifications of the RSO. The RSO for a broad scope license must be sufficiently qualified to manage the day-to-day operations of the radiation safety program. Depending on the size and scope of the program, the necessary qualifications may vary for different licensees. Draft NUREG–1516 describes a systematic approach for effectively managing radiation safety programs at medical facilities by defining and emphasizing the roles of the institution's executive management, RSC, and RSO. Draft Regulatory Guide DG–0005 suggests that an application for a Type A license should include a statement of the authority of the RSC to oversee the licensed program and its responsibility for control and direction of the radiation safety program and the RSO. The NRC is soliciting public comments on the need for specific requirements delineating the roles and responsibilities of the RSC and the RSO and the establishment of minimum training and experience criteria for the RSO.

3. Should Specific Minimum Training and Experience Criteria for Authorized Users Be Incorporated Into Part 33?

Currently, the requirements in § 33.15 for issuance of a Type C specific license of broad scope include specific training and experience criteria for individuals using byproduct material. There are no specific training and experience criteria stated in the requirements for the issuance of other types of broad scope licenses. However, Appendix J of draft Regulatory Guide DG–0005 provides guidance for elements of a broad scope training program for authorized users as well as for supervised individuals. The guidance does allow the licensee the flexibility to develop a program commensurate with potential radiological health protection problems but suggests that the training for authorized users for nonmedical use should be at least equivalent to that currently specified in § 33.15(b)(1) and (2). The NRC is soliciting comment on whether training and experience criteria

should be incorporated into the regulations or be addressed in guidance documents.

4. Should the NRC Incorporate Specific Requirements for Inventory and Accountability of Byproduct Material in Use, or Modify Its Existing Guidance?

The team reviewing one of the internal contamination incidents found that regulatory guidance for the security and control of small quantities of unsealed byproduct material was inconsistent. Consequently, NRC staff committed to review existing regulations, guidance, and license standard review plans, with reference to the security and control of radioactive materials, as well as the establishment of restricted, unrestricted, and controlled areas. Additionally, NRC inspectors have identified some broad scope licensees who do not adequately account for sealed sources (e.g., PuBe sources). The NRC is soliciting comments as to codification, in the regulations, of requirements regarding accounting for, and inventory of, radioactive materials.

5. Should the NRC Consider the Risks Associated With Internal Exposure Pathways (e.g., Ingestion, Inhalation, Absorption) Separate From Those Associated With External Radiation?

The two recent events discussed in the background section both dealt with ingestion of radioactive material in contrast to external exposure. In some cases, it appears that, because of the greater uncertainties associated with dose estimates for internal exposure than external, the public, some workers, and some licensees consider that greater protective measures are necessary to minimize exposures from internal pathways. Although the Commission recognizes that there may be greater uncertainties with the estimation of internal exposure, the revision of 10 CFR Part 20 assumes that internal and external exposure are equivalent in terms of risk. This is the underlying basis behind the total effective dose equivalent (TEDE). The NRC is soliciting comments on whether the risks from internal exposure should be considered separately from the risks from external exposure.

6. Are There Other Specific Aspects of the Draft Regulatory Guide DG–0005 That Should Be Codified in Part 33?

In October 1994, draft Regulatory Guide DG–0005 (second proposed Revision 2 to Regulatory Guide 10.5) was issued for public comment. This revision is substantially more comprehensive than previous guidance in identifying the information needed to complete NRC Form 313 when applying for a license of broad scope for byproduct material. It includes such aspects of the radiation safety program as administrative procedures, material inventory and accountability, audits and appraisals, safety evaluations, and exposure control. There are currently no specific requirements in 10 CFR Part 33 addressing these topics, or additional topics discussed in the guidance. The NRC is soliciting comments on which, if any, aspects of the draft regulatory guidance for broad scope facilities should be codified in the regulations.

7. Should Broad Scope Licensees Be Allowed To Make Changes in Their Radiation Safety Program Similar to Those Authorized for Production and Utilization Facilities in § 50.59?

