of service would be catastrophic to Penn Central's present operations. Penn Central asserts that in its present condition it is virtually powerless to prevent other track which now complies with Class 1 standards from falling out of compliance.

Section 202(c) of the Federal Railroad Safety Act of 1970 (45 U.S.C. 431(c)) authorizes waiver of compliance from these standards, in whole or in part, after hearing, if the waiver is found to be in the public interest and consistent with safety.

Accordingly, an initial public hearing is hereby set for 10:00 a.m. on October 16, 1973, in Room 2230, Nassif Building, 400 Seventh Street SW., Washington, D.C. 20590. The purpose of the initial hearing is to afford interested persons an opportunity to express their views as to whether and under what conditions Penn Central should be allowed to continue to operate over any or all of the substandard track involved pending additional hearings and subsequent decision on what relief if any should be granted with respect to the various segments of track encompassed within the petition.

The additional hearings will commence on October 23, 1973 at the same hour and place as the initial hearings. These hearings will afford interested persons an opportunity for oral presentation as to whether or not the petition should be granted. The purpose of these hearings will be to obtain information to assist the Federal Railroad Administrator in determining whether granting of the petition, in whole or in part, would be in the public interest and consistent with railroad safety. Specific information is requested with respect to the following:

1. The adverse effects which would result from a halting of rail operations on the track involved;

2. The nature and extent of hazards which would result from continued operation on the sub-standard track; and

3. Conditions necessary to obviate these hazards to maintain safety of operation.

The hearings will be informal, not judicial or evidentiary. There will be no cross-examination of persons making statements. A representative of the FRA will make an opening statement outlining the matter set for hearing. Interested persons will then have an opportunity to present their oral statements. At the completion of all initial oral statements, those persons who wish to make rebuttal statements will be given the opportunity to do so in the same order in which they made their initial statements. Additional procedures for conducting the hearings will be announced at the hearings.

Interested persons may also present written statements at the hearings. All statements will be made a part of the record of the hearings and be a matter of public record.

Interested persons are also invited to submit written data, views, or comments. Communications should identify the regulatory docket number and notice number and should be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Attention: Docket No. RST-1, Waiver Petition No. 17, 400 Seventh Street SW., Washington, D.C. 20590. Communications received before October 24, 1973 will be considered by the Federal Railroad Administrator before taking final action on this petition. The public docket including the petition and all comments received, will be available for examination by interested persons at any time during regular working hours in Room 5101, Nassif Building, 400 Seventh Street, Washington, D.C.

(Federal Railroad Safety Act of 1970, 84 Stat. 971 et seq.; 45 U.S.C. 421 et seq., 49 CFR 1.49(n))

Issued in Washington, D.C. on October 12, 1973.

JOHN W. INGRAM,
Administrator.

[FR Doc.73-22088 Filed 10-12-73;11:32 am]

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WASHINGTON, D.C.

Volume 38 ■ Number 198

PART II

ENVIRONMENTAL PROTECTION AGENCY

■

OCEAN DUMPING

Final Regulations and Criteria

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER H—OCEAN DUMPING

TRANSPORTATION FOR DUMPING AND DUMPING OF MATERIAL INTO OCEAN WATERS

Pursuant to title I of the Marine Protection, Research, and Sanctuaries Act of 1972, Public Law 92-532, (hereinafter, "the Act"), the Environmental Protection Agency (EPA) published on April 5, 1973, interim regulations, effective immediately, describing procedures for application for, and issuance and denial of, permits for ocean dumping under the Act. Interim criteria for the evaluation of permit applications for ocean dumping under P.L. 92-532 were published May 16, 1973, as part of the interim regulations.

These criteria also satisfied the requirement of section 403(c) of the Federal Water Pollution Control Act Amendments of 1972, Public Law 92-500, which require, under the heading of "Ocean Discharge Criteria," that EPA promulgate guidelines for determining the degradation of the waters of the territorial sea, the contiguous zone, and the oceans, in compliance with which permits under section 402 of P.L. 92-500 must be issued after promulgation.

The EPA is publishing herewith the final regulations describing procedures for application for, and issuance and denial of, permits for ocean dumping under the Act. Final criteria for the evaluation of permit applications for ocean dumping under the Act or for permits for ocean discharge of pollutants as required by section 403(c) of P.L. 92-500, are published as Part 227 of these regulations.

Public comment periods for the Regulations expired June 4, 1973, and for the Criteria June 23, 1973. The final regulations and criteria published herewith were revised from the interim criteria based on comments received from the general public and from marine scientists, and from EPA operating experience during the first five months of the program.

The following analysis summarizes comments received on the cited sections of the interim Regulations and Criteria and presents a rationale for the changes made. Sources of comments are referenced to Attachment A by the numeral in parentheses.

Section 220.1. There was a comment that "fish wastes", "territorial sea", "contiguous zone", and "ocean" should be defined (5). All of these terms except "fish wastes" are defined in the Act and are referenced in § 220.2. "Fish wastes" seems self-explanatory, so no changes were made in response to this comment.

A new § 220.1(a) has been added to clarify the relationship between these regulations and the International Ocean Dumping Convention (IODC). This merely points out that the basis for the control of ocean dumping under these regulations is the same as required by the IODC and lists the criteria of the IODC. This change was recommended by the Department of State for inclusion as soon as the Convention was ratified by the U.S.

This section has also been changed by the addition of a section on the placement of materials for enhancement of fisheries and the basis on which a permit will not be required under this Act. This change is made based on a comment received (5) and on discussions with other Federal agencies on how this matter could be most easily handled.

Section 220.3. Several comments were received on the categories of permits, with the general permit the subject of most concern. Environmental groups (7, 10) were concerned that detailed criteria for the issuance of general permits were not given and were concerned about the basis on which general permits would be issued. On the other hand, suggestions were made that the general permit could be used to allow the dumping of municipal sewage sludge (9), as an interim measure for all wastes (8), and for the dumping of materials such as fly ash (2).

Other comments were concerned with setting an outside time limit on permits of one year (2, 3, 4, 6). Because of the time required to obtain permits and the budgetary cycles of municipalities, periods ranging from two to five years were recommended.

There appeared to be a general confusion and misunderstanding of the manner in which EPA intended to use the general permit, and also some confusion about the overall relationship among general, special, interim special, and emergency permits (9, 2). The listing of permit categories was split among several sections of the interim Regulations and Criteria; to facilitate understanding, therefore, all the categories of permits and the general basis for issuance were consolidated into § 220.3 and more precise definitions were applied to remove the apparent basis of confusion. In summary the permit categories as revised are:

1. *General permits.* Requirement for a fixed expiration date was removed. Since this will be used only for such things as the dumping of galley waste and burial at sea, an expiration date is inappropriate.

2. *Special permits.* Only for wastes that meet the numerical criteria of §§ 227.22 and 227.3. The outside time limit is lengthened to three years.

3. *Emergency permits.* Language unchanged. Covers materials which do not meet § 227.22 (trace contaminants) and requires consultation with State for materials violating § 227.22.

4. *Interim permits.* These are a subset of "special permits" within the meaning of the Convention and are identified in these regulations as a separate category of permits to cover the dumping of materials which do not meet the numerical requirements of § 227.22 or § 227.3, but must be dumped at present because there is no feasible alternative. This would require an implementation plan (the time limit is keyed to the plan and may not exceed one year), and the permits are not renewable. A new permit may be issued on proof of satisfactory progress in implementation.

5. *Research permits.* This was also a subset of special permits. It is broken out separately to permit more flexible review not only by the public, but also by the scientific community to determine its merit on a continuing basis. Research permits would be granted only for 18 months, but could be renewed after review by EPA. This type of permit is needed to allow for research on ocean dumping, research which would be illegal without such a permit.

Section 220.4. The New York Conservation Department (5) feels that this delegation would allow EPA Regional Administrators to issue permits for dumping within New York territorial waters without the consent of New York. This is not the case; § 222.3(c) allows for State certification, and § 227.1(f) states that no permit will be issued which violates State water quality standards. The Section has been rewritten to clarify the nature and extent of the delegation to Regional Administrators based on this and other comments concerning conditions which may be imposed on permits and on administrative jurisdictional problems arising during the first months of the program.

The delegation of authority to the regions extends only to the issuance or denial of special and interim permits and review of Corps permits. General, emergency, and research permits are all retained in Headquarters primarily because of the national coordination required prior to their issuance.

Section 221.1. Comments were received (7, 10) stating that the alternatives to dumping must be clearly spelled out on the application. Sections 221.1(j) and 227.4 on requirements of implementation plans cover these requirements adequately. A comment was also received that municipal and industrial sludges should be treated differently and the requirements placed on municipal sludges should be less stringent as far as the information submitted is concerned (9). The composition of municipal sewage sludge can vary quite widely, and the same degree of care in its disposal is necessary as for industrial sludges. No changes were made in the text.

Sections 221.3 and 221.4. Comments were received concerning the permittee being able to warrant accuracy of the information furnished him by someone else (5, 9). The permittee can, as part of his contract with the supplier of the waste, hold him responsible for any false information given him; also, the applicant is required to certify to EPA that the information he provides on the application is correct, and a permit would be granted on the basis of that information. There seem to be adequate safeguards to protect the permittee who is not the applicant. No changes were made.

Section 221.5. The suggestion was made that there should be no exemptions from the processing fee (5). This was

rejected because it would involve additional administrative work in merely shifting tax dollars from one pocket to another. It was suggested that contractors working for a government agency be exempt from any fee (4). This can be accomplished by the government agency applying for the permit rather than the contractor without a change in language.

The processing fees have been increased because the original estimates of processing costs were too low.

Section 222.1. There was a comment that negative action or denial is anticipated as final action on permit applications (7). This is not the case; each permit application is to be evaluated fairly based on the criteria as stated in the regulations. The Act requires strict regulation of dumping, not prohibition.

Section 222.2. Several comments were received stating that the 10 day period to make a tentative determination on permit applications was too short (7, 10). The language has been changed to require notification of an applicant within 10 days as to whether his application is complete and to allow 30 days after a completed application for preparation of a tentative determination of action and publication of a public notice.

Other comments were received concerning the interim time limits (3, 6, 7, 10); this section no longer applies and has been deleted.

Section 222.3. One comment received said that States should certify not only for dumping in territorial waters but also in dumping which could affect their territorial waters (1); the language has been changed to include requesting certification for dumping within the contiguous zone, but denial of certification will be accepted only if the State can demonstrate its water quality standards in the territorial sea will be violated by dumping in the contiguous zone. Other comments dealt with including additional information with the public notice, such as an environmental impact statement, monitoring requirements, etc. (5, 7, 10). The public notice is a brief summary of the permit application and intended action, suitable for publication in a newspaper or posting in a public place. Inclusion of the detail suggested is not feasible in the public notice, but all documentation of the application will be available for public inspection as § 222.3(a)(4) states.

Section 222.4. Comments were received suggesting that there is an implied intent to approve permits in the regulations (7, 10); the language has been changed to correct any such impression. The question was also raised as to the basis on which States are expected to certify applications (5). The language has been changed to state that certification as to impact on water quality standards is required.

Section 222.5. This Section deals with the circumstances under which a public hearing may be called. Comments by environmental groups suggest that any time anyone requests a public hearing such a hearing must be held. The regulations merely state that anyone requesting a public hearing must state in writing what his objections are, and what issues are to be raised at such a hearing. These are reasonable requirements, and serve merely to screen out the irresponsible people who have no issues to raise, but just want to have a public forum for speechmaking which would not contribute to the basis for consideration of a permit application and would be done at the expense of the taxpayers.

Section 222.7. Comments were made on the necessity of making the entire permit application available to the public (7, 10). This is covered adequately in § 222.3(a)(4).

Section 222.9. One comment was made on the "ominous" tone of the regulations (7). This relates to the findings of the presiding officer of the public hearing; the language explicitly states he must give full consideration to all views and arguments presented at the hearing and forward his recommendations to the appropriate authority. This seems quite adequate to serve the public interest, and the "ominous" nature of the regulations is not apparent.

Section 222.10. There was an objection to limiting consideration of permit applications to 180 days, apparently on the basis that this is too short a period for full examination and study in the "light of ecological criteria" (10). Six months seems quite adequate for full consideration by competent professionals of any permit application.

Section 223.1. This Section deals with the contents of permits; comments were received suggesting that the composition requirements on municipal sewage sludges were too exhaustive (9), and that monitoring requirements should be spelled out in some detail (7, 10). The regulations specifically state in this Section that a permit shall include such monitoring as the Administrator determines is feasible; additional detail is extraneous, since monitoring requirements must be imposed on a case-by-case basis.

Section 223.3. One comment states that the permit must be displayed on the vessel doing the dumping (10); the Act states that this must be done and suitable language has been explicitly included in § 223.1.

Section 224.1. This Section refers to the records to be kept by permittees. One comment stated that the information required should be obtained by EPA rather than individual sewerage authorities (7); the information required is that which a dumper would normally be expected to acquire in the course of carrying out the conditions of a permit. The dumper, of course, may not be the applicant; this seems to be the basis for the comment. A comment was made that the records should be submitted to EPA; this is required in § 224.2.

Section 224.2. Reports on emergency actions have been changed to a time limit of 10 days rather than 30 days in response to two comments (4, 5). Comments were also made that EPA should require reports more often than every six months (7, 10); the regulations specify other reporting requirements may be imposed. The six-months interval is a basic requirement, and other, more restrictive requirements may be imposed as the Administrator or his designee deems necessary.

Part 225. Two comments were received regarding the 15-day time limit for responding to notification by the Corps of Engineers of proposed action on dredged material permits (7, 10). This is not considered adequate for full consideration of a permit application by those commenting. If the tests specified in the criteria have been applied, this time is quite sufficient; if they have not been applied, the time is ample for pointing this out.

Part 226. One comment was received on to whom the penalties apply (9). It seems obvious from the law and from the regulations that whoever dumps illegally, or in violation of a permit issued to him is subject to the penalties under the law.

Part 227. These criteria are intended to apply both to P.L. 92-532 and to section 403(c) of P.L. 92-500. Comments were received indicating that this relationship is not apparent (24). Language has been introduced to include the statement "dumping or other discharge" where appropriate, instead of "dumping." The sections on Release Zone, § 227.72 and Mixing Zone, § 227.73, have also been modified appropriately.

Section 227.1. Comments were received stating that the overall thrust of the criteria was confusing (14, 24). A section has been introduced (§ 227.1(c)) to clarify the general basis on which permits may be granted. Other comments suggested relatively minor changes which were incorporated (19, 20, 21, 28). These were to insert in § 227.1(a) "in quantities" after "ocean waters of any material" and to change § 227.1(e) "because of" to "to prevent or minimize". Because of some doubt as to the scientific advisability of using locations off the continental shelf (37), the last sentence of § 227.1(h) was eliminated. One comment suggested incorporating the concept of elimination of ocean discharges by 1985 (24), a policy goal of P.L. 92-500, not P.L. 92-532.

Section 227.21. A comment by AEC (18) says that we should define radiological warfare agents. This term appears to be self-explanatory and is not defined either in the International Convention or in P.L. 92-532.

Section 227.22. Numerous comments were received on the prohibition of these materials except in trace concentrations (24, 19, 20, 21, 25, 26). The comments made on this section also relate to the definition of "trace" and those pertinent to this definition will be considered in the discussion under § 227.74. The burden of the comments was basically that this requirement is highly restrictive except for the exclusion in para-

graph (e). Comments by industry suggested that EPA, by using these limitations, could effectively eliminate all ocean dumping; comments by NRDC suggested that EPA might use this exclusion to permit a lot more ocean dumping. It was pointed out that the term "trace concentrations" does not follow the language of the Ocean Dumping Convention which uses the term "trace contaminants". This is true and the language has been changed from "wastes containing more than trace concentrations of the following materials" to "wastes containing the following materials as other than trace contaminants". A definition of trace contaminants and allowable levels for their discharge has been included in this section.

The City of Philadelphia (26) wanted organohalogens, mercury, and cadmium to be removed from this section and placed in § 227.31. This cannot be done because of the requirements imposed by the Ocean Dumping Convention.

Industrial representatives (19, 28) wanted the language of § 227.22(e) broadened; the present language reflects the usage of the International Ocean Dumping Convention and has not been changed.

Section 227.3. NRDC (24) says that EPA should define acceptable bioassay. A procedure for bioassay is being prepared and should be available by December 1; however, there seems to be little point in including the procedure in these regulations. The language of § 227.31(a)(2) was changed to show that the volume of the mixing zone is a factor in determining the limiting permissible concentration. Several industries (19, 21, 29) wanted a reference to titanium dioxide wastes in § 227.31(b)(3) eliminated. The list of processes given are those in which ocean dumping has been used in the past and which are the ones for which particular care must be taken. One industry (14) objects to the inclusion of oxygen consuming and/or biodegradable organic matter as a material requiring special care. Such materials if dumped in large quantities and concentrated in one place can cause extreme oxygen depletion with concomitant kills of biota. The AEC (18) wants the section on containment of radiological wastes eliminated; we feel that containment of radiological wastes is an important means of disposal and the section should be retained.

The AEC (18) wanted more specific language about containerization of radioactive wastes incorporated; the present language incorporates the approach they would like to use and no changes were made.

NRDC (24) wanted the terminology of § 227.33 changed by eliminating "single time and place"; making this change would completely change the meaning of the section, so no change was made. In § 227.34 NRDC (24) wanted "no permanent damage" to refer instead to 100 years. We think that the present language is far more comprehensive and can see no significance in making the suggested change.

NRDC also wants a definition for "environmentally innocuous materials" in § 227.35; the term appears self-explanatory and it is certain not subject to quantitative definition.

In § 227.36 the Corps of Engineers (11, 31) wanted the term dredged material removed and the State of Pennsylvania (30) wanted the term sewage sludge removed. The language was broadened to include any material.

Section 227.4. The American Petroleum Institute (6) says that the requirement that, in the exploration of alternatives to ocean dumping changes in plant processes be considered, means that the Administrator could insist that a company make a product in a particular way. This is not true; this is merely a requirement that all means possible for reducing or eliminating a waste material be explored. The only decision that EPA will make is whether or not to grant an ocean dumping permit and it is a reasonable requirement to ask a manufacturer to explore other ways of getting rid of the waste besides ocean dumping.

NRDC (24) wants implementation plans to be provided for all discharges which fall under the jurisdiction of the FWPCA. This would be a matter to be covered in permits granted under the NPDES rather than under P.L. 92-532. This section merely establishes the criteria upon which an acceptable implementation plan will be judged in evaluating a permit application, not whether an implementation plan will be required.

