

ning. Under the general supervision and direction of the Attorney General, the Director of Policy and Planning shall:

(a) Provide an overview of problems in the criminal justice system.

(b) Initiate, implement and evaluate proposals—

(1) To improve the effectiveness and the fairness of crime control and criminal justice administration; and

(2) To promote consistency and coordination in the handling of accused and convicted offenders by law enforcement, court, and correctional agencies in the Federal and District of Columbia systems.

(c) Undertake such other projects relating to policy development as may specifically be assigned by the Attorney General.

§ 0.7 [Amended]

3. In § 0.7 of Subpart B, the phrase "Under the general supervision of the Attorney General and the direction of the Deputy Attorney General" is revised to read "Under the general supervision and direction of the Attorney General."

§ 0.17 [Deleted]

4. Section 0.17 of Subpart C is revoked.

§§ 0.25 and 0.27 [Amended]

5. In § 0.25 of Subpart E and section 0.27 of Subpart E-1, the phrase "Subject to the general supervision of the Attorney General and the direction of the Deputy Attorney General" is revised to read "Subject to the general supervision and direction of the Attorney General."

§ 0.33 [Amended]

6. In § 0.33 of Subpart P, the phrase "Subject to the general supervision of the Attorney General, and under the direction of the Deputy Attorney General" is revised to read "Subject to the general supervision and direction of the Attorney General."

Dated: September 9, 1975.

EDWARD H. LEVI,
Attorney General.

[FR Doc. 75-24637 Filed 9-15-75; 8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER E—PESTICIDE PROGRAMS

[FRL 431-6; OPP-30002A]

PART 162—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Registration, Reregistration and Classification Procedures; Correction

In FR Doc. 75-17018 appearing on page 28242 in the issue for Thursday, July 3, 1975, the following changes should be made.

The third paragraph in the third column on page 28283 should read as follows:

"(C) Results in a maximum calculated concentration following direct applications."

tion to a 6-inch layer of water less than 1/10 the acute LC50 for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as specified in the Registration Guide-

On that same page and in that same column, there should be a paragraph "D" after "C" and before "(2) Classification criteria for previously registered products." Paragraph "D" should read as follows:

"(D) The pesticide causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of non-target organisms, resulting from exposure to the product ingredients, their metabolites, or degradation products, whether due to direct application or otherwise resulting from application, such as through volatilization, drift, leaching or lateral movement in soil."

Dated: September 9, 1975.

VICTOR J. KIMM,
Acting Assistant Administrator
for Water and Hazardous Materials.

[FR Doc. 75-24510 Filed 9-15-75; 8:45 am]

Title 41—Public Contracts and Property Management

CHAPTER 14—DEPARTMENT OF THE INTERIOR

PART 14-3—PROCUREMENT BY NEGOTIATION

Determinations and Findings—Cost Accounting Standards

Correction

In FR Doc. 75-23216, appearing on page 40517, of the issue of Wednesday, September 3, 1975, the subpart heading in the second column on page 40517 should be changed to read as follows:

"Subpart 14-3.12—Cost Accounting Standards"

CHAPTER 114—DEPARTMENT OF THE INTERIOR

[IPMR Release No. 75-3]

PART 114-60—PERSONAL PROPERTY MANAGEMENT

Subpart 114-60.5—Classification of Property

CRITERIA

Pursuant to the authority of the Secretary of the Interior contained in 5 U.S.C. 301 and section 205(c), 63 Stat. 390; 40 U.S.C. 485(c), § 114-60.501 of Chapter 114, Title 41 of the Code of Federal Regulations, is amended as set forth below.

This amendment relates only to matters of internal Department practice. It is, therefore, determined that the public rulemaking procedure is unnecessary and this amendment shall become effective on September 16, 1975.

RICHARD R. HITE,
Deputy Assistant Secretary of
the Interior.

SEPTEMBER 9, 1975.

Section 114-60.501 is revised by deleting paragraphs (a) through (d) and substituting new paragraphs (a) through (c) to read as follows:

§ 114-60.501 Classification criteria.

(a) As a general rule, any single item of property having an original cost value of more than \$300 when new should be capitalized. Classification of substantially similar items should be consistent, however. In cases where a portion of the total inventory of similar items is acquired at more than \$300 and a portion at less than \$300, all items should either be classified as capitalized or non-capitalized.

(b) Property may also be classified as capitalized for accountability control purposes even though the original cost value is under the guideline figure. Sensitive items requiring such control include small electronic calculators, tape recorders, radios, photographic and projection equipment, typewriters and other office machines, firearms, survey instruments, binoculars, power tools, or other equipment which because of its general use characteristics and ease of transport is particularly susceptible to misappropriation or theft.

