CATEGORIES RECORDS IN THE SYSTEM:

Investigatory material relating to any category of individual described above; applications for employment; agent availability for special protective assignments; intelligence reports; fingerprints; photographs; internal memoranda.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7311 and 7531–33; 8 U.S.C. 1104; 18 U.S.C. 111, 112, 201, 202, 1114, 1116, 1117, 1541, 1542, 1543, 1544, 1545, 1546; 22 U.S.C. 211a, 846, 911, 2454, and 2667; Executive Order 10450; Executive Order 12065; Executive Order 10855; 22 CFR Subchapter M.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The principal users of this information outside the Department of State are: Department of Treasury; U.S. Office of Personnel Management; Agency for International Development; International Communications Agency; Arms Control and Disarmament Agency; U.S. Secret Service; Immigration and Naturalization Service; Department of Defense; Central Intelligence Agency; Department of Justice; National Security Agency; Drug Enforcement Administration; and other Federal agency inquiring pursuant to law or Executive Order in order to make a determination of general suitability for employment or retention in employment, to grant a contract or issue a license, grant, or security clearance; any other Federal, state, of municipal law enforcement agency for law enforcement purposes; any other agency or Department of the Federal government pursuant to statutory intelligence responsibilities or other lawful purposes; any other agency or Department of the Executive Branch having oversight or review authority with regard to its investigative responsibilities; to the extent necessary to identify the individual adequately, to any other record custodian in order to obtain information relevant to a legitimate investigative or intelligence interest of the Department of State. The information may also be released to other government agencies who have statutory or other lawful authority to maintain such information. Also see "Routine Uses" of Prefatory Statement.

POLICIES AND PRACTICES FOR STORING RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Hard copy; microfilm; microfiche; computer media.

RETRIEVABILITY:

By individual name.

SAFEGUARDS:

All employees of the Department of State have undergone a thorough security investigation. Access to the Department of State building and its annexes is controlled by security guards, and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. All records containing personal information are maintained in secured file cabinets or in restricted areas, access to which is limited to authorized personnel.

RETENTION AND DISPOSAL:

Retention of these records varies, depending upon the specific kind of record involved. They are retired or destroyed in accordance with published schedules of the Department of State. More specific information may be obtained by writing the Information and Privacy Coordinator, Foreign Affairs Document and Reference Center, Room 1239, Department of State, 2201 C Street, N.W., Washington, D.C. 20520.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Assistant Secretary for Security, Room 2513, Department of State, 2201 C Street, N.W., Washington, D.C. 20520.

NOTIFICATION PROCEDURE:

Individuals who wish to find out if the Office of Security has records pertaining to them should write to the Information and Privacy Coordinator, Foreign Affairs Document and Reference Center, Room 1239, Department of State, 2201 C Street, N.W., Washington, D.C. 20520. At a minimum, the individual must include: name; date and place of birth; current mailing address and zip code; signature.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to or amend records pertaining to themselves should write to the Information and Privacy Coordinator, Foreign Affairs Document and Reference Center (address above).

CONTESTING RECORD PROCEDURES:

(See above).

RECORD SOURCE CATEGORIES:

The individual; persons having knowledge of the individual; persons having knowledge of incidents or other matters of investigative interest to the Department; pertinent records of other Federal, state, or local agencies or foreign governments; pertinent records of private firms or organizations; public sources.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

Certain records contained within this system of records are exempted from 5 U.S.C. 552a(c)(3); (d), (e)(1), (e)(4)(G), and (H), and (I), and (f). See Department of State Rules published in the **Federal Register**. Pursuant to Section (j)(2) of the Act, records compiled by the Special Assignments Staff and the Passport and Visa Fraud Branch of the Office of Security may be exempted from the requirements of any part of the Act except subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11), and (i) to the extent necessary to assure the effective completion of the investigative and judicial processes.

[FR Doc. 80-1794 Filed 1-17-80; 8:45 am]
BILLING CODE 4710-05-M

VETERANS ADMINISTRATION

Station Committee on Educational Allowances; Meeting

Notice is hereby given pursuant to Section V, Review Procedure and Hearing Rules, Station Committee on Educational Allowances that on February 11, 1980 at 9:30 a.m., the St. Paul VA Center Station Committee on Educational Allowances shall at Room 114B, Federal Bldg., Fort Snelling, St. Paul, Minnesota 55111 conduct a hearing to determine whether Veterans Administration benefits to all eligible persons enrolled in Minneapolis Community College (formerly known as Metropolitan Community college), at 1501 Hennepin Avenue, Minneapolis, Minnesota 55403 should be discontinued, as provided in 38 CFR 21.4134, because a requirement of law is not being met or a provision of the law has been violated. All interested persons shall be permitted to attend, appear before, or file statements with the committee at that time and place.

January 9, 1980.

Morris Nooner, Jr.,

Director, VA Center, Federal Bldg., Ft. Snelling, St. Paul, MN 55111.

[FR Doc. 80-1606 Filed 1-17-80; 8:45 am]
BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 45, No. 13
Friday, January 18, 1980

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94–409) 5 U.S.C. 552b(e)(3).

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1

[M–264, Amdt. 2; Jan. 16, 1980]

CIVIL AERONAUTICS BOARD.

Addition of items to the January 15, 1980, meeting.

TIME AND DATE: 9:30 a.m., January 15, 1980.

PLACE: Room 1027, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT:

14. Docket 34396, Request of Braniff Airways for a discussion authorization under § 412 and an antitrust exemption under § 414. Braniff has asked that the Board sanction discussions, as it has done in the past, aimed at controlling arrivals at the International Arrival Building at Kennedy Airport during its summer peak period (Memo 9423, BDA, OGC).

15. Domestic Fare Policy (BDA, OEA).

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673–5068.

SUPPLEMENTARY INFORMATION: Item 14 was added to the January 15th meeting because discussions for which authorization is requested are scheduled to begin January 21, 1980, and this is the last scheduled Board meeting before that date. The Board felt that Item 15 should be added to the agenda because of the great concern about the need for additional fare flexibility and should be discussed as soon as possible. Accordingly, the following Members have voted that agency business requires the addition of items 14 and 15 to the January 15, 1980 agenda and that no earlier announcement of these additions was possible:

Chairman, Marvin S. Cohen
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

[S–106–80 Filed 1–16–80; 3:47 pm]

BILLING CODE 6320–01–M

2

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.

TIME AND DATE: 9:30 a.m. (Eastern Time), Tuesday, January 22, 1980.

PLACE: Commission Conference Room, No. 5240, on the fifth floor of the Columbia Office Building, 2401 E Street N.W., Washington, D.C. 20506.

STATUS: Part will be open to the public and part will be closed to the public.

MATTERS TO BE CONSIDERED:

Open to the Public

1. Freedom of Information Act Appeal No. 79–12–FOIA–420, concerning a request for the entire file on a charge filed by a Federal employee.

2. Freedom of Information Act Appeal No. 79–11–FOIA–412, concerning whether or not an attorney representing a third party should have access to a charge file.

3. Several proposed sole source contracts for services needed in connection with court cases.

4. Report on Commission Operations by the Executive Director.

Closed to the Public

Litigation authorization; General Counsel Recommendations.

Note.—Any matter not discussed or concluded may be carried over to a later meeting.

CONTACT PERSON FOR MORE INFORMATION: Marie D. Wilson, Executive Officer, Executive Secretariat, at (202) 634–6748.

This notice issued January 15, 1980.

[S–107–80 Filed 1–16–80; 3:47 pm]

BILLING CODE 6570–06–M

3

FEDERAL COMMUNICATIONS COMMISSION.

PREVIOUSLY ANNOUNCED TIME AND DATE OR MEETING: 9:30 a.m., Wednesday, January 16, 1980.

PLACE: Room 856, 1919 M Street, N.W., Washington, D.C.

STATUS: Commission Open Meeting.

CHANGES IN THE MEETING: The following item has been deleted:

Agenda, Item No., and Subject

General—1—Title: Notice of Proposed Rule Making to implement changes in the frequencies, operating procedures and other criteria relating to radiotelephony in the band 4,000–23,000 kHz in the maritime mobile service adopted at the World Maritime Administrative Radio Conference, Geneva, 1974. Summary: The FCC is proposing to finalize the frequencies now assigned in the temporary assignment plan and make changes which will redefine the classes of stations to separate radiotelegraphy and radiotelephony stations and define the radiotelephony stations by the frequency band assigned. There will be a temporary requirement for coast stations to submit utilization data on all frequencies assigned to assist us in evaluating the frequency assignments to satisfy the operational requirements of the maritime mobile service.

Additional information concerning this meeting may be obtained from Edward Dooley, FCC Public Affairs Office, telephone number (202) 632–7260.

Issued: January 15, 1980.

[S–100–80 Filed 1–16–80; 12:24 pm]

BILLING CODE 6712–01–M

4

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9:30 a.m., Tuesday, January 22, 1980.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Closed Commission Meetings following Oral Arguments.

MATTERS TO BE CONSIDERED: The Commission will hold two closed meetings Tuesday, January 22, 1980 for the purpose of issuing instructions to the staff following scheduled oral arguments.

Oral Arguments, which are open to the public are scheduled to start at 9:00 a.m. (renewal application of Janus Broadcasting Company, WGNE and WGNE–FM, Panama City Beach, Florida, Docket Nos. 20952 and 20953, and followed by West Coast Media, Inc., KDIG–FM, San Diego, California, Docket No. 20971) in Room 856, 1919 M Street NW., Washington, D.C. (see Orders, FCC 80 M–73 and FCC 80 M–75).

The closed meetings will take place at the same location after the conclusion of the oral arguments.

These meetings may be continued the following day to allow the Commission to complete appropriate actions.

If additional information is required concerning these meetings it may be obtained from Edward Dooley, FCC Public Affairs Office, Telephone Number (202) 632-7260.

Issued: January 15, 1980.

[S-101-80 Filed 1-16-80; 12:24 pm]

BILLING CODE 6712-01-M

5

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 45 FR 2993.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., January 16, 1980.

CHANGE IN MEETING: The following item has been added:

Item No., Docket No. and Company

CAP-7. ER77-6 and ER77-7, Otter Tail Power Company.

Kenneth F. Plumb,

Secretary.

[S-105-80 Filed 1-16-80; 3:01 pm]

BILLING CODE 6450-01-M

6

FEDERAL HOME LOAN BANK BOARD.

TIME AND DATE: 9:30 a.m., January 23, 1980.

PLACE: 1700 G Street, N.W., Sixth Floor, Washington, D.C.

STATUS: Open Meeting.

CONTACT PERSON FOR MORE INFORMATION: Franklin O. Bolling (202-377-6677).

MATTERS TO BE CONSIDERED:

Application for Bank Membership—Western New York Savings Bank, Buffalo, New York.

Applications for Bank Membership and Insurance of Accounts—49er Savings & Loan Association, Oakhurst, California.

Application for Insurance of Accounts—Little River Savings & Loan Association, Ashdown, Arkansas.

Application for Insurance of Accounts—Investors Savings & Loan Association of El Reno, El Reno, Oklahoma.

Permission to Organize a New Federal Association—Horace Richter, *et al.*, Hamilton, Georgia.

Concurrent Branch Office Applications—First Federal Savings & Loan Association of Eau Claire, Eau Claire, Wisconsin and Barron County Federal Savings & Loan Association, Barron, Wisconsin.

Further Extension of Time to Open a Branch Office—Joliet Federal Savings & Loan Association, Joliet, Illinois.

Merger—Tri-County Savings & Loan Association of Hudson, Hudson, Wisconsin into First Federal Savings & Loan Association of La Crosse, La Crosse, Wisconsin.

Conversion to a State-Chartered Mutual Association—Smithville, Federal Savings & Loan Association, Smithville, Texas.

Application to Convert from the Federal Stock Form of Organization—Germania Federal Savings & Loan Association of Alton, Alton, Illinois.

Application for Permission to Convert to a Michigan Chartered Stock Association-Metropolitan Savings & Loan Association, Farmington Hills, Michigan.

No. 310, January 16, 1980.

[S-104-80 Filed 1-16-80; 3:01 pm]

BILLING CODE 6720-01-M

7

FEDERAL MARITIME COMMISSION.

TIME AND DATE: 10:00 a.m., January 22, 1980.

PLACE: Hearing Room 1, 1100 L Street, N.W., Washington D.C. 20573.

STATUS: Open.

MATTER TO BE CONSIDERED: Informal Docket No. 653(I): *J. T. Baker Company* v. *Yamashita-Shinnihon Line*—Review of Settlement Officer Decision.

CONTACT PERSON FOR MORE INFORMATION: Francis C. Hurney, Secretary (202) 523-5725.

[S-99-80 Filed 1-16-80; 11:26 am]

BILLING CODE 6730-01-M

8

FEDERAL RESERVE SYSTEM.

TIME AND DATE: 10:00 a.m., Wednesday, January 23, 1980.

PLACE: 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Summary Agenda

Because of its routine nature, no substantive discussion of the following item is anticipated. This matter will be voted on without discussion unless a member of the Board requests that the item be moved to the discussion agenda.

1. Proposed interpretation of section 2(g)(3) of the Bank Holding Company Act regarding whether certain routine extensions of credit will not be regarded as indebtedness for the purposes of this section.

Discussion Agenda

1. Proposed regulation to implement the Electronic Fund Transfer Act dealing with documentation of transfers, preauthorized transfers to a consumer's account, error resolution, and services offered by financial institutions not holding consumer's accounts. (Proposed earlier for public comment; docket No. R-0251.)

2. Any agenda items carried forward from a previously announced meeting.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board, 202-452-3204.

Griffith L. Garwood,

Deputy Secretary of the Board.

[S-96-80 Filed 1-15-80; 4:34 pm]

BILLING CODE 6210-01-M

9

INTER-AMERICAN FOUNDATION.

TIME AND DATE: 2:30 p.m., January 29, 1980.

PLACE: Board Room, Inter-American Foundation, 1515 Wilson Blvd., Arlington, Va. 22209.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Chairman's Report.
2. President's Report.
3. Financial Report.
4. Project Summaries.

CONTACT PERSON FOR MORE INFORMATION: Lawrence E. Bruce, Jr. (703) 841-3812.

[S-103-80 Filed 1-16-80; 3:01 pm]

BILLING CODE 7025-01-M

10

SECURITIES AND EXCHANGE COMMISSION.

Notice is hereby given, pursuant to the provisons of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of January 21, 1980, in Room 825, 500 North Capitol Street, Washington, D.C.

Closed meetings will be held on Tuesday, January 22, 1980, at 9:00 a.m. and immediately following the 10:00 a.m. open meeting, and on Thursday, January 24, 1980 at 10:00 a.m. and immediately following the 2:30 p.m. open meeting. Open meetings will be held on Tuesday, January 22, 1980 at 10:00 a.m. and 3:00 p.m. and Thursday, January 24, 1980 at 2:30 p.m.

The Commissioners, their legal assistants, the Secretary of the Commission, and recording secretaries will attend the closed meetings. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meetings may be considered pursuant to one or more of the exemptions set forth in 5

U.S.C. 552b(c) (4), (8), (9)(A), and (10) and 17 CFR 200.402(a) (4), (8), (9)(i), and (10).

Chairman Williams and Commissioners Evans and Pollack determined to hold the aforesaid meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, January 22, 1980, at 9:00 a.m., will be:

Administrative proceeding of an enforcement nature.
Litigation matter.

The subject matter of the closed meeting scheduled for Tuesday, January 22, 1980, immediately following the 10:00 a.m. open meeting, will be:

Formal order of investigation.
Institution of administrative proceeding of an enforcement nature.
Regulatory matter bearing enforcement implications.

The subject matter of the closed meeting scheduled for Thursday, January 24, 1980, at 10:00 a.m., will be:

Formal orders of investigation.
Freedom of Information Act appeal.
Institution and settlement of administrative proceedings of an enforcement nature.

The subject matter of the closed meeting scheduled for Thursday, January 24, 1980, immediately following the 2:30 p.m. open meeting, will be:

Post oral argument discussion.

The subject matter of the open meeting scheduled for Tuesday, January 22, 1980, at 10:00 a.m., will be:

1. Consideration of whether to issue and order, pursuant to Section 11A(a)(3)(B) of the Securities Exchange Act of 1934, granting permanent approval of a plan governing the implementation and operation of the consolidated quotation system. For further informaton, please contact Bruce Beatt at (202) 272–2888.

2. Consideraton of whether to issue a release announcing the filing of, and requesting comments with respect to, a proposed plan, filed under Section 11A(a)(3)(B) of the Securities Exchange Act by the five national securities exchanges trading options, which if approved by the Commission would authorize those exchanges to act jointly in the development and operation of system for the reporting of consolidated options last sale reports and quotation information. For further informaton, please contact Willam Muller at (202) 272–2415.

3. Consideration of whether to issue a release proposing to amend Form N–1 [17 CFR 239.15, 274.11] under the Securities Act of 1933 [15 U.S.C. 77a–77aa] ("Securities Act") and the Investment Company Act of 1940 [15 U.S.C. 80a–1–80a–52], and Rule 434d [17 CFR 230.434d] under the Securities Act. The amendments would require money market funds to include in their prospectuses a yield quotation and a description of the method by which yield is computed. The amendments would require that the yield computations be made according to a standardized method for use both in regular prospectuses and advertisements use pursuant to Rule 434d. The Commission will also consider the withdrawal of a prior proposal to standardize quotations of yield by money market funds. For further information, please contact Anthony A. Vertuno at (202) 272–2107.

The subject matter of the open meeting scheduled for Tuesday, January 22, 1980, at 3:00 p.m., will be:

Meeting with the American Society of Corporate Secretaries.

The subject matter of the open meeting scheduled for Thursday, January 24, 1980, at 2:30 p.m., will be:

The Commission will hear oral argument on appeals by Robert Berkson, Secretary of the former brokerage firm of Packer, Wilbur & Co., Inc., and the Division of Enforcement from the initial decision of an administrative law judge. The law judge concluded that Berkson should be barred from association with any broker-dealer with the provision that, after 18 months, he may become so associated in a non-proprietary and non-supervisory capacity, upon an appropriate showing of adequate supervision. For further informaton, please contact Herbert V. Efron at (202) 272–2754.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: John Granda at (202) 272–2091.

January 15, 1980.

[S–97–80 Filed 1–15–80; 4:34 pm]

BILLING CODE 8010–01–M

federal register

Friday
January 18, 1980

Part II

Department of Health, Education, and Welfare

Food and Drug Administration

Medical Devices; Procedures for Investigational Device Exemptions

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 16, 20, 809 and 812

[Docket No. 76N-0324]

Medical Devices; Procedures for Investigational Device Exemptions

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule sets forth the procedures and conditions under which investigations of medical devices involving human subjects may be exempt from certain requirements of the Federal Food, Drug, and Cosmetic Act, in accordance with the Medical Device Amendments of 1976. The rule sets out the procedures to obtain an investigational device exemption (IDE); it delineates the responsibilities of sponsors, institutional review boards, and clinical investigators with respect to clinical investigations of medical devices; and the rule also prescribes informed consent requirements and specifies recordkeeping and reporting requirements.

EFFECTIVE DATE: The reporting and recordkeeping requirements contained in this rule have been submitted for approval by the Office of Management and Budget (OMB) in accordance with the Federal Reports Act of 1942. This regulation will become effective July 16, 1980, provided that approval of the OMB is received by that date. If OMB does not approve, without change, the reporting and recordkeeping requirements contained in the rule, FDA will revise the rule as necessary to comply with the decision of OMB. FDA will publish a notice in a future issue of the **Federal Register** concerning OMB's decision on these requirements.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Bureau of Medical Devices (HFK-403), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-8162.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (Pub. L. 94-295), referred to here as "the amendments," amended the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040 et seq. (21 U.S.C. 201 et seq.)), referred to here as "the act." Section 520(g) of the act (21 U.S.C. 360j(g)) sets out requirements that apply to investigational use of medical devices.

Section 520(g) authorizes the exemption of devices from provisions of the act that relate to misbranding, registration, premarket notification, performance standards, premarket approval, banned devices, recordkeeping and reporting requirements, restrictions on distribution of devices, good manufacturing practice requirements, and use of color additives, to permit devices to be shipped for clinical investigations to determine their safety and effectiveness.

An investigation is considered approved and may begin 30 days after an application for an IDE is submitted to the Food and Drug Administration (FDA), unless FDA notifies the applicant within 30 days that the application is not approved. An application for an IDE for a banned device must be approved by FDA in writing before the investigation may begin.

FDA will enforce this regulation under section 301(q) of the act (21 U.S.C. 331(q)), which prohibits failure or refusal to comply with a requirement prescribed under section 520(g). Section 301(q)(2) also prohibits the submission of reports that are materially false or misleading. In addition, a device is adulterated under section 501(f) and (i) of the act (21 U.S.C. 351(f) and (i)) if the device fails to comply with applicable requirements of the IDE regulation. Adulterated devices may be seized under section 304 (21 U.S.C. 334).

Prior Federal Register Documents and Public Hearing

In the **Federal Register** of August 20, 1976 (41 FR 35282), FDA proposed regulations on IDE's (the original proposal). The proposal was finalized with respect to intraocular lenses (IOL's), but not with respect to other medical devices, by regulations published in the **Federal Register** of November 11, 1977 (42 FR 58874) and codified in Part 813 (21 CFR Part 813). Paragraph 34 below discusses the regulations that now apply to IOL investigations.

Because of the heavy volume of comments and the desire to increase public participation in the development of the IDE regulation, FDA issued a reproposal in the form of a tentative final regulation in the **Federal Register** of May 12, 1978 (43 FR 20726) (the reproposal). A **Federal Register** notice of October 6, 1978 (43 FR 46321), extended the deadline for comments from September 11, 1978, to December 5, 1978. This extension was in response to several requests to allow comments on the relation of the reproposal to two related proposed rules published by FDA on August 8, 1978, that is, Standards for Institutional Review Boards for Clinical Investigations (43 FR 35186) and Obligations of Clinical Investigators of Regulated Articles (43 FR 35210), and to the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Commission) on Institutional Review Boards and Informed Consent. (See the **Federal Register** of November 30, 1978 (43 FR 56174).)

A public hearing on the reproposal was held in Rockville MD, on August 7, 1978. Fourteen persons made presentations at the hearing. A transcript of the hearing is on file in the office of the Hearing Clerk, FDA, Rockville, MD. Comments offered at the hearing were considered in preparing this final regulation.

Decision To Publish Regulation as a Final Rule

A comment on the reproposal requested that revisions made in the reproposal be published as another reproposal rather than as a final regulation, to allow more public participation.

FDA has elected to publish a final regulation. The changes made in this document are consistent with, and generally are in response to, the written comments received on the original proposal or the reproposal and comments at the public hearing. FDA believes that this final regulation is based on sufficient public participation and that an additional reproposal is neither legally required nor desirable as a policy matter.

Relationship to Sponsor/Monitor, Institutional Review Board, Clinical Investigator, and Informed Consent Regulations

In the original proposal, Subparts C, D, and E set forth responsibilities of sponsors, institutional review boards (IRB's) and investigators, respectively. The reproposal did not repropose Subparts D and E and portions of Subparts C. FDA did not withdraw these provisions in the original proposal, but stated its intention that the agency-wide bioresearch monitoring regulations, discussed below, would apply to these aspects of device investigations when those regulations became final. FDA has concluded that the conduct of clinical investigations of drugs, devices, and biologics are sufficiently similar to warrant uniform, agency-wide regulations. For drugs and biologics, these regulations will be revisions of existing requirements in Part 312 (21 CFR Part 312). For devices, the only present requirements for clinical investigations are those in § 809.10(c) (21 CFR 809.10(c)) for in vitro diagnostic

products, Part 813 for IOL's, the notice in the Federal Register of March 9, 1973 (38 FR 6419) for acupuncture devices, and Part 312 for devices formerly considered new drugs or antibiotic drugs.

The Federal Register of September 27, 1977 (42 FR 49612), contained a proposed regulation on obligations of sponsors and monitors of clinical investigations. In the Federal Register of August 8, 1978, FDA issued proposed regulations on standards for institutional review boards for clinical investigations (43 FR 35186) and obligations of clinical investigators of regulated articles (43 FR 35210). In part because of the report on these matters by the Commission (see discussion above) on August 14, 1979, FDA reproposed regulations on institutional review boards (44 FR 47699) and a new proposal on informed consent (44 FR 47713).

These proposed agency-wide bioresearch monitoring regulations have not yet been published as final rules. FDA has concluded that the time required to prepare agency-wide regulations for final publication would entail unacceptable delays in the application of regulatory safeguards to device development. FDA is concerned about preventing unreasonable risks to subjects of investigations, providing guidance to sponsors who are required to submit premarket approval applications, and avoiding further nonadherence to the statutory timetable for the IDE regulation in section 520(g)(2)(A) of the act. Accordingly, rather than allowing further delay in publication of the final IDE regulation until publication of the final agency-wide regulations, FDA is making final the requirements for sponsors, IRB's, and investigators in Subparts C, D, and E of Part 812 in this document (21 CFR Part 812). Adequate notice and opportunity for comment on these requirements were afforded in the original IDE proposal and, on some matters, in the reproposal as well.

To reduce administrative burdens on affected parties, FDA has conformed this final regulation closely to FDA's anticipated final regulations on obligations of sponsors and monitors, and investigators. An exception to this general rule is that this regulation does not contain provisions that were not parts of previous proposals on which public comments have been received. If the final bioresearch monitoring regulations differ from the IDE final regulation, FDA will make conforming changes in the IDE regulation. The IRB and informed consent requirements in this regulation do not reflect many of the provisions present in the August 14, 1979 proposals. The agency stresses that the differences between the final IDE regulation and the August 14, 1979 proposals should not be taken as indications of the agency's decision on the form of final IRB and informed consent regulations. The public comments on the August 14, 1979 proposals are being analyzed, and the final orders will reflect a full consideration of those comments. The IRB and informed consent requirements in this regulation represent relatively basic provisions that are generally consistent with current practice and statutory requirements.

FDA recognizes that there may be some inconvenience if the final IDE regulation is changed to conform to the final bioresearch monitoring regulations. FDA has concluded, however, that any such inconvenience is outweighed by the advantages, discussed above, of having the IDE regulation in effect.

Comments on the Reproposal

Many comments were received from academic sources, industry, private practitioners, and a public interest group. The comments were constructive and often complex. A summary of the comments and FDA's responses to them follow.

Effect on Research

1. Several comments stated that few investigators and IRB's will be willing to continue participation in device investigations, in view of the administrative burdens imposed by the IDE regulation.

FDA is sensitive to this concern and has changed the final regulation to limit paperwork to essential requirements. Moreover, the final regulation's applicability to investigations of preamendments devices has been restricted, as discussed below in paragraph 21. Of those investigations now subject to the regulation, only those involving significant risk devices are subject to all requirements of the regulation. A sponsor of an investigation that does not involve a significant risk device ("a nonsignificant risk device investigation") does not need to submit an IDE application to FDA or obtain FDA approval before beginning an investigation, unless FDA notifies the sponsor that approval is required. The sponsor must, however, properly label the device, obtain and maintain IRB approval, ensure that investigators document informed consent, maintain certain basic records, evaluate and submit reports concerning such vital matters as unanticipated adverse device effects, and comply with requirements for monitoring studies, prohibitions against commercialization, and undue prolonging of investigations.

A sponsor of a significant risk device investigation must submit an IDE application to FDA. The elements of an application have been simplified. A sponsor need not routinely submit background information on investigators or complete copies of the investigational plan. The general record retention period has been reduced from 5 to 2 years following the later of two dates: The date when the investigation is terminated or completed, or the date when the investigation is no longer needed to support an application for premarket approval or a notice of completion of a product development protocol.

FDA believes that these and other modifications will reduce the cost of investigating a device without weakening the controls required by section 520(g) of the act. The agency has retained requirements that are critical to protection of subjects in all investigations, e.g., informed consent, institutional review, and reporting of unanticipated adverse device effects.

2. Several comments argued that the reproposal was written in confusing legal jargon.

The final regulation is in plain and simple language consistent with legal requirements.

3. A few comments suggested that regulation of clinical investigations should be controlled at the local level and would be better supervised if the control were university based rather than supervised at the Federal level.

Section 520(g) of the act requires a sponsor to submit an application to FDA. Therefore, control over significant risk device investigations cannot be, and is not, vested solely in local officials. Local IRB's will, however, play an important role in the control of all device investigations, especially those that do not involve significant risk devices, as discussed further in paragraph 17 of this preamble.

Economic Impact

4. Many comments argued that FDA did not properly consider the economic impact of the regulation and that costs to industry will exceed $100 million.

FDA does not have definitive data on costs to industry because hard data on costs were not submitted in support of these comments. FDA believes that the final regulation will not have a major economic impact, given the changes in the regulation summarized in paragraph 1.

5. A number of comments stated the reproposal would increase the direct costs of developing a medical device.

One comment estimated the incremental cost to be from $250,000 to $500,000 per device, but did not explain how this estimate was derived. Another comment expressed concern about the unit cost of a product, if the cost of IDE requirements is applied to a device that is produced in limited quantities. Many comments expressed a general concern about the expected cost burdens of the administrative requirements. Other comments observed, however, that the incremental cost is impossible to estimate because it depends on the extent to which current investigational practices satisfy the regulation's requirements.

The changes in the regulation summarized in paragraph 1 will greatly reduce incremental costs of compliance.

6. Several comments addressed the long-range economic impact of the IDE regulation. These comments predicted that the cumulative effect of the regulation would be to discourage medical device research and development in the United States. One comment predicted that the regulation would drive device research and development abroad. It was argued that the regulation would discourage participation of investigators and IRB's, reduce sponsor incentives to develop devices of limited commercial value, discourage noncommercial research (that is, much of the research conducted at universities), and would affect adversely the development of improvements in already marketed medical devices.

FDA believes that the implementation of the final IDE regulation will not discourage medical device research and development in the United States. Even the requirements for clinical studies of significant risk devices do not require significant deviation from current research practices in the scientific community. Because of the changes in the regulation summarized in paragraph 1 above, there should be little, if any, change in the willingness of investigators and IRB's to participate in medical device research and little, if any, reduction in sponsors' incentives to develop devices of limited commercial value or to make improvements in already-marketed devices.

7. A number of comments expressed concern that the reproposal may have a disproportionate impact on small businesses, and these comments imputed a general anticompetitive tendency to the IDE reproposal.

To minimize such effects, FDA's Office of Small Manufacturers Assistance is available to guide small firms through the IDE process or to assist them in preparing the investigational phase of a product development protocol (PDP) under section 515(f) of the act (21 U.S.C. 360e(f)). Moreover, FDA believes that changes made to simplify the IDE regulation will reduce the burden on small business.

8. Several comments questioned the assumptions in FDA's original inflation impact assessment. The original assessment assumed that the average costs for clinical investigations of significant risk devices would be increased by $125,000 over a 3-year period for each of 150 devices already on the market, and it projected an increase of $125,000 a year for 3 years for each of the estimated 10 to 20 new devices developed each year. (The estimated number of new devices each year was derived from the number of annual FDA determinations, in response to premarket notifications under section 510(k) of the act (21 U.S.C. 360(k)) and Subpart E of Part 812 (21 CFR Part 812, Subpart E), that devices described in these notifications were not substantially equivalent to devices in commercial distribution before the amendments, and were therefore in class III (premarket approval) under section 513(f) of the act (21 U.S.C. 360c(f)).) Comments suggested that: (a) The cost impact per investigation would or might be higher than the $125,000 to $375,000 range, and (b) in projecting the number of IDE's, FDA overlooked numerous "limited purpose" studies (for example, studies for minor improvements of existing products and studies establishing labeling information) that would also be affected.

The comments submitted by the device industry did not contain detailed cost analyses or projections of the number of clinical investigations. FDA has concluded that because the cost of the final regulation will fall primarily on clinical testing of new, significant risk devices, the assumptions in the original assessment are correct.

9. One comment suggested that FDA consider the combined cost impact of related regulations, such as those concerning premarket approval and obligations of sponsors and monitors, clinical investigators, and institutional review boards, rather than the separate cost of each regulation.

FDA is sensitive to the issue of cumulative regulatory burden. In developing each of these regulations, FDA has been attentive to the cumulative effects of all of them together. The final IDE regulation reflects an effort to eliminate unnecessary regulatory burdens, and FDA will make similar efforts in preparing the final agency-wide bioresearch monitoring regulations. Detailed evaluation of the cumulative effects of these regulations would not, in any event, affect the general approach of the final IDE regulation because of the need to require compliance with statutory mandates for device investigations.

10. Comments suggested that the inflationary impact assessment should have attempted to estimate benefits as well as cost impacts, and should have included a review of alternative regulatory approaches.

FDA rejects these comments.

These types of analyses would have been required under Executive Order 11821 (superseded by Executive Order 12044 by notice in the **Federal Register** of March 24, 1978 (43 FR 12661)) if a major inflationary impact had been identified. However, no such impact was identified.

Furthermore, FDA believes that the orginal proposal and the reproposal, coupled with its responses to the comments demonstrate that ample consideration has been given to the benefits of the regulation and to all practical options.

11. One comment asserted that the inflation impact assessment failed to evaluate certain long-range unfavorable effects on the competitive structure of the industry and on the rate of new medical device development.