AEC (18) wants a requirement for best practicable technology and best available technology to be eliminated. This matter is a point of EPA policy and the change is not made.

Section 227.5. NRDC (24) says that EPA cannot guarantee the nontoxicity of all other materials not specified in §§ 227.22 and 227.31. The referenced sections are written so as to include practically all waste materials which are likely to contain toxic materials. A permit must still be granted for materials regulated under § 227.5; these sections just categorize some materials for which less extensive testing may be required than the materials listed in §§ 227.22 and 227.31.

Section 227.6. One industrial corporation (15) objected to the latitude being given in making decisions on disposal of dredged spoil. NRDC also objects to the discretionary language in the disposal of dredged spoil. This particular section was developed after considerable negotiation between EPA and the Corps of Engineers. It is recognized that the test procedure described in § 227.61(c) has limited applicability. The present test as specified is an interim indicator of short-term effects to determine whether dredged spoil is polluted. Upon completion of research now underway by the Corps of Engineers (June 1974), modifications to this test may be proposed.

Section 227.71. Several comments were received about the definition of limiting permissible concentrations. Most of the comments dealt with choice of an application factor (24, 14, 18, 6, 19, 20, 25, 28, 29). NRDC stated we must provide justification for an application factor of 0.01. Various industries' comments suggested values of 0.5, 0.1, and at the discretion of the Regional Administrator. The application factor of 0.01 was recommended by the National Technical Advisory Committee on Water Quality Criteria as a conservative factor to use in cases where a waste of unknown ecological impact is involved. This factor is also used by the British Government in the regulation of ocean dumping around the British Isles. A number of scientists have been asked to comment on the bioassay procedure. All have commented upon the difficulty of running bioassays involving marine specimens, but none has suggested that another application factor would be preferable. We feel that the 0.01 factor represents a sound conservative approach toward interpretation of the bioassay results and their application in the environment and that this approach is based upon the best available scientific knowledge and experience.

Sections 227.72 and 227.73. The language has been changed in these sections to state explicitly how these definitions apply for disposal through an outfall or other structure.

Section 227.74. The definition of trace concentrations was the subject of considerable comment by industrial representatives. Several modifications to the definition in the interim criteria were suggested (3, 8, 14, 19, 21, 28, 29), and a new definition incorporating some of the suggestions has been developed and incorporated into § 227.22. Section 227.74 has been eliminated as unnecessary.

List of approved interim dump sites. Numerous questions were raised on the selection and use of dump sites. The modifications required in response to these questions will require substantive changes in the list and the addition of a new section to these regulations. This addition will be published as proposed rulemaking for additional public comment before being promulgated as part of the final regulations. Until then, no changes will be made in the list of approved dump sites.

These regulations and criteria will be revised periodically to reflect additional public comment, additional operating experience, and advances in scientific understanding of the impact of pollutants on the marine environment, and the recommendations of international scientific bodies on contaminant concentrations permissible in the oceans.

Comments on these regulations and criteria will be considered in all future revisions. Comments should be addressed to Office of Air and Water Programs, Environmental Protection Agency, Attention: Mr. T. A. Wastler, Room 735, East Tower, Waterside Mall, 401 M Street SW., Washington, D.C. 20460.

The International Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter was ratified by the U.S. Senate on Au-

gust 3, 1973. These regulations and criteria form the basis for the operating program to enforce the Convention when it comes into force after ratification by fifteen nations. They will be modified to be fully consistent with the Convention when it comes into force for the United States.

All applications for ocean dumping permits received after October 15, 1973, will be processed in accordance with these final regulations. All permits granted under the interim regulations, and which expire prior to February 13, 1974, are hereby extended until February 13, 1974; all other permits will expire as stated in the permit, except that all permits issued under the interim regulations will expire no later than April 15, 1974.

Dated October 2, 1973.

JOHN QUARLES,
Acting Administrator.

LIST OF COMMENTS ON OCEAN DISPOSAL CRITERIA

1. State Senate, Commonwealth of Massachusetts.
2. Consolidated Edison Company of New York, Inc.
3. Manufacturing Chemists Association, Washington, D.C.
4. Office of Legislation, EPA.
5. State of New York Department of Environmental Conservation.
6. American Petroleum Institute.
7. Williams College, Williamstown, Massachusetts.
8. E. I. DuPont de Nemours & Company, Wilmington, Delaware.
9. Passaic Valley Sewerage Commissioners, Newark, New Jersey.
10. Natural Resources Defense Council, Inc., Washington, D.C.
11. Department of the Army, Office of the Chief of Engineers.
12. City of New York Environmental Protection Administration.
13. Department of the Interior.
14. Mobil Oil Corporation, New York, New York.
15. California Marine Affairs and Navigation Conference, San Francisco, California.
16. New York State Department of Environmental Conservation, Albany, New York.
17. State of Hawaii Department of Transportation, Honolulu, Hawaii.
18. Atomic Energy Commission.
19. Manufacturing Chemists Association, Washington, D.C.
20. American Cyanamid Company, Wayne, New Jersey.
21. NL Industries, Inc., New York, New York.
22. Shell Oil Company, Houston, Texas.
23. State of California Resources Agency, Department of Fish and Game, Sacramento, California.
24. Natural Resources Defense Council, Inc., Washington, D.C.
25. The Chlorine Institute, Inc., New York, New York.
26. City of Philadelphia Water Department.
27. Dr. Wallace W. Harvey, Jr., Memorial Clinic, Manteo, North Carolina.
28. Rohm and Haas Company, Philadelphia, Pennsylvania.
29. E. I. DuPont de Nemours & Company, Wilmington, Delaware.
30. Commonwealth of Pennsylvania Department of Environmental Resources, Harrisburg, Pennsylvania.
31. U.S. Army Corps of Engineers.
32. Massachusetts Institute of Technology, Cambridge, Massachusetts.
33. The Commonwealth of Massachusetts Water Resources Commission, Boston, Massachusetts.
34. Department of the Interior Fish and Wildlife Service, Bureau of Sport Fisheries and Wildlife.
35. Fulligant, Doremus & Karaman, Savannah, Georgia.
36. Betz Laboratories, Inc., Trevose, Pennsylvania.
37. Woods Hole Oceanographic Institution, Woods Hole, Massachusetts.

Chapter I of Title 40 is amended by replacing as final regulations Subchapter H, Ocean Dumping, as follows:

SUBCHAPTER H—OCEAN DUMPING

Part

PART 220—GENERAL

Sec.

AUTHORITY: Title I, Pub. L. 92-532, 86 Stat. 1052 (33 U.S.C. 1411-1421).

§ 220.1 Purpose and scope.

(a) *Relationship to international agreements.* The Act is the enabling domestic legislation for enforcement of U.S. commitments made by ratification of the "Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter." The regulations and criteria included in this Subchapter are based on the provisions specified in the Convention to be considered in the development of criteria governing the issuance of permits for the dumping of matter at sea.

(b) *General.* This Part establishes procedures for the issuance of permits by EPA pursuant to section 102 of the Act. Subject to the exclusions in subsection (c), the Act prohibits:

(1) Transportation from the United States of radiological, chemical, or biological warfare agents, or of any high-level radioactive wastes, for the purpose of dumping them into ocean waters, and the dumping of any such materials into the territorial sea, or into the contiguous zone (to the extent it may affect the territorial sea or the territory of the United States);

(2) Transportation from the United States of material not specified in paragraph (b)(1) of this section for the purpose of dumping it into ocean waters, and the dumping of any such material into the territorial sea, or into the contiguous zone (to the extent it may affect the territorial sea or the territory of the United States), without a permit from EPA; or, in the case of dredged material, from the Corps of Engineers.

(3) Transportation from any location outside the United States, of materials specified in paragraph (1), for the purpose of dumping them into ocean waters, by any officer, employee, agent, department, agency, or instrumentality of the United States.

(4) Transportation of any material not specified in paragraph (b)(1) of this section from any location outside the United States, for the purpose of dumping it into ocean waters, by any officer, employee, agent, department, agency or instrumentality of the United States, without a permit from EPA; or, in the case of dredged material, from the Corps of Engineers.

(c) *Exclusions.* (1) This part does not apply to the transportation and dumping of fish wastes unless such dumping occurs in:

(i) Harbors or enclosed coastal waters; or

(ii) Any other location where the Administrator finds that such dumping could endanger health, the environment or ecological systems in a specific location; provided, that nothing herein shall be construed as requiring a permit under the Act for the dumping of fish wastes in areas inside the base line from which the territorial sea is measured as provided for in the Convention on the Territorial Sea and the Contiguous Zone (15 UST 1606; TIAS 5639).

(2) This part does not apply to the placement or deposit of materials for the purpose of enhancing fisheries; provided, such placement or deposit is certified to EPA to be part of an authorized State or Federal program by the agency authorized to administer the program; and provided further, that the National Oceanic and Atmospheric Administration, the U.S. Coast Guard, and the U.S. Army Corps of Engineers concur in such placement or deposit as it may affect their responsibilities under the Act. For the placement or deposit of materials for enhancement of fisheries, letters of concurrence from these agencies are acceptable in lieu of an application for permit for dumping.

§ 220.2 Definitions.

As used in this part, the term "Act" means the Marine Protection, Research and Sanctuaries Act of 1972, Public Law 92-532, 33 U.S.C. Unless otherwise provided herein, all other terms shall have the meanings assigned to them by the Act.

§ 220.3 Categories of permits.

(a) *General permits.* From time to time the Administrator may authorize, by general permit, the dumping of certain materials, such as galley waste from ships or other non-toxic materials generally disposed of in small quantities. Such general permits shall be published in the FEDERAL REGISTER and shall specify the types and amounts of materials which may be dumped, the designated dumping sites for such dumping activities, and any other conditions deemed appropriate by the Administrator. A general permit may be granted by the

Administrator under this section on application of an interested person in accordance with the procedures of Part 221, or may be granted by the Administrator on his own initiative, subject to the notice and hearing requirements of Part 222 of this subchapter.

(b) *Special permits.* The dumping of material requiring an EPA permit under the Act, and not covered by a general permit published in the FEDERAL REGISTER under paragraph (a) of this section, will require a special permit issued to a specified applicant, having a fixed expiration date, (which shall be no later than three years from the date of issue) and specifying the exact amount of material permitted to be dumped thereunder. Special permits will be granted only on application in accordance with the requirements of Part 221 of this subchapter. No special permit shall be granted for any material which does not meet the criteria of §§ 227.22 and 227.31 of this subchapter. Special permits may be renewed upon application at the discretion of the Administrator or his designee.

(c) *Emergency permits.* After consultation with the Department of State and with such other persons as may be appropriate, the Administrator may issue an emergency permit to dump materials specified in § 227.22 of this subchapter where there is demonstrated to exist an emergency requiring the dumping of such material, which poses an unacceptable risk relating to human health and admits of no other feasible solution. As used herein, "emergency" refers to situations requiring action with a marked degree of urgency, but is not limited in its application to circumstances requiring immediate action.

(d) *Interim permits.* It is the intent of this program to prevent or strictly regulate the disposal to the marine environment of any materials damaging to that environment. The quantitative basis for determining limiting concentrations and quantities of known toxic or otherwise damaging materials which can be dumped without measurable damage, based on existing knowledge, is given in §§ 227.22 and 227.31 of this subchapter. When an applicant wishes to dump any of the materials listed in § 227.31 of this subchapter in excess of the limiting permissible concentrations, or when the constituents identified in § 227.22 of this subchapter are present as trace contaminants as defined in § 227.22(e) of this subchapter but are in excess of the levels at which they may be dumped under special permit, he may, under certain conditions, be granted an interim permit at the discretion of the Administrator or his designee. These conditions are:

(1) An environmental assessment of the potential environmental impact of the dumping will be required as part of each application and, in addition, a thorough review of the actual need for the dumping and possible alternatives will be made in evaluating the permit application. The decision on whether or not to grant an interim permit will be based, in part, on consideration of the following factors relative to the need for and alternatives to dumping:

(i) Degree of treatment feasible for the waste to be dumped, and whether or not the waste material has been or will be treated to this degree before dumping.

(ii) Manufacturing or other processes resulting in the waste, and whether or not these processes are essential, or if other less polluting processes could be used.

(iii) The relative environmental impact and cost for ocean dumping as opposed to other possible alternatives, for example land disposal or deep well injection, after the best practical waste treatment has been carried out.

(iv) Temporary and/or permanent effect of the dumping on alternative uses of the oceans, such as navigation, living resources exploitation, nonliving resource exploitation, scientific study, and other legitimate uses of the oceans, as opposed to the impact on other parts of the environment of alternate means of disposal.

(2) An interim permit will require the development and active implementation of a plan to either eliminate the discharge entirely from the ocean or to bring it within the limitations of § 227.3 of this subchapter. Such plans must meet the requirements of § 227.4 of this subchapter. The expiration date of an interim permit will be determined by completion of sequential phases of the development and implementation of the required plan, and will not exceed one year from the date of issue. An interim permit may not be renewed, but a new interim permit may be issued upon application according to Part 221 of this subchapter upon satisfactory completion of each phase of the development and implementation of the plan.

(3) No interim permit will be granted for the dumping of waste from a new facility or from the expansion of a facility after the effective date of these regulations without the completion of Phase A of an implementation plan.

(e) *Research permits.* A permit for the dumping of materials (other than those prescribed in §§ 227.21 and 227.22 of this subchapter) into the ocean as part of research into the impact of materials on the marine environment may be issued by the Administrator when he determines the scientific merit of the proposed project outweighs the potential damage that may occur from the dumping. A research permit will be issued only under the following conditions:

(1) The applicant provides to the Administrator a detailed statement of the proposed project, including an assessment of the probable environmental impact of carrying out the project.

(2) There is public notice and opportunity for public hearing.

(3) Research permits will be issued for no longer than 18 months, but may be renewed after review by the Administrator.

§ 220.4 Delegation of authority.

(a) *Special and interim permits.* Subject to the exclusion of paragraph (b) of this section, Regional Administrators or their designees have the authority to initiate and carry out enforcement proceedings and to issue, deny, and to impose conditions on special and interim permits for:

(1) The dumping of material in that portion of the territorial sea which is subject to the jurisdiction of any State within their respective regions, and in those portions of the contiguous zone coterminous with such parts of the territorial sea;

(2) The dumping of any material within any other dump site, or other designated area explicitly assigned as a regional management responsibility by these regulations, amendments to them, or by order of the Administrator.

(3) The transportation for dumping of any material from a location in a State in their respective regions and its dumping at a designated site, except to the extent a different Regional Administrator has such authority by virtue of paragraph (a) (1) or (2) of this section.

(b) *Exclusions.* (1) Where transportation for dumping is to initiate in one region and dumping is to occur in another region, the former region will be responsible for review of the application and prepare the technical evaluation of the need for dumping and alternatives to ocean disposal. The latter region will specify the conditions to be imposed, give public notice, and issue or deny the permit. If both regions do not concur in the disposition of the permit application, the Administrator will make the final decision on issuance or denial of a permit and on the conditions to be imposed.

(2) All activities involving monitoring of the disposal site shall be approved by the Administrator.

(c) *Other permits.* In all cases not described in paragraph (a) or (b) of this section, the Administrator, or such other EPA employee as he may from time to time designate in writing, shall issue, deny or impose conditions on special, interim, general, emergency, or research permits issued pursuant to the Act.

(d) *Designation of new disposal sites.* Disposal sites will be designated by publication in the FEDERAL REGISTER in this subchapter. Recommendations for designation will be based on baseline studies and monitoring of sites, and will be approved by the Administrator prior to designation.

(e) *Corps of Engineers permits.* Authority to review and approve or disapprove Corps of Engineers permits for ocean disposal of dredged material is granted to each Regional Administrator for those dredged material dumping sites within their regional jurisdiction.

PART 221—APPLICATIONS

Sec.

AUTHORITY: Title I, Pub. L. 96-532, 86 Stat. 1052 (33 U.S.C. 1411-1421).

§ 221.1 Application forms for special permits.

Applications for EPA special or interim permits under the Act may be filed with the Administrator or the Regional Administrator, if any, authorized by § 220.4 to act on the application. Unless and until printed application forms are made available, an application may be made by letter. Any application for a permit under this subchapter will include at a minimum:

(a) Name and address of applicant;

(b) Name of the person or firm (if not the applicant), and the name or other identification and usual location of the conveyance, to be used in the transportation and dumping of the material involved;

(c) Physical and chemical description of material to be dumped, including results of tests necessary to meet the requirements of Part 227 of this subchapter, and the number, size, and physical configuration of the materials and any containers to be dumped;

(d) Quantity of material to be dumped;

(e) Means of conveyance and anticipated dates and times of disposal;

(f) Proposed dump site; and in the event such proposed dumping site is not a designated dumping site designated in this subchapter, detailed physical information on the nature of the proposed dump site;

(g) Proposed method of disposal at the dump site;

(h) Identification of the specific process or activity giving rise to the production of the material;

(i) Information on the manner in which the type of material in question has been previously disposed of by or on behalf of the applicant;

(j) A description of available alternative means of disposal of the material, with explanations of why each of such alternatives is thought by the applicant to be inappropriate.

§ 221.2 Other information.

In the event the Administrator, Regional Administrator, or a person designated by either to review permit applications, determines that additional information is needed in order to apply the criteria set forth in Part 227 of this subchapter, he shall so advise the applicant in writing. For purposes of applying the time limitation of § 222.1, an application will not be considered complete until all additional information requested pursuant to this section is received, and all such information shall be deemed part of the application.

§ 221.3 Applicant.

Any person may apply for a permit under this Part, even though the proposed dumping may be carried on by a permittee who is not the applicant. However, issuance of a permit will not excuse the permittee from any civil or criminal liability which may attach by virtue of his having transported or dumped materials in violation of the terms or conditions of a permit, notwithstanding that the permittee may not have been the applicant.

§ 221.4 Adequacy of information.

No permit issued under this Part will be valid for the transportation or dumping of any material which is not accurately and fully described in the application. No permittee shall be relieved of any liability which may arise as a result of the transportation or dumping of material which does not conform to information provided in the application solely by virtue of the fact that such information was furnished by an applicant other than the permittee.

§ 221.5 Processing fees.

(a) A processing fee of $1,000 will be charge in connection with each application for a permit for dumping in an existing dump site designated in this subchapter.

(b) A processing fee of an additional $3,000 will be charged in connection with each application for a permit involving the use of a dump site other than a designated dump site.

