Region VIII—Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming: Room 311, 909 17th Street, Denver, Colo. 80202, Regional Flood Insurance Staff, 303-837-5041.

Region IX—Arizona, California, Hawaii, and Nevada: 450 Golden Gate Avenue, P.O. Box 36006, San Francisco, Calif. 94102, Regional Flood Insurance Staff, 415-556-3543.

Region X—Alaska, Idaho, Oregon, and Washington: Arcade Plaza Building, Room 3068, 1321 Second Avenue, Seattle, Wash. 98101, Regional Flood Insurance Staff, 206-442-1026.

Guidelines for the Mandatory Purchase of Flood Insurance are discussed in the Environmental Impact Statement issued by the Department on September 9, 1976, in connection with the Revised Flood Plain Management Regulations of the National Flood Insurance Program.

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

Issued at Washington, D.C., February 3, 1978.

PATRICIA ROBERTS HARRIS,
Secretary, Housing and Urban Development.

[FR Doc. 78-4265 Filed 2-16-78; 8:45 am]

FRIDAY, FEBRUARY 17, 1978
PART V

ENVIRONMENTAL PROTECTION AGENCY

POLYCHLORINATED BIPHENYLS (PCBs)

Disposal and Marking

federal register

[6560-01]

Title 40—Protection of Environment

[FRL 838-5]

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER R—TOXIC SUBSTANCES CONTROL ACT

PART 761—POLYCHLORINATED BIPHENYLS (PCB's)

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: These regulations prescribe disposal and marking requirements for polychlorinated biphenyls (PCB's), and are promulgated pursuant to section 6(e)(1) of the Toxic Substances Control Act (Pub. L. 94-469). The intent of these regulations is to protect the environment from further contamination by PCB's resulting from improper handling and disposal of PCB's.

IMPLEMENTATION: Section 6(e)(1) of the Toxic Substances Control Act (Pub. L. 94-469) (hereinafter referred to as TSCA) required the promulgation of rules prescribing marking and disposal requirements for PCB's by July 1, 1977. Due to the delay in proposing these rules and the requirement to conduct adequate rulemaking proceedings, it was necessary to postpone the promulgation of the rules.

EFFECTIVE DATE: April 18, 1978.

FOR FURTHER INFORMATION CONTACT:

David Wagner, Office of Toxic Substances (TS-788), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-426-9000. Joni T. Repasch is the Record and Hearing Clerk for this rulemaking. The official record of rulemaking is located in Room 520 WSME, EPA Headquarters, 401 M Street SW., Washington, D.C. 20460, 202-755-1188. The record is available for viewing and copying from 9 a.m. to 4 p.m., Monday through Friday excluding holidays.

SUPPLEMENTARY INFORMATION: On May 24, 1977, the Office of Toxic Substances of the Environmental Protection Agency published in the FEDERAL REGISTER (42 FR 26564-26577) a proposed rule which prescribed disposal and marking requirements for PCB's. The informal hearings required under section 6(c)(2) and 6(e)(4) of TSCA for this proposed rule were held on June 24, 27, 28, and 29, 1977. Over 100 comments and reply comments were received during the rulemaking.

The preamble to the proposed regulations included a description of the legal authority, background of the PCB problem, definitions, description of persons affected by the regulation, a discussion of the methods of disposal and marking, and a summary of the economic consequences of the proposed regulation. The description of the legal authority, background of the PCB problem, and summary of economic consequences are incorporated here by reference.

A support document titled, "PCB Marking and Disposal Regulations, Final Action—Support Document," is available from Ms. Joni T. Repasch at the address stated above. The support document contains an evaluation of the comments received in the rulemaking proceeding and explains in detail the reasons for the EPA's modifications to the proposed regulation. Reprints of this FEDERAL REGISTER Notice are available from the Industry Assistance Office, 800-424-9065.

DISCUSSION OF THE RULE

DEFINITIONS

"Disposal" is defined very broadly to include any action that may be related to the ultimate disposition of a PCB substance, article, or mixture. An accidental or intentional release of PCB chemical substances or mixtures to the environment, including spills, is considered to be an act of disposal. Under this regulation, proper disposal of material contaminated as a result of a spill must be performed. This regulation does not preempt the provisions of the Federal Water Pollution Control Act (FWPCA) (Pub. L. 92-500) governing spills.

The definitions of "Administrator", "Agency", "chemical substance", "distribute in commerce", "manufacture", and "process" are identical to the definitions of these terms in TSCA.

"PCB chemical substances" are defined as chemical substances containing only a biphenyl molecule that has been chlorinated to varying degrees. This definition is the basic building block for defining other forms of PCB's. Any modification other than chlorination to a biphenyl molecule is sufficient to remove it from classification as a PCB.

"PCB mixtures" are defined to mean mixtures, including sludges from municipal and other sewage treatment facilities, that contain 0.05 percent or greater of PCB chemical substances (on a dry weight basis). The definition for PCB mixtures covers mixtures found in both commercial applications and waste materials.

"PCB article" includes any manufactured item, other than PCB containers, whose surfaces have been in direct contact with PCB chemical substances or PCB mixtures. The definition includes commercial products, such as electrical capacitors and transformers, that have liquid PCB chemical substances and PCB mixtures contained within their internal mechanisms as a functioning part of the electrical device. Other examples of PCB articles are piping, pumps, radiators, and other components of heat transfer systems, as well as electric motors, that use PCB chemical substances and PCB mixtures as an internal coolant.

"PCB container" means any package, can, bottle, bag, barrel, drum, tank, box, or other device used to contain PCB chemical substances, PCB mixtures, or leaking PCB articles. The definition is meant to cover containers where PCB chemical substances or PCB mixtures are, or have been, in direct contact with their internal or external surfaces but where the PCB chemical substances or mixtures are, or were not performing any function.

"PCB article container" means any package, can, bottle, bag, barrel, drum, tank, box, or other device used to contain PCB articles. This includes containers used to package or protect PCB articles that are intact and not releasing PCB chemical substances or mixtures. Thus, PCB article containers do not have PCB substances or mixtures on their surfaces, and, when a PCB article is removed from a PCB article container, the container no longer requires special marking, handling, or disposal. Buildings are not considered to be article containers.

"PCB equipment" means manufactured items, other than a PCB container or a PCB article container, that contain PCB articles. PCB equipment would contain PCB articles only because the articles were performing a function in the equipment. Examples of PCB equipment are television sets, microwave ovens, high intensity light fixtures, and fluorescent light fixtures that use a PCB article such as a capacitor containing PCB's.

The phrases "PCB" and "PCBs" mean one or more of the following: "PCB chemical substance", "PCB mixture", "PCB article", "PCB container", and "PCB equipment." This definition is included to provide an abbreviated reference to all forms of PCBs.

"Transport vehicles" includes motor vehicles or railcars used to transport cargo. If this cargo contains PCB's as defined in these regulations, then special marking requirements apply. However, the marking or labeling requirements apply only when PCBs are being carried on a transport vehicle as cargo.

DISPOSAL AND MARKING REQUIREMENTS

The regulation applies to all persons who manufacture, process, distribute in commerce, use, or dispose of PCBs, including local, State, and Federal governments.

High temperature incineration is required for all PCB liquids, PCBs drained from transformers, and large

high and low voltage capacitors. Transformers drained of PCBs, dredge spoils, municipal sewage sludge, and materials contaminated by spills are required to be disposed of either in an incinerator or in a chemical waste landfill. Large high and low voltage capacitors may be placed in a chemical waste landfill until January 1, 1980.

Storage of PCB's and PCB articles prior to disposal is allowed under specified conditions in special facilities that provide a margin of safety against release of PCBs to the environment. Capacitors can be stored next to, but are not required to be inside of, a special storage facility until January 1, 1983. This latter type of storage is allowed in order to reduce storage facility costs and, at the same time, have contained storage facility immediately available should a leak develop.

Small capacitors in home appliances and fluorescent light ballasts may be disposed of as municipal solid waste. However, small capacitors owned by capacitor and equipment manufacturers and acquired in the course of such manufacturing, which are being disposed of, must be incinerated or landfilled just like large capacitors.

All containers of PCB liquids, not-in-service PCB transformers, and not-in-service large high voltage capacitors are required to be labeled by July 1, 1978. All transport vehicles carrying PCBs are required to be labeled beginning October 1, 1978. All in-service transformers, in-service large high voltage capacitors, and new equipment with small PCB capacitors are required to be labeled by January 1, 1979.

All newly manufactured non-PCB large low voltage capacitors, small alternating current capacitors, and fluorescent light ballasts are to be labeled, "No PCBs" beginning July 1, 1978.

PCB incineration, chemical waste landfill, and storage facility specifications are provided. The EPA Regional Administrators must approve all incinerator and chemical waste landfill sites before they can be used for PCB disposal and can waive any particular condition imposed on an incinerator or landfill if they find that waiving that condition will not result in the incinerator or landfill posing any additional risk of injury to health or the environment. They may also waive the incineration method totally in favor of another method that provides PCB destruction of equal efficiency.

In addition, EPA Regional Administrators may waive incineration requirements for PCB articles other than capacitors on the basis of technological infeasibility, and instead allow disposal of such articles in a chemical waste landfill.

EPA Regional Administrators are granted authority to approve types of disposal other than incineration or landfill for dredge spoils and municipal sewage treatment sludges upon a showing that incineration or landfilling is not feasible and that an alternate method will provide adequate protection to health and the environment.

Decontamination procedures, marking formats, and recordkeeping and monitoring procedures are provided in the form of Annexes attached to these regulations.

RULE MODIFICATIONS

An explanation of EPA's modifications to the proposed regulation is set forth below. Only those modifications that resulted in substantive changes to the definitions or requirements are explained.

CHANGES IN § 761.2 DEFINITIONS

Section 761.2(v) of both the proposed rule and the final rule define "PCB mixture" to mean any mixture with 500 parts per million (ppm) of PCB.

The Agency is aware that adverse health and environmental effects can result from exposure to PCB's at levels lower than 500 ppm; however, at this time the Agency is not establishing a level based on health effects or environmental contamination but rather a level at which regulated disposal of most PCB's can be implemented as soon as possible. The 500 ppm PCB concentration was selected in the proposed regulation because it appeared to include those commerical products which are generally called PCB's and those contaminated as the result of the deliberate introduction of PCB's and to exclude other widely used commercial products which may contain lower levels of PCB's as a result of the manufacturing process or exposure to the general environment containing PCB's. The Agency was concerned about inadvertently controlling disposal of mixtures where there was insufficient information about the regulatory impact on commercial products.

In the period between proposal and promulgation, the Agency has obtained more information bearing on the definition of PCB mixture. The impact on commerical products of defining lower levels of contamination as "PCB Mixtures" appears less than first believed. Futhermore, disposal criteria for lower level PCB's such as PCB contaminated dredge spoils, sludges, waste oils, and spill materials appear necessary in order to reduce additional environmental contamination. Since most of this information was not included in the record of the proposed marking and disposal regulations and did not become a significant issue in the informal hearing, the definition of PCB mixture cannot be changed to a lower concentration level until the Agency first proposes the lower concentration definition. As a consequence, the 500 ppm level definition for a PCB mixture, as proposed, is included in this final rulemaking. However, the Agency plans to propose a lower concentration of PCB's, possibly in the range of 50 ppm or below, to define PCB mixture in the forthcoming PCB manufacturing, processing, use and distribution regulations. At the same time, the Agency anticipates that some variations in the disposal requirements will be proposed for PCB's at these lower levels. These proposed regulations will appear shortly in the FEDERAL REGISTER, and informal hearings on all of these proposals will be held simultaneously.

It should be noted that the regulations promulgated today do not preempt more stringent requirements that may be placed in dredging permits and in other regulatory tools employed by EPA in controlling the release of PCB's. In particular, if there is a risk that materials such as dredge spoils or sewage sludge will be deposited in water or where they can be carried into water, stricter controls than specified in these regulations may be appropriate. Water has been the most significant pathway for PCB contamination, and serious environmental damage can be expected to result from the deposit in or near water of material containing PCB's even in low concentrations. This is particularly true for dredge spoils and sewage sludge, given the huge quantities of these materials that may be generated.

EPA Regional Offices making decisions on permits for dredge and fill disposal under section 404 of the Federal Water Pollution Control Act and issuing discharge permits under the FWPCA or dumping permits under the Marine Protection, Research and Sanctuaries Act of 1972 or exercising any other relevant authority, will be expected to take such factors into account and to regulate PCB's at levels below 500 parts per million under that order authority, wherever appropriate.

CHANGES IN § 761.10 DISPOSAL OF PCB'S

A new section 761.10(b)(3) has been added to the final rule to allow the use of chemical waste landfills for disposal of soil and debris contaminated with PCB's as a result of a spill or from placement of PCB's in a disposal site prior to the effective date of these regulations. Under the proposed rules, incineration would have been required. This change was made to permit the use of a more practical disposal method for the large volumes of soil and debris, such as trash, trees, lumber, and other rubbish, that may be involved in a spill clean-up operation or in removal or excavation of materials from an old disposal site,

such as a pit, pond lagoon, dump, or landfill. This provision does not apply to PCB liquids, slurries, industrial sludges, damaged PCB articles, or any production wastes related to PCB processing or manufacturing; such items must be disposed of in accordance with section 761.10(b) (1) or (2).

Section 761.10(c)(1) of the proposed regulation required that all transformers be drained and flushed prior to disposal so that no more than two percent of the dielectric fluid remained, or in other words, that all transformers be drained of 98 percent of their total PCB's. In the final regulation, section 761.10(c)(1) has been modified to require that, prior to disposal, a transformer be drained of all free-flowing liquid, filled with solvent, and drained out after at least 18 hours. A number of hearing witnesses challenged the technical feasibility of the 98 percent draining requirement. In addition, whether anyone could realistically determine that 98 percent of the liquid had been removed was questioned. EPA believes these objections are correct and therefore has modified the requirement.

Section 761.10(c)(2)(iii) of the proposed regulation required that any PCB capacitor which is separated from PCB equipment should be disposed of in an incinerator complying with Annex I, or until July 1, 1979, in a chemical waste landfill complying with Annex II. Numerous comments from industry urged that disposal of all small capacitors without special precautions be allowed indefinitely in view of the practical difficulties involved in their disposal and the relatively small amounts of PCB's contained in each individual capacitor. The three major problems relating to the regulation of small capacitors are (1) the practical difficulties of enforcement, (2) the expense of collecting a large number of small capacitors and concentrating them for disposal and (3) deciding who will pay for the cost of disposal. In view of these problems, EPA has eliminated special disposal requirements for all classes of small capacitors (except those owned by capacitor manufacturers or PCB article manufacturers as a result of manufacturing activities). EPA believes, however, that the problems cited above do not apply to the disposal of capacitors owned by capacitor manufacturers and PCB article manufacturers and has, therefore, retained disposal requirements for such capacitors. This provision only requires incineration of capacitors which the manufacturer has already decided to dispose of in some way, such as capacitors rejected for failure to meet quality control standards.