(c) All office furniture may be exempted from classification as capitalized equipment at the discretion of the bureau or office head, provided that suitable custodial controls are otherwise in effect to properly safeguard the Government-owned property.

[FR Doc. 75-24571 Filed 9-15-75; 8:45 am]

Title 45—Shipping

CHAPTER I—COAST GUARD, DEPARTMENT OF TRANSPORTATION

SUBCHAPTER D—TANK VESSELS

SUBCHAPTER F—MARINE ENGINEERING

[CGD 73-254]

MARINE ENGINEERING SYSTEMS AND COMPONENTS

Miscellaneous Amendments; Correction

In FR Doc. 75-23028, appearing at page 40163 in the FEDERAL REGISTER of September 2, 1975, change the effective date from September 29, 1975 to October 2, 1975.

Dated: September 10, 1975.

O. W. SILER,
Admiral, U.S. Coast
Guard Commandant.

[FR Doc. 75-24584 Filed 9-15-75; 8:45 am]

Title 49—Transportation

CHAPTER V—NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

[Docket No. 3-3; Notice 9]

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

Flammability of Interior Materials;

Response to Petition for Reconsideration

On March 31, 1975, the National Highway Traffic Safety Administration (NHTSA) issued a notice modifying the test procedures and specimen prepara-

tion requirements of Motor Vehicle Safety Standard No. 302, 49 CFR 571.302, *Flammability of interior materials* (40 FR 14318). Petitions for reconsideration of the rule were received from American Motors Corporation, General Motors Corporation, White Motor Corporation, Chrysler Corporation, Volkswagen of America, Inc., Toyota Motor Sales, U.S.A., Inc., Ford Motor Company, and the Motor Vehicle Manufacturers Association of the United States, Inc.

The NHTSA notice established a process of surrogate testing for components which were too small to test without difficulty using the procedures previously prescribed by Standard No. 302. The objections raised to this new process by the petitioners were that (a) the surrogate testing procedure is an entirely new departure, and the public should have been afforded an opportunity for comment, (b) the results of surrogate testing will in certain cases differ from the results of testing the actual component, (c) the creation of a surrogate testing sample of certain materials, such as elastic cord, is impossible, and (d) the dimensions of the surrogate sample are inappropriate.

It should be fully understood that small components which would otherwise be included within the purview of Standard No. 302 are not excluded by virtue of their size. Further, the NHTSA intends to utilize a surrogate testing procedure, among other testing procedures, in the case of small components as the first step in determining whether a safety defect exists pursuant to section 152 of the National Traffic and Motor Vehicle Safety Act. Since the testing of small components is a more difficult process, the NHTSA concluded in amending Standard No. 302 to include the surrogate testing process that the new requirement was less stringent than that currently required by the standard. Further, by amending the standard the industry could also be fully apprised of one of the methods the NHTSA intended to use to determine whether a section 152 defect existed.

Nonetheless, it appears from the petitions for reconsideration which were received that a number of manufacturers feel that they should be allowed an opportunity for comment. The NHTSA concludes their request is reasonable and the rule, as it relates to surrogate testing, is hereby revoked and is reissued as a notice of proposed rulemaking in this issue of the *FEDERAL REGISTER*.

A number of the petitioners questioned the need for including any small components within the ambit of Standard No. 302, citing the notice of proposed rulemaking (38 FR 12934, May 17, 1973) which stated that certain small components designed to absorb energy are not fire hazards. Therefore, the petitioners believe the NHTSA has reversed its previous position.

This understanding is correct. As the NHTSA said in the preamble to the proposed amendment to Standard No. 302, issued concurrently with the amendment to the Standard (March 31, 1975, 40 FR 14340):

On May 11, 1973, the NHTSA issued a notice (38 FR 12934) which proposed, inter alia, amending paragraph S4.1 of Standard No. 302 to enumerate the interior components of vehicle occupant compartment which fell within the ambit of the standard.

Comments to the notice, however, have made clear that the enumeration of components, even with the proposed amendment, will continue to confuse manufacturers required to meet the standard.

While some materials exposed to the occupant compartment air space are not fire hazards, the burden of ascertaining that fact should properly lie with the manufacturer.

Several petitions also questioned what safety benefits would come from applying the standard to small components. As petitioner American Motors pointed out, the purpose of Standard No. 302 is to provide sufficient time for the occupants of a vehicle to exit in case of an interior fire. Thus, even small components which are highly flammable would hasten the spreading of fires in motor vehicles, resulting in a serious hazard.