No factual support was submitted to document these concerns. As described above in paragraph 1, the major requirements of the final IDE regulation apply fully only to investigations of new, significant-risk devices. FDA believes that the IDE regulation will not unduly discourage new product development, reduce competition, or adversely affect small business.

Effective Date

12. Several comments suggested extending the effective date of the regulation beyond the 120-day period that was reproposed.

FDA agrees that extending the effective date will provide for a more orderly transition period. To provide sponsors with sufficient lead time to comply with the final rule, this regulation will be effective July 16, 1980.

Sponsors of new investigations and ongoing long-term investigations may wish to submit applications for FDA review before the effective date. FDA will accept and review applications received before the effective date.

General Provisions

Scope

13. Numerous comments on the reproposal questioned whether FDA was seeking to achieve the stated objective of "encouraging the discovery and devlopment os useful devices."

FDA is sensitive to concerns that the IDE reproposal might have discouraged innovation. Accordingly, FDA has altered the final regulation to minimize interference with device development and costs of preparing an IDE application, while retaining provisions essential to subject protection. See paragraphs 1 and 6 above.

14. One comment argued that the regulation should state that a product for which an IDE has been approved will be exempt from section 501 (21 U.S.C. 351), relating to adulteration, and section 518 (21 U.S.C. 360h), relating to notification of risk and repair, replacement or refund, in addition to those sections enumerated in section 520(g) of the act.

FDA disagrees. Section 520(g) of the act does not provide for exemptions from sections 501 and 518, nor is there any reason to grant such exemptions.

Applicability

15. Several comments argued that an IDE should not be required for an investigation to expand medical knowledge or conduct fundamental research.

FDA agrees with these comments insofar as they concern clinical investigations conducted for purposes other than determination of safety or effectiveness. Accordingly, § 812.2(a) (21 CFR 812.2(a)) has been rewritten to provide that the regulation applies only to clinical investigations of medical devices to determine safety and effectiveness. If the expansion of medical knowledge or the conduct of fundamental research involves an investigation to determine the safety or effectiveness of a device, an IDE will be required.

16. One comment suggested that an IDE should not be required if testing of the device occurs within the boundaries of one State. The comment questioned FDA's authority to act if a sponsor's testing activities are solely intrastate.

FDA does not agree with this comment. Neither section 301(q) (21 U.S.C. 331(q)), which prohibits violations of the IDE regulation, nor section 501(i) of the act, which deems a device adulterated if there has been a failure to comply with the IDE regulation, is limited in its applicability to devices that are in interstate commerce. Compare section 301(q) with section 301 (a) through (d), (k), and (o). In addition, section 304(a)(2) of the act (21 U.S.C. 334(a)(2)) authorizes FDA to seize adulterated devices without regard to interstate commerce (*United States* v. *Undetermined Quantities of an Article of Device * * * "Depilatron Epilator,"* 473 F. Supp. 913 (S.D. N.Y. 1979)). Also, section 709a of the act (21 U.S.C. 379a) provides that interstate commerce is presumed to exist in any action to enforce the requirements of the act concerning a device. Finally, *United States* v. *Dianovin Pharmaceuticals,* 475 F.2d 100 (1st Cir. 1973), and *United States* v. *Pinocchio Brand Oil,* 289 F.2d 343 (2d Cir. 1961), hold that the necessary connection with interstate commerce exists if any component of the product was shipped from outside a State.

17. Numerous comments suggested that FDA limit the applicability of the regulation, for example by basing applicability on the degree of risk, or the incremental risk, presented to subjects by use of the device. One comment offered an alternative regulatory scheme under which FDA review would be related to the risk of the clinical investigation and the extent of IRB oversight.

FDA agrees with many of the suggestions set forth in these comments and has incorporated them in the final regulation. The final regulation varies the amount of regulatory control, depending on the degree of risk to the subject.

Investigations of significant risk devices are subject to detailed regulatory control and require IRB and FDA approval. A sponsor of such an investigation must submit an investigational plan and report of prior investigations to an IRB and an IDE application to FDA.

Less regulatory control is exercised over investigations of nonsignificant risk devices. Nonsignificant risk devices include a miscellany of articles such as crutches, elastic knee braces, bedboards, bedpans, medical chairs, and tongue depressors, as ordinarily used.

A sponsor of a nonsignificant risk device investigation who meets the conditions set forth in § 812.2(b)(1) is considered to have an approved exemption, without actually having to submit an application, unless notified under § 812.20(a) (21 CFR 812.20(a)) that approval of an application is required.

Section 520(g)(2)(A) of the act authorizes FDA to establish conditions for the granting of IDE's. Section 520(g)(2)(B)(i) provides that one of the conditions shall be "[a] requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify."

FDA believes that the provisions in the final IDE regulation concening investigations of devices that do not present a significant risk satisfy this statutory requirement. Under § 812.2(b)(1)(ii), the sponsor must obtain an IRB's approval of an investigation of such a device. Thus, the IRB serves as the surrogate for the Secretary with respect to the receipt and approval of the application. The IRB functions in this capacity under regulations issued by FDA. Moreover, under § 812.2(b)(1)(ii) the sponsor of a nonsignificant risk device investigation is required to explain why the device is not a significant risk device, both in its application to the IRB for approval and in records kept for FDA inspections. In addition, the sponsor of a nonsignificant risk device investigation is required to submit to FDA reports of unanticipated adverse effects, withdrawals of IRB approval, recall requests, failures to obtain informed consent, and, upon request, any additional material that FDA may need to assure the protection of the public health and safety and compliance with the act, applicable regulations, and ethical standards. Thus the sponsor's initial decision about the level of risk is subject to review in all cases by the IRB, and FDA may audit both the sponsor's decision and the IRB's review. In § 812.20(a)(1), FDA has retained the option of requiring submission and FDA approval of an IDE application for a nonsignificant risk device investigation. Furthermore, an IDE for a nonsignificant risk device may be withdrawn under the same procedures that apply to IDE's for significant risk devices.

This system of review carries out the purpose of section 520(g)(2)(B) in accordance with the overriding congressional policy set forth in section 520(g)(1) "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose." The regulation's distinction between significant and nonsignificant risk devices is consistent with this policy and carries out the policy of Executive Order 12044, which provides that regulations shall not impose unnecessary burdens on the economy or private organizations.

Mistakes by sponsors in applying the distinction are likely to be relatively rare. Any mistakes should be detected by the IRB's that are required to review and approve device investigations. IRB's are likely to give investigations of nonsignificant risk devices at least as much attention as could FDA if FDA were to require that applications for IDE's for nonsignificant risk devices be submitted to it. Whereas FDA would be faced with numerous applications, each IRB will review relatively few. To help IRB's carry out their responsibilities for nonsignificant risk device investigations, FDA is requiring investigators to send reviewing IRB's reports of unanticipated adverse device effects, failures to obtain informed consent, and other information about an investigation if requested by an IRB. Sponsors must report to reviewing IRB's concerning evaluation of unanticipated adverse effects, withdrawal of approval by another IRB or FDA, progress of the investigation, recall requests, and other information about an investigation if requested by an IRB, as well as final report. If an IRB determines that an investigation involves a significant risk device, the sponsor must report this determination to FDA, submit an IDE application to FDA, and not begin the investigation except as provided in § 812.30.

By dispensing with the sumbission to FDA of applications concerning nonsignificant risk devices, the regulatory system will avoid an unnecessary and costly paperwork burden on sponsors, an excessive processing burden on FDA, and delays in approval, without sacrificing protection of human subjects. FDA has concluded that the protection of human subjects is not fostered by requiring a sponsor to submit an application to FDA for approval before commencing an investigation of a nonsignificant risk device. Protection of the public health and safety and the application of community-based ethical standards are adequately assured by the role of IRB's in reviewing such investigations.

Moreover, the statutory language must be interpreted and implemented in light of common sense and available resources. Little or no public benefit would result from the submission to FDA and FDA review of a large volume of applications, the vast majority of which could not possibly present and significant risk to subjects. Moreover, FDA simply does not have, and for the foreseeable future is not likely to have, the resources that would be needed to conduct detailed reviews of all investigations of both significant and nonsignificant risk devices. An investment of tax dollars and Federal personnel for stringent regulation of nonsignificant risk device investigations is not needed to achieve the objectives of subject protection, and this investment would be wasteful. An attempt by FDA to review all such investigations would dilute the quality of the review of investigations of significant risk devices and would divert resources from more important medical device regulatory activities. The practical result would be both to reduce public protection and to delay unduly the development of useful devices.

Exempted Investigations

18. Devices described in § 812.2(c) that are not subject to Part 812 are still subject to other regulatory requirements of the act, for example, those concerning labeling, premarket approval of class III devices, and the good manufacturing practice regulation in Part 820 (21 CFR Part 820).

19. Several comments argued that IDE's should be required only for investigations of class III devices.

Under § 812.2 of the final regulation, IDE's will generally not be required for devices other than class III devices.

20. Several comments suggested making the regulation applicable only to studies initiated after the effective date of the regulation.

FDA rejects these comments. FDA believes that exempting all ongoing investigations would not provide adequate protection of the public health and safety or assurance of compliance with ethical standards. Section 812.2(b)(2) exempts only those investigations that were begun before the effective date and that are completed on or before 1 year after the date of publication of the regulation. Investigations that will continue for more than 1 year from now will be continuing for a substantial period after the effective date and should be subject to these regulations, just as newly started investigations will be. FDA regards present investigations that will end less than 1 year from now as not continuing for a substantial period. As to these investigations, the burdens of requiring compliance with Part 812 outweigh the benefits.

Among the requirements that apply to sponsors of present investigations that are ongoing after 1 year is the requirement that informed consent in accordance with Subpart F be obtained from all subjects still participating in the study, as well as any new subjects.

21. Many comments suggested that preamendments devices, that is, devices in commercial distribution before May 28, 1976, be grandfathered and not subject to the regulation if used or investigated in accordance with labeling in effect at that time.

FDA agrees, in part, with these comments. Accordingly, § 812.2(c)(1) (21 CFR 812.2(c)(1)) now provides that the IDE regulation does not apply to a device in commercial distribution before May 28, 1976, if used or investigated in accordance with indications in the labeling in effect at that time, unless the device is a transitional device as defined in § 812.3(r) (21 CFR 812.3(r)). Section 812.2(c)(2) (21 CFR 812.2(c)(2)) contains a similar provision for postamendments devices other than transitional devices that are substantially equivalent to preamendments devices and that are used or investigated in accordance with the indications in the labeling FDA reviewed in determining substantial equivalence. FDA determines substantial equivalence when it reviews premarket notification submissions under section 510(k) of the act and Subpart E of Part 807 of the regulations (21 CFR Part 807, Subpart E).

However, § 812.2(d) provides a time limit on the exemptions in § 812.2(c) (1) and (2). A class III device exempted under § 812.2(c) (1) or (2) is subject to the IDE regulation after FDA calls for the submission of an application for premarket approval by regulation under section 515(b) of the act, if the sponsor does not submit an application or if FDA disapproves an application that the sponsor submitted. A sponsor of such a device shall obtain an approved IDE for further testing of the device or cease distribution of the device. Similarly, the IDE regulation applies to a class II device that was in commercial distribution with the same labeling immediately before May 28, 1976, or to a substantially equivalent postamendments device, after the date stipulated in an applicable performance standard that the device does not meet. A preamendments device, or a postamendments, substantially equivalent device, that is classified into class I will never need premarket approval or a standard or, consequently, an IDE.

Because of § 812.2(c) (1) and (2), the IDE regulation will apply initially only to investigations of two categories of devices: first, new devices that are not substantially equivalent to preamendments devices and, second, transitional devices, that is, devices that FDA considered new drugs or antibiotic drugs before the amendments. Sections 513(f) and 520(1) of the act classify new devices and transitional devices into class III, and section 501(f)(1) (B) and (C)

deems these devices adulterated if the sponsor has obtained neither premarket approval under section 515 of the act nor an approved IDE.

The IDE regulation thus will not apply to any preamendments device (or postamendments, substantially equivalent device) other than a transitional device until after passage of the temporary grace period from premarket approval that section 501(f)(2)(B) grants such devices. Under this provision, such a device is not required to have premarket approval under section 515 until the later of the following dates: (1) the last day of the 30th calendar month beginning after the month in which the classification into class III became effective, or (2) the 90th day after the promulgation of a regulation under section 515(b) of the act calling for submission of premarket approval applications for the device. Section 501(f)(2)(B) enables preamendments devices (or postamendments, substantially equivalent devices) that are not transitional devices to be commercially distributed until expiration of the grace period prescribed therein.

FDA has concluded that Congress intended that any preamendments device (and any postamentments, substantially equivalent device) other than a transitional device be exempt from the IDE regulation until expiration of the temporary grace period in section 501(f)(2)(B) for a class II device, or until the effective date of an applicable standard for a class II device. This conclusion is based on several provisions of the act, discussed below. (The discussion in the remainder of this numbered paragraph does not apply to transitional devices.)

There is no statutory duty to obtain an IDE unless use of a device for investigational purposes would violate an otherwise applicable section of the act listed in section 520(g)(2)(A), that is, section 502, 510, 514, 515, 516, 519, 520 (e) or (f), or 706 (21 U.S.C. 352, 360, 360d, 360e, 360f, 360i, 360j, or 376). If a sponsor may lawfully distribute a device for commercial purposes without violating one or more of these sections, the sponsor should not have to obtain an IDE to distribute the device lawfully for investigational purposes. FDA interprets the act to mean that the sponsor of a preamendments class III device (or postamendments, substantially equivalent device) with the labeling then in effect (or the labeling that was reviewed by FDA in determining substantial equivalence) does not need an IDE to continue shipping the device until after expiration of the grace period from premarket approval of 30 months or longer. Similarly, the sponsor of a class II device of a type marketed before the amendments with the same or equivalent labeling does not need an IDE until an applicable performance standard that the device does not meet becomes effective.

The original IDE proposal and reproposal would have applied to investigations of preamendments devices and postamendments, substantially equivalent devices, on the theory that a device would not be the subject of an investigation unless it needed an exemption from one of the provisions of the act listed in section 520(g)(2)(A), usually from the misbranding provisions in section 502. FDA has concluded that this theory does not support application of the IDE regulation to a preamendments device during the statutory grace period if that device is being used or investigated under the labeling used immediately before the amendments. Nor does the theory support application of the regulation to a postamendments device that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before the amendments and that is used or investigated in accordance with the indications in the labeling FDA reviewed in determining substantial equivalence.

Supporting FDA's conclusion that, during the grace period from the requirement of premarket approval, Congress did not intend to require investigations of preamendments class III devices (or postamendments, substantially equivalent devices) to be subject to the IDE regulation is the absence of a provision in section 501 of the act, the adulteration provisions, addressing the legality of these investigations before the effective date of the IDE regulation.

As explained above, it is a premise of the IDE provisions in section 520(g) of the act that an IDE is required only if use of a device for investigational purposes would violate an otherwise applicable provision of the act listed in that section. If the investigational use of preamendments class III devices (or postamendments, substantially equivalent devices) were intended to be subject to section 520(g), then any investigational use of these devices before the effective date of the IDE regulation would be illegal, absent a special statutory exemption. Congress knew that sponsors of these devices would need to conduct studies during the time preceding the imposition of premarket approval requirements for their devices; indeed, the very purpose of the statutory grace period was to allow sponsors to develop the data and conduct the studies needed to support approval. See H.R. Rep. No. 95–853, 94th Cong., 2d Sess. 42 (1976). Congress also knew that FDA had begun preliminary device classification efforts before enactment of the amendments. *Id.* at 11, 39; S. Rep. No. 94–33, 94th Cong., 1st Sess. 10–11. These efforts included identification of devices that would likely be classified into class III, the premarket approval category, often because of the lack of adequate testing. It is improbable that Congress meant for sponsors to await the effective date of the IDE regulation before beginning investigations of devices that likely would be classified into class III.

In sum, Congress surely would have written the amendments so as to allow investigations of preamendments devices or their postamendments equivalents to continue, or to be initiated, during the period between the enactment date of the amendments and the effective date of the IDE regulation If it was intended that these investigations would eventually be subject to the IDE regulation, there would have been a provision for their temporary dispensation from illegality until the effective date of the regulation. Such a provision was included to permit investigations of postenactment, not substantially equivalent devices: section 501(f)(2)(A) allows these devices to be distributed solely for investigational use until 90 days after the promulgation of the IDE regulation.

Yet Congress did not include a provision for investigations of preamendments devices or postamendments, substantially equivalent devices before the effective date of the IDE regulation. The absence of such a provision, considered in light of the expectation expressed in the House committee report that such investigations would occur, supports FDA's conclusion that Congress did not intend for investigations of preamendments devices or their postamendments equivalents to be subject to the IDE regulation during the statutory grace period from the requirement of premarket approval.

The provision for commercial distribution of preamendments class III devices (and postamendments, substantially equivalent devices) during a 30-month or longer grace period also supports the position that investigations of these devices during this period were not intended to be subject to the IDE regulation. It would be anomalous to interpret one provision of the act

(section 520(g)) as requiring strict safeguards for investigations of these devices when another provision of the same statute (section 501(f)(2)(B)) clearly allows the same device to be distributed commercially during the grace period with preamendments indications in the labeling, subject only to the general controls of the act. Commercial distribution of the device would generally expose many more patients to a device, and to its potential risks, than would its distribution for investigational use. Furthermore, a sponsor of a preamendments device (or a postamendments, substantially equivalent device) that may lawfully be commercially distributed should comply with the general controls provisions of the act, including the provisions from which an IDE would grant an exception, when distributing the device for investigational use. Finally, FDA would encounter enforcement difficulties in applying the usual prohibition against commercialization of an investigational article to a device that is simultaneously being investigated and lawfully marketed.

The IDE regulation generally applies, however, if a sponsor of a preamendments device (or a postamendments, substantially equivalent device) seeks to test the safety and effectiveness of the device for a new use, that is, an indication not contained in the labeling immediately before May 28, 1976, or not reviewed by FDA in making its substantial equivalence determination under section 510(k) of the act. In such a case, the sponsor must have an IDE under § 812.2(b)(1), for a nonsignificant risk device, or under § 812.30, for a significant risk device. If the device that the sponsor wants to test for a new use is a diagnostic device, the investigation may be exempt from the IDE regulation under § 812.2(c)(3) and subject only to § 809.10(c).

22. Comments on the reproposal argued that the exemption for diagnostic devices should be extended to devices that do not introduce potentially harmful amounts of energy into the body.

FDA rejects these comments because often there is no way to specify an acceptable or safe amount of energy. Investigations of diagnostic devices meeting the conditions set forth in § 812.2(c)(3) of the final regulation are not required to be subject to the IDE regulation. Such investigations either do not truly involve human subjects or present risks so small as to be negligible, or present no risk at all. Consequently, the policy set forth in section 520(g)(1) of the act does not require regulation of investigations of such devices. Even investigational diagnostic products for life-threatening conditions would, if they meet the conditions of § 812.2(c)(3), not present significant risk. Investigations of diagnostic products for life-threatening conditions would, however, present risk and be subject to the regulation if the conditions of § 812.2(c)(3) are not satisfied; for example, if a diagnostic product were used as the basis for diagnosis without confirmation. For example, investigations of the alpha fetoprotein test for prenatal diagnosis of neural tube defects using maternal sera or amniotic fluid will be subject to the IDE regulation and regarded as investigations of a significant risk device.

Devices that are designed to emit energy are subject to this regulation because FDA has determined that there is no way to specify an acceptable or safe limit of energy. However, devices such as investigational electrocardiographs and electroencephalographs that are not intended to introduce energy into the body but do so only from leakage are not subject to the final IDE regulation if the sponsor meets the other conditions of § 812.2(c)(3).

23. One comment argued that the reproposal exempted investigational electrocardiographs and electroencephalographs from IDE control. The comment expressed the view that such devices are "life-supporting" or "life-sustaining" and that the testing of such devices should not escape FDA and IRB scrutiny.

FDA rejects this comment. For the reasons set forth in the preceding paragraph, FDA believes that investigations of devices that meet the conditions of § 812.2(c)(3) should not be subject to the regulation. These investigations do not present a significant risk to the health, safety, or welfare of a subject when the results are confirmed by another, medically established product or procedure.

24. Comments argued that the exemption for diagnostic devices in the reproposal should be expanded to encompass both use of surplus samples that remain from previously obtained samples and low-risk venipuncture.

FDA agrees with the comments. FDA believes that an investigation of an in vitro diagnostic device should not be subject to the IDE regulation if the test uses a previously obtained surplus sample that was taken for noninvestigational purposes and if the results are not used for diagnosis without confirmation. If these conditions are met, it does not matter whether the sample was taken by simple venipuncture or another method, for example, a spinal tap. In either case, no IDE is required. There is no reason to waste surplus samples or to expose subjects to the added risks of obtaining new samples when surplus samples are available.

FDA also believes that sampling procedures for experimental tests and procedures employing simple venipuncture should not be subject to IDE control. This procedure is routine in nature, and the risk involved is negligible. FDA has included provisions in the definition of "noninvasive" in § 812.3(k) that implement the policy described in this paragraph.

25. Several comments suggested amending the reproposal to exclude from the IDE regulation's applicability the testing of a combination of more than two lawfully marketed devices, if no safety or effectiveness testing is involved.

FDA agrees with these comments. Section 812.2(c)(4) of the final regulation permits testing, without IDE controls, of a combination of two or more lawfully marketed devices, if the testing is not for the purpose of determining safety or effectiveness.

26. Section 812.2(c)(6) provides that a device shipped solely for research on or with laboratory animals is not subject to this regulation if labeled in accordance with § 812.5(c) (21 CFR 812.5(c)). No purpose of section 520(g) of the act would be served by subjecting such a device to other requirements of the regulations. Some nonclinical investigations of devices are, however, subject to the good laboratory practices regulation in Part 58 (21 CFR Part 58). Section 812.5(c) enumerates requirements that previously were proposed under Subpart H—Tests That Do Not Involve Human Subjects, and it condenses these requirements into a single paragraph.

27. Section 812.2(c)(7) provides that a "custom device" as defined in § 812.3(b) is not subject to the IDE regulation unless the device is being used to determine safety and effectiveness for commercial distribution. Section 520(b) of the act exempts custom devices from the requirements of section 514 (performance standards) and section 515 (premarket approval). An FDA regulation (21 CFR 807.56(a)) exempts custom devices from premarket notification under section 510(k) of the act. Because it is not subject to these requirements, a custom device as defined in § 812.3(b) does not need an exemption from these requirements to be shipped or used. If, however, a custom device is used by a practitioner

to conduct what amounts to a clinical investigation to determine safety or effectiveness of a device for commercial distribution, an IDE is required. Furthermore, custom devices are subject to other provisions of the act, except sections 510(k), 514 and 515, and are thus subject to FDA regulatory action in the event of a violation.

28. Numerous comments were received on reproposed § 812.2(d) concerning custom devices. One comment argued that a provision stating that FDA has discretion to determine whether the specific use of a custom device is subject to the IDE regulation exceeds FDA's statutory authority.

FDA rejects the comments. FDA has authority to determine that a custom device is not exempt from the regulation if the device's special regulatory status is being abused, for example, when a device that purportedly is a custom device is in fact being used for investigational purposes. Under § 812.2(c)(7) FDA retains the discretion to determine whether the use of a custom device is an investigation of safety or effectiveness for commercial distribution and is subject to regulation under Part 812. FDA believes that this provision is consistent with the congressional intent expressed in section 520(g)(3) that FDA regulate "testing involving human subjects." See also H.R. Rep. No. 94–853, 94th Cong., 2d Sess. (1976). The report states at p. 45 that "[custom] devices are not exempt from otherwise applicable provisions of the proposed legislation, such as provisions with respect to investigational use * * *."

29. Another comment argued that FDA does not have authority to exclude custom devices from the IDE regulation. The comment argued that the omission from section 520(b) of the act of any reference to section 520(g) is a clear sign that FDA has no authority to treat custom devices as it proposed to do under the reproposal. The comment also argued that section 520(g) itself requires that custom devices be subject to the IDE regulation.

FDA rejects the comment. The agency interpreted section 520 (b) and (g) of the act and the legislative history quoted in paragraph 27 above. Although it is true that section 520(b) of the act does not include investigational device controls under section 520(g) of the act as one of the enumerated provisions from which custom devices are exempted, it is also true that section 520(g) only applies to a device that needs to have an exemption from one of the enumerated requirements in order to be lawfully shipped or used. Critical among the enumerated requirements from which investigational devices are exempt are sections 514 and 515 of the act concerning performance standards and premarket approval. Because section 520(b) already exempts custom devices from these two sections, there is no need for custom devices to be subject to approved IDE's unless their safety or effectiveness is being investigated for commercial distribution. Custom devices are, however, subject to the remaining requirements enumerated in section 520(g) from which investigational devices are exempt, as well as other device provisions of the act.

The sentence in the House Committee Report quoted in paragraph 28 above means that an investigation of a custom device to determine its safety and effectiveness for commercial distribution is subject to the IDE regulation. If a custom device is used for a therapeutic purpose for an individual patient, however, and not for the purpose of determining safety or effectiveness for commercial distribution, the evident congressional purpose reflected in section 520(b) of the act warrants that it not be subject to the IDE regulation.

30. The same comment argued that section 519 of the act with respect to records and reports on devices also requires that custom devices be subject to the regulation.

FDA rejects the comment. Nothing in section 519 requires that the IDE regulation apply to use of a custom device that does not involve determination of safety or effectiveness for commercial distribution. Records and reports requirements for investigational devices are imposed under authority of section 520(g)(2)(B) (ii) and (iii), not under authority of section 519 of the act. It is clear both from section 519(b)(2) and from section 520(g)(2)(A) that the two authorities for records and reports requirements are intended to be mutually exclusive.

31. A comment asked who determines that a custom device is exempt from the regulation.

This determination is made initially by the physician or dentist, but may be overruled by a manufacturer requested to provide a custom device, an IRB that, under institutional policies, reviews use of custom devices at the institution notwithstanding their exemption from the IDE regulation, or by FDA upon determining whether a custom device is being used to determine safety or effectiveness for commercial distribution.

32. A comment asked whether components of custom devices are subject to the IDE regulation.

Components of a custom device are not subject to Part 812 if they are "integrated" into the custom device, that is, they are being used as parts of the custom device and not as separate and independent devices. If components of a custom device are used as separate and independent devices, the applicability to them of the IDE regulation is to be determined under other provisions of § 812.2.

33. A comment argued that FDA's exempting custom devices sanctions engineering judgments by health professionals.

FDA acknowledges that in certain instances the customizing of a marketed device or design of a custom device by a health professional does involve engineering judgments. FDA believes that section 520(b) of the act reflects a congressional intent to permit health professionals to make such judgments in the course of their professional practices, so long as they do not conduct investigations of safety or effectiveness for commercial distribution.

Effect on Intraocular Lens (IOL) Investigations

34. The preamble to FDA's regulations on IOL investigational device exemptions, published in the **Federal Register** of November 11, 1977 (42 FR 58876) and codified in Part 813 of the regulations, stated that Part 813 would be repealed when the IDE regulation is made final. Owing to the delay in development of the final IDE regulation and the advanced state of IOL investigations under Part 813, FDA has concluded that repeal of Part 813 is not warranted. Sponsors, investigators, IRB's, and FDA are thoroughly familiar with Part 813. A change in ground rules at this stage would serve no useful purpose. Moreover, subjecting IOL investigations to new Part 812 rather than to Part 813 would not afford greater subject protection than now exists and could disrupt ongoing investigations. For these reasons, § 812.2(c)(8) provides that Part 812 will not apply to ongoing or newly started IOL investigations.

Effect on Investigations Under IND's

35. On its own initiative, FDA has added § 812.2(e), which discusses the effect of the IDE regulation on sponsors having effective IND's under Part 312 for investigations of devices that FDA previously considered drugs on the effective date of the IDE regulation. Section 812.2(e) requires such a sponsor to continue to comply with the requirements of Part 312 until 90 days after the effective date. To initiate or continue an investigation after this 90-

day period, a sponsor must have an approved IDE.

A sponsor who has an effective IND for an investigation of a device and wishes to obtain an IDE to continue that investigation after the 90-day period should inform the Bureau of Medical Devices, FDA, by letter of the IND number and the phases of the investigation that have been completed (Phases I, II, or III). Such letters should be submitted as soon as possible to avoid disruption of ongoing studies. The Bureau will inform the sponsor whether the investigation may continue and what conditions will apply. For example, if FDA determines that the protocol and other procedures being followed under Part 312 satisfy the requirements of Part 812, FDA may consider the investigation to have an approved IDE and may allow it to continue without changes.

Sponsors of investigational transitional devices subject to Part 812 that do not have an effective IND before the effective date of this regulation will have to obtain an IDE. (See § 812.3(r) of the regulation for a definition of "transitional device.")

Investigations of transitional devices that are significant risk devices are subject to all requirements of Part 812. Investigations of transitional devices that are not significant risk devices must comply only with § 812.2(b)(1) unless FDA informs the sponsor under § 812.20(a) that submission of an application is necessary.

36. Numerous comments were received on the definitions in the reproposal. Many comments stated that certain definitions lacked clarity and were not helpful. Some comments submitted alternative definitions that would have changed the effect of the applicability section. The latter comments have been discussed elsewhere in this preamble.

As indicated below, FDA has responded to many of these comments. FDA on its own initiative has deleted the definitions of "investigational plan" and "institutionalized subject" because they are unnecessary.

37. FDA on its own initiative has redefined "custom device" in § 812.3(b). The term "physician or dentist" has been substituted for the term "health professional" to be consistent with section 520(b) of the act. Although section 520(b) authorizes FDA, after opportunity for an oral hearing, to issue regulations allowing specially qualified individuals other than physicians or dentists to obtain and use custom devices, no such regulations have been issued. Thus, at this time, only physicians and dentists qualify for the custom device exemption in the act and the IDE regulation.

38. One comment argued that FDA's definition of "custom device" went beyond the statutory intent, and that the examples given were not well thought out and should be deleted.

FDA agrees that the definition of "custom device" should more closely follow the statute. FDA has deleted the requirement that if a custom device is an implant it must be made of "safe and suitable" materials, in response to comment that this provision was vague and unworkable. FDA believes that the examples of custom devices discussed in the reproposal, however, still provide useful guidance on FDA's interpretation of the effect of the act on custom devices.

39. Some comments suggested including psychologists or microbiologists as individuals who could order custom devices. Other comments sought to retain the term "health professional" but to expand its scope beyond physicians and dentists.

FDA rejects these comments because there currently are in effect no regulations under section 520(b) of the act concerning the use of custom devices by individuals other than physicians and dentists. A proceeding for the issuance of such a regulation may be initiated by a citizen petition filed under § 10.30 (21 CFR 10.30) or by FDA on its own initiative.

40. On its own initiative, FDA has added a definition of "implant." The definition is consistent with the definition in FDA's classification regulation at § 860.3(d) (21 CFR 860.3(d)). Section 812.3(d) defines "implant" as a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA reserves the right to determine that implants placed in patients for shorter periods are also "implants" for purposes of Part 812.

41. One comment suggested that the definition of "institution" in reproposed § 812.3(b) (now § 812.3(e)) be modified to include a clinic or practitioner's office in order to permit clinical investigations to be carried on by sole practitioners.

FDA disagrees with the comment. Including a clinic or practitioner's office within the definition does not reflect accurately the common or ordinary meaning of the term. However, excluding clinics and practitioners' offices from the definition does not, in most cases, preclude sole practitioners from being investigators. If an investigator's work cannot be reviewed by a duly constituted IRB, for example an IRB at an institution in the same locality, the sponsor is required to submit the application, investigational plan, and report of prior investigations directly to FDA in accordance with section 520(g)(3)(A)(ii) of the act. In some cases, however FDA may believe that review by a local IRB is critical to the protection of the rights, safety, and welfare of subjects and will refuse to authorize conduct of an investigation without IRB review.

42. One comment argued that "institution" should not include a manufacturer because a manufacturer should not be required to create an in-house IRB.

FDA disagrees. A manufacturer must be subject to the requirements of institutional review if an investigation is carried out on the manufacturer's premises, for example, using employees as subjects of the investigation. Employees are entitled to the same protections, including IRB review, as other subjects.

43. FDA has shortened and modified the definition of "investigational device" in § 812.3(g). The term includes transitional devices as defined in ne. § 812.3(r).

44. A comment suggested that FDA permit qualified medical personnel to administer or dispense the device in the absence of, but under the direction of, the primary investigator.

FDA does not believe the definition of "investigator" prohibits this practice. No change has been made in the definition.

45. The term "noninvasive" as defined in § 812.3(k) includes devices that penetrate or pierce the nose, ear, or eye. The definition has been clarified to mean intentional penetration or piercing. If misused, virtually any device might penetrate or pierce the body. Only those devices deliberately designed or intentionally used to penetrate or pierce are considered invasive.

46. Comments objected to the reproposed definitions of "substantial risk," "low risk," "vital device," and "nonvital device." Some comments argued that the definitions were too subjective and obscured the issue of risk.

FDA agrees with the comments and has replaced the categories used in the reproposal in favor of a simpler distinction between "significant risk devices" and devices that are not significant risk devices ("nonsignificant risk devices").