There are no specific regulations governing changes to the radiation safety program for broad scope licensees. In contrast, medical use licensees may make minor changes in their radiation safety procedures described in an application for license, renewal, or amendment, that are not potentially important to safety, pursuant to § 35.31. Nuclear power reactor licensees may make changes in the facility or procedures as described in the safety analysis report (SAR) or conduct tests or experiments not described in the SAR, without prior Commission approval, unless the proposed change, test, or experiment involves a change in the technical specifications of the license or an unreviewed safety question. The licensee must maintain a written safety evaluation of the change. Although an unreviewed safety question, as defined in § 50.2, is not applicable to materials licensees, § 36.53(c) for irradiator licensees, allows licensees to revise operating and emergency procedures, provided, in part that any changes should not reduce the safety of the facility. The NRC is soliciting comments on allowing broad scope licensees to have the flexibility to make changes to their radiation safety program as is afforded to irradiator and nuclear power licensees.

8. Should the Different Types of Broad Scope Licenses Currently in Part 33 (Types A, B, and C) Be Deleted and Replaced With a Single Type?

The current NRC regulation 10 CFR Part 33, ''Specific Domestic Licenses of Broad Scope for Byproduct Material,'' provides for three distinct types of licenses of broad scope (i.e., Type A, Type B, and Type C), which are defined in § 33.11. There is no difference in the fees associated with each of the three types of broad scope license, for a specific category of license (e.g., manufacturer, research and development, medical, etc.). As the majority (approximately 240) of NRC licenses of broad scope are Type A, NRC is considering the elimination of Types B and C. The activities previously authorized as a Type B or C license of broad scope (approximately 60 licenses) would be conducted under a specific license of limited scope or the licensee could modify its program to meet the requirements for a Type A specific license of broad scope and commit to the necessary program oversight and use of a RSC. The NRC is soliciting comments on whether to eliminate Types B and C specific licenses of broad scope.

9. Should a Category for ''Master Materials Licenses'' Be Incorporated Into Part 33 With the Respective Necessary Requirements?

The NRC currently has issued a single ''master materials license'' to each of three federal departments, the U.S. Navy, Air Force, and Department of Agriculture. A ''master material license'' authorizes a single entity to issue permits for its facilities at multiple sites in multiple regions. The NRC does not review or approve new users and/or locations before use, and does not inspect each of the permitted facilities under the routine inspection frequency for that type of facility. Unlike NRC inspection of other multi-site broad scope licenses, the NRC inspects a sample of master materials facilities each year. These licensees are inspected less frequently because they conduct inspections of their permittees. These licensees are not permitted to authorize releases of byproduct material to the environment nor grant exemptions to NRC's regulations, without prior NRC approval. To date, the master materials program has worked well and could serve as a model for external regulation of some DOE activities. The scope of authority and conditions in this type of license and the requirements imposed on these licensees have not been subjected to the public comment process. The NRC is considering whether specific requirements for issuance of a master materials license should be codified in Part 33. The draft language includes a definition for a master materials license, but does not include any distinct requirements. The NRC is soliciting comments on this issue.

10. Should Requirements for ''Multi-Site Facilities'' Be Codified in Part 33 or Should This Be Defined Only in 10 CFR Part 30?

A multi-site license is one that includes two or more locations of use identified in the license, such as: (1) stand-alone facilities that would otherwise be licensed individually; or (2) satellite facilities that are not located within the principal job site, and for which NRC licensed material use is ongoing (excluding temporary job sites, broad scope licensees, or mobile nuclear medicine services). A multi-site facility may also include those licensees for which the addresses of use are geographically separated and which may each be under the direction of the same or different RSO(s). Regardless of the number of sites authorized under one license or the geographic distance between sites, the adequacy of the overall radiation safety management structure must be reviewed by the licensee and the NRC to ensure safe operations at each site.

Although there are many aspects of a multi-site license that require licensee commitments similar to those made by broad scope licensees, they may not meet all the criteria in 10 CFR 33.13 for issuance of a Type A specific license of broad scope. For example, a multi-site licensee must have a management structure to ensure adequate control and conduct of the program, but may not have the expertise or need for the degree of flexibility given to broad scope licensees. Therefore, although some multi-site licensees may meet the requirements for a broad scope license, many would continue to be limited specific licenses. The NRC is soliciting comments on whether a separate category for multi-site licenses should be included within Part 33 with commensurate requirements for licensing, or if a multi-site license should be defined in Part 30 with specific requirements, as necessary, for management controls.

