SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of November 30, 1976 (41 FR 52482), the agency issued a proposal that all animal drugs containing chloroform as an ingredient are new animal drugs within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act or misbranded under section 502 of the act (21 U.S.C. 321(w), 352). Interested persons were given till December 30, 1976, to submit comments. No comments were received in response to the proposal. Therefore, the Commissioner of Food and Drugs is establishing the regulation as proposed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 301, 501, 502, 512, 701(a), 52 Stat. 1042–1043 as amended, 1049–1050 as amended, 1055, 82 Stat. 343–351 (21 U.S.C. 331, 351, 352, 360b, 371(a)) and under authority delegated to the Commissioner (21 CFR Part 5.1), Part 510 is amended to add § 510.413 to read as follows:

§ 510.413 Chloroform used as an ingredient (active or inactive) in animal drug products.

(a) Chloroform has been used as an ingredient in animal drug products such as cough preparations, linaments, and some pastes. Although considered safe for many years, recent information has become available associating chloroform with carcinogenic effects in animals. Studies conducted by the National Cancer Institute have demonstrated that the oral administration of chloroform to mice and rats induced hepatocellular carcinomas (liver cancer) in mice and renal tumors in male rats.

(b) Any drug product intended for use in or on animals and containing chloroform as an ingredient is deemed to be either (1) a new animal drug within the meaning of section 201(w) of the act, and unsafe within the meaning of section 512 of the act and adulterated under section 501 of the act and subject to regulatory action under sections 301, 501, and 512 of the act; or (2) misbranded under section 502 of the act, and therefore subject to regulatory action under sections 301 and 502 of the act. Any animal drug product containing chloroform in residual amounts from its use as a processing solvent during manufacture of the drug product, or from the synthesis of a drug ingredient, is not, for the purpose of this regulation, considered to contain chloroform as an ingredient.

(c) Any holder of an approved new animal drug application for a drug product containing chloroform as an ingredient shall submit to the Food and Drug Administration on or before October 3, 1977, a supplemental application providing for a revised formulation removing chloroform as an ingredient.

(1) The supplemental application shall contain:

(i) A full list of articles used as components and a full statement of the composition of the drug product.

(ii) The date that the composition of the drug product will be changed.

(iii) Data showing that the change in composition does not interfere with any assay or other control procedures used in manufacturing the drug product, or that the assay and other control procedures are revised to make them adequate.

(iv) Data available to establish the stability of the revised formulation and, if the data are too limited to support a conclusion that the drug will retain its declared potency for a reasonable marketing period, a commitment from the applicant:

(a) To test the stability of marketed batches at reasonable intervals;

(b) To submit the data as they become available; and

(c) To recall from the market any batch found to fall outside the approved specifications for the drug.

(v) Copies of the label and all other labeling to be used for the drug product—a total of nine copies if in final printed form, three copies if in draft form.

(2) If such drug product contains more than 1 percent chloroform, the revised formulation containing no chloroform shall not be marketed before the receipt of written notice of approval of the supplemental application by the Food and Drug Administration.

(3) If such drug product now contains 1 percent or less chloroform, the revised formulation containing no chloroform may be marketed after submission of the supplemental application but prior to the receipt of written notice of its approval by the Food and Drug Administration.

(d) Any sponsor of a "Notice of Claimed Investigational Exemption for a New Animal Drug" (INAD notice) for an animal drug product containing chloroform as an ingredient shall amend the INAD notice on or before October 3, 1977, to revise the formulation removing chloroform as an ingredient.

(e) The Commissioner will initiate action to withdraw approval of a new animal drug application or terminate an INAD notice in accordance with the applicable provisions of section 512 of the act and Parts 511 and 514 of this chapter upon failure of a holder of an approved new animal drug application or sponsor of an INAD notice to comply with the provisions of paragraph (c) or (d) of this section.

(f) Any drug product intended for animal use containing chloroform as an ingredient that is introduced or delivered for introduction into interstate commerce following the effective date of this regulation will be subject to regulatory action under sections 301, 501, 502, and 512 of the act.

Effective date: October 3, 1977.

(Secs. 301, 501, 502, 512, 701(a), 52 Stat. 1042–1043 as amended, 1049–1050 as amended, 1055, 82 Stat. 343–351 (21 U.S.C. 331, 351, 352, 360b, 371(a)).)

Dated: August 25, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-25413 Filed 9-1-77;8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Phenylbutazone Tablets and Boluses

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application filed by Western Research Labs, Inc., providing for the use of a 100 milligram phenylbutazone tablet for the relief of inflammatory conditions associated with a musculoskeletal system of dogs. This application reflects the National Academy of Sciences/National Research Council (NAS/NRC) evaluation of the product.

EFFECTIVE DATE: September 2, 1977.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV–112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857 (301–443–3430).

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the act, Part 520 of the regulations is amended to reflect approval of a new animal drug application (NADA 102–824V) filed by Western Research Labs., Inc., 301 South Cherokee St., Denver, Colo. 80223.

This application concerns a product which is similar to those evaluated by the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group (see the FEDERAL REGISTER of August 12, 1970 (35 FR 12790)). The NAS/NRC report reviewed certain drug products containing phenylbutazone marketed by Jensen-Salsbery laboratories, specifically:

1. Jen-Sal Butazolidin Injectable, 20 percent (200 milligrams per milliliter).

2. Jen-Sal Butazolidin Bolus (horses only), 4 grams per bolus.

3. Jen-Sal Butazolidin Tablets (horses only), 1 gram per tablet.

4. Jen-Sal Butazolidin Tablets (dogs only), 100 milligrams per tablet.

The Academy evaluated these drugs as probably effective as a nonhormonal anti-inflammatory agent for use in horses and dogs. The Academy noted that:

1. The package insert implies the drug results in permanent cures for certain conditions. The Academy felt these statements are not supported by adequate documentation.

2. The analgesic activity of the drug has not been documented. The Academy notes this effect may be the result of the drug's anti-inflammatory properties.