Under the definition of "significant risk device" in § 812.3(m), most but not all implants would be treated as significant risk devices. However, certain implants, such as many dental amalgams, would not be significant risk devices because they would not present

a serious risk to the health, safety, or welfare of a subject. On the other hand, sponsors of clinical investigations involving investigational contraceptive devices, for example, diaphragms, must submit an IDE application. Although many of these devices are not implants, FDA has determined that investigational contraceptive devices are for a use of substantial importance in preventing impairment of human health and present a potential for serious risk to the health, safety, or welfare of a subject in the event of an unplanned pregnancy.

Sponsors are encouraged to contact FDA informally for guidance on whether an IDE application is required for the investigation of a specific device.

47. Several definitions in § 812.3, for example the definition of "subject" in § 812.3(p), differ slightly from the definitions found in proposed FDA bioresearch monitoring regulations. No differences in meaning are intended, and the minor wording differences will be eliminated when the agency publishes the other regulations.

48. FDA, on its own initiative, has added a definition of "termination" in § 812.3(q). The term includes all conditions under which, and reasons for which, a sponsor would stop a clinical investigation before its completion.

49. FDA, on its own initiative, has added a definition of "transitional device" in § 812.3(r). It replaces the term "transitional period," which appeared in the reproposal at § 812.3(p).

50. FDA has added a definition of "unanticipated adverse device effect," in § 812.3(s). The term has the same meaning as "serious adverse effect," which appeared in reproposed § 812.46(c)(1) (21 CFR 812.46(c)(1)).

Labeling of Investigational Devices

51. Comments on reproposed § 812.5 argued that the labeling requirements of this section duplicated those in proposed Subpart H.

FDA agrees with these comments and has deleted Subpart H from the final regulation. For ease of reference, labeling requirements have been consolidated in § 812.5.

52. Comments questioned whether compliance with § 812.5 would relieve a sponsor from an obligation to comply with § 809.10(c), which requires special labeling for investigational in vitro diagnostic devices, and notifications to FDA of shipment of such devices.

FDA has concluded that the sponsor of an investigation of a diagnostic device that meets the conditions of § 812.2(c)(3) for exemption from the IDE regulation should continue to comply with § 809.10(c). The sponsor of an investigation of a diagnostic device that is subject to Part 812 does not have to comply with § 809.10(c). In response to the comments, FDA is publishing a conforming amendment to § 809.10(c) to clarify the relationship between that provision and Part 812. This amendment also eliminates the provision in § 809.10(c)(4) requiring compliance with the drug listing regulations in § 207.25 (21 CFR 207.25) when the sponsor of an investigation of an in vitro diagnostic device initiates commercial distribution. Section 809.10(c)(4) is obsolete and is inconsistent with the premarket notification requirements for devices under section 510(k) of the act and Subpart E of Part 807.

Promotion of Investigational Devices

53. Section 812.7(a) prohibits sponsors, investigators, and their agents from promoting or test marketing an investigational device until the device has been approved for commercial distribution. This section ensures that investigational devices are not advertised before their claims are established, helps prevent such devices from being distributed too widely, and prevents an IDE from serving as a subterfuge for unapproved marketing. Test marketing of a device, which is prohibited, differs from consumer preference testing of a device, which is authorized. Test marketing involves sale of a device. Consumer preference testing involves tests to determine whether consumers prefer certain packaging or other features of a device unrelated to its safety or effectiveness, but does not involve its sale. Consumer preference testing may involve use of a device so long as the use does not involve testing of safety or effectiveness or put subjects at risk.

54. Comments objected to provisions of the reproposal that prohibited sponsors from charging for the device in certain cases. Comments also objected to provisions that authorized FDA to determine whether a charge for the device is reasonable. Comments argued that FDA has no expertise in determining reasonable costs.

FDA recognizes that practical problems may be encountered in administering this provision, but believes that special expertise is not required to determine whether charges are excessive. Many devices, unlike most drugs, are expensive to manufacture, and it is unrealistic to prohibit a sponsor from recovering costs. It is a well-established ethical principle, however, that no profit should be made on experimental drugs or devices. Accordingly, § 812.7(b) prohibits charging for the device a price larger than that needed to recover manufacturing, research, development, and handling costs. FDA has deleted as unnecessary the provision in the original proposal for FDA to determine whether charges are unreasonable. FDA will make the determinations necessary to enforce § 812.7(b).

Waivers

55. Comments on reproposed § 812.10 objected to requiring submission of a citizen petition to obtain a waiver. Several comments argued that the procedure was unduly cumbersome and time consuming and required unnecessary paperwork. Other comments stated that, because a citizen's petition is subject to public disclosure, the confidentiality of the original IDE application would be compromised.

FDA agrees with these comments. Modified § 812.10 permits sponsors to request waivers by letter.

56. A comment suggested that the regulation specify those requirements of section 520(g) that are not subject to waiver. The comment also suggested that § 812.10 be revised to state that no waiver may be granted that could expose any human subject to undue risk of harm.

FDA has revised § 812.10(b) to clarify that FDA may waive only a requirement that FDA finds is not required by the act. FDA also agrees that no waiver should be granted that could result in harm to subjects, and has further revised the section to clarify that only requirements that FDA finds are unnecessary to protect the rights, safety, or welfare of human subjects may be waived.

57. Other comments suggested that FDA respond to a waiver request within a specified time, preferably within 30 days.

FDA rejects these comments. Waiver requests may range from a simple, one-time variation to very complex matters presenting difficult issues. Due to this variation, FDA concludes that a specified time frame is inappropriate. FDA intends to evaluate quickly all requests for waivers.

Import and Export Requirements

58. Section 812.18 (21 CFR 812.18) of the final regulation has been simplified without substantive change. Some comments suggested that § 812.18(b) repeated the statute; others argued that the provisions of § 812.18(b) did not comply with the statute. Some comments suggested the statute itself is unconstitutional with respect to exported devices.

FDA has modified § 812.18(b) to require an exporter to "obtain FDA's

prior approval, as required by section 801(d) of the act." This modification eliminates any question of deviation from the statutory requirements. The requirements that were described in the original proposal and the reproposal have been deleted because FDA believes that the statute provides sufficient guidance to exporters. The preamble to the reproposal discussed the constitutionality of the export provisions of the statute.

59. A comment objected to the deletion of the requirement in the original proposal that the exporter have, or assure that another person has, complied with the requirements on submittal of an application and on the responsibilities of sponsors. The comment further objected that the reproposal did not require the agency to find that human subjects would not be exposed to undue risks and that the foreign country has adequate mechanisms to control use of the device after export.

FDA did not include these requirements in the reproposal and has not included them in the final regulation because FDA concluded that literal application of these requirements in all cases would be unduly burdensome, would present enforcement difficulties, and was not required by section 801(d) of the act (21 U.S.C. 381(d)). FDA concluded that the statute itself affords adequate protection to subjects of investigations conducted in foreign countries. Under section 801(d), sponsors may obtain FDA's permission to export an investigational device by writing to FDA's Bureau of Medical Devices a letter enclosing a copy of the foreign government's approval of importation of the device. After verifying the approval, if necessary, and determining that the exportation of the device is not contrary to the public health and safety, the Bureau will approve and export request. When necessary for the protection of the public health and safety, the Bureau may, in selected cases, require the exporter to submit an application and comply with the responsibilities of sponsors or assure that another person complies with these requirements.

60. A comment suggested that FDA respond to export requests within a specified time.

FDA rejects the comment. A time limit is not required by the law. Requests may vary from the simple to the complex. Specified time frames for action on export requests are not practical because it sometimes is difficult to verify approvals from foreign countries. All requests will be processed as quickly as circumstances permit.

Application and Administrative Action Notification Procedure

61. A number of comments objected to proposed §§ 812.20 and 812.21 because the notification permitted for certain studies required most of the information that is required in a full application for substantial risk, vital device studies. Comments argued that the definition of "vital device" did not provide adequate guidance to determine whether to submit a notification or an application. Some comments suggested inclusion of an abbreviated IDE procedure for low-risk investigations. Comments stated that provisions for submission of summaries of documents, for example a summary of the investigational plan, are more burdensome than requirements to submit the complete document.

FDA agrees that the notification procedure in the reproposal largely duplicated the application procedure. Accordingly, FDA has replaced the notification procedure with a set of requirements in § 812.2(b)(1) for investigations of devices that are not "significant risk devices." These requirements are discussed in paragraphs 1, 17, and 46. Section 812.20(a)(1) requires a sponsor to submit an application to FDA if a significant risk device is to be investigated with human subjects or if FDA notifies a sponsor that an application is required.

62. A comment contended that the notification procedure was inadequate to protect subjects and should be either tightened or abandoned. The comment argued that the procedure placed too much reliance on an IRB's assessment of risk, without providing FDA with enough information to make possible an independent judgment. The comment suggested that a notification be required to include an explanation of the IRB's reasoning, a summary of the evidence on which the IRB relied, a description of the risk involved, copies of any dissents by IRB members, copies of consent forms and informational materials to be given to subjects, a statement as to whether any other IRB has taken adverse action on a similar study, a detailed description of the device, and manufacturing information.

FDA disagrees with the comment. IRB's should have a substantial role in all investigations. IRB's can act on FDA's behalf, subject to agency oversight, in reviewing investigations of devices other than significant risk devices. FDA does not accept the comment's assumption that low-risk studies need the same degree of regulation as high-risk studies and that IRB decisions on nonsignificant risk device investigations need close FDA scrutiny. As explained in paragraph 17 above, allowing sponsors to adhere to abbreviated requirements and IRB's to take principal responsibility for review of investigations of nonsignificant risk devices will allow FDA to devote the attention and resources necessary for regulation of significant risk device investigations. A sponsor is required to submit to the IRB an explanation why the device is not a significant risk device and to provide any other information requested by an IRB, which may include the information listed in the comment. For the reasons stated in paragraph 17 above, FDA does not expect that this approach will expose subjects to risk of harm. Furthermore, FDA retains its ability to oversee such investigations through records inspections and required reports.

To help IRB's carry out their responsibility to review nonsignificant risk device investigations, FDA has required that sponsors and investigators submit certain reports to reviewing IRB's. These requirements are discussed in paragraphs 141, 144, 145, and 146.

Application Procedure

63. In response to the comments described in paragraph 59 above, FDA has made several changes in the regulation with respect to investigations for which an application must be sumitted to FDA. Once IRB approval has been obtained, a sponsor shall submit to FDA an application that may include either the plan itself or a summary of specified sections of the plan. FDA also has clarified the procedure to be used if an investigation is to be conducted at several institutions. An application may be submitted to FDA as soon as one IRB has approved the investigation after considering the investigational plan and report of prior investigations. FDA approval of the investigation, however, applies only to the institution at which an IRB also has approved it. As each additional IRB approves the investigation, the sponsor shall submit to FDA one or more supplemental applications under § 812.35(b).

If an investigation involves testing at several institutions, IRB's should not interpret FDA approval of a part of an investigation at one institution as the basis for approval, without careful review, of a part of the investigation at other institutions.

64. Several comments observed that it might be difficult to obtain local IRB review and requested a clarification of the procedure to follow.

FDA recognizes that occasionally a sponsor may encounter difficulty in finding an IRB in a particular location to review a proposed investigation. Section

520(g)(3)(A)(ii) of the act (21 U.S.C. 360j(g)(3)(A)(ii) authorizes the sponsor to submit the application to FDA if no IRB exists or if FDA finds IRB review inadequate. FDA believes that a local IRB applying community standards to a proposed investigation generally provides an indispensable form of subject protection. The absence of a local IRB may expose subjects to risk that the local community regards as unreasonably, and FDA may have little capacity to determine what risks are acceptable in that community and to function as an IRB. In accordance with the apparent intent of Congress, however, FDA will attempt to perform the functions of the local IRB with respect to an otherwise meritorious investigation if no IRB exists or an IRB's review is inadequate, unless the agency finds that IRB review is critical to subject protection. This policy is described in § 812.20(a)(2). If FDA so finds, a sponsor would have to conduct the investigation at a location where an IRB can review the study, or not conduct it.

Contents of an Application

65. In response to comments, FDA has revised § 812.20(b) to simplify the application requirements. The investigational plan requirements have been integrated with those for the application so that those portions of the investigational plan that may be summarized are distinguished form portions that may not be.

66. Comments argued that FDA should not ask for manufacturing or processing information.

FDA disagrees. This information helps FDA to determine the risk presented by the device and whether the device will be manufactured with consistency. Lack of uniformity in making a device could result in investigational devices that vary. Such variation could produce differing results that yield invalid data and require repeated investigations that present further risks.

67. Other comments suggested that the description of facilities required by § 812.20(b)(3) should be omitted if a quality assurance program is in effect.

FDA disagrees. A quality assurance program consists of procedures necessary to assure and verify confidence in the quality of the process used to manufacture a finished device. For the reasons stated in paragraph 66 above, FDA needs detailed information on manufacturing methods, facilities and controls. A quality assurance program does not provide sufficiently specific information about the manufacturing process to be followed for a particular investigational device.

68. Comments objected to the submission of manufacturing or processing information to an IRB.

This information is now required only in the application to FDA. An IRB may, however, require submission of manufacturing or processing information if it believes that review of the information is necessary to its decision.

Signed Investigator Agreements

69. Section 812.20(b) (4) and (5) differs from the reproposal by requiring that, in lieu of submitting all signed investigator agreements, sponsors submit an example of the agreements, a list of investigators, and a certification that all investigators listed have signed the agreement. A related provision, § 812.150(b)(4), requires the sponsor to submit to FDA every 6 months a current list of the names and addresses of all investigators participating in the investigation. FDA initiated these changes to avoid unnecessary paperwork for sponsors and FDA. FDA can check the current list of those who have signed agreements against its files for adverse information. A sponsor shall submit the actual agreements if FDA so requests under § 812.150(b)(10). In addition, FDA inspectors can verify the list provided by the sponsor against the actual agreements kept in the sponsors' records to assure that the list is accurate and that investigators are not added until they have signed agreements. These procedures will assure attention to investigator responsibilities and will protect the public without the cumbersome requirement that all individual agreements be sent routinely to FDA. Waste of resources from routine FDA review of signed investigator agreements will be avoided, and FDA will be able to concentrate its limited resources on important scientific aspects of applications. Routine sponsor paperwork submissions are also reduced. In these circumstances, FDA believes that it has regulatory discretion to permit sponsors to maintain the agreements in their files, subject to FDA inspection or submission to FDA on request, and that this approach satisfies the requirement of section 520(g)(3)(C) of the act that the investigators' agreements be "submit[ted] * * * to the Secretary."

Disclosure of IRB Action

70. Section 812.20(b)(6) requires the sponsor to list the names, locations, and chairpersons of all IRB's that have been asked to review the investigation, and to certify the action concerning the investigation taken by each IRB. Sponsors will thus disclose whether an IRB has approved, disapproved, or terminated an investigation, or found a device that the sponsor characterized as a nonsignificant risk device to be a significant risk device.

Comments argued that prior IRB disapproval or termination of an investigation is irrelevant and that a requirement to disclose such IRB actions in an application might prejudice FDA decisions.

FDA disagrees with the comments. Disapproval, suspension, or withdrawal of approval suggests the possibility of a flaw in an investigation that should be evaluated before the investigation is approved. If such a previous action were disclosed after an investigation had begun, FDA might have to withdraw approval of the investigation and order it stopped pending further inquiry. In such a case, subjects might be exposed to unnecessary risks, and sponsors and investigators might be inconvenienced.

71. Section 812.20(b)(7) requires the sponsor to submit the name and address of any institution at which a part of the investigation may be conducted if that institution is not identified under § 812.20(b)(6). This provision ensures that FDA has complete information on where an investigation is to be conducted, if an investigator's part of a study is not on the premises of the institution whose IRB has agreed to review the investigator's part of the study. FDA needs this information to review the scope of the investigation and to schedule necessary inspections.

72. A comment suggested that the application disclose any dissent from IRB approval.

FDA rejects the comment. Such disclosure could be implemented only by requiring IRB's to keep records of each dissent. Committee decisions frequently result from divided opinions. If detailed records of dissenting views were required, IRB's might feel compelled to issue a written opinion approving the investigation despite the lack of an FDA requirement for such an opinion. To require documentation of minority views, therefore, might unnecessarily delay IDE decisions and disrupt IRB operations. Furthermore, such a requirement would commit FDA to review documents that are not likely to yield valuable information. Even if dissents contain useful information, there is too little likelihood that the same information would not have been discovered by FDA during its review of the application to justify the paperwork burden that would result from a requirement that dissents be submitted to FDA. An IRB member may oppose an investigation for reasons relevant to the particular institution but irrelevant to the standards for approval under the act

and these regulations. FDA would therefore find it necessary to distinguish between dissents that have to be submitted to FDA and those that do not, thus burdening IRB's with the requirement that they make this distinction.

The collective assessment of the IRB is what matters to FDA in its review of an IRB's judgment. FDA will, in any event, conduct its own independent review of each application. IRB's may choose, however, to maintain records of dissents or summaries of dissents; and IRB's or individual IRB members may notify FDA of dissenting views.

Disclosure of Intent To Sell or Charge for the Device

73. Comments argued that FDA has no authority to require disclosure of an intent to sell the device or the amount to be charged and that FDA cannot effectively use the information.

FDA rejects the comments. FDA will use the information required by § 812.20(b)(8) in determining whether the device is being commercially distributed in violation of the conditions of the IDE. FDA is authorized by sections 301(q), 501(f), 520(g)(2)(B), and 701(a) (21 U.S.C. 371(a)) of the act to impose this requirement.

Investigational Plan

74. FDA has made explicit in § 812.25(b) the requirement for a written protocol describing the methodology used in an investigation. This requirement was implied in the original proposal and reproposal.

75. A comment on reproposed § 812.25 suggested that the investigational plan include a description of any characteristics that render the patient population vulnerable.

FDA agrees and has included this description as part of a required analysis of risks to subjects, justification for the study, and description of the patient population in terms of the number of subjects and their age, sex, and condition. The term "condition" includes relevant characteristics that render the patient population vulnerable. This provision focuses on the purpose of investigational controls: Protection of subjects through an analysis of risks, including the manner in which the risks will be minimized. FDA expects the analysis to be brief and to be directed to the additional or incremental risks (as distinguished from risks inherent in the subjects' medical condition) that use of the device presents to the rights, safety, or welfare of subjects. FDA believes that careful analysis of risks by sponsors, IRB's, and FDA will enable regulatory controls to be targeted on those investigations that are most likely to expose subjects to undue risks.

76. Comments suggested that the requirement to submit a description of each important device component was burdensome, and that only those components that increase risk should be described.

FDA rejects the comments. Trying to decide which components increase risk and which do not is a difficult and, perhaps, impossible task. IRB's and FDA should be able to review each important component of an investigational device. The requirement is retained in § 812.25(d).

77. Other comments suggested that the investigational plan disclose whether any IRB's had ever suspended, disapproved, or terminated an investigation.

FDA agrees, and § 812.25(h) requires sponsors to certify the action by each IRB that has reviewed the investigation. Among the actions required to be reported are findings by another IRB that the investigation involves a significant risk device.

78. Section 812.25(h) duplicates the requirement in the application for a list of the names, locations, and chairpersons of all IRB's that have been asked to review the investigation. FDA added this provision to enable IRB's to consult with each other concerning an investigation.

79. Section 812.25(j) requires a description in the investigational plan only of any records and reports that are in addition to those required by Subpart G of this regulation. FDA made this change to eliminate needless description of records already required by Subpart G.

Report of Prior Investigations

80. Comments argued that reproposed § 812.27(d) implied that animal testing must be completed in every case before human testing is initiated.

FDA appreciates that some devices cannot be tested in animals before they are tested in humans. FDA has deleted the proposed requirements for prior animal testing from the final regulation because they did not provide useful guidance as to when and to what extent animal studies would be required. FDA will determine, in its review of IDE applications, whether prior animal testing should have been conducted. IRB's should also look closely at this point. The approach FDA is using here is consistent with its general policy that, where possible, relevant animal testing should be completed before initiating human testing. FDA will not approve an IDE or an application for premarket approval if animal testing should first be completed.

81. Comments suggested that only information relevant to the investigation be submitted, rather than all information relevant to the device.

FDA agrees with the comments. Furthermore, § 812.27(b)(1) has been revised to require only a bibliography of relevant publications and copies of all published and unpublished adverse information. To reduce unnecessary paperwork, copies of other significant publications need be submitted only if requested by a reviewing IRB or FDA. Also, § 812.27(b)(2) provides that only a summary of other relevant unpublished information is required. Relevant information includes both information that is adverse and information that supports a proposed investigation.

82. Comments suggested that the IRB, not FDA, should decide on the adequacy of the report of prior investigations.

FDA disagrees with the comments. FDA has final responsibility for the proper conduct of device investigations. Therefore, in the case of a significant risk investigation, FDA should review the report of prior investigations and determine its adequacy. Although FDA expects that it will generally concur in IRB assessments, it cannot guarantee that it will never overrule an IRB judgment based on a review of the report of prior investigations.

FDA Action on Applications

83. Comments suggested that the criteria for disapproval and withdrawal were similar and should be combined. Other comments noted minor differences between the criteria for disapproval and withdrawal.

FDA agrees with the first set of comments. Accordingly, the criteria have been combined in § 812.30.

84. A comment suggested that § 812.30 be revised to prohibit approval of seriously deficient applications. The comment also suggested that safety-related grounds for withdrawal of approval of IDE's should be placed in a separate mandatory withdrawal category, distinct from discretionary grounds for withdrawal. The comment suggested further that the regulation compel FDA to withdraw exemptions in cases of non-safety-related deficiencies that are not corrected within a reasonable time, for example, 60 days after notification.

FDA has not adopted the comment. Because FDA will not approve seriously deficient applications, there is no need to include in the regulation a provision prohibiting such approvals. With respect to the suggestion that FDA revise § 812.30(b) to state that FDA "shall"

withdraw approval if certain safety-related grounds exist, the agency would still retain the discretion to determine whether one or more of the specified grounds exist, for example, that it is "unsafe to begin or to continue an investigation," § 812.30(b)(4). No change in wording can eliminate FDA's discretion to determine whether a ground for action exists. Also, some of the grounds for action in § 812.30 would be characterized as safety-related in some cases but not in others. With respect to the suggested deadline for FDA withdrawals for non-safety-related reasons, FDA believes that such matters are better handled by internal agency procedures than by regulations.

Supplemental Applications and Submissions

85. Comments argued that the reproposal's requirements for supplemental applications were too restrictive and that supplemental applications should be limited to changes affecting the safety of subjects or the validity of the investigation.

FDA believes that this was the intent of the reproposal, but has clarified § 812.35, the counterpart provision in the final rule, to reflect clearly this policy. Supplemental applications are required only for the addition of new institutions to an investigation and for changes in the investigational plan that may affect the scientific soundness of the study or the rights, safety, or welfare of subjects. IRB and FDA approvals are required before initiating any such changes, except for deviations from the investigational plan to protect a subject in an emergency. These deviations shall be reported later under §§ 812.150(a)(4) and 812.35(a).

86. Comments suggested that, once an IRB has approved a change in the plan, FDA approval of the change is not needed.

FDA rejects these comments. Sections 812.35(a) and 812.150(a)(4) of the final regulation require that any change in the investigational plan that may affect its scientific soundness or the rights, safety, or welfare of subjects be approved by both the IRB and FDA. In significant risk device investigations, nonemergency changes that may have such an effect should receive the same prior review as an application. Less important changes in the investigational plan for significant risk device investigations, and any changes in the plan for nonsignificant risk device investigations, need not, however, be reported to FDA.

87. Some comments argued that all deviations from the investigational plan should be approved by the sponsor before FDA or IRB approval is sought. Other comments suggested that such deviations do not require prior FDA or IRB approval.

Under §§ 812.110 and 812.150(a)(4), an investigator shall not institute a change in or deviation from the investigational plan without first obtaining the sponsor's approval. If the deviation or change may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, prior IRB and FDA approval also is required. An exception from these requirements is that, in an emergency situation, as described in § 812.35(a), prior approval of a deviation by the sponsor, the IRB, and FDA is unnecessary. Emergency deviations shall be reported later under §§ 812.150(a)(4) and § 812.35(a). These provisions are designed to deter careless deviations from the investigational plan, without unduly restricting an investigator at the scene of the investigation from exercising initiative on behalf of patient rights, safety, or welfare in a medical crisis.

Confidentiality of Data and Information

88. Section 812.38(a) of the final regulation states that FDA will not disclose the existence of an IDE unless its existence has been publicly disclosed or acknowledged, until FDA approves an application for premarket approval of the device subject to the IDE, or a notice of completion of a product development protocol for the device becomes effective. This provision, which is based on current FDA policy with respect to notices of investigational exemption for new drugs (IND's), was published in the original IDE proposal. The provision was omitted from the IDE reproposal because FDA had published in the **Federal Register** of March 28, 1978 (43 FR 12869), correction published in the **Federal Register** of March 31, 1978 (43 FR 13587), a proposal to change FDA policy regarding disclosure of the existence of applications or notices to conduct research on, or to market, drugs or devices. Under the March 28, 1978 proposal, FDA would disclose the existence of such an applcation or notice whether or not its existence had previously been disclosed or acknowledged. FDA is still reviewing the numerous comments received on the proposal. For now, FDA believes that current policy with respect to disclosure of the existence of IND's should apply to disclosure of the existence of IDE's, and has so provided in § 812.38(a).

Section 812.38(b) of the reproposal stated that public disclosure of IDE data and information would be made in accordance with § 314.14 on the confidentiality of data and information in new drug application (NDA) files. In the final regulation, FDA has moved this provision to paragraph (d) of § 812.38 and has revised it to state that NDA confidentiality rules apply only until the effective date of the final regulation concerning the confidentiality of data and information in applications for premarket approval of devices. FDA plans to publish a proposal on procedures for these applications, including confidentiality of the contents of these applications, in the near future.

89. A comment argued that reference in § 812.38 to the drug confidentiality rules in § 314.14 is inappropriate because of the special statutory protections in section 520(c) of the act for device trade secrets and condifential commercial information.

FDA rejects the comment. It is true that the act does not contain a provision precisely like section 520(c) that applies to drugs the same protection for trade secrets and confidential commercial information that section 520(c) applies to devices. However, in § 314.14 the agency has construed section 301(j) of the act and 18 U.S.C. 1905 as preventing public disclosure of the same types of information about drugs that section 520(c) treats as confidential.Thus, with respect to public disclosure of trade secrets and confidential commercial information, section 520(c) provides the same degree of protection as section 301(j) and 18 U.S.C. 1905. Accordingly, reference to confidentiality rules applicable to drugs generally is appropriate. As noted above, when final regulations on device premarket appproval applications become effective, these regulations will contain rules for confidentiality of device data and information so that it will no longer be necessary to refer to the drug confidentiality rules in § 314.14.

90. Another comment stated that reference in § 812.38 to the drug confidentiality rules in § 314.14 is inappropriate because of the provisions in section 520(h) of the act for summaries of device safety and effectiveness information. The comment interprets section 520(h) as requiring public disclosure of such information in IDE files, under any circumstances.

FDA agrees that it must revise § 812.38 of the reproposal for consistency with section 520(h) of the act and with § 812.30(f) of the reproposal. FDA has therefore revised § 812.38(b) of the final regulation.

FDA disagrees with the comment's interpretation of section 520(h) of the act as imposing a requirement for public disclosure of the records contained in IDE files. It is clear from its face that section 520(h) only requires disclosure of

a detailed summary of safety and effectiveness information, not disclosure of the records from which this summary is developed, and does so only when FDA takes one of several specified actions. See also H.R. Rep. No. 94–853, 94th Cong., 2d Sess. 48–51 (1976).

Moreover, section 520(h)(3) states that information in a summary "shall be made available subject to" section 520(c) of the act. Section 520(c) specifically describes safeguards for trade secrets and confidential commercial information concerning devices and is discussed in paragraph 89 above. Because of section 520(c), a summary prepared under section 520(h) may not contain trade secret or confidential commercial information, including confidential safety and effectiveness data.

91. One comment argued that safety and effectiveness data should be released only after an applicant has exhausted all administrative and judicial appeals of a denial of an application.

FDA agrees but believes no change is required. Under paragraph (f)(2) of § 314.14, referred to in § 812.38(d), FDA will not disclose confidential commercial information not previously disclosed to the public until a final determination is made that an application for premarket approval is unapprovable, and all legal appeals have been exhausted.

92. Other comments objected to the provision for disclosing copies of adverse reaction reports to subjects.

FDA rejects these comments and has retained the provision. FDA believes that access by subjects to reports of their adverse reactions is necessary for protection of subjects, an interest that outweighs the concerns of sponsors or investigators that such reports may be used in malpractice or product liability suits. Moreover, disclosure to a subject of such a record about himself or herself is required by the Freedom of Information Act and is consistent with the objectives of the Privacy Act.

Sponsor Responsibilities

93. Subpart C prescribes general duties of sponsors. This subpart is a simplified version of provisions in the original proposal and reproposal. Sponsor responsibilities concerning inspection, records, reports, and commercialization of the device are set forth in Subpart G.

94. Comments questioned whether independent studies must be conducted concurrently or sequentially.

Both concurrent studies and sequential studies can provide independent proof of device safety and effectiveness. Either approach is satisfactory. The ability to replicate the results of an investigation is the important factor. Because sponsors may terminate investigations for a variety of reasons, for example economic nonfeasibility, Part 812 does not require independent investigations. Independent investigations are, however, required for premarket approval.

Investigator Agreements

95. Consistent with the change in § 812.20(b)(5) described in paragraph 69, FDA has initiated a change in the requirement of reproposed § 812.43(b) that a sponsor obtain a signed agreement from an investigator and submit it to FDA with an application. Final § 812.43(c) requires that the sponsor obtain signed agreements, and § 812.145(b) requires the sponsor to maintain them subject to FDA inspection. Sponsors must submit the actual agreements or make them available for inspection if FDA so requests.

96. Section 812.43(c) also simplifies the information required in the investigator's agreement. A curriculum vitae should provide the type of information required by proposed § 812.43(b)(1) (**Federal Register** of August 20, 1976 (41 FR 35306)).

97. Comments on reproposed § 812.43(b)(4) argued that the requirement to disclose to the sponsor whether prior research by an investigator has ever been terminated by a sponsor, an IRB, or FDA is irrelevant and might prejudice approval of the investigation.

FDA disagrees with the comments that the information is irrelevant. It may well be relevant to a prediction as to whether the investigator will respect the rights and protect the safety and welfare of subjects and otherwise comply with applicable statutory and regulatory requirements. In addition, a study conducted by an investigator who has been disqualified by FDA may not be accepted in support of a premarket approval application or other application to conduct research on, or market, a product. The investigator's agreement will not be submitted to FDA routinely and will be reviewed only if specifically requested or during an inspection.

98. Comments suggested that an investigator at a teaching hospital in which residents and interns frequently rotate would be required constantly to amend the agreement if, as reproposed § 812.43(b)(5) required, the investigator's agreement must contain the names of subordinate investigators.

FDA agrees with the comments. Final § 812.43(c) no longer requires that subordinate investigators be named in a participating supervisory investigator's agreement. The requirement is for sponsors to obtain from each participating investigator a signed agreement to be maintained for FDA inspection or submission to FDA on request. Supervisory investigators' agreements need not be amended each time a new subordinate investigator is added. Sponsors are, however, required to submit to FDA a current list of names and addresses of clinical investigators (including supervisors and subordinates) at 6-month intervals, in accordance with § 812.150(b)(4).

Notice of Approval

99. Comments objected to notifying investigators when premarket approval had been obtained.

FDA agrees with the comments and has deleted this requirement. Although it is desirable for investigators to know the regulatory status of products, sponsors generally have an economic incentive to inform investigators that a device has been approved. Accordingly, an FDA requirement for notification of investigators of premarket approval is unnecessary.

Securing Investigators' Compliance

100. A comment suggested that § 812.46 be modified so that the sponsor has a definite time frame, for example 30 days, in which to secure an investigator's compliance, or else discontinue shipments to the investigator or terminate the study.

FDA rejects the comment. Although sponsors must terminate the participation of an investigator who fails or refuses to comply with applicable requirements, FDA does not believe it practical to specify a particular time frame in which such termination must occur. The urgency with which a sponsor must act will vary depending on the seriousness of the violations. In some cases, 30 days would be an excessive time frame for securing investigators' compliance, while in others 30 days would be an inadequate time frame. If experience under the IDE regulation shows that a uniform time frame for investigators' compliance would be desirable, FDA will add this provision to the regulation. In any event, FDA will consider withdrawing approval of the IDE of a sponsor that fails to secure an investigator's compliance in a timely manner consistent with the seriousness of the violations.

Unanticipated Adverse Device Effects

101. Section 812.46(b)(1) provides for the sponsor to conduct an evaluation of any unanticipated device effect. Section 812.150(b)(1) provides for reporting the results of such evaluations. Comments suggested various time periods for the submission of the reports of special evaluations, for example, 5 days, 2 weeks, and 10 calendar days.

FDA believes that 10 working days after the sponsor first receives notice of an effect is sufficient for both completing the evaluation and submitting the results to FDA and all participating investigators and reviewing IRB's. Because IRB's and FDA may not be able to respond on nonworking days, it seems reasonable to base the notification requirement on working days.