11. What Balance Should Be Maintained Between a Performance-Based and a Prescriptive Approach to Regulating Broad Scope Licensees?

The Commission is considering improvements to increase efficiency and the need to revise regulations to be more risk-informed and performance-based rather than prescriptive. Currently, many of NRC's regulations are a combination of performance-based and prescriptive. The occupational dose limits specified in § 20.1201 and the requirement for a radiation protection program pursuant to § 20.1101, are examples of performance-based regulations, whereas the requirements for training for radiographers specified in § 34.31 is an example of a prescriptive regulation. The staff considers that a risk-informed, performance-based regulatory approach should have at least four key elements: (1) There are measurable or calculable parameters to monitor licensee performance; (2) objective criteria are established to assess performance; (3) licensee has the flexibility to determine how to meet established performance criteria; and (4) failure to meet a performance criterion will not have an intolerable outcome. The NRC is specifically soliciting comments associated with those provisions where a performance-based approach would be satisfactory to accomplish the purposes of the Atomic Energy Act of 1974, as amended, and where more prescriptive requirements are necessary to provide appropriate safety.

III. Request for Regulatory Analysis Information

If a change of requirements is needed, the NRC will prepare a regulatory analysis to support any proposed or final rule. The analysis will examine the costs and benefits of regulatory alternatives available to the Commission.

The NRC requests public comment on costs and benefits, normal business practices, new trends, and other information that should be considered in the regulatory analysis. Comments may be submitted as indicated in the **ADDRESSES** heading.

IV. Specific Examples of Possible Regulatory Language

The NRC's review of Part 33 was discussed at the All-Agreement State meeting in October 1995. At that time, representatives from the State of Illinois indicated that they were reviewing their existing regulations for broad scope licenses and provided draft language to the NRC. Therefore, the NRC, in partnership with the State of Illinois, has developed language that may be applicable to a revision of Part 33. This draft text reflects many of the issues as described. The NRC solicits comments on the following draft text, including the extent to which the text addresses the issues described. The NRC also solicits suggestions of alternative text that would address these issues.

List of Subjects in 10 CFR Part 33

Byproduct material, Criminal penalties, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

PART 33—SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

1. The authority citation for part 33 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, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. A new § 33.2 is added to read as follows:

§ 33.2 Definitions.

Authorized user means an individual specifically named and authorized by the Radiation Safety Committee to use licensed material.

Management means the chief executive officer (or equivalent) or that person's delegate or delegates.

Radiation Safety Committee means a committee responsible for the development and administration of a licensee's radiation safety program, including responsibility for approval of all proposals for radionuclide use and users.

Radiation Safety Officer means the individual, identified on the license, responsible for the day-to-day operation of the licensee's radiation safety program.

3. A new § 33.5 is added to read as follows:

§ 33.5 Records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

4. Section 33.11 is revised to read as follows:

§ 33.11 Types of specific licenses of broad scope.

(a) A ''specific license of broad scope'' is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of any byproduct material in the quantities specified in the license, for

purposes authorized by the Act. A broad scope license authorizes a wide scope of radionuclides for a diversity of uses and allows licensees to name their own users and areas of use.

(b) A ''master materials license'' is a specific license of broad scope authorized by and issued by the Commission for multisite, to include multiregional, materials (byproduct) licensees. This special type of broad license authorizes a single entity, to issue permits, authorize uses, conduct enforcement, and perform oversight inspections or audits for facilities at multiple sites in multiple regions, including broad scope permits, such that NRC does not review or approve new users and/or locations prior to approval, and does not inspect the permitted facilities under the routine inspection frequency for that type of facility.

5. Section 33.12 is revised to read as follows:

§ 33.12 Applications for license, amendment, or renewal.