Testing procedures. Petitioners pointed out that while the preamble provides that the surface of the specimen closest to the occupant compartment air space face downward on test frame, this is not made entirely clear in the body of the standard itself. The standard is amended to clarify this matter. Likewise, a definition of the term "occupant compartment air space" is added, although this term was used in the notice of proposed rulemaking without raising a problem for those commenting.

Extension of effective date of amendment. Several petitioners asked for an extension of the effective date. As the surrogate testing procedures have been revoked and reissued as a proposed rule, the NHTSA concludes that an extension of the effective date is not necessary.

Redesignation of Docket 3-3; Notice 7. Through a clerical error, two notices were issued with the heading, "Docket 3-3; Notice 7" (July 11, 1973, 38 FR 18564; March 31, 1975, 40 FR 14318). The notice appearing at 38 FR 18564 is hereby redesignated "Notice 7a" and that appearing at 40 FR 14318 is redesignated "Notice 7b."

In consideration of the foregoing, Motor Vehicle Safety Standard No. 302, 49 CFR 571.302, is amended as follows:

1. A new definition of "occupant compartment air space" is added to S3A., Definitions, in the appropriate alphabetical sequence:

§ 571.302 [Amended]

"Occupant compartment air space" means the space within the occupant compartment that normally contains refreshable air.

2. S4.1.1 is deleted and reserved.

3. In § 5.2.2, the last sentence is amended so that the paragraph reads:

§ 5.2.2 The specimen is produced by cutting the material in the direction that provides the most adverse test results. The specimen is oriented so that the sur-

face closest to the occupant compartment air space faces downward on the test frame.

Effective date: September 16, 1975.

Because this amendment relieves a restriction, it is found for good cause shown that an immediate effective date is in the public interest.

(Secs. 103, 119, Pub. L. 89-563, 80 Stat. 718 (15 U.S.C. 1392, 1407); delegation of authority at 49 CFR 1.51.)

Issued on September 10, 1975.

JAMES B. GREGORY,
Administrator.

[FR Doc.75-24644 Filed 9-11-75; 4:34 pm]

Title 50—Wildlife and Fisheries

CHAPTER I—U.S. FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 32—HUNTING

Cibola National Wildlife Refuge, Ariz. and Calif. and Havasu National Wildlife Refuge; Correction

In FR Doc. 75-22801, appearing on page 39513 in the issue for Thursday, August 28, 1975, the hunting season for doves in California should read as follows:

California—mourning and white-winged doves, from September 1 through September 30, 1975, inclusive, and from November 22 through December 7, 1975, inclusive.

In FR Doc. 75-22801, appearing on page 39513 of the issue for Thursday, August 28, 1975, the hunting season for doves in Arizona should read as follows:

Arizona—mourning and white-winged doves, from September 1 through September 21, 1975, inclusive; mourning doves only, from December 7, 1975 through January 4, 1976, inclusive.

ROBERT F. STEPHENS,
Acting Regional Director,
Albuquerque, New Mexico.

SEPTEMBER 9, 1975.

[FR Doc.75-24569 Filed 9-15-75; 8:45 am]

PART 32—HUNTING

Swan Lake National Wildlife Refuge, Missouri

The following special regulations are issued and effective on September 16, 1975. Time limitations preclude issuance of a public notice of proposed rulemaking.

§ 32.12 Special regulations; migratory game birds; for individual wildlife refuge areas.

MISSOURI

SWAN LAKE NATIONAL WILDLIFE REFUGE

Public hunting for geese only is permitted only on designated areas comprising 2,500 acres within Swan Lake National Wildlife Refuge, Missouri. Hunting shall be in accordance with all applicable State and Federal regulations subject to the following.

(1) Each hunter must obtain a State permit issued at the checking station prior to hunting, hunt only from his lottery-assigned blind, fire no more than ten (10) shells, and include not more than one (1) Canada goose on his daily bag.

(2) Hunting will be in accordance with State regulations.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife refuge areas generally which are set forth in Title 50, Code of Federal Regulations, Part 32.

ALFRED O. MANKE,
Refuge Manager, Swan Lake
National Wildlife Refuge,
Sumner, Missouri 64681.

AUGUST 25, 1975.

[FR Doc.75-24570 Filed 9-15-75; 8:45 am]

PART 32—HUNTING

Seville National Wildlife Refuge, New Mexico

On August 20, 1975, there was published in the FEDERAL REGISTER (40 FR 36377) a notice of proposed special regulations for hunting of migratory game birds on Seville National Wildlife Refuge.