Termination

102. Section 812.46(b)(2) requires a sponsor who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects to terminate all investigations or parts of investigations presenting that risk as soon as possible, but not later than 5 working days after making this determination and not later than 15 working days after first receiving notice of the effect. If a sponsor obtains sufficient information to warrant termination, the investigation should be terminated immediately. However, administrative difficulties may make immediate termination difficult, particularly if an investigation is conducted at several sites.

IRB Responsibilities

103. A simplified version of Subpart D of the original IDE proposal is included in this regulation as Subpart D. IRB responsibilities concerning inspection, records, and reports are set forth in Subpart G.

Review of Investigation

104. Section 812.60 has been revised to clarify the purpose of IRB review and the type of inquiry that FDA expects IRB's to conduct. FDA expects an IRB to apply local community attitudes and ethical standards in making a judgment that the benefits to subjects and the knowledge to be gained outweigh the risks.

An IRB's judgment involves an evaluation of the ethics of an investigation, including, where relevant, whether children, pregnant women, the elderly, or members of a minority group should participate in an investigation and whether informed consent has been obtained. In determining risks and benefits, the IRB must assess the scientific soundness of the investigation. An investigation that approaches the frontiers of existing knowledge requires a probing and cautious IRB review.

IRB Membership

105. Comments on the original proposal objected that IRB's were being required to possess competence that they do not have to review the scientific validity of investigations.

In response to these comments, FDA has restated the requirements for membership on an IRB. Section 812.62(d) and (e) requires that IRB members be able to comprehend the nature of the investigation. If additional scientific competence is required, § 812.62(e) permits the use of nonvoting consultants. FDA does not expect an IRB to render judgments as to the adequacy of the statistical and design assumptions on which the investigation is based or other details bearing on the validity of an investigation. An IRB ned not exhaustively examine a well-designed investigation to assure that it yields the maximum scientific results. Nonetheless, an IRB collectively must be able to evaluate the risks and scientific soundness of proposed investigations in order to determine, for example, that an investigation is not disguised quackery or clearly will not yield useful results. In particular, an IRB must be able to review carefully and critically a sponsor's characterization of an investigational device as not presenting a significant risk. If the device does present a significant risk, the investigation may not begin until FDA has approved it.

Minority and Sex Representation

106. Comments on the original proposal suggested that an IRB be required to include members of minority racial groups and both male and female members.

FDA agrees with the comments, but has not adopted them at this time. An IRB must be broadly representative of the comunity it serves and must not discriminate against any group in its composition, policies, or decisions. FDA encourages IRB's to include in their membership members of minority groups and both women and men. FDA believes, however, that this requirement should be considered in the proceeding initiated by the August 14, 1979 reproposal on Standards for Institutional Review Boards.

Conflicts of Interest

107. Section 812.62(f) prohibits investigators and sponsors from participating in the selection of IRB members who will review investigations conducted or sponsored by them. In the case of investigations sponsored by academic institutions, FDA will entertain requests for waivers of this provision.

108. Comments on the original proposal noted that members of an IRB having a conflict of interest seemed to be prohibited from furnishing information requested by the IRB.

FDA has revised § 812.65(a)(3) to make it clear that members having a conflict of interest may furnish information to an IRB at its request.

Quorum

109. Comments on the original proposal suggested that a quorum include at least one scientist, one licensed physician, and one lay member.

FDA agrees with these comments. Section 812.65(a)(2) provides for a quorum to be not less than a majority of the members and to include a licensed physician, a nonphysician scientist, and one member whose primary activities are in a nonscientific field. This requirement ensures a mix of backgrounds and disciplines to enable an IRB to explore all facets of a proposed investigation.

110. Comments objected to the requirement that one lay member, that is, a member whose primary activities are in a nonscientific field, and a licensed physician be present in every quorum because the lay member or physician could exert a veto on IRB deliberations by being absent.

FDA disagrees with the comments. Under § 812.65(a)(2), only if the IRB has only one lay member and only one member who is a physician could such a veto occur. FDA believes that protection of the rights, safety, and welfare of subjects is enhanced by a diversity of the members' backgrounds. FDA believes that the need for diverse points of view requries that all investigations subject to IRB review obtain review by a properly composed IRB. The absence of a lay member might result in a decision that reflects the enthusiasm of the scientific members, but fails to reflect community standards that the lay member helps to represent.

FDA has no objection to an institution's disciplining or removing recalcitrant members who fail to attend IRB meetings, or adding sufficient lay members so that absenteeism is not a problem. Such actions are not prohibited by § 812.65(a)(2).

111. Comments suggested that at least one member have a biomedical engineering background to ensure adequate review of those investigations that involve engineering problems.

FDA does not agree that a biomedical engineer member should be required in every case. An IRB may obtain the services of nonvoting consultants when necessary to delve deeply into engineering or scientific matters. FDA expects that members of an IRB will, in any event, render judgments weighing all factors and that they will seek expert assistance if necessary.

FDA cautions that a member whose primary activities are in a scientific field, for example, biomedical engineering, will not qualify as a lay member. A biomedical engineer, however, would satisfy the requirement of § 812.62(b) for a scientifically trained member.

For purposes of this regulation, a social scientist is considered to be an individual whose primary activities are in a nonscientific field. Thus a social scientist may serve as a lay member on an IRB.

IRB Action on an Investigation

112. Several comments asked for clarification of the criteria FDA wants IRB's to use in reviewing investigations.

Section 812.65(a)(4) clarifies the criteria for disapproving a clinical investigation. No judgment concerning the statistical validity of the design of an investigation is required. What is required of an IRB that disapproves an investigation is a judgment that the benefits do not outweigh the risks to subjects, that informed consent is inadequate, that the proposed investigation is scientifically unsound, that there is reason to believe that the device is ineffective, or that it is otherwise unreasonable, unsafe, improper, or not in the best interests of the institution to begin or continue the investigation. FDA no longer specifies the factors that an IRB should use in arriving at its decision, but refers to the factors described in § 812.30(b). Subpart F states precisely the factors for evaluating the adequacy of informed consent.

113. Approval with modification under § 812.65(a)(4) is an approval with changes made in the investigational plan. The purpose of such changes usually will be to reduce or eliminate risks to subjects contained in the plan submitted to the IRB. Suspension under § 812.65(a)(4) involves temporary cessation of an investigation, an action short of withdrawal of approval that an IRB may order if it suspects or believes that the rights, safety, or welfare of subjects are in jeopardy, for example due to an adverse device effect. After suspension, an IRB may determine whether approval should be withdrawn.

114. An IRB must disapprove or withdraw approval of an investigation if it finds that any of the conditions set forth in § 812.65(a)(4) is present. In evaluating safety, an IRB should consider only those incremental or increased risks to which the subjects will be exposed by participating in the research, not risks to which subjects are exposed by virtue of their medical conditions. Thus, the risk to be addressed is that presented by the investigational therapy instead of therapy of accepted safety and effectiveness.

115. Comments suggested that the scientific review function be separated from IRB review. Several comments envisioned peer review followed by IRB review.

FDA has not adopted these specific comments. Scientific review and subject protection are inseparable. The IRB should assure itself of the scientific soundness of a proposed investigation. The procedures by which the IRB may generate that assurance are not specified. One approach would be for individual members of an IRB with a technical background to comment on the technical aspects of a proposal and its scientific acceptability. If necessary to protect subjects, scientific consultants should be employed. Although this regulation does not mandate peer review, FDA does not object to its use as one mechanism of assuring the scientific soundness of investigations. FDA cautions that because of the many comments received on this aspect of the Aug. 14, 1979 IRB reproposal, further clarification of the role of the IRB in the review of clinical investigations will be found in the IRB final regulation.

116. Comments suggested that IRB approval should be final without further FDA review.

FDA rejects these comments. They reflect a view that the IRB has the total responsibility to evaluate an investigation, without further review by FDA. Although FDA expects to concur in most IRB approvals, FDA has a statutory responsibility for final judgments on investigations. Moreover, FDA has a nationwide perspective concerning regulation of medical device research that is not duplicated in local IRB's.

Waiver of IRB Review

117. Comments contended that § 812.42(d)(1) of the reproposal would allow waivers of IRB review in situations where this review is required by statute.

FDA has deleted the provision for waiver of IRB review in view of strong policy reasons favoring such review, expressed in section 520(g) of the act, the National Commission report mentioned earlier in this preamble, and FDA's August 14, 1979 reproposal on Standards for Institutional Review Boards. Section 520(g)(3)(A) requires submission of an IDE application to FDA where no IRB exists or FDA finds that an IRB's process of review is inadequate. In some such cases, FDA may refuse to approve an application because of the need for IRB review to protect subjects.

118. A comment argued that an IRB should be considered to "exist," for purposes of section 520(g)(3)(A)(ii), if an IRB exists within a local jurisdiction but not on the premises where the investigation is being conducted.

FDA agrees that IRB's can review investigations, or parts of investigations, that are conducted in the same locale but not on the premises of the institution that created the IRB. The regulation allows, but does not require, this review. A requirement in this regulation that an IRB review studies concucted elsewhere than at the institution would cause problems that most IRB's are now unprepared to solve. This issue is better addressed in the proceeding involving the August 14, 1979 IRB reproposal.

Independence of IRB Decisions

119. Section 812.65(c) provides that the decision of one IRB on an investigation does not preclude another IRB from reaching a different decision. This provision clarifies the independent nature of IRB decisions.

120. Comments requested clarification of the authority of other institutional officials to review IRB decisions. Some comments suggested that an IRB's decsion should be subject to appeal.

FDA disagrees in part with the latter comments. Only an IRB should approve an investigation. FDA believes that only an IRB can bring together the diversity of backgrounds necessary to ensure the protection of human subjects. The value of an IRB's decision to disapprove an investigation would be undermined if it could be overruled. The same considerations do not apply, however, when an IRB approval is overruled by a person or body other than the IRB because human subjects are not thereby exposed to risks that an IRB has determined to be unacceptable. Therefore, under § 812.70, an institution may overrule an IRB decision to approve an investigation.

Responsibilities of Investigators

121. A simplified version of Subpart E of the original proposal has been incorporated in this final regulation. Investigator responsibilities concerning

inspections, records, reports, and commercialization of the device are set forth in Subpart G.

Informal Requests To Participate in Investigations

122. Comments on the proposal argued that investigators should be permitted to determine whether potential subjects would be interested in participating before obtaining IRB and FDA approval.

FDA agrees with these comments. Section 812.110(a) has been rewritten to permit such determinations of interest, short of requests for informed consent.

Disqualification

123. Section 812.119 of the original proposal on disqualification of investigators, which received many comments, has been deleted. Disqualification of investigators will be addressed in FDA's final regulation on obligations of clinical investigators of regulated articles.

Informed Consent

124. Subpart F, which has not been changed in substance, applies to investigations of significant and nonsignificant risk devices.

125. Several comments suggested that § 812.120 include a procedure for documenting that oral informed consent has been properly obtained. One comment suggested that such a procedure would be appropriate for low-risk studies.

FDA agrees with the latter comment. In the case of a nonsignificant risk device investigation, informed consent need not be evidenced by a written document signed by the subject, if the investigator obtains and documents oral informed consent.

Section 812.122 also allows documented oral informed consent in the case of an illiterate subject, or an illiterate representative of an incompetent subject, whether the investigation is of a significant risk or a nonsignificant risk device. The inclusion of a procedure in § 812.122 for documenting oral informed consent from illiterate subjects is not meant to imply that FDA believes that illiterate individuals are, as a general rule, suitable subjects in device investigations. Such a procedure is necessary, however, to cover the situation where a study population includes illiterates, in order to permit those individuals to have the same access to investigational devices that other individuals have.

126. Sections 812.122, 812.123, and 812.130 have been shortened and simplified without change in meaning. For example, the prohibition against obtaining informed consent through coercion, deception, or undue influence also prohibits obtaining informed consent through fraud, deceit, force, or duress. When FDA publishes final agency-wide regulations on informed consent, based on the August 14, 1979 proposal, FDA will publish conforming changes in Subpart F.

127. The requirements of proposed § 812.123(b) that mandate the documentation and reporting of the use of a device without obtaining informed consent are now found in §§ 812.140(a)(3)(i) and 812.150 (a)(5) and (b)(8).

128. A comment on reproposed § 812.123 suggested that the requirement to obtain informed consent be waived in those situations where obtaining informed consent would interfere with protection of a subject's bodily function.

FDA rejects this comment. Section 520(g)(3)(D) of the act specifies clearly the situations in which the requirement to obtain informed consent may be waived. The only permissible waiver of such consent is if a life-threatening situation exists and it is not feasible to obtain consent from the subject or the subject's legal representative.

129. Another comment objected that to comply with Subpart F many hospitals will be required to revise existing informed consent forms.

FDA rejects the comment. Revision of forms may, indeed, be necessary, but Congress intended that result when it enacted the amendments and provided specific guidance on the elements of informed consent.

130. A comment suggested that § 812.130 be altered to permit placebo studies.

FDA rejects the comment. No change is required because placebo studies are not prohibited.

Records and Reports

131. Subpart G, dealing with records, reports, and inspections, consolidates requirements applicable to sponsors, investigators, and IRB's. These requirements were previously scattered throughout Subparts C through F of the original proposal and reproposal.

Inspections

132. Comments on the original proposal objected that sponsors or investigators should not be held responsible for failure to grant access to facilities for FDA inspection in cases where the sponsor or investigator lacks proprietary or other authority to grant this access.

FDA agrees with the comment. Final § 812.145(a) requires a person who is a sponsor or investigator to permit FDA representatives to inspect those facilities to which the person has authority to grant access.

133. Many comments on the original proposal objected to the provision that required FDA access to patient records and names on the grounds that it violates patient confidentiality and investigator ethics.

FDA rejects the comments. FDA believes that the provisions must be retained because inspection is the only feasible way of verifying that actual subjects were used, that their rights were protected, and that reports to sponsors and IRB's were accurate. FDA believes that most subjects would approve of this requirement because it is designed to protect them from unethical practices. FDA advises, however, that this authority will be used carefully. Investigators are encouraged to make clear to potential subjects at the time informed consent is obtained that their records may be examined by FDA.

Records

134. Section 812.140(a) requires investigators to maintain records of relevant correspondence, device receipt, use, and disposition, subjects' case history and device exposure, and a current copy of the protocol. FDA may require that other records be kept if FDA determines it is necessary for a category of investigations or a particular investigation. For example, in Part 813 FDA has imposed certan special requirements for investigations of IOL's, to ensure traceability of the devices after implantation.

135. Section 812.140(b) requires sponsors to maintain records of relevant correspondence, device shipment and disposition, signed investigator agreements, and adverse device effects. Relevant correspondence includes copies of materials submitted to FDA in support of an IDE application. Special recordkeeping requirements, discussed in paragraph 136, apply to sponsors of nonsignificant risk device investigations. FDA may require a sponsor to keep other records if FDA determines they are necessary for a category of investigation or a particular investigation.

Records of Nonsignificant Risk Device Investigations

136. To implement its decision to reduce regulation of nonsignificant risk device investigations, FDA has added special recordkeeping requirements for sponsors of such investigations. Section 812.140(b)(4) requires these sponsors to maintain records of such investigations in one location and make them available for FDA inspection and copying.

Required records include: the name and intended use of the device, the objectives of the investigation, a brief explanation of why the device is not a significant risk device, the name and address of each investigator, the name and address of each IRB that reviewed the investigation, a statement of the extent to which the good manufacturing practice regulation in Part 820 will be followed, and a copy of any quality assurance program, and records concerning adverse device effects and complaints.

137. Section 812.140(c) requires that each IRB maintain records of relevant correspondence, membership and its members' employment relationships, and relevant minutes.

Retention Period

138. Comments suggested that the 2-year and 5-year retention requirements for records were confusing and served no useful purpose.

In response to the comments, FDA has changed the regulation to require that records be retained for a 2-year period after the later of two dates: The date when the investigation is terminated or completed, or the date when the investigation is no longer required to support approval of an application for premarket approval or a notice of completion of a product development protocol.

Transfer of Records Custody

139. Custody of records may be transferred, as reproposed, but the transferee must accept responsibility for such records including the requirement to permit FDA inspection and copying under § 812.145. FDA must be notified within 10 working days of such a transfer. The requirement that the transferee accept responsibility and that notice be given to FDA were added to close possible regulatory loopholes.

Reporting Requirements

140. Section 812.150(a) requires investigators to submit reports to sponsors, IRB's, and FDA, as specified, on unanticipated adverse device effects, withdrawal of IRB approval, progress of the investigation, deviations from the investigational plan, use of a device without informed consent, termination or completion of an investigation, and other matters upon request by a reviewing IRB or FDA.

141. Comments on the reproposal suggested that IRB's receive reports of unanticipated adverse device effects.

FDA agrees with the comments, and § 812.150 (a)(1) and (b)(1) so provide. This change and those described in paragraphs 144, 145, and 146 below will strengthen the ability of IRB's to review investigations.

142. Comments suggested that the time allowed for reporting unanticipated adverse device effects be extended from 5 to 10 days, and that the time period be stated in working days rather than calendar days.

FDA agrees with the comments and has amended § 812.150(a)(1) accordingly.

143. Section 812.150(b)(4) requires the sponsor to provide FDA with a current list of investigators at 6-month intervals. This provision applies only to investigations of significant risk devices. The purpose of the list is explained in paragraph 69 above.

144. A comment suggested that sponsors notify all reviewing IRB's when an investigation is terminated or completed.

Section 812.150(b)(7) adopts the suggestion with respect to significant risk device investigations.

145. A comment suggested that progress reports and a final report be submitted to reviewing IRB's.

FDA has adopted this comment as well, with respect to both significant risk device investigations and nonsignificant risk device investigations, and § 812.150(b)(5) so provides.

146. A comment suggested that the regulation require sponsors to notify all reviewing IRB's, as well as FDA, of sponsors' requests to return or dispose of devices.

FDA agrees and has amended § 812.150(b)(6) accordingly.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 301, 501, 502, 520, 701(a), 702, 704, 801, 52 Stat. 1042–1043 as amended, 1049–1051 as amended, 1055, 1056–1058 as amended, 67 Stat. 476–477 as amended, 90 Stat. 565–574 (21 U.S.C. 331, 351, 352, 360j, 371(a), 372, 374, 381)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. By revising in § 16.1(b)(1) the statutory provision paragraph for section 520(g)(4) and (5) of the act, to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) Statutory provisions:

* * * * *

Section 520(g)(4) and (5) of the act relating to disapproval and withdrawal of approval of an application for an investigational device exemption (see §§ 812.19(c), 812.30(c), 813.30(d), and 813.35(c)).

* * * * *

PART 20—PUBLIC INFORMATION

2. By amending § 20.100 by reserving paragraph (c)(32) and adding new paragraph (c)(33), to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(32) [Reserved]

(33) Investigational device exemptions in § 812.38 of this chapter.

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

3. By revising § 809.10(c) to read as follows:

§ 809.10 Labeling for in vitro diagnostic products.

* * * * *

(c) A shipment or other delivery of an in vitro diagnostic product shall be exempt from the requirements of paragraphs (a) and (b) of this section and from a standard promulgated under Part 861 of this chapter:

(1) In the case of a shipment or delivery for an investigation subject to Part 812, if there has been compliance with Part 812; or

(2) In the case of a shipment or delivery for an investigation that is not subject to Part 812 (see § 812.2(c)), if the following conditions are met:

(i) For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."

(ii) For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: "For Investigational Use Only. The performance characteristics of this product have not been established."

(iii) The person making a shipment or delivery under paragraph (c)(2)(ii) of this section shall submit to FDA at the address in § 812.19 a notification that such shipments are being made.

4. By adding new Part 812 to read as follows:

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

Subpart A—General Provisions

Sec.
812.1 Scope.
812.2 Applicability.
812.3 Definitions.
812.5 Labeling of investigational devices.
812.7 Prohibition of promotion and other practices.
812.10 Waivers.
812.18 Import and export requirements.
812.19 Address for correspondence.

Subpart B—Application and Administrative Action

812.20 Application.
812.25 Investigational plan.
812.27 Report of prior investigations.
812.30 FDA action on applications.
812.35 Supplemental applications.
812.38 Confidentiality of data and information.

Subpart C—Responsibilities of Sponsors

812.40 General responsibilities of sponsors.
812.43 Selecting investigators and monitors.
812.45 Informing investigators.
812.46 Monitoring investigations.

Subpart D—Responsibilities of Institutional Review Boards

812.60 General responsibilities of Institutional Review Boards.
812.62 Membership.
812.65 Procedures.
812.70 Review of IRB actions.

Subpart E—Responsibilities of Investigators.

812.100 General responsibilities of investigators.
812.110 Specific responsibilities of investigators.

Subpart F—Informed Consent

812.120 General.
812.122 Requirements.
812.123 Exception.
812.130 Elements of informed consent.

Subpart G—Records and Reports

812.140 Records.
812.145 Inspections.
812.150 Reports.

Subpart A—General Provisions

§ 812.1 Scope.

(a) The purpose of this part is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose. This part provides procedures for the conduct of clinical investigations of devices. An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. An IDE approved under § 812.30 or considered approved under § 812.2(b) exempts a device from the requirements of the following sections of the act and regulations issued thereunder: Misbranding under section 502, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation under section 516, records and reports under section 519, restricted device requirements under section 520(e), good manufacturing practice requirements under section 520(f) (unless the sponsor states an intention to comply with these requirements under § 812.20(b)(3) or § 812.140(b)(4)(v)) and color additive requirements under section 706.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 812.2 Applicability.

(a) *General.* This part applies to all clinical investigations of devices to determine safety and effectiveness, except as provided in paragraph (c) of this section.

(b) *Abbreviated requirements.* The following categories of investigations are considered to have approved applications for IDE's, unless FDA has notified a sponsor under § 812.20(a) that approval of an application is required:

(1) An investigation of a device other than a significant risk device, if the device is not a banned device and the sponsor:

(i) Labels the device in accordance with § 812.5;

(ii) Obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;

(iii) Ensures that each investigator participating in an investigation of the device obtains and documents informed consent under Subpart F for each subject under the investigator's care;

(iv) Complies with the requirements of § 812.46 with respect to monitoring investigations;

(v) Maintains the records required under § 812.140(b) (4) and (5) and makes the reports required under § 812.150(b) (1) through (3) and (5) through (10);

(vi) Ensures that participating investigators maintain the records required by § 812.140(a)(3)(i) and make the reports required under § 812.150(a) (1), (2), (5), and (7); and

(vii) Complies with the prohibitions in § 812.7 against promotion and other practices.

(2) An investigation of a device other than one subject to paragraph (e) of this section, if the investigation was begun on or before July 16, 1980, and to be completed, and is completed, on or before January 19, 1981.

(c) *Exempted investigations.* This part does not apply to investigations of the following categories of devices:

(1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

(2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under Subpart E of Part 807 in determining substantial equivalence.

(3) A diagnostic device, if the sponsor complies with applicable requirements in § 809.10(c) and if the testing (i) is noninvasive, (ii) does not require an invasive sampling procedure that presents significant risk, (iii) does not by design or intention introduce energy into a subject, and (iv) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

(4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

(5) A device intended solely for veterinary use.

(6) A device shiped solely for research on or with laboratory animals and labeled in accordance with § 812.5(c).

(7) A custom device as defined in § 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

(8) An intraocular lens. An intraocular lens shall not be used unless it is subject to an approved IDE under Part 813 or an approved application for premarket approval under section 515 of the act.

(d) *Limit on certain exemptions.* In the case of class II or class III device described in paragraph (c)(1) or (2) of this section, this part applies beginning on the date stipulated in an FDA

regulation or order that calls for the submission of premarket approval applications for an unapproved class III device, or establishes a performance standard for a class II device.

(e) *Investigations subject to IND's.* A sponsor that, on July 16, 1980, has an effective investigational new drug exemption (IND) for an investigation of a device shall continue to comply with the requirements of Part 312 until 90 days after that date. To continue the investigation after that date, a sponsor shall comply with paragraph (b)(1) of this section, if the device is not a significant risk device, or shall have obtained FDA approval under § 812.30 of an IDE application for the investigation of the device.

§ 812.3 Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act (sections 201–901, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301–392)).

(b) "Custom device" means a device that:

(1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;

(2) Is not generally available to, or generally used by, other physicians or dentists;

(3) Is not generally available in finished form for purchase or for dispensing upon prescription;

(4) Is not offered for commercial distribution through labeling or advertising; and

(5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

(c) "FDA" means the Food and Drug Administration.

(d) "Implant" means a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also "implants" for purposes of this part.

(e) "Institution" means a person, other than an individual, who engages in the conduct of research on subjects or in the delivery of medical services to individuals as a primary activity or as an adjunct to providing residential or custodial care to humans. The term includes, for example, a hospital, retirement home, confinement facility, academic establishment, and device manufacturer. The term has the same meaning as "facility" in section 520(g) of the act.

(f) "Institutional review board" (IRB) means any board, committee, or other group formally designated by an institution to approve and review investigations. The term has the same meaning as "institutional review committee" in section 520(g) of the act.

(g) "Investigational device" means a device, including a transitional device, that is the object of an investigation.

(h) "Investigation" means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

(i) "Investigator" means an individual who actually conducts an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used.

(j) "Monitor," when used as a noun, means an individual designated by a sponsor or contract research organization to oversee the progress of an investigation. The monitor may be an employee of a sponsor or a consultant to the sponsor, or an employee of or consultant to a contract research organization. "Monitor," when used as a verb, means to oversee an investigation.

(k) "Noninvasive," when applied to a diagnostic device or procedure, means one that does not by design or intention: (1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os. For purposes of this part, blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for noninvestigational purposes is also considered noninvasive.

(l) "Person" includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency or organizational unit of a Government agency, and any other legal entity.

(m) "Significant risk device" means an investigational device that:

(1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

(2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

(3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

(4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

(n) "Sponsor" means a person who initiates, but who does not actually conduct, the investigation, that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

(o) "Sponsor-investigator" means an individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under this part include those of an investigator and those of a sponsor.

(p) "Subject" means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.

(q) "Termination" means a discontinuance, by sponsor or by withdrawl of IRB or FDA approval, of an investigation before completion.

(r) "Transitional device" means a device subject to section 520(l) of the act, that is, a device that FDA considered to be a new drug or an antibiotic drug before May 28, 1976.

(s) "Unanticipated adverse device effect" means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

§ 812.5 Labeling of investigational devices.

(a) *Contents.* An investigational device or its immediate package shall bear a label with the following information: The name and place of

business of the manufacturer, packer, or distributor (in accordance with § 801.1); the quantity of contents if appropriate; all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions; and the following statement: "CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use."

(b) *Prohibitions.* The labeling of an investigational device shall not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated.

(c) *Animal research.* An investigational device shipped solely for research on or with laboratory animals shall bear on its label the following statement: "CAUTION—Device for investigational use in laboratory animals or other tests that do not involve human subjects."

§ 812.7 Prohibition of promotion and other practices.

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:

(a) Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.

(b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.

(c) Unduly prolong an investigation. If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.

(d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated.

§ 812.10 Waivers.

(a) *Request.* A sponsor may request FDA to waive any requirement of this part. A waiver request, with supporting documentation, may be submitted separately or as part of an application to the address in § 812.19.

(b) *FDA action.* FDA may by letter grant a waiver of any requirement that FDA finds is not required by the act and is unnecessary to protect the rights, safety, or welfare of human subjects.

(c) *Effect of request.* Any requirement shall continue to apply unless and until FDA waives it.

§ 812.18 Import and export requirements.

(a) *Imports.* In addition to complying with other requirements of this part, a person who imports or offers for importation an investigational device subject to this part shall be the agent of the foreign exporter with respect to investigations of the device and shall act as the sponsor of the clinical investigation, or ensure that another person acts as the agent of the foreign exporter and the sponsor of the investigation.

(b) *Exports.* A person exporting an investigational device subject to this part shall obtain FDA's prior approval, as required by section 801(d) of the act.

§ 812.19 Address for IDE correspondence.

All applications, supplemental applications, reports, requests for waivers, requests for import or export approval, and other correspondence relating to matters covered by this part shall be addressed to the Bureau of Medical Devices, Document Control Center (HFK–20), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910. The outside wrapper of each submission shall state what the submission is, for example an "IDE application," a "supplemental IDE application," or "correspondence concerning an IDE (or an IDE application)."

Subpart B—Application and Administrative Action

§ 812.20 Application.

(a) *Submission.* (1) A sponsor shall submit an application to FDA if the sponsor intends to use a significant risk device in an investigation or if FDA notifies the sponsor that an application is required for an investigation.

(2) A sponsor shall submit an investigational plan and a report of prior investigations to an IRB for approval, and obtain IRB approval, before submitting an application to FDA for approval. If no IRB exists or if FDA finds that an IRB's review is inadequate, a sponsor may submit an application to FDA without first seeking and obtaining an IRB's approval of the investigation; in such a case, however, FDA may refuse to approve the application without prior IRB approval of the investigation if FDA finds that IRB review is necessary to assure protection of the rights, safety, or welfare of subjects.

(3) A sponsor shall not begin an investigation for which FDA's approval of an application is required until FDA has approved the application. If more than one IRB must approve an investigation, and these approvals occur after submission of an application to FDA, a sponsor shall submit a supplemental application under § 812.35(b) to FDA following each additional IRB approval. A sponsor shall not begin an investigation or part of an investigation at an institution until the IRB and FDA both have approved the application or supplemental application relating to the investigation or part of an investigation at that institution.

(4) A sponsor shall submit three copies of a signed "Application for an Investigational Device Exemption" (IDE application), together with accompanying materials, by registered mail or by hand to the address in § 812.19. Subsequent correspondence concerning an application or a supplemental application shall be submitted by registered mail or by hand.

(b) *Contents.* An IDE application shall include, in the following order:

(1) The name and address of the sponsor.

(2) A complete report of prior investigations of the device and an accurate summary of those sections of the investigational plan described in § 812.25(a) through (e) or, in lieu of the summary, the complete plan. The sponsor shall submit to FDA a complete investigational plan and a complete report of prior investigations of the device if no IRB has reviewed them, if FDA has found an IRB's review inadequate, or if FDA requests them.

(3) A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device.

(4) An example of the agreements to be entered into by all investigators to comply with investigator obligations under this part, and a list of the names and addresses of all investigators who have signed the agreement.

(5) A certification that all investigators who will participate in the investigation have signed the agreement, that the list of investigators includes all the investigators participating in the investigation, and that no investigators will be added to the investigation until they have signed the agreement.

(6) A list of the name, address, and chairperson of each IRB that has been or will be asked to review the investigation and a certification of the action

concerning the investigation taken by each such IRB.

(7) The name and address of any institution at which a part of the investigation may be conducted that has not been identified in accordance with paragraph (b)(6) of this section.

(8) If the device is to be sold, the amount to be charged and an explanation of why sale does not constitute commercialization of the device.

(9) An environmental analysis report meeting the requirements of Part 25, when requested by FDA.

(10) Copies of all labeling for the device.

(11) Copies of all forms and informational materials to be provided to subjects to obtain informed consent.

(12) Any other relevant information FDA requests for review of the application.

(c) *Additional information.* FDA may request additional information concerning an investigation or revision in the investigational plan. The sponsor may treat such a request as a disapproval of the application for purposes of requesting a hearing under Part 16.

(d) *Information previously submitted.* Information previously submitted to the Bureau of Medical Devices in accordance with this chapter ordinarily need not be resubmitted, but may be incorporated by reference.

§ 812.25 Investigational plan.

The investigational plan shall include, in the following order:

(a) *Purpose.* The name and intended use of the device and the objectives and duration of the investigation.

(b) *Protocol.* A written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound.

(c) *Risk analysis.* A description and analysis of all increased risks to which subjects will be exposed by the investigation; the manner in which these risks will be minimized; a justification for the investigation; and a description of the patient population, including the number, age, sex, and condition.

(d) *Description of device.* A description of each important component, ingredient, property, and principle of operation of the device and of each anticipated change in the device during the course of the investigation.

(e) *Monitoring procedures.* The sponsor's written procedures for monitoring the investigation and the name and address of any monitor.

(f) *Labeling.* Copies of all labeling for the device.

(g) *Consent materials.* Copies of all forms and informational materials to be provided to subjects to obtain informed consent.

(h) *IRB information.* A list of the names, locations, and chairpersons of all IRB's that have been or will be asked to review the investigation, and a certification of any action taken by any of those IRB's with respect to the investigation.

(i) *Other institutions.* The name and address of each institution at which a part of the investigation may be conducted that has not been identified in paragraph (h) of this section.

(j) *Additional records and reports.* A description of records and reports that will be maintained on the investigation in addition to those prescribed in Subpart G.

§ 812.27 Report of prior investigations.

(a) *General.* The report of prior investigations shall include reports of all prior clinical, animal, and laboratory testing of the device and shall be comprehensive and adequate to justify the proposed investigation.

(b) *Specific contents.* The report also shall include:

(1) A bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety or effectiveness of the device, copies of all published and unpublished adverse information, and, if requested by an IRB or FDA, copies of other significant publications.

(2) A summary of all other unpublished information (whether adverse or supportive) in the possession of, or reasonably obtainable by, the sponsor that is relevant to an evaluation of the safety or effectiveness of the device.