3. No controlled experimental studies appear to have been performed in dogs or horses.

4. The drug's use in the treatment of otitis externa in dogs is doubtful.

5. Instructions for dosage in dogs could be improved.

6. Package label for the injectable drug does not state route of administration.

7. Evidence has not been supplied indicating the boluses and tablets disintegrate in the gastrointestinal tract to produce the desired effects.

The Food and Drug Administration concurred in the Academy's evaluation and concluded that additional labeling information was required on the dosage schedule to improve clarity, such as reference to frequency of administration and maximum daily dose. It further stated that veterinary drugs of this type are prescription drugs and should bear the veterinary prescription legend. Holders of NADA's were provided 6 months to submit adequate documentation in support of the labeling used.

Jensen-Salsbery Laboratories submitted supplemental NADA's providing for safe and effective use of phenylbutazone tablets, boluses, and injections in dogs and horses. Their applications were approved by a regulation in the FEDERAL REGISTER of May 26, 1972 (37 FR 10662). These products were approved for the relief of inflammatory conditions associated with the musculoskeletal system in dogs and horses. It is administered orally to dogs at a dosage level of 20 milligrams per pound of body weight in three divided doses daily with the maximum daily dosage of 800 milligrams. It is administered orally to horses at a dosage level of 1 to 2 grams per 500 pounds of body weight daily, not to exceed 4 grams per day. Use of the drug is limited to veterinary prescription use and for nonfood animals only. It is administered intravenously at one-half the oral dosage.

The current regulation for oral use of phenylbutazone tablets and boluses in dogs and horses is editorially revised to reflect that the drug has been NAS/NRC reviewed, that the existing approvals comply with the evaluation, and that submission of similar applications reflecting the same conditions of use and dosage regimen need not include data required by § 514.111 (21 CFR 514.111), but require submission of bioequivalency and safety data.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulation (21 CFR 514.11(e)(2)(ii)), a summary of the safety data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between 9 a.m. and 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 520 is amended by revising § 520.1720a, to read as follows:

§ 520.1720a Phenylbutazone tablets and boluses

(a) *Specifications.* Each tablet contains 100, 200, or 400 milligrams, or 1 gram of phenylbutazone. Each bolus contains 2 or 4 grams of phenylbutazone.

(b) *Sponsor.* See sponsor numbers in § 510.600(c) of this chapter, as follows:

(1) No. 017220 for use of 100- or 400-milligram or 1-gram tablets, or 2- or 4-gram boluses, in dogs and horses.

(2) No. 000010 for use of 100- or 200-milligram or 1-gram tablets in dogs and horses.

(3) Nos. 000031, 000591, 000856, 000864, 011519, and 012518 for use of 100-milligram or 1-gram tablets in dogs and horses.

(4) Nos. 000832 and 011519 for use of 100-milligram tablet in dogs.

(5) No. 011398 for use of 1-gram tablets in horses.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Twenty milligrams per pound of body weight daily.[1]

(ii) *Indications for use.* The drug is used for the relief of inflammatory conditions associated with a musculoskeletal system.[1]

(iii) *Limitations.* Administer in three divided doses daily. Do not exceed a total daily dose of 800 milligrams regardless of body weight. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at a level capable of producing the desired clinical response. Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

(2) *Horses*—(i) *Amount.* One to two grams per 500 pounds of body weight daily.[1]

(ii) *Indications for use.* The drug is used for the relief of inflammatory conditions associated with the musculoskeletal system.[1]

(iii) *Limitations.* Do not exceed a daily dosage of 4 grams per day. Administer at a relatively high dosage level for the first 48 hours and then reduce gradually to a maintenance dosage level with the lowest dosage maintained at the level capable of producing the desired clinical response. Not for use in animals intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

Effective date. September 2, 1977.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: August 25, 1977.

PHILIP D. CAZIER,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc.77-25423 Filed 9-1-77;8:45 am]

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

PART 546—TETRACYCLINE ANTIBIOTIC DRUGS FOR ANIMAL USE

CFR Correction

In Title 21 (Parts 500-599) of the Code of Federal Regulations, revised as of April 1, 1977, Footnote 1 in § 546.110c beginning on page 305 and cited in paragraphs (c)(5)(iii)(*a*) and (*b*) and (iv)(*a*) and (*b*) was inadvertently omitted on page 307. It reads as set forth below:

[1] These claims are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specifed by § 514.111 of this chapter.

[Docket No. 77N-0186]

PART 570—FOOD ADDITIVES

Irradiation and Radiation Sources; Republication

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document republishes the authority for irradiation in the production, processing, and handling of animal feed and pet food. This authority was inadvertently omitted in the Food and Drug Administration recodification of regulations relating to animal feed and pet food.

EFFECTIVE DATE: September 2, 1977.

FOR FURTHER INFORMATION CONTACT:

Robert S. Brigham, Bureau of Veterinary Medicine (HFV-238), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, (301-443-6243).

SUPPLEMENTARY INFORMATION: In a document published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302), FDA recodified certain regulations relating to food for human consumption. Among the regulations recodified were those which concern irradiation in the production processing, and handling of food for human consumption. The regulations were transferred from former Part 121, which related to food for human consumption as well as, in certain instances, to animal feed and pet food. In a companion document in the same issue of the FEDERAL REGISTER (42 FR 14091), the recodified regulations that also pertained to animal feed and pet food were transferred to Part 570, which pertains to animal feed and related products. However, the regulations pertaining to authority for irradiation in the production, processing, and handling of animal feed and pet food were inadvertently omitted in the companion document.

Since this document merely republishes the authority for irradiation in the production, processing, and handling of animal feed and pet food, notice and public procedure are not required.

Therefore, Part 570 is amended by adding new § 570.12 to read as follows:

§ 570.12 Irradiation in the production, processing, and handling of animal feed and pet food.

Regulations providing for irradiation in the production, processing and handling of food in Part 179 of this chapter are incorporated in Subchapter E as applicable to use in the production, processing, and handling of animal feed and pet food.

Effective date: This amendment shall be effective September 2, 1977.

Dated: August 26, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-25656 Filed 9-1-77;8:45 am]

SUBCHAPTER F—BIOLOGICS

[Docket No. 77N-0047]

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Normal Serum Albumin (Human) and Plasma Protein Fraction (Human); Extension of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Extension of effective date.