Applications for a new license, an amendment, or a renewal of a specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in §§ 30.32 and 30.33 of this chapter;

(b) The applicant has engaged in a reasonable range and number of activities involving the use of byproduct materials under a specific license of limited scope;

(c) The applicant's previous performance as a licensee demonstrates an ability to maintain a program in compliance with the Commission's regulations;

(d) The licensee designates a Radiation Safety Officer meeting the requirements of § 33.21(b) responsible for implementing the radiation safety program;

(e) The licensee establishes a Radiation Safety Committee meeting the requirements of § 33.22(a);

(f) The applicant establishes and submits a description of an adequate management structure and oversight, as well as the mechanisms used to ensure control over licensed activities;

(g) The applicant establishes administrative controls and provisions relating to organization and management reviews that are necessary to ensure safe operations; and

(h) The applicant establishes, implements, and maintains written policies and procedures, reviewed and approved by the Radiation Safety Committee, adequate for:

(1) Authorizing the procurement of byproduct material only in accordance with approved permits;

(2) Receiving and safely opening packages of byproduct material;

(3) Maintaining inventory control and records of transfers of byproduct material;

(4) Storing and using byproduct material safely;

(5) Requiring notification of the Radiation Safety Officer of emergencies involving byproduct material;

(6) Establishing frequencies for performing radiation surveys as required by §§ 20.1501 and 20.1906(b) of this chapter, or by the conditions of the license;

(7) Performing calibrations of survey instruments and other equipment used to demonstrate compliance with the regulations of this chapter, if those calibrations are to be performed in-house;

(8) Performing tests for leakage or contamination of sealed sources, if those tests are to be performed by the licensee;

(9) Disposing of byproduct material in accordance with the requirements of subpart K, §§ 20.2001 through 20.2007 of this chapter.

(10) Providing or supervising the provision of radiation safety training to personnel prior to their working in or frequenting areas where byproduct material is used or stored;

(11) Conducting radiation safety evaluations of proposed authorized users of byproduct material, including training and experience and proposed uses;

(12) Conducting radiation safety evaluations of proposed uses of radioactivity, including an evaluation of the facilities and equipment;

(13) Establishing criteria used to determine if a location formerly authorized under the broad scope license may be released for unrestricted use, including the performance of monitoring, acceptable decontamination levels, and documentation of such results; and

(14) Reporting and investigating overexposures; accidents; spills; losses or thefts; unauthorized receipts, uses, transfers or disposal of byproduct material; and other deviations from radiation safety practices as approved by the Radiation Safety Officer, the Radiation Safety Committee, or the Commission, and implementing corrective actions as necessary.

6. Section 33.17 is revised to read as follows:

§ 33.17 Requirements of specific licenses of broad scope.

Persons granted a specific license of broad scope shall meet the following requirements:

(a) Unless specifically authorized pursuant to other parts of this chapter, persons licensed under this part shall not:

(1) Conduct tracer studies in the environment involving direct release of byproduct material;

(2) Conduct activities for which a specific license issued by the Commission under parts 32, 34, 35, 36, or 39 of this chapter is required; or

(3) Add or cause the addition of byproduct material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

(b) Each specific license of broad scope issued under this part shall be subject to the condition that byproduct material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's Radiation Safety Committee in accordance with the following:

(1) Byproduct material for non-human use will be used only by, or under the supervision of, individuals whose qualifications have been reviewed and approved in accordance with the licensee's established procedures, and

(2) Byproduct material for medical use will be used only by, or under the supervision of, individuals who meet the applicable training and experience criteria specified in subpart J, §§ 35.900 through 35.981 of this chapter.

(c) The licensee's management shall notify the Commission, in writing, no later than 30 days after a Radiation Safety Officer permanently discontinues performance of duties as the Radiation Safety Officer under the license, or the name or mailing address of the licensee, as it appears on the license, changes.

(d) The licensee's management shall apply for and must receive a license amendment:

(1) Before naming a permanent Radiation Safety Officer;

(2) Before it orders byproduct material in excess of the amount, or radionuclide or form different than authorized on the license; and

(3) Before it adds to or changes the address or addresses of use identified in the application or on the license.