(3) If information on nonclinical tests is provided, a statement that all nonclinical tests have been conducted in compliance with applicable requirements in the good laboratory practice regulations in Part 58, or a detailed description of, and justification for, all differences between the practices used in the tests and those required by Part 58. Failure or inability to comply with this requirement does not justify failure to provide information on a relevant nonclinical test.

§ 812.30 FDA action on applications.

(a) *Approval or disapproval.* FDA will notify the sponsor in writing of the date it receives an application. FDA may approve an investigation as proposed, approve it with modifications, or disapprove it. An investigation may not begin until:

(1) Thirty days after FDA receives the application at the address in § 812.19 for the investigation of a device other than a banned device, unless FDA notifies the sponsor that the investigation may not begin; or

(2) FDA approves, by order, an IDE for the investigation.

(b) *Grounds for disapproval or withdrawal.* FDA may disapprove or withdraw approval of an application if FDA finds that:

(1) There has been a failure to comply with any requirement of this part or the act, any other applicable regulation or statute, or any condition of approval imposed by an IRB or FDA.

(2) The application or a report contains an untrue statement of a material fact, or omits material information required by this part.

(3) The sponsor fails to respond to a request for additional information within the time prescribed by FDA.

(4) There is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or if there is reason to believe that the device is ineffective, or it is otherwise unreasonable to begin or to continue the investigation owing to the way in which the device is used or the inadequacy of:

(i) The report of prior investigations or the investigational plan;

(ii) The methods, facilities, and controls used for the manufacturing, processing, packaging, storage, and, where appropriate, installation of the device; or

(iii) Monitoring and review of the investigation.

(5) There is reason to believe that the device, as used in the investigation, is ineffective.

(c) *Notice of disapproval or withdrawal.* If FDA disapproves an application or propose to withdraw approval of an application, FDA will notify the sponsor in writing.

(1) A disapproval order will contain a complete statement of the reasons for disapproval and a statement that the sponsor has an opportunity to request a hearing under Part 16.

(2) A notice of a proposed withdawal of approval will contain a complete statement of the reasons for withdrawal and a statement that the sponsor has an opportunity to request a hearing under Part 16. FDA will provide the opportunity for hearing before withdrawal of approval, unless FDA determines in the notice that continuation of testing under the exemption will result in an unreasonble

risk to the public health and orders withdrawal of approval before any hearing.

§ 812.35 Supplemental applications.

(a) *Changes in investigational plan.* A sponsor shall (1) submit to FDA a supplemental application if the sponsor or an investigator proposes a change in the investigational plan that may affect its scientific soundness or the rights, safety, or welfare of subjects, and (2) obtain IRB and FDA approval of the change before implementation. These requirements do not apply in the case of a deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency, which deviation shall be reported to FDA within 5 working days after the sponsor learns of it.

(b) *New institutions.* A sponsor shall submit to FDA a supplemental application if an IRB other than one whose approval as a part of an investigation is certified in an application is to participate in the investigation. If the investigation is otherwise unchanged, the supplemental application shall consist of a certification of IRB approval, and updating of the information required by § 812.20(b), and a description of any modifications in the investigational plan required by the IRB as a condition of approval. A sponsor may not begin a part of an investigation at an institution until the IRB has approved the investigation and FDA has approved the supplemental application relating to that part of the investigation.

§ 812.38 Confidentiality of data and information.

(a) *Existence of IDE.* FDA will not disclose the existence of an IDE unless its existence has previously been publicly disclosed or acknowledged, until FDA approves an application for premarket approval of the device subject to the IDE; or a notice of completion of a product development protocol for the device has become effective.

(b) *Availability of summaries or data.* (1) FDA will make publicly available, upon request, a detailed summary of information concerning the safety and effectiveness of the device that was the basis for an order approving, disapproving, or withdrawing approval of an application for an IDE for a banned device. The summary shall include information on any adverse effect on health caused by the device.

(2) If a device is a banned device or if the existence of an IDE has been publicly disclosed or acknowledged, data or information contained in the file is not available for public disclosure before approval of an application for premarket approval or the effective date of a notice of completion of a product development protocol except as provided in this section. FDA may, in its discretion, disclose a summary of selected portions of the safety and effectiveness data, that is, clinical, animal, or laboratory studies and tests of the device, for public consideration of a specific pending issue.

(3) If the existence of an IDE file has not been publicly disclosed or acknowledged, no data or information in the file are available for public disclosure except as provided in paragraphs (b)(1) and (c) of this section.

(c) *Reports of adverse effects.* Upon request or on its own initiatives, FDA shall disclose to an individual on whom an investigational device has been used a copy of a report of adverse device effects relating to that use.

(d) *Other rules.* Except as otherwise provided in this section, the availability for public disclosure of data and information in an IDE file shall be handled in accordance with § 314.14, which concerns the confidentiality of data and information in new drug applications, until the effective date of regulations concerning the confidentiality of data and information in applications for premarket approval of devices.

Subpart C—Responsibilities of Sponsors

§ 812.40 General responsibilities of sponsors.

Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, submitting an IDE application to FDA, and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation. Additional responsibilities of sponsors are described in Subparts B and G.

§ 812.43 Selecting investigators and monitors.

(a) *Selecting investigators.* A sponsor shall select investigators qualified by training and experience to investigate the device.

(b) *Control of device.* A sponsor shall ship investigational devices only to qualified investigators participating in the investigation.

(c) *Obtaining agreements.* A sponsor shall obtain from each participating investigator a signed agreement that includes:

(1) The investigator's curriculum vitae.

(2) Where applicable, a statement of the investigator's relevant experience, including the dates, location, extent, and type of experience.

(3) If the investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination.

(4) A statement of the investigator's commitment to (i) conduct the investigation in accordance with the agreement, the investigational plan, this part and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA; (ii) supervise all testing of the device involving human subjects; and (iii) ensure that the requirements for obtaining informed consent are met.

(d) *Selecting monitors.* A sponsor shall select monitors qualified by training and experience to monitor the investigational study in accordance with this part and other applicable FDA regulations.

§ 812.45 Informing investigators.

A sponsor shall supply all investigators participating in the investigation with copies of the investigational plan and the report of prior investigations of the device.

§ 812.46 Monitoring investigations.

(a) *Securing compliance.* A sponsor who discovers that an investigator is not complying with the signed agreement, the investigational plan, the requirements of this part or other applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA shall promptly either secure compliance, or discontinue shipments of the device to the investigator and terminate the investigator's participation in the investigation. A sponsor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.

(b) *Unanticipated adverse device effects.* (1) A sponsor shall immediately conduct an evaluation of any unanticipated adverse device effect.

(2) A sponsor who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects shall terminate all investigations or parts of investigations presenting that risk as soon as possible. Termination shall occur not later than 5 working days after the sponsor makes this determination and not later than 15 working days after the sponsor first received notice of the effect.

(c) *Resumption of terminated studies.* If the device is a significant risk device, a sponsor may not resume a terminated investigation without IRB and FDA approval. If the device is not a significant risk device, a sponsor may not resume a terminated investigation without IRB approval and, if the investigation was terminated under paragraph (b)(2), FDA approval.

Subpart D—Responsibilities of Institutional Review Boards

§ 812.60 General responsibilities of institutional review boards.

The principal responsibility of an IRB is to protect the rights, safety, and welfare of human subjects by making an initial judgment that a proposed investigation is acceptable, after reviewing the risks and benefits to human subjects, the knowledge to be gained, and the adequacy of informed consent. An IRB expresses local community attitudes and ethical standards when reviewing proposed investigations. An IRB also is responsible for ensuring that an investigation is conducted in a manner consistent with institutional policies, applicable law, and standards of professional practice. Additional responsibilities of IRB's for recordkeeping and reporting are described in Subpart G.

§ 812.62 Membership.

(a) *General.* An IRB shall be composed of not fewer than five individuals sufficiently qualified through maturity, experience, expertise, and diversity of background to ensure broad respect for its advice for safeguarding the rights, safety, and welfare of human subjects.

(b) *Diversity.* An IRB shall include at least one licensed physician, one nonphysician scientist, and one individual whose primary activities are in a nonscientific field, e.g., a lawyer, member of the clergy, ethicist, or consumer.

(c) *Nonaffiliated member.* An IRB shall include at least one member whose only affiliation with the institution is IRB membership.

(d) *Specific qualifications.* In addition to possessing the professional competence necessary to understand an investigation, the IRB as a whole shall be able to ascertain the acceptability of an investigation in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, community attitudes, and ethical standards.

(e) *Scientific or technical knowledge.* An IRB shall have among its members or shall obtain by means of nonvoting consultants sufficient scientific and technical knowledge and expertise to be able to review proposed investigations in order to determine that the rights, safety, and welfare of human subjects are adequately protected.

(f) *Prohibition.* No IRB, institution, or other person may permit an investigator or sponsor to participate in the selection of members of an IRB that will review an investigation conducted or sponsored by that investigator or sponsor.

§ 812.65 Responsibilities and procedures.

(a) *Requirements.* An IRB shall:

(1) Adopt and follow written procedures for conducting its review of investigational plans and reports of prior investigations and for reporting its findings to the institution, investigator, and, where appropriate, the sponsor.

(2) Conduct business by a quorum of not less than a majority of the members of the IRB physically present. Regardless of the number of members physically present, a quorum shall include at least one licensed physician, one nonphysician scientist, and one member whose primary activities are in a nonscientific field.

(3) Ensure that any member having a conflict of interest, as determined by the IRB, relating to a particular investigation does not participate in the review of that investigation. This requirement does not prohibit a member from furnishing information requested by an IRB.

(4) In a timely manner review and approve, approve with modifications, disapprove, suspend, or withdraw approval of an investigation for any reason the IRB considers appropriate. An IRB may not approve an investigation unless it has determined that risks to subjects have been minimized to the extent possible consistent with the purposes of the investigation. An IRB shall disapprove or withdraw approval of an investigation if the risks to the subject are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or if informed consent is inadequate, or if the investigation is scientifically unsound, or if there is reason to believe the device is ineffective, or if it is otherwise unreasonable, unsafe, improper, or not in the best interests of the institution to begin or to continue an investigation owing to the way in which the device is used or for any of the reasons set forth in § 812.30(b)(4)(i) through (iii).

(5) Notify the investigator and, where appropriate, the sponsor of each decision it makes about the investigation and the basis for its decision. If an IRB determines that an investigation presented for approval under § 812.2(b)(1)(ii) involves a significant risk device, it shall so notify the investigator and, where appropriate, the sponsor. A sponsor may not begin the investigation except as provided in § 812.30(a).

(6) Continue to review an investigation that the IRB has approved until the investigation is completed or terminated. Such review shall be undertaken at intervals appropriate to the degree of risk, but not less than once a year.

(b) *Additional information.* An IRB may request an investigator or sponsor to submit additional information concerning an investigation.

(c) *Independence.* The decision of one IRB does not preclude a different decision on the same investigation by another IRB.

§ 812.70 Review of IRB actions.

Institutional officials may review and approve or reject actions by an IRB, but may not overrule an IRB disapproval; suspension; withdrawal of approval; a modification of an investigational plan determined by the IRB to be necessary or desirable to protect the rights, safety, or welfare of human subjects; or a finding that a device is a significant risk device.

Subpart E—Responsibilities of Investigators

§ 812.100 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with Subpart F. Additional responsibilities of investigators are described in Subpart G.

§ 812.110 Specific responsibilities of investigators.

(a) *Awaiting approval.* An investigator may determine whether potential subjects would be interested in participating in an investigation, but shall not request the written informed consent of any subject to participate, and shall not allow any subject to paticipate before obtaining IRB and FDA approval.

(b) *Compliance.* An investigator shall conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, this part and other applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA.

(c) *Supervising device use.* An investigator shall permit an investigational device to be used only with subjects under the investigator's supervision. An investigator shall not supply an investigational device to any person not authorized under this part to receive it.

(d) *Disposing of device.* Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator shall return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.

Subpart F—Informed Consent

§ 812.120 General.

Informed consent is a critical element of subject protection in the conduct of an investigation. The requirements in this subpart are designed to ensure that subjects understand fully the nature of potential risks and benefits of an investigation to aid them in making a voluntary choice whether to participate in it.

§ 812.122 Requirement.

(a) Before including any individual as a subject in an investigation, an investigator shall obtain from the individual, without coercion, deception, or undue influence, informed consent to participate in the investigation.

(b) Except as provided in paragraph (c), in an investigation of a significant risk device informed consent shall be evidenced by a document that includes the elements specified in § 812.130 and that is signed by the subject or, if the subject lacks legal capacity, the subject's legal representative.

(c) In the following case, an investigator may obtain informed consent by reading to the subject or the subject's legal representative a document that includes the elements specified in § 812.130 and obtaining and documenting oral informed consent:

(1) If the investigation is of a device other than a significant risk device and is subject to § 812.2(b)(1), or

(2) If a significant risk device is to be used on a subject who lacks legal capacity and whose legal representative is illiterate.

§ 812.123 Exception.

Informed consent is required, unless:

(a) The investigator determines and documents that:

(1) A life-threatening situation exists that necessitates the use of the investigational device;

(2) There is no effective alternative to use of the device;

(3) It is not feasible to obtain informed consent from the subject; and

(4) There is not sufficient time to obtain such consent from the subject's legal representative.

(b) The investigator obtains concurrence of a licensed physician not involved in the investigation, unless immediate use of the device is necessary to save the life of the subject and there is not sufficient time to obtain the concurrence of a physician.

§ 812.130 Elements of informed consent.

(a) *Requirements.* In seeking informed consent, an investigator shall provide to a subject, or to the subject's legal representative, information that includes:

(1) An explanation of the procedures to be followed, including an explanation of each procedure that is experimental.

(2) An explanation of the nature of the investigational device and an explanation of the expected duration and purpose of the use of the investigational device.

(3) A description of any attendant discomforts and risks reasonably to be expected.

(4) An explanation of likely results should the procedures fail.

(5) A description of any benefits to the subject or others reasonably to be expected.

(6) A disclosure of any appropriate alternative procedures that might be advantageous to the subject.

(7) A description of the scope of the investigation, including the number of subjects involved.

(8) An offer to answer any inquiries concerning the investigation.

(9) A disclosure that the subject, or the subject's legal representative, is free to decline participation in the investigation or to withdraw consent and to discontinue participation at any time without prejudice to the subject.

(10) A disclosure that the investigational device is being used for research purposes.

(b) *Prohibitions.* An informed consent document shall not include language that waives, or appears to waive, any of the subject's legal rights or releases the institution, its agents, the sponsor, or the investigator from liability for negligence.

Subpart G—Records and Reports

§ 812.140 Records.

(a) *Investigator records.* A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:

(1) all correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.

(2) Records of receipt, use or disposition of a device that relate to:

(i) The type and quantity of the device, the dates of its receipt, and the batch number or code mark.

(ii) The names of all persons who received, used, or disposed of each device.

(iii) Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

(3) Records of each subject's case history and exposure to the device. Such records shall include:

(i) Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent.

(ii) All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.

(iii) A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.

(4) The protocol, with documents showing the dates of and reasons for each deviation from the protocol.

(5) Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

(b) *Sponsor records.* A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:

(1) All correspondence with another sponsor, a monitor, an investigator, an IRB, or FDA, including required reports.

(2) Records of shipment and disposition. Records of shipment shall include the name and address of the consignee, type and quantity of device, date of shipment, and batch number or

code mark. Records of disposition shall describe the batch number or code marks of any devices returned to the sponsor, repaired, or disposed of in other ways by the investigator or another person, and the reasons for and method of disposal.

(3) Signed investigator agreements.

(4) For each investigation subject to § 812.2(b)(1) of a device other than a significant risk device, the records described in paragraph (b)(5) of this section and the following records, consolidated in one location and available for FDA inspection and copying:

(i) The name and intended use of the device and the objectives of the investigation;

(ii) A brief explanation of why the device is not a significant risk device:

(iii) The name and address of each investigator:

(iv) The name and address of each IRB that has reviewed the investigation:

(v) A statement of the extent to which the good manufacturing practice regulation in Part 820 will be followed in manufacturing the device and a copy of any quality assurance program that is followed with respect to the device: and

(vi) Any other information required by FDA.

(5) Records concerning adverse device effects (whether anticipated or unanticipated) and complaints and

(6) Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation.

(c) *IRB records.* A reviewing IRB shall maintain the following accurate, complete, and current records relating to that IRB's review of an investigation:

(1) All correspondence with another IRB, an investigator, a sponsor, a monitor, or FDA.

(2) Records of the membership of the IRB and of its members' employment relationship with the institution with which the IRB is associated, for example full-time or part-time employee, member of governing panel or board, paid or unpaid consultant. Such records shall include:

(i) Each member's name, earned degrees (if any), position or occupation, specialty field (if any), representative capacity, and other pertinent indications of qualifications, such as board certifications or licenses;

(ii) Each member's employment or other relationship with an investigator or sponsor whose investigation is reviewed by the IRB, for example full-time or part-time employee, member of governing panel or board, paid or unpaid consultant; and

(3) Minutes of attendance at each meeting and of each decision concerning an investigation.

(d) *Retention period.* Records required by this subpart shall be maintained during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

(e) *Records custody.* An investigator, sponsor, or IRB may withdraw from the responsibility to maintain records for the period required in paragraph (d) of this section and transfer custody of the records to any other person who will accept responsibility for them under this part, including the requirements of § 812.145. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs.

§ 812.145 Inspections.

(a) *Entry and inspection.* A sponsor or an investigator who has authority to grant access shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).

(b) *Records inspection.* A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.

(c) *Records identifying subjects.* An investigator shall permit authorized FDA employees to inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.

§ 812.150 Reports

(a) *Investigator reports.* An investigator shall prepare and submit the following complete, accurate, and timely reports:

(1) *Unanticipated adverse device effects.* An investigator shall submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

(2) *Withdrawal of IRB approval.* An investigator shall report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.

(3) *Progress.* An investigator shall submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.

(4) *Deviations from the investigational plan.* An investigator shall notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice shall be given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and, if these changes or deviations may affect scientific soundness of the plan or the rights, safety, or welfare of human subjects, IRB and FDA approval under § 812.35(a) also is required.

(5) *Informed consent.* If an investigator uses a device without obtaining informed consent, the investigator shall report such use to the sponsor and the reviewing IRB withing 5 working days after the use occurs.

(6) *Final report.* An investigator shall, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

(7) *Other.* An investigator shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

(b) *Sponsor reports.* A sponsor shall prepare and submit the following complete, accurate, and timely reports:

(1) *Unanticipated adverse device effects.* A sponsor who conducts an evaluation of an unanticipated adverse device effect under § 812.46(b) shall report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests.

(2) *Withdrawal of IRB approval.* A sponsor shall notify FDA and all reviewing IRB's and participating investigators of any withdrawal of

approval of an investigation or a part of an investigation by a reviewing IRB within 5 working days after receipt of the withdrawal of approval.

(3) *Withdrawal of FDA approval.* A sponsor shall notify all reviewing IRB's and participating investigators of any withdrawal of FDA approval of the investigation, and shall do so within 5 working days after receipt of notice of the withdrawal of approval.

(4) *Current investigator list.* A sponsor shall submit to FDA, at 6-month intervals, a current list of the names and addresses of all investigators participating in the investigation. The sponsor shall submit the first such list 6 months after FDA approval.

(5) *Progress reports.* At regular intervals, but in no event less often than yearly, a sponsor shall submit progress reports to FDA and to all reviewing IRB's.

(6) *Recall and device disposition.* A sponsor shall notify FDA and all reveiwing IRB's of any request that an investigator return, repair, or otherwise dispose of any units of a device. Such notice shall occur within 30 working days after the request is made and shall state why the request was made.

(7) *Final report.* In the case of a significant risk device, the sponsor shall notify FDA within 30 working days of the completion or termination of the investigation and shall submit a final report to FDA and all reviewing the IRB's and participating investigators within 6 months after completion or termination. In the case of a device that is not a significant risk device, the sponsor shall submit a final report to all reviewing IRB's within 6 months after termination or completion.

(8) *Informed consent.* A sponsor shall submit to FDA a copy of any report by an investigator under paragraph (a)(5) of this section of use of a device without obtaining informed consent, within 5 working days of receipt of notice of such use.

(9) *Significant risk device determinations.* If an IRB determines that a device is a significant risk device, and the sponsor had proposed that the IRB consider the device not to be a significant risk device, the sponsor shall submit to FDA a report of the IRB's determination within 5 working days after the sponsor first learns of the IRB's determination.

(10) *Other.* A sponsor shall, upon request by a reveiwing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

Effective date. The reporting and recordkeeping requirements contained in this rule have been submitted for approval by the Office of Management and Budget (OMB) in accordance with the Federal Reports Act of 1942. This regulation will become effective July 16, 1980, provided that approval of the OMB is received by that date. If OMB does not approve, without change, the reporting and recordkeeping requirements contained in the rule, FDA will revise the rule as necessary to comply with the decision of OMB. FDA will publish a notice in a future issue of the **Federal Register** concerning OMB's decision on these requirements.

(Secs. 301, 501, 502, 520, 701(a), 702, 704, 801, 52 Stat. 1042–1043 as amended, 1049–1051 as amended, 1055, 1056–1058 as amended, 67 Stat. 476–477 as amended, 90 Stat. 565–574, (21 U.S.C. 331, 351, 352, 360, 371(a), 372, 374, 381))

Dated: January 8, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80-1258 Filed 1-17-80; 8:45 am]

BILLING CODE 4110-03-M

federal register

Friday
January 18, 1980

Part III

Consumer Product Safety Commission

Proposed Safety Standard Requiring Oxygen Depletion Safety Shutoff Systems (ODS) for Unvented Gas-Fired Space Heaters

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1212

Safety Standard Requiring Oxygen Depletion Safety Shutoff Systems (ODS) for Unvented Gas-Fired Space Heaters; Proposed Standard

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes a consumer product safety standard that will require the application of an oxygen depletion sensor and fuel gas cutoff device (an ODS) to unvented gas-fired space heaters. At this time, such heaters permit carbon monoxide (CO) to be discharged directly into the living space, resulting in possible carbon monoxide poisoning. The ODS required by the proposed standard acts to avoid CO buildup by shutting off the supply of gas to the heater when oxygen is so depleted as to create an atmosphere hazardous to human life. Thus the proposed standard is expected to reduce the number of deaths from CO poisoning that are associated with unvented gas-fired space heaters.

DATES: (1) Effective date: The Commission proposes that any final standard for this product apply to all unvented gas-fired space heaters manufactured or imported after midnight December 30, 1980.

(2) Comments should be received by the Commission by March 18, 1980. The Commission will consider comments received after this date to the extent practicable. Interested persons will have an opportunity to make an oral presentation of data, views, or arguments regarding this proposal at a meeting on March 10, 1980, at 10:00 a.m. Those wishing to make oral presentations should notify the Office of the Secretary at (202 634–7700) by March 3, 1980. A summary or copy of testimony should be submitted to the Office of the Secretary by March 5, 1980.

ADDRESSES: Written comments, preferably in 5 copies, should be submitted to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. All material which the Commission has that is relevant to this proceeding, including any comments which may be received on this proposal, may be seen in, or copies obtained, from the Office of the Secretary, 3rd floor, 1111 18th Street, NW., Washington, D.C. 20207. The meeting will be held in the Commission hearing room at the same location.

FOR FURTHER INFORMATION CONTACT: Stan Morrow, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207, 301/492–6453.

A. Background

For several years the Commission has been examining and evaluating the hazards associated with vented and unvented gas-fired space heaters. On January 10, 1974, the Missouri Public Interest Research Group (PIRG) petitioned the Commission to develop mandatory safety standards and labeling requirements for space heaters (CP 74–10)(*7*).[1] The Commission examined the possible hazards associated with several different kinds of space heaters, including space heaters fueled by wood, kerosene, gas, and those powered by electricity. After reviewing the information then available to it, the Commission preliminarily concluded that only gas-fired space heaters presented unreasonable risks of injury to the public from such hazards as carbon monoxide poisoning and/or asphyxiation, contact burns, and fabric ignition. Therefore, the Commission partially denied petition CP 74–10, for space heaters fueled by energy sources other than gas (40 FR 4112, Sept. 5, 1975)(*5*).

At the same time, the Commission directed the staff to develop technical information on gas-fired space heaters for possible development of a proposed mandatory standard for these products. Concurrently, the Commission staff monitored the development of voluntary standards for vented and unvented gas-fired space heaters and wall furnaces by the American National Standards Institute (ANSI Z21.11.1, Z21.11.2, Z21.44, and Z21.49). At a public briefing of the Commission on May 19, 1977, the staff advised the Commission that since 1975 the voluntary standards for vented gas space heaters had been significantly improved; provisions for the safe ignition of vented heaters, reducing surface temperatures, preventing fabric ignition, and minimizing asphyxiation hazards had been, and were continuing to be, substantially upgraded. Additionally, the Commission noted that conformance by manufacturers to the industry's voluntary standards and industry certification programs [2] for vented gas space heaters is high. Industry certification of gas appliances to be installed in residences is widely prescribed by various state and local building codes and safety regulations. The Commission subsequently concluded that a mandatory safety regulation did not appear to be necessary at that time to address any risks of injury that might be associated with vented gas space heaters. A Notice of Decision to this effect was published September 14, 1977 (42 FR 46072)(*4*). The Commission staff continues to monitor these voluntary efforts in order to advise the Commission on further safety developments in the voluntary standards.

However, the Commission determined that the risk of injury from carbon monoxide poisoning associated with unvented gas space heaters was not adequately addressed by the voluntary standards for unvented gas space heaters. Carbon monoxide produced by a vented gas space heater will ordinarily pose a minimal threat from carbon monoxide poisoning because the combustion gases are vented out of the living space through flue openings. Unvented gas space heaters, on the other hand, discharge the products of this combustion directly into the space being heated.

Consequently, on February 14, 1978 (43 FR 6253) (*6*), the Commission proposed a ban of unvented gas space heaters because the Commission determined that the hazard of CO poisoning associated with this product, as further described below, presented an unreasonable risk of injury to the public, and the information then available to the Commission indicated that no feasible standard under the CPSA could adequately protect the public from this unreasonable risk.

Approximately 300 comments on the proposed ban were received from trade associations, distributors of liquid petroleum gas, manufacturers, retailers, individual consumers, consumer interest groups, and government officials. The majority of these commenters were opposed to the proposed ban on the grounds that it would remove from the market a relatively inexpensive source of heat, whose primary users are the elderly, and low and fixed-income

[1] The numbers in parenthesis, from *1–28*, are citations to the bibliography included at the end of this notice. The documents cited are available for review at the Office of the Secretary.

[2] The American Gas Association (AGA), a trade association of the gas distribution industry in the U.S., operates a nationally recognized testing and certification program for gas equipment. The AGA laboratories in Cleveland, Ohio evaluate gas appliances submitted by appliance manufacturers for testing under applicable ANSI voluntary standards. AGA certifies appliances that conform to these standards. Production plants are regularly inspected by AGA to determine manufacturers' continuing conformance to the ANSI requirements. State and local building codes generally regard AGA certification as a prerequisite to permitting installation of gas appliances.

families in the southern United States (*22, 23*).

During the comment period allowed for the proposed ban, the Commission was advised that manadatory standards adopted by several foreign countries require that unvented gas space heaters incorporate a sensing and control device designed to detect the depletion of oxygen in the living space and shut off the flow of gas to the heater before carbon monoxide emissions can build up to a hazardous concentration (*8*). This device, known as an oxygen depletion safety shutoff system (ODS), does not directly measure carbon monoxide in the living space, but senses when the atmospheric oxygen available for combustion is reduced, thereby permitting CO buildup. The device had not, to the Commission's knowledge, ever been adopted for use on unvented gas space heaters by American manufacturers. However, performance requirements addressing the optional use of an ODS on American manufactured heaters were included as part of the ANSI Z21.11.2 standard in effect at that time for unvented gas-fired space heaters (1).

The Commission requested the National Bureau of Standards (NBS) to evaluate the ODS to determine if the use of the ODS in an unvented gas space heater affords an adequate level of safety from CO poisoning.

The results of the National Bureau of Standards evaluation of the ODS show that, under laboratory conditions, the device repeatedly operated satisfactorily to shut down an unvented gas space heater when the room oxygen content was depleted to between 20.4% adn 18.2%. Carbon monoxide concentrations at these levels of oxygen depletion were in a range from 90 to 7 parts per million (ppm), with an average concentration of 37 ppm. During the NBS evaluations, deliberate changes to the heater air shutter to simulate burner maladjustment, and blockage of the ODS air ports to simulate sensor maladjustment and adverse conditions, did not significantly affect the operation of the ODS. Additionally, the ODS operated satisfactorily when used with a variety of representative fuel gases in use in the United States, including propane, butane, and natural gases (*11, 12*).

During this period, the Commission received information cencerning an additional control device, known as a temperature limiting device (TLD), which was purported to prevent a hazardous buildup of carbon monoxide in the living space by shutting off the gas supply to the heater when a room temperature of 100°F was reached. The operation of this device is based on the premise that as combustion air availability decreases, and the potential for higher levels of CO emissions increases due to inadequate air infiltration into the room in which the heater is operating, the room temperature will increase. A TLD requirement for unvented gas space heaters was incorporated into the industry voluntary standard, ANSI–Z21.11.2, on July 26, 1978. However, since very little test data on this device were available, the Commission concluded that additional information was needed to determine the degree of safety a TLD affords when applied to unvented gas space heaters. Therefore, the Commission requested the NBS to evaluate the performance and reliability of the TLD.

The NBS investigation of the TLD indicates that this device appears to be inadequate to address the carbon monoxide poisoning hazard under a variety of limited room ventilation and heat loss conditions. The results of the analyses show that high concentrations of carbon monoxide can exist at various levels of oxygen depletion in ventilated rooms and at temperatures below the shut-off point of TLD.

Complete copies of both NBS reports entitled: (1) Testing for an Oxygen Depletion Detecting for Unvented Gas Fueled Heaters, June 1978,(*11*); (2) Unvented Heater Tests and Analysis of Standards for a Temperature Sensitive Limit Device, November 1978, (*12*), are available through the Office of the Secretary.

Upon review of these test results, particularly the results of the ODS study, the Commission concluded that it could promulgate a feasible consumer product safety standard addressed to the unreasonable risk of carbon monoxide poisoning associated with unvented gas space heaters and that it was not necessary to ban this product. Such a safety standard would require an ODS device which has the capability of indirectly detecting a hazardous atmosphere resulting from carbon monoxide emissions and shutting off the gas supply to the heater.

The Commission also noted: (1) That the oxygen depletion sensor described in the ANSI Z21.11.2–1978 voluntary industry standard entitled *Gas-Fired Room Heaters, Vol. II-Unvented Room Heaters* (*1*), appears to be adequate for the task of reducing or eliminating this risk; and (2) that such a voluntary standard could be proposed as a mandatory standard. Authority for such a proposal is provided by section 7(c)(2). (15 U.S.C. 2056(c)(2)), of the CPSA as amended by section 5 of the Consumer Product Safety Act Authorization Act of 1978 (Pub. L. 95–631). Prior to this amendment, the Commission could publish an existing standard as a proposed standard only after publishing a notice under section 7(b) of the CPSA soliciting persons to either submit an existing standard for Commission consideration or offer to develop a standard for possible proposal. Congress decided with this amendment that the Commission should no longer be required to solicit submission of existing standards when it already knew of an existing standard that could adequately address an unreasonable risk. The amendment also clarified Commission authority to adopt selected provisions of an existing standard or standards. This amendment, which can be expected to save Commission time and resources, is being used by the Commission for the first time in the standard proposed below.

Section 7(c) now provides that where the Commission determines there is a standard issued by a qualified agency, organization or institution which would eliminate or reduce an unreasonable risk of injury if issued in whole or in part, or in combination with any other standard, the Commission may publish such a standard in whole, in part or in combination and with nonmaterial modifications, as a proposed standard.

The Commission directed its staff to prepare for Commission review and publication a draft proposed standard for public comment to incorporate the appropriate sections of the ANSI standard dealing with oxygen depletion sensors for unvented gas-fired space heaters.

On November 29, 1978 in accordance with section 9(a)(1)(b) (15 U.S.C. 2058(a)(1)(b)) of the CPSA, the Commission proposed to withdraw its proposal to ban these products and announced its intention to publish a proposed safety standard (43 FR 55772). During the comment period, the Commission received five comments, none of which opposed the withdrawal of the ban. The Commission, on March 28, 1979 (44 FR 18516) published a final withdrawal of its proposal of February 14, 1978 to declare that unvented gas-fired space heaters are banned hazardous products.

B. Nature of the Risk of Injury

The risk of injury associated with unvented gas-fired space heaters that is addressed by the standard below arises from the poisonous gas, carbon monoxide, entering the human respiratory system.

Unvented gas-fired space heaters derive oxygen needed for combustion

from the space being heated and discharge the products of combustion directly into this same space. The principal products of combustion for any hydrocarbon fuel, whether solid, liquid or gas, are carbon dioxide (CO_2), water vapor (H_2O), and a small amount of carbon monoxide (CO). None of these products poses a serious injury problem for healthy individuals from an acute or short-term exposure at the concentrations given off under usual conditions. However, if the room oxygen is sufficiently depleted due to inadequate ventilation, a dangerous build-up of CO may occur. Additionally, malajustment of the burner, such as can occur by the blockage of burner primary air passages or shutter maladjustment, can also increase CO concentrations in the living space (*2D–3*).