(c) A processing fee of $700 will be charged in connection with each application for renewal of a permit.

(d) Notwithstanding the foregoing, no agency or instrumentality of the United States or of a State or local government will be required to pay the processing fees specified in paragraphs (a), (b), and (c) of this section.

PART 222—ACTIONS ON APPLICATIONS

Sec.

AUTHORITY: Title I, Pub. L. 96-532, 86 Stat. 1052 (33 U.S.C. 1411-1421).

§ 222.1 General.

Decisions as to the issuance, denial, or imposition of conditions on a permit issued by EPA pursuant to this Part will be made in the light of the factors set forth in section 102(a) of the Act and after issuance of criteria pursuant thereto, in the light of such criteria. In all cases, final action on any application for a special permit, or renewal thereof, will be taken by EPA within 180 days from: (1) The date the application is filed, or, (2) in the event the application is deficient, from the date on which the applicant provides all requisite information, whichever is later, provided, that if a hearing is convened pursuant to Part 222 of this subchapter, such 180 day limit to grant a permit will be extended by the time required for such hearing.

§ 222.2 Tentative determinations.

An applicant shall be informed within 30 days whether or not his application is complete and what additional information is required. Within 30 days after receipt of a completed permit application, EPA shall publish a public notice including a tentative determination with respect to issuance or denial of the permit applied for. If such tentative determination is to issue the permit, the following additional tentative determinations will be made:

(a) Proposed time limitations, if any;

(b) Proposed dumping site; and

(c) A brief description of any other proposed special conditions determined to be appropriate for inclusion in the permit in question.

§ 222.3 Notice of applications.

(a) *Contents.* Public notice of every complete permit application received shall be circulated to inform the public. Each such public notice shall include at least the following:

(1) A summary of the information included in the permit application;

(2) Any tentative determinations made pursuant to § 222.2;

(3) A brief description of the procedures set forth in § 222.5 for requesting a public hearing on the proposed dumping; and

(4) The location at which interested persons may obtain further information on the proposed dumping, including copies of any relevant documents.

(b) *Publication.* (1) Notice given pursuant to paragraph (a) of this section shall be circulated within the geographical area of any port through or from which material is proposed to be transported for dumping in the territorial sea, as follows:

(i) Published in at least one daily newspaper, or, if there is none, in a newspaper of general circulation in such port;

(ii) Posted in the post office in such port;

(iii) Published in a daily newspaper in the city in which the office with authority to issue the permit is located.

(2) Notice shall be mailed to any person, group, or State or Federal Agency upon request. Any such request may be a standing request for notice of all permit applications received by EPA, or of any class of such permit applications.

(c) *Notice to States.* In addition to the public notice required by § 222.3(a), notice of each application for dumping, including all the material required to be included in a public notice, will be mailed to the State water pollution control agency for the State, if any, contiguous to that portion of the territorial sea, if any, within which proposed dumping will occur or which might be affected by dumping within the contiguous zone coterminous to its territorial sea. Certification under section 401 of the Federal Water Pollution Control Act is not required in connection with applications for dumping outside the territorial sea

unless the State can demonstrate that dumping in the contiguous zone will violate water quality standards within the part of the territorial sea under its jurisdiction.

(d) *Notice to Corps of Engineers.* In addition to other notice required by this section, notice of each application for dumping will be forwarded to the appropriate office of the U.S. Army Corps of Engineers for review in accordance with section 106(c) of the Act (pertaining to navigation, harbor approaches, and artificial islands on the outer continental shelf). Unless advice to the contrary is received within 30 days of the date such notice is transmitted to the identified agencies by the Administrator, Regional Administrator or their designees, these agencies will be deemed to have no objection on account of matters required to be considered pursuant to section 106 (c) of the Act.

(e) *Notice to Coast Guard.* In addition to other notice required by this section, notice of each application for dumping will be forwarded to the appropriate district office of the U.S. Coast Guard for review in accordance with section 104(a)(5) of the Act.

(f) *Fish and Wildlife Coordination Act.* The Fish and Wildlife Coordination Act, Reorganization Plan No. 4 of 1970, and P.L. 92–532 require Regional Administrators to consult with appropriate regional officials of the Departments of Commerce and Interior, the Regional Director of the NMFS–NOAA, the agency exercising administrative jurisdiction over the fish and wildlife resources of the State subject to any dumping. Unless advice to the contrary is received within 30 days of the date such notice is transmitted to the identified agencies by the Administrator, Regional Administrator or their designees, these agencies will be deemed to have no objection on account of matters required to be considered pursuant to section 106(c) of the Act.

§ 222.4 Issuance or denial of permits without hearing.

(a) *General.* Subject to the receipt of certification, if required, pursuant to section 401 of the Federal Water Pollution Control Act, from any State to which notice has been sent pursuant to § 222.3 (c), the Administrator, Regional Administrator or their designees will issue or deny permits in accordance with § 222.1, as soon as all provisions of § 222.3(a) (pertaining to public notice) have been complied with, unless a request for a public hearing has been granted pursuant to § 222.5(b), or unless objection is received from the Corps of Engineers pursuant to § 222.3(d).

(b) *Waiver of State certification.* State certification as to the probable impact of the proposed dump on State water quality standards pursuant to section 401 of the Federal Water Pollution Control Act will be deemed waived, in accordance with the terms thereof, if such certification is not received within 60 days of notice to the appropriate State agency under § 222.3(c), or such longer period to which the Administrator, Regional Administrator or their designees, may agree.

§ 222.5 Initiation of hearings.

(a) Any person may, within 30 days of the date on which all provisions of § 222.3(b) have been complied with, request a public hearing to consider the issuance or denial of any permit applied for under this Part. Any such request for a public hearing must be in writing, and must state any objections to the issuance or denial of the proposed permit, and the issues which are proposed to be considered at the hearing.

(b) Upon receipt of a written request meeting the requirements of paragraph (a) of this section, or at his own discretion, the Administrator, Regional Administrator or a designee of either, will fix a time and place for a public hearing, and shall publish notice of such hearing in accordance with § 222.7, whenever such request presents bona fide issues amenable to resolution by public hearing.

(c) In the event the Administrator, Regional Administrator or a designee of either, determines that a request purportedly made pursuant to this section does not comply with the requirements of paragraph (a) of this section, he shall so advise, in writing, the person requesting the hearing, and shall proceed to rule on the permit application in accordance with § 222.4(a).

§ 222.6 Time and place of hearings.

When the Administrator or Regional Administrator grants a request for a public hearing pursuant to § 222.5(a), he shall designate an appropriate location for such hearings, and an appropriate time which shall be no sooner than 30 days following the receipt of such request. Where possible, public hearings shall be held in a location in the States, if any, to which notice of the permit application was given pursuant to § 222.3 (c).

§ 222.7 Notice of hearings.

Notice of public hearings, including information as to their time and place, shall be given, at a minimum, to persons to whom, and in the manner in which, notice of the permit application was published pursuant to § 222.3.

§ 222.8 Conduct of hearings.

The Administrator or Regional Administrator may designate a presiding officer to conduct a hearing convened pursuant to this part. The presiding officer shall be responsible for the expeditious conduct of the hearing, and shall cause a suitable record (including, if appropriate, a verbatim transcript) of the proceedings to be made. Any person may appear at a hearing convened pursuant to this Part whether or not he requested the hearing, and may be represented by counsel or any other authorized representative. The presiding officer is authorized to set forth reasonable restrictions on the nature or amount of documentary material or testimony presented at a hearing, giving due regard to the relevancy of any such information, and to the avoidance of undue repetitiveness of information presented. No cross-examination of any person, including the applicant, appearing at a hearing shall be permitted, although the presiding officer, may, in his discretion, address to persons or their authorized representatives questions submitted in writing by participants at a hearing.

§ 222.9 Recommendations of presiding officer.

At any time following the adjournment of a public hearing convened pursuant to this part, the presiding officer may prepare written recommendations relating to the issuance or denial of the proposed permit, or relating to any conditions which he believes may appropriately be imposed on any such permit, after full consideration of the views and arguments expressed at the hearing: provided, that the presiding officer's findings and recommendations, if any, and the record of the hearing, will in all cases be completed and forwarded to the Administrator, Regional Administrator, or their designated representatives within 30 days following adjournment of the hearing. Copies of the presiding officer's findings and recommendations, if any, shall be provided to any interested person on request, free of charge. Copies of the record will be provided in accordance with § 2.111 of this title.

§ 222.10 Issuance of permits after hearings.

Within 30 days following receipt of the presiding officer's findings and recommendations, if any, but in no event later than 180 days from the time limit specified in § 222.1. The Administrator, Regional Administrator, or their designees, shall make a final determination with respect to the issuance, denial, or imposition of conditions on, any permit applied for under this part.

PART 223—CONTENTS OF PERMITS

Sec.
223.1 Contents of permits.
223.2 Generally applicable conditions of permits.

AUTHORITY: Title I, Pub. L. 92–532, 86 Stat. 1052 (33 U.S.C. 1411–1421).

§ 223.1 Contents of permits.

Permits, other than general permits, which may be issued on forms to be published by EPA and must be displayed on the vessel engaged in dumping, will include at a minimum the following:

(a) Name of permittee;

(b) Means of conveyance and methods and procedures for disposal of material to be dumped; and, in the case of permits for the transportation of material for dumping, the port through or from which such material will be transported;

(c) A complete description, including all relevant chemical and physical properties and quantities, of the material to be dumped;

(d) The disposal site;

(e) The times at which the permitted dumping may occur;

(f) Such monitoring relevant to the assessment of the impact of permitted dumping activities on the marine environment at the disposal site as the Administrator determines is feasible; and

(g) Any other terms and conditions, including those with respect to release procedures, determined to be necessary and adequate in order to conform the permitted dumping activities to the factors set forth in section 102(a) of the Act, and the criteria set forth in Part 227.

§ 223.2 Generally applicable conditions of permits.

(a) *Modification or revocation.* Any permit issued under this Part shall be subject to modification, or revocation in whole or in part for cause, as follows:

(1) Violation of any term or condition of the permit;

(2) Misrepresentation, inaccuracy, or failure to disclose all relevant facts in the permit application;

(3) Changed circumstances, such as changes in conditions obtaining at the designated dumping site, and newly discovered scientific data relevant to the granting of the permit;

(4) Failure to keep the records, and to notify appropriate officials of dumping activities, as specified in §§ 224.1 and 224.2.

(b) *Suspension.* In addition to the conditions of a permit imposed pursuant to paragraph (a) of this section, each permit shall be subject to suspension by the Administrator or Regional Administrator if he determines that the permitted dumping has resulted, or is resulting, in imminent and substantial harm to human health or welfare or the marine environment. Such suspension shall be effective immediately upon receipt of notification thereof by the permittee.

(c) *Hearings.* Within 30 days after receipt of notice of revocation or modification pursuant to paragraph (a) of this section, or of suspension pursuant to paragraph (b) of this section, a permittee or other interested person may request in writing a hearing on the issues raised by any such revocation or suspension. Upon receipt of any such request, the Administrator or Regional Administrator shall appoint a hearing officer to conduct an adjudicatory hearing as may be required by law and by this subchapter as now or hereafter in effect.

PART 224—RECORDS

Sec.
224.1 Records of permittees.
224.2 Reports.

AUTHORITY: Title I, Pub. L. 92-532, 86 Stat. 1052 (33 U.S.C. 1411-1421).

§ 224.1 Records of permittees.

Each permittee and each person availing himself of the privilege conferred by a general permit, shall maintain complete records, which will be available for inspection by the Administrator, Regional Administrator, the Commandant, U.S. Coast Guard, or their designees, of:

(a) The nature, including a complete description of relevant physical and chemical characteristics, of material dumped pursuant to the permit;

(b) The precise times and locations of dumping;

(c) Any other information reasonably required as a condition of a permit by the Administrator, Regional Administrator or their designees:

(1) For the purpose of determining whether dumping has in fact been accomplished in accordance with all terms and conditions of the permit;

(2) To assess the impact of permitted dumping activities on the marine environment.

§ 224.2 Reports.

(a) *Periodic reports.* Information included in records required to be kept pursuant to § 224.1 shall be reported to the EPA official who issued the permit in question, as follows:

(1) As of the end of each six-month period, if any, measured from the effective date of the permit and ending before its expiration;

(2) As of the expiration of the permit, unless renewed; and

(3) As otherwise required in the conditions of the permit.

(b) *Time of reporting.* Reports required by this section must be received by EPA within 30 days of the date as of which the information is required to be reported; provided, that if an application for renewal of a special permit is pending at such time, the report required by paragraph (a)(2) of this section may be deferred until 30 days after the date of a denial of the renewal application.

(c) *Emergencies.* If material, the dumping of which is regulated under this subchapter, is dumped without a permit in an emergency to safeguard life at sea, the owner or operator of the vessel from which such dumping occurs shall as soon as feasible inform the Administrator or the nearest Coast Guard district of the incident by radio, telephone, or telegraph and shall within 10 days report to the Administrator the information required under § 224.1, and a complete description of the emergency which occasioned the dumping.

PART 225—CORPS OF ENGINEERS PERMITS

Sec.
225.1 General.
225.2 Review of Corps permit applications.
225.3 Waivers.

AUTHORITY: Title C, Pub. L. 96-532, 86 Stat. 1052 (33 U.S.C. 1411-1421).

§ 225.1 General.

As indicated in § 220.1, the U.S. Army Corps of Engineers has the authority to issue permits for the transportation and dumping of dredged material. As defined in the Act, "dredged material" means "any material excavated or dredged from the navigable waters of the United States." EPA personnel will not act initially on any application received for the transportation or dumping of dredged material, but will forthwith forward any such application to the appropriate office of the Corps, which will, in acting on any such application, apply the criteria in Part 227 of this subchapter.

§ 225.2 Review of Corps permit applications.

Within 30 days following receipt of notification, pursuant to section 103(c) of the Act, the Administrator, Regional Administrator or the designee of either, will notify in writing the Corps of his disagreement, if any, to the issuance of the permit in question, on the grounds that it would not be in accordance with the criteria of Part 227 of this subchapter, or would violate section 102(c) of the Act (pertaining to critical areas).

§ 225.3 Waivers.

If, after notice of disagreement is given the Corps pursuant to § 225.2, a request for a waiver is received pursuant to section 103(d) of the Act, such request will be forwarded to the Administrator; provided, that if any such request does not include the finding required by section 103(d) of the Act as to economically feasible methods of disposal, and the basis for such finding, the request will be denied. The Administrator will act on the request for a waiver in accordance with section 103(d) of the Act, within 30 days of receipt thereof by EPA.

PART 226—ENFORCEMENT

Sec.
226.1 Civil penalties.
226.2 Enforcement hearings.
226.3 Determinations.
226.4 Final action.

AUTHORITY: Title I, Pub. L. 92-532, 86 Stat. 1052 (33 U.S.C. 1411-1421).

§ 226.1 Civil penalties.

In addition to the criminal penalties provided for in section 105(b) of the Act, the Administrator or his designee may assess a civil penalty of not more than $50,000 for each violation of the Act and of this subchapter. Upon receipt of information that any person has violated any provision of the Act or of this subchapter, the Administrator of his designee will notify such person in writing of the violation with which he is charged, and will convene a hearing to be convened no sooner than 60 days after such notice, at a convenient location, before a hearing officer. Such hearing shall be conducted in accordance with the procedures of § 226.2.

§ 226.2 Enforcement hearings.

Hearings convened pursuant to § 226.1 shall be hearings on a record before a hearing officer. Parties may be represented by counsel, and will have the right to submit motions, to present evidence in their own behalf, to cross-examine adverse witnesses, to be apprised of all evidence considered by the hearing offi-

cer, and to receive copies of the transcript of the proceedings. Formal rules of evidence will not apply. The hearing officer will rule on all evidentiary matters, and on all motions, which will be subject to review pursuant to § 226.3.

§ 226.3 Determinations.

Within 30 days following adjournment of the hearing, the hearing officer will in all cases make findings of facts and recommendations to the Administrator, including, when appropriate, a recommended appropriate penalty, after consideration of the gravity of the violation, prior violations by the person charged, and the demonstrated good faith by such person in attempting to achieve rapid compliance with the provisions of the Act and this subchapter. A copy of the findings and recommendations of the hearing officer shall be provided to the person charged at the same time they are forwarded to the Administrator. Within 30 days of the date on which the hearing officer's findings and recommendations are forwarded to the Administrator, any party objecting thereto may file written exceptions with the Administrator.

§ 226.4 Final action.

A final order on a proceeding under this Part will be issued by the Administrator or by such other person designated by the Administrator to take such final action, no sooner than 30 days following receipt of the findings and recommendations of the hearing officer. A copy of the final order will be served by registered mail (return receipt requested) on the person charged or his representative. In the event the final order assesses a penalty, it shall be payable within 60 days of the date of receipt of the final order, unless judicial review of the final order is sought by the person against whom the penalty is assessed.

PART 227—CRITERIA FOR THE EVALUATION OF PERMIT APPLICATIONS

Sec.

AUTHORITY: Title I, Pub. L. 92-532, 86 Stat. 1052 (33 U.S.C. 1411-1421).

§ 227.1 General grounds for the issuance of permits.

(a) It is the policy of the Environmental Protection Agency to regulate the dumping of all types of materials into ocean waters and to prevent or to regulate strictly the dumping or other discharge into ocean waters of any material in quantities which would adversely affect human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities, or plankton, fish, shellfish, wildlife, shorelines, or beaches.

(b) These criteria apply to the evaluation of permit applications for the dumping or discharge through outfalls or other structures of gaseous, solid, and/or liquid matter of any kind or description.

(c) Sections 102(c) of PL 92-532 and 403(c) of PL 92-500 both require that applications for permits for the dumping or other discharge of any materials into the marine environment be evaluated on the basis of the impact of the materials on the marine environment and marine ecosystems, on the present and potential uses of the ocean, and on the economic and social factors involved.

(d) The disposal of some types of waste materials into the marine environment is prohibited because of explicit legislative requirements. Such prohibited waste materials are identified in § 227.21 (a), (b), (c).

(e) The disposal of some types of waste materials into the marine environment is strictly regulated to prevent or minimize known or potential adverse effects on the aquatic ecosystem or human health and welfare. These materials and limiting concentrations and conditions upon the disposal of these materials are given in § 227.3. The concentrations and quantities of materials identified in this section are based on the most current scientific knowledge and will be subject to revision as more knowledge of marine processes and ecosystems becomes available. It is the goal of the ocean dumping permit program of the Environmental Protection Agency to require development of implementation plans for elimination of dumping of any materials in excess of these concentrations and quantities as rapidly as possible.