SUMMARY: This document extends the time within which manufacturers must comply with §§ 640.82(d) and 640.92(d) concerning the sodium content of Normal Serum Albumin (Human) and Plasma Protein Fraction (Human). The Commissioner has concluded that a 6-month extension of the effective date will provide sufficient time for manufacturers to comply with the regulations and relieve any undue hardships in implementing the processing changes.

DATES: Effective September 2, 1977; compliance with §§ 640.82(d) and 640.92(d) by February 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Al Rothschild, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014, 301-443-1920.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs issued in the FEDERAL REGISTER of May 31, 1977 (42 FR 27575) additional standards for Normal Serum Albumin (Human) and Plasma Protein Fraction (Human). Under §§ 640.82(d) and 640.92(d), the Commissioner required that the sodium content of the final Normal Serum Albumin (Human) and Plasma Protein Fraction (Human) products, respectively, shall be 130 to 160 milliequivalents per liter, regardless of protein concentration. Although these sodium requirements are more stringent than those originally proposed in the FEDERAL REGISTER of February 20, 1975 (40 FR 7456), the Commissioner concluded that the more stringent requirements would significantly improve the safe use of these products. (See 42 FR 27577, paragraph 22.) It was anticipated that the prescribed range for sodium content could be implemented at the same time as the other additional standards since most products currently on the market contain at least 130 milliequivalents sodium per liter. However, the Commissioner has received requests from manufacturers to extend the effective date for compliance with §§ 640.82(d) and 640.92(d). It has been noted that the establishment of an absolute minimum of 130 milliequivalents will require changes in processing from the methods that currently result in most, but not all, products achieving this level. These processing changes will have to be tested to assure that they do not adversely affect the product as it is approved in the license application and now in use. Verification will promote a safe transition to the new method and the continued quality of the product.

Accordingly, the Commissioner is granting a 6-month extension. Changes in processing methods, and the results of verification testing, must be submitted to the Director, Bureau of Biologics, in the form of a license amendment. Manufacturers should note that the labeling requirements remain effective November 28, 1977.

Therefore, in order to provide sufficient time for the manufacturers to comply with the regulations, the Commissioner extends the effective date for compliance with §§ 640.82(d) and 640.92(d) to February 28, 1978.

Dated: August 25, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-25674 Filed 9-1-77;8:45 am]

SUBCHAPTER J—RADIOLOGICAL HEALTH

[Docket No. 75N-0259]

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Exemptions From Performance Standards for Products Intended for United States Government Use

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule provides for exemptions from radiation safety performance standards for electronic products that are intended for use by departments or agencies of the United States. The rule is made to facilitate Federal procurement or construction of needed electronic products, which generally differ in design and application from those used by the general public. The rule provides that either the manufacturer or procuring agency may request the exemption.

EFFECTIVE DATE: October 3, 1977.

FOR FURTHER INFORMATION CONTACT:

Melvyn R. Altman, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857 (301-443-3426.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of September 30, 1975 (40 FR 44846), the Commissioner of Food and Drugs proposed to add new § 1010.5 (21 CFR 1010.5) to provide for exemptions from radiation safety standards for electronic products intended for use by departments or agencies of the United States.

In part, the proposal would have made the commercial manufacturer of an electronic product responsible for applying for any needed exemption from standards after procurement specifications had been finalized by the Federal agency.

In response to comments received concerning the proposal and those provided at a public meeting of January 29, 1976 (see meeting notice published in the FEDERAL REGISTER of December 19, 1975 (40 FR 58883)), the Commissioner withdrew the earlier proposal and issued a revised proposed rule in the FEDERAL REGISTER of October 1, 1976 (41 FR 43412).

The procedures in the October 1, 1976 proposal provided that products to be exempted under section 358(a)(5) of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.) might be manufactured either by Federal agencies or by private concerns. It also provided that either the procuring agency or the manufacturer could apply for the exemption. In addition, it was broadened to include administrative procedures for exemption applications under section 360B(b) of the act for electronic products or classes of products intended for U.S. government research, investigations, studies, demonstrations, or training, or for reasons of national security.

Four comments were submitted in response to the reproposal: one a supplement to a letter that commented on the September 30, 1975 proposal, two from manufacturers of electronic products, one from a hospital, and the fourth from an association of physicians. A summary of the comments on the reproposal and the Commissioner's conclusions follow:

1. One comment suggested that a statement of assumption of liability should be required from the procuring agency and from the manufacturer and implied that the applicant for exemption should be required to specify, in its application; the mechanism that would be used in taking corrective action in case of nonadherance to radiation safety procurement specifications.

In paragraph 5 of the preamble to the October 1, 1976 reproposal, the Commissioner stated that the procuring agency, as a matter of course, will be responsible for assuring that acquired products meet the contract procurement specifications and that, if the procuring agency does not require that a manufacturer take corrective action in cases of nonadherence, FDA could withdraw the exemption from the agency. Similarly, if the manufacturer has obtained the exemption and does not adhere to its provisions, FDA could withdraw the exemption. No new evidence of the need for a statement of assumption of liability was presented by the comment, and the Commissioner still disagrees that such a statement is necessary. He also believes that it is not reasonable to require applicants to specify, in advance, plans for corrective action mechanisms. Corrective action procedures would depend on the nature and severity of the radiation safety problems associated with the products in question. Accordingly, no change is made in the final rule.

2. One manufacturer appeared to object to the proposed regulation because he assumed that exemptions for products intended for local and State government agencies could not be obtained. Another comment suggested that exemptions should be available to nongovernment manufacturers and assemblers of medical X-ray equipment.

The Commissioner notes that although § 1010.5 provides the administrative exemption procedures only for products intended for Federal agencies, section 360B (b) of the act authorizes exemption for any product or class of products intended for research, investigations, studies, demonstrations, or training, or for reasons of national security, regardless of whether the product or class is intended for Federal agency use. No procedural regulations for exempting products not intended for Federal agency use have been promulgated because, to date, there have been no requests for such exemptions. Because there exists authority under section 360B(b) of the act, requests for exemptions for products not intended for Federal use could be granted. Conditions may, however, be imposed on such exemptions as necessary to protect the public health and safety.