The injury resulting from dangerous levels of CO is caused by a depletion of blood oxygen. Oxygen in the blood combines reversibly with hemoglobin to produce oxyhemoglobin. In this form, oxygen is transported by the blood from the lungs to the body tissues. In the tissues, the oxygen is released from hemoglobin and becomes available to the cells. CO, however, combines with hemoglobin about 200 times more readily than oxygen, to form carboxyhemoglobin, thereby reducing the amount of hemoglobin available to carry needed oxygen. Further, increasing formation of carboxyhemoglobin exerts an inhibitory effect on the remaining oxyhemoglobin in the blood. The reduction of oxygen in the tissues below normal levels is called anoxia and may result in injury to the tissues and death of the individual ([*2D–3, D–4, D–5*] *16*).

The general physiological effects of acute, short-term exposure to increasing air concentrations of CO are presented in Table 1:

TABLE I

Percent CO in atmosphere	Parts per million	Response
0.005	50	Threshold Limit Value, no apparent toxic symptoms.
0.01	100	No poisoning symptoms for long periods of time. Allowable for several hours.
0.02	200	Possible headache, mild frontal in 2-3 hrs.
0.04	400	Frontal headache and nausea after 1-2 hrs.
0.08	800	Headache, dizziness and nausea in 45 min.; collapse and possible unconciousness in 2 hrs.
0.16	1600	Headache, dizziness, nausea in 20 min.; collapse, unconsciousness, possible death in 2 hrs.
0.32	3200	Headache and dizziness in 5-10 min.; unconciousness and possible death in 10-15 min.
0.64	6400	Headache and dizziness in 1-2 min.; unconciousness and possible death in 10-15 min.
1.28	12800	Immediate effect, unconciousness and danger of death 1-3 min.

Source: *Industrial Toxicology*, 3rd ed. Alice Hamilton, M.D. and Harriet L. Hardy, M.D. Publishing Sciences Group. 1974.

It should be pointed out that time to response in Table 1, is very important when considering the health effects of a particular concentration of CO since a concentration that can be tolerated for short periods may be fatal over several hours. The medical condition of the individual involved is also important in assessing the potential health hazard. Thus, pregnant women (as well as fetuses), smokers, those living at high altitudes or taking certain medication, those with heart/lung impairment or anemia may be subject to increased risk of injury or death even from relatively low concentrations of CO ([*2 D–3, D–5*], *16, 17, 20*).

Exposure to low concentrations of CO from unvented gas space heaters may, however, also occur over a period of weeks or months, thereby rasing the possibility of chronic health effects, that is, health impairment resulting from prolonged or continuous use. Thus, a concentration of CO which might be tolerated for a period of hours may result in health impairment or death if allowed to continue over weeks or months. Studies with animals have indicated that the heart and central nervous system are the organs most sensitive to CO. A number of epidemiological and physiological studies have reported heart and central nervous system effects in humans due to CO exposure. As with acute exposure, the presence of sensitive populations must also be considered, since these same types of individuals as described above might be similarly subject to increased risk of injury or death from chronic CO exposure. ([*2 D–4, D–5*] *16, 17, 20*).

The risk of injury associated with unvented gas space heaters, therefore, derives from the inhalation of CO and the resultant decrease in blood oxygen. Depending on the degree to which blood oxygen is lowered and the period for which it is lowered, there is the possibility of tissue damage and even death. The degree of risk is thus a direct function of the concentration of CO and the duration of exposure and individual sensitivity (*2 D–3, D–4*).

As is evident from the discussion below in Degree of the Risk of Injury, the information available to the Commission on the hazard arising from CO poisoning associated with unvented gas-fired space heaters is predominantly death data. The information suggests that the primary risk is from a sufficiently high, one-time (acute) exposure to CO emissions. The information shows that such acute exposure to CO emissions results in anoxia and death and is, therefore, of particular concern during sleeping hours (*2 D–3*).

As described elsewhere in this preamble, at this time it is economically unfeasible and technologically impracticable to produce a device that can detect certain CO levels of emission and shut off the supply of gas to a heater (*6*). However, as discussed below under Technical Considerations, the acute health risk from high levels of CO that may be produced by unvented gas-fired space heaters can be eliminated or reduced by the proposed standard because the requirement for an ODS can help detect and avoid an atmosphere hazardous to human life (*11*).

Since an ODS functions as a detector and monitor of oxygen depletion, it cannot postively prevent a buildup of CO above levels that may present chronic hazards to certain, sensitive persons. However, insofar as an ODS-equipped unvented heater can affect a reduction of CO emissions by detecting the depletion of oxygen and shutting off the gas supply, such heaters are expected to at least reduce levels of CO available that may present a possible chronic hazard (*2 D–1, D–3, D–5*).

In addition, the standard proposed below requires a permanently-affixed label that warns of CO poisoning and describes persons who may be particularly susceptible to CO emissions.

Notwithstanding these factors, additional work remains to be done in relation to the possible chronic hazard associated with CO emissions from this and other products. Therefore, the Commission staff will continue to study the chronic effects of exposure to CO (including sensitive populations) in order to more fully evaluate the problem of CO exposure in the home.

In assessing the nature and degree of the risk of injury associated with unvented gas-fired space heaters, the Commission was also assisted by experimental and human studies that have been published in the scientific literature and elsewhere (*14* through *21*).

C. Degree of the Risk of Injury

The epidemiological data available to the Commission concerning CO poisoning associated with unvented gas-fired space heaters is summarized in the Commission's 1978 Hazard Analysis Report concerning this product (*3*), and has been updated since that time. The data, predominately death data, are based primarily on a death certificate collection program rather than in-depth investigations, since during most of that time, not many in-depth investigations had been made (*2 C–2*).

An in-depth investigation is usually a personal interview with family or witnesses to the incident. Although these investigations may not be statistically representative of all injuries, they do provide helpful details concerning product identification as well as the cause of injury. The death certificate program collects information from 54 health jurisdictions which include the 50 states and New York City, the District of Columbia, Puerto Rico and the Virgin Islands (*2 C–2*).

As reported in the 1978 Hazard Analysis of Unvented Gas-Fired Space Heaters the Commission death certificate files contain 533 deaths related to gas-fired space heaters for the period from January 1973 to May 1978; 412 of these deaths resulted from CO poisoning. In 72 of the 412 deaths, the gas-fired space heater involved was identified as unvented.[3] From the language used in the cause of death narratives on the death certificates, 64 additional deaths were attributed to unvented gas-fired space heaters bringing the total to 136. A portion of the remaining death certificates involving CO poisoning and gas space heaters could also involve unvented gas space heaters, but this proportion is unknown because the information included in the death certificates was limited (*2 C–2*).

Aside from the Commission data sources, 50 deaths from CO poisoning for the period 1958 through 1978 were reported by consumers and state officials during the comment period for the Commission's proposed ban of unvented gas-fired space heaters (*2 C–1*) published in the **Federal Register** on February 14, 1978 (the proposal was subsequently withdrawn (*2 B–1, B–2*)).

[3] In an effort to help determine the levels of fatal blood carboxyhemoglobin (COHb) for these 72 victims, Commission epidemiologists learned from the medical examiners involved that autopsies had been performed in 23 of these cases; COHb levels had been noted for 15 victims. Also, the medical examiner for Dade County, Florida submitted COHb information from 7 additional autopsies involving CO poisoning associated with unvented gas heaters (*9*). The small sample, graphically described in table 2, (*2 C–1*) shows that tolerances to COHb levels vary greatly.

Of the 50 reported deaths, 10 deaths were confirmed by Commission epidemiologists as having resulted from CO poisoning associated with unvented gas-fired space heaters. These ten deaths are represented in the data discussed above.

To estimate the number of deaths annually attributable to CO poisoning from unvented gas-fired space heaters, the Commission staff reviewed the Commission's death certificate files for 1977 and compared the findings to the death certificates for CO poisoning from the use of residential fuels (excluding those associated with actual fires) compiled by the National Center for Health Statistics (NCHS) of the Department of Health, Education, and Welfare for the same time period.

In the case of CO poisoning associated with the use of domestic fuels, the Commission's death certificate file has, since 1974, identified about 75 percent of the total number of such deaths reported to NCHS, the source of our national mortality data. In 1977, 348 poisonings were reported from the use of residential fuels; CPSC death certificate files include 289 or 83 percent of these deaths. A distribution of these 289 deaths by the product involved indicates that about one half involved gas space heaters. Although 30 of these cases specified unvented heaters, the majority did not specifically identify the kind of heater involved. Therefore, other data sources were reviewed to provide more specificity.

Between 1973 and 1979, Commission in-depth investigation files show that 41 investigations were made of 41 CO poisoning incidents associated with gas-fired space heaters. A review of this information indicates that of the 41 incidents, 25 (61%) involved vented gas-fired space heaters; 12 incidents (22%) were unvented gas-fired space heaters; the type of heater in the remaining 10% are unknown.

These 41 in-depth investigations do not represent a randomly drawn sample of gas space heater deaths represented in the death certificate file. Most of them were initiated on the basis of newspaper accounts and others from NEISS or consumer complaints. The value of an IDI, in addition to providing information on the cause of injury, is as a source of product information.

On the basis of this detailed product information, CPSC staff assumed that the ratio of unvented to vented gas-fired space heater deaths shown in the IDI files could be extrapolated to the 176 CO poisoning deaths from all domestic-fueled heaters estimated to have occurred in 1977. These calculations, after adjustment for regional differences and possible bias in IDI heater files, result in an overall estimate of about 70 deaths from unvented and 110 deaths from vented gas-fired space heaters (*2 C–2*).

Thus, the Commission estimates that approximately 70 deaths associated with CO poisoning and unvented gas-fired space heaters occur each year in the U.S. This may represent a conservative estimate of such deaths because the effects of CO poisoning impact strongly on the cardiovascular and neurological systems of the body; therefore CO deaths may be easily misdiagnosed and thus may be attributed to other physiological causes (*9*).

There is evidence, from information provided from comments to the proposed ban, to indicate that many nonfatal cases of CO poisoning may go undocumented. In these cases, either an improper diagnosis is made because the symptoms of CO poisoning resemble those of other illnesses such as headaches, dizziness, nausea, or the victims recover at home and do not seek medical attention. These incidents would not appear on any medical records, or in any data sources, as CO poisoning. Therefore, the above number of CO poisonings resulting in injuries and/or deaths that have been reported must be considered a minimum number for this type of injury (*2 C–2*).

TABLE 2

CO POISONING DEATHS FROM UNVENTED GAS HEATERS FOR WHICH CPSC HAS COHb LEVELS

COHb Scale	COHb Levels From Records of Death	Age of Victim and Comments
75%	76%	37
70%	73% 72%	21 19-pregnant; fetus had 84%
65%	68%	81-coronary history
60%	60%	21
55%	57% 56% 55%	36 43 36
50%	54% 52%	35 45
45%	47% 45% 45%	46 77 21
40%	43% 42% 41% 40%	40 48 67-hypertensive heart disease 22
35%	36% 35%	52 69-arteriosclerotic Disease
30%	33% 33%	49 23-cardiorespiratory failure
25%	26%	54-blood alcohol 0.12%
20%		
15%		
10%		
5%		
0%		

D. Description of the Proposed Standard

Purpose and coverage

The Consumer Product Safety Commission has preliminarily determined that unvented gas-fired space heaters present an unreasonable risk of injury to the public of carbon monoxide poisoning, because carbon monoxide (CO), a toxic product of combustion, can be emitted directly into the atmosphere of the area being heated. The Commission has also preliminarily determined that a device known as an oxygen depletion safety shutoff system (ODS) can shut off the heater's gas supply before the CO can build up to an atmosphere hazardous to human life. Therefore, the Commission believes that an ODS would be adequate to help eliminate or reduce the unreasonable risk.

Proposed Part 1212 provides that on the effective date of the standard, an ODS, as defined in § 1212.3(n) shall be contained in all unvented gas-fired space heaters, not specifically excluded from the standard, that are customarily produced for sale to or for the personal use or enjoyment of consumers in or around a household or residence, a school, in recreation or otherwise. Proposed Part 1212 contains two Subparts—Subpart A describes the safety standard; Subpart B contains the rules for manufacturers and importers to follow concerning certification of compliance with the standard and the maintenance of records showing the basis, in testing, of such certification. The proposed standard also provides for permanently affixed cautionary labels. Also provided is a test procedure which the Commission will use to determine compliance with the standard.

Unvented gas-fired space heaters—inclusions and exclusions

For the purposes of this proposal, an unvented gas-fired space heater is an unvented, self-contained, free-standing or recessed, gas-burning appliance which furnishes warm air to the surrounding living space by gravity convection, fan circulation, or radiation directly from the heater and without duct connections. The heater discharges carbon dioxide and water vapor, and any carbon monoxide in the combustion products, directly into the heated space. Although kitchen ranges and ovens may fit this product description, they are not included within this definition because their function is not to provide room

heat, but to serve as a source of localized heat for food preparation.

Within the scope of this definition, unvented gas-fired space heaters include unvented circulators, radiant heaters, and wall heaters with unvented closed fronts. These products are defined as follows:

(1) "Unvented circulator" is a room heater designed to convert the energy in the fuel to convected and radiant heat, by direct mixing of air to be heated with the combustion products and excess air inside the jacket. Unvented circulators have an external jacket surrounding the burner and may be equipped with radiants with the jacket open in front of the radiants.

(2) "Radiant heater" is an open front unvented room heater designed primarily to convert the energy in the fuel to radiant heat by means of refractory radiants or similar radiating materials. A radiant heater has no external jacket.

(3) "Wall heater, unvented closed front" is an unvented circulator having a closed front for insertion in or attachment to a wall or partition.

The following unvented heaters are excluded from the proposed rule for the reasons set forth below: Gas logs; coal baskets; fireplace inserts (categorized as decorative gas appliances for purposes of this rule); portable catalytic camp heaters; portable camp heaters other than catalytic; and infrared heaters.

(1) "Decorative gas appliances" are excluded. These are gas logs, coal baskets, and fireplace inserts; they are excluded from the rule for the following reasons:

(a) An investigation of available data bases for product-related injuries/deaths revealed no data specific to these products. Although the magnitude of the injury/death problem associated with these decorative gas appliances cannot be accurately determined, it appears to the Commission that consumer use of these appliances is primarily limited to decorative use in vented fireplaces where the risk of CO poisoning is minimal.

(b) The American National Standards Institute (ANSI), a voluntary standards organization, has published a certification standard and labeling requirement for decorative gas appliances for installation in vented fireplaces (ANSI–Z21.60). The large majority of such decorative gas appliances are labeled for use in a vented fireplace.

(c) There has been a steadily declining market for these products over the past several years—approximately 20,000 units were produced in 1976 compared to approximately 42,000 units in 1974.

(2) Catalytic camp heaters and non-catalytic camp heaters are excluded.

(a) Catalytic camp heaters are open faced, unvented heating appliances which utilize a catalyst in the combustion process. The Commission has denied a petition, (CP 75–16, 42 FR 32565, June 27, 1977), to develop a safety standard addressing the hazards of CO poisoning, anoxia and hot surfaces associated with catalytic heaters because, among other considerations, the voluntary standard developed by the ANSI Z21 Subcommittee on standards for Portable Gas-Fired Camping Equipment (Camping Equipment), and adopted by ANSI, appears to reasonably address the possible hazards which may be associated with catalytic heaters. Therefore, the Commission sees no need to include these in the proposed rule.

(b) Non-catalytic camp heaters are unvented portable heating devices of other than the catalytic type for use with liquefied petroleum gases. Because the safety problems inherent to these heaters are essentially the same as the safety problems encountered with catalytic heaters, the ANSI Z21 Camping Equipment Subcommittee has developed and ANSI has adopted a voluntary standard for non-catalytic camp heaters which closely parallels the catalytic heater standard. Therefore, the Commission proposes to exclude non-catalytic camp heaters from this rule.

(3) Infrared heaters are excluded because they are generally used for heating outdoor spaces or non-residential, non-recreational indoor spaces. In these situations the CO poisoning hazard of unvented gas-fired space heaters is not likely to occur.

Requirements

The standard requires that manufacturers, including importers (referred to collectively as manufacturers) of unvented gas-fired space heaters shall be responsible for equipping their products with an oxygen depletion safety shutoff system (ODS). The ODS must shut off the gas supply to the heater when oxygen in the surrounding atmosphere is depleted to less than 18%. In order to avoid the possibility that the ODS would be rendered insensitive to hazardous oxygen depletion levels, the standard provides that the ODS shall be constructed or placed in such a manner that it cannot be adjusted by home users.

Test procedure, certification and recordkeeping

For enforcement purposes, all unvented gas-fired space heaters subject to the standard must be able to pass the test described in proposed § 1212.6. That section requires an unvented gas-fired space heater equipped with an ODS to be placed in a chamber which is closed against outside air. The heater is operated at maximum gas input and measurements are made as the oxygen is depleted. The Commission will use the test to determine whether the ODS on products subject to the standard shuts off the gas supply to the heater when oxygen in the surrounding atmosphere is depleted to less than 18%. While manufacturers are not required to perform this test, they must certify that their products comply with the standard. Such certification of compliance must be based either on a test of each heater or on a reasonable testing program. Manufacturers are responsible for maintaining records of testing performed for certification purposes, whether the tests are performed by the manufacturer or an independent, qualified laboratory in accordance with the provisions of Subpart B.

Origin of the proposed standard for ODS

The proposed standard is adapted from sections of an existing voluntary standard of the American National Standards Institute (ANSI) entitled, *Gas-Fired Room Heaters, Vol. II—Unvented Room Heaters,* Z21.11.2–1978, (ANSI standard) (*1*). Under section 7(c) of the CPSA, as amended (15 U.S.C. 2056(c)), the Commission may publish as a consumer product safety rule, in whole or in part, or in combination with any other standard or portion thereof, a standard proposed or adopted by a qualified agency, organization or institution, and may make nonmaterial modifications to the existing standard before proposing it for public comment.

The ODS part of the ANSI standard was included as an optional provision of the ANSI standard in 1974 for manufacturers of unvented gas-fired space heaters. In 1979, ANSI revised its standard to make this optional provision a requirement, (*2L*), although AGA, the industry's organization responsible for certifying conformance of gas heaters to the ANSI standard, is not yet requiring the ODS device for certification. Consequently, and ODS has not yet been used by U.S. manufacturers of unvented gas-fired space heaters.

However, the ODS section of the ANSI standard was proposed and adopted by the usual procedures of ANSI, a qualified organization, and the ODS sections of the ANSI standard are therefore considered by the Commission to be appropriate for adoption under section 7(c) of the CPSA.

Labeling

The proposed standard provides that a label be permanently attached to unvented gas-fired heaters complying with the standard. The label is cautionary and describes the hazard of CO poisoning; it also describes the ODS system.

E. Technical Considerations

In proposing this standard to eliminate or reduce deaths from CO poisoning associated with unvented gas-fired space heaters, the Commission considered the process by which CO evolution takes place, and measures needed to avoid CO build up. This section of the preamble discusses that process (*11*), and also discusses the ODS systems and the Commission's reasons for proposing this standard.

How carbon monoxide is produced

Many materials react with oxygen, a process called oxidation. When oxygen reacts with a substance to produce large amounts of heat rapidly the process is called combustion or burning. Three things are needed for combustion to take place—fuel, oxygen and heat. For burning the fuel gas, all three elements must be present. Gas alone will not burn. Air, which at sea level normally consists of 20.9% oxygen, supplies the oxygen needed. An open flame (pilot) or electrical means may be used to ignite the gas in gas appliances. Then the gas flame itself provides the heat needed to sustain combustion. Combustion of gas is a chemical reaction between fuel gas and oxygen. The basic elements of fuel gases are hydrogen and carbon. When hydrogen burns, water vapor is produced. Complete burning of carbon in fuel gases carbon dioxide. The water vapor and carbon dioxide are called the products of combustion and are the only by-products that result if a fuel gas is completely burned. To obtain complete combustion enough air must be supplied to the process. This air must have a reasonably normal oxygen content. If not enough air is supplied there is not enough oxygen to combine with the carbon to form carbon dioxide; instead carbon monoxide is formed. Carbon monoxide is a colorless, oderless and highly poisonous gas (*11*).

There are many products that operate by the combustion of fuel gas, including furnaces, boilers, ranges, water heaters and space heaters. Most gas burning appliances are vented which means that the products of combustion are removed from the inside of the building by means of vent pipes. This presents a minimal hazard of carbon monoxide poisoning since any CO produced by incomplete burning of gas is discharged outside. However, appliances which are unvented discharge the products of combustion directly into the space being heated. Gas-fired space heaters may be manufactured as either vented or unvented heaters.

Why unvented heaters produce CO

Unvented gas space heaters can produce CO for several different reasons. If the air supply is not adequate to allow complete combustion, CO will be produced. This is caused by poor ventilation—too few openings in the building to allow air to enter. Other reasons for CO production are related to design of the burner and adjustment of the parts that control the combustion process (*2D–3*).

When an unvented heater is operated in a room that is sealed tightly against air coming in or leaving, the oxygen concentration decreases with time and the CO concentration increases as the combustion process is starved for oxygen. The oxygen concentration decreases steadily from the normal 20.9 percent to between 15 and 16 percent. At about 15% oxygen, the combustion process for most gas appliances stops due to lack of oxygen. The CO concentration increases gradually at first until the oxygen concentration is reduced to below 18% and then proceeds to rise more rapidly. The time it takes for this to occur depends on the room size and the fuel burning rate of the heater. A graphic example of this process as it occurs in a closed room is shown in figure 1. As oxygen is depleted in the combustion process, carbon dioxide is produced and increases steadily. However, CO is produced at an increasing rate at the combustion process is starved (*2D–3*). (To find the CO produced at any given oxygen level, find that oxygen level on the O_2 scale on figure 1; trace right to the oxygen line, then from that point, up or down to CO line. Read this point on the CO scale.)

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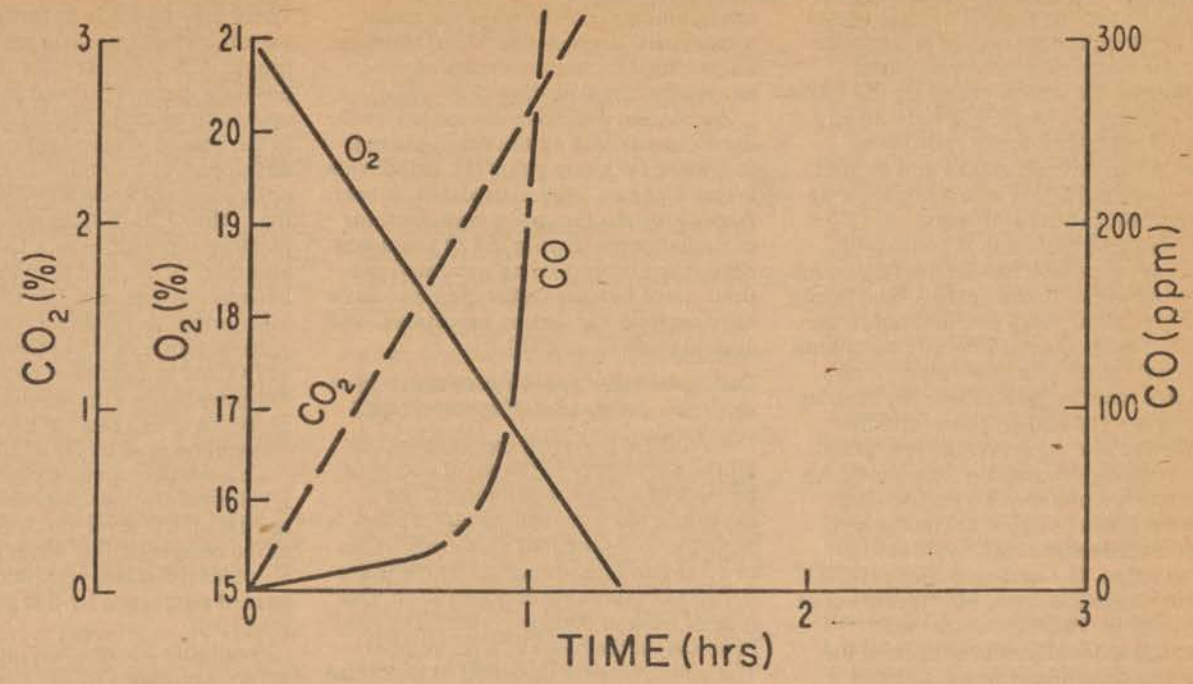


FIG 1—TYPICAL *CLOSED ROOM* CONDITIONS
for
UNVENTED HEATER OPERATION

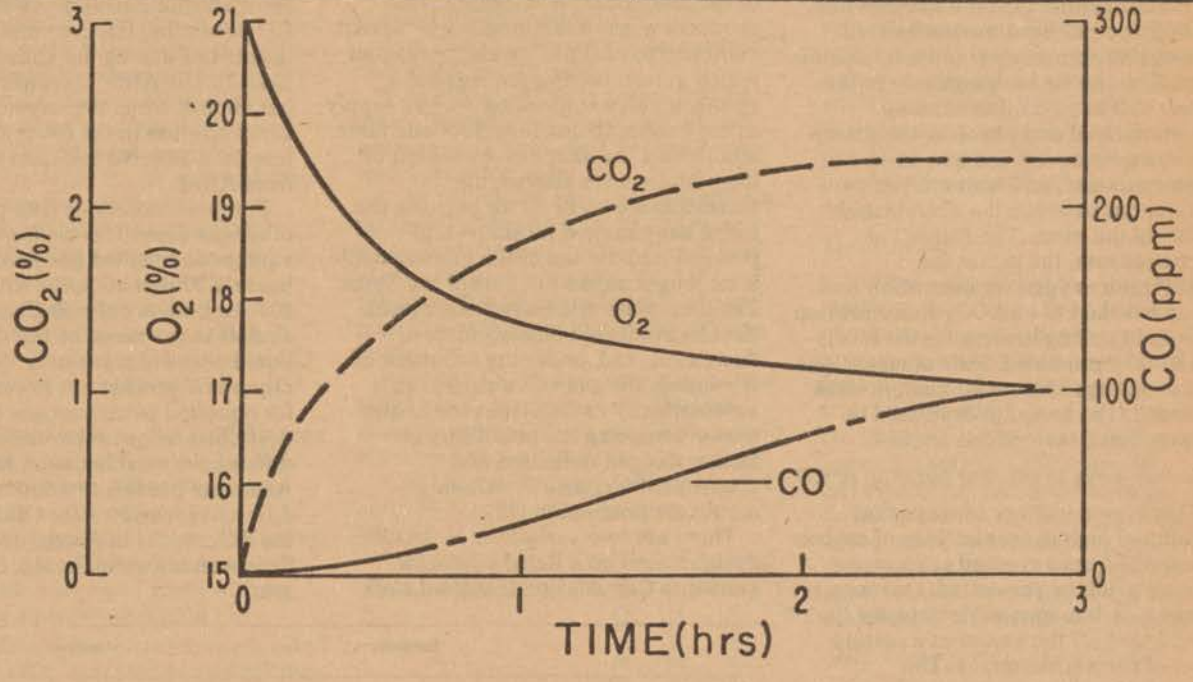


FIG 2—TYPICAL *VENTILATED ROOM* CONDITIONS
for
UNVENTED HEATER OPERATION

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The closed (or sealed) room is useful for studying the process of combustion and for measuring the depletion of oxygen at the time of cutoff for the ODS, but a house or dwelling is not a tightly sealed unit. Air is constantly being exchanged through cracks and around windows and doors which allow air to enter (infiltration) and leave (exfiltration) the room. A ventilated room is one which has air passages such as windows or doors opened specifically to allow air to move into and out of the room. The oxygen and carbon monoxide concentrations in a ventilated (or non-sealed) room behave differently than in the closed (or sealed) room, and the room size and air exchange rate affect this behavior. A graphic example of the combustion process in a non-sealed room is given in figure 2. The oxygen content decreases and levels out at some value. The carbon dioxide (CO_2) content increases, and also levels out at some value. The CO content will increase gradually at first; then as the oxygen content is reduced, CO will increase more rapidly and finally will level out at a certain concentration as did the oxygen and CO_2. This condition is known as equilibrium, which means that the conditions of the room will remain the same as long as the heater fuel burning rate, the air exchange rate, and other conditions are unchanged. The equilibrium oxygen content depends in part on the air exchange rate in the room. This is a function of many environmental and physical conditions such as the amount and size of air openings, wind, and temperature differences between the outside and inside of the room. The higher the exchange rate, the higher the equilibrium oxygen concentration and the lower the CO and CO_2 concentration (*2D–3*). In testing heaters for the levels of CO they produced, tests at conditions of various equilibrium air change were included. The tests are described in greater detail later in this section.

Possible ways to prevent build-up of CO

There are a number of ways that buildup of high concentrations of carbon monoxide from unvented gas space heaters could be prevented. One way is to use a carbon monoxide detector that would shut off the heater at a certain level of carbon monoxide. The Commission determined that this was not feasible because there is no device, at present, that is both technically and economically practicable for performing this function (*6*). A second way is to ban the manufacture of unvented gas space heaters. The Commission proposed this action, but withdrew the proposal after learning that it is possible to measure an environmental condition of the room atmosphere (oxygen depletion) that can be predictably related to carbon monoxide concentration (*2 B–1, B–2*).

An oxygen depletion device has been used successfully on unvented heaters in Europe for many years (*8*). The device is known as an oxygen depletion sensor. According to a European manufacturer of such devices, during the 20 years this device has been used on unvented gas-fired space heaters in Europe there have been no reported deaths associated with such heaters (*8*, p. 32ff.).

Description and operation of the oxygen depletion safety shutoff system (ODS)

An ODS is a system designed to shut off the gas supply to the main and pilot burners of a gas space heater if the oxygen in the surrounding atmosphere is depleted to a specified value regardless of other conditions such as temperature or carbon monoxide concentration. One type of oxygen depletion shutoff system operates on the basis of a flame pilot. The pilot burner is designed to maximize the effect on the flame of operating in an atmosphere in which the oxygen content has been decreased. A device called a thermocouple is positioned in the flame. When the flame is normal (that is, burning in a normal atmosphere) the top of the thermocouple is heated. This produces a small thermoelectric current sufficient to energize an electromagnet which in turn holds open, against a spring, a valve controlling the gas supply to the heater. If, due to lack of adequate ventilation, the shape and position of the pilot flame is altered, the thermocouple cools down because the flame has changed its shape and position and the top of the thermocouple is no longer on the hot part of the flame. The thermoelectric current decreases, the electromagnet holding force is decreased; and, under the influence of the spring, the gas valve closes. This automatically extinguishes the heater burner removing the possibility of further oxygen reduction and consequent increase in carbon monoxide production (*11*).

There are two variations of the ODS design based on a flame pilot now known to Commission technical staff. There may be other potential design variations but the basic principle of operation would likely be the same. It is possible that other basic principles of operation meeting the definition of ODS in the proposed standard could be developed, but no other feasible theories or devices are known to CPSC at this time. The ODS devices now considered feasible cannot measure CO directly, and there is no precise relationship between oxygen and CO that is valid for all conditions. However, there is a general relationship between production of CO and reduction of oxygen, as described above, from which the presence of CO can be inferred from the measurement of oxygen (*2D–2*).

The selection of an oxygen shutdown level involves consideration of a maximum CO level and a determination of the corresponding oxygen level that provides adequate protection from the hazard addressed by this proposed standard.

Available information indicates that severe symptoms of CO poisoning would not occur until CO levels of 200–300 parts per million or more exist for over four hours, and death not until exposure to 1000–2000 ppm or more for at least 2–4 hours (2 D–4).

In considering an oxygen shutdown level adequate to address the hazard of CO poisoning, the Commission noted disparities among the known standards (2 D–2). The ANSI standard provides for gas shutoff when the oxygen concentration in the room atmosphere is less than 18%. No test data are available from ANSI.

European countries (26), provide for other gas shutoff levels for ODS-equipped unvented gas fired space heaters. France requires shutoff at 19.4–20% for butane only. England requires shutoff in the range of 18.7–19.7 for liquid petroleum gas only. Germany requires shutoff at not lower than 19.4% for liquefied petroleum gas only. As described below, other important differences exist between European and American heaters in addtion to the different provisions for ODS. Some of the differences in American and European unvented heater technology are:

	European	American
Installation	Portable	Fixed
Rated Input	16,000 Btu/hr max	15,000–40,000 Btu/hour.
Valves	Off/on type valve	Throttling valve.
Burners	Vertical face	Horizontal face.
Fuel	LPG	Natural gas LPG, and manfactured gas.
Fuel Supply	Self contained LPG bottle	External supply: ● Natural gas main; ● LP gas tank.
Fuel Composition	Constant and controlled	Variable—Natural gas can be Algerian natural gas, peak shaving gas, domestic gas or combinations.
Ignition	Manual	Automatic.
Pilot	Intermittent	Continuous.

The higher than 18% shutdown levels provided for in European heaters present difficulties of application to American heaters. Among the important differences that could affect such application are size and geometry of the heater, fuel composition and fuel supply pressure. U.S. heaters are generally larger and have higher gas input rates. This could require relocation of the pilot which in turn could affect ignition of the heater. In the U.S., a variety of different gases are available and the burning characteristics of these gases could affect the shutdown point of the ODS. Fuel for European heaters is generally located in a container on the heater itself, whereas fuels for U.S. heaters are outside the residence; thus the gas pressure regulator for the European heater serves a much smaller range. The differences in gas pressures could also have an effect on ODS shutdown (2 D–2).