(f) The disposal of some types of waste materials is subject to less strict regulation and permission because of the minimal adverse environmental effects to be anticipated by reason of such disposal. These waste materials are described in § 227.5.

(g) Irrespective of other stated specific requirements, no permit will be issued which would result in the violation of applicable existing state water quality standards.

§ 227.2 Prohibited acts.

§ 227.21 Materials for which no permit will be issued.

The dumping, or transportation for dumping, of the following materials will not be approved by EPA under any circumstances:

(a) High-level radioactive wastes as defined in § 227.75.

(b) Materials in whatever form (e.g., solids, liquids, semi-liquids, gases or in a living state) produced for radiological, chemical or biological warfare.

(c) Materials insufficiently described in terms of their physical, chemical, or biological properties to permit evaluation of their impact on marine ecosystems.

(d) Persistent inert synthetic ir natural materials which may float or remain in suspension in the ocean may not be dumped. They may, however, be dumped when they have been processed in such a fashion that they will sink to the bottom and remain in place.

§ 227.22 Other prohibited materials.

Subject to the exclusion of paragraph (h) of this section, the dumping, or transportation for dumping, of wastes containing the following materials as other than trace contaminants will not be approved by EPA:

(a) Organohalogen compounds and compounds which may form such substances in the marine environment.

(b) Mercury and mercury compounds.

(c) Cadmium and cadmium compounds.

(d) Crude oil, fuel oil, heavy diesel oil, and lubricating oils, hydraulic fluids, and any mixtures containing these, taken on board for the purpose of dumping, insofar as these are not regulated under P.L. 92-500.

(e) The materials listed in paragraphs (a)-(d) of this section will be considered as trace contaminants when they are present in sewage sludge, dredged material, or in wastes from industries which do not use or produce the constituents identified in this section.

(f) Wastes containing these constituents as trace contaminants as defined in paragraph (e) of this section may be dumped under special permit when the following limits are not exceeded:

(1) Mercury and its compounds are not present in any solid phase of a waste in concentrations greater than 0.75 mg/kg, and the total concentration of mercury in the liquid phase of a waste does not exceed 1.5 mg/kg.

(2) Cadmium and its compounds are not present in any solid phase of a waste in concentrations greater than 0.6 mg/kg, and the total concentration of cadmium in the liquid phase of a waste does not exceed 3.0 mg/kg.

(3) The total concentrations of organohalogens do not exceed the limiting permissible concentration of pollutants as defined in section 227.71.

(4) The total amounts of oils and greases as identified in paragraph (d) of this section do not produce a visible surface sheen in an undisturbed water sample when added at a rate of one part waste material to 100 parts of water.

(g) Those constituents identified in paragraphs (a)–(d) of this section will be regarded as trace contaminants in the waste material of an industrial process or plant which uses them as raw materials or produces any of them only when the limitations of paragraph (f) of this section are not exceeded.

(h) Paragraphs (a)–(d) of this section do not apply to materials which are harmless or are rapidly rendered harmless by physical, chemical, or biological processes in the sea; provided they will not, if dumped, make edible marine organisms unpalatable; or will not, if dumped, endanger human health or that of domestic animals, fish, shellfish, and wildlife.

§ 227.3 Strictly regulated dumping.

Evidence of the acceptability of proposed acts of disposal will be required from the applicant according to the criteria in §§ 227.31 through 227.36.

§ 227.31 Materials requiring special care.

(a) Permits may be issued for the dumping or other disposal of the materials described in paragraph (b) of this section if the applicant can demonstrate that the material proposed for disposal meets the limiting permissible concentration of total pollutants as defined in § 227.71 considering both the concentration of pollutants in the waste material itself and the total mixing zone available for initial dilution and dispersion.

(b) Wastes containing one or more of the following materials shall be treated as requiring special care:

(1) The elements, ions, and compounds of:

Arsenic.	Vanadium.
Lead.	Beryllium.
Copper.	Chromium.
Zinc.	Nickel.
Selenium.	

(2) Organosilicon compounds and compounds which may form such substances in the marine environment:

(3) Inorganic processing wastes, including cyanides, fluorides, titanium dioxide wastes, and chlorine.

(4) Petrochemicals, organic chemicals, and organic processing wastes, including, but not limited to:

Aliphatic solvents.	Amines.
Phenols.	Polycyclic aromatics.
Plastic intermediates and by-products.	Phthalate esters.
Plastics.	Detergents.

(5) Biocides not prohibited elsewhere, including, but not limtied to:

Organophosphorus compounds.	Herbicides.
Carbamate compounds.	Insecticides.

(6) Oxygen-consuming and/or biodegradable organic matter.

(7) Radioactive wastes not otherwise prohibited. As a general policy, the containment of radioactive materials (§ 227.35) is indicated rather than their direct dispersion and dilution in ocean waters.

(8) Materials on any list of toxic pollutants published under section 307(a) of P.L. 92–500, and materials designated as hazardous substances under section 311(b)(2)(A) of P.L. 92–500, unless more strictly regulated under § 227.2.

(9) Materials that are immiscible with seawater, such as gasoline, carbon disulfide, toluene.

§ 227.32 Hazards to fishing or navigation.

Wastes which may present a serious obstacle to fishing or navigation may be disposed of only at dumping sites and under conditions which will insure no interference with fishing or navigation.

§ 227.33 Large quantities of materials.

Substances of a non-toxic nature which may damage the ocean environment due to the quantities in which they are dumped, or which are liable to seriously reduce amenities, may be dumped only when the quantities to be dumped at a single time and place are controlled to prevent damage to the environment or to amenities.

§ 227.34 Acids and alkalis.

In the dumping of large quantities of acids and alkalis, consideration shall be given: (a) To the effects of any change in acidity or alkalinity of the water at the disposal site; and (b) to the potential for synergistic effects or for the formation of toxic compounds in the dumping area.

§ 227.35 Containerized wastes.

(a) Wastes containerized solely for transport to the dumping site and expected to rupture or leak on impact or shortly thereafter must meet the requirements of §§ 227.22, 227.31, 227.32, and 227.36.

(b) Other containerized wastes will be approved for dumping only under the following conditions:

(1) The materials to be disposed of decay, decompose or radiodecay to environmentally innocuous materials considering the life expectancy of the containers and/or their inert matrix:

(2) Materials to be disposed of are present in such quantities and are of such nature that only short-term localized adverse effects will occur should the containers rupture at any time; and

(3) Containers are disposed of at depths and locations where they will cause no threat to navigation or fishing.

§ 227.36 Materials containing living organisms.

It is prohibited to dump any material which would:

(a) Extend the range of biological pests, viruses, pathogenic microorganisms or other agents capable of infesting, infecting or altering the normal populations of organisms.

(b) Degrade uninfected areas, or

(c) Introduce viable species not indigenous to an area.

§ 227.4 Implementation plan requirements for interim permits.

As a condition on every interim permit, the applicant must carry out two phases to bring his waste within acceptable limits:

PHASE A—PLANNING

(a) Make a thorough review of the actual need for the dumping;

(b) Submit an evaluation of potential environmental impact:

(1) Description of proposed action;

(2) Environmental impact of the proposed action;

(3) Adverse impacts which cannot be avoided should the proposal be implemented;

(4) Alternatives to the proposed action:

(i) Land fill;

(ii) Deep well injection;

(iii) Shallow well injection;

(iv) Incineration;

(v) Spread of material over open ground;

(vi) Recycling of material for:

(a) Reuse in process;

(b) By-products;

(vii) Biological, chemical, or physical treatment;

(5) Relationship between short-term uses of man's environment and the maintenance and enhancement of long-term productivity;

(6) Irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented;

(7) A discussion of problems and objections raised by other Federal, State and local agencies and by interested persons in the review process;

The content of an acceptable plan for different waste materials will vary but the following requirements should be recognized and met:

(a) If the waste is treated to the degree necessary to bring it into compliance with the ocean disposal criteria, the applicant should provide a description of the treatment and a scheduled program for treatment and a subsequent analysis of treated material to prove the effectiveness of the process.

(b) If treatment cannot be effected by post-process techniques the applicant should, determining the offending constituents, examine his raw materials and his total process to determine the origin of the pollutant. If the offending constituents are found in the raw material the applicant should consider a new supplier and provide an analysis of the new material to prove compliance. Raw materials are to include all water used in the process. Water from municipal sources complying with drinking water standards is acceptable. Water from other sources such as private wells should be analyzed for contaminants. Water that has been used in the process should be considered for treatment and recycling as an additional source of process water.

(c) If offending constituents are a result of the process, it is recommended that a consultant be employed by the applicant to investigate and describe the source of the constituents. A report of this information will be submitted to EPA and the applicant will then submit a proposal describing possible alternatives to the existing process or processes and level of cost and effectiveness.

(d) Schedule and documentation for implementation of approved control process:

(1) Engineering plan.

(2) Financing approval.

(3) Starting date for change.
(4) Completion date.
(5) Operation starting date.

(e) If an acceptable alternative does not exist, the applicant will demonstrate a commitment to an investigation of the problem either by submitting an acceptable in-house research program or by employing a competent research institution to study the problem. The program of research will then be submitted by the permittee/applicant.

(f) Schedule and documentation for implementation of a research program:
(1) Approaches.
(2) Experimental design.
(3) Starting date.
(4) Reporting intervals.
(5) Proposed completion date.
(6) Report of recommendations.

PHASE B—IMPLEMENTATION

In no event will an interim permit be granted for the dumping of materials which do not meet the provisions of § 227.3 unless the permit applicant can: (a) demonstrate the need for the proposed dumping as compared to alternative locations and methods of disposal or recycling, (b) demonstrate that the need for the proposed dumping outweighs the potential harm which may take place as a result of such dumping, and (c) provide a satisfactory implementation plan covering future dumping activities and fully adhere to the plan. For industrial sources, any such plan shall provide for:

(a) By not later than July 1, 1977, the application of the best practicable technology currently available for the removal of such materials, as determined by the Administrator;

(b) By not later than July 1, 1983, the application of the best available technology economically available for the removal of such material, as determined by the Administrator, which will result in reasonable further progress toward the goal of achieving compliance with the requirements of this part.

§ 227.5 Less strictly regulated dumping and disposal acts.

§ 227.51 Wastes of a non-toxic nature.

Liquid waste phases containing none of the materials listed in §§ 227.22 and 227.31 may be regarded as basically non-toxic in the marine environment. Solid waste phases containing any or all of the materials listed in §§ 227.22 and 227.31 in forms insoluble or soluble but not exceeding the acceptable limits of § 227.22(f) or limiting permissible concentrations of § 227.71 may also be regarded as non-toxic in the marine environment. Permit applications for such materials may be evaluated on the basis of the chemical composition and physical nature of the waste without the need for a bioassay as required under § 227.31.

§ 227.52 Solid wastes.

Solid wastes of natural minerals or materials compatible with the ocean environment may be generally approved for ocean disposal provided they are insoluble above the applicable trace or limiting permissible concentrations and are rapidly and completely settleable, or they are of a particle size and density that they would be deposited or rapidly dispersed without damage to benthic, demersal, or pelagic biota.

§ 227.6 Disposal of dredged material.

The dumping of any material dredged or excavated from the navigable waters of the United States is regulated by the U.S. Army Corps of Engineers. With respect to the dumping of such material in the ocean, the following definitions and criteria will be considered:

(a) Dredged materials are bottom sediments that have been dredged or excavated from the navigable waters of the United States. In that sediments are known to include and/or to exhibit a capacity for absorption and adsorption of a wide variety of chemical substances, including man-made pollutants, the presence or absence of pollutants within sediments may be used as an index of the history of exposure of the sediments to domestic and industrial discharges, as well as urban and agricultural runoff.

(b) Because the natural processes of sediment absorption, adsorption, deposition, resuspension, and redeposition may alter the toxic or other pollutional properties of municipal, industrial, or runoff wastes incorporated into bottom sediments, practical implementation of the criteria of §§ 227.22 and 227.31 will be achieved through the procedures of the following sections in differentiating between unpolluted and polluted dredged material.

(c) The dumping of dredged material in the ocean will be permitted subject to the conditions outlined in §§ 227.61 through 227.64 unless there is evidence that the proposed disposal will have an unacceptable adverse impact on municipal water supplies, shellfish beds, wildlife, fisheries (including spawning and breeding areas), or recreational areas.

(d) Decisions concerning the disposal of dredged material in the ocean will be based on considerations of the actual need for such disposal, alternatives to ocean dumping, the nature and extent of the environmental impact, and the economic costs or benefits involved.

§ 227.61 Unpolluted dredged material.

Dredged material may be classified as unpolluted based on the known primary source(s) of the sediments, the history of its exposure to pollutants, and its physical composition. If the sediments cannot be classified as unpolluted according to the following criteria, laboratory analyses will be required. Dredged material will be considered unpolluted if it meets one of the following conditions:

(a) The dredged material is composed essentially of sand and/or gravel, or of any other naturally occurring sedimentary materials with particle sizes larger than silts and clays, generally found in inlet channels, ocean bars, ocean entrance channels to sounds and estuaries, and other areas of normally high wave energy such as predominates at open coastlines.

(b) If the water quality at and near the dredging site is adequate, according to the applicable State water quality standards, for the propagation of fish, shellfish, and wildlife, and if the biota associated with the material to be dredged are typical of a healthy ecosystem, taking into account the normal frequency of dredging, the sediments can be reasonably classified as unpolluted.

(c) If it produces a standard elutriate in which the concentration of no major constituent is more than 1.5 times the concentration of the same constituent in the water from the proposed disposal site used for the testing. The "standard elutriate" is the supernatant resulting from the vigorous 30-minute shaking of one part bottom sediment with four parts water from the proposed disposal site followed by one hour of letting the mixture settle and appropriate filtration or centrifugation. "Major constituents" are those water quality parameters deemed critical for the proposed dredging and disposal sites taking into account known point or areal source discharges in the area, and the possible presence in their wastes of the materials in §§ 227.22 and 227.31.

§ 227.62 Disposal of unpolluted dredged material.

Material which is determined to be unpolluted may be dumped at any site which has been approved for the dumping of settleable solid wastes of natural origin.

§ 227.63 Polluted dredged material.

Any dredged material which cannot be classified as unpolluted according to the requirements of § 227.61 is regarded as polluted dredged material.

§ 227.64 Disposal of polluted dredged material.

Polluted dredged material may be disposed of in the ocean if it can be shown that the place, time, and conditions of dumping are such as not to produce an unacceptable adverse impact on the areas of the marine environment cited in § 227.60(c). When material has been found to be polluted in accordance with § 227.61(c), bioassay tests may be performed when it can be shown that the results of such tests can be used to assist in setting disposal conditions. To minimize the possibility of any such harmful effects, disposal conditions must be carefully set, with particular attention being given to the following factors:

(a) *Disposal site selection.* (1) Disposal sites should be areas where benthic life which might be damaged by the dumping is minimal.

(2) The disposal site must be located such that disposal operations will cause no unacceptable adverse effects to known nursery or productive fishing areas. Where prevailing currents exist, the currents should be such that any suspended or dissolved matter would not be carried in to known nursery or productive fishing areas or populated or protected shoreline areas.

(3) Disposal sites should be selected whose physical environmental characteristics are most amenable to the type of dispersion desired.

(b) *Dumping conditions.* (1) Times of dumping should be chosen, where possible, to avoid interference with the seasonal reproductive and migratory cycles of aquatic life in the disposal area.

(2) If the type of material involved and the environmental characteristics

of the disposal site should make either maximum or minimum dispersion desirable, the discharge from and movement of the vessel during dumping should be in such a manner as to obtain the desired result to the fullest extent feasible.

§ 227.65 Revision of test procedures.

Test procedures and values mentioned above are based on the best currently available knowledge and are subject to revision and modification based on the general increase of knowledge or specific information on the effects of the disposal of dredged materials in the ocean.

§ 227.7 Definitions.

§ 227.71 Limiting permissible concentrations.

The limiting permissible concentration is:

(a) That concentration of a waste material or chemical constituent in the receiving water which, after reasonable allowance for initial mixing in the mixing zone, will not exceed 0.01 of a concentration shown to be toxic to appropriate sensitive marine organisms in a bioassay carried out in accordance with approved EPA procedures; or

(b) 0.01 of a concentration of a waste material or chemical constituent otherwise shown to be detrimental to the marine environment.

§ 227.72 Release zone.

A release zone is the area swept out by the locus of points constantly 100 meters from the perimeter of the conveyance engaged in dumping activities, beginning at the first moment in which dumping is scheduled to occur and ending at the the last moment in which dumping is scheduled to occur. For disposal through an outfall or other fixed stucture, the release zone is measured from the point at which the waste material enters the ocean if no diffuser is used, or from the length of outfall along which diffuser ports are located.

§ 227.73 Mixing zone.

(a) The mixing zone is the region into which a waste is initially dumped or otherwised discharged, and into which the waste will mix to a relatively uniform concentration within four hours after dumping. It is required that the concentration of all waste materials or trace contaminants be at, or below, the limiting permissible concentration at the boundaries of the mixing zone at all times and within the mixing zone four hours after discharge. The actual configuration of a mixing zone will depend upon vessel speed, method of disposal, type of waste, and ocean current and wave conditions. For the purposes of these regulations a volume equivalent to that of a mixing zone is the column of water immediately contiguous to the release zone, beginning at the surface of the water and ending at the ocean floor, the thermocline or halocline, if one exists, or 20 meters, whichever is the shortest distance.

(b) For disposal through an outfall or other structure, the volume of the mixing zone will be measured by projecting the release zone at the depth of the point of release or the waste to the nearest hydrodynamic discontinuities above and below that point, but in no case exceeding 20 meters in total distance. Diffusion of wastes beyond the limits of the mixing zone will be estimated by standard oceanographic methods of calculation acceptable to the Administrator or his designee.

§ 227.74 High-level radioactive wastes.

High-level radioactive waste means the aqueous waste resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated waste from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuels or irradiated fuel from nuclear power reactors.

§ 227.8 Amendment of criteria.

In the event that the Administrator or his delegate concludes that it is desirable to amend this Part, he shall announce his intention of doing so by publishing notice thereof in the FEDERAL REGISTER, and shall thereafter follow the procedures prescribed in section 4 of the Administrative Procedures Act (5 U.S.C. 553). Any person proposing amendments to this Part shall notify the Administrator of the amendments so proposed, and the justifications supporting the amendments so proposed. Should the Administrator reject the amendments so proposed, he shall notify the proponent of such action within 30 days of the date upon which such amendments were given to him.