7. Sections 33.21 and 33.23 are redesignated as §§ 33.61 and 33.63, respectively under the undesignated center heading ''Violations'', and new §§ 33.21, 33.22, and 33.23 are added to read as follows:

§ 33.21 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

(b) At a minimum, the Radiation Safety Officer shall have an academic degree in physical or biological science or engineering, specific training in radiation health sciences and at least 5 years experience with a broad spectrum of radioactive material related to the types, quantities, and uses of the licensee's program.

(c) The Radiation Safety Officer shall:

(1) Ensure the implementation of written policies and procedures as specified in § 33.12 (g) and (h);

(2) Assist the Radiation Safety Committee in the performance of its duties, including the provision of necessary reports to the Committee to enable the Committee to conduct the reviews required by § 33.17(f);

(3) Report to management once each year on the byproduct material program; and

(4) Keep a copy of all records and reports required by the Commission's regulations in 10 CFR Chapter 1, a copy of 10 CFR Chapter 1, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations of this chapter.

§ 33.22 Radiation Safety Committee.

Each licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material.

(a) The Radiation Safety Committee shall meet the following administrative requirements:

(1) Membership shall consist of the Radiation Safety Officer; at least one user authorized by the Radiation Safety Committee from each of the departments, groups, or activities that will use byproduct materials permitted by the license; and at least one representative of management who is neither an authorized user nor a Radiation Safety Officer. For medical broad scope licensees, the Radiation Safety Committee should also include a representative of the nursing service and an authorized user for each type of medical use permitted by the license;

(2) The Committee shall meet four times a year at intervals not to exceed 4 months;

(3) Minutes shall be prepared for each meeting. Each member of the Committee shall be provided with a copy of the meeting minutes before the next meeting, and the Committee shall retain one copy of the meeting minutes for 5 years from the meeting date; and

(4) To establish a quorum and to conduct business, at least one-half of the Committee membership must be in attendance, and shall include, at a minimum, the management's representative, an authorized user and the Radiation Safety Officer.

(b) To oversee the use of licensed material, the Radiation Safety Committee shall:

(1) Ensure the radiation protection programs meet the requirements of § 20.1101 of this chapter;

(2) Ensure the implementation of written policies and procedures, as specified in § 33.12 (g) and (h), include:

(i) Review of the training and experience of, and approval or disapproval of, the application of any individual who seeks approval as an authorized user;

(ii) Review, on the basis of radiation safety, and approval or disapproval of, each proposed use of byproduct material, including periodic reevaluations of approved uses;

(iii) Review and approve radiation safety program changes on the basis of safety;

(iv) Review, with the assistance of the Radiation Safety Officer, the records of individual monitoring results of all individuals for whom monitoring was required pursuant to § 20.1502 of this Chapter;

(v) Review, with the assistance of the Radiation Safety Officer, all incidents or reports made to the Commission involving byproduct material with respect to cause and subsequent actions taken; and

(vi) Establish investigational levels for occupational doses that, when exceeded, require investigations and considerations of action by the Radiation Safety Officer; and

(3) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

§ 33.23 Statements of authority and responsibilities.

(a) A licensee shall provide the Radiation Safety Officer and the Radiation Safety Committee sufficient authority, organizational freedom, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Terminate any activity, involving byproduct material, in which health and safety may be compromised to an unacceptable level, immediately, without consulting licensee management;

(3) Approve or disapprove all proposals for byproduct material use prior to procurement of material;

(4) Initiate, recommend, or provide corrective actions; and

(5) Verify implementation of corrective actions.

(b) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee, and retain the current edition of these statements as a record until the Commission terminates the license.

8. A new § 33.25 is added to read as follows:

§ 33.25 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety procedures established by the licensee, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(b) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user is responsible for the acts and omissions of the supervised individual.

9. A new § 33.59 is added under the undesignated center heading ''Specific Licenses of Broad Scope'' to read as follows:

§ 33.59 Radiation safety program changes.

(a) The holder of a specific license of broad scope for byproduct material may make changes in the facility or procedures as described in the license application, after review and approval by the Radiation Safety Committee, without prior Commission approval, unless the proposed change involves a change in a specific license condition or is less restrictive than the regulations.