ODS Shutoff at Less Than 18% Oxygen

Information developed during testing of the ODS by the National Bureau of Standards was helpful in determining an oxygen depletion level that would reasonably address the hazard of CO poisoning associated with unvented gas-fired space heaters. The tests of ODS at NBS consisted of: (a) Testing of ODS devices in closed room or non-ventilated conditions to study the levels of oxygen at which the ODS would shut off under various conditions; and (b) testing of unvented heaters to study the level of CO emitted by the heaters under partially ventilated conditions that may be experienced in residences. The testing also included operating the heaters at full and partial inputs of fuel and with primary air shutters in different positions to simulate foreseeable maladjustments which would result in greater quantities of CO being produced during combustion (*11, 12*).

The series of tests on the ODS devices at NBS was conducted on two foreign heaters using seven different foreign ODS devices under various gas pressures and gas input rates, and using different types of gases. The heaters were placed in a closed room with no ventilation and operated until the oxygen content decreased to the level at which the ODS operated to shut off the heater. The tests resulted in the following data relative to the selection of an oxygen depletion shutoff level:

- The ODS devices operated to shut off the heaters at room oxygen concentration of 18.2–20.4%.
- The carbon monoxide concentrations in the closed room at ODS shutoff operated were in the range of 7–90 ppm and averaged 37 ppm.
- The extreme concentrations of both CO and O_2 were:

Extreme O_2 (percent):	CO (ppm)
18.2	51
20.4	7
Extreme CO (ppm):	**O_2 (per cent)**
7	20.4
90	19.0

- Deliberate changes to heater and ODS characteristics to simulate maladjustment and abnormal conditions did not affect ODS operation.
- The ODS operated satisfactorily when used with various representative fuel gases including propane, butane and several natural gases.

The series of tests conducted to study CO levels emitted under partial ventilation conditions was performed on a total of four American-made heaters, representing each of the three American manufacturers, under various gas input rates, air shutter settings, and flame disturbance from drafts. The oxygen content was stabilized at various levels and CO content was allowed to buildup until constant. These conditions were designated in order to simulate foreseeable conditions in homes in which the amount of ventilation provided is a critical level resulting in a CO buildup prior to heater shutdown by the ODS (*11, 12, 2D–2*). The results showed the following:

- At 19% O_2, two data points were CO levels of 5 and 36 ppm.
- At 18% O_2, 13 data points for CO levels ranged from 7–120 ppm with an average at 43 ppm. All CO levels were well below 200 ppm.
- At 17% O_2, 20 data points were in a range of CO levels from 10–245 ppm with an average of 71. The four values above 100 ppm were 245, 190, 155, and 140 ppm. The highest CO level of 245 ppm is significantly above the 200 ppm level.
- At 16% O_2, 17 data points were in a range of CO levels from 41–395 ppm with an average of 182 ppm. Five values were well above 200 ppm.
- CO levels for these tests at 16, 17, 18 and 19% O_2 concentration were as follows:

Equilibrium O_2 in %	16	17	18	19
CO levels in ppm	41	10	7	5
	60	12	8	36
	75	12	15	
	80	15	15	
	85	20	15	
	135	20	20	
	150	20	20	
	160	25	30	
	170	25	60	
	170	45	72	
	170	65	78	
	175	75	105	
	225	80	120	
	280	85		
	355	87		
	375	100		
	395	140		
		155		
		190		
		245		

For an 18% oxygen level, NBS tests show that under partial ventilation conditions in the room the range of CO in the room was between 7 and 120 ppm, with an average of 43 ppm, well below the level of 200–300 ppm which health data indicate could result in severe symptoms of CO poisoning if experienced for over 4 hours (*2 D–3, D–4, D–5*). In addition, the highest level of CO reached at 18% in the NBS tests was only 120 ppm, a level generated by maladjusting the primary air shutter to the full open position (*2 D–2*). Also from the death data available to the Commission at this time (see table 2 under Degree of the Risk of Injury) the lowest figure of COHb associated with a death is 26% COHb. The Commission believes that the lowest CO exposure which is likely to have resulted in this figure is 200 ppm for exposure of 10–15 hours or more.

The Commission concludes, therefore, that an ODS which shuts off gas to the heater when surrounding oxygen is depleted to less than 18%, would be adequate to address the acute hazard and thereby reduce the number of deaths from CO poisoning assoicated with unvented gas-fired space heaters. Further, since the ODS can be expected to effect a reduction in CO emissions by shutting off the gas supply, such a reduction can also help reduce levels of available CO that may present a chronic hazard as described above in Nature of the Risk of Injury. Therefore, a Commission proposes to adopt the ODS provision of the ANSI standard which provides for shutoff at less than 18% oxygen.

Test Gases

Section 1212.6(b) of the proposed standard describes the approximate characteristics of gases that would be used to measure the oxygen cutoff point for purposes of testing under the standard. In addition, measurements of the oxygen cutoff point using four other gases to represent the range of combustion characteristics of gases found in the United States, are also being made by industry (27, 28). The Commission welcomes comments on the gases, and their use in tests, from members of the industry and others.

ODS in the Proposed Standard

In proposing to mandate the ODS described in the ANSI standard, the Commission does not imply that this is the only ODS device that would be acceptable under this Part, and would welcome information about other ODS devices that are capable of complying with the standard.

The chart below, presented for ease of comparison, provides the ANSI

requirements for ODS, the requirements of the proposed standard, and explanations of differences between them. In some instances the CPSC provision is the same as the ANSI provision, but both are presented in order that each standard can be read as a separate entity. In addition, the rationale column may contain no explanation of an ANSI provision that CPSC has accepted unchanged. In general, such items in the ANSI standard result from engineering judgment based on experience and skill in the development and manufacture of gas appliances, and the Commission is not aware of any basis for questioning these technical assumptions.

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ANSI	CPSC	RATIONALE
	DEFINITIONS	
Part 4	Section 1212.3	
BTU. Abbreviation for British Thermal Unit. The quantity of heat required to raise the temperature of one pound of water 1°F.	(a) BTU. Abbreviation for British Thermal Unit. The quantity of heat required to raise the temperature 1 pound ( ) of water 1°F ( ).	No modifications except that metric equivalent to be inserted in standard.
BURNER. A device for the final conveyance of the gas or a mixture of gas and air, to the combustion zone. 1. Injection Bunsen Burner. A burner employing the energy of a jet of gas to inject air for combustion into the burner and mix it with the gas. a. Atmospheric Injection Burner. A burner in which the air at atmospheric pressure is injected into the burner by a jet of gas. 2. Luminous or Yellow-Flame Burner. A burner in which secondary air only is depended on for the combustion of gas. 3. Power Burner. A burner in which either gas or air or both are supplied at pressures exceeding, for gas, the line pressure; and for air, atmospheric pressure; this added pressure being applied at the burner. a. Premixing Burner. A power burner in which all or nearly all of the air for combustion is mixed with the gas as primary air. 4. Pressure Burner. A burner which is supplied with an air-gas mixture under pressure (usually 0.5 to 14 inches of water and occasionallly higher).	(b) BURNER. A device for the final conveyance of the gas, or a mixture of gas and air, to the combustion zone.	The specific types of burners defined in the ANSI standard may have some bearing on other parts of the standard. They have been deleted from the CPSC proposal as they are not needed for ODS purposes.
CUBIC FOOT OF GAS. The amount of gas would occupy 1 cubic foot when at a temperature of 60° F if saturated with water vapor and under a pressure equivilant to that of 30 inches of mercury.	(c) CUBIC FOOT OF GAS. The amount of gas which would occupy 1 cubic foot ( ) when at a temperature of 60° F if saturated with water vapor and under a pressure equivalent to that of 30 inches of mercury ( ).	No modifications, except that metric equivalent will be inserted in standard.
NONE	(d) FIELD ADJUSTMENT MEANS. A part, device, or mechanism which allows a change in setting by the user.	The definition is added by Commission staff to clarify the term used in Sec. 1212.5.
HEATING VALUE TOTAL. The number of British Thermal Units produced by the combustion at constant pressure of 1 cubic foot of gas when the products of combustion are cooled to the initial temperature of the gas and air, when the water vapor formed during combustion is condensed, and when all the necessary corrections have been applied.	(e) HEATING VALUE. The number of British Thermal Units ( ) produced by the combustion at constant pressure of 1 cubic foot ( ) of gas when the the products of combustion are cooled to the initial temperature of the gas and air, when the water vapor formed during combustion is condensed, and when corrected to a temperature of 60° F ( ) at a pressure equivalent to 30 inches of mercury ( ).	The definition is changed to incorporate the temperature and pressure corrections which appear elsewhere in the ANSI standard.
INPUT RATING. The gas burning capacity of an appliance in Btu per hour as specified by the manufacturer. Appliance input ratings are based on sea level operation and need not be changed for operation up to 2,000 feet elevation. For operation at elevations above 2, 000 feet, input ratings should be reduced at the rate of 4 percent for each 1,000 feet above sea level.	(f) INPUT RATING. The maximum gas-burning capacity of an appliance in Btu per hour ( ) as specified on the nameplate by the manufacturer.	The definition is changed to specify that input rating be the "maximum" achievable by the heater being tested. The input rating shall be that which appears "on the nameplate" so that if more than one input is shown by the manufacturer the maximum value will be used for the purposes of this test.

ANSI	CPSC	RATIONALE
	DEFINITIONS	
Part 4	Section 1212.3	
Class I. Integral Marking. Marking that is embossed, cast, stamped or otherwise formed in the part.	(g) INTEGRAL MARKING. Marking that is embossed, cast, stamped or otherwise formed in the part.	No modifications.
LIQUEFIED PETROLEUM GASES. The terms "Liquefied Petroleum Gases," "LPG," and "LP-Gas," as used in this standard shall mean and include any material which is composed predominantly of any of the following hydrocarbons, or mixtures of them; propane, propylene, butanes (normal butane or isobutane), and butylenes.	(h) LIQUEFIED PETROLEUM GASES. Any material which is composed predominantly of any of the following hydrocarbons, or mixtures of them: propane, propylene, butanes (normal butane or isobutane), and butylenes.	No modifications.
LP GAS-AIR MIXTURES. Liquefied petroleum gases distributed at relatively low pressures and normal atmospheric temperatures which have been diluted with air to produce desired heating value and utlization characteristics.	(i) LP GAS-AIR MIXTURES. Liquefied petroleum gas, distributed at relatively low pressures, and normal atmospheric temperatures, which nave been diluted with air to produce desired heating value and utilization characteristics.	Editorial changes are made for clarity.
NONE	(j) MANUFACTURED GAS. A gas produced from coal, coke, or oil, or by reforming of natural or liquified petroleum gases or any mixtures thereof, and including any natural or liquified petroleum gas if used for enriching.	This definition has been added for completeness. The definition is taken from the Gas Engineer's Handbook. The gas is typical of the gases recommended by manufacturers for use with their heaters. Where a manufacturer specifies the use of a particular gas, that gas would be the gas used by CPSC staff in testing procedures to determine compliance.
NONE	(k) MIXED GAS. A gas in which manufactured gas is co-mingled with natural or liquefied petroleum gas in such a manner that the resulting product has a Btu value higher than that previously produced by the utility prior to the time of the introduction of natural or liquefied petroleum gas.	(See "Manufactured Gas" above)
NONE	(l) NATURAL GAS. A naturally occurring mixture of hydrocarbon and nonhydrocarbon gases found in porous formations beneath the earth's surface, often in association with crude petroleum. The natural gas of commerce supplied to fuel gas markets, usually contains from 80 to 95 percent methane and lesser amounts of ethane and propane. Most of the remainder is nitrogen.	(See "Manfuactured Gas" above)
NORMAL BUTANE (N-BUTANE), TECHNICAL GRADE. A liquefied petroleum gas composed of a minimum of 95 percent n-butane (C_4H_{10}) which may contain other impurities such as isobutane, butylenes and propane not in excess of 5 percent.	(m) NORMAL BUTANE (N-BUTANE), TECHNICAL GRADE A liquefied petroleum gas composed of a minimum of 95 percent n-butane (C_4H_{10}) which may contain other impurities such as isobutane, butylenes and propane not in excess of 5 percent.	No modifications.
OXYGEN DEPLETION SAFETY SHUTOFF SYSTEM. A system designed to act to shut off the gas supply to the main and pilot burners if the oxygen in the surrounding atmosphere is depleted to the percent concentration specified by the manufacturer, but not lower than 18.0 percent.	(n) OXYGEN DEPLETION SAFETY SHUTOFF SYSTEM (ODS). A system designed to act to shut off the gas supply to the main and pilot burners if the oxygen in the surrounding atmosphere is depleted to a specified value (see Section 1212.5(b), regardless of other conditions, such as temperature or carbon monoxide concentration. (The system shall depend primarily on lack of oxygen for actuation and not on other phenomena in the surrounding atmosphere such as temperature or CO concentration.)	Specifying the 18% oxygen level is a requirement and not necessary for the definition. A phrase was added to clarify and emphasize that the ODS shall operate at a specified oxygen level regardless of of other conditions such as temperature or carbon monoxide concentration. This was done to preclude other types of devices from qualifying under this standard by chance without necessarily responding to a depleted oxygen condition.

ANSI	CPSC	RATIONALE
	DEFINITIONS	
Part 4	Section 1212.3	
Class II. Permanent Plate Shall be made of metal having a minimum thickness of 0.012 inch and shall be securely attached by mechanical means.	(o) PERMANENT PLATE MARKING. Marking that is made of metal having a minimum thickness of 0.012 inch ( ) and that is securely attached so that it will remain with the heater throughout its life expectancy.	The purpose of this modification is to require that the label remain with the heater throughout its life expectancy. Any technique to accomplish this purpose would be acceptable.
PILOT. A gas flame(s)utilized to ignite the gas at the main burner(s).	(p) PILOT. A small flame which is utilized to ignite the gas at the main burner(s).	No modifications.
PROPANE HD-5. A special grade of liquefied petroleum gas composed of a minimum of 90 percent liquid volume of propane (C_3H_8) and a maximum of 5 percent liquid volume of propylene (C_3H_6).	(q) PROPANE HD-5. A special grade of liquified petroleum gas composed of a minimum of 90 percent liquid volume of propane (C_3H_8) and a maximum of 5 percent liquid volume of propylene (C_3H_6).	No modifications.
SPECIFIC GRAVITY. As applied to gas, the ratio of the weight of a given volume to that of the same volume of air, both measured at the same temperature and pressure.	(r) SPECIFIC GRAVITY. As applied to gas specific gravity is the ratio of the weight of a given volume to that of the same volume of air, both measured at the same temperature and pressure.	No modifications.
NONE	(s) STOICHIOMETRIC COMBUSTION. The rapid oxidation of fuel gases, having the exact proportions of fuel and air required for theoretically complete chemical reaction.	This definition has been added to aid in understanding the standard, since the term is used in the test procedure.
UNVENTED ROOM HEATER. An unvented self-contained, free-standing, nonrecessed (except as noted under 6 of the following classifications), gas-burning appliance for furnishing warm air by gravity or fan circulation to the space in which installed directly from the room heater without duct connection. Unvented room heaters shall not have a normal input rating in excess of 40,000 Btu per hour, except as noted under 6 of the following classifications.	(t) UNVENTED GAS SPACE HEATER. A self-contained, free-standing or recessed, gas-burning appliance which furnishes warm air to the surrounding or adjacent living space by gravity convection, fan circulation or radiation directly from the heater and without duct connections, and which discharges combustion products such as carbon monoxide, carbon dioxide, and water vapor directly into the heated space. The term includes the following:	The definition in the Commission draft is taken from the proposed ban on unvented heaters published in the Federal Register of February 14, 1978 (43 FR 6235). This definition defines the products identified as associated with the unreasonable risk of injury. The basis for the definition is discussed in Section D above.
1. Unvented Circulator. A room heater designed to convert the energy in fuel gas to convected and radiant heat by direct mixing of air to be heated with the combustion products and excess air inside the jacket. Unvented circulators have an external jacket surrounding the burner and may be equipped with radiants with the jacket open in front of the radiants.	(1) "Unvented Circulator." A room heater designed to convert the energy in the fuel to convected and radiant heat by direct mixing of air to be heated with the combustion products and excess air inside the jacket. Unvented circulators have an external jacket surrounding the burner and may be equipped with radiants with the jacket open in front of the radiants.	
2. Coal Basket. An unvented, open-flame type room heater consisting of a metal basket filled with simulated coals which gives the appearance of a coal fire when in operation. A coal basket is for installation in an incombustible fireplace only.	(2) "Wall Heater, Unvented Closed Front." An unvented circulator having a closed front for insertion in or attachment to a wall or partition.	
3. Fireplace Insert. An unvented open-flame radiant-type heater mounted in a decorative metal panel to cover the fireplace or mantel opening. A fireplace insert is for installation in an incombustible fireplace only.	(3) "Radiant Heater." An open-front unvented room heater designed primarily to convert the energy in the fuel to radiant heat by means of refractory radiants or similar radiating materials. A radiant heater has no external jacket.	

ANSI	CPSC	RATIONALE
	DEFINITIONS	
Part 4	Section 1212.3	
4. Gas Log. An unvented, open-flame type room heater consisting of a metal frame or base supporting simulated logs. A gas log is for installation in an incombustible fireplace only.		
5. Radiant Heater. An open-front unvented room heater designed primarily to convert the energy in fuel gas to radiant heat by means of refractory radiants or similar radiating materials. A radiant heater has no external jacket. A radiant heater is for installation in an incombustible fireplace only.		
6. Wall Heater, Unvented Closed Front. An unvented circulator having closed front, for insertion in or attachment to a wall or partition. These heaters shall be plainly marked, "UNVENTED HEATER" in letters ½ inch high and shall not have normal input ratings in excess of 25,000 Btu per hour.		
	REQUIREMENTS	
Oxygen Depletion Safety Shutoff Systems		
Section 1.8 A room heater equipped with an oxygen depletion sensitive safety shutoff system shall comply with the applicable provisions of this standard and, in addition, shall comply with the following specifications.	Section 1212.5 Requirements for ODS (a) Each heater shall be equipped with an oxygen depletion safety shutoff system (ODS) capable of shutting off the gas supply if the oxygen in the surrounding atmosphere is depleted. (The system shall depend primarily on lack of oxygen for actuation and not on other phenomena in the surrounding atmosphere such as temperature or CO concentration.)	Section 1212.5 of the proposal lists three requirements for Oxygen Depletion Sensors as discussed below.
1.8.1 The system shall shut off the gas supply to the main and pilot burners when the oxygen in the surrounding atmosphere is depleted to the percent concentration specified by the manufacturer, but not lower than 18.0 percent.	(b) The concentration of oxygen in the surrounding atmosphere at time of shutoff shall not be less than 18% when corrected to 70 degrees Fahrenheit ( ) at a barometric pressure equivalent to 30 inches of mercury ( ).	Section 1212.5(b) requires the ODS to shut off the main and pilot burners of the unvented gas space heater when the oxygen in the surrounding atmosphere is depleted to less than 18% concentration when corrected to a standard condition of 70°F and a pressure of 30 inches of mercury. The requirement for shutoff not lower than at 18% oxygen was added to the ANSI standard in 1974. The Commission has verified through testing in 1978 at the National Bureau of Standards that an 18% oxygen concentration at heater shutdown is adequate for addressing the risk of carbon monoxide poisoning/asphyxiation associated with unvented gas space heaters. The NBS report suggests that a 19% oxygen concentration requirement might be desirable because higher shutdown levels have been established for European heaters and would provide assurance that high carbon monoxide levels would never occur. Review of NBS data by Commission staff, however, indicates that the risk of acute lethality from overnight exposure to CO at an oxygen depletion level of 18% is relatively low. The rationale for the 18% shutoff level is discussed in detail in Section F above, "Technical Considerations." The ANSI standard allows the manufacturer to specify oxygen cutoff concentration down to and including 18%, but this is irrelevant for the purpose of the proposed standard and has been deleted.
1.8.2 The system shall not incorporate field adjustment means capable of changing the set point at which the system acts to shut off the gas supply to the room heater.	(c) The ODS system shall not incorporate field adjustment means capable of changing the set point at which the system acts to shut off the gas supply to the heater	Section 1212.5(c) requires the ODS to be manufactured so that its set point for oxygen depletion shutdown cannot be adjusted by the user. This requirement is from the ANSI standard and is necessary to prevent users from tampering with the ODS, rendering it inoperative or insensitive to hazardous oxygen depletion.

ANSI	CPSC	RATIONALE
	TEST EQUIPMENT AND PROCEDURES	
Section 2.9 Oxygen Depletion Safety Shutoff Systems	Section 1212.6 Test Equipment and Procedures	
On a room heater equipped with an oxygen depletion sensitive safety shutoff system, the system shall act to shut off the gas to the main and pilot burners when the oxygen level in the surrounding atmosphere is reduced to not less than 18.0 percent.	This section describes the equipment and procedures to be used by CPSC for evaluating the shutdown performance of unvented gas space heaters fitted with oxygen depletion sensors. Alternate procedures and equipment may be substituted where equivalency can be demonstrated to CPSC.	The purpose of the test is to verify that the oxygen depletion sensor shuts off the gas flow to the unvented heater before the room oxygen concentration decreases below 18%. This test method is based on the ANSI standard. The format has been reorganized substantially. Some aspects have been changed as noted below.
Method of Test	(a) Facilities Equipment and Conditions	
The burner and primary air adjustments shall be made in accordance with 2.3.3.		
The room heater shall be installed in a 1000 cubic foot room constructed so as to prevent infiltration of air. The room heater shall be operated for 15 minutes with the door of the room open and the room completely ventilated. The door shall then be sealed and the ventilation stopped. The heater shall be operated at normal test pressure. During the conduct of this test, the room air temperature shall be maintained at 80 F, plus or minus 5 F.	(1) Test Room or Chamber Size. The test shall be conducted in a room or chamber of sufficient size to hold the necessary equipment for conduction of the test, but no larger than 1000 cubic feet ( ) in volume.	The procedure requires the test to be conducted in a room of sufficient size to hold the necessary equipment but not larger than 1000 cubic feet in volume. The ANSI standard specifies that the test be conducted in a 1000 cubic foot room. However, room size is not significant in conducting this test. As the room becomes larger the time to deplete the oxygen increases, thereby increasing the time to conduct the test. The 1000 cubic foot limit on room size is equivalent to the ANSI requirement.
A sample of the room atmosphere shall be withdrawn at the start of the test and analyzed for CO_2 and O_2. The percent oxygen* in the room atmosphere shall be continuously monitored during the entire test. When the oxygen depletion shutoff system acts to shut off the gas supply to the room heater, the oxygen content of the room atmosphere, expressed in percent volume, shall not be less than 18.0 percent.		
This test shall be repeated with the heater operating at both the reduced and increased inlet test pressures specified in 2.3.1 with no change in adjustments.		
The above tests shall be conducted with the type(s) of gas selected by the manufacturer.		
	2) Air Infiltration The room, including the door, shall be constructed so that air infiltration into the room shall not exceed 0.25 volume changes per hour when determined under the following conditions: Heater input rate = 40,000 Btu/hr ( ), Room Temperature = 70°F ( ), Temperature External to Test Room = 70°F ( ), Wind velocity External to Test Room = Zero mph ( ).	The test is best conducted in a sealed room since the greater the amount of air leaking into the room, the longer it will take oxygen to deplete to the 18% shut off level. However, since the test is only measuring the level of oxygen at ODS shutdown, air filtration is not critical. Section 1212.6(a)(2) of the CPSC standard requires the room to be constructed so that air infiltration into the room shall not exceed 0.25 volume changes per hour when determined under specific conditions. This is a change from the ANSI standard which requires prevention of infiltration. However, the Commission believes that since the NBS achieved satisfactory performance of the ODS in a room constructed so that air infiltration was limited to 0.25 volume changes per hour, it is not necessary to require a test facility with a better seal. Air infiltration of 0.25 changes per hour is sufficiently low that the test can be conducted and accurate results achieved.
	These restrictions are specified to establish a base for determining air infiltration rate only and are not conditions for the test.	

* As an alternate to monitoring oxygen concentration, carbon dioxide concentration may be monitored and converted to percentage oxygen by use of the graph or formulas shown in Appendix E.

APPENDIX E.

RELATIONSHIP OF CARBON DIOXIDE TO OXYGEN IN THE CLOSED ROOM TEST SPECIFIED IN 2.9 OF THIS STANDARD
(This Appendix is informative and is not part of the standard).
When a gas-burning appliance is operated in a room constructed so as to prevent the infiltration of air, the rate of increase in the precent carbon dioxide in the closed room atmosphere is directly proportional to the rate of decrease in the precent oxygen in that closed room atmosphere. The specific ratio between CO_2 and O_2 is dependent on the ultimate CO_2 resulting from the combustion of the particular fuel gas used. The ultimate CO_2, which will vary as a result of the specific composition of the fuel gas, for each of the Test Gases specified in this standard is as follows:

ANSI	CPSC	RATIONALE
TEST EQUIPMENT AND PROCEDURES		

Test Gases	Ultimate CO_2
A	12.2
B and C	11.82
D, E, F, and G	14.0

The following equations may be used to calculate the relative values of CO_2 and O_2 in the closed room atmosphere for a specific test gas.

$$x = 20.93 - y\left(\frac{20.93}{y_1}\right)$$

When a gas-burning appliance is operated

$$y = \frac{y_1}{20.93}\ (20.93 - x)$$

where:

x = percent O_2
y = percent CO_2, and
y_1 = ultimate percent CO_2

Using the above equations, the graph shown in Figure A-1 was developed as an example to show the relationship of oxygen to carbon dioxide in the atmosphere of a closed room in which a gas-fired appliance is operated on natural gas (test Gas A) and on liquefied petroleum gases (test Gases D and E) and a 1400 LP gas-air mixture (test Gas G.)

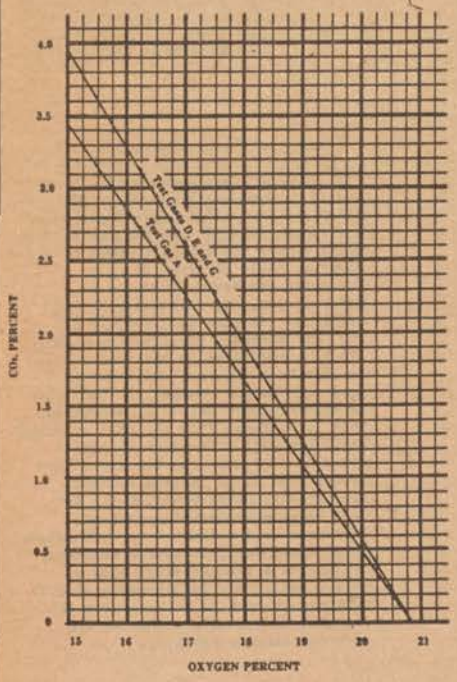


Figure E-1

Relationship of CO_2 to O_2 in the Closed Room Test (Sec 2.9)

3) Provisions for Remote Measurement

Provisions shall be made for the remote measurement and recording of the room air temperature, oxygen or carbon dioxide concentration, and barometric pressure. Room air temperature shall be measured with at least five thermocouples at different levels and plan locations to provide an average room air temperature. The oxygen or carbon monoxide concentration in the room atmosphere shall be measured at a minimum of five locations, the same as the thermocouples above. Five separate measurements or a single measurement through the use of a manifold which samples at the five locations may be used. Barometric pressure may be measured at any location in the test room.

The requirement in Section 1212.6(a)(3) provides for remote measurement and recording of room air temperature, oxygen or carbon dioxide concentration and barometric pressure. This is not a specific requirement in the ANSI standard but is implied because these parameters are necessary in the determination of the heater and ODS performance. CPSC wishes to make clear the parameters which are necessary to measure. The same section specifies that the temperature shall be measured with at least five thermocouples at different locations, that the oxygen or carbon dioxide concentration shall be measured at the same locations as the temperature, and that the barometric pressure may be measured anywhere in the test room. Measurement of temperature and oxygen concentrations are necessary at several locations in order to assure an accurate average. CPSC will use five locations for measuring temperature and oxygen or carbon dioxide concentration in order to assure an accurate average temperature and an accurate oxygen or carbon dioxide concentration. Barometric pressure is naturally uniform through the room.

4) Air Temperature. During the conduct of this test the room air temperature shall not exceed 80°F ( ) nor fall below 60°F ( ). The temperature shall be measured and recorded during the entire test to the nearest 1°F (°C). The correction for conversion to the standard condition of 70 degrees Fahrenheit and 30 inches of mercury is:

Corrected Oxygen at Shutdown =
Measured Oxygen at Shutdown $\times \frac{(460+70)}{(460+T_R)} \times \frac{(P_B)}{(30)}$

Where T_R = ambient temperature (°F) in test room at shutdown, and P_B = barometric pressure (inches Hg) in test room at shutdown.

In section 1212.6(a)(4) the allowable variation in room temperature has been changed from the ANSI requirement of 80 ± 5 °F to between 60-80° F. This has been done because a 10°F range is too restrictive. The room temperature is not a critical factor in the test because the results are corrected to 70° F regardless of the test conditions. The requirement for measuring temperture to 1° F is specifed in the CPSC standard so that the use of temperature measuring devices with sufficient accuracy are used to assure reasonable maintanence of conditions without being unnecessarily severe. The correction to 70° F is not included in the ANSI standard but has been added to the proposed standard so that test results of different temperatures and barometric pressures can be referenced to a standard condition for purposes of evaluation.

ANSI	CPSC	RATIONALE
	TEST EQUIPMENT AND PROCEDURES	
	5) Oxygen/Carbon Dioxide Concentration. The oxygen or carbon dioxide concentration in the room atmosphere shall be measured during the entire test and recorded to the nearest 0.1%. When carbon dioxide is measured the following equation will be used to calculate the relative value of oxygen in the room atmosphere for a specific test gas. $x = 20.93 - y \frac{(20.93)}{y_1}$ where: x = percent O_2 in room, y = percent CO_2 measured in room, y_1 = ultimate percent CO_2 resulting from stoichiometric combustion of the specific test gas, 20.93 = maximum percent oxygen	The test procedure at Section 1212.6(a)(5) of the proposed standard incorporates provisions of the ANSI standard which address measurement of oxygen or carbon dioxide in the room atmosphere. The ANSI standard requires sampling for CO_2 and O_2 at the start of the test. This requirement has been excluded from the proposed standard because it is not necessary for the ODS test. ANSI uses it when the ODS test and a test required in another part of the ANSI standard (the combustion test) are performed concurrently. The proposed standard does however, contain a requirement for monitoring oxygen or carbon dioxide during the entire test, including ODS shutoff, but not continuously as specified in the ANSI standard. The Commission believes that while it is necessary to have a coherent record of O_2 and CO_2, it is not necessary to have a continuous history. Periodic measurements of O_2 and CO_2 are believed to be sufficient for the purposes of the ODS test. Another requirement of the proposed test procedure is concerned with the method of converting the measurement of CO_2 to the appropriate O_2 value by means of a basic equation. This procedure is taken from the ANSI Standard and is used when CO_2 is monitored instead of direct monitoring of O_2. Monitoring CO_2 is easier than monitoring O_2 because equipment is less complex and less costly. There is no difference in test results when measuring either CO_2 or O_2 because there is an explicit and predictable relationship between CO_2 and O_2 in a closed room.
	6) Air Circulation. The atmosphere of the room shall be evenly mixed and shall not interfere with the operation of the heater under test. Air circulation shall be provided so that sufficient mixing is attained without causing movement of the main burner, pilot burner or oxygen depletion sensor flame. A fan or blower with a discharge capacity of 320 cubic feet per minute ( ) shall be used in a 1000 cubic foot ( ) room. (Smaller test rooms will require a lower discharge capacity.)	At Section 1212.6(a)(6) the requirement for air circulation to mix the room atmosphere has been added so that meaningful test results can be obtained from any part of the room. ANSI has added this to its standard for certain other tests in Z21.11.2 and is proposing to add it to the ODS test requirement. In addition, NBS recommended that this requirement be added. The air circulation equipment discharge rate is not a part of the ANSI standard but included in the proposal to provide information about the air movement.
2.2 TEST GASES In conducting the performance tests specified herein, gases with characteristics approximately as shown in Table VIII shall be used. TABLE VIII CHARACTERISTICS OF TEST GASES Gas A (Natural) 1075 0.65 Gas B (Manufactured) 535 0.38 Gas C (Mixed) 800 0.50 Gas D (N-Butane) 3200 2.00 Gas E (Propane HD-5) 2500 1.55 Gas F (Propane-Air) 700 1.16 Gas G (Butane-Air) 1400 1.42 Gas H (Propane-Air) 1400 1.30	(b) Test Gases The test shall be conducted with the type(s) of gas for which the heater is designed, as specified by the manufacturer, except that a heater for use with Natural gas shall be tested with Natural gas and butane-air. Gases with characteristics approximately as shown below shall be used. CHARACTERISTICS OF TEST GASES Natural 1075 0.65 12.2 Manufactured 535 0.38 11.82 Mixed 800 0.50 11.82 N-Butane 3200 2.00 14.0 Propane HD-5 2500 1.55 14.0 Propane-Air 700 1.16 14.0 Butane-Air 1400 1.42 14.0 Propane-Air 1400 1.30 14.0	The proposed standard requires at section 1212.6(b) that the test of the ODS is to be conducted with the types of gases for which it is designed The characteristics of the test gases to be used are described. This requirement is taken from the ANSI standard and is justified on the basis that the ODS should be tested with the gas for which the heater is designed. Natural gas heaters are to be tested with natural gas and butane air gas to demonstrate the ODS equipped heater is capable of operating with a variety of gas compositions likely to be available in Natural gas lines in the United States. The column showing ultimate CO_2 (%) values is included in this chart for convenience. It is taken from Appendix A of ANSI Z21.11.2.