An estimated 180 million pounds of PCB's are associated with small PCB capacitors currently in use. EPA intends to try, during the next year, to identify viable alternatives for adequate disposal of small capacitors. Initially, alternatives will be sought through public meetings with the disposal industry, the waste collection industry, consumer groups, the public utilities, and other interested parties.

Since provisions for disposal of most small capacitors have been eliminated, requirements relating to their storage prior to disposal are unnecessary. Therefore, section 761.42(c), stipulating storage conditions for small capacitors, has been deleted.

The proposed regulation required incineration of large high voltage and low voltage capacitors after July 1, 1979. This disposal requirement was disputed in the rulemaking. Many commentors favored continued use of chemical waste landfills indefinitely. A properly operated chemical waste landfill is an appropriate type of disposal facility for many hazardous waste materials. However, incineration is the only currently available means of destroying the PCBs and thus ensuring their permanent removal from the environment. Furthermore, based on tests carried out by TRW Systems and Rollins Environmental Services, Inc., and based on the opinions received from several power industry representatives, EPA has concluded that it is technically and economically feasible to incinerate large capacitors. Because there is a likelihood of delay in having sufficient incineration capacity available, storage of large capacitors is permitted until January 1, 1984.

A new § 761.10(b)(3) has been added to the final rule to authorize EPA Regional Administrators to permit disposal of municipal sewage treatment sludge, as well as dredge spoils, by a means other than incineration or chemical waste landfill, provided such disposal does not present an unreasonable risk of injury to health and the environment. Likewise, a new § 761.10(c)(3) has been added to allow Regional Administrators to grant exemptions from the incineration requirements for PCB articles on a case-by-case basis upon a showing that incineration is not technologically feasible. These changes respond to comments that the proposed disposal requirements lacked necessary flexibility and would be impossible to comply with where unusually shaped articles or very large quantities of material contaminated at a low level with PCBs were concerned.

Finally, special disposal requirements for PCB equipment have been eliminated, since they no longer serve any purpose. Because small PCB capacitors are no longer subject to special disposal requirements, there is no need to include special provisions for disposal of equipment containing them, while transformers, large PCB capacitors, and other PCB articles must be removed from the equipment and disposed of separately in any case.

CHANGES IN § 761.20 MARKING

Section 761.20(a)(1) of the proposed regulation required that all PCB articles manufactured after January 1, 1978, be marked at the time of manufacture with the mark M_L as described in Annex V. The final regulation has been modified regarding the specific articles to be marked at the time of manufacture. Section 761.20(a)(1) (ii) and (iii) of the final regulation requires that each PCB large high voltage capacitor and each transformer manufactured after July 1, 1978, be marked at the time of manufacture with the mark M_L as described in Annex V. Other articles, such as small capacitors and large low voltage capacitors, will not have to be marked M_L at the time of manufacture, although large low voltage capacitors will have to be marked at the time of removal from use.

Small capacitors, large low voltage capacitors, and fluorescent light ballasts which do not contain PCBs will be required, under § 761.20(a)(6), to be marked with a label indicating that fact. This provision requires that each large low voltage capacitor, small capacitor, or fluorescent light ballast manufactured during the twenty years between July 1, 1978 and July 1, 1998, which does not contain PCB's be marked "No PCB's". This marking requirement will assist disposers in distinguishing the large numbers of large low voltage capacitors, small alternating current type capacitors, and fluorescent light ballasts currently in use, practically all of which contain PCB's, from like items produced in the future, most of which will not contain PCB's.

In the proposed regulation, § 761.20(a)(2) required that PCB equipment manufactured after January 1, 1978, be marked at the time of manufacture with the mark M_L. The final regulation requires that after July 1, 1978, equipment containing a PCB transformer or a PCB large high voltage capacitor be marked at the time of manufacture with the mark M_L, (see § 761.20(a)(1)(iv)) and that after January 1, 1979, equipment containing PCB small capacitors be marked with the statement, "This equipment contains PCB capacitor(s)" (see § 761.20(a)(4)). This latter marking requirement has been retained despite the elimination of all disposal requirements for such equipment in order to discourage massive stockpiling of PCB articles and incorporation of the items in equipment indefinitely into the future.

The provision regarding marking of PCB equipment in inventory has been modified. Proposed § 761.20(a)(4) re-

quired each PCB article, except small PCB capacitors, contained in PCB equipment in inventory after January 1, 1978, to be marked with the mark M_L before being distributed in commerce. The final regulation provides in § 761.20(a)(1)(iv) that equipment containing a PCB transformer or a PCB large high voltage capacitor must be marked after July 1, 1978, with the mark M_L before distribution in commerce. Equipment in inventory containing large low voltage capacitors as well as other equipment containing PCB articles will not have to be marked with the mark M_L as EPA had proposed.

Note that § 761.20(a)(1) (ii) and (iii) of the final regulation requires that transformers and large high voltage capacitors not included in equipment also be marked before distribution in commerce.

The requirement for marking PCB items removed from use has been modified. Section 761.20(a)(7) of the proposed regulation required that all PCB articles removed from use after January 1, 1978, be marked with the mark M_L or placed in a PCB container marked with the mark M_L, except for small PCB capacitors disposed of as municipal solid waste.

Section 761.20(a)(1) (ii), (iii), (iv), and (v) of the final regulation requires that only transformers, PCB large high and low voltage capacitors, or equipment containing a PCB transformer or large high or large low voltage capacitor when removed from use after July 1, 1978, shall at the time of removal be marked with the mark M_L.

Section 761.20(b)(2) of the proposed regulation has been deleted. This provision required that each PCB large low voltage capacitor and each PCB HID capacitor in use after March 31, 1978, be marked with the mark M_L as soon as the capacitor is available for marking as the result of direct access to the equipment for servicing. The deletion of this provision means that marking of HID capacitors and large low voltage capacitors during normal servicing operations will not be required. Many commenters argued that, where HID capacitors were concerned, this procedure would result in the marking of very few capacitors, would impose a substantial risk of electric shock, and would be much more expensive than the EPA had estimated.

A great many commenters objected to proposed § 761.20(b)(1) as requiring a utility truck to be labelled whenever it carried a few large high voltage capacitors. As explained at the hearing, this is not a correct reading. The intent was to require labelling whenever the truck carries PCB mixtures or chemical substances that are not part of any PCB article or when it carries a transformer. Labelling when capacitors are carried is not required.

With this understanding, the proposed language has been included in the final regulation (see section 761.20(a)(2)).

CHANGES IN § 761.42 STORAGE FOR DISPOSAL

Section 761.42(c)(1) of the proposed regulation, requiring the storage of small capacitors in sound, non-leaking containers within a building, has been deleted. Since provisions for the disposal of small capacitors have been eliminated, requirements relating to storage prior to disposal are unnecessary.

A new § 761.42(c)(1) has been added to the final regulation, to permit non-leaking PCB articles and equipment to be stored in a temporary storage area up to 30 days. Thus, for a period up to thirty days, non-leaking PCB articles, PCB equipment, and PCB containers may be placed in a temporary storage area, instead of in the roofed and diked enclosure with an impermeable floor specified in § 761.42(b) of the final regulation.

A new § 761.42(c)(2) has been added to the final regulation. This subsection provides that until January 1, 1983, non-leaking and structurally undamaged PCB-containing large high voltage capacitors may be stored on pallets next to a storage facility meeting the requirements of Annex III. This section also requires that capacitors so stored be checked weekly. This provision therefore permits an alternative means of storing non-leaking, structurally undamaged PCB large high voltage capacitors to that specified in § 761.42(b).

Section 761.42(c)(2) will permit low-cost storage of any temporary excess of PCB large capacitors caused by delays in constructing incineration facilities. A number of utility industry spokesmen had argued that the proposed requirement was costly and overly burdensome for storing structurally undamaged large capacitors. The agency agrees.

SECTION 761.44 CHANGES IN MARKING FORMATS

The marking format required under § 761.44 of the proposed regulation provided that the U.S. Coast Guard National Response Center be contacted in the case of an accident or spill. The label format, as provided in § 761.44 of the final regulation, has been revised to include a space for the identification of the owner of the transformers or capacitors and the owner's telephone number, in addition to the Coast Guard emergency number. Thus, in the event of a spill, the owner of the equipment as well as the U.S. Coast Guard could be contacted. Numerous utilities and other industries suggested that their own telephone numbers be placed on the marking label as the contact in case of a spill. EPA believes such an addition to the label would improve responses to spills, and hence that suggestion has been accepted. In addition, the color, yellow, has been included as an alternate background for the label formats because in certain industrial situations, that color is more visible than the white background provided for.

SECTION 761.45 CHANGES IN RECORDS AND MONITORING

Section 761.45(a) was modified in order to make clear that records on the disposition of PCBs will have to be maintained by each owner or operator of a facility containing at least 45 kilograms of PCB chemical substance or PCB mixture, or one or more PCB transformers or 50 or more large capacitors. Proposed § 761.45(a) did not include the words "at least," nor did it cover facilities containing PCB transformers.

Some comments by PCB users suggested that the proposed regulation would have required them to determine the exact amount of PCBs in each of their capacitors and transformers, and to keep an exact record of where each capacitor and transformer was located. In fact, the regulation, both as proposed and promulgated, only requires such records for "facilities" which contain transformers or large number of PCB capacitors, and does not require any estimate of the amounts of PCBs in capacitors.

STATE EXEMPTIONS

Officials of the State of Michigan appeared at the legislative hearing and urged that any Federal action leave intact their State program regarding the marking and disposal of PCB's. Oregon, Indiana, Minnesota and Wisconsin have also enacted similar State requirements affecting the marking and disposal of PCB's.

EPA has determined that under TSCA, State requirements regarding disposal of PCB's are completely exempt from Federal preemption insofar as they prescribed what may be done within the State boundaries, but that a State may not require PCB's generated within its boundaries to be disposed of in a method less restrictive than prescribed by these regulations. In other words, a State may forbid the burning of PCB articles within its boundaries, but it may not require disposal in a chemical waste landfill where EPA's rules require the articles to be incinerated, outside the State if necessary. (This determination is expanded upon in the Support Document.) However, because State marking requirements are specifically preempted under section 18(a) of TSCA, except when EPA grants an exemption under section 18(b) by rule, EPA has determined that such requirements

are preempted by implication for purposes of section 6(e) and these regulations.

ECONOMIC CONSEQUENCES OF RULE MODIFICATIONS

The major economic impact of EPA's modifications to the proposed rule will apply to utilities owning and using PCB-containing large high voltage capacitors, owners and users of high intensity discharge (HID) lighting capacitors, PCB small capacitors, PCB large low voltage capacitors, or equipment containing such capacitors, manufactures of equipment containing PCB articles (such as microwave oven manufacturers), and manufacturers of large low voltage capacitors, small capacitors and fluorescent light ballasts.

Utilities should incur approximately $1.4 million less storage costs per year than previously estimated by EPA as a result of the addition of § 761.42(c)(2) of Annex III "Storage for Disposal". That paragraph provides for the storage of non-leaking and structurally undamaged PCB-containing large high voltage capacitors on pallets next to an approved storage facility. This provision substantially reduces both capital costs (incurred primarily in 1978) and the loss in economic revenues associated with the use of storage space.

Under the final rule, owners and users of HID capacitors will no longer be required to label such articles when they are removed from equipment. The proposed rule was further modified to eliminate any disposal requirement for HID capacitors. These changes to the proposed rule should reduce the impact on the affected owners by at least $3.8 million in 1978, with the annual "savings" decreasing approximately seven percent each year thereafter.

The addition of § 761.20(a)(6) to the final rule, which provides that at the time of manufacture each large low voltage capacitor, fluorescent light ballast, and small capacitor that does not contain PCB's be marked with a label stating, "No PCB," should result in increased total manufacturing costs of approximately $25,000 per year for each of 20 years.

Manufactures of PCB equipment should save approximately $100,000 in 1978 because EPA has moved back the effective date for marking PCB equipment from January 1, 1978 to January 1, 1979. This estimate is based on the assumption that no PCB capacitors will be maufactured after the first half of 1978.

The modification to § 761.10(c)(1), which now permits the user of a transformer who intends to dispose of it in a chemical waste landfill simply to drain the PCB mixture, fill it with solvent, and then redrain (instead of being required to achieve 98 percent removal of PCB's), will result in some undetermined cost savings associated with testing transformers.

Finally, the modification to § 761.10(c)(3), which permits PCB articles other than transformers and capacitors to be disposed of in chemical waste landfills until adequate and technically feasible incineration is available (compared to the incineration-only requirement in the proposed rule), should reduce disposal costs for a number of users of such articles. EPA is not able to quantify this reduction in disposal costs.

In summary, as a result of the modifications to the proposed rule, annual operating costs associated with compliance with the final rule will be reduced by at least $5.2 million from the $58.3 million associated with the proposed rule to $53.1 million for the twelve months ending May 30, 1979, and to $55.8 million for the following twelve months. Annual operating costs should decrease by seven percent each year thereafter.

OFFICIAL RECORD OF RULEMAKING—PCB MARKING AND DISPOSAL REGULATIONS

Section 19(a)(3) of TSCA defines the term "rulemaking record" for purposes of judicial review as follows:

> For purposes of this section, the term "rulemaking record" means:
>
> (A) The rule being reviewed under this section;
>
> (B) in the case of a rule under section 4(a), the finding required by such section, in the case of a rule under section 5(b)(4), the finding required by such section, in the case of a rule under section 6(a) the finding required by section 5(f) or 6(a), as the case may be, in the case of a rule under section 6(a), the statement required by section 6(c)(1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such section, as the case may be;
>
> (C) any transcript required to be made of oral presentations made in proceedings for the promulgation of such rule;
>
> (D) any written submission of interested parties respecting the promulgation of such rule; and
>
> (E) any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, in a notice published in the FEDERAL REGISTER.

In accordance with the requirements of section 19(a)(3)(E) quoted above, EPA is publishing the following list of documents constituting the record of this rulemaking. Public comments, the transcript of the rulemaking hearing, and submissions made at the rulemaking hearing and in connection with it are exempt from FEDERAL REGISTER listing under section 19(a)(3) and have not been listed. However, a full listing of these materials is available on request from the Record and Hearing Clerk.

DOCUMENTS

Proposed Regulation:

USEPA-OTS. Polychlorinated Biphenyls (PCBs) Marking and Disposal Requirements: Notice of Proposed Rulemaking.

Twelve Working drafts dated January 21, 1977 through May 17, 1977.

Final FR 26564, May 24, 1977. "Polychlorinated Biphenyls (PCBs), Toxic Substance Control."

Support Documents:

USEPA-OTS. PCB Marking and Disposal Regulations—Support Document—Toxic Substance Control—Polychlorinated Biphenyls (PCBs). Undated.