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Interested parties were given an opportunity to submit written comments, suggestions or objections regarding the proposed special regulations. Because of the limited time available to implement the proposed rulemaking, if adopted, the United States Fish and Wildlife Service found that "good cause" existed to require a shortening of the comment period to 5 days. Accordingly, comments received by the 25th of August were considered by the Service. No unfavorable comments were received and the amendment is adopted as set forth below with minor editorial changes.

Additionally, the United States Fish and Wildlife Service has determined that a finding of "good cause" is warranted within the terms of 5 U.S.C. 553(d) (3) to expedite the implementation of this rulemaking because final Federal migratory bird hunting regulations were not published until September 5, 1975, and the teal season begins September 20, 1975.

These special regulations will therefore become effective on September 20, 1975.

P. V. SCHMIDT,
Acting Director,
U.S. Fish and Wildlife Service.

§ 32.12 Special regulations; migratory game birds; for individual wildlife refuge areas.

NEW MEXICO

SEVILLE NATIONAL WILDLIFE REFUGE

Public hunting of ducks, geese and coots on the Seville National Wildlife Refuge, New Mexico, is permitted as follows: The Special Teal Season from September 20 through September 28 inclusive, ducks and coots from October 28 through January 18, 1976, and geese from December 27 through January 11, 1976, inclusive; but only on the areas designated by signs as open to hunting. These open areas, comprising 1,992 acres, are delineated on maps available at headquarters of the Bosque del Apache National Wildlife Refuge, and from the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103. Hunting shall be in accordance with all applicable State and Federal regulations covering the hunting of ducks, geese and coots subject to the following special conditions:

(1) Hunting during the general waterfowl season will be permitted only on Tuesday, Thursday and Sunday until 1 p.m.

(2) Hunting during the special teal season will be on each day of the season.

(3) No camping will be permitted.

(4) Vehicle entry and parking will be restricted to areas as posted and designated on hunt map.

(5) There will be no entry to the hunt area earlier than two hours before sunrise.

(6) All hunters must be out of the hunt area and off the refuge by two hours after shooting hours.

(7) The use of dogs in the hunt area is allowed for the purpose of waterfowl hunting only. Dogs not to exceed two per hunter.

(8) Hunters and dogs may not enter closed areas to retrieve birds.

(9) Fires of any type are prohibited.

(10) The construction of temporary blinds is permitted. Pits and permanent blinds are prohibited.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife refuge areas generally which are set forth in Title 50, Code of Federal Regulations, Part 32, and are effective through January 18, 1976.

[FR Doc.75-24578 Filed 9-15-75; 8:45 am]

PART 28—PUBLIC ACCESS, USE AND RECREATION

Illinois, Iowa, Minnesota and Wisconsin Upper Mississippi River Wild Life and Fish Refuge; Correction

In FR appearing on page 30966, Vol. 40, No. 143 of the issue for Thursday, July 24, 1975, under Sec. 28.28, Paragraph (8) should read as follows:

(8) The placement on the refuge of boathouses, boat docks, boat slips, storage boxes or sheds, stairways, wells, septic systems, sewer systems of any type, and all other kinds and types of construction is prohibited without written authorization of the refuge manager or his authorized representative. All structures, including boathouses, docks, piers and floats authorized by permit to be moored, anchored, or secured along the shoreline and on the waters of the Mississippi River within the Upper Mississippi River Wild Life and Fish Refuge must use flotation methods and devices of a type constructed of polyurethane, high-impact polyethylene fiberglass material, or other inert materials to provide flotation. The use of any iron or steel container not fabricated originally for flotation purposes, including barrels, tanks and other containers originally constructed for the purpose of containing fluids, powders or similar products is prohibited unless filled with polyurethane. Flotation devices must be completely converted to conform to these requirements by June 30, 1976. The provisions of this special regulation supplement the regulations which govern public access use and recreation on wildlife refuge areas generally which are set forth in Title 50, Code of Federal Regulations, Part 28, and are effective until June 30, 1976.

Dated: September 9, 1975.

WAYNE E. GUESWEL,
Refuge Manager.

[FR Doc.75-24636 Filed 9-15-75; 8:45 am]

proposed rules

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

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 1000]

[Docket No. 75N-0148]

SPECIFIC AREA GONAD SHIELDING

Guideline for Use on Patients During Medical Diagnostic X-ray Procedures

The Commissioner of Food and Drugs is proposing a guideline for specific area gonad shielding for patients undergoing x-ray examination. Interested persons have until November 17, 1975 to submit comments.