[FR Doc.73-21343 Filed 10-12-73;8:45 am]

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PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

RADIOLOGICAL HEALTH

Reorganization and Republication

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Recodification Docket No. 1]

SUBCHAPTER J—RADIOLOGICAL HEALTH

REORGANIZATION AND REPUBLICATION

The Commissioner of Food and Drugs, for the purpose of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations. This is the first document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

The regulations formerly under Part 278—Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968 have been reorganized into eight parts in an effort to provide greater clarity and adequate space for the development of future regulations.

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. For the convenience of the user the entire text of the revised Subchapter J—Radiological Health is set forth below.

Dated October 5, 1973.

SAM D. FINE,
Associate Commissioner for Compliance.

Therefore, Part 278 of Chapter I, Subchapter F, is redesignated as Subchapter J consisting of Parts 1000–1030 and republished to read as set forth below.

SUBCHAPTER J—RADIOLOGICAL HEALTH

Parts
1000 General.
1002 Records and Reports.
1003 Notification of Defects or Failure to Comply.
1004 Repurchase, Repairs or Replacement of Electronic Products.
1005 Importation of Electronic Products.
1010 Performance Standards for Electronic Products: General.
1020 Performance Standards for Ionizing Radiation Emitting Products.
1030 Performance Standards for Microwave and Radio Frequency Emitting Products.

PART 1000—GENERAL

Subpart A—General Provisions

Sec.
1000.3 Definitions.

Subpart B—Statements of Policy and Interpretation

1000.15 Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968.

AUTHORITY: Secs. 215, 356, 58 Stat. 690, 82 Stat. 1174; 42 U.S.C. 216, 263d.

Subpart A—General Provisions

§ 1000.3 Definitions.

As used in this Subchapter J:

(a) "Electronic product radiation" means—

(1) Any ionizing or nonionizing electromagnetic or particulate radiation, or

(2) Any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

(b) "Electromagnetic radiation" includes the entire electromagnetic spectrum of radiation of any wavelength. The electromagnetic spectrum illustrated in Figure 1 includes, but is not limited to, gamma rays, X-rays, ultraviolet, visible, infrared, microwave, radiowave, and low frequency radiations.

(c) "Particulate radiation" is defined as charged particles such as protons, electrons, alpha particles, heavy particles, etc., which have sufficient kinetic energy to produce ionization or atomic or electron excitation by collision, electrical attractions or electrical repulsion or uncharged particles such as neutrons, which can initiate a nuclear transformation or liberate charged particles having sufficient kinetic energy to produce ionization or atomic or electron excitation by collision.

(d) "Infrasonic, sonic (or audible) and ultrasonic waves" refer to energy transmitted as an alteration (pressure, particle displacement or density) in a property of an elastic medium (gas, liquid or solid) that can be detected by an instrument or listener.

(e) "Electronic product" means (1) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (2) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in subparagraph (1) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation.

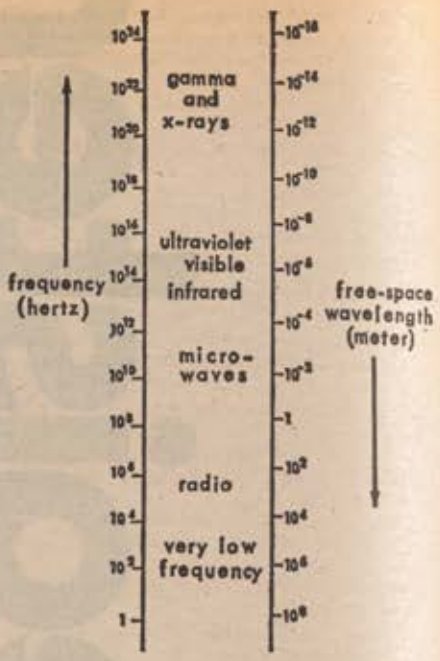

Figure 1. The Electromagnetic Spectrum

(f) "Manufacturer" means any person engaged in the business of manufacturing, assembling, or importing of electronic products.

(g) "Commerce" means (1) commerce between any place in any State and any place outside thereof, and (2) commerce wholly within the District of Columbia.

(h) "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

(i) "Act" means the Radiation Control for Health and Safety Act of 1968 (Public Law 90–602, 42 U.S.C. 263b et seq.).

(j) "Secretary" means the Secretary of the Department of Health, Education, and Welfare.

(k) "Federal standard" means a performance standard issued pursuant to section 358 of the Act.

(l) The term "dealer" means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(m) The term "distributor" means a person engaged in the business of offering electronic products for sale to dealers without regard to whether such person is or has been primarily or customarily engaged in such business.

(n) The term "purchaser" means the first person who, for value, or as an award or prize, acquires an electronic

product for purposes other than resale, and also includes a person who leases an electronic product for purposes other than subleasing.

(o) The term "model" means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

Subpart B—Statements of Policy and Interpretation

§ 1000.15 Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968.

The following listed electronic products are intended to serve as illustrative examples of sources of electronic product radiation to which the regulations of this part apply.

(a) Examples of electronic products which may emit X-rays and other ionizing electromagnetic radiation, electrons, neutrons, and other particulate radiation include:

Ionizing electromagnetic radiation:
- Television receivers.
- Accelerators.
- X-ray machines (industrial, medical, research, educational).

Particulate radiation and ionizing electromagnetic radiation:
- Electron microscopes.
- Neutron generators.

(b) Examples of electronic products which may emit ultraviolet, visible, infrared, microwaves, radio and low frequency electromagnetic radiation include:

Ultraviolet:
- Biochemical and medical analyzers.
- Tanning and therapeutic lamps.
- Sanitizing and sterilizing devices.
- Black light sources.
- Welding equipment.

Visible:
- White light devices.

Infrared:
- Alarm systems.
- Diathermy units.
- Dryers, ovens, and heaters.

Microwave:
- Alarm systems.
- Diathermy units.
- Dryers, ovens, and heaters.
- Medico-biological heaters.
- Microwave power generating devices.
- Radar devices.
- Remote control devices.
- Signal generators.

Radio and low frequency:
- Cauterizers.
- Diathermy units.
- Power generation and transmission equipment.
- Signal generators.
- Electromedical equipment.

(c) Examples of electronic products which may emit coherent electromagnetic radiation produced by stimulated emission include:

Laser:
- Art-form, experimental and educational devices.
- Biomedical analyzers.
- Cauterizing, burning and welding devices.
- Cutting and drilling devices.
- Communications transmitters.
- Rangefinding devices.

Maser:
- Communications transmitters.

(d) Examples of electronic products which may emit infrasonic, sonic, and ultrasonic vibrations resulting from operation of an electronic circuit include:

Infrasonic:
- Vibrators.

Sonic:
- Electronic oscillators.
- Sound amplification equipment.

Ultrasonic:
- Cauterizers.
- Cell and tissue disintegrators.
- Cleaners.
- Diagnostic and nondestructive testing equipment.
- Ranging and detection equipment.

PART 1002—RECORDS AND REPORTS

Subpart A—General Provisions

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AUTHORITY: Sec. 360A, 82 Stat. 1182; 42 U.S.C. 2631.

Subpart A—General Provisions

§ 1002.1 Applicability.

The provisions of this part are applicable to manufacturers, dealers, and distributors of electronic products as specified herein, but, except for § 1002.20, are not applicable to:

(a) Manufacturers of electronic products intended solely for export if such a product is labeled or tagged to show that the product is intended for export, and the product meets all the applicable requirements of the country to which such product is intended for export, and

(b) Manufacturers of listed products sold exclusively to other manufacturers for use as components of electronic products to be sold to purchasers.

(c) Manufacturers of electronic products which are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification.

§ 1002.2 Definitions.

As used in this part:

(a) The term "dealer" means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(b) The term "distributor" means a person engaged in the business of offering electronic products for sale to dealers without regard to whether such person is or has been primarily or customarily engaged in such business.

(c) The term "purchaser" means the first person who, for value, or as an award or prize, acquires an electronic product for purposes other than resale, and also includes a person who leases an electronic product for purposes other than subleasing.

(d) The term "accidental radiation occurrence" means a single event or series of events occurring in the course of the manufacturing, testing, or use of any electronic product which has resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a direct result of the manufacturing, testing, or use of that product.

(e) The term "model" means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

§ 1002.3 Records and reports on components.

Records and reports required for products listed in § 1002.61 shall include information on all components which the manufacturer may provide with the listed product and which affect the quantity, quality, or direction of the radiation emissions.

§ 1002.4 Confidentiality of information.

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to this part, which concerns or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code, except that such information may be disclosed to other officers or employees of the Department and of the other agencies concerned with carrying out the requirements of the Act. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

Subpart B—Required Manufacturers' Reports for Listed Electronic Products

§ 1002.10 Initial reports.

Every manufacturer of a product listed under § 1002.61, shall submit an initial report to the Director, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852, in accordance with this section. The report shall be submitted within 90 days following the effective date of this subpart or prior to the introduction of such product into commerce, whichever is later. The report shall be distinctly marked "Initial Report of (Name of Manufacturer)" and shall:

(a) State in the report for each model of a listed product whether the report is submitted pursuant to paragraph (a), (b), or (c) of § 1002.61.

(b) Identify each model of the listed product together with sufficient information concerning the manufacturer's code or other system of labeling sufficient to enable the Secretary to determine the date and place of manufacture.

(c) Describe the function, operational characteristics affecting radiation emissions, and intended and known uses of each model of the listed product.

(d) State the standards or design specifications, if any, for each model with respect to electronic product radiation safety. Reference may be made to a Federal standard, if applicable.

(e) For each model, describe the physical or electrical characteristics such as shielding, or electronic circuitry, etc., incorporated into the product in order that the standards or specifications reported pursuant to paragraph (d) of this section are met.

(f) Describe the methods and procedures employed, if any, in testing and measuring each model with respect to electronic product radiation safety including the control of unnecessary, secondary, or leakage electronic product radiation, the applicable quality control procedures used for each model, and the basis for selecting such testing and quality control procedures.

(g) For those products which may produce increased radiation with aging, describe the methods and procedures used, and frequency of testing each model for durability and stability with respect to electronic product radiation safety. Include the basis for selecting such methods and procedures, or for determining that such testing and quality control procedures are not necessary.

(h) Provide sufficient results of the testing and measuring of electronic product radiation safety and of the quality control procedures described in accordance with paragraphs (f) and (g) of this section to enable the Secretary to determine the effectiveness of the methods and procedures used to accomplish the stated purposes.

(i) Report for each model, all warning signs, labels and instructions, for installation, operation, and use which relate to electronic product radiation safety.

(j) Provide upon request such other information as the Secretary may reasonably require to enable him to determine whether the manufacturer has acted or is acting in compliance with the Act and any standards prescribed thereunder, and to enable the Secretary to carry out the purposes of the Act.

§ 1002.11 Annual reports.

(a) Every manufacturer of products listed under § 1002.61(b) and (c) shall submit an annual report summarizing the contents of the records required to be maintained by § 1002.30(a).

(b) The first annual report shall be submitted by September 1, 1971, with subsequent reports due annually thereafter. Such reports shall cover the 12-month period ending on June 30 preceding the due date of the report.

§ 1002.12 Reports of model changes.

Prior to the introduction into commerce of a new or modified model of a product listed in § 1002.61 for which an initial report under § 1002.10 was required, each manufacturer shall submit a report with respect to such new or modified model containing any changes in the information submitted in the initial report.

Subpart C—Manufacturers' Reports on Accidental Radiation Occurrences

§ 1002.20 Reporting of accidental radiation occurrences.

(a) Manufacturers of electronic products shall, where reasonable grounds for suspecting that such an incident has occurred, immediately report to the Director, Bureau of Radiological Health, all accidental radiation occurrences reported to or otherwise known to the manufacturer and arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce by such manufacturer. Reasonable grounds include, but are not necessarily limited to, professional, scientific, or medical facts or opinions documented or otherwise, that conclude or lead to the conclusion that such an incident has occurred.

(b) Such reports shall be addressed to the Director, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852, and the reports and their envelopes shall be distinctly marked "Report on § 1002.20" and shall contain all of the following information where known to the manufacturer:

(1) The nature of the accidental radiation occurrence;

(2) The location at which the accidental radiation occurrence occurred;

(3) The manufacturer, type, and model number of the electronic product or products involved;

(4) The circumstances surrounding the accidental radiation occurrence, including causes;

(5) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence, the nature and magnitude of their exposure and/or injuries and, if requested by the Director, Bureau of Radiological Health, the names of the persons involved;

(6) The actions, if any, which may have been taken by the manufacturer, to control, correct, or eliminate the causes and to prevent reoccurrence; and

(7) Any other pertinent information with respect to the accidental radiation occurrence.

Subpart D—Manufacturers' Records

§ 1002.30 Records to be maintained by manufacturers.

(a) Manufacturers of products listed under paragraphs (b) and (c) of § 1002.61 shall establish and maintain the following records with respect to such products:

(1) Description of the quality control procedures with respect to electronic product radiation safety.

(2) Records of the results of tests for electronic product radiation safety, including the control of unnecessary, secondary or leakage electronic product radiation, the methods, devices, and procedures used in such tests, and the basis for selecting such methods, devices, and procedures.

(3) For those products displaying aging effects which may increase electronic product radiation emission, records of the results of tests for durability and stability of the product, and the basis for selecting these tests.

(4) Copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed product.

(b) In addition to the records required by paragraph (a) of this section, manufacturers of products listed in paragraph (c) of § 1002.61 shall establish and maintain the following records with respect to such products:

(1) A record of the manufacturer's distribution of products in a form which will enable the tracing of specific products or production lots to distributors or to dealers in those instances in which the manufacturer distributes directly to dealers.

(2) Records received from dealers or distributors pursuant to § 1002.41.

§ 1002.31 Preservation and inspection of records.

(a) Every manufacturer required to maintain records pursuant to this part, including records received pursuant to § 1002.41, shall preserve such records for a period of 5 years from the date of the record.

(b) Upon reasonable notice by an officer or employee duly designated by the Department, manufacturers shall permit such officer or employee to inspect appropriate books, records, papers, and documents as are relevant to determining whether the manufacturer has acted or is acting in compliance with Federal standards.

(c) Upon request of the Director, Bureau of Radiological Health, a manufacturer of products listed in paragraph (c) of § 1002.61 shall submit to the Director, copies of the records required to

be maintained by paragraph (b) of § 1002.30.

Subpart E—Dealer and Distributor Records

§ 1002.40 Records to be maintained by dealers and distributors.

(a) Dealers and distributors of electronic products listed in paragraph (c) of § 1002.61, for which there are applicable Federal standards under this subchapter and for which the retail price is not less than $50, shall obtain and preserve for a period of 5 years from the date of the sale, award, or lease of each such product such information as is necessary to permit tracing of specific products to specific purchasers.

(b) Such information shall include:

(1) The name and mailing address of the distributor, dealer, or purchaser to whom the product was transferred.

(2) Identification and brand name of the product.

(3) Model number and serial or other identification number of the product.

(4) Date of sale, award, or lease.

§ 1002.41 Records furnished to manufacturers by dealers and distributors.

(a) Information obtained by dealers and distributors pursuant to § 1002.40 shall immediately be forwarded to the appropriate manufacturer unless:

(1) The dealer or distributor elects to hold and preserve such information and to immediately furnish it to the manufacturer when advised by the manufacturer or the Director, Bureau of Radiological Health, that such information is required for purposes of section 359 of the Act; and

(2) The dealer or distributor, upon making the election under subparagraph (1) of this paragraph, promptly notifies the manufacturer and the Director, Bureau of Radiological Health, of such election; such notification shall be in writing and shall identify the dealer or distributor and the electronic product or products for which the information is being accumulated and preserved.

(b) Every dealer or distributor obtaining information pursuant to this part shall take such steps as are necessary to insure that such information is furnished to the manufacturer prior to the time the dealer or distributor discontinues the dealing in or distribution of electronic products.

§ 1002.42 Confidentiality of records furnished by dealers and distributors.

All information furnished to manufacturers by dealers and distributors pursuant to this part shall be treated by such manufacturers as confidential information which may be used only as necessary to notify persons pursuant to section 359 of the Act.

Subpart F—Exemptions from Records and Reports Requirements

§ 1002.50 Special exemptions.

(a) Manufacturers of electronic products listed under paragraphs (b) and (c) of § 1002.61 may submit to the Director, Bureau of Radiological Health, with or subsequent to the submission of the initial report required by § 1002.10, a request, together with accompanying justification, that a product be exempted from the annual reporting and recordkeeping requirements. In addition to other information which may be required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested:

(1) Cannot emit electronic product radiation in sufficient intensity or of such quality under any conditions of use or product failure to be hazardous; or

(2) Is produced in such small numbers as to negate the need for continuous recordkeeping and reporting, and is to be used by trained individuals who are knowledgable of the hazards involved in such use.

(b) The Director, Bureau of Radiological Health, may exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which he may possess or may require of the manufacturer if he determines that such exemption is in keeping with the purposes of the Act.

§ 1002.51 Exemptions for manufacturers of products intended for the U.S. Government.

Upon application therefore by the manufacturer, the Director, Bureau of Radiological Health, may exempt from the provisions of this part a manufacturer of any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

Subpart G—Codes for Reporting Listed Electronic Products

§ 1002.61 List of specific product groups.

(a) *Group A.* (1) Lasers and products containing lasers which have a reporting index number N, less than one (1). Reporting index numbers shall be calculated in accordance with Appendix A.

(2) Ultrasonic products.

(3) Microwave heating equipment not listed in paragraph (c) of this section.

(4) High voltage vacuum switches, high voltage rectifier tubes, shunt regulator tubes, and cathode ray tubes which are intended to be operated at voltages greater than 5,000 volts but less than 15,000 volts.

(b) *Group B.* (1) Television receivers which, on or after the effective date of this subpart, meets the Federal standard in effect on June 1, 1971, provided also that the voltage on the cathode ray tube and any other vacuum tube component cannot exceed 15,000 volts under the test conditions required by the Federal standard at that time.

(2) High voltage vacuum switches, high voltage rectifier tubes, shunt regulator tubes, and cathode ray tubes, which are intended to operate at voltages of 15,000 volts or greater.

(c) *Group C.* (1) Products subject to Federal standards prescribed under Parts 1010, 1020, and 1030 of this Subchapter J except for television receivers described in paragraph (b)(1) of this section.

(2) Products which are intended to produce x radiation.