USEPA-OTS. Microeconomic Impact of the Proposed Marking and Disposal Regulations for PCBs. April 1977. EPA 560/6-77-013. PB 267833 VERSAR INC.

Publicly Announced Meetings or Hearings:

USEPA. Stenographic Transcript of Hearings in the Matter of Polychlorinated Biphenyls: Panel Discussion. December 20, 1976. Washington, D.C. together with documents submitted, agenda, and FEDERAL REGISTER Notices.

USEPA. Stenographic Transcript of Hearings in the Matter of: PCBs Public Hearing. Use, Labeling and Disposal of Polychlorinated Biphenyls. January 24, 1977. Washington, D.C. together with documents submitted, agenda, and FEDERAL REGISTER Notices.

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This Rule is issued under authority of section 6 of the Toxic Substances Control Act, 15 U.S.C. section 2605(e).

Dated: February 8, 1978.

DOUGLAS M. COSTLE,
Administrator.

A new 40 CFR Part 761 is established to read as follows:

Subpart A—General

Sec.
761.1 Applicability.
761.2 Definitions.

Subpart B—Disposal of PCB's

761.10 Disposal requirements.

Subpart C—Marking of PCB's

761.20 Marking requirements.

Subpart D—[Reserved]

Subpart E—List of Annexes

ANNEX NO. I

761.40 Incineration.

ANNEX NO. II

761.41 Chemical waste landfills.

ANNEX NO. III

761.42 Storage for disposal.

ANNEX NO. IV

761.43 Decontamination.

ANNEX NO. V

761.44 Marking formats.

ANNEX NO. VI

761.45 Records and monitoring.

AUTHORITY: Sec. 6, Toxic Substances Control Act, 15 U.S.C. 2605(e).

Subpart A—General

§ 761.1 Applicability.

(a) This subpart establishes procedures, methods, and other requirements for the disposal, storage, and marking of polychlorinated biphenyls (PCB's).

(b) This subpart applies to all persons who manufacture, process, distribute in commerce, use, or dispose of PCB's.

(c) The basic requirements of these regulations are set forth in Subpart B—Disposal of PCB's and Subpart C—Marking of PCB's. Subpart E elaborates on the requirements which are referred to in the disposal and marking sections. Definitions of terms used in all of these sections are found in Subpart A.

(d) Section 15 of the Toxic Substances Control Act (TSCA) states that failure to comply with these regulations is unlawful. Section 16 imposes liability for civil penalties upon any person who violates these regulations. Section 16 also subjects a person to criminal prosecution for a violation which is knowing or willful. In addition, section 17 authorizes Federal district courts to enjoin activities prohibited by these regulations, compel the taking of actions required by these regulations, and to issue orders to seize PCB's processed or distributed in violation of these regulations.

(e) These regulations do not preempt other more stringent Federal statutes and regulations.

§ 761.2 Definitions.

For the purpose of this part:

(a) "Administrator" means the Administrator of the Environmental Protection Agency, or any employee of the Agency to whom the Administrator may either herein or by order delegate his authority to carry out his functions, or any person who shall by operation of law be authorized to carry out such functions.

(b) "Agency" means the United States Environmental Protection Agency.

(c) "Capacitor" means a device for accumulating and holding a charge of electricity, consisting of conducting surfaces separated by a dielectric. Types of capacitors are as follows:

(1) "Small Capacitor" means a capacitor which contains less than 1.36 kg (3 lbs.) of dielectric fluid.

(2) "Large High Voltage Capacitor" means a capacitor which contains 1.36 kg (3 lbs.) or more of dielectric fluid and which operates at 2000 volts a.c. or above.

(3) "Large Low Voltage Capacitor" means a capacitor which contains 1.36 kg (3 lbs.) or more of dielectric fluid and which operates below 2000 volts A.C.

(d) (1) Except as provided in subparagraph (2) of this paragraph, the term "Chemical Substance" means any organic or inorganic substance of a particular molecular identity, including:

(i) Any combination of such substances occurring in whole or part as a result of a chemical reaction or occurring in nature, and

(ii) Any element or uncombined radical.

(2) Such term does not include:

(i) Any mixture,

(ii) Any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) Tobacco or any tobacco product,

(iv) Any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) Any article the sale of which is subject to the tax imposed by section 418 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provisions of such Code), and

(vi) Any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

(e) "Chemical Waste Landfill" means a landfill at which protection is provided from PCB's deposited therein against risk of injury to health or the environment by locating, engineering, and operating such landfill as specified in § 761.41 so as to prevent migration of PCB's to land, water, or the atmosphere.

(f) "Commerce" means trade, traffic, transportation, or other commerce

(1) Between a place in a State and any place outside of such State, or

(2) Which affects trade, traffic, transportation, or commerce described in subparagraph (1) of this paragraph.

(g) "Disposal" means to intentionally or accidentally discard, throw away, or otherwise complete or terminate the useful life of an object or substance. Disposal includes actions related to containing, transporting, destroying, degrading, decontaminating, or confining those substances, mixtures, or articles that are being disposed.

(h) "Distribute in Commerce" and "Distribution in Commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture means to sell or to transfer the ownership of the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(i) "Fluorescent Light Ballast" means a device which electrically controls fluorescent light fixtures and which includes a capacitor containing 0.1 kg or less of dielectric.

(j) "Incinerator" means any facility operated for disposal of PCBs by incineration.

(k) "Leak" or "leaking" means any instance in which a PCB article, PCB container, or PCB equipment has any PCB chemical substance or PCB mixture on any portion of its external surface.

(l) "Manufacture" means to produce, manufacture, or import into the customs territory of the United States.

(m) "Mark" means the descriptive name, instructions, cautions, or other information applied to chemical substances, mixtures, articles, containers, equipment, or other objects or activities described in these regulations.

(n) "Marked" means the marking of PCB's, PCB's storage areas and transport vehicles by means of applying a legible mark by painting, fixation of an adhesive label, or other method that meets the requirements of this regulation.

(o) "Mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

(p) "Municipal Solid Wastes" means garbage, refuse, sludges, wastes, and other discarded materials resulting from residential and non-industrial operations and activities.

(q) "PCB" and "PCB's" mean one or more of the following: "PCB Chemical Substance", "PCB Mixture", "PCB Article", "PCB Equipment", and "PCB Container."

(r) "PCB Article" means any manufactured item, other than a PCB container, whose surface(s) has been in direct contact with a PCB chemical substance or a PCB mixture, and includes capacitors, transformers, electric motors, pumps, and pipes.

(s) "PCB Article Container" means any package, can, bottle, bag, barrel, drum, tank or other device used to contain PCB articles or PCB equipment, and whose surface(s) has not been in direct contact with a PCB chemical substance or PCB mixture.

(t) "PCB Chemical Substance" means any chemical substance which is limited to the biphenyl molecule which has been chlorinated to varying degrees.

(u) "PCB Container" means any package, can, bottle, bag, barrel, drum, tank, or other device used to contain a PCB chemical substance, PCB mixture, or PCB article, and whose surface(s) has been in direct contact with a PCB chemical substance or PCB mixture.

(v) "PCB Equipment" means any manufactured item, other than a PCB container or a PCB article container, which contains a PCB article or other PCB equipment, and includes microwave ovens, electronic equipment, and fluorescent light ballasts and fixtures.

(w) "PCB Mixture" means any mixture which contains 0.05 percent (on a dry weight basis) or greater of a PCB chemical substance, and any mixture which contains less than 0.05 percent PCB chemical substance because of any dilution of a mixture containing more than 0.05 percent PCB chemical substance. This definition includes, but is not limited to, dielectric fluid and contaminated solvents, oils, waste oils, other chemicals, rags, soil, paints, debris, sludge, slurries, dredge spoils, and materials contaminated as a result of spills.

(x) "Person" means any natural or juridical person including any individual, corporation, partnership, or association, any State or political subdivision thereof, any interstate body and any department, agency, or instrumentality of the Federal government.

(y) "Process" means the preparation or use of a chemical substance or mixture, after its manufacture, for distribution in commence:

(1) In the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(2) As part of an article containing the chemical substance or mixture.

(z) "Storage for Disposal" means temporary storage of PCB's that have been designated for disposal.

(aa) "Transport Vehicle" means a motor vehicle or rail car used for the transportation of cargo by any mode. Each cargo-carrying body (e.g., trailer, railroad freight car) is a separate transport vehicle.

Subpart B—Disposal of PCBs

§ 761.10 Disposal requirements.

NOTE.—These regulations do not require removal of PCB's from service and disposal earlier than would normally be the case. However, when PCB's are removed from service and disposed of, disposal must be undertaken in accordance with these regulations. Future regulations will be directed to the manufacture, processing, distribution in commerce, and use of PCB's and may result in some cases in disposal at an earlier date than would otherwise occur.

(a) *PCB chemical substances.* (1) Any PCB chemical substance shall be

disposed of in an incinerator which complies with Annex I.

(2) When storage is desired prior to disposal, a PCB chemical substance shall be stored in accordance with the requirements of Annex III.

(b) *PCB Mixtures.* (1) Except as provided in subparagraphs (2), (3) and (4) of this paragraph, any PCB mixture shall be disposed of in an incinerator which complies with Annex I.

(2) Any non-liquid PCB mixture in the form of contaminated soil, rags, or other debris shall be disposed of

(i) In an incinerator which complies with Annex I, or

(ii) Until January 1, 1980, in a chemical waste landfill which complies with Annex II.

(3) Soil and debris which have been contaminated with PCB's as a result of a spill or as a result of placement of PCB's in a disposal site prior to the publication date of these regulations shall be disposed of

(i) In an incinerator which complies with Annex I, or

(ii) In a chemical waste landfill

(4) All dredge spoils and municipal sewage treatment sludges that are PCB mixtures shall be disposed of

(i) In an incinerator which complies with Annex I, or

(ii) In a chemical waste landfill which complies with Annex II, or

(iii) Upon application, a disposal method to be determined by the Agency's Regional Administrator in the EPA Region in which the PCB mixture is located. Applications for disposal in a manner other than prescribed in (i) or (ii) above must be made in writing to the Regional Administrator. The application must contain information that disposal in an incinerator or chemical waste landfill is not reasonable and appropriate, based on technical, environmental or economic considerations, and information that the alternate disposal method will provide adequate protection to health and the environment. The Regional Administrator may request other information he or she believes to be necessary for evaluation of the alternate disposal method(s). Any approvals by the Regional Administrator shall be in writing and may contain any appropriate limitations on the approved alternate method for disposal. In addition to these regulations, the Regional Administrator shall consider other applicable agency guidelines, criteria, and regulations to ensure that the discharges of dredged material and sludges which can be defined as PCB mixtures are adequately controlled to protect the environment from all contaminants contained therein. The person to whom such approval is issued must comply with all limitations contained in the approval.

(5) When storage is desired prior to disposal, a PCB mixture shall be stored in a facility which complies with Annex III.

(c) *PCB Articles*—(1) *PCB Transformers.* Any PCB transformers shall be disposed of in accordance with either of the following:

(i) in an incinerator which complies with Annex I, or

(ii) in a chemical waste landfill which complies with Annex II: *Provided,* the transformer is first drained of all free flowing liquid, filled with solvent, and allowed to stand for at least 18 hours, and then drained thoroughly. PCB chemical substances and PCB mixtures which are removed shall be disposed of in accordance with paragraphs (a) and (b) of this section.

NOTE.—Solvents may include kerosene, xylene, toluene and other solvents in which PCB's are readily soluble. Precautionary measures should be taken, however, that the solvent flushing procedure is conducted in accordance with applicable safety and health standards as required by Federal or State regulations.

(2) *PCB Capacitors.* (i) The disposal of any capacitor normally used in alternating current circuits shall comply with all requirements of this subpart unless it is known from label information, manufacturer's literature, or chemical analysis that the capacitor does not contain PCB chemical substances or PCB mixtures.

(ii) Any person may dispose of small PCB capacitors as municipal solid waste, unless that person is subject to the requirements of subparagraph (iv).

(iii) Any large high or low voltage PCB capacitor owned by any person shall be disposed of in accordance with either of the following:

(A) Disposal in an incinerator which complies with Annex I; or

(B) Until January 1, 1980, disposal in a chemical waste landfill which complies with Annex II.

(iv) Any small PCB capacitor owned by any person who manufactures or at any time manufactured PCB capacitors or PCB equipment and acquired the PCB capacitors in the course of such manufacturing shall be disposed of in accordance with either of the following:

(A) Disposal in an incinerator which complies with Annex I; or (B) Until January 1, 1980, disposal in a chemical waste landfill which complies with Annex II.

(3) Other PCB articles. Any other PCB articles shall be disposed of in an incinerator which complies with Annex I. If there is a question as to the technological feasibility of incinerating any such article, written application requesting disposal in a chemical waste landfill which complies with Annex II may be made to the Agency's Regional Administrator in the EPA Regional Office in which the PCB article is located. Such application must contain information that disposal of such PCB article in such an incinerator would be technologically infeasible. The Regional Administrator may request other information he or she believes to be necessary for evaluation of the application. The Regional Administrator shall determine whether or not chemical waste landfills may be used on the grounds of technological infeasibility of incineration. Such determination shall be made in writing and signed by the Regional Administrator.

Such determination may contain any limitations for disposal or storage of the PCB article which the Regional Administrator deems reasonable and the person to whom such waiver is issued must comply with all limitations contained in such determination.

(4) Storage of PCB articles—except for a PCB article described in subparagraph (2) (ii) of this paragraph, any PCB article shall be stored in accordance with Annex III prior to disposal.

(d) *PCB Containers.* (1) Unless decontaminated in accordance with Annex IV, a PCB container shall be disposed of

(i) In an incinerator which complies with Annex I, or

(ii) In a chemical waste landfill which complies with Annex II. *Provided,* That if the PCB chemical substances or mixtures are in liquid state, the PCB container shall first be drained of liquid and the liquid shall be disposed of as a PCB chemical substance or a PCB mixture.

(2) Prior to disposal, a PCB container shall be stored in a facility which complies with Annex III.

(e) *Spills.* (1) Spills and other uncontrolled discharges of PCB chemical substances or PBC mixtures constitute the disposal of PCB chemical substances or PCB mixtures.

(2) PCB chemical substances and PCB mixtures resulting from spill incidents shall be stored and disposed of in accordance with paragraphs (a) and (b), respectively of this section.

In order to determine if a spill of PCBs has produced at any point in a suspected zone of soil, gravel, sludge, fill, rubble, or other land based substances a contamination level that exceeds 500 parts per million of PCBs, the person who spills PCBs should consult with the appropriate EPA Regional Administrator to obtain information on sampling methods and analytical procedures for determining the contamination levels associated with the spill.

(3) This subsection does not exempt owners or operators responsible for a spill from any actions or liability under other statutory authorities, including section 311 of the Federal Water Pollution Control Act (Pub. L. 92-500) and the Resource Conservation and Recovery Act (94-580).