The Food and Drug Administration (FDA), Department of Health, Education, and Welfare, under the authority of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 82 Stat. 1173 et seq., (42 U.S.C. 263b et seq.)) conducts and supports research, training, and operational activities to minimize the exposure of the public to unnecessary electronic product radiation. In carrying out the purposes of the act, the Commissioner is authorized to make recommendations that he considers appropriate relating to control of electronic product radiation (section 356(b) of the act.) Accordingly, it is hereby proposed to amend Chapter I of Title 21 of the Code of Federal Regulations by adding a new Subpart C, "Guidelines and Recommendations," to Part 1000 (21 CFR Part 1000), and prescribe an advisory guideline for health practitioners concerning the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures in a new § 1000.50 (21 CFR 10050) of the subpart. Subpart C of Part 1000 would contain all future voluntary guidelines issued by the Commissioner concerning the control of electronic product radiation. Such guidelines would be implemented through educational programs and cooperative activities with professional organizations and State radiation control agencies. Recommendations regarding the shielding of other radiation-sensitive tissues and organs of patients, such as the thyroid, bone marrow, and developing fetus, during medical diagnostic x-ray procedures, are also under study by the FDA and would be proposed for inclusion in this subpart when sufficient scientific and technical information are available.

Shielding of the gonads during a diagnostic x-ray procedure is accomplished by interposing lead or lead-impregnated material between the x-ray source and the germinal tissues of the patient to

reduce the x-ray dose to those tissues. A thickness of material equivalent to 0.25 millimeter of lead is sufficient to reduce the transmitted intensity of a 100 kVp (kilovolts peak) primary x-ray beam by approximately 90 percent. For a 150 kVp x-ray beam, a thickness of material equivalent to 0.5 millimeter of lead is sufficient to achieve this reduction.

Gonad shielding is desirable because studies indicate that exposure to ionizing radiation causes mutations in germinal tissue, which may adversely affect future generations. A significant portion of the gonad dose to the population incurred during medical x-ray examinations could be eliminated by the use of shielding, without adversely affecting medical radiological diagnoses. Exposure of the gonads is not necessary, unless the use of shielding would interfere with the visualization of adjacent anatomical structures of interest, or the gonads themselves must be visualized.

Two general types of gonad shields are currently available: Wide area and specific area shields.

Wide area shields, such as lead aprons, cover an extended area of the body, and are frequently used to protect patients from scattered and other secondary sources of x-rays, such as tube housing leakage. They are also used by fluoroscopists, technicians, and other persons who may be exposed to secondary radiation during x-ray examinations. However, they are not generally useful for patients when the gonads lie within or in close proximity to the primary x-ray field because wide area shielding frequently interferes with the objectives of the examination.

Specific area shields cover an area slightly larger than the region of the gonads. This permits their use on patients during many procedures in which the gonads lie within, or are in close proximity to the x-ray field, such as examinations of the abdominal, upper femoral and pelvic regions, without interfering with the objectives of the examination. Among the diagnostic x-ray procedures currently in use, the largest gonad doses are incurred by patients during such examinations. Therefore, the magnitude of the gonad dose reduction that can be achieved by a facility solely by wide area shielding of patients is considerably smaller than that attainable by a program that also incorporates the appropriate use of specific area shielding.

Specific area shielding is commercially available in three basic forms: Shadow shielding; flat, contact shielding; and shaped, contact shielding.

Shadow shielding consists of a piece of radiopaque material held in the primary x-ray beam, usually near the x-ray tube, so as to cast a shadow over the patient's gonads. Proper positioning requires a clearly visible and accurately aligned beam-defining light. Because it does not touch the patient, shadow shielding offers advantages when sterile fields are required or when the patient is incapacitated. Although the acquisition cost is higher than for other types of shielding, a single device may be used indefinitely.

Flat, contact shielding usually consists of a small, flat piece of lead-impregnated material that is placed on or taped to the patient so as to cover the gonads but not obscure the area of diagnostic interest. This type of shielding can be inexpensively fabricated from old lead aprons or film blockers, or may be obtained commercially. It is most effective in anteroposterior (AP) examinations of the abdominal region when the patient is recumbent; however, because it is difficult to secure, it is not well suited to projections other than AP, or to situations in which the patient is not recumbent.

Shaped, contact shielding can be used only for male patients. It consists of a lead-impregnated, cup-shaped shield that is enclosed in a disposable plastic bag and inserted into a pouch sewn into a carrier garment, such as briefs or an athletic supporter. This type of shielding is now commercially available with suitable carrier garments for children and adults. Because of its contoured design and method of attachment, it is appropriate for AP or lateral projections, and is effective in reducing some radiation scattered from adjacent parts of the body. Also, patients may be repositioned for different views without repositioning the shield. Acquisition cost is low; however, there is a continuing cost for laundering or replacing carrier garments. Satisfactory programs can be designed around any one or a combination of the types of specific area gonad shields discussed above.