(3) Microwave ovens intended to be used in homes, restaurants, food vending or service establishments, on interstate carriers and in similar locations.

(4) Microwave diathermy machines.

(5) Lasers and products or devices containing lasers which have a reporting index number of N, equal to or greater than one (1). Reporting index numbers shall be calculated in accordance with Appendix A.

Appendix A—Laser Reporting Index Number

(a) For laser products, the reporting index number N, shall be calculated using the relation $N = BU/A$. The appropriate value of B may be determined from Table 1 for a given wave-length. U is the radiant energy in joules (J). For continuous operation, U is the radiant energy per second in the laser emission. For single pulse operation, U is the true radiant energy per pulse. For repetitively pulsed lasers, reporting index numbers will be computed using both energy per pulse and energy per second. When computing the reporting index number using energy per pulse, that value of B corresponding to the pulse duration of the laser emission in Table 1 will be used. When computing the reporting index number using energy per second, that value of B found in the column "continuous to 0.1 sec" of Table 1 will be used.

(b) A, as used in the relation above, is the actual beam area in square centimeters. For parallel or divergent beams, A is measured at 30 centimeters (cm) from the permanent instrument housing[1] at the points of closest approach to the exit port or ports of the laser beam; for convergent beams, A is measured at that distance from the permanent instrument housing which results in a value of N which is maximal.

Table 1

Wavelength in micrometers	Values of B for different laser pulse durations		
	Continuous to 0.1 sec	0.1 to 10^{-4} sec	Less than 10^{-4} sec
μm	cm^2/J	cm^2/J	cm^2/J
0.40–0.79	23,000	160,000	2,000,000
0.80–0.99	3,700	26,000	320,000
1.00–1.19	1,100	8,000	100,000
1.20–1.39	100	670	8,000
1.40–1.69	2	17	200
Greater than 1.60	1	10	100

(c) If more than one value of N can be determined for a given product, the largest value shall be used for reporting purposes. When simultaneous emission of more than one wavelength occur, an individual reporting index number shall be calculated for each wavelength. The sum of the individual reporting index numbers shall be used as the

[1] "Permanent instrument housing" means that exterior part of the product, without which the laser beam cannot be produced.

reporting index number for the product. Where N cannot be calculated, a reporting index number of 1,000 shall be used.

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

Subpart A—General Provisions

Sec.

Subpart B—Discovery of Defect or Failure to Comply

Subpart C—Notification

Subpart D—Exemptions from Notification Requirements

AUTHORITY: Sec. 359, 82 Stat. 1180; 42 U.S.C. 263g.

Subpart A—General Provisions

§ 1003.1 Applicability.

The provisions of this part are applicable to electronic products which were manufactured after October 18, 1968.

§ 1003.2 Defect in an electronic product.

For the purpose of this part, an electronic product shall be considered to have a defect which relates to the safety of use by reason of the emission of electronic product radiation if:

(a) It is a product which does not utilize the emission of electronic product radiation in order to accomplish its purpose, and from which such emissions are unintended, and as a result of its design, production or assembly (1) it emits electronic product radiation which creates a risk of injury, including genetic injury, to any person, or (2) it fails to conform to its design specifications relating to electronic radiation emissions; or

(b) It is a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended, and as a result of its design, production or assembly it (1) fails to conform to its design specifications relating to the emission of electronic product radiation; or (2) without regard to the design specifications of the product, emits electronic product radiation unnecessary to the accomplishment of its primary purpose which creates a risk of injury, including genetic injury to any person; or (3) fails to accomplish the intended purpose.

§ 1003.5 Effect of regulations on other laws.

The remedies provided for in this subchapter shall be in addition to and not in substitution for any other remedies provided by law and shall not relieve any person from liability at common law or under statutory law.

Subpart B—Discovery of Defect or Failure to Comply

§ 1003.10 Discovery of defect or failure of compliance by manufacturer; notice requirements.

Any manufacturer who discovers that any electronic product produced, assembled, or imported by him, which product has left its place of manufacture, has a defect or fails to comply with an applicable Federal standard shall:

(a) Immediately notify the Secretary in accordance with § 1003.20, and

(b) Except as authorized by § 1003.30, furnish notification with reasonable promptness to the following persons:

(1) The dealers or distributors to whom such product was delivered by the manufacturer; and

(2) The purchaser of such product and any subsequent transferee of such product (where known to the manufacturer or where the manufacturer upon reasonable inquiry to dealers, distributors, or purchasers can identify the present user).

§ 1003.11 Determination by Secretary that product fails to comply or has a defect.

(a) If, the Secretary, through testing, inspection, research, or examination of reports or other data, determines that any electronic product does not comply with an applicable Federal standard issued pursuant to the Act or has a defect, he shall immediately notify the manufacturer of the product in writing specifying:

(1) The defect in the product or the manner in which the product fails to comply with the applicable Federal standard;

(2) The Secretary's findings, with references to the tests, inspections, studies, or reports upon which such findings are based;

(3) A reasonable period of time during which the manufacturer may present his views and evidence to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of electronic product radiation.

(b) Every manufacturer who receives a notice under § 1003.11(a) shall immediately advise the Secretary in writing of the total number of such product units produced and the approximate number of such product units which have left the place of manufacture.

(c) If, after the expiration of the period of time specified in the notice, the Secretary determines that the product has a defect or does not comply with an applicable Federal standard and the manufacturer has not applied for an exemption, he shall direct the manufacturer to furnish the notification to the persons specified in § 1003.10(b) in the manner specified in § 1003.21. The manufacturer shall within 14 days from the date of receipt of such directive furnish the required notification.

Subpart C—Notification

§ 1003.20 Notification by the manufacturer to the Secretary.

The notification to the Secretary required by § 1003.10(a) shall be confirmed in writing and, in addition to other relevant information which the Secretary may require, shall include the following:

(a) Identification of the product or products involved;

(b) The total number of such product units so produced, and the approximate number of such product units which have left the place of manufacture;

(c) The expected usage for the product if known to the manufacturer;

(d) A description of the defect in the product or the manner in which the product fails to comply with an applicable Federal standard;

(e) An evaluation of the hazards reasonably related to defect or the failure to comply with the Federal standard;

(f) A statement of the measures to be taken to repair such defect or to bring the product into compliance with the Federal standard;

(g) The date and circumstances under which the defect was discovered; and

(h) The identification of any trade secret information which the manufacturer desires kept confidential.

§ 1003.21 Notification by the manufacturer to affected persons.

(a) The notification to the persons specified in § 1003.10(b) shall be in writing and, in addition to other relevant information which the Secretary may require, shall include:

(1) The information prescribed by § 1003.20 (a), (d), and instructions with respect to the use of the product pending the correction of the defect;

(2) A clear evaluation in nontechnical terms of the hazards reasonably related to any defect or failure to comply; and

(3) The following statement:

The manufacturer will, without charge, remedy the defect or bring the product into compliance with each applicable Federal standard in accordance with a plan to be approved by the Secretary of Health, Education, and Welfare, the details of which will be included in a subsequent communication to you.

Provided, That if at the time the notification is sent, the Secretary has approved a plan for the repair, replacement or refund of the product, the notification may include the details of the approved plan in lieu of the above statement.

(b) The envelope containing the notice shall not contain advertising or other extraneous material, and such mailings will be made in accordance with this section.

(1) No. 10 white envelopes shall be used, and the name and address of the manufacturer shall appear in the upper left corner of the envelope.

(2) The following statement is to appear in the far left third of the envelope in the type and size indicated and in reverse printing, centered in a red rectangle 3¾ inches wide and 2¼ inches high:

IMPORTANT
ELECTRONIC PRODUCT
RADIATION WARNING

The statement shall be in three lines, all capitals, and centered. "Important" shall be in 36-point Gothic Bold type. "Electronic Product" and "Radiation Warning" shall be in 36-point Gothic Condensed type.

(3) Envelopes with markings similar to those prescribed in this section shall not be used by manufacturers for mailings other than those required by this part.

(c) The notification shall be sent:

(1) By certified mail to purchasers of the product and to subsequent transferees.

(2) By certified mail or other more expeditious means to dealers and distributors.

(d) Where products were sold under a name other than that of the manufacturer of the product, the name of the individual or company under whose name the product was sold may be used in the notification required by this section.

§ 1003.22 Copies of communications sent to purchasers, dealers or distributors.

(a) Every manufacturer of electronic products shall furnish to the Secretary a copy of all notices, bulletins, or other communications sent to the dealers or distributors of such manufacturers or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any defect in such product or any failure of such product to comply with an applicable Federal standard.

(b) In the event the Secretary deems the content of such notices to be insufficient to protect the public health and safety, the Secretary may require additional notice to such recipients, or may elect to make or cause to be made such notification by whatever means he deems appropriate.

Subpart D—Exemptions From Notification Requirements

§ 1003.30 Application for exemption from notification requirements.

(a) A manufacturer may at the time of giving the written confirmation required by § 1003.20 or within 15 days of the receipt of any notice from the Secretary pursuant to § 1003.11(a), apply for an exemption from the requirement of notice to the persons specified in § 1003.10(b).

(b) The application for exemption shall contain the information required by § 1003.20 and in addition shall set forth in detail the grounds upon which the exemption is sought.

§ 1003.31 Granting the exemption.

(a) If, in the judgment of the Secretary, the application filed pursuant to § 1003.30 states reasonable grounds for an exemption from the requirement of notice, the Secretary shall give the manufacturer written notice specifying a reasonable period of time during which he may present his views and evidence in support of the application.

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable.

(c) If, during the period of time afforded the manufacturer to present his views and evidence, the manufacturer proves to the Secretary's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall issue an exemption from the requirement of notification to the manufacturer and shall notify the manufacturer in writing specifying:

(1) The electronic product or products for which the exemption has been issued; and

(2) Such conditions as the Secretary deems necessary to protect the public health and safety.

PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS

Sec.

AUTHORITY: Sec. 359, 82 Stat. 1180; 42 U.S.C. 263g.

§ 1004.1 Manufacturer's obligation to repair, replace, or refund cost of electronic products.

(a) If any electronic product fails to comply with an applicable Federal standard or has a defect and the notification specified in § 1003.10(b) of this chapter is required to be furnished, the manufacturer of such product shall (1) without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied; or (2) replace such product with a like or equivalent product which complies with each applicable Federal standard and which has no defect relating to the safety of its use; or (3) make a refund of the cost of the product to the purchaser.

(b) The manufacturer shall take the action required by this section in accordance with a plan approved by the Secretary pursuant to § 1004.6 of this part.

§ 1004.2 Plans for the repair of electronic products.

Every plan for bringing an electronic product into conformity with applicable Federal standards or for remedying any defect in such product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product involved.

(b) The approximate number of defective product units which have left the place of manufacture.

(c) The specific modifications, alterations, changes, repairs, corrections, or adjustments to be made to bring the product into conformity or remedy any defect.

(d) The manner in which the operations described in paragraph (c) will be accomplished, including the procedure for obtaining access to, or possession of, the products and the location where such operations will be performed.

(e) The technical data, test results or studies demonstrating the effectiveness of the proposed remedial action.

(f) A time limit, reasonable in light of the circumstances, for completion of the operations.

(g) The system by which the manufacturer will provide reimbursement for any transportation expenses incurred in connection with having such product brought into conformity or having any defect remedied.

(h) The text of the statement which the manufacturer will send to the persons specified in § 1003.10(b) of this chapter informing such persons (1) that the manufacturer, at his expense, will repair the electronic product involved, (2) of the method by which the manufacturer will obtain access to or possession of the product to make such repairs, (3) that the manufacturer will reimburse such persons for any transportation expenses incurred in connection with making such repairs, and (4) of the manner in which such reimbursement will be effected.

(i) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of electronic products repaired.

§ 1004.3 Plans for the replacement of electronic products.

Every plan for replacing an electronic product with a like or equivalent product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product to be replaced.

(b) A description of the replacement product in sufficient detail to support the manufacturer's contention that the replacement product is like or equivalent to the product being replaced.

(c) The approximate number of defective product units which have left the place of manufacture.

(d) The manner in which the replacement operation will be effected including the procedure for obtaining possession of the product to be replaced.

(e) A time limit, reasonable, in light of the circumstances for completion of the replacement.

(f) The steps which the manufacturer will take to insure that the defective product will not be reintroduced into commerce, until it complies with each applicable Federal standard and has no defect relating to the safety of its use.

(g) The system by which the manufacturer will provide reimbursement for any expenses for transportation of such product incurred in connection with effecting the replacement.

(h) The text of the statement which the manufacturer will send to the persons specified in § 1003.10(b) of this chapter informing such persons (1) that the manufacturer, at its expense, will replace the electronic product involved, (2) of the method by which the manufacturer will obtain possession of the product and effect the replacement, (3) that the manufacturer will reimburse such persons for any transportation expenses incurred in connection with effecting such replacement, and (4) of the manner in which such reimbursement will be made.

(i) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of electronic products replaced.

§ 1004.4 Plans for refunding the cost of electronic products.

Every plan for refunding the cost of an electronic product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product involved.

(b) The approximate number of defective product units which have left the place of manufacture.

(c) The manner in which the refund operation will be effected including the procedure for obtaining possession of the product for which the refund is to be made.

(d) The steps which the manufacturer will take to insure that the defective products will not be reintroduced into commerce, until it complies with each applicable Federal standard and has no defect relating to the safety of its use.

(e) A time limit, reasonable in light of the circumstances, for obtaining the product and making the refund.

(f) A statement that the manufacturer will refund the cost of such product together with the information the manufacturer has used to determine the amount of the refund.

(g) The text of the statement which the manufacturer will send to the persons specified in § 1003.10(b) of this chapter informing such persons (1) that the manufacturer, at his expense, will refund the cost of the electronic product plus any transportation costs, (2) of the amount to be refunded exclusive of transportation costs, (3) of the method by which the manufacturer will obtain possession of the product and make the refund.

(h) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of refunds made.

§ 1004.6 Approval of plans.

If, after review of any plan submitted pursuant to this subchapter, the Secretary determines that the action to be taken by the manufacturer will expeditiously and effectively fulfill the manufacturer's obligation under § 1004.1 in a manner designed to encourage the public to respond to the proposal, the Secretary will send written notice of his approval of such plan to the manufacturer. Such approval may be conditioned upon such additional terms as the Secretary deems necessary to protect the public health and safety.

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

Subpart A—General Provisions

Sec.

Subpart B—Inspection and Testing

Subpart C—Bonding and Compliance Procedures

AUTHORITY: Secs. 215, 356, 58 Stat. 690, 82 Stat. 1174; 42 U.S.C. 216, 263d.

Subpart A—General Provisions

§ 1005.1 Applicability.

(a) The provisions of §§ 1005.1 through 1005.24 are applicable to electronic products which are subject to the standards prescribed in Parts 1010, 1020, and 1030 of this chapter and are offered for importation into the United States.

(b) Section 1005.25 is applicable to every manufacturer of electronic products offering an electronic product for importation into the United States.

§ 1005.2 Definitions.

As used in this part:

The term "owner" or "consignee" means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

§ 1005.3 Importation of noncomplying goods prohibited.

The importation of any electronic product for which standards have been prescribed under section 358 of the Act (42 U.S.C. 268f) shall be refused admission into the United States unless there is affixed to such product a certification in the form of a label or tag in conformity with section 358(h) of the Act (42 U.S.C. 263f(h)). Merchandise refused admission shall be destroyed or exported under regulations prescribed by the Secretary of the Treasury unless a timely and adequate petition for permission to bring the product into compliance is filed and granted under §§ 1005.21 and 1005.22.

Subpart B—Inspection and Testing

§ 1005.10 Notice of sampling.

When a sample of a product to be offered for importation has been requested by the Secretary, the District Director of Customs having jurisdiction over the shipment shall, upon the arrival of the shipment, procure the sample and shall give to its owner or consignee prompt notice of the delivery or of the intention to deliver such sample to the Secretary. If the notice so requires, the owner or consignee will hold the shipment of which the sample is typical and not release such shipment until he receives notice of the results of the tests of the sample from the Secretary, stating that the product is in compliance with the requirements of the Act. The District Director of Customs will be given the results of the tests. If the Secretary notifies the District Director of Customs that the product does not meet the requirements of the Act, the District Director of Customs shall require the exportation or destruction of the shipment in accordance with customs laws.

§ 1005.11 Payment for samples.

The Department of Health, Education, and Welfare will pay for all import samples of electronic products rendered unsalable as a result of testing, or will pay the reasonable costs of repackaging such samples for sale, if the samples are found to be in compliance with the requirements of the Radiation Control for Health and Safety Act of 1968. Billing for reimbursement shall be made by the owner or consignee to the Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852. Payment for samples will not be made if the sample is found to be in violation of the Act, even though subsequently brought into compliance pursuant to terms specified in a notice of permission issued under § 1005.22.

Subpart C—Bonding and Compliance Procedures

§ 1005.20 Hearing.

(a) If, from an examination of the sample or otherwise, it appears that the product may be subject to a refusal of admission, the Secretary shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony unless the owner or consignee indicates his intention to

bring the product into compliance. Upon timely request, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article and may be introduced orally or in writing.

(b) If the owner or consignee submits or indicates his intention to submit an application for permission to perform such action as is necessary to bring the product into compliance with the Act, such application shall include the information required by § 1005.21.

(c) If the application is not submitted at or prior to the hearing, the Secretary may allow a reasonable time for filing such application.

§ 1005.21 Application for permission to bring product into compliance.

Application for permission to perform such action as is necessary to bring the product into compliance with the Act may be filed only by the owner, consignee, or manufacturer and, in addition to any other information which the Secretary may reasonably require, shall:

(a) Contain a detailed proposal for bringing the product into compliance with the Act;

(b) Specify the time and place where such operations will be effected and the approximate time for their completion; and

(c) Identify the bond required to be filed pursuant to § 1005.23 of this part.

§ 1005.22 Granting permission to bring product into compliance.

(a) When permission contemplated by § 1005.21 is granted, the Secretary shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of a representative of the Department of Health, Education, and Welfare;

(4) A reasonable time limit for completing the operations; and

(5) Such other conditions as he finds necessary to maintain adequate supervision and control over the product.

(b) Upon receipt of a written request for an extension of time to complete the operations necessary to bring the product into compliance, the Secretary may grant such additional time as he deems necessary.

(c) The notice of permission may be amended upon a showing of reasonable grounds thereof and the filing of an amended application for permission with the Secretary.