3. One comment requested that procurement specifications be required as part of all applications for exemptions.

The October 1, 1976 reproposal established two separate sets of criteria (§ 1010.5 (a)(1) and (a)(2)) for exemption eligibility, only one of which included a requirement that procurement specifications must provide for control of radiation emissions. The Commissioner advises that the two sets of criteria were established to include exemption authority under two separate provisions of the act. Section 358(a)(5) of the act requires that the procuring agency prescribe procurement specifications governing emissions of electronic product radiation, while section 360B(b) of the act contains no such requirement. The Commissioner therefore believes that to require procurement specifications for all exemption requests is beyond the intent of the act, and, in addition, would be an unnecessary burden in some cases.

4. One comment suggested that the procuring agency should be notified of exemptions granted, amended, or withdrawn.

The Commissioner agrees to provide such notification when so requested by the procuring agency. Section 1010.5(b) is amended accordingly.

5. One comment urged that § 1010.5 (e)(2) be revised so that the procuring agency would be solely responsible for compliance with modifications to an exemption imposed by the Director, Bureau of Radiological Health, under his authority to amend or withdraw an exemption.

The Commission believes that a change in this regulation is not needed. As stated in paragraph 2 of the preamble to the reproposal, the potential problems and additional expense resulting from modification of an exemption could be dealt with by appropriate contingency clauses written into the procurement contract or by mutual agreement between the procuring agency and the manufacturer on an amended contract.

6. One comment suggested that the regulation would be improved by certain word changes.

The Commissioner agrees. In response to the comment and on his own initiative, he is making the following changes where appropriate: the words "issue[d]" and "approve[d]" are changed to "grant-[ed]", and the word "inform" is changed to "notify". In addition, in the first sentence of § 1010.5(e)(1) the word "containing" is replaced with the phrase "including in the written notice of exemption"; and in § 1010.5(b) the words "this part" are replaced with "this subchapter."

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (secs. 358 and 360B, 82 Stat. 1177–1179 (42 U.S.C. 263f and 263j)) and under authority delegated to the Commissioner, (21 CFR 5.1) Part 1010 is amended by adding new § 1010.5 to Subpart A, to read as follows:

§ 1010.5 Exemptions for products intended for United States Government use.

(a) *Criteria for exemption.* Upon application by a manufacturer (including assembler) or by a United States department or agency, the Director, Bureau of Radiological Health, Food and Drug Administration, may grant an exemption from any performance standard under Subchapter J of this chapter for an electronic product, or class of products, otherwise subject to such standard when he determines that such electronic product or class is intended for use by departments or agencies of the United States and meets the criteria set forth in paragraphs (a)(1) or (2) of this section.

(1) The procuring agency shall prescribe procurement specifications for the product or class of products governing emissions of electronic product radiation, and the product or class shall be of a type used solely or predominantly by a department or agency of the United States.

(2) The product or class of products is intended for research, investigations, studies, demonstration, or training, or for reasons of national security.

(b) *Consultation between the procuring agency and the Food and Drug Administration.* The United States department or agency that intends to procure or manufacture a product or class of products subject to electronic product radiation safety standards contained in this subchapter should consult with the Bureau of Radiological Health, Food and Drug Administration, whenever it is anticipated that the specifications for the product or class must deviate from, or be in conflict with, such applicable standards. Such consultation should occur as early as possible during development of such specifications. The department or agency should include in the specifications all requirements of such standards that are not in conflict with, or are not inappropriate for, the special or unique uses for which the product is intended. The procuring agency should indicate to the Bureau of Radiological Health if it desires to be notified of the approval, amendment, or withdrawal of the exemption.

(c) *Application for exemption.* An application for exemption, or for amendment or extension thereof, shall be submitted in quintuplicate to the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852. For an exemption pursuant to the criteria prescribed in paragraph (a)(1) of this section, the application shall include the information prescribed in paragraph (c)(1) through (12) of this section. For an exemption pursuant to the criteria prescribed in paragraph (a)(2) of this section, the application shall include the information prescribed in paragraph (c)(3) through (12) of this section. An application for exemption, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure in the office of the Hearing Clerk, except for confidential or proprietary information submitted in accordance with Part 4 of this chapter. Information classified for reasons of national security shall not be included in the application. Except as indicated above, the application for exemption shall include the following:

(1) The procurement specifications for the product or class of products that govern emissions of electronic product radiation.

(2) Evidence that the product or class of products is of a type used solely or predominantly by departments or agencies of the United States.

(3) Evidence that such product or class of products is intended for use by a department or agency of the United States.

(4) A description of the product or class of products and its intended use.

(5) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

(6) A description of the manner in which it is proposed that the product or class of products shall deviate from the requirements of the applicable standard.

(7) An explanation of the advantages to be derived from such deviation.

(8) An explanation of how means of radiation protection will be provided where the product or class of products deviates from the requirements of the applicable standard.

(9) The period of time it is desired that the exemption be in effect, and, if appropriate, the number of units to be manufactured under the exemption.

(10) The name, address, and telephone number of the manufacturer or his agent.

(11) The name, address, and telephone number of the appropriate office of the United States department or agency purchasing the product or class of products.

(12) Such other information required by regulation or by the Director, Bureau of Radiological Health, to evaluate and act on the application.

(d) *Amendment or extension of an exemption.* An exemption is granted on the basis of the information contained in the original application. Therefore, if changes are needed in the radiation safety specifications for the product, or its use, or related radiation control procedures such that the information in the original application would no longer be correct with respect to radiation safety, the applicant shall submit in advance of such changes a request for an amendment to the exemption. He also shall submit a request for extension of the exemption, if needed, at least 60 days before the expiration date. The application for amendment or extension of an exemption shall include the following information:

(1) The exemption number and expiration date.

(2) The amendment or extension requested and basis for the amendment or extension.

(3) If the radiation safety specifications for the product or class of products or the product's or class of products' use or related radiation control procedures differ from the description provided in the original application, a description of such changes.