(f) Any person who is required to incinerate any PBC under this subpart

and who contends that there is available to him a means of destroying PCB's which is as efficient in destroying PCB's as the incineration procedure provided in Annex I, may submit information to the Regional Administrator to support that contention as well as information that such means will not present an unreasonable risk of injury to health or the environment as a result of its operation. On the basis of such information and any other available information, the Regional Administrator may, in his discretion, find that the alternate disposal method will not present an unreasonable risk of injury to health or the environment and approve the use of the alternate method. Any such approval must be stated in writing and may contain such conditions and provisions as the Regional Administrator deems appropriate and the person to whom such waiver is issued must comply with all limitations contained in such determination.

(g) (1) Each operator of a chemical waste landfill, incinerator, or alternative to incineration approved under paragraph (f) shall give the following written notices to the state and local governments within whose jurisdiction the disposal facility is located:

(i) Notice at least thirty days before a facility first is used for disposal of PCBs required by this regulation, and

(ii) At the request of any state or local government, annual notice during the time the facility is used for disposal of PCBs of the quantities and general description of PCBs disposed of during the year. This notice shall be given no more than thirty days after the end of the year covered.

(2) Any person who disposes of PCBs under an exemption from incineration or chemical waste landfilling authorized by paragraph (b)(4)(iii) shall give at least thirty days prior written notice of such disposal to the state and local governments within whose jurisdiction the disposal is to take place.

Subpart C—Marking of PCB's

§ 761.20 Marking requirements.

(a) The following marking requirements shall apply:

(1) Each of the following items in existence on or after July 1, 1978 shall be marked as illustrated in Figure 1 in Annex V—Section 761.44(a): The mark illustrated in Figure 1 is referred to as M_L throughout this subpart.

(i) PCB containers:

(ii) PCB transformers at the time of manufacture, at the time of distribution in commerce if not already labeled, and at the time of removal from use if not already labeled;

(iii) PCB large high voltage capacitors at the time of manufacture, at the time of distribution in commerce if not already labeled, and at the time of removal from use if not already labeled;

(iv) Equipment containing a PCB transformer or a PCB large high voltage capacitor at the time of manufacture, at the time of distribution in commerce if not already labeled, and at the time of removal of the equipment from use if not already labeled.

(v) PCB large low voltage capacitors at the time of removal from use.

(vi) Electric motors using PCB coolants.

(vii) Hydraulic machinery using PCB hydraulic fluid.

(viii) Heat transfer systems (other than transformers) using PCB's.

(ix) PCB article containers containing articles or equipment that must be marked under provisions (i) through (viii) above.

(x) Each storage area used to store PCB's for disposal.

(2) As of October 1, 1978, each transport vehicle loaded with PCB containers with more than 45 kg. (99.4 lbs.) of PCB chemical substances or PCB mixtures in the liquid phase or with one or more PCB transformers shall be marked with M_L as described in Annex V—section 761.44(a).

(3) As of January 1, 1979, the following PCB's shall be marked with mark M_L as described in Annex V—section 761.44(a):

(i) All transformers not marked under paragraph (1) of this section;

(ii) All large high voltage capacitors not marked under paragraph (1) of this section in accordance with one of the following methods:

(A) each individual capacitor is to be marked with mark M_L, or

(B) if one or more PCB large high voltage capacitors are installed in a protected location as on a power pole, or structure, or behind a fence; the pole, structure, or fence is to be marked with mark M_L and a record or procedure identifying the PCB capacitors is to be maintained by the owner or operator at the protected location.

(4) As of January 1, 1979, all PCB equipment containing a small PCB capacitor at the time of manufacture shall be marked with the statement "This equipment contains PCB capacitor(s)". The mark shall be of the same size as the mark M_L.

(5) Where mark M_L is specified but the PCB article or PCB equipment is too small to accommodate the smallest permissible size of mark M_L, mark M_S as described in Annex V—Sec. 761.44(b), may be used instead of Mark M_L.

(6) Each large low voltage capacitor, each small capacitor normally used in alternating current circuits, and each fluorescent light ballast manufactured between July 1, 1978 and July 1, 1998 that does not contain PCB's shall be marked by the manufacturer at the time of manufacture with the statement, "No PCB's". The mark shall be of similar durability and readability as other markings that indicate electrical information, part numbers, or manufacturer's name.

Subpart D—[Reserved]

Subpart E—List of Annexes

ANNEX I

§ 761.40 Incineration.

(a) *Liquid PCB's.* An incinerator used for incinerating PCB chemical substances or liquid PCB mixtures shall be approved by the Agency Regional Administrator pursuant to paragraph (d) of this section. Such incinerator shall meet all of the requirements specified in subparagraph (1) through (9) of this paragraph, unless a waiver from these requirements is obtained pursuant to paragraph (d)(5) of this section. In addition, the incinerator shall meet any other requirements which may be prescribed pursuant to paragraph (d) (4) of this section.

(1) Combustion criteria shall be either of the following:

(i) Maintenance of the introduced liquids for a 2-second dwell time at 1200°C (±100°C) and 3 percent excess oxygen in the stack gas, or

(ii) Maintenance of the introduced liquids for a 1½-second dwell time at 1600°C (±100°C) and 2 percent excess oxygen in the stack gas.

(2) Combustion efficiency shall be at least 99 percent computed as follows:

$$\text{Combustion efficiency} = \frac{Cco_2 - Cco}{Cco_2} \times 100.$$

where

Cco_2 = Concentration of carbon dioxide.
Cco = Concentration of Carbon monoxide.

(3) The rate and quantity of PCB's which are fed to the combustion system shall be measured and recorded at regular intervals of no longer than 15 minutes.

(4) The temperatures of the incineration process shall be continuously measured and recorded. The combustion temperature of the incineration process shall be based on either direct (pyrometer) or indirect (wall thermocouple-pyrometer correlation) temperature readings.

(5) The flow of PCB's to the incinerator shall stop automatically whenever the combustion temperature drops below the temperatures specified in subparagraph (1) of this paragraph.

(6) Monitoring of stack emission products shall be conducted:

(i) When an incinerator is first used for the disposal of PCB's under the provisions of this regulation, and

(ii) When an incinerator is first used for the disposal of PCB's after the in-

cinerator has been modified in a manner which may effect the characteristics of the stack emission products.

(iii) At a minimum such monitoring shall be conducted for the following parameters: (*a*) O_2; (*b*) CO; (*c*) CO_2; (*d*) Oxides of Nitrogen (NO_x); (*e*) Hydrochloric Acid (HCL); (*f*) Total Chlorinated Organic Content (RCL); (*g*) PCB Chemical Substances; (*h*) Total Particulate Matter.

(7) At a minimum, continuous monitoring and recording of combustion products and incineration operations shall be conducted for the following parameters whenever the incinerator is incinerating PCB's: (i) O_2; (ii) CO; (iii) CO_2.

(8) Incinerator operations shall be immediately suspended when any one or more of the following conditions occur:

(i) Failure of monitoring operations specified in subparagraph (7) of this paragraph.

(ii) Failure of the PCB rate and quantity measuring and recording equipment specified in subparagraph (3) of this paragraph, or

(iii) Combustion temperature, dwell time, or excess oxygen fall below those specified in subparagraph (1) of this paragraph.

(9) Water scrubbers shall be used for HCl control during PCB incineration and shall meet any performance requirements specified by the appropriate EPA Regional Administrator. Scrubber effluent shall be monitored and shall comply with applicable effluent or pretreatment standards, and any other State and Federal laws and regulations. An alternate method of HCl control may be used if the alternate method has been approved by the Regional Administrator.

(b) *Non-liquid PCB's.* An incinerator used for incinerating non-liquid PCB mixtures, PCB articles, PCB equipment, or PCB containers shall be approved by the Agency Regional Administrator pursuant to paragraph (d) of this section. Such incinerator shall meet all of the requirements specified in subparagraphs (1) through (3) of this paragraph, unless a waiver from these requirements is obtained pursuant to paragraph (d) (5) of this section. In addition, the incinerator shall meet any other requirements which may be prescribed pursuant to paragraph (d) (4) of this section.

(1) The mass air emissions from the incinerator shall be no greater than 0.001g PCB chemical substances/Kg of PCB chemical substance introduced into the incinerator.

(2) Such incinerator shall comply with the provisions of §§ 761.40(a) (2), (3), (4), (6), (7), (8) (i) and (ii) and (9).

(3) The flow of PCB's to the incinerator shall stop automatically whenever the combustion temperature falls below the temperatures specified in any approvals issued by the Regional Administrator pursuant to paragraph (d) of this section. Incinerator operations shall stop immediately whenever the excess oxygen measurements fall below those specified in any approvals issued by the Regional Administrator pursuant to paragraph (d) of this section.

(c) *Maintenance of data and records.* All data and records required by this section shall be maintained in accordance with Annex VI—§ 761.45, Records and Monitoring.

(d) *Approval of incinerators.* Prior to the incineration of PCBs, the owner or operator of an incinerator shall receive the written approval of the Agency Regional Administrator of the Region in which the incinerator is located. Such approval shall be obtained in the following manner:

(1) *Initial report.* The owner or operator shall submit to the Regional Administrator an initial report which contains:

(i) The location of the incinerator.

(ii) A detailed description of the incinerator including general site plans and design drawings of the incinerator.

(iii) Engineering reports or other information on the anticipated performance of the incinerator.

(iv) Sampling and monitoring equipment and facilities available.

(v) Waste volumes expected to be incinerated.

(vi) Any local, State, or Federal permits or approvals.

(vii) Schedules and plans for complying with the approved requirements of this regulation.

(2) *Trial burn.* (i) Following receipt of the report described in subparagraph (1) of this paragraph, the Regional Administrator shall notify the person who submitted the report whether a trial burn of PCBs must be conducted. The Regional Administrator may require the person who submitted the report described in subparagraph (1) of this paragraph to submit such other information as the Regional Administrator finds to be reasonably necessary to determine the need for a trial burn. Such other information shall be restricted to the types of information required in (1)(i) through (1)(vii) above.

(ii) If the Regional Administrator determines that a trial burn must be held, the person who submitted the report described in subparagraph (1) of this paragraph shall submit to the Regional Administrator a detailed plan for conducting and monitoring the trial burn. At a minimum, the plan must include:

(*a*) Date trial burn is to be conducted.

(*b*) Quantity and type of PCBs to be incinerated.

(*c*) Parameters to be monitored and location of sampling points.

(*d*) Sampling frequency and methods and schedules for sample analyses.

(*e*) Name, address, and qualifications of persons who will review analytical results and other pertinent data and who will perform a technical evaluation of the effectiveness of the trial burn.

(iii) Following receipt of the plan described in subdivision (ii) of this subparagraph, the Regional Administrator will approve the plan, require additions or modifications to the plan, or disapprove the plan. If the plan is disapproved, the Regional Administrator will notify the person who submitted the plan of such disapproval, together with the reasons why it was disapproved. That person may thereafter submit a new plan in accordance with subdivision (ii) of this subparagraph. If the plan is approved (with any additions or modifications which the Regional Administrator may prescribe), the Regional Administrator will notify the person who submitted the plan of such approval. Thereafter the trial burn shall take place at a date and time to be agreed upon between the Regional Administrator and the person who submitted the plan.

(3) *Other information.* In addition to the information contained in the report and plan described in subparagraphs (1) and (2) of this paragraph, the Regional Administrator may require the owner or operator to submit such other information as the Regional Administrator finds to be reasonably necessary to determine whether an incinerator shall be approved.

NOTE.—The Regional Administrator will have available for review and inspection an Agency manual containing information or sampling methods and analytical procedures for the parameters required in § 761.40(a) (3), (4), (6), and (7) plus any other parameters he may determine to be appropriate. Owners or operators are encouraged to review this manual prior to submitting any report required in this Annex.

(4) *Contents of Approval.* (i) Except as provided in subparagraph (5) of this paragraph, the Regional Administrator may not approve an incinerator for the disposal of PCB's unless he finds that the incinerator meets all of the requirements of paragraphs (a) and/or (b) of this section, whichever is applicable.

(ii) In addition to the requirements of paragraphs (a) and/or (b) of this section, the Regional Administrator may include in an approval such other requirements as the Regional Administrator finds are necessary to ensure that operation of the incinerator does not present an unreasonable risk of injury to health or the environment from PCB's. Such requirements may include a fixed period of time for which the approval is valid.

(5) *Waivers.* An owner or operator of the incinerator may submit evidence to the Regional Administrator that operation of the incinerator will not present an unreasonable risk of injury to health or the environment from PCB's, when one or more of the requirements of paragraphs (a) and/or (b) of this section are not met. On the basis of such evidence and any other available information, the Regional Administrator may in his discretion find that any such requirements are not necessary to protect against such risk and may waive such requirements in any approval for that incinerator. Any such finding and waiver must be stated in writing and included as part of the approval.

(6) *Persons Approved.* An approval will designate the persons who own and who are authorized to operate the incinerator, and will apply only to such persons.

(7) *Final Approval.* Approval of an incinerator will be in writing and signed by the Regional Administrator. The approval will state all requirements applicable to that incinerator.

ANNEX II

§ 761.41 Chemical waste landfills.

(a) *General.* A chemical waste landfill used for the disposal of PCB's shall be approved by the Agency Regional Administrator pursuant to paragraph (c) of this section. Such landfill shall meet all of the requirements specified in paragraph (b) of this section, unless a waiver from these requirements is obtained pursuant to paragraph (c)(4) of this section. In addition, the landfill shall meet any other requirements which may be prescribed pursuant to paragraph (c)(3) of this section.

(b) *Technical requirements.* Requirements for chemical waste landfills used for the disposal of PCB's are as follows:

(1) *Soils.* The landfill site shall be located in thick, relatively impermeable formations such as large-area clay pans. Where this is not possible, the soil shall have a high clay and silt content with the following parameters:

(i) In-place soil thickness, 4', or compacted soil liner thickness, 3'.

(ii) Permeability (cm/sec), 01×10^{-7}.

(iii) Percent soil passing No. 200 Sieve, >30.

(iv) Liquid Limit, >30.

(v) Plasticity Index, >15.

(vi) Artificial Liner Thickness, >30 mil.

NOTE.—In the event that an artificial liner is used at a landfill site, special precautions shall be taken to insure that its integrity is maintained and that it is chemically compatible with PCB's. Soil underlining shall be provided as well as a soil cover.

(2) *Hydrology.* The bottom of the landfill shall be substantially above the historical high groundwater table. Floodplains, shorelands, and groundwater recharge areas shall be avoided. There shall be no hydraulic connection between the site and standing or flowing surface water. The site shall have monitoring wells and leachate collection and shall be at least fifty feet from the nearest groundwater.

(3) *Flood protection.* (i) If the landfill site is below the 100-year floodwater elevation, the operator shall provide surface water diversion dikes around the perimeter of the landfill site with a minimum height equal to two feet above the 100-year floodwater elevation.