(d) If ownership of a product included in a notice of permission changes before the operations specified in the notice have been completed, the original owner will remain responsible under its bond, unless the new owner has executed a superseding bond on customs Form 7601 and obtained a new notice.

(e) The Secretary will notify the District Director of Customs having jurisdiction over the shipment involved, of the determination as to whether or not the product has in fact been brought into compliance with the Act.

§ 1005.23 Bonds.

The bond required under section 360 (b) of the Act shall be executed by the owner or consignee on the appropriate form of a customs single-entry bond, customs Form 7551 or term bond, customs Form 7553 or 7595, containing a condition for the redelivery of the shipment or any part thereof not complying with the laws and regulations governing its admission into the commerce of the United States upon demand of the District Director of Customs and containing a provision for the performance of any action necessary to bring the product into compliance with all applicable laws and regulations. The bond shall be filed with the District Director of Customs.

§ 1005.24 Costs of bringing product into compliance.

The costs of supervising the operations necessary to bring a product into compliance with the Act shall be paid by the owner or consignee who files an application pursuant to § 1005.21 and executes a bond under section 360(b) of the Act. Such costs shall include:

(a) Travel expenses of the supervising officer;

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law;

(c) Services of the supervising officer to be calculated at a flat rate of $12 per hour (which shall include administrative expense) except that such services performed by a customs officer and subject to the provisions of the Act of February 13, 1911, as amended (section 5, 36 Stat. 901, as amended; 19 U.S.C. 267), shall be calculated as provided by that Act;

(d) The minimum charge for services of supervising officers shall be not less than the charge for 1 hour and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than one-half hour.

§ 1005.25 Service of process on manufacturers.

(a) Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer's agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 360(d) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263h(d)) and this section. The agent may be an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

(b) The designation shall be addressed to the Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852. It shall be in writing and dated; all signatures shall be in ink. The designation shall be made in the legal form required to make it valid and binding on the manufacturer under the laws, corporate bylaws, or other requirements governing the making of the designation by the manufacturer at the place and time where it is made, and the persons or person signing the designation shall certify that it is so made. The designation shall disclose the manufacturer's full legal name and the name(s) under which he conducts his business, if applicable, his principal place of business, and mailing address. If any of the products of the manufacturer do not bear his legal name, the designation shall identify the marks, trade names, or other designations of origin which these products bear. The designation shall provide that it will remain in effect until withdrawn or replaced by the manufacturer and shall bear a declaration of acceptance duly signed by the designated agent. The full legal name and mailing address of the agent shall be stated. Until rejected by the Secretary, designations are binding on the manufacturer even when not in compliance with all the requirements of this section. The designated agent may not assign performance of his function under the designation to another.

(c) Service of any process, notice, order, requirement, or decision specified in section 360(d) of the Radiation Control for Health and Safety Act of 1968 may be made by registered or certified mail addressed to the agent with return receipt requested, or in any other manner authorized by law. In the absence of such a designation or if for any reason service on the designated agent cannot be effected, service may be made as provided in section 360(d) by posting such process, notice, order, requirement, or decision in the Office of the Director, Bureau of Radiological Health and publishing a notice that such service was made in the FEDERAL REGISTER.

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Subpart A—General Provisions

Subpart B—Alternate Test Procedures

Subpart C—Exportation of Electronic Products

AUTHORITY: Sec. 358, 82 Stat. 1177; 42 U.S.C. 263f.

Subpart A—General Provisions

§ 1010.1 Scope.

The standards listed in this part, and Parts 1020 and 1030 of this chapter are prescribed pursuant to section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined

necessary for the protection of the public health and safety.

§ 1010.2 Certification.

(a) Every manufacturer of an electronic product for which an applicable standard is in effect under Parts 1020 and 1030 of this chapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under Parts 1020 and 1030 of this chapter.

(b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification.

(c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Secretary may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standard prescribed under Parts 1020 and 1030 of this chapter.

(d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer, the Secretary may approve an alternate means by which such certification may be provided.

§ 1010.3 Identification.

(a) Every manufacturer of an electronic product to which a standard under Parts 1020 and 1030 of this chapter is applicable shall set forth the information specified in subparagraphs (1) and (2) of this paragraph. This information shall be provided 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 applicable standard.

(1) The full name and address of the manufacturer of the product: Abbreviations such as "Co.," "Inc.," or their foreign equivalents and the first and middle initials of individuals may be used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously supplied the Secretary with sufficient information to identify the manufacturer of the product.

(2) The month, year, and place of manufacture: This information may be expressed in code provided the manufacturer has previously supplied the Secretary with the key to such code.

(b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the manufacturer, the Secretary may approve an alternate means by which such identification may be provided.

(c) Every manufacturer of an electronic product to which is applicable a standard under Parts 1020 and 1030 of this chapter shall provide the Secretary with a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

Subpart B—Alternate Test Procedures

§ 1010.13 Special test procedures.

The Secretary may, on the basis of a written application by a manufacturer, authorize test programs other than those set forth in the standard for an electronic product if he determines that such products are not susceptible to satisfactory testing by the procedures set forth in the standard and that the alternative test procedures assure compliance with the standard.

Subpart C—Exportation of Electronic Products

§ 1010.20 Electronic products intended for export.

The performance standard prescribed in Parts 1020 and 1030 of this chapter shall not apply to any electronic product which is intended solely for export if (a) such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and (b) such product meets all the applicable requirements of the country to which such product is intended for export.

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

Sec.
1020.10 Television receivers.
1020.20 Cold-cathode gas discharge tubes.
1020.30 Diagnostic x-ray systems and their major components.
1020.31 Radiographic equipment.
1020.32 Fluoroscopic equipment.

AUTHORITY: Sec. 358, 82 Stat. 1177; 42 U.S.C. 263f.

§ 1020.10 Television receivers.

(a) *Applicability.* The provisions of this section are applicable to television receivers manufactured subsequent to January 15, 1970.

(b) *Definitions.* (1) "External surface" means the cabinet or enclosure provided by the manufacturer as part of the receiver. If a cabinet or enclosure is not provided as part of the receiver, the external surface shall be considered to be a hypothetical cabinet, the plane surfaces of which are located at those minimum distances from the chassis sufficient to enclose all components of the receiver except that portion of the neck and socket of the cathode-ray tube which normally extends beyond the plane surfaces of the enclosure.

(2) "Maximum test voltage" means 130 root mean square volts if the receiver is designed to operate from nominal 110 to 120 root mean square volt power sources. If the receiver is designed to operate from a power source having some voltage other than from nominal 110 to 120 root mean square volts, maximum test voltage means 110 percent of the nominal root mean square voltage specified by the manufacturer for the power source.

(3) "Service controls" means all of those controls on a television receiver provided by the manufacturer for purposes of adjustment which, under normal usage, are not accessible to the user.

(4) "Television receiver" means an electronic product designed to receive and display a television picture through broadcast, cable, or closed circuit television.

(5) "Usable picture" means a picture in synchronization and transmitting viewable intelligence.

(6) "User controls" means all of those controls on a television receiver, provided by the manufacturer for purposes of adjustment, which on a fully assembled receiver under normal usage, are accessible to the user.

(c) *Requirements*—(1) *Exposure rate limit.* Radiation exposure rates produced by a television receiver shall not exceed 0.5 milliroentgens per hour at a distance of five (5) centimeters from any point on the external surface of the receiver, as measured in accordance with this section.

(2) *Measurements.* Compliance with the exposure rate limit defined in subparagraph (1) of this paragraph shall be determined by measurements made with an instrument, the radiation sensitive volume of which shall have a cross section parallel to the external surface of the receiver with an area of ten (10) square centimeters and no dimension larger than five (5) centimeters. Measurements made with instruments having other areas must be corrected for spatial nonuniformity of the radiation field to obtain the exposure rate average over a ten (10) square centimeter area.

(3) *Test conditions.* All measurements shall be made with the receiver displaying a usable picture and with the power source operated at supply voltages up to the maximum test voltage of the receiver and, as applicable, under the following specific conditions:

(i) On television receivers manufactured subsequent to January 15, 1970, measurements shall be made with all user controls adjusted so as to produce maximum x-radiation emissions from the receiver.

(ii) On television receivers manufactured subsequent to June 1, 1970, measurements shall be made with all user controls and all service controls adjusted to combinations which result in the production of maximum x-radiation emissions.

(iii) On television receivers manufactured subsequent to June 1, 1971, measurements shall be made under the conditions described in subdivision (ii) of this subparagraph, together with condi-

tions identical to those which result from that component or circuit failure which maximizes x-radiation emissions.

(4) *Critical component warning.* The manufacturer shall permanently affix or inscribe a warning label, clearly legible under conditions of service, on all television receivers which could produce radiation exposure rates in excess of the requirements of this section as a result of failure or improper adjustment or improper replacement of a circuit or shield component. The warning label shall include the specification of operating high voltage and an instruction for adjusting the high voltage to the specified value.

§ 1020.20 Cold-cathode gas discharge tubes.

(a) *Applicability.* The provisions of this section are applicable to cold-cathode gas discharge tubes designed to demonstrate the effects of a flow of electrons or the production of x radiation as specified herein.

(b) *Definitions.* "Beam blocking device" means a movable or removable portion of any enclosure around a cold-cathode gas discharge tube, which may be opened or closed to permit or prevent the emergence of an exit beam.

"Cold-cathode gas discharge tube" means an electronic device in which electron flow is produced and sustained by ionization of contained gas atoms and ion bombardment of the cathode.

"Exit beam" means that portion of the radiation which passes through the aperture resulting from the opening of the beam blocking device.

"Exposure" means the sum of the electrical charges on all of the ions of one sign produced in air when all electrons liberated by photons in a volume element of air are completely stopped in air divided by the mass of the air in the volume element. The special unit of exposure is the roentgen. One (1) roentgen equals 2.58×10^{-4} coulombs/kilogram.

(c) *Requirements.* (1) Exposure rate limit:

(i) Radiation exposure rates produced by cold-cathode gas discharge tubes shall not exceed 10 mR./hr. at a distance of thirty (30) centimeters from any point on the external surface of the tube, as measured in accordance with this section.

(ii) The divergence of the exit beam from tubes designed primarily to demonstrate the effects of x radiation, with the beam blocking device in the open position, shall not exceed π (Pi) steradians.

(2) Measurements:

(i) Compliance with the exposure rate limit defined in (c)(1)(i) shall be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters.

(ii) Measurements of exposure rates from tubes in enclosures from which the tubes cannot be removed without destroying the function of the tube may be made at a distance of thirty (30) centimeters from any point on the external surface of the enclosure, provided:

(a) In the case of enclosures containing tubes designed primarily to demonstrate the production of x radiation, measurements shall be made with any beam blocking device in the beam blocking position, or

(b) In the case of enclosures containing tubes designed primarily to demonstrate the effects of a flow of electrons, measurements shall be made with all movable or removable parts of such enclosure in the position which would maximize external exposure levels.

(3) Test conditions:

(i) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

(ii) Measurements shall be made with the tube operated under forward and reverse polarity.

(4) Instructions, labels, and warnings:

(i) Manufacturers shall provide, or cause to be provided, with each tube to which this section is applicable, appropriate safety instructions, together with instructions for the use of such tube, including the specification of a power source for use with the tube.

(ii) Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and: (a) In the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x rays in excess of allowable limits; and (b) in the case of tubes designed primarily to demonstrate the production of x radiation, a warning that this device produces x rays when energized.

(iii) The tag or label required by this paragraph shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

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

(a) *Applicability.* The provisions of this section and §§ 1020.31 and 1020.32 are applicable as specified herein to:

(1) The following components of diagnostic x-ray systems which are manufactured after August 1, 1974. Tube housing assemblies, x-ray controls, x-ray high-voltage generators, fluoroscopic imaging assemblies, tables, cradles, film changers, casette holders, and beam-limiting devices; and

(2) Diagnostic x-ray systems incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§ 1020.31 and 1020.32 which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(b) *Definitions.* As used in this section and §§ 1020.31 and 1020.32, the following definitions apply:

(1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(2) "Aluminum equivalent" means the thickness of aluminum (type 1100 alloy)[1] affording the same attenuation, under specified conditions, as the material in question.

(3) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem.

(4) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation.

(5) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

(6) "Beam axis" means a line from the source through the centers of the x-ray fields.

(7) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

(8) "Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C=\frac{s}{\bar{X}}=\frac{1}{\bar{X}}\left[\sum_{i=1}^{n}\frac{(X_i-\bar{X})^2}{n-1}\right]^{\frac{1}{2}}$$

where

s = Estimated standard deviation of the population.

$\bar{X}$ = Mean value of observations in sample.

X_i = ith observation sampled.

n = Number of observations sampled.

(9) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

(10) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(11) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

(12) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

(13) "Equipment" means x-ray equipment.

(14) "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

(15) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in "Aluminum Standards and Data" (1969). Copies may be obtained from: The Aluminum Association, New York, NY.

cathode is due solely to the action of an electric field.

(16) "Fluoroscopic imaging assembly" means a component which comprises a reception system in which x-ray photons produce a fluoroscopic image. It includes equipment housings, electrical interlocks if any, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.

(17) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(18) "Half-value layer, HVL" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(19) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

(20) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(i) The useful beam and

(ii) Radiation produced when the exposure switch or timer is not activated.

(21) "Leakage technique factors" means the technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:

(i) For capacitor energy storage equipment, the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mAs) or the minimum obtainable from the unit, whichever is larger.

(ii) For field emission equipment rated for pulsed operation, the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.

(iii) For all other equipment, the maximum rated continuous tube current for the maximum rated peak tube potential.

(22) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

(23) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

$$\text{Percent line-voltage regulation} = 100(V_n - V_l)/V_l$$

where

V_n = No-load line potential and
V_l = Load line potential.

(24) "Maximum line current" means the rms current in the supply line of an x-ray machine operating at its maximum rating.

(25) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(26) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

(27) "Rated line voltage" means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

(28) "Rated output current" means the maximum allowable load current of the x-ray high-voltage generator.

(29) "Rated output voltage" means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

(30) "Rating" means the operating limits specified by the manufacturer.

(31) "Recording" means producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).

(32) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

(33) "Source" means the focal spot of the x-ray tube.

(34) "Source-image receptor distance, (SID)" means the distance from the source to the center of the input surface of the image receptor.

(35) "Stationary equipment" means equipment which is installed in a fixed location.

(36) "Technique factors" means the conditions of operation. They are specified as follows:

(i) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

(iii) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(37) "Tube" means an x-ray tube, unless otherwise specified.

(38) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

(39) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(40) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

(41) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

(42) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

(43) "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment which controls the technique factors of an x-ray exposure.

(44) "X-ray equipment" means an x-ray system, subsystem, or component thereof.

(45) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(46) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

(47) "X-ray system" means an assemblage of components for the controlled production of x rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

(48) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

(49) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Certification of components.* Each component subject to this section and §§ 1020.31 and 1020.32 shall be certified by the manufacturer thereof as a product which meets all applicable standards in accordance with the provisions of § 1010.2 of this chapter. Certification that the product conforms to all applicable standards under this part shall be construed to mean that the component can meet the applicable provisions of this section and §§ 1020.31 and 1020.32 if installed in a diagnostic x-ray system in accordance with instructions.

(d) *Certification by assembler.* An assembler who installs one or more components certified as required by paragraph (c) of this section into an x-ray system shall install certified components that are of the type required by § 1020.31 or § 1020.32 and, except as provided for in subparagraph (2) of this paragraph, shall assemble, install, adjust, and test the certified components in accordance with the instructions of their respective

manufacturers. All assemblers who install certified components shall file a report of such assembly as specified in subparagraphs (1) and (2) of this paragraph. The report shall be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. All assembler reports shall be on a form prescribed by and available from the Director, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852. Completed reports shall be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection, within 15 days following completion of the assembly.

(1) *Reporting compliance.* An assembler who installs one or more certified components into an x-ray system or subsystem, having properly followed the assembly instructions provided him by the component manufacturer, shall certify to this by filing a report containing the information prescribed on the form which shall include the following:

(i) The full name and address of the assembler and the date of assembly or installation.

(ii) The name and address of the purchaser and the location and specific identification of the x-ray system or subsystem.

(iii) An affirmation that all instruction manuals and other information as required by paragraph (h) of this section applicable to the newly installed x-ray equipment have been delivered to the purchaser.

(iv) A statement of the type and intended use of the x-ray system or subsystem into which the certified components were assembled or installed, such as "radiographic—stationary general purpose."

(v) A list of all certified components which were assembled or installed by him into the x-ray system or subsystem in accordance with the instructions of the component manufacturers, identifying the components by type, manufacturer, model number, and serial number.

(vi) An affirmation that the certified components listed pursuant to subdivision (v) of this subparagraph were assembled according to the instructions provided by the manufacturer(s) of such components.

(vii) An affirmation that all certified components installed in the x-ray system or subsystem were of the type required by § 1020.31 or § 1020.32.

(viii) An affirmation that a copy of this report will be transmitted to the purchaser and, where applicable, to the State agency responsible for radiation protection, in accordance with the requirements of this paragraph.

(2) *Reporting noncompatibility.* An assembler who installs a certified component into an x-ray system shall file a report indicating noncompatibility if he is unable to follow the instructions of the manufacturer of such certified component, provided other component(s) of the system do not meet the manufacturer's specifications for compatibility as given by the certified component manufacturer pursuant to paragraph (g) of this section and provided there is no commercially available certified component of a similar type which is compatible with the x-ray system. In addition, the component(s) of the system not meeting the specification for compatibility must either be of a type listed in paragraph (a)(1) of this section which does not bear a certification label due to date of manufacture, or if it is a component not of the type listed in paragraph (a)(1) of this section, it must have been purchased as new prior to August 1, 1974. No assembler shall perform any modification of a certified component which will adversely affect the performance of the certified component with respect to the requirements of this section and §§ 1020.31 and 1020.32. The assembler shall file a report indicating noncompatibility containing information prescribed on the form which shall include the following:

(i) The full name and address of the assembler and the date of assembly or installation.

(ii) The name and address of the purchaser and the location and specific identification of the x-ray system or subsystem.

(iii) An affirmation that all instruction manuals and other information as required by paragraph (h) of this section applicable to the newly installed x-ray equipment have been delivered to the purchaser.

(iv) A statement of the type or intended use of the x-ray system or subsystem into which the certified components were assembled or installed, such as "radiographic—stationary general purpose."

(v) A list of all certified component(s) which were assembled or installed by him into the x-ray system or subsystem and which could not be assembled, installed, adjusted, and tested in accordance with the manufacturer's instructions due to reasons specified in this subparagraph (this paragraph (d)(2)), identifying the components by type, manufacturer, model number, and serial number.