A number of medical, professional, and radiological health organizations have previously published recommendations favoring use of gonad shielding. Twenty-three State radiation control agencies have issued related regulations or recommendations. In spite of this, gonad shielding is not consistently employed during most of the medical radiological procedures where it is appropriate. This may be because it has not been consistently or effectively taught in training programs for x-ray technologists and medical practitioners, and the public has

not been adequately informed of its benefits. Also, the enforcement of regulations governing the use of gonad shielding is difficult. Due to the inherent variability in diagnostic x-ray procedures, it is not possible to compile a complete regulatory list of examinations for which shielding should always be used, and in which its use will not interfere with clinical objectives. Because effective specific area gonad shields are now available which are easy to use and which minimize the chances of interference with the objectives of a variety of examinations, it is anticipated that a renewed voluntary effort using more effective educational materials will increase the clinical use of this highly desirable radiation protection technique.

The proposed guideline has been reviewed by the Medical Radiation Advisory Committee, a committee established pursuant to section 222 of the Public Health Service Act, (42 U.S.C. 217a). This committee advises the Commissioner on formulation of policy and development of coordinated national programs relating to optimal application of ionizing radiation for medical purposes. In addition, medical and professional organizations, radiological health groups, government agencies, and other interested parties were invited to submit written comments regarding the proposed guideline during its development. The comments received generally supported the principles set forth in the guideline. Some changes were suggested, and they have been incorporated wherever possible. One medical organization has implicitly endorsed the concept of specific area shielding by distributing informational material and sample shields to its members.

The guideline proposed by the Commissioner concerning the use of specific area gonad shielding would consist of three criteria of general applicability that should be used by health practitioners as a basis for decisions concerning the need for such shielding in individual cases. Practical guidance concerning the implementation of these criteria would also be provided. Adherence to the guideline at the clinical level would require that instructions and procedures that can be easily followed by x-ray personnel with minimal disruption of radiological services be established by each facility. The criteria and guidance proposed, and the rationale for these are as follows:

1. Proposed § 1000.50(a) recommends that specific area gonad shielding be used if the gonads of the patient will lie within the primary x-ray field, or in close proximity (about 5 centimeters), despite proper beam limitation.

This recommendation is based upon studies conducted by FDA that indicate that specific area gonad shielding yields testicular dose reductions ranging from approximately 85 percent when the testes lie within the x-ray field, to approximately 50 percent when they lie within the immediate proximity of the field. Possible ovarian dose reductions under similar circumstances were found to range from 45 to 30 percent. These potential ovarian dose reductions are smaller than comparable testicular dose reductions be-

cause the ovaries lie approximately at the mid-plane of the abdomen, and a greater portion of ovarian dose comes from x-rays scattered from adjacent tissues.

The criterion proposed in § 1000.50(a) does not urge the use of specific area gonad shielding when the gonads are more than 5 centimeters from the edge of the primary x-ray field because FDA studies have indicated that in such cases gonad doses are small. For example, in a properly collimated postero-anterior chest examination the testicular exposure is typically less than 0.03 milliroentgens. As a result, it has been concluded that the use of specific area shielding for such examinations cannot be defended on the basis of cost-effectiveness. The criterion proposed in § 1000.50(a) would not preclude the use of shielding when the gonads are more than 5 centimeters from the edge of the primary x-ray field. However, health practitioners who choose to do so should not neglect the use of specific area shielding when the gonads lie within, or are in close proximity to the primary x-ray field.

Proposed § 1000.50(a) (1) and (2) provide practical guidance concerning the types of examinations for which specific area testicular shielding should be considered. For reasons discussed in item 2. below of this preamble, it is not presently feasible to present such practical guidance for the use of specific area ovarian shielding.

Proposed § 1000.50(a) (1) recommends that, in the absence of extenuating circumstances, such as those stated in § 1000.50 (b) and (c), specific area testicular shielding should always be used for those examinations in which the testes usually are in the primary x-ray field. This category includes examinations of the pelvis, hip, upper femur and other examinations where the testes usually are not excluded from the x-ray field by collimation alone, using conventional techniques. In these examinations, the general application of specific area testicular shielding will result in substantial dose reductions.