(ii) If the landfill site is above the 100-year floodwater elevation, the operators shall provide diversion structures capable of diverting all of the surface water runoff from a 24-hour, 25-year storm.

(4) *Topography.* The landfill site shall be located in an area of low to moderate relief to minimize erosion and to help prevent landslides or slumping.

(5) *Monitoring Systems*—(i) *Water Sampling.* (*a*) The ground and surface water from the disposal site area shall be sampled for use as baseline operations.

(*b*) Defined water sources shall be sampled at least monthly when the landfill is being used for disposal operations.

(*c*) Defined water sources shall be sampled indefinitely on a frequency of no less than once every six months after final closure of the disposal area.

(ii) *Groundwater Monitor Wells.* (*a*) If underlying earth materials are homogeneous, impermeable, and uniformly sloping in one direction, only three sampling points shall be necessary. These three points shall be equally spaced on a line through the center of the disposal area and extending from the area of highest water table elevation to the area of the lowest water table elevation on the property.

(*b*) All monitor wells shall be cased and the annular space between the monitor zone (zone of saturation) and the surface shall be completely backfilled or plugged with portland cement to effectively prevent percolation of surface water into the well bore. The well opening at the surface shall have a removable cap to provide access and to prevent entrance of rainfall or stormwater runoff. The well shall be pumped to remove the volume of liquid initially contained in the well before obtaining a sample for analysis. The discharge shall be treated to meet applicable State or Federal discharge standards or recycled to the chemical waste landfill.

(iii) *Water analysis.* As a minimum, all samples shall be analyzed for the following parameters, and all data and records of the sampling and analysis shall be maintained as required in Annex VI. Sampling methods and analytical procedures for these parameters shall be as specified in 40 CFR Part 136 as amended in 41 FR 52779 of December 1, 1976.

(*a*) PCB's.

(*b*) pH.

(*c*) Specific Conductance.

(*d*) Chlorinated Organics.

(6) *Leachate Collection.* A leachate collection monitoring system shall be installed beneath the chemical waste landfill. Leachate collection systems shall be monitored monthly for quantity and quality of leachate produced. The leachate should be either treated to acceptable limits for discharge in accordance with a State or Federal permit or disposed of by another State or Federal approved method. Water analysis shall be as provided in subparagraph (5)(iii) of this paragraph. Acceptable leachate collection monitoring/collection systems shall be one of the following designs unless a waiver is obtained pursuant to paragraph (c)(4) of this section.

(i) *Simple Leachate Collection.* This system consists of a gravity flow drainfield installed under the waste disposal facility liner. This design is recommended for use when semi-solid or leachable solid wastes are placed in a lined pit excavated into a relatively thick, unsaturated, homogeneous layer of low permeability soil.

(ii) *Compound Leachate Collection.* This system consists of a gravity flow drainfield installed under the waste disposal facility liner and above a secondary installed liner. This design is recommended for use when semiliquid or leachable solid wastes are placed in a lined pit excavated into relatively permeable soil.

(iii) *Suction Manometers.* This system consists of a network of porous "stones" connected by hoses/tubing to a vacuum pump. The porous "stones" or suction manometers are installed along the sides and under the bottom of the waste disposal facility liner. This type of system works best when installed in relatively permeable unsaturated soil immediately adjacent to the disposal facility's bottom and/or sides.

(7) *Chemical Waste Landfill Operations.* (i) PCB's shall be placed in the landfill in a manner that will prevent damage to containers or articles. Other wastes placed in the landfill that are not chemically compatible with PCB's or PCB containers shall be segregated from the PCB's throughout the waste handling and disposal process.

(ii) An operations plan shall be developed and submitted to the Regional Administrator for approval as required in paragraph (c) of this section. This plan shall include detailed explanations of the procedures to be used for

recordkeeping, excavation and backfilling, waste segregation burial coordinates, vehicle and equipment movement, use of roadways, leachate collection systems, sampling and monitoring procedures, monitoring wells, and security measures to protect against vandalism and unauthorized waste placements. EPA guidelines entitled "Thermal Processing and Land Disposal of Solid Waste" (39 FR 29337 of August 14, 1974) are a useful reference in preparation of this plan.

(iii) Records shall be maintained for all PCB disposal operations and shall include the three dimensional burial coordinates for PCB's. Additional records shall be developed and maintained as provided in Annex VI.

(8) *Supporting Facilities.* (i) A six foot woven mesh fence, wall, or similar device shall be provided around the site to prevent unauthorized persons and animals from entering.

(ii) Roads shall be maintained to and on the site which are adequate to operate and maintain the site without causing safety or nuisance problems or hazardous conditions.

(iii) The site shall be operated and maintained in a manner to prevent safety problems or hazardous conditions resulting from spilled liquids and windblown materials.

(c) *Approval of chemical waste landfills.* Prior to the disposal of any PCB's in a chemical waste landfill, the owner or operator of the landfill shall receive written approval of the Agency Regional Administrator of the Region in which the landfill is located. Such approval shall be obtained in the following manner:

(1) *Initial Report.* The owner or operator shall submit to the Regional Administrator an initial report which contains:

(i) The location of the landfill.

(ii) A detailed description of the landfill including general site plans and design drawings.

(iii) An engineering report describing the manner in which the landfill complies with the requirements for chemical waste landfills in paragraph (b) of this section.

(iv) Sampling and monitoring equipment and facilities available.

(v) Expected waste volumes of PCB's.

(vi) General description of waste materials other than PCB's that are expected to be disposed of in the landfill.

(vii) Landfill operations plan as required in paragraph (b) of this section.

(viii) Any local, State, or Federal permits or approvals.

(ix) Any schedules or plans for complying with the approval requirements of these regulations.

(2) *Other Information.* In addition to the information contained in the report described in subparagraph (1) of this section, the Regional Administrator may require the owner or operator to submit such other information as the Regional Administrator finds to be reasonably necessary to determine whether a chemical waste landfill should be approved. Such other information shall be restricted to the types of information required in (1)(i) through (1)(ix) above.

(3) *Contents of Approval.* (i) Except as provided in subparagraph (4) of this paragraph the Regional Administrator may not approve a chemical waste landfill for the disposal of PCB's unless he finds that the landfill meets all of the requirements of subparagraph (6) of this paragraph.

(ii) In addition to the requirements of paragraph (b) of this section, the Regional Administrator may include in an approval such other requirements as the Regional Administrator finds are necessary to ensure that operation of the chemical waste landfill does not present an unreasonable risk of injury to health or the environment from PCB's. Such requirements may include a fixed period of time for which the approval is valid.

Such requirements may also include a stipulation that the operator of the chemical waste landfill report to the Regional Administrator any instance of detection of PCB's through any of the monitoring requirements of this section.

(4) *Waivers.* An owner or operator of a chemical waste landfill may submit evidence to the Regional Administrator that operation of the landfill will not present an unreasonable risk of injury to health or the environment from PCB's, when one or more of the requirements of paragraph (b) of this section are not met. On the basis of such evidence and any other available information, the Regional Administrator may in his discretion find that any such requirements are not necessary to protect against such risk and may waive such requirements in any approval for that landfill. Such finding and waiver will be stated in writing and included as part of the approval.

(5) *Persons Approved.* Any approval will designate the persons who own and who are authorized to operate the chemical waste landfill, and will apply only to such persons.

(6) *Final Approval.* Approval of a chemical waste landfill will be in writing and will be signed by the Regional Administrator. The approval will state all requirements applicable to that landfill.

ANNEX III

§ 761.42 Storage for disposal.

(a) Any PCB article or PCB container stored for disposal before January 1, 1983, shall be removed from storage and disposed of as required by this Part before January 1, 1984. Any PCB article or PCB container stored for disposal after January 1, 1983, shall be removed from storage and disposed of as required by this Part within one year from the date when it was first placed into storage.

(b) Except as provided in paragraph (c) of this section, after July 1, 1978, owners or operators of any facilities used for the storage of PCB's designated for disposal shall comply with the following requirements:

(1) Such facilities shall have:

(i) An adequate roof and walls to prevent rain water from reaching the stored PCBs.

(ii) An adequate floor which has continuous curbing with a minimum six inch high curb. Such floor and curbing must provide a containment volume equal to at least two times the internal volume of the largest PCB article or PCB container stored therein or 25 percent of the total internal volume of all PCB equipment or containers stored therein, whichever is greater.

(iii) No drain valves, floor drains, expansion joints, sewer lines, or other openings that would permit liquids to flow from the curbed area.

(iv) Floors and curbing constructed of continuous smooth and impervious materials such as Portland cement concrete or steel to prevent or minimize penetration of PCB chemical substances or mixtures.

(v) No storage facility shall be located at a site which is below the 100-year flood water elevation.

(c)(1) Non-leaking PCB articles and equipment may be stored temporarily in an area that does not comply with the requirements of paragraph (b) for up to thirty days from the date of removal from service.

(2) Storage of non-leaking and structurally undamaged PCB large high voltage capacitors on pallets next to a storage facility meeting the requirements of paragraph (b) shall be permitted until January 1, 1983. Such storage will be permitted only when the storage facility meeting the requirements of paragraph (b) has immediately available unfilled storage space equal to 10 percent of the volume of capacitors stored outside the facility. These capacitors shall be checked for leaks weekly.

(3) Any storage area subject to the requirements of paragraph (b) or subparagraph (1) of this section shall be marked as required in Subpart C—section 761.20(a)(6).

(4) No item of movable equipment used for handling PCBs in the storage facilities and which actually comes in contact with PCB chemical substances or PCB mixtures shall be removed from the storage facility area unless it has been decontaminated as specified in annex IV.

(5) All PCB containers and articles in storage shall be checked for leaks at

least once every 30 days. All such leaking containers and articles and their contents shall be transferred immediately to properly marked non-leaking containers. Any spilled or leaked materials shall be immediately cleaned up using sorbents or other adequate means, and the cleaned materials and residues shall be disposed of in accordance with Subpart B—section 761.10(b).

(6) Any PCB container used for the storage of liquid PCB chemical substances or liquid PCB mixtures shall comply with the specifications of the Department of Transportation (DOT), 40 CFR 173.346, revised December 31, 1976. For 55 gallon drums, an 18 gauge steel or heavier and 2-bung head shall be used. For 5 gallon drums, 24 gauge steel or heavier shall be used. They must also meet DOT Specification 17E. Any PCB container used for the storage of non-liquid PCB mixtures, PCB articles, or PCB equipment shall meet the requirements of the DOT Specifications 5, 5B, or 17C with a removable head.

(7) PCB articles and PCB containers shall be dated when they are placed in storage under paragraph (b) or subparagraphs (c)(1) or (c)(2). The storage shall be managed so that the PCB articles and PCB containers can be located by the date they entered storage.

(8) Owners or operators of storage facilities shall establish and maintain records as provided in Annex VI.

ANNEX IV

§ 761.43 Decontamination.

(a) Any PCB container to be decontaminated shall be decontaminated by flushing of the internal surfaces of the container three times with a solvent containing less than 0.05 percent PCB chemical substance in which the solubility of PCB's is five percent or more by weight. Each rinse shall use a volume of the normal diluent equal to approximately ten percent of the PCB container's capacity. The solvent may be reused for decontamination until it contains 0.5 percent PCB chemical substance. The solvent shall then be disposed of as a PCB mixture, in accordance with § 761.10(b). Materials used in decontamination procedures will be disposed of in accordance with the provisions of § 761.10(b)(2).

(b) Movable equipment used in storage areas shall be decontaminated by swabbing surfaces that have contacted PCB chemical substances or PCB mixtures with a solvent meeting the criteria of paragraph (a) of this section.

NOTE.—Precautionary measures should be taken that the solvent meets safety and health standards as required by Federal regulations.

ANNEX V

§ 761.44 Marking formats

The following formats shall be used for marking:

(a) Large PCB Mark—M_L—Mark M_L shall be as shown in Figure 1, letters and striping on a white or yellow background and shall be sufficiently durable to equal or exceed the life (including storage for disposal) of the equipment or container. The size of the mark shall be at least 15.25 cm (6 inches) on each side. If the PCB equipment is too small to accommodate this size, the mark may be reduced in size proportionately down to a minimum of 5 cm (2 inches) on each side.

(b) Small PCB Mark—M_S—Mark M_S shall be as shown in Figure 2, letters and striping on a white or yellow background, and shall be sufficiently durable to equal or exceed the life (including storage for disposal) of the equipment or container. The mark shall be a rectangle 2.5 by 5 cm (1 inch by 2 inches). If the PCB equipment is too small to accommodate this size, the mark may be reduced in size proportionately down to a minimum of 1 by 2 cm (.4 by .8 inches).

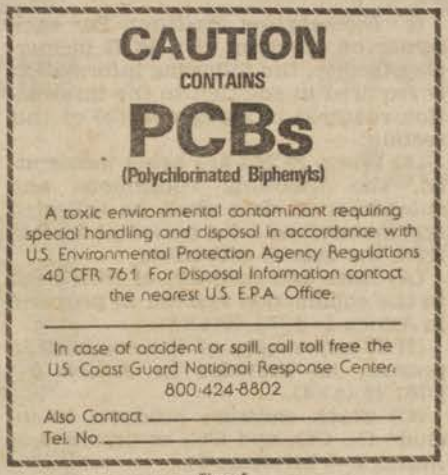

Figure 1

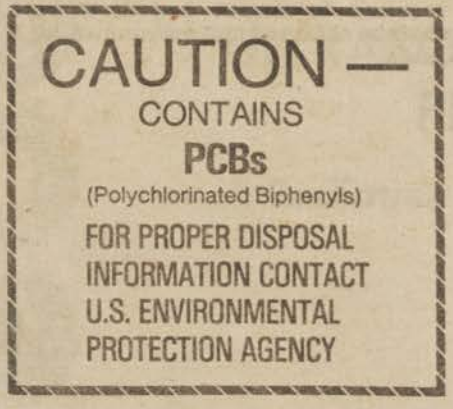

Figure 2

ANNEX VI

§ 761.45 Records and monitoring.

(a) PCB's in service or projected for disposal. Beginning July 2, 1978, each owner or operator of a facility containing at least 45 kilograms (99.4 pounds) of PCB chemical substances or PCB mixtures contained in a PCB container or PCB containers, or one or more PCB transformers, or 50 or more PCB large high or low voltage capacitors shall develop and maintain records on the disposition of PCB's. These records shall form the basis of an annual document prepared for each facility by July 1 covering the previous calendar year. Owners or operators with more than one facility which contains PCB's in the quantities described above may maintain the records and documents at a single location, provided the identity of this location is available at each facility containing PCB's that is normally manned for 8 hours a day. The records and documents shall be maintained for at least five years after the facility ceases containing PCBs in the prescribed quantities. The following information for each facility shall be included in the annual document:

(1) The dates when PCB's are removed from service, are placed into storage for disposal, and are placed into transport for disposal. The quantities of such PCB's shall be indicated using the following breakdown:

(i) Total weight in kilograms of any PCB chemical substances or PCB mixtures in PCB containers, including the identification of container contents, such as liquids, and capacitors.