(e) *Ruling on an exemption.* (1) The Director, Bureau of Radiological Health, may grant an exemption including in the written notice of exemption such conditions or terms as may be necessary to protect the public health and safety and shall notify the applicant in writing of his action. The conditions or terms of the exemption may include specifications concerning the manufacture, use, control, and disposal of the excess or surplus exempted product or class of products as provided in the Code of Federal Regulations, Title 41, Subtitle C. Each exemption will be assigned an identifying number.

(2) The Director, Bureau of Radiological Health, shall amend or withdraw an exemption whenever he determines that such action is necessary to protect the public health or otherwise is justified by provisions of the act or this subchapter. Such action shall become effective on the date specified in the written notice of the action sent to the applicant, except that it shall become effective immediately when the Director determines that it is necessary to prevent an imminent health hazard.

(f) *Identification of equipment covered by exemption.* The manufacturer of any product for which an exemption is granted shall provide the following identification in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the exemption:

CAUTION

This electronic product has been exempted from Food and Drug Administration radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. _____, granted on _____

Effective date. This regulation shall become effective on October 3, 1977.

(Secs. 358 and 360B, 82 Stat. 1177-1179 (42 U.S.C. 263f, 263j))

Dated: August 25, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-25676 Filed 9-1-77;8:45 am]

[Docket No. 75N-0331]

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

Performance Standard for Diagnostic X-Ray Systems and Their Major Components

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule amends the performance standard for diagnostic X-ray systems and their major components to: (1) change the applicability of the X-ray standard to include image receptor supports for mammographic X-ray systems and add a definition of these components, (2) revise the X-ray field limitation and alignment requirements for mammographic X-ray systems and attachments, (3) establish a limit on the transmission of the X-ray beam through the image receptor support on mammographic X-ray systems, (4) allow alternative means for limiting and aligning the X-ray field for certain special purpose X-ray systems, and (5) modify the test method for measuring exposure reproducibility.

EFFECTIVE DATES: November 1, 1977, except § 1020.31(b)(2) and (1), which will be effective September 5, 1978.

FOR FURTHER INFORMATION CONTACT:

Harvey Rudolph, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857 (301-443-3426).

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of February 23, 1976 (41 FR 7957), the Commissioner of Food and Drugs proposed to amend § 1020.31 (21 CFR 1020.31) regarding X-ray field limitation and alignment, beam transmission, and exposure reproducibility. Fifteen comments were received on that proposal within the 60-day comment period. In response to several of the comments and a request by a manufacturers' association, a public meeting was held on July 21, 1976 (see the FEDERAL REGISTER of July 19, 1976 (41 FR 29739)) to discuss the reasonableness and technical and clinical feasibility of the proposal. As a result of that meeting and the comments on the original proposal, the Commissioner issued a second notice of proposed rulemaking, which was published in the FEDERAL REGISTER of March 4, 1977 (42 FR 12441), to add "image receptor support" to the list of definitions in § 1020.30(b) (21 CFR 1020.30(b)) and to the list of components that must be certified by the manufacturer in § 1020.30(a)(1) (21 CFR 1020.30(a)(1)). A 30-day public comment period was allowed for the second proposal, during which only one comment was received.

Of the 15 comments received in response to the February 23, 1976 proposal, 2 were submitted by medical practitioners, 1 by the Environmental Protection Agency, 1 by a State health agency, 10 by representatives of affected manufacturers, and 1 by a national manufacturers' association. The comment on the March 4, 1977, proposal was submitted by a manufacturer. The issues raised in these letters have been analyzed, and a summary of the Commissioner's analysis and final actions follows.

A. IMAGE RECEPTOR SUPPORTS

One comment expressed concern that the use of the phrase "in a horizontal plane" in the definition of image receptor support in § 1020.30(a)(54) might be misinterpreted to mean that the image receptor support could only be maintained in a horizontal orientation. The Commissioner recognizes that in most mammographic X-ray systems the image receptor support can be rotated out of a horizontal position so that different views of the breast may be recorded. The definition contained in § 1020.30(b)(54) does not prohibit such a design. The intent of the definition is to assure that the X-ray beam transmission limit con-

tained in § 1020.31(l) will be applied to any image receptor support capable of holding the image receptor in the horizontal plane, whether the support is fixed or movable, such that any possible gonad dose is minimized. The definition does not place any restriction on an image receptor support that may be provided with the mammographic X-ray system. It merely describes the type of image receptor support that must be certified as meeting the requirements of the X-ray standard. Therefore, no change from the proposal is required.

B. Reproducibility Testing

Two comments stated that the proposed amendment to § 1020.31(b)(2) concerning exposure reproducibility would have little effect on retake rates and that very little dose savings would occur. In addition, two other comments claimed that the 0.05 coefficient of variation of radiation exposures specified in § 1020.31(b)(1) was too strict when combined with the proposed change in exposure reproducibility testing and suggested either an effective date of 2 years following publication of the final rule to allow for possible redesign or a 0.1 coefficient of variation.

Comments of this type were received at the time the diagnostic x-ray equipment performance standard, §§ 1020.30 through 1020.32 (21 CFR 1020.30 through 1020.32), was first proposed and published in the Federal Register of October 8, 1971 (36 FR 19607). The Commissioner determined then that the 0.05 coefficient of variation was necessary to eliminate inconsistency and the resultant need for retakes and to facilitate the establishment of optimum technique charts for minimizing patient exposure. For example, if the assumption is made that the exposure latitude for a diagnostically useful film is +20 percent and that the exposures follow a normal distribution, x-ray equipment which just meets a 0.1 coefficient of variation requirement would produce diagnostically unusable radiographs 5 percent of the time independently of the care exercised by the equipment operator. Under the same assumptions, equipment meeting a 0.05 coefficient of variation requirement, however, would reduce this contribution to the retake rate to less than 1 percent.

The proposed amendment requires that variable controls for technique factors be set to alternate values during reproducibility testing. The comments have interpreted this as being stricter than the current regulations. Before the promulgation of the x-ray standard, x-ray exposure reproducibility data were obtained from manufacturers using a protocol similar to the proposed testing procedure. A summary of this data is on file with the Hearing Clerk. At that time, it was found that most of the x-ray generators being sold could meet the reproducibility criteria. Although the Commissioner acknowledges that the revision in the test method may be a more stringent test than currently used by some manufacturers, adequate evidence has not been submitted to justify an effective date in excess of 1 year following publication of this final rule.