Proposed § 1000.50(a) (2) addresses those examinations in which the testes may be within the primary x-ray field, or within 5 centimeters of its edge, depending upon several variables that affect the distance between the edge of the x-ray field and the testes. These variables, which are unique to facilities, x-ray machines, patients, and examination techniques, include the beam and image receptor size used, the location of the image receptor relative to the testes, the alignment of the beam and image receptor, and the distance between the testes and adjacent bony landmarks. The cumulative effect of these variables is such that whether the testes will be within or in close proximity to the primary x-ray field cannot be predicted without individual analysis of the circumstances involved in the performance of each examination. Consequently, the dose reductions to be derived from the use of specific area testicular shielding during such examinations are highly dependent upon the above examination variables. Some examples of this category are ab-

dominal, lumbar spine and lumbosacral spine examinations, intravenous pyelograms, and abdominal scout films for barium enemas and upper GI series. Proposed § 1000.50(a) (2) recommends that each facility evaluate its procedures, techniques, and equipment, and compile a list of such examinations for which specific area testicular shielding should be routinely considered. As a basis for judgment, it would be recommended that specific area testicular shielding be considered for those examinations of male patients in which the pubic symphysis can be visualized on the film.

Proposed § 1000.50(a) (3) emphasizes that gonad shielding should never be used as a substitute for careful positioning, the use of correct technique factors and film processing, or proper beam limitation (confinement of the x-ray field to the area of diagnostic interest). This substitution could result in unnecessary doses to other sensitive tissues, and could also adversely affect the quality of the radiograph.

2. Section 1000.50(b) recommends that specific area gonad shielding be used only if the clinical objectives of the examination will not be compromised.

This recommendation is based on the premise that patients receive health benefits from those necessary diagnostic x-ray examinations for which shielding cannot be used that override the associated genetic risks to the population. Therefore, if specific area shielding would probably or definitely interfere with diagnosis, its use is not justified. The decision to use such shielding on any particular patient for a diagnostic procedure should be based on the professional judgment of a practitioner of the healing arts operating within the framework of the guideline provisions.

Proposed § 1000.50(b) (1) recommends that specific area testicular shielding be considered for use during the majority of abdominal region examinations of male patients. The anatomical location of the testes is such that covering them with a properly positioned specific area shield usually does not obscure needed clinical information; therefore, the use of specific area shielding for males can be easily implemented without modification of existing radiological procedures. It has been found that such shielding usually does not obscure needed clinical information during abdominal area examinations, except in a few cases such as retrograde urethrograms, voiding cystourethrograms, oblique views of the hip, visualization of the rectum and occasionally the pubic symphysis.

Proposed § 1000.50(b) (2) advises that effectively shielding the ovaries from the primary x-ray field is frequently impractical at present because their exact location is difficult to estimate, and the shielding may obscure radiological visualization of adjacent structures, due to the proximity to the spine, ureters, and small and large bowel. Since reducing both ovarian and testicular doses are important, specific area gonad shields should ideally be provided during appropriate procedures for patients of

either sex. It may be possible for a practitioner to use specific area ovarian shielding during selected views in some examinations, but these techniques are not well established. Although the guideline proposed herein is applicable to specific area shielding of both male and female patients, there is no practical guidance presently available on implementing the proposed criteria for females. It is anticipated that comments submitted in response to this proposed guideline may provide additional technical and clinical information concerning the appropriate use of specific area ovarian shielding.

3. Proposed § 1000.50(c) recommends that specific area gonad shielding be used if the patient has a reasonable reproductive potential.

This recommendation is made because the purpose of gonad shielding is to prevent adverse effects on future generations. Therefore, § 1000.50(c) (1) states that patients, who for some reason cannot or are not likely to have children in the future, need not be considered as candidates for shielding. To avoid the necessity of obtaining additional information from each patient, a radiological facility could comply with the intent of § 1000.50(c) by choosing the simplified procedure of employing specific area shielding for all patients under a chosen age. Census information regarding the expected number of future children versus the age of a potential parent is provided in the table in § 1000.50(c) (2). Using this data, a facility could exercise its own judgment in establishing an age limitation above which specific area shielding would not be routinely applied. However, facilities employing an age limit should recognize that some persons below that specified age who are sterile, or who do not intend to reproduce, may object to being shielded, and some over that age may object to not being shielded. A facility employing an age limit should be prepared to alter its procedures for patients whose objections may interfere with their medical care.

Pertinent background data and information on the guideline proposed herein, including an environmental impact assessment report, are on file in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 356, 82 Stat. 1175 (42 U.S.C. 263d)) and under the authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Part 1000 of Subchapter J of Chapter I of Title 21 of the Code of Federal Regulations by establishing Subpart C consisting at this time of § 1000.50, to read as follows:

Subpart C—Guidelines and Recommendations

§ 1000.50 Guideline for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures.