(ii) Total number of PCB transformers and total weight in kilograms of any PCB chemical substances and PCB mixtures contained in the transformers.

(iii) Total number of PCB large high or low voltage capacitors.

(2) For PCB's removed from service, the location of the initial disposal or storage facility and the name of the owner or operator of the facility.

(3) Total quantities of PCB's remaining in service at the end of the calendar year using the following breakdown:

(i) Total weight in kilograms of any PCB chemical substances and PCB mixtures in PCB containers, including the identification of container contents such as liquids and capacitors.

(ii) Total number of PCB transformers and total weight in kilograms of any PCB chemical substances and PCB mixtures contained in the transformers;

(iii) Total number of PCB large high or low voltage capacitors.

(b) *Disposal and storage facilities.* Beginning July 1, 1979, each owner or operator of a facility used for the storage or disposal of PCB's shall by July

1 of each year prepare and maintain a document which specifies the manner in which PCB's were handled at the facility during the previous calendar year. Such document shall be retained at each facility for at least 5 years after the facility is no longer used for the storage or disposal of PCB's, except that in the case of chemical waste landfills such documents shall be maintained at least 20 years after the chemical waste landfill is no longer used for the disposal of PCB's. Such documents shall be available at the facility for inspection by authorized representatives of the Environmental Protection Agency. If the facility ceases to be used for PCB storage or disposal, the owner or operator of such facility shall promptly notify the Agency Regional Administrator of the region in which the facility is located that the facility has ceased storage or disposal operations and shall specify where the documents required to be maintained by this paragraph shall be located. The following information shall be included in each document:

(1) The date when any PCB's are received by the facility during the previous calendar year for storage or disposal, and the identification of the person and facility from whom such PCB's were received.

(2) The date when any PCB's are disposed of at the disposal facility or transferred to another disposal or storage facility, including the identification of the specific types of PCB chemical substances, PCB mixtures, or PCB articles in containers; PCB transformers; and PCB equipment or PCB articles not in containers which were stored or disposed of.

(3) Total weight in kilograms of any PCB containers and the total weight in kilograms of any PCB chemical substances or PCB mixtures contained in any PCB transformers, received during the calendar year, transferred to other storage or disposal facilities during the calendar year, and remaining on the disposal or storage facility site at the end of the calendar year, respectively, including, where applicable, the identification of PCB container contents such as liquids, capacitors, etc. When PCB containers or PCB chemical substances or PCB mixtures contained in a transformer are transferred to other storage or disposal facilities, the identification of the facility to which such PCB's were transferred shall be included.

(4) Total number of any PCB articles or PCB equipment, not in PCB containers, received during the calendar year, transferred to other storage or disposal facilities during the calendar year, and remaining on the facility site at the end of the calendar year, respectively, including the identification of the specific types of PCB articles and PCB equipment received, transferred, or remaining on the facility site. When PCB articles and PCB equipment are transferred to other storage or disposal facilities, the identification of the facility to which such PCB articles and PCB equipment were transferred must be included.

NOTE.—Any requirements for weights in kilograms of PCBs may be calculated values if the internal volume of containers and transformers is known and included in the reports, together with any assumptions on the density of the PCB chemical substances or PCB mixtures contained in the containers or transformers.

(c) *Incineration facilities.* For each owner or operator of a PCB incinerator facility, the following information is required in addition to the information required in paragraph (b) of this section:

(1) When PCB's are being incinerated, the following continuous and short-interval data shall be collected and maintained for a period of 5 years from the date of collection:

(A) Rate and quantity of PCB's fed to the combustion system, as provided in Annex I—§ 761.40(a)(3).

(B) Temperature of the combustion process, as provided in Annex I—§ 761.40 (a)(4).

(C) Stack emission products to include O_2, CO, and CO_2 as provided in Annex I—§ 761.40(a)(7).

(2) When PCBs are being incinerated, data and records resulting from the monitoring of stack emissions as required in Annex I—§ 761.40(d)(2), shall be collected and maintained for 5 years.

(3) Total weight in kilograms of any solid residues generated by the incineration of PCB's during the calendar year, the total weight in kilograms of any solid residues disposed of by such facility in chemical waste landfills, and the total weight in kilograms of any solid residues remaining on the facility site shall be retained for 5 years.

(4) When PCBs are being incinerated, additional periodic data shall be collected and maintained as specified by the Regional Administrator pursuant to Annex I—§ 761.40(d)(4).

(5) A document shall be prepared on any suspension of the operation of any incinerator by the owner or operator thereof, as required in Annex I—§ 761.40(a)(3). The document shall, at a minimum, include the date and time of the suspension and an explanation of the circumstances causing the suspension of operation. The document shall be sent to the appropriate Regional Administrator within 30 days of any such suspension.

(d) Retention of Special Records by Storage and Disposal Facilities. In addition to the information required to be maintained by paragraphs (b) and (c) of this section, each owner or operator of a PCB storage or disposal facility shall collect and maintain for the time period required in paragraph (c) of this section the following data:

(1) All documents, correspondence, and data provided to the owner or operator by any State or local government agency that pertain to the storage or disposal of PCBs at such facility.

(2) All documents, correspondence, and data provided by the owner or operator of such facility to any State or local government agency that pertain to the storage or disposal of PCBs at such facility.

(3) Any applications and related correspondence sent by the owner or operator of such facility to any local, State, or Federal authorities in regard to waste water discharge permits, solid waste permits, building permits, or other permits or authorizations, such as those required by Annex I—§ 761.40(d) and Annex II-§ 61.41(c).

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federal register

FRIDAY, FEBRUARY 17, 1978

PART VI

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ULTRASONIC THERAPY PRODUCTS

Radiation Safety Performance Standard

[4110-03]

Title 21—Food and Drugs

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

[Docket No. 76N-0034]

PART 1050—PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS

Ultrasonic Therapy Products

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule prescribes a radiation safety performance standard for ultrasonic therapy products for use in physical therapy. The standard applies to any device intended to generate and emit ultrasonic radiation for therapeutic purposes at frequencies above 16 kilohertz and to generators or applicators designed or specifically designated for use in such devices. The standard will require ultrasonic therapy equipment to be capable of delivering a prescribed amount of ultrasonic energy to the patient and will assure that sufficient information on beam characteristics is supplied to allow medical personnel to make informed judgments regarding the application of ultrasound energy.

EFFECTIVE DATE: February 17, 1979.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of June 14, 1976 (41 FR 23973), the Commissioner of Food and Drugs proposed to establish a radiation safety performance standard for ultrasonic therapy and surgery products because he recognized a need for a regulatory standard for such equipment to protect the public health and safety. Interested persons had until August 13, 1976, to file written comments on the proposal.

The agency received 13 comments on the proposal—six from government agencies (one foreign), three from health care organizations, two from manufacturers, one from a consumer, and one from a practitioner/user. Six comments generally supported the proposed standard; seven comments indicated neither approval nor disapproval, but suggested changes or additions to the regulation. A summary of the significant comments and the Commissioner's conclusions are as follows:

1. One comment asked that the standard require inspection of equipment currently in use.

Inspections of equipment would normally be part of the compliance program for an established performance standard. The Commissioner notes that the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602) does not authorize application of a performance standard to equipment manufactured before the effective date of the standard, and it would be inappropriate to include such a requirement. But he advises that manufacturers of currently marketed ultrasonic therapy products must have submitted detailed reports on their products to the Bureau of Radiological Health before the products were introduced into commerce. Also, some laboratory and field checks of equipment have been performed. Products manufactured after October 18, 1968, and found to have defects related to safety of use by reason of emission of electronic product radiation are subject to corrective action programs under the act, including the repurchase, repair, or replacement of such defective products.

2. A comment expressed concern that the standard would control the use of ultrasound therapy equipment and at the same time urged that the output power of such devices be correctly indicated to the user.

The Commissioner notes that the standard in no way places restrictions on the use of ultrasound therapy devices and that § 1050.10(c)(1) requires such devices to be equipped with a means to indicate the ultrasonic power within a specified precision. Therefore, no change in the standard is needed.

3. Two comments asked that information on coupling media and their effect on equipment performance be required under § 1050.10(f)(2).

The Commissioner believes that coupling media (fluid used between applicator and tissue to facilitate transmission of ultrasonic energy) have little effect on ultrasound attenuation or beam patterns; and, further, that there is little difference between different coupling media with regard to these parameters. Therefore, it is presently not justified to specifically require information on coupling media in the standard. However, the Commissioner emphasizes that if the radiation safety or dose delivery of a particular ultrasonic device were critically dependent on the choice of coupling medium, then the provisions of § 1050.10(f)(2)(i) would require such information to be supplied by the manufacturer.

4. One reviewer believed that the definition of "effective radiating surface" in § 1050.10(b)(11) is unnecessary because it is only used in the definition of "effective radiating area" in § 1050.10(b)(10). The comment also asserted that the reason for the 5 millimeter (mm) distance in § 1050.10(b)(11) is not clear. Because "effective radiating surface" is used in several definitions other than § 1050.10(b)(10), i.e., § 1050.10 (b)(1, (b)(7), and (b)(13), § 1050.10(b)(11) is considered appropriate. The choice of 5 mm distance from the applicator face as the distance at which to define "effective radiating surface" is consistent with the American Standard Specification for Ultrasonic Therapeutic Equipment of the American National Standards Institute (reference Z24.18-1956) and is considered reasonable. The Commissioner therefore rejects these comments.

5. A suggestion was made to change the definition of "focal length" in § 1050.10(b)(13) to avoid requiring measurements using a surface in space as a reference. The comment urged that the phrase "centroids of the effective radiating surface" be replaced with "center of the face of the transducer."

The Commissioner notes that the term "center of the face of the transducer" has no meaning for nonsymmetric surfaces and therefore is not accepting the revised definition. The current definition accounts for all possible transducer shapes.

6. One comment said that in § 1050.10(b)(19), in the definition of "pressure amplitude," the term $P_1(t)$ should be $p_1(t)$. The Commissioner agrees with the change and also is changing $P_2(t)$ to $p_2(t)$ in the definition.

7. One comment suggested that the international system of units (SI units) be used in the standard and that in particular, the SI unit for intensity, watts per square meter (Wm^{-2}), should be used rather than watts per square centimeter (Wcm^{-2}).

The Commissioner believes that while use of SI units would be desirable, it is necessary to deviate from that system in situations where a non-SI unit is commonly used in other related standards, common test instruments, and in manufacturing practice. Therefore, no changes are made. The Commissioner further notes that the unit Wcm^{-2} is consistent with SI units because a unit for intensity is not included in the international system of units. Although the SI unit for length is meters (m), it is acceptable to use a submultiple such as centimeters (cm).

8. One comment asked that the demarcation between modulated and continuous waveforms in § 1050.10(b)(7) be at a peak-to-average ratio of 1.25 rather than 1.05 so that the U.S. standard is compatible with that of the International Electrotechnical Commission (IEC).

The Commissioner is aware of evidence indicating that pulsed (modulat-

ed) ultrasound may be capable of producing biological effects other than thermal when compared to continuous-wave ultrasound of the same average intensity. A waveform characterized as continuous under the standard need not have any further information supplied with regard to temporal properties. For a waveform to be characterized as continuous it should have minimal amplitude variation with time, and the Commissioner concludes that the peak-to-average ratio of 1.05 should be retained. The Commissioner also notes that the value of 1.05 has been recommended by user groups while justification for the peak-to-average ratio in the IEC standard is not known to FDA. The Commissioner invites further data and information that would show that adopting the IEC provision would not adversely affect the public health.

9. One comment said the measurements of the beam cross-section as defined in § 1050.10(b)(3) and effective radiating area in § 1050.10(b)(10) seem to be impractical and should use the baffle technique in accordance with IEC Publication 150.

The baffle technique is a method where the beam area is determined by measuring the acoustic power passing through successively larger circular apertures and noting that aperture size for which 90 percent of the acoustic power is transmitted. The Commissioner advises that the baffle technique is impractical for the variety of transducer sizes and shapes currently available. There is general agreement within the U.S. delegation to the IEC that the scanning technique in this regulation is preferable to the baffle technique. The suggestion to change the measurement basis is therefore not accepted.

10. One comment suggested use of the IEC definition of "maximum intensity." Others asked that the terms "temporal-average," "temporal-maximum," "spatial-average," and "spatial-maximum" be defined.

The Commissioner disagrees that additional definitions are needed. The IEC definition of maximum intensity specifies measurements over a 1 centimeter diameter area, which is inappropriate for smaller transducers. The Commissioner does not believe the term "spatial-average" needs a definition because size of the detector used for determining spatial distribution of the ultrasonic field is specified in § 1050.10(e)(3). There is a generally accepted formal definition for "temporal-average" (IEEE Standard 100-1972 (Institute of Electrical and Electronics Engineers, Inc., 345 East 47th Street, New York, N.Y. 10017), ANSI C42.100-1972 (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018)), which essentially defines the term as an average over one or more cycles of a periodic waveform. "Spatial-maximum" and "temporal-maximum" are self-explanatory in that they refer respectively to the greatest value over all space and the greatest value over all time.

11. One comment said there does not appear to be any important difference between the definitions of "focal area" and "focal surface" in § 1050.10 (b)(12) and (b)(14).

In accordance with strict mathematical usage, there is a difference between a surface and the area of a surface. Furthermore, the term "focal surface" is needed for the definition of "focal length" in § 1050.10(b)(13). The Commissioner believes that both definitions are needed, and therefore no change is made.

12. A suggestion was made that "ultrasonic frequency" as defined in § 1050.10(b)(23) should be expressed in megahertz (MHz) rather than Hertz (Hz) so that typical numbers used are kept small.

The Commissioner agrees with the suggestion and is changing the definition to allow the units of Hz, MHz, or kilohertz (kHz).

13. One comment stated that because the time average power for modulated waveforms is more important for patient treatment and safety than instantaneous power, the time average power should be used for calculating "ultrasonic power." Thus, the comment urged that § 1050.10(b)(24) require averaging emitted power over one cycle of the modulating waveform rather than over each cycle of the carrier wave. Another comment suggested that devices subject to §1050.10(c)(1)(ii) be required to indicate the temporal-average power and intensity as well as the temporal maximum power and intensity generated by the device because the average quantities are of as much importance in tissue heating as the maximum quantities.

As stated in paragraph 8 above, there is evidence that nonthermal biological effects associated with exposure to modulated ultrasonic radiation may be related to the temporal-maximum acoustic power and intensity of the waveform. Therefore, it is important that these quantities be indicated to the user. Users wanting to determine the time average power can do so by using the ratio of temporal-maximum to temporal-average effective intensity required by § 1050.10(d)(3)(ii) to be stated on the generator label. The Commissioner therefore concludes that no change in the standard is needed.