Several comments questioned the ability of certain existing x-ray systems to meet the reproducibility requirements. They claimed that equipment with continuously variable x-ray generator controls would have difficulty due to the poor response characteristics of electrically driven motors. It was also noted that parallax errors introduced by the reading of meters and dial settings could contribute significantly to poor reproducibility. The Commissioner agrees that these types of problems can occur and that for such x-ray systems the new compliance testing procedure may prove more stringent. However, in order to be useful, the reproducibility requirements must be met under clinical conditions. In diagnostic radiology, an x-ray system with variable technique factors will probably be subject to frequent changes in the setting of the x-ray controls. The proposed test method is intended to simulate the clinical environment to assure that the benefits of reproducible x-ray exposures will accrue in practical situations. Because appropriately designed meters and dials can correct errors such as parallax and because no data have been submitted to show that the requirements cannot be met by state-of-the-art designs, the Commissioner concludes that the proposed amendment concerning reproducibility testing will become final without change.

C. Field Limitation for Equipment Used with Intraoral Image Receptors

One comment on proposed § 1020.31(f)(1) stated that, considering the size of intraoral film packets and the level of current technology with regard to aligning the image receptor, field sizes ought to be limited to 5.0 and 6.0 centimeters (cm), respectively. For several commonly used film sizes in dental radiography, such a restriction would mean that full coverage of the film with the x-ray field would not always be obtained. When errors due to positioning of dental film packets are also considered, cone-cutting problems could become substantial. Further restriction of the x-ray field could lead to a higher incidence of nondiagnostic dental radiographs and possibly to more wasted radiation than would be saved by the added field restriction. The Commissioner rejects this comment because no data were presented to demonstrate that such a requirement would provide equivalent diagnostic information or would not lead to an increase in the retake rate.

In the preamble to the final order establishing the diagnostic x-ray equipment performance standard, published in the Federal Register of August 15, 1972 (37 FR 16461), the Commissioner responded to a comment concerning the precision of the numerical requirements of the standard in which he stated that normal roundoff procedures could be employed in determining compliance with such numerical requirements. It was, in part, problems with interpretation of this statement that led to the proposal to specify the field limitation requirements of § 1020.31(f)(1) more accurately. Since the proposal was published, it has been noted that similar problems can be foreseen in the interpretation of the accuracy implied by other numerical limits contained in the diagnostic x-ray equipment standard. Hence, the Commissioner has determined that an overall policy should be established regarding the accuracy of limits given in the x-ray standard and how roundoff procedures may or may not be applied in determining compliance.

While roundoff of measurement results might generally be permissible, section 360B(a)(5)(B) of the Public Health Service Act (42 U.S.C. 263j) states that it is prohibited for a manufacturer "to issue * * * a certification * * * when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect." Therefore, manufacturers may not use roundoff procedures that result in the certification of a product known to exceed a limit imposed by a performance standard. The Commissioner has concluded that numerical limits contained in the x-ray standard should continue to be stated in absolute terms to avoid giving the erroneous impression that numerical roundoff could permit certification of a noncompliant product. Thus, if the standard limits the x-ray field to a 6 cm diameter circle, a measured maximum field dimension greater than 6 cm may not be a basis for certification of compliance. Under this policy, the proposal to amend § 1020.31(f)(1) is unnecessary and is withdrawn.

The Commissioner is aware that misinterpretations in the use of the numerical roundoff methods may have led to questionable certification of diagnostic x-ray components or systems. In this sense, such treatment of numerical limits as absolute limits may have the effect of an additional restriction on certification procedures. In order not to impose undue hardship, the Commissioner proposes to use his authority under section 360C(d) of the Public Health Service Act (42 U.S.C. 263k(d)) and may, if the deviation is insubstantial, consider as minor violations any certifications found to be invalid due to misapplication of numerical roundoff methods until September 5, 1978. After that date, it will be the obligation of all manufacturers to adjust rejection levels or any other quality control criteria such that they assure total compliance with the absolute limits set by the diagnostic x-ray equipment performance standard.

D. Field Limitation and Alignment for Mammographic and Other Special Purpose X-Ray Systems

Several comments stated that the difficulty in patient positioning associated with mammography and the need to include the majority of the breast in the examination may not have been evalu-

ated sufficiently in proposing the requirement in § 1020.31(f)(3) that the x-ray beam be contained entirely within the image receptor. It was suggested that the x-ray beam be allowed to extend past the edge of the image receptor adjacent to the chest wall by up to 2 percent of the source-image receptor distance. In addition, during the July 21, 1976, meeting, it was demonstrated that if the beam were confined within the boundary of the image receptor, some loss of diagnostic information could occur. This is true for most image receptors and poses a significant problem for xeroradiography where the strong electric field gradient at the edge of the exposed area of the image receptor causes a loss of toner particles such that diagnostic information is lost. The overlap of the x-ray field with a small portion of the chest wall would allow the entire breast up to the chest wall to be visualized.

The Commissioner agrees with these arguments and notes that, due to the low energy x-rays used in mammography and the typical angle of incidence of the x-ray beam to the chest wall and the high attenuation of the x-ray beam in the boney structure of the chest wall, the allowed overlap will not cause a significant gonad dose. Therefore, § 1020.31(f)(3) in this final order reflects the suggested change.

The labeling requirements for mammographic x-ray systems and components proposed in § 1020.31(f)(4) caused confusion among several of those commenting on the proposal. One comment expressed the opinion that the proposal could only be applied to mammography systems where the beam-limiting device and image receptor support were marketed by the same manufacturer. Two other comments indicated that the proposal to change § 1020.31(f)(4)(ii) and (iii) appeared to specify compatibility of the beam-limiting device and image receptor support to a degree that would be commercially restrictive and might prohibit the use of general purpose x-ray systems for mammography. It was also argued that the regulation could be interpreted to require that the image receptor itself contain labeling information. This subject of labeling was also discussed at the July 21, 1976 open meeting.