Specific area gonad shielding covers an area slightly larger than the region of the gonads. It may therefore be used to

protect the germinal tissue of patients from radiation exposure that may cause genetic mutations during many medical x-ray procedures in which the gonads lie within, or are in close proximity to the x-ray field, without interfering with the objectives of the examination. Such shielding should be provided when the following conditions exist:

(a) The gonads will lie within the primary x-ray field, or within close proximity (about 5 centimeters), despite proper beam limitation. Except as provided in paragraph (b) or (c) of this section:

(1) Specific area testicular shielding should always be used during those examinations in which the testes usually are in the primary x-ray field, such as examinations of the pelvis, hip, and upper femur; and

(2) Specific area testicular shielding may also be warranted during other examinations of the abdominal region in which the testes may lie within, or in close proximity to the primary x-ray field, depending upon the size of the patient and the examination techniques and equipment employed. Some examples of these are: Abdominal, lumbar spine and lumbosacral spine examinations, intravenous pyelograms, and abdominal scout film for barium enemas and upper GI series. Each x-ray facility should evaluate its procedures, techniques, and equipment and compile a list of such examinations for which specific area testicular shielding should be routinely considered for use. As a basis for judgment, specific area testicular shielding should be considered for all examinations of male patients in which the pubic symphysis will be visualized on the film; and

(3) Specific area gonad shielding should never be used as a substitute for careful patient positioning, the use of correct technique factors and film processing, or proper beam limitation (confinement of the x-ray field to the area of diagnostic interest), because this could result in unnecessary doses to other sensitive tissues, and could adversely affect the quality of the radiograph.

(b) The clinical objectives of the examination will not be compromised.

(1) Specific area testicular shielding usually does not obscure needed information except in a few cases such as oblique views of the hip, retrograde urethrograms and voiding cystourethrograms, visualization of the rectum, and, occasionally, the pubic symphysis. Consequently, specific area testicular shielding should be considered for use in the majority of x-ray examinations of male patients in which the testes will lie within the primary beam or within 5 centimeters of its edge.

(2) The use of specific area ovarian shielding is frequently impractical at present because the exact location of the ovaries is difficult to estimate, and the shield may obscure visualization of portions of adjacent structures such as the spine, ureters, and small and large bowel. However, it may be possible for practitioners to use specific area ovarian shielding during selected views in some examinations.

(c) The patient has a reasonable reproductive potential.

(1) Specific area shielding need not be used on patients who cannot, or are not likely to have children in the future.

(2) The following table of statistical data regarding the average number of children expected by potential parents in various age categories during their remaining lifetimes is provided for x-ray facilities that wish to use it as a basis for judging reproductive potential.

Expected number of future children versus age of potential parent¹

Age	Male parent	Female parent
Fetus	2.6	2.6
0 to 4	2.6	2.5
5 to 9	2.7	2.5
10 to 14	2.7	2.6
15 to 19	2.7	2.6
20 to 24	2.6	2.2
25 to 29	2.0	1.4
30 to 34	1.1	.6
35 to 39	.5	.2
40 to 44	.2	.04
45 to 49	.07	0
50 to 54	.03	0
55 to 59	.01	0
Over 60	0	0

¹ Derived from data published by the National Center for Health Statistics, "Final Natality Statistics 1970," HRA 74-1130, vol. 22, No. 12, Mar. 20, 1974.

Interested persons may, on or before November 17, 1975 submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments regarding this proposal. Comments shall be filed in quintuplicate (except that individuals may submit single copies), and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office Monday through Friday, from 9 a.m. to 4 p.m., except on Federal legal holidays.

Dated: September 9, 1975.

SAM D. FINE,
Associate Commissioner for
Compliance.

[FR Doc. 75-24534 Filed 9-15-75; 8:45 am]

DEPARTMENT OF TRANSPORTATION

Coast Guard

[46 CFR Parts 32, 35, 77, 78, 96, 167, 184, 185, 195, 196]

[CGD 75-074]

VESSEL INSPECTION REGULATIONS

Proposed Rulemaking

The purpose of these amendments to the vessel inspection regulations is to publish within the Code of Federal Regulations amendments to the Convention for Safety of Life at Sea, 1960.

The assembly of the Intergovernmental Maritime Consultative Organization (IMCO) at its fourth extraordinary session held in London, November 1968, adopted three amendments to the International Convention for the Safety of Life at Sea, 1960. These amendments were an outgrowth of a study by IMCO