(b)(1) The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new facility or procedure, the reason for the change, a summary of radiation safety matters that were considered before making the change, and the signatures of the Radiation Safety Officer, Radiation

Safety Committee chairman, and the management representative.

(2) The licensee shall submit a report within 30 days of the effective date of the change, containing a brief description of any changes, including the reason for the change and a summary of the radiation safety matters that were considered for each.

(c) A licensee who desires to make a change that modifies an existing license condition shall submit an application for amendment to its license pursuant to § 30.38 of this chapter.

Dated at Rockville, Maryland, this 6th day of November, 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 96–28998 Filed 11–13–96; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 94–SW–24–AD]

Airworthiness Directives; Bell Helicopter Textron, Inc., Model 214B, 214B–1 and 214ST Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to Bell Helicopter Textron, Inc. (BHTI) Model 214B, 214B–1, and 214ST series helicopters, that currently establishes a retirement life of 40,000 high-power events for the lower planetary spider (spider). This action would require changing the method of calculating the retirement life for the spider from high-power events to a maximum accumulated Retirement Index Number (RIN) of 80,000 and would make this RIN applicable to an additional part numbered spider. This proposal is prompted by fatigue analyses and tests that show certain spiders fail sooner than originally anticipated because of the unanticipated higher number of external load lifts and takeoffs (torque events) performed with those spiders in addition to the time-in-service (TIS) accrued under other operating conditions. The actions specified by the proposed AD are intended to prevent fatigue failure of the spider, which could result in failure of the main transmission and subsequent loss of control of the helicopter.

DATES: Comments must be received by January 13, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Assistant Chief Counsel, Attention: Rules Docket No. 94–SW–24–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Bell Helicopter Textron, Inc., P.O. Box 482, Ft. Worth, Texas 76101.

FOR FURTHER INFORMATION CONTACT: Mr. Uday Garadi, Aerospace Engineer, FAA, Rotorcraft Certification Office, Rotorcraft Directorate, Fort Worth, Texas 76193–0170, telephone (817) 222–5157, fax (817) 222–5959.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 94–SW–24–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 94–SW–24–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Discussion

On August 13, 1993, the FAA issued AD 93–05–02, Amendment 39–8608 (58 FR 45833, August 31, 1993), to require changing the method of calculating the retirement life for the spider, part number (P/N) 214–040–080–101, from flight hours to high-power events calculated using the number of takeoffs and external load lifts. That action was prompted by reports of four failures of the spider, two of which were detected during the 2,500 hour TIS overhaul inspection. The other two failures occurred in flight. The requirements of that AD are intended to prevent fatigue failure of the spider, which could result in failure of the main transmission and subsequent loss of control of the helicopter.

Since the issuance of that AD, BHTI has issued BHTI Information Letter GEN–94–54, dated April 15, 1994, Subject: Retirement Index Number (RIN) For Cycle Lifed Components, which introduces a different method of accounting for fatigue damage on components that have shortened service lives as a result of frequent torque events. Additionally, BHTI has issued BHTI Alert Service Bulletin (ASB) 214–94–53, which is applicable to the Model 214B helicopters, and ASB 214ST–94–68, which is applicable to the Model 214ST helicopters, both of which are dated November 7, 1994 and describe procedures for converting flight hours and total number of torque events into a RIN for the spider, P/N 214–040–080–001 and –101. Although ASB 214–94–53 does not state that it applies to Model 214B–1 helicopters, this was an oversight by the manufacturer. That ASB was intended to apply to both Model 214B and 214B–1 helicopters. Additionally, P/N 214–040–080–001 was omitted from the existing AD, and is included in the applicability portion of this AD.

Since an unsafe condition has been identified that is likely to exist or develop on other BHTI Model 214B, 214B–1, and 214ST helicopters of the same type design, the proposed AD would supersede AD 93–05–02 to require creation of a component history card using the RIN system, and a system for tracking increases to the accumulated RIN, and establish a maximum accumulated RIN for the spider of 80,000.

The FAA estimates that 11 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately (1) 48 work hours to replace a spider affected by the new