(vi) An affirmation that the certified component(s) listed pursuant to subdivision (v) of this subparagraph could not be assembled, installed, adjusted, and tested in accordance with the installation instructions of their respective manufacturers due to reasons specified in this subparagraph (this paragraph (d)(2)), and that no certified component was modified so as to adversely affect its performance with respect to the requirements of this section and §§ 1020.31 and 1020.32.

(vii) For each certified component listed pursuant to subdivision (v) of this subparagraph, a full and complete explanation of why the manufacturer's installation instructions could not be followed in performing the assembly, including a listing by type, manufacturer, and model number of the incompatible component(s) already in the system, and either evidence of its date of purchase as new if it is not a type of component listed in paragraph (a)(1) of this section, or if it is a type of component listed in paragraph (a)(1) of this section, a statement that it did not bear a certification label due to its date of manufacture.

(viii) An affirmation that all certified components installed in the x-ray system or subsystem were of the type required by § 1020.31 or § 1020.32.

(ix) An affirmation that a copy of this report will be transmitted to the purchaser and, where applicable, to the State agency responsible for radiation protection, in accordance with the requirements of this paragraph.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in § 1010.3 of this chapter, manufacturers of components subject to this section and §§ 1020.31 and 1020.32, except high-voltage generators contained within tube housings, and beam-limiting devices which are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product, so as to be legible and accessible to view.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* The replacement of an x-ray tube in a previously manufactured tube housing assembly shall constitute manufacture of a new tube housing assembly and the manufacturer shall be subject to the provisions of subparagraph (1) of this paragraph. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels which are no longer applicable.

(f) *Limits of responsibility*—(1) *Manufacturer.* The manufacturer of a certified component installed or assembled into an x-ray system or subsystem by another person shall not be liable for the noncompliance of such component which is attributable solely to the improper installation or assembly of the component into the system, but shall be held responsible for noncompliance if improper assembly was a result of inadequate instructions provided by such component manufacturer.

(2) *Assembler.* The person who certified as to the assembly of an x-ray system or subsystem shall not be liable for noncompliance of a certified component if such assembly is in accordance with the instructions provided by the manufacturer of the component, but shall be held responsible for noncompliance of a component which is attributable solely to improper assembly or installation into the system or subsystem.

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing

of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 1020.31 and 1020.32 when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible.

(h) *Information to be provided for users.* Manufacturers of x-ray equipment shall provide for purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§ 1020.31 and 1020.32 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 1020.31 and 1020.32.

(2) *Tube housing assemblies.* For each tube housing assembly, there shall be provided:

(i) Statements of the maximum rated peak tube potential, leakage technique factors, the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) Tube rating charts.

If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self-rectified, single-phase half-wave rectified, single-phase full-wave rectified, three-phase six pulse, three-phase 12 pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, he shall provid. necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(s);

(iii) A statement of the technique factors that constitute the maximum line current condition described in subdivision (ii) of this subparagraph;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the indication given by labeled control settings and/or meters during any exposure when the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated; and

(vii) A statement defining the measurement basis (or bases) upon which the exposure time, peak tube potential, tube current, and/or other technique factors are stated pursuant to subdivisions (iii) and (vi) of this subparagraph.

(4) *Variable-aperture beam-limiting device.* For each variable-aperture beam-limiting device, there shall be provided:

(i) Specifications of tube housing assemblies for which the device is designed or is compatible with respect to the requirements of paragraph (k) of this section and §§ 1020.31(d) and (e); and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(i) *Variances*—(1) *Criteria for variances.* Upon application by a manufacturer (including assembler), the Director, Bureau of Radiological Health, may grant a variance from one or more provisions of this section and §§ 1020.31 and 1020.32 applicable to any diagnostic x-ray system, subsystem, or component when he determines that the granting of such variance is in keeping with the purposes of the Act and that the requested variance:

(i) Is designed to have identifiable technical advantages and is to be used either as a prototype or experimental equipment for clinical evaluation, or

(ii) Is required for obtaining diagnostic information not obtainable with equipment meeting all the requirements of this section and §§ 1020.31 and 1020.32, or

(iii) Utilizes alternate means for providing protection at least equal to that provided by equipment which conforms to this section and §§ 1020.31 and 1020.32.

(2) *Applications for variances.* Applications for variances shall be submitted to the Director, Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, and shall include the following information:

(i) A description of the product and its intended use,

(ii) An explanation of how compliance with this section and §§ 1020.31 and 1020.32 would restrict this intended use,

(iii) A description of the manner in which it is proposed to deviate from the requirements of this section and §§ 1020.31 and 1020.32,

(iv) A description of the advantages to be derived from such deviation,

(v) An explanation of how alternate means of protection will be provided,

(vi) The number of units the applicant wishes to manufacture and/or for what period of time it is desired that the variance be in effect, and

(vii) In the case of prototype or experimental equipment, the proposed location of each unit.

(3) *Administration of variances.* (i) Written notification will be provided by the Director, Bureau of Radiological Health, to the manufacturer of the granting or refusal of a variance. Notification of an approved variance will state the number of units for which the variance is approved and/or the termination date of the variance. Variances will be identified by a number and date of issuance.

(ii) A public file of approved variances and information related to pending actions will be maintained by the Director, Bureau of Radiological Health, and, where applicable, affected State radiation regulatory authorities will be notified of action with respect to variances. Information containing trade secrets will be administered in accordance with the provisions of section 360A(e) of the Act.

(iii) After reasonable notice to the manufacturer and opportunity for a hearing, the variance will be withdrawn if the Director, Bureau of Radiological Health, deems that such withdrawal is necessary to protect the public health.

(iv) In the event that the Director, Bureau of Radiological Health, determines that an imminent public health hazard is presented by the continuation of a variance, he shall immediately withdraw such variance after due notification to the manufacturer. Such withdrawal shall not prejudice a manufacturer's opportunity for a hearing following the withdrawal.

(4) *Certification of equipment covered by variance.* The manufacturer of any diagnostic x-ray equipment for which a variance is granted shall modify the tag, label, or other certification required by §§ 1010.2 and 1010.3 of this chapter, or this section and §§ 1020.31 and 1020.32 to state:

(i) That the item is in conformity with this section and §§ 1020.31 and 1020.32 except with respect to those characteristics covered by the variance;

(ii) That the item is in conformity with the provisions of the variance; and

(iii) The assigned number of the variance and date assigned.

(j) *Warning label.* The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(k) *Leakage radiation from the diagnostic source assembly.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(l) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Beam quality*—(1) *Half-value layer.* The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I.

TABLE I

Design operating range (Kilovolts peak)	Measured potential (Kilovolts peak)	Half-value layer (Millimeters of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made. Positive means * shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

(2) *Measuring compliance.* For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

(n) *Aluminum equivalent of material between patient and image receptor.* The aluminum equivalent of each of the items listed in Table II, which are used between the patient and image receptor, shall not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam which has a half-value layer of 2.7 millimeters of aluminum. This requirement is applicable to front panel(s) of cassette holders and film changers provided by the manufacturer for purposes of patient support and/or to prevent foreign object intrusions. It does not apply to such items as a screen and its associated mechanical support panel or grids.

TABLE II

Item	Aluminum equivalent (millimeters)
Front panel(s) of cassette holder (total of all)	1.0
Front panel(s) of film changer (total of all)	1.0
Stationary tabletop	1.0
Moveable tabletop (including stationary subtop)	1.5
Cradle	2.0

(o) *Battery charge indicator.* On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

§ 1020.31 Radiographic equipment.

The provisions of this section apply to equipment for the recording of images, except those involving use of an image intensifier.

(a) *Control and indication of technique factors*—(1) *visual indication.* The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(2) *Timers.* Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(ii) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) *Automatic exposure controls.* When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in subdivision (iii) of this subparagraph, and manual resetting shall be required before further automatically timed exposures can be made.

(4) *Accuracy.* Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with § 1020.30(h)(3).

(b) *Reproducibility.* The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3):

(1) *Coefficient of variation.* For any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05.

(2) *Measuring compliance.* Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. 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. In the case of automatic exposure controls, compliance shall be determined with the attenuation block placed in the primary beam, and the technique factors shall be such as 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.

(c) *Linearity.* The following requirement applies when the equipment allows a choice of x-ray tube current settings and is operated on a power supply as

* In the case of a system which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlock with the kilovoltage selector which will prevent x-ray emission if the minimum required filtration is not in place.

specified by the manufacturer in accordance with the requirements of § 1020.30 (h) (3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) *Average exposure ratios.* The average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is:

$|\bar{X}_1-\bar{X}_2| \leq 0.10\ (\bar{X}_1+\bar{X}_2)$; where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of two consecutive tube current settings.

(2) *Measuring compliance.* Determination of compliance will be based on 10 exposures at each of two consecutive x-ray tube current settings made within 1 hour. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors. Where tube current selection is continuous, $\bar{X}_1$ and $\bar{X}_2$ shall be obtained at current settings differing by no greater than a factor of 2.

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

(1) *Variable x-ray field limitation.* There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 by 5 centimeters.

(2) *Visual definition.* (i) Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 millimeter.

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

(1) *Field indication and alignment.* (i) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(ii) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(iii) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within 2 percent of the SID when the beam axis is perpendicular to the plane of the image receptor; and

(iv) Compliance measurements will be made at discrete SID's and image receptor dimensions in common clinical use (such as SID's of 36, 40, 48, and 72 inches and nominal image receptor dimensions of 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

(2) *Positive beam limitation.* (i) Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within 5 seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than 5 seconds or is manual, will prevent production of x rays until such adjustment is completed. At SID's at which the device is not intended to operate, the device shall prevent the production of x rays.

(ii) The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than 3 percent of the SID and that the sum of the length and width differences without regard to sign be no greater than 4 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

(iii) The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of 100 centimeters shall be equal to or less than 5 by 5 centimeters. Return to positive beam limitation as defined in subdivisions (i) and (ii) of this subparagraph shall occur upon a change in image receptor.

(iv) Positive beam limitation may be bypassed when radiography is conducted which does not use the cassette tray or permanently mounted vertical cassette holder, or when either the beam axis or table angulation is not within 10° of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation shall be automatic.

(v) A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key shall be required to override the positive mode. It shall be impossible to remove the key while the positive mode is overriden.

(f) *Field limitation on radiographic x-ray equipment other than general purpose radiographic systems*—(1) *Equipment for use with intraoral image receptors.* Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and

(ii) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(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.

(3) *Other x-ray systems.* Radiographic systems not specifically covered in paragraphs (d), (e), of this section, subparagraph (2) of this paragraph and paragraph (g) of this section, and systems covered in subparagraph (1) of this paragraph which are designed for use with extraoral as well as intraoral image receptors 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 recep-

tor to within 2 percent of the SID. 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.

(g) *Field limitation and alignment for spot-film devices.* When a spot-film device is used, the following requirements shall apply:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.

(2) The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, shall not exceed 3 percent of the SID. The sum without regard to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percent of the SID.

(3) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters.

(4) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

(h) *Source-skin distance.* (1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(i) Eighteen centimeters if operable above 50 kilovolts peak, or

(ii) Ten centimeters if not operable above 50 kilovolts peak.

(2) Mobile or portable x-ray systems other than dental shall be provided with means to limit source-to-skin distance to not less than 30 centimeters.

(i) *Beam-on indicators.* The x-ray control shall provide visual indication whenever x rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(j) *Multiple tubes.* Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(k) *Standby radiation from capacitor energy storage equipment.* Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The response time of the (radiation measuring) instrument system shall be no less than 3 and no greater than 20 seconds.

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopy and for the recording of images through an image intensifier.

(a) *Primary protective barrier*—(1) *Limitation of useful beam.* The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID. The fluoroscopic tube shall not produce x rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) *Measuring compliance.* The entrance exposure rate shall be measured in accordance with paragraph (d) of this section. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*—(1) *Nonimage-intensified fluoroscopy.* The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size at the greatest SID shall be equal to or less than 5 by 5 centimeters.

(2) *Image-intensified fluoroscopy.* For image-intensified fluoroscopic equipment the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the image receptor along any dimension of the visually defined field in the plane of the image receptor shall not exceed 3 percent of the SID. The sum, without regard to sign, of the misalignment along any two orthogonal dimensions intersecting at the center of the visible area of the image receptor shall not exceed 4 percent of the SID. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters.

(c) *Activation of tube.* X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(d) *Entrance exposure rate limits*—(1) *Equipment with automatic exposure rate control.* Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(2) *Equipment without automatic exposure rate control.* Fluoroscopic equip-

ment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high level control is activated.

Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be provided to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(3) *Measuring compliance.* Compliance with this paragraph (d) shall be determined as follows:

(i) If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.

(ii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iii) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(e) *Indication of potential and current.* During fluoroscopy and cinefluorography x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer in accordance with § 1020.30(h)(3).

(f) *Source-skin distance.* Means shall be provided to limit the source-skin distance to not less than 38 centimeters on stationary fluoroscopes and to not less than 30 centimeters on mobile fluoroscopes. In addition, for image-intensified fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 centimeters. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in § 1020.30(h).

(g) *Fluoroscopic timer.* Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x rays are produced until the timing device is reset.

(h) *Mobile fluoroscopes.* In addition to the foregoing requirements of this section, mobile fluoroscopes shall provide intensified imaging.

PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

§ 1030.10 Microwave ovens.

(a) *Applicability.* The provisions of this standard are applicable to microwave ovens manufactured after October 6, 1971.

(b) *Definitions.* (1) "Microwave oven" means a device designed to heat, cook, or dry food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal ISM heating bands ranging from 890 megahertz to 6,000 megahertz. As defined in this standard, "microwave ovens" are limited to those manufactured for use in homes, restaurants, food vending, or service establishments, on interstate carriers, and in similar facilities.

(2) "Cavity" means that portion of the microwave oven in which food may be heated, cooked, or dried.

(3) "Door" means the movable barrier which prevents access to the cavity during operation and whose function is to prevent emission of microwave energy from the passage or opening which provides access to the cavity.

(4) "Safety interlock" means a device or system of devices which is intended to prevent generation of microwave energy when access to the cavity is possible.

(5) "Service adjustments or service procedures" mean those servicing methods prescribed by the manufacturer for a specific product model.

(6) "Stirrer" means that feature of a microwave oven which is intended to provide uniform heating of the load by constantly changing the standing wave pattern within the cavity or moving the load.

(7) "External surface" means the outside surface of the cabinet or enclosure provided by the manufacturer as part of the microwave oven, including doors, door handles, latches, and control knobs.

(c) *Requirements*—(1) *Power density limit.* The power density of the microwave radiation emitted by a microwave oven shall not exceed one (1) milliwatt per square centimeter at any point 5 centimeters or more from the external surface of the oven, measured prior to acquisition by a purchaser, and thereafter, 5 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven.

(2) *Door and safety interlocks.* (i) Microwave ovens shall have a minimum of two operative safety interlocks one of which must be concealed. A concealed safety interlock on a fully assembled microwave oven must not be operable by (*a*) any part of the body, or (*b*) a rod 3 millimeters or greater in diameter and with a useful length of 10 centimeters. A magnetically operated interlock is considered to be concealed only if a test magnet, held in place on the oven by gravity or its own attraction, cannot operate the safety interlock. The test magnet shall have a pull at zero air gap of at least 4.5 kilograms and a pull at 1 centimeter air gap of at least 450 grams when the face of the magnet which is toward the interlock switch when the magnet is in the test position is pulling against one of the large faces of a mild steel armature having dimensions of 80 millimeters by 50 millimeters by 8 millimeters.

(ii) Failure of any single mechanical or electrical component of the microwave oven shall not cause all safety interlocks to be inoperative.

(iii) Service adjustments or service procedures on the microwave oven shall not cause the safety interlocks to become inoperative or the microwave radiation emission to exceed the power density limits of this section as a result of such service adjustments or procedures.

(iv) Insertion of an object into the oven cavity through any opening while the door is closed shall not cause microwave radiation emission from the oven to exceed the applicable power density limits specified in this section.

(v) One (the primary) required safety interlock shall prevent microwave radiation emission in excess of the requirement of paragraph (c)(1) of this section; the other (secondary) required safety interlock shall prevent microwave radiation emission in excess of 5 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven. The two required safety interlocks shall be designated as primary or secondary in the service instructions for the oven.

(vi) A means of monitoring one or both of the required safety interlocks shall be provided which shall cause the oven to become inoperable and remain so until repaired if the required safety interlock(s) should fail to perform required functions as specified in this section. Interlock failures shall not disrupt the monitoring function.

(3) *Measurements and test conditions.* (i) Compliance with the power density limits in this paragraph shall be determined by measurements of microwave power density made with an instrument system which (*a*) reaches 90 percent of its steady-state reading within 3 seconds when the system is subjected to a stepped input signal and which (*b*) has a radiation detector with an effective aperture of 25 square centimeters or less as measured in a plane wave, said aperture having no dimension exceeding 10 centimeters. This aperture shall be determined at the fundamental frequency of the oven being tested for compliance. The instrument system shall be capable of measuring the power density limits of this section with an accuracy of plus 25 percent and minus 20 percent (plus or minus 1 decibel).

(ii) Microwave ovens shall be in compliance with the power density limits if the maximum reading obtained at the location of greatest microwave radiation emission does not exceed the limits specified in this paragraph when the emis-

sion is measured through at least one stirrer cycle. Pursuant to § 1010.13 of this chapter, manufacturers may request alternative test procedures if, as a result of the stirrer characteristics of a microwave oven, such oven is not susceptible to testing by the procedures described in this subdivision.

(iii) Measurements shall be made with the microwave oven operating at its maximum output and containing a load of 275±15 milliliters of tap water initially at 20°±5° centigrade placed within the cavity at the center of the load-carrying surface provided by the manufacturer. The water container shall be a low form 600-milliliter beaker having an inside diameter of approximately 8.5 centimeters and made of an electrically nonconductive material such as glass or plastic.

(iv) Measurements shall be made with the door fully closed as well as with the door fixed in any other position which allows the oven to operate.

(4) *Instructions.* Manufacturers of microwave ovens to which this section is applicable shall provide or cause to be provided:

(i) To servicing dealers and distributors and to others upon request, for each oven model, adequate instructions for service adjustments and service procedures including clear warnings of precautions to be taken to avoid possible exposure to microwave radiation;

(ii) With each oven, adequate instructions for its safe use including clear warnings of precautions to be taken to avoid possible exposure to microwave radiation.

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

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