14. Two comments argued that the definition of an ultrasonic therapy product in § 1050.10(b)(25) should exclude devices with frequencies below 18 or 20 kHz because such devices produce audible radiation and are thus not "ultrasonic."

The Commissioner notes that there is no commonly accepted lower frequency limit for ultrasonic radiation. The lower frequency limit of 16 kHz will be retained in the standard to be consistent with possible future standards for other ultrasonic devices such as cleaners, rodent repellers, alarm systems, and dental devices, some of which operate below 20 kHz.

15. One comment said the 20-percent allowable error in proposed § 1050.10(c)(1)(ii) should apply individually to the errors in the power and intensity ratio rather than to the sum of the errors. In support of this, the comment noted that proposed § 1050.10(c)(1)(i) would permit a maximum error of ± 20 percent for the ultrasonic power of continuous waveforms.

The Commissioner does not accept the suggested change. The maximum allowable error of ±20 percent must be applied to the sum of the errors so that the temporal-average power may be derived from the two quantities with an error not exceeding ±20 percent. This would then be consistent with the maximum allowable error of ±20 percent for the temporal-average power in the case of continuous waveforms.

16. One comment stated that to label ultrasonic generators with the information required in § 1050.10(d)(3)(ii) would require too much space and that the data should only be required in accompanying documents. Similarly, except for frequency and maximum intensity information, the applicator label information required by §1050.10(d)(4)(iii) should only be required in the accompanying documents.

The Commissioner does not agree with the suggestion because such labeling information is necessary for each user of ultrasonic therapy products and this can only be assured if such information appears on the product. Accompanying documents may be misplaced by the user.

The Commissioner also advises that because ultrasonic therapy products are devices under the Federal Food, Drug, and Cosmetic Act, as amended, these products must also comply with the device labeling requirements in 21 CFR Part 801. To clarify this, special reference to Part 801 is added to § 1050.10(d). In cases where the labeling requirements of this regulation cannot be met because of space limitations, the Director of the Bureau of Radiological Health may approve alternate means of labeling (§ 1050.10(d)(5)).

17. One comment said the requirement in proposed §1050.10(e)(2)(iii) of ±10 percent for line voltage variations is too stringent for testing compliance with the error limits of § 1050.10(c)(1). It was noted that IEC Publication 150

allows additional ultrasonic power variations of ±10 percent for line voltage variations of ±5 percent.

The Commissioner believes that because line voltage variations of ±10 percent are not uncommon, the allowable error limits of ±20 percent in ultrasonic power indication should not be exceeded for such variations. Thus, a change in the regulation is not required, but the Commissioner welcomes further data and information that would show that less stringent provisions would not adversely affect the public health.

18. One comment suggested deletion of proposed § 1050.10(e)(3) because the specified detector size (i.e., with dimensions of less than one wave length in water) would often have dimensions of about 1 mm, an impractical size.

The Commissioner rejects the suggestion because detectors with dimensions as small as 0.25 mm are commercially available. This corresponds to an ultrasonic frequency of about 6 MHz. Furthermore, no marketed ultrasonic therapy products now operate above about 1 MHz, which would require a detector size no larger than about 1.5 mm. It is unlikely that products operating above 3 MHz (corresponding to a detector size of approximately 0.75 mm) will be marketed because the attenuation would be too great. It should also be noted that § 1050.10(e)(3) allows for an "equivalent measurement technique" in cases where compliance with the detector size requirement would be impractical.

19. One comment urged that instead of only requiring that the user be informed of the percentage errors in frequency and effective radiating area (§ 1050.10(f)(2)(iii)), maximum allowable errors for these parameters should be specified in § 1050.10(c). The comment noted that the IEC error limits for frequency and effective radiating area are ±5 percent and ±10 percent, respectively.

The Commissioner has insufficient information to justify specific error limits for ultrasonic frequency and effective radiating area. However, for an ultrasonic therapy product to be used properly, the errors in these parameters must be known by the practitioner. The Commissioner believes this will be effectively done via the user information required by § 1050.10(f)(2)(iii). He also advises that the quantities derived from the effective radiating area, such as the temporal-average effective intensity, are subject to error limits in § 1050.10(c)(1). The Commissioner welcomes data and information that would show the need for also specifying frequency and effective radiating area error limits.

20. One comment asked that the standard require manufacturers to supply maintenance manuals containing considerable explanatory information so hospital personnel can provide proper preventive maintenance on the devices. The comment also said FDA should monitor this required information to assure that the testing methods and maintenance scheduling are essential and necessary.

The Commissioner advises that § 1050.10(f)(1) already requires manufacturers to provide a maintenance schedule and instructions for operation, service, and calibration necessary to keep equipment in compliance with the standard. In addition, through its compliance programs, FDA will monitor the required informational material to assure that it is adequate.

21. One comment asked if the tests for compliance with the standard are intended for hospitals using the devices. If so, some of the required measurements, such as for the effective radiating area, would entail a sophisticated measuring capability and might have a significant cost impact.

The Commissioner points out that the compliance tests in § 1050.10(e) are not intended to be routine maintenance procedures. These are tests upon which manufacturers base their certification that a device is in compliance with the standard and which provide the basis for compliance measurements made by FDA. The device must remain in compliance with the standard for its useful life, provided the manufacturer's instructions for operation, service, and calibration are followed.

22. One comment said the large discrepancy between indicated and measured output from ultrasonic therapy products demonstrates the need for a performance standard. However, while admitting that such devices can induce damage to cells and tissues, the respondent alleged there is no evidence that the devices create a health hazard.

The need and rationale for this standard is discussed at length in the preamble to the June 14, 1976 proposal. The Commissioner notes that there have been documented instances of serious patient injury from exposure to ultrasound therapy (Medical World News, September 1964; Journal of the American Podiatry Association, Vol. 50, No. 8, p. 650; ibid, Vol. 51, No. 8, p. 574, copies of which are on file with the Hearing Clerk, FDA). As the comment notes, the need for a standard is justified on the basis of discrepancies between indicated and actual operating parameters. The potential for human injury and the known biological effects of ultrasound are sufficient reasons for development of a performance standard, even if documented cases of patient injury were not available.

23. One comment contained the suggestion that the standard should include a temperature limitation for the transducer face.

The Commissioner is not aware of any evidence that heating of the transducer face has produced actual problems in the use of ultrasonic therapy products. This lack of such evidence, along with the expected problems of technical feasibility of temperature measurements on the transducer face, has led to the rejection of such a requirement at the present time.

24. One comment recommended that a tolerance (e.g., ±5° C) be included with the specified temperature (30° C) of the measurement medium in § 1050.10(e)(2)(ii).

The Commissioner notes that water temperature is not a critical factor for the required measurements. A temperature is specified simply to standardize the procedures. It would be difficult to justify a temperature tolerance limit on the basis of protection of the public health and safety, and the Commissioner advises that he did not intend the stated temperature to represent an exact number. Furthermore, the regulation describes an idealized situation and only requires that an equivalent measurement medium be used. For example, oil at 20° C could be used instead of water at 30° C, provided the measurements were corrected to the idealized situation described in § 1050.10(e)(2)(ii). If it proves necessary, the Bureau of Radiological Health will provide a compliance guide for this standard, describing acceptable measurement techniques.

25. One comment on proposed § 1050.10(f)(2)(ii) said the user information should include at least one measurement of the ultrasonic radiation field along the applicator axis. The comment also said that a more rigorous specification of the number and accuracy of the required measurements should be included.

The Commissioner rejects the suggestions because the types of measurements necessary for an adequate description of the ultrasound field depend on the applicator configuration and thus vary.

26. One comment asked about the purpose of the visual indicator required in § 1050.10(c)(5). The comment said that a nonquantitative indication of electrical energy input to the transducer is not sufficient and that a quantitative indication of acoustic output from the applicator should be required.

The Commissioner advises that the visual indicator in § 1050.10(c)(5) is intended merely to alert the operator that the ultrasonic transducer(s) is energized. Quantitative indications of the power and intensity are required by § 1050.10(c)(1). It should be noted that the means necessary to comply with § 1050.10(c)(1) could be so de-

signed as to also fulfill the requirements of § 1050.10(c)(5).

27. One comment recommended that the standard require that a booklet of condensed operating instructions be affixed to the device.

The Commissioner believes that such a requirement is inappropriate and unnecessary. Manufacturers are required by § 1050.10(f)(2) to supply adequate operating instructions. It would not be prudent to have incomplete instructions affixed to the devices. Furthermore, the likelihood of persons losing or not using the currently required instructions for this type of medical device should be much less than for consumer products such as microwave ovens.

28. One comment questioned the need for the labeling information in § 1050.10(d)(3) concerning the ratio of temporal-maximum effective intensity to the temporal-average effective intensity (peak-to-average ratio). The comment said that most clinical situations do not require determining the relation between peak and average outputs.

The Commissioner believes that the labeling information should not be changed because the peak-to-average ratio is necessary to be able to convert from peak intensity to average intensity when operating in the pulsed mode. The average intensity must be known to be able to determine the tissue-heating effect (see paragraph 13, above).

29. One comment recommended that the description of the ultrasonic radiation field required in § 1050.10(f)(2)(ii) be provided for each applicator rather than for a model line because there can be vast differences between individual applicators of the same model.

The Commissioner has determined that no change is needed in the regulation. As currently worded, the description of the ultrasonic radiation field spatial distribution must be for the specific device with which the applicator is supplied. If there were significant differences between devices of the same model, individualized information would be necessary to comply with § 1050.10(f)(2)(ii).

30. One comment said the proposed warning in § 1050.10(f)(2)(iv) against adjusting nonuser controls is inadequate and misleading. The comment argued that by this warning, the manufacturer is granted exclusive responsibility and authority for nonoperator device adjustment, even though the user, such as a hospital, has qualified resident service personnel.

The intent of the warning is to caution untrained individuals that service controls or adjustments should not be used during normal operation. The Commissioner realizes that not all expertise rests with the manufacturer and advises that he did not intend to grant exclusive authority to perform service to any group. In fact, § 1050.10(f)(1), which requires that servicing information be provided to any person, is intended to make appropriate instructions available to all service personnel, including qualified hospital service personnel.

31. One comment noted that the "periodic" functions mentioned in § 1050.10(b)(19) are actually "quasi-periodic" because they are periodic functions multiplied by two step functions. The comment acknowleged that the distinction is unimportant for ultrasonic products for use in physical therapy, but suggested it may in the future be important for ultrasonic surgery products.

The Commissioner believes that no changes are needed in the regulation because the distinction between periodic and quasi-periodic waveforms for the equipment covered by this standard does not affect safety and health considerations. The need to distinguish between the functions will be considered for any future regulation applicable to ultrasonic surgery products.

32. A comment said the requirement for servicing information in § 1050.10(f)(1) is too vague and suggested that the following technical information should be specifically required: circuit diagrams, parts list, repair and service check lists, recommended preventive maintenance program and schedule, operational tests, block diagram if applicable, and installation manual. The comment also urged that consumer service personnel be specifically identified as persons to whom servicing information is to be made available by manufacturers.

The Commissioner does not agree. The regulation currently requires that adequate instructions be provided specifically including several items similar to those mentioned by the comment, e.g., maintenance schedule and calibration information. If information described in the comment is considered necessary for radiation safety reasons, such information must be provided by the manufacturer to meet the intent of § 1050.10(f)(1). However, the necessary information may vary from product to product, and so it is not practical to exactly specify a complete list of required information. Finally, § 1050.10(f)(1) currently requires that servicing information be made available to all persons upon request.

33. One manufacturer of ultrasonic therapy devices believes that the allowable tolerances for the timer in § 1050.10(c)(2) are too restrictive. The information accompanying the comment describes a 15-minute and 30-minute timer, though only the former is employed in ultrasonic therapy devices known to FDA. The 15-minute timer would not comply with § 1050.10(c)(2) for times less than 7.5 minutes, where its accuracy would be ±45 seconds (the standard requires ±0.5 minute for times less than 5 minutes, ±10 percent for times from 5 to 10 minutes, and ±1 minute for emission times greater than 10 minutes).

The Commissioner believes that the timer accuracy specifications in the proposal are necessary to assure that neither significant overexposures or underexposures occur for short treatment times (less than 7.5 minutes). It should be noted that underexposure may result in unnecessary exposure because the therapeutic effect may not occur with less than the prescribed exposure. The agency understands that short exposure times are being used in fractionated treatment regimens. Furthermore, the accuracy requirements could economically be met by currently available and relatively inexpensive timers.

34. One comment said the ratio of smallest beam cross-section to effective radiating area in the definition of focusing applicator (§ 1050.10(b)(15)) should be 0.95 rather than 0.5, to be consistent with the value of 1.05 for the peak-to-average pressure amplitude ratio in § 1050.10(b)(7). It suggested alternatively that the peak-to-average ratio be taken as 1.25 and the cross section-to-radiating area ratio be taken as 0.75. Those values would be consistent with IEC terminology (see comment 8, above).

The Commissioner does not accept the suggestion because there is no apparent reason why the demarcation between continuous and modulated waveforms should be at the same level as the demarcation between focusing and nonfocusing applicators. The spatial distribution of the ultrasonic field must be provided for all (focusing and nonfocusing) applicators. However, indication of temporal characteristics is required only for modulated waveforms. Therefore, waveforms characterized as continuous must have minimal temporal variations, i.e., peak-to-average amplitude ratio less than or equal to 1.05. However, as also stated in response to comment 8 above, the Commissioner welcomes further data and information that would justify adopting IEC provisions.

35. One manufacturer said the requirement for unique identification of applicators in § 1050.10(d)(4) implies a variability between applicators. Provision should be made for permanently attached applicators and for field replacement where all available applicators are essentially identical. To provide for this, the comment suggested that the phrase "Unless the applicator is permanently attached, or unless all physically interchangeable applicators are identical insofar as the parameters defined in (iii) below are concerned,

* * *" be inserted at the beginning of the introductory sentence of § 1050.10(d)(4).

The Commissioner is not changing the requirement because it is important to have all applicators individually labeled for those situations where different applicators do vary significantly. From a practical standpoint, because applicators are subject to specific performance requirements of this regulation and to the certification requirements of § 1010.2 (21 CFR 1010.2), the labeling in § 1050.10(d)(4) would be important for recall purposes in cases of noncompliance. Further, the Commissioner believes it would be difficult to adequately define the term "permanently attached." Most currently available applicators would probably be considered detachable.

36. One comment said a maintenance schedule as required by § 1050.10 (f)(1) and (f)(2)(i) is not always necessary and should be included in instructions only where necessary.

The Commissioner believes that no change in the regulation is needed. As currently worded, § 1050.10 (f)(1) and (f)(2)(i) refer to "a schedule of maintenance necessary to keep equipment in compliance." Thus instructions for service and for users would not require a maintenance schedule provided the manufacturer could substantiate that no maintenance is necessary to keep the device in compliance with the standard.