The Commissioner concludes that the issues raised in the comments received on the original proposal and the discussion at the open meeting necessitate a revision of the proposed amendment. In addition, he has determined that it is necessary to have a more simple and concise statement of the labeling requirements for mammographic x-ray systems that use the beam-limiting device for compression of the breast. Thus, the proposed changes in § 1020.31(f)(4)(ii) and (iii) are set forth in § 1020.31(f)(3) in this final regulation and reworded to reflect the concerns expressed in the comments.

One additional comment pointed out an ambiguity in the original wording of proposed § 1020.31(f)(4). As written, it appeared that systems designed for use with extraoral as well as intraoral image receptors would be subjected to the field limitation and alignment requirements for either type of use rather than for only extraoral use. This was not the Commissioner's intent, and the final rule contains clarifying language on this point.

E. X-Ray Beam Transmission Limit for Mammographic X-Ray Systems

Two comments noted that although the transmission limit was intended for systems designed only for mammography, the proposal does not accurately reflect this and could be interpreted as applying to other types of x-ray systems that may use mammographic attachments. The Commissioner agrees and has clarified § 1020.31(l) in this final rule.

In the comments and the public meeting on the proposal, questions were raised over the usefulness and achievability of the transmission limit of 0.1 milliroentgen per tube activation. One consideration was the contribution of scatter radiation to the measurements made. The added weight and bulk of the image receptor support were additional concerns. In general, there was little disagreement on the utility of minimizing the magnitude of the transmitted X-Ray beam. However, there was some concern that the trend toward the use of higher peak kilovoltages (kVp) in mammography would make it difficult to achieve such a low transmission limit.

The transmission limit is intended to minimize that portion of the unused X-Ray beam which can be reduced by means of a performance standard. The Commissioner recognizes that the contribution to patient dose from scattered radiation would be difficult to control and notes that the proposal was designed only to minimize that portion of the beam which passes through the image receptor. The final rule clarifies this point. Even assuming a peak tube potential of 70 kVp (much higher than currently used for mammography) and the worst case exposure conditions, the added weight of lead or lead-equivalent material necessary to reduce the exposure beneath the image receptor supports on systems now manufactured is not significant. The Commissioner is aware that the trend toward the use of higher peak tube potentials makes the transmission limit more difficult to achieve. However, it is also true that the higher peak tube potentials generate X-Ray beams that also penetrate body tissues more readily and could contribute to a greater gonad dose. He has, therefore, determined that the transmission limit shall remain as 0.1 milliroentgen per tube activation.

There were two comments regarding the requirement that compliance be tested at the maximum peak tube potential. They noted that many systems use tubes rated at voltages higher than the maximum voltage allowed by other components of the system. The Commissioner recognizes that this problem could occur, and has concluded that the final rule must state that compliance be measured at the maximum rated peak tube potential for the system. For example, if the generator supplied with the system can operate only at or below 50 kilovolts and the X-Ray tube is rated at 75 kilovolts, compliance will be measured at 50 kilovolts and at the maximum rated product of tube current and time for that potential.

The Commissioner has carefully considered the environmental effects of the amendments and, because the action would not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. Copies of the FDA environmental impact assessment and other pertinent background data on which the Commissioner relies in promulgating these amendments are on file and may be seen at the office of the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f)) and under authority delegated to him (21 CFR 5.1), the Commissioner amends Part 1020 as follows:

1. In § 1020.30 by adding paragraphs (a)(1)(v) and (b)(54) to read as follows:

§ 1020.30 Diagnostic X-ray systems and their major components.

(a) * * *

(1) * * *

(v) Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978.

* * * * *

(b) * * *

(54) "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

* * * * *

2. In § 1020.31 by revising paragraphs (b)(2), (d), (e), and (f)(2); by revising paragraph (f)(3) and redesignating it as (f)(4); and by adding new paragraphs (f)(3) and (l) to read as follows:

§ 1020.31 Radiographic equipment.

* * * * *

(b) * * *

(2) *Measuring compliance.* Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978 shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having

automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

* * * * *

(d) *Field limitation and alignment for mobile and stationary general purpose x-ray systems.* Except when spot-film devices or special attachments for mammography are in service, mobile and stationary general purpose radiographic x-ray systems shall meet the following requirements:

* * * * *

(e) *Field limitation and alignment on stationary general purpose x-ray equipment.* Except when spot-film devices or special attachments for mammography are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

* * * * *

(f) * * *

(2) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(3) *Systems designed for or provided with special attachments for mammography.* Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in paragraphs (f)(4) (i), (ii), and (iii) of this section. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in paragraphs (f)(4) (ii) and (iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(4) *Other x-ray systems.* Radiographic systems not specifically covered in paragraphs (d), (e), (f) (2) and (3), and (g) of this section and systems covered in paragraph (f)(1) of this section, which also are designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e)(1) of this section; or, when alignment means are also provided, may be met with either:

(ii) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(iii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

* * * * *

(l) *Transmission limit for image receptor supporting devices used for mammography.* For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Effective date: The new paragraph (l) in § 1020.31 (21 CFR 1020.31) concerning the x-ray transmission limit for mammographic x-ray systems and the change to § 1020.31(b)(2) for reproducibility testing will be effective on September 8, 1978. All other amendments will be effective on November 1, 1977.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f).)

Dated: August 22, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-25425 Filed 9-1-77;8:45 am]

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

Community Services Administration

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: The position of Staff Assistant, Office of Interagency and External Affairs, is excepted from the competitive service under Schedule C because it is confidential in nature.

EFFECTIVE DATE: September 2, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3373(g)(2) is added as set out below:

§ 213.3373 Community Services Administration.

* * * * *

(g) *Office of Interagency and External Affairs.* * * *

(2) One Staff Assistant.

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954-1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77-25784 Filed 9-1-77;8:45 am]

PART 213—EXCEPTED SERVICE

Federal Energy Administration

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment excepts under Schedule C one position of Special Assistant to the Assistant Administrator for Regulatory Programs because the position is confidential in nature.

EFFECTIVE DATE: September 2, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3388(o)(1) is amended as set out below:

* * * * *

§ 213.3388 Federal Energy Administration.

* * * * *

(o) *Office of the Assistant Administrator for Regulatory Programs.*

(1) Three Special Assistants to the Assistant Administrator.

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954–1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.77-25785 Filed 9-1-77;8:45 am]

Title 24—Housing and Urban Development

CHAPTER X—FEDERAL INSURANCE ADMINISTRATION, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

[Docket No. 3323]

PART 1915—IDENTIFICATION AND MAPPING OF SPECIAL FLOOD HAZARD AREAS

Communities with Minimal Hazard Areas

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: The Federal Insurance Administrator, after consultation with local officials of the communities listed below, has determined, based upon analysis of existing conditions in the Special Flood Hazard areas, that it is appropriate at this time to convert the communities listed below to the Regular Program without determining base flood elevations.

EFFECTIVE DATE: Date of this notice.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard W. Krimm, Assistant Administrator, Office of Flood Insurance, 202–755–5581 or toll free line 800–424–8872, Room 5270, 451 Seventh St. SW., Washington, D.C. 20410.

SUPPLEMENTARY INFORMATION: In these areas, there is no reason not to make full limits of coverage available. The available limits of coverage for flood insurance in these communities is increased to $70,000 for 1–4 family residential structures, $200,000 for other residential and commercial structures, $20,000 for contents of residential structures, and $200,000 for contents of commercial structures. Flood insurance is available at Zone C rates throughout the entire community.

Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the National Flood Insurance Association servicing company for the State.

The effective date of conversion to the Regular Program will not appear in the Code of Federal Regulations except for the page number of this entry in the FEDERAL REGISTER.

Section 1915.7 is added; the entry reads as follows:

§ 1915.7 List of communities with minimal hazard areas.

State	County	Community name
Alabama	Butler	City of Georgiana.
Do	Geneva	City of Hartford.
Do	Coffee	Town of New Brockton.
Do	Covington	Town of River Falls.
Idaho	Boundary	City of Bonners Ferry.
Iowa	Dubuque	City of Epworth.
Kansas	Harvey	City of Burrton.
Do	Johnson and Wyandotte.	City of Lake Quivira.
Louisiana	Bossier	Town of Benton.
Do	Tangipahoa.	Town of Independence.
Do	Madison	Village of Mound.
New York	Wyoming	Village of Perry.
Do	Lewis	Village of Turin.
North Carolina	Halifax	Town of Hobgood.
Ohio	Butler	City of Hamilton.
Oklahoma	Washington.	Town of Copan.
Pennsylvania	Lehigh	Township of Upper Saucon.
Washington	King	City of Seattle.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; and Secretary's delegation of authority to Federal Insurance Administrator, 34 FR 2680, February 27, 1969, as amended by 39 FR 2787, January 24, 1974.)

Issued: August 16, 1977.

PATRICIA ROBERTS HARRIS,
Secretary.

[FR Doc.77-25558 Filed 9-1-77;8:45 am]

Title 28—Judicial Administration

CHAPTER I—DEPARTMENT OF JUSTICE

PART 2—PAROLE, RELEASE, SUPERVISION AND RECOMMITMENT OF PRISONERS, YOUTH OFFENDERS, AND JUVENILE DELINQUENTS

Paroling, Recommitting and Supervising Federal Prisoners; Correction

AGENCY: The United States Parole Commission.

ACTION: Correction.

SUMMARY: This document is to correct certain typographical errors in the publication of the Commission's rules which appeared on August 5, 1977, at 42 FR 39808.

EFFECTIVE DATE: August 29, 1977.

FOR FURTHER INFORMATION CONTACT:

Michael A. Stover, Office of the General Counsel, United States Parole Commission, 320 First Street NW., Washington, D.C. 20537, Telephone 202–724–3092.

SUPPLEMENTARY INFORMATION: The publication of the Commission's rules which appeared at 42 FR 39808, August 5, 1977 contained several typographical errors which require correction. These are as follows:

In § 2.14 *Subsequent proceedings.* In paragraph (b)(1), the words "presumptive parole dates" should read "presumptive parole date". (42 FR 39812) In (b)(2)(iii) "commence" should be substituted for the word "commerce". (42 FR 39812)

In § 2.17 *Original Jurisdiction Cases,* paragraph (b)(2)(ii) should read:

(b) * * *

(2) * * *

(i) * * * Was part of a large scale criminal conspiracy or a continuing criminal enterprise" instead of "was part of a large scale criminal conspiracy of a criminal enterprise." (42 FR 39812)

In § 2.20 *Paroling Policy Guidelines; statement of general policy.* In the offense severity table, the words "(in months)" should appear under the heading "Guidelines for decisionmaking" and not under the sub-heading "offender characteristics". (42 FR 39813, 39814 and 39815).

In § 2.23 *Delegation to hearing examiners.* In paragraph (b), first sentence, substitute the word "required" for the word "requested". (42 FR 39815)

In § 2.33 *Release of Plans.* Omit the word "of" in the title of this rule (42 FR 39817).

Accordingly, pursuant to the provisions of 18 U.S.C. 4203(a)(1) and 4204(a)(6), 28 CFR Chapter I, Part 2, is amended as set forth above, effective August 29, 1977.

Dated: August 29, 1977.

CURTIS C. CRAWFORD,
Acting Chairman,
United States Parole Commission.

[FR Doc.77-25699 Filed 9-1-77;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

[FRL 750-4]

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Alabama—Approval of Plan Revisions

AGENCY: Environmental Protection Agency.

ACTION: Final Rule.

SUMMARY: This rule includes the incorporation by reference of EPA's New Source Performance Standards (40 CFR Part 60), and the requirements for continuous monitoring of stationary sources (40 CFR 51.19).

ADDRESSES: Copies of the information submitted by Alabama and the Alabama plan itself may be examined by the public during normal hours at the following locations:

Air Programs Branch, Air & Hazardous Materials Division, Environmental Protection Agency, 345 Courtland Street NE., Atlanta, Ga. 30308.

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.