37. A manufacturer said the warning in § 1050.10(f)(2)(iv) is undesirable because: (1) Air is a poor conductor of ultrasound so the only danger is through direct contact with the transducer; (2) periosteal pain is a far more sensitive warning than any document; (3) such a warning detracts from the more significant warnings of electric shock, fire, and burn hazards, which are required by FDA and Underwriters Laboratory; (4) the warning is easily misunderstood by laymen, requiring extensive explanation that the "hazardous radiation" does not refer to ionizing radiation (e.g., x-rays) or ultraviolet radiation.

The Commissioner agrees that the term "hazardous radiation" could be misleading and is changing the warning to clarify that the attendant hazards derive from ultrasonic energy. However, he remains convinced the warning is necessary to divert nonservice personnel from changing nonuser controls or adjustments that might result in incorrect patient dose application and/or unintended exposure to the patient or operator.

38. One comment suggested that the applicator label required in § 1050.10(d)(4) should include the serial number(s) of designated generators to clarify to which generators the applicator has been tuned.

The Commissioner believes that requiring a specific generator serial number on an applicator implies that it should only be used with that specific generator even though with proper tuning and recalibration most applicators are interchangeable. He therefore rejects the suggestion.

39. One reviewer recommended that the user information required in § 1050.10(f)(2)(i) include a description of any known procedures that could alter compliance of the product with the standard.

The Commissioner is not changing the regulation because § 1050.10(f)(2)(i) already requires instructions on safe use, safety procedures, and precautions that may be necessary regarding the use of ultrasonic radiation. Also, § 1050.10(f)(2)(iv) requires a warning against possibly hazardous adjustments or procedures.

On his own initiative the Commissioner is changing the wording of § 1050.10(a) on applicability and § 1050.10(b)(25) defining "ultrasonic therapy product," to better reflect the original intent of this standard. The standard is intended to apply to ultrasonic devices used in physical therapy primarily for deep tissue heating. All currently known ultrasonic surgery devices (including those for cataract removal) operate by a mechanical vibratory action and have significantly different characteristics from devices used in physical therapy and so are not included in this regulation. The proposed standard excluded "products designed for use in dentistry," although the intent was to exclude only dental scaling devices. A specific exclusion of ultrasonic dental scalers is not needed because such devices are not used in physical therapy. Ultrasonic devices not covered by this regulation may be the subject of future FDA regulatory action.

The Physical Medicine Device Classification Panel and the American Academy of Physical Medicine and Rehabilitation expressed concerns that requirements be developed to assure that ultrasonic therapy devices provide sufficient power output to achieve therapeutic effectiveness. The commissioner welcomes further comments, suggestions, and supporting information on the need for such requirements. Such requirements, including appropriate indications for use and any necessary restrictions on use, will be considered at a later date in accordance with the priorities and other recommendations made by the appropriate classification panel.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to him (21 CFR 5.1), the Commissioner amends Chapter I, Subchapter J of Title 21 of the Code of Federal Regulations by adding new Part 1050, to read as follows:

§ 1050.10 Ultrasonic therapy products.

(a) *Applicability.* The provisions of this section are applicable as specified herein to any ultrasonic therapy product for use in physical therapy manufactured on or after February 17, 1979.

(b) *Definitions.* The following definitions apply to words and phrases used in this section:

(1) "Amplitude modulated waveform" means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is greater than 1.05.

(2) "Applicator" means that portion of a fully assembled ultrasonic therapy product that is designed to emit ultrasonic radiation and which includes one or more ultrasonic transducers and any associated housing.

(3) "Beam cross-section" means the surface in any plane consisting of the points at which the intensity is greater than 5 percent of the spatial-maximum intensity in that plane.

(4) "Beam nonuniformity ratio" means the ratio of the temporal-average spatial-maximum intensity to the temporal-average effective intensity.

(5) "Centroid of a surface" means the point whose coordinates are the mean values of the coordinates of the points of the surface.

(6) "Collimating applicator" means an applicator that does not meet the definition of a focusing applicator as specified in paragraph (b)(15) of this section and for which the ratio of the area of at least one beam cross-section, whose centroid is 12 centimeters from the centroid of the effective radiating surface, to the area of the effective radiating surface is less than two.

(7) "Continuous-wave waveform" means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is less than or equal to 1.05.

(8) "Diverging applicator" means an applicator that does not meet the definition of a collimating applicator or a focusing applicator as specified in paragraphs (b) (6) and (15) of this section.

(9) "Effective intensity" means the ratio of the ultrasonic power to the focal area for a focusing applicator. For all other applicators, the effective intensity is the ratio of the ultrasonic power to the effective radiating area. Effective intensity is expressed in watts per square centimeter (Wcm^{-2}).

(10) "Effective radiating area" means the area consisting of all points

of the effective radiating surface at which the intensity is 5 percent or more of the maximum intensity at the effective radiating surface, expressed in square centimeters (cm^2).

(11) "Effective radiating surface" means the surface consisting of all points 5 millimeters from the applicator face.

(12) "Focal area" means the area of the focal surface, expressed in square centimeters (cm^2).

(13) "Focal length" means the distance between the centroids of the effective radiating surface and the focal surface, for a focusing applicator, expressed in centimeters (cm).

(14) "Focal surface" means the beam cross-section with the smallest area of a focusing applicator.

(15) "Focusing applicator" means an applicator in which the ratio of the area of the beam cross-section with the smallest area to the effective radiating area is less than one-half.

(16) "Generator" means that portion of a fully assembled ultrasonic therapy product that supplies electrical energy to the applicator. The generator may include, but is not limited to, a power supply, ultrasonic frequency oscillator, service controls, operation controls, and a cabinet to house these components.

(17) "Maximum beam nonuniformity ratio" means the maximum value of the beam nonuniformity ratio characteristic of a model of an ultrasonic therapy product.

(18) "Operation control" means any control used during operation of an ultrasonic therapy product that affects the ultrasonic radiation emitted by the applicator.

(19) "Pressure amplitude" means the instantaneous value of the modulating waveform, and is $p_1(t)$ in the expression for a pressure wave, $p(t)=p_1(t)\,p_2(t)$, where $p(t)$ is the instantaneous pressure, $p_1(t)$ is the modulating envelope, and $p_2(t)$ is the relative amplitude of the carrier wave normalized to a peak height of one. All are periodic functions of time, t, at any point in space. The period of $p_1(t)$ is greater than the period of $p_2(t)$.

(20) "Pulse duration" means a time interval, expressed in seconds, beginning at the first time the pressure amplitude exceeds the minimum pressure amplitude plus 10 percent of the difference between the maximum and minimum pressure amplitudes, and ending at the last time the pressure amplitude returns to this value.

(21) "Pulse repetition rate" means the repetition frequency of the waveform modulating the ultrasonic carrier wave expressed in pulses per second (pps).

(22) "Service control" means any control provided for the purpose of adjustment that is not used during operation and can affect the ultrasonic radiation emitted by the applicator, or can alter the calibration or accuracy of an indicator or operation control.

(23) "Ultrasonic frequency" means the frequency of the ultrasonic radiation carrier wave, expressed in Hertz (Hz), kilohertz (kHz), or megahertz (MHz).

(24) "Ultrasonic power" means the total power emitted in the form of ultrasonic radiation by the applicator averaged over each cycle of the ultrasonic radiation carrier wave, expressed in watts.

(25) "Ultrasonic therapy product" means:

(i) Any device intended to generate and emit ultrasonic radiation for therapeutic purposes at ultrasonic frequencies above 16 kilohertz (kHz); or

(ii) Any generator or applicator designed or specifically designated for use in a device as specified in paragraph (b)(25)(i) of this section.

(26) "Ultrasonic transducer" means a device used to convert electrical energy of ultrasonic frequency into ultrasonic radiation or vice versa.

(c) *Performance requirements.* The requirements of this paragraph are applicable to each ultrasonic therapy product as defined in paragraph (b)(25) of this section when the generator and applicator are designated or intended for use together, or to each generator when the applicator(s) intended for use with the generator does not contain controls that affect the functioning of the generator.

(1) *Ultrasonic power and intensity—*(i) *Continuous-wave waveform operation.* A means shall be incorporated to indicate the magnitudes of the temporal-average ultrasonic power and the temporal-average effective intensity when emission is of continuous-wave waveform. The error in the indication of the temporal-average ultrasonic power shall not exceed ±20 percent for all emissions greater than 10 percent of the maximum emission.

(ii) *Amplitude-modulated waveform operation.* A means shall be incorporated to indicate the magnitudes of the temporal-maximum ultrasonic power and the temporal-maximum effective intensity when the emission is of amplitude-modulated waveform. The sum of the errors in the indications of the temporal-maximum ultrasonic power and the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity specified in paragraph (d)(3)(ii) of this section shall not exceed ±20 percent for all emissions greater than 10 percent of the maximum emission.

(2) *Treatment time.* A means shall be incorporated to enable the duration of emission of ultrasonic radiation for treatment to be preset and such means shall terminate emission at the end of the preset time. Means shall also be incorporated to enable termination of emission at any time. Means shall be incorporated to indicate the magnitude of the duration of emission (expressed in minutes) to within 0.5 minute of the preset duration of emission for settings less than 5 minutes, to within 10 percent of the preset duration of emission for settings of from 5 minutes to 10 minutes, and to within 1 minute of the preset duration of emission for settings greater than 10 minutes.

(3) *Pulse duration and repetition rate.* A means shall be incorporated for indicating the magnitudes of pulse duration and pulse repetition rate of the emitted ultrasonic radiation, if there are operation controls for varying these quantities.

(4) *Ultrasonic frequency.* A means shall be incorporated for indicating the magnitude of the ultrasonic frequency of the emitted ultrasonic radiation, if there is an operation control for varying this quantity.

(5) *Visual indicator.* A means shall be incorporated to provide a clear, distinct, and readily understood visual indicator when and only when electrical energy of appropriate ultrasonic frequency is being applied to the ultrasonic transducer(s).

(d) *Labeling requirements.* In addition to the labeling requirements in Part 801 and the requirements of §§ 1010.2 and 1010.3 of this chapter, each ultrasonic therapy product shall be subject to the applicable labeling requirements of this paragraph.

(1) *Operation controls.* Each operation control shall be clearly labeled identifying the function controlled and, where appropriate, the units of measure of that function. If a separate control and indicator are associated with the same function, then labeling the appropriate units of measure of that function is required for the indicator but not for the control.

(2) *Service controls.* Each service control that is accessible without displacement or removal of any part of the ultrasonic therapy product shall be clearly labeled identifying the function controlled and shall include the phrase "for service adjustment only."

(3) *Generators.* (i) Each generator shall bear a label that states: The brand name, model designation, and unique serial number or other unique identification so that it is individually identifiable; ultrasonic frequency (unless there is an operation control for varying this quantity); and type of waveform (continuous wave or amplitude modulated).

(ii) Generators employing amplitude-modulated waveforms shall also bear a label that provides the following information: Pulse duration and pulse repetition rate (unless there are operation controls for varying these quantities), an illustration of the amplitude-modulated waveform, and the

ratio of the temporal-maximum effective intensity to the temporal-average effective intensity. (If this ratio is a function of any operation control setting, then the range of the ratio shall be specified, and the waveform illustration shall be provided for the maximum value of this ratio.)

(4) *Applicators.* Each applicator shall bear a label that provides the following information:

(i) The brand name, model designation, and unique serial number or other unique identification so the applicator is individually identifiable;

(ii) A designation of the generator(s) for which the applicator is intended; and

(iii) The ultrasonic frequency, effective radiating area, maximum beam nonuniformity ratio, type of applicator (focusing, collimating, diverging), and for a focusing applicator the focal length and focal area.

(5) *Label specifications.* Labels required by this paragraph shall be permanently affixed to or inscribed on the ultrasonic therapy product; they shall be legible and clearly visible. If the size, configuration, or design of the ultrasonic therapy product would preclude compliance with the requirements of this paragraph, the Director, Bureau of Radiological Health, may approve alternate means of providing such label(s).

(e) *Tests for determination of compliance*—(1) *Tests for certification.* Tests on which certification pursuant to § 1010.2 of this chapter is based shall account for all measurement errors and uncertainties. Such tests shall also account for increases in emission and degradation in radiation safety that occur with age.

(2) *Test conditions.* Except as provided in § 1010.13 of this chapter, tests for compliance with each of the applicable requirements of this section shall be made:

(i) For all possible combinations of adjustments of the controls listed in the operation instructions.

(ii) With the ultrasonic radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30° C for measurements concerning the ultrasonic radiation.

(iii) With line voltage variations in the range of ±10 percent of the rated value specified by the manufacturer.

(3) *Measurement parameters.* Measurements for determination of the spatial distribution of the ultrasonic radiation field shall be made with a detector having dimensions of less than one wavelength in water or an equivalent measurement technique.

(f) *Informational requirements*—(1) *Servicing information.* The manufacturer of an ultrasonic therapy product shall provide or cause to be provided to servicing dealers and distributors, and to others upon request, at a cost not to exceed the cost of preparation and distribution, adequate instructions for operation, service, and calibration, including a description of those controls and procedures that could be used to increase radiation emission levels, and a schedule of maintenance necessary to keep equipment in compliance with this section. The instructions shall include adequate safety precautions that may be necessary regarding ultrasonic radiation exposure.

(2) *User information.* The manufacturer of ultrasonic therapy product shall provide as an integral part of any user instruction or operation manual that is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each ultrasonic therapy product, and to others upon request, at a cost not to exceed the cost of preparation and distribution:

(i) Adequate instructions concerning assembly, operation, safe use, any safety procedures and precautions that may be necessary regarding the use of ultrasonic radiation, and a schedule of maintenance necessary to keep the equipment in compliance with this section. The operation instructions shall include a discussion of all operation controls, and shall describe the effect of each control.

(ii) Adequate description of the spatial distribution of the ultrasonic radiation field and the orientation of the field with respect to the applicator. This will include a textual discussion with diagrams, plots, or photographs representative of the beam pattern. If there is more than one ultrasonic transducer in an applicator and their positions are not fixed relative to each other, then the description must specify the spatial distribution of the ultrasonic radiation field emitted by each ultrasonic transducer and present adequate examples of the combination field of the ultrasonic transducers with regard to safe use. The description of the ultrasonic radiation field shall state that such description applies under conditions specified in paragraph (e)(2)(ii) of this section.

(iii) Adequate description, as appropriate to the product, of the uncertainties in magnitude expressed in terms of percentage error, of the ultrasonic frequency, effective radiating area, and, where applicable, the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity, pulse duration, pulse repetition rate, focal area, and focal length. The errors in indications specified in paragraphs (c)(1) and (c)(2) of this section shall be stated in the instruction manual.

(iv) A listing of controls, adjustments, and procedures for operation and maintenance, including the warning "Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy."

Effective date: This regulation shall become effective February 17, 1979.

(Sec. 358, 82 Stat. 1177-1179 (21 U.S.C. 263f).)

Dated: February 9, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

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