ANSI	CPSC	RATIONALE
	TEST EQUIPMENT AND PROCEDURES	
(See paragraph 2.9 Oxygen Depletion Safety Shutoff Systems - Method of Test, above)	(c) Procedures The heater shall be assembled and adjusted in accordance with any instructions provided by the manufacturer. It shall be installed near the geometric center of the test room floor. The heater shall be started and set at maximum input. The door of the room shall then be closed. The heater shall be operated at maximum input until the oxygen depletion sensor shuts off the heater. When the oxygen depletion sensor acts to shut off the gas supply to the heater the following shall be determined and recorded: 1) oxygen (or carbon dioxide) concentration of the room atmosphere 2) average room temperature 3) barometric pressure The necessary corrections and conversions shall be made and the test results recorded.	The proposed procedure at section 1212.6(c) requires the heater to be assembled and adjusted in accordance with the manufacturer instructions. This is a change from the ANSI standard which specifies certain detailed adjustment requirements that the Commission believes are unnecessarily restrictive for the intended purpose of the test. Consumers generally would assemble and operate a heater in accordance with instructions supplied with the heater by the manufacturer. Therefore, assembling the heater for testing in accordance with the manufacturers instructions tends to simulate actual consumer use. The proposed procedure also at section 1212.6(c) requires installation of the heater in the test room, operation of the heater at maximum input rating, closing the door, and then continuing to operate the heater at maximum input until the oxygen depletion sensor operates to shut off the heater. These requirements are from the ANSI standard test procedure. However, the ANSI requirement for 15 minutes of preheating has been deleted because ANSI runs the ODS shutdown test concurrently with a closed room combustion test that is not part of the proposed standard. The preheating period is needed in that test so that the heater temperature is stabilized. Gas combustion in the presence of cold surfaces can generate higher levels of CO, thereby causing an undue bias in combustion test results. The requirement for operating the heater at the maximum input rating has been added in section 1212.6(c) for clarity. It is specified in other sections of the ANSI standard and should be applied also to this test. Heaters designed for operation over a range of inputs shall be operated at the maximum input of gas only because there is no need to simulate a particular set of room atmosphere conditions, good or bad, to determine the oxygen level at ODS operation. A requirement in the ANSI standard which has not been included in the proposal specifies that the ODS test is to be repeated with the heater operating at both reduced and increased inlet test pressures. This requirement has been excluded because testing at NBS has shown than inlet test pressures had a negligible effect on ODS shutdown performance. Also, heaters are required by ANSI to have pressure regulators which control inlet pressures and, therefore, only slight non-critical pressure variations would occur.

ANSI	CPSC	RATIONALE
	LABELING	
Section 1.21 Marking 1.21.4 Each room heater shall bear a clearly legible Class III marking adjacent to the lighting or control area on which appears the following statement: "WARNING: Minimum fresh air opening of _____ square inch must be provided for ventilation." The size opening specified shall be no less than 1 square inch per 1,000 Btu per hour input. The word "WARNING" shall be in letters at least ¼ inch high and the remainder of the wording in letters at least 1/8 inch high. 1.21.5 A room heater equipped with an oxygen depletion safety shutoff system shall bear a Class IIIA marking in a location where it can be easily observed on which appears the following statement: "This heater is equipped with an oxygen depletion safety shutoff system."	Section 1212.8 Labeling (a) Each heater shall bear an Integral Marking or Permanent Plate Marking which shall be conspicuous and clearly legible when the heater is in an installed position. The marking shall contain the following statement: **WARNING** When used without fresh air this heater may give off CARBON MONOXIDE, an odorless, poisonous gas. Open a window an inch or two for fresh air. This heater has a pilot light safety system that turns off the heater if not enough fresh air is available. Do not tamper with this safety system. If the heater shuts off, do not relight until you provide fresh air. If the heater keeps shutting off, have it serviced. Keep the burner and control compartment clean. Carbon monoxide poisoning may lead to death. Early signs of carbon monoxide poisoning resemble the flu, with headache, dizziness and/or nausea. If you have these signs, the heater may not be working properly. Get fresh air at once, and have the heater serviced Some people -- pregnant women, persons with heart or lung disease, anemia, those under the influence of alcohol, those at high altitudes -- are more affected by carbon monoxide than others. The word "WARNING" shall be in letters at least 1/4 inch high and the remainder of the wording in letters at least 1/8 inch high.	The proposed standard has a labeling requirement which is more comprehensive than the the labeling requirement in the ANSI standard. The label provides warning information on ventilation requirements, identifies populations which are at greatest risk, provides information on the function of the ODS, and instructions on what action to take if the heater shuts off. The warnings are necessary to provide sufficient information to allow the user to operate the heater safely, and to be aware of the potential hazards associated with the use of unvented gas space heaters in unventilated spaces. The label construction and material are specified in the proposed standard to insure that it will remain with the heater during its useful life. Definitions of label types are taken from the ANSI standard (see Class I and Class II labels in the definitions section above). The requirement also contains provisions related to the visibility of the labels.

BILLING CODE 6355-01-C

Modifications to the ANSI Standard

The section of the CPSA unde which the Commission proposes to adopt these sections of the ANSI standard, section 7(c)(2), (15 U.S.C. 2056(c)), provides that the Commission may make nonmaterial modifications to the existing standard before adopting the standard. A material modification is one which would substantially alter the purpose of the existing standard or the way in which the purpose of the standard is achieved. In this case, the purpose of the provision of the ANSI standard dealing with ODS is to shut off the supply of gas to unvented gas fired space heaters in order to avoid creation of high CO concentrations. Further, the ODS provision of the ANSI standard requires gas shutoff at less than 18% oxygen which is adequate for achieving the purpose of avoiding creation of high CO concentrations (2D–2). In proposing to adopt unchanged these provisions of the ANSI standard, the Commission is proposing those substantive provisions which are the essence of the ODS sections of the ANSI standard. The changes referred to in the chart above as well as the comprehensive labeling provisions of the proposed standard described, do not affect the inherent nature of the ANSI ODS provisions. Therefore, the changes noted in the above chart and the labeling requirement are nonmaterial modifications and are within the provisions of section 7(c)(2) of the CPSA.

Another function of the labeling requirements is to provide consumers with performance and safety information. Section 27(e) of the CPSA (15 U.S.C. 2076(e)) provides that the Commission may, by rule, require manufacturers to provide such information. Therefore, the labeling provisions, in addition to being proposed under the authority of Section 7(c)(2) are also proposed under the authority of section 27(e).

Labeling—Notification to Consumers of Performance and Safety Information

In considering what information should be provided to users of unvented gas-fired space heaters containing an ODS device, the Commission examined the information called for by labels required to be permanently installed on the heater under the ANSI standard. Such labels contain statements on (1) the necessity for keeping the burner and control compartment clean; (2) the need to provide for fresh air; and (3) a note that the heater is supplied with an ODS device (if it is so supplied).

However, since no information is provided on the reasons that an ODS is needed, namely, to avoid the hazard of CO poisoning, the ANSI label appears to be deficient in meeting the purpose of the ODS section of the ANSI standard. To remedy this situation § 1212.8 of the standard provides a requirement for a label warning of the hazards of CO exposure and describing the functioning of the ODS system (2G). Because the hazard of CO poisoning is not one of which people may ordinarily be aware as they might be of hazards that can be seen or touched, this information should be permanently and prominently affixed to the heater.

As described elsewhere in the preamble, the ODS system detects and monitors oxygen depletion; it cannot positively prevent CO emissions that could be a cause of concern to certain sensitive members of the population. Therefore, the label emphasizes the need for adequate ventilation.

Relationship of ODS to Other Parts of the Product

The proposed standard requiring and ODS system for unvented gas-fired space heaters to address the hazard of CO poisoning, should have no effect on other parts of the heaters or on any other potential hazards that may exist. On the other hand, the effectiveness of the ODS in reducing the CO hazard can depend, in part, on the predictable operating characteristics of the heater, such as providing for proper combustion with a minimum of CO production (1).

The Commission considers that the proposed ODS standard does not replace any voluntary standards or parts of such standards that may apply to other performance or construction characteristics of the heaters for addressing any other potential hazards such as thermal burns or fires. The Commission has not evaluated any provisions of voluntary standards that may deal with these other hazards and, therefore, neither approves nor disapproves them. However, a properly designed and constructed consumer product helps promote safety. Therefore, manufacturers of unvented gas-fired space heaters equipped with ODS systems are encouraged to adhere to customary good manufacturing practices such as may be needed to ensure that the products would be generally acceptable under state and local building codes.

F. Economic Considerations

The Commission has considered the potential economic effects of the proposed standard on industry and consumers, including possible changes in the cost of production and retail prices of unvented gas-fired space heaters equipped with ODS systems. A preliminary economic impact report, prepared by the Commission's economics staff in October, 1979 provides a more detailed discussion of the matters summarized below (*2E, 24*).

Owners of unvented gas-fired space heaters are concentrated in the south central and southeastern United States where climate conditions make central heating systems uneconomic for many households. These owners tend to be the elderly and low income groups of these regions and are most likely to be from among the rural population. Most households chose unvented gas-fired space heaters primarily for the low initial purchase price and low operating costs. These heaters have been among the least expensive heating appliances on the market, although improved voluntary industry standards have increased the price of these heaters. Retail gas space heater prices in 1978 for both vented and unvented heaters were about $140.00 for medium-sized 25,000 BTU heaters. Nevertheless, unvented gas-fired space heaters are not expensive to operate; since they have no flue openings to exhaust energy away from the heated area, they have a thermal efficiency approaching 100 percent and their fuel costs are lower than fuel costs for vented heaters.

Sales of unvented gas-fired space heaters have been steadily declining since 1967, due to rising consumer affluence, preference for central heating, and higher purchase price. In 1976, the last full year of production, about 180,000 heaters were produced. Production was sharply curtailed in 1977 to 82,000 heaters (possibly because industry anticipated government regulation) and was nonexistent in 1978. The declining production and sales pattern might change, however, in light of the rapid increase of energy costs and the efficiency and relatively low operating costs of unvented gas-fired space heaters. Information from the industry indicates that after these years of curtailed production, manufacture of unvented gas-fired space heaters (without ODS devices) has been resumed (*2 J–2*). While specific production data are not yet available, based on informal discussions with manufacturers and industry associations, Commission economists estimate that production for the year 1979 would be about 120,000, mostly targeted at the heater replacement market.

United States heater manufacturers are engaged in research to produce

unvented gas-fired space heaters equipped with ODS systems, and some have submitted their heaters to the French manufacturer of ODS devices for testing application of the European ODS device to U.S. heaters. A heater manufacturer has also sent heaters for testing of ODS application to a U.S. manufacturer of gas controls (*2 J–3*). Commission economists estimate that the cost to manufacturers of applying the European ODS device would be no more than $5.00, including materials and development costs. If design changes to U.S. heaters are needed, as some heater manufacturers believe, the increase at the retail level for ODS-equipped heaters is estimated to be between $10.00 and $17.50. It may be, however, that competitive pressures could keep the final retail price increase using the European device to about $10.00.

If heater manufacturers use an American ODS device now being tested by an American gas controls manufacturer, the cost picture could change because no new hardware or significant heater redesign appears to be needed. Thus, increased cost (about $2.00) would be incurred only for laboratory testing and certification of the ODS system and prototype heaters equipped with ODS systems, resulting in a possible retail price increase of from $4.00 to $7.00.

Commission economists estimate that beginning with 1980, production of unvented gas-fired space heaters could approach the 1976 production level of 180,000, the last year of full production. Rising production may continue, since unvented gas-fired space heaters provide efficient, inexpensive, noncentral heat. Constantly rising fuel costs are considered a factor in the expectation of rising production (*2E*).

Costs and Benefits

Commission economists examined the matter of costs and benefits in relation to a standard for unvented gas-fired space heaters equipped with ODS systems (*2E*). The staff assumed based on industry projections, that 120,000 units would be produced in 1980. Based on industry information, the average life expectancy of such a heater was assumed to be 15 years, plus or minus 5 years (that is, at the end of 15 years, one half of the original 120,000 heaters would still be in use). A maximum lifespan of 25 years was assumed, by the end of which most of the 120,000 heaters would be replaced by newer heaters. From such factors as heater life and number of heaters produced in the past, it was estimated that 7,681,000 heaters were in use in 1977, the same year for which CPSC staff estimated 70 deaths were associated with unvented gas-fired space heaters (see discussion above under Degree of the Risk of Injury). Using the figures 7,681,000 heaters in use and the estimate of 70 deaths per year, an expected death rate associated with CO poisoning of .0000091 per heater was derived. This number was then applied to the 120,000 heaters predicted to be manufactured in 1980, in order to calculate the number of deaths that would occur over the lifespan of these heaters.

For the 120,000 heaters produced in 1980 without an ODS device, it is estimated that 16 lives would be lost. If these 120,000 could have been equipped with ODS devices, and assuming that the ODS is 90 percent effective in preventing CO deaths, the addition of an ODS would save 14 of the 16 lives. (The figure of 16 lives lost is derived over the 25 year lifespan of the heater.) * It would be expected that deaths associated with these 1980 produced heaters would rise as the heaters age. The ratio of .0000091, the estimate of 70 deaths a year, and the number of 1980 units in use over 25 years, result in the estimate of 16 lives lost from the 1980 units during their 25 year lifespan. The estimate of 90 percent effectiveness of ODS in reducing CO deaths is based on an examination of autopsy reports for 22 CO deaths described in table 2, Degree of the Risk of Injury. CPSC estimates from the amount of carboxyhemoglobin detected in the autopsies, that 20 of the 22 individuals would have survived if an ODS system had been attached to these heaters and shut off the gas supply when oxygen was depleted below 18 percent.

The benefit to society from lives saved are extremely difficult to estimate in dollars. Therefore, the Commission staff examined price increases of unvented gas-fired space heaters equipped with ODS to determine how much it would cost to save lives that could be lost to heaters not equipped with ODS systems. Assuming that the American-produced ODS discussed earlier would increase by $2.00 the cost to the manufacturer, the figure of 120,000 heaters produced in 1980 would cost manufacturers an additional $240,000 if equipped with ODS systems. For consumers, the American-produced ODS would increase the cost for a heater by $4.00 to $7.00, or by an additional $480,000 to $840,000 for the projected 1980 output of 120,000. For heaters with the European system the increased cost for 120,000 units to manufacturers would be no more than $5.00 per heater or $600,000 for 120,000 heaters. The increased cost to consumers for the European device would be $10 to $17.50 for a single heater or between $1.2 million and $2.1 million for the projected 1980 output of 120,000.

If the cost estimate of $480,000 to $840,000 for the American ODS is divided by the number of lives expected to be saved, 14, the ODS device would cost approximately $33,300 to $40,000 per life saved. If the cost estimates of $1.2 million to $2.1 million of the European device are used, the cost for a life saved would range from $83,300 to $146,000 (*2E*).

In the area of consumer product safety, the Commission believes it is inappropriate and further, it is not necessary, to assign a monetary value to human life. Nevertheless, since value-of-life estimates (based either on the discounted future earnings methodology which start at about ¼ million dollars per life, or the willingness-to-pay approach which ranges upward to 2 million dollars per life) are considerably higher than $146,000, the highest estimate of a cost per life saved, the Commission considers adoption of an ODS system to be a worthwhile objective. (For a discussion of the methodology of cost/benefit analysis and estimates of the value of life, refer to "Suggested Readings for Cost Benefit Analysis, Value of Life and Discount Rates", a summary of readings on these subjects suggested by Commission economist, (*10*).

The safety benefits (lives saved) by requiring that unvented gas-fired space heaters be equipped with ODS, would occur over a number of years, while costs for such heaters would occur in the year of purchase. In the years following adoption of the proposed standard, the benefits would increase as heaters equipped with ODS devices replace older heaters not similarly equipped. By the time almost all unvented gas-fired space heaters comply with the standard, the expected safety benefits would be 63 lives saved per year (*2E*).

G. Environmental Considerations

An assessment has been made of the potential environmental impact of the proposed standard (*2E*). The assessment addresses potential effects of the proposed regulatory action on the production, distribution, consumption and disposal of unvented gas-fired

* It assumes that in the first year of life of the 120,000 heaters, all 120,000 are in use. Therefore, 120,000 heaters times the death rate (.0000091) means that 1.09 deaths occur in the first year. In each succeeding year some of the 120,000 heaters go out of service and thus the number of deaths attributable to that year's production is lowered. When the deaths for each year for 25 years are added together, the result is 16 deaths.

space heaters and concludes that the proposed standard would not have a significant effect on the quality of the human environment.

Unvented gas-fired space heaters equipped with ODS would result in a safe product that is 100% thermally efficient because energy is not exhausted outside the residence. Thus, consumers could experience savings in fuel consumption over other kinds of heaters. Technical innovation related to this standard could have a beneficial impact on fuel consumption in the future, since the use of ODS could be considered for other products. Patterns of disposal of this product are not expected to be altered by this proposed standard. Moreover, a safety standard would not be expected to result in such changes in methods, materials or other factors of production and distribution that would be of significant consequence to the environment.

Upon reviewing these factors and others raised in the environmental assessment report and accompanying finding of no significant impact on file at the Office of the Secretary, it appears to the Commission that the proposed standard would not lead to any significant impact on air and water quality, solid waste disposal, land use, energy use, or other aspects of the physical environment. Since a significant effect on the quality of the human environment is not anticipated from this proposed standard, the Commission concludes that an environmental impact statement is not needed.

H. Effective Date

Among the factors considered in determining a proposed effective date are the need for the standard in order to reduce the risk of injury adressed by the standard and the time it would take the industry to produce the product described in the standard that is intended to reduce the risk.

In proposing this standard, the Commission preliminarily determines that an unreasonable risk of injury from CO poisoning is associated with unvented gas-fired space heaters. Information available to the Commission indicates that 120,000 of these heaters were produced in 1979, and that a like number will be produced in 1980, (*2E*).

Therefore, the proposed standard, which requires products to be equipped with ODS systems for the purpose of preventing an atmosphere that may be hazardous to human life, should be issued at the earliest possible time. Although ODS systems are not now available on unvented gas-fired heaters produced in the U.S., the Commission has preliminarily concluded that the technology exists for U.S. manufacturers to apply ODS systems to U.S. products, and that it is feasible to manufacture unvented gas-fired space heaters equipped with ODS systems (*2 D–2*).

Upon careful consideration of the relevant information, as discussed below, the Commission proposes that the effective date of this proposed standard be December 31, 1980.

Additional time is needed to develop an ODS for application to U.S. heaters. In the gas appliance industry, it is customary to have a device of new application such as ODS tested by an independent qualified gas testing laboratory prior to using it in a product (*25*). This customary industry practice of having gas appliances evaluated by a qualified gas testing laboratory appears to be a routine practice and is a prerequisite, in many areas, to acceptance of the gas appliance under state and local building codes. The laboratory certifies to the user of the device, in this case the heater manufacturer that the device is suitable for use. The heater manufacturer would then obtain the ODS devices from the manufacturer of gas controls and incorporate the device into the gas appliance after making whatever modifications may be necessary to the appliance. Further, in accordance with usual industry practice, the assembled product, an unvented gas-fired space heater equipped with ODS, would then be examined and tested as an entity by the gas testing laboratory which would certify to the heater manufacturer and customers of the heater manufacturer that the unit is suitable for use. Production of the heater by the manufacturer would generally not take place until the examination is concluded in order to be certain that further modification of the heater is not needed (*2 J–3*).

Manufacturers of unvented gas-fired space heaters are having their heaters examined by manufacturers of gas controls with a view toward developing an ODS that can be applied to U.S. heaters. The manufacturer of ODS systems generally used in European heaters plans to submit to the American Gas Association testing laboratory for evaluation, an ODS device suitable for American heaters (*2 D–2*).

Several American manufacturers of gas controls are also developing ODS systems for American heaters. One of the ODS systems now being tested has shown the capability of gas cutoff at 17.9% oxygen when tested alone in a test chamber. On a heater, this ODS system has achieved gas shutoff at 17.4% oxygen in just a few months of application effort. Three other U.S. manufacturers of gas controls have also committed resources to ODS development.

On the basis of this continuing effort, the Commission's engineering staff estimates that a working ODS device will be available from manufacturers of gas controls by the end of 1979. At that time, the gas testing laboratory would be expected to take approximately 3 months to conduct the performance and life cycle tests necessary to evaluate the ODS device (*2 D–2, J–3*).

Once an ODS device has been tested by the gas testing laboratory, manufacturers of unvented gas-fired space heaters can take the steps needed to begin production. The first and most technical phase of this process is development of prototype models containing the ODS, and testing and evaluation by the laboratory of these prototypes. Manufacturers have estimated the time for this activity to be from 6–12 months depending on the extent of heater redesign needed to incorporate the ODS device. Minor redesign would require about 6 months; more extensive redesign could require 12 months. Commission technical staff and industry spokesmen do not consider it likely that major redesign would be needed; therefore, the Commission considers that 6 months would be adequate for any redesign. Optimistic estimates of the time needed for production of ODS-equipped heaters, based on the assumption that redesign would not be needed, were two to three months (*2 D–2*).

For the second or production phase, manufacturers estimate that to prepare the qualified prototypes for production could take from 6–12 months to redesign and fabricate tooling, order materials, establish a quality control program and set up the production line. The technical problems of heater redesign for the purpose of incorporating ODS devices that might be needed during the first phase of the process are likely to be more complex than the second phase, preparing for production. Thus, where heater redesign problems are considered to be minor, it is likely that production problems would also be minor. Therefore, since heater redesign, if needed, could probably take place within six months, it is likely that six months would be sufficient to prepare for production of ODS-equipped unvented gas-fired space heaters.

These estimates, provided by members of the industry, indicate that ODS-equipped heaters could be ready for the American market from 9 to 15 months after an ODS system is

submitted to a gas testing laboratory for evaluation, (*2 D–2, J–3*). This means that by allowing a reasonable development period estimated by industry for its needs, the production of tested and evaluated unvented gas-fired space heaters equipped with ODS systems could be accomplished by March 31, 1981; by allowing a short development period, for example, if no redesign is needed, production of ODS-equipped heaters could be accomplished some time in September 1980.

Theoretically, a September 1980 effective date for the proposed standard could effect the most immediate reduction in the risk of injury addressed by the standard. However, a review of the usual manufacturing and marketing practices of the unvented gas-fired space heater industry shows that September 1980 would not be a practicable effective date.

The usual practice of the industry is to obtain order commitments from heater distributors during the first calendar quarter of the year. Manufacture and distribution of the product generally does not take place until the second and third calendar quarters. Consumers usually buy unvented gas-fired space heaters in the fall and winter (*2E*). Thus, an effective date in September 1980 would have little influence on 1980 production, since 1980 production would have begun by March 1980 and probably ended by late May or early June 1980. (A March 1980 effective date would not be reasonable since the most optimistic prediction for ability to produce an ODS-equipped heater is September 1980). Therefore, an early effective date such as September 1980, since it could not affect a production cycle, would provide little benefit in the way of reduced risk of injury.

To avoid marketing of unvented gas-fired space heaters manufactured during the next, 1981, production cycle, it would be necessary for the effective date of the standard to be no later than March 31, 1981. Coincidentally, this is the end date for the industry estimated development period for producing ODS-equipped heaters that appears, at this time, to be reasonable. Therefore, it could be assumed that a March 31, 1981 effective date would probably have no adverse impact on industry. Since a March 31, 1981 effective date would precede the 1981 production cycle, it would also avoid possible proliferation of products not equipped with ODS systems.

However, a March 31, 1981 effective date may still contain elements of uncertainty because it occurs three months into the manufacturing/marketing cycle. Distributors may not know whether or not the heaters for the selling season will be equipped with ODS systems. Manufacturers of gas controls may be uncertain as to whether ODS systems are required components of unvented gas-fired space heaters for the 1981 production season. To avoid these uncertainties, it appears to the Commission that an effective date of December 31, 1980 would be preferable. It is consonant with the beginning of the production cycle and provides certainty to all the elements of the industry. Since December 31, 1980 is just prior to usual industry planning for the 1981 production year, it would be expected to have even less impact on industry than would an effective date of March 31, 1981.

The Commission believes it worthy of commendation that many elements of the industry, including heater manufacturers, gas controls manufacturers, as well as voluntary standards and trade groups are diligently engaged in resolving the remaining problems of applying ODS systems to unvented gas-fired space heaters. This ongoing activity, in which the Commission staff is actively involved, indicates that ODS technology is ready for application to U.S. heaters (*2 D–2, F–1, J–3*). Therefore, the proposed effective date of the proposed standard contained in § 1212.2 below, December 31, 1980, is realistic and technologically attainable.

Comments are particularly invited on the issue of the proposed effective date. Such comments will be carefully considered by the Commission before any final standard is issued.

Stockpiling

Section 9(d)(2) of the CPSA (15 U.S.C. 2058(d)(2)) provides that the Commission may, by rule, prohibit manufacturers from stockpiling a product to which a standard applies. Stockpiling to circumvent the purpose of a standard, is defined in the CPSA as manufacturing or importing a product between the date a standard is issued and its effective date, at a rate which is significantly greater than the rate at which it was produced during a base period stated in the rule.

A stockpiling requirement for the period between the issuance and effective dates of this proposed standard is not provided because, at this time, it would serve no useful purpose. As explained in the discussion above on effective date, the production of unvented gas-fired space heaters is generally confined to the second quarter of the production cycle (which corresponds to the second quarter of the calendar year). The probable issuance of a final standard for this product is some time in the third quarter of 1980 and the proposed effective date is December 31, 1980. This means that the period between issuance and effective date would fall during a period of the production cycle when manufacture of unvented gas-fired space heaters would not be taking place. Since section 9(d)(2) provides that a stockpiling provision would apply only to the period between issuance and effective date of the standard, the Commission concludes there is no need for such a provision at a time when only distribution and sale rather than manufacture is taking place. Subsequent events such as changes in manufacturing practices, not now foreseen, may show that a rule is needed, in which case a stockpiling rule would be proposed for public comment. In the interim, the Commission solicits comments from manufacturer of unvented gas-fired space heaters concerning their anticipated manufacturing cycles for the next several years.

I. Enforcement Considerations

Certification of Compliance by Manufacturers and Importers

All manufacturers and importers of unvented gas-fired space heaters subject to the standard are responsible for manufacturing products that meet its requirements.

Section 14(a) of the CPSA (15 U.S.C. 2063(a)) requires manufacturers (including importers) and private labelers of a product subject to standard to issue a certificate of compliance that accompanies the product to the distributor or retailer to whom it is delivered. The certificate must state that the product complies with any applicable standard, name the standard, provide the name of the manufacturer, and the date and place of manufacture. The certificate must be based on a test of each product or upon a reasonable testing program.

Section 14(b) of the CPSA also provides that the Commission may, by rule, prescribe reasonable testing programs for products requiring certification. In addition, section 14(b) provides that, at the option of the manufacturer, the tests which are the basis for certification of compliance may be performed by another person such as an independent laboratory qualified to perform such tests.

Section 14(c) provides that the Commission may, by rule, require the use and prescribe the form and content of labels containing certification by manufacturers that products comply with the standard, and information

relating to identification of the manufacturer.

Under the proposed standard, manufacturers are responsible for certifying that their products comply with the standard. Since it would serve no useful purpose to have private labelers also certify that products manufactured by another comply with the standard, it would be unnecessarily duplicative to require certification by private labelers. Further, manufacturers are in the best position to either test the product or provide for a reasonable testing program. Therefore, manufacturers continue to be responsible for certifying that their products comply with the standard even though the product bears the name of a private labeler and is distributed through the facilities of the private labeler. Thus, manufacturers are responsible for issuing certificates of compliance.

Importers of unvented gas-fired space heaters are responsible for issuing certificates of compliance. If tests or a reasonable testing program have been performed by the foreign manufacturer, the importer may rely on such tests to support the certificate of compliance so long as the importer is a resident of the U.S. or has a resident agent in the U.S. and the test records are maintained in the U.S. Importers are responsible for assuring that the testing required to support the certificate of compliance has been performed properly with acceptable results, and that records of the tests are accurate and complete. Manufacturers and importers are also responsible for maintaining records of tests or testing programs whether these are performed by the manufacturer, or a qualified, independent laboratory. The proposed standard provides that certification by the manufacturer or importer shall be stated on a permanently affixed label which also explains the presence of the ODS system.

Testing

Section 1212.6 of the proposed standard describes the test procedures which the Commission will use to determine whether unvented gas-fired heaters meet the requirements of the standard, although there is no provision in the standard requiring manufacturers to use the same test procedures to determine compliance with the standard. Section 1212.21 describes general requirements for manufacturers concerning testing but does not specify a reasonable testing program.

The test described at § 1212.6 is fairly simple and inexpensive to perform, and does not impair the product. The test may be used for each individual heater or may provide the basis of a reasonable testing program.

The Commission observes that U.S. manufacturers of gas appliances have had considerable experience in being responsible for testing their products because many state and local jurisdictions provide that gas appliances must meet certain building code requirements before they can be installed for residential use. Many jurisdictions require, in addition, that gas appliances such as unvented gas-fired space heaters be certified by qualified testing laboratories as a prerequisite to permitting installation in homes (*13*). Thus, the Commission anticipates that manufacturers who adhere to customary good manufacturing practices that are generally acceptable under state and local building codes would be able to certify to the Commission that their products comply with the proposed standard.

The Commission is presently unaware of information indicating that it will be necessary to prescribe a specific reasonable testing program for unvented gas-fired space heaters equipped with ODS. Therefore, manufacturers and importers may either test each heater, or develop their own reasonable testing programs for certification purposes. Further, so long as the responsible firm certifies compliance with the standard, a reasonable testing program may be performed by a qualified testing laboratory, such as those qualified testing laboratories that perform tests generally found acceptable under state and local building codes.

Should the Commission's enforcement activities relative to these products indicate that the testing programs used are not adequate to ensure that the heaters comply with the standard, the Commission could develop and issue a mandatory testing program.

Recordkeeping

Proposed § 1212.23 of Subpart B requires that manufacturers and importers of unvented gas-fired space heaters subject to the standard maintain written records demonstrating that compliance certificates are based on tests of unvented gas-fired space heaters or a reasonable testing program, and to retain such records for 3 years.

No specific format is prescribed for the record, but the records are required to contain sufficient information to show the nature of a firm's testing procedures, to identify the heater or group of heaters that are certified as a result of the test data, and to show whether the space heaters which are being marketed and certified to comply with the standard, are essentially identical in every respect that relates to compliance with the standard, to the space heaters that were tested for conformance with the standard.

These records, besides aiding Commission enforcement of the standard could be helpful to a manufacturer or importer in limiting the scope of a possible recall order under section 15 of the CPSA. (The Commission is authorized under section 15 to order a manufacturer (including importer), or distributor or retailer of a product which is found, after opportunity for a hearing, to present a "substantial product hazard" to elect one of the following remedies: repair the defective product, replace the product with a non-defective product, or refund the purchase price of the product.) "Substantial product hazard" is described in section 15 to mean a failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public, or a product defect, which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of risk, or otherwise) creates a substantial risk of injury to the public.

The recordkeeping requirements of § 1212.23 are issued under the authority of section 16(b) of the CPSA, which authorizes requirements for the establishement and maintenance of records that are necessary to implement the act or to determine compliance with regulations issued under the act. The records are necessary to monitor compliance with the standard requiring ODS systems for unvented gas-fired space heaters.

Section 16(b) further provides that these records must be made available for inspection by duly designated agents of the Commission upon request.

Product Certification and Labeling

Proposed § 1212.22 requires manufacturers and importers of unvented gas-fired space heaters to affix to the heaters permanent labels which shall be considered a "certificate" of compliance, as the term is used in section 14(a) of the CPSA. Section 14(c) authorizes the Commission to issue rules requiring a product to bear a label containing information similar to that required by section 14(a) for certificates.

The proposed certification label is required to be visible and legible to the consumer and is to include the following information:

1. The statement "Meets CPSC requirements for oxygen depletion safety shutoff systems."

2. The name of the manufacturer or importer issuing the certification label, (unless this information is permanently affixed elsewhere on the heater in a place easily visible to the consumer). This information may be in code when the product bears a private label provided the code mark permits the seller to identify the manufacturer to the purchaser upon his request.

3. The month, year and place of manufacture. This information may be provided in code, such as a serial number, so long as the meaning of each symbol in the code can be made available upon request by consumers, persons in the distribution chain and CPSC.

The proposed certification label is required to be incorporated in the permanent label described in § 1212.8(a) which describes the purpose of the oxygen depletion system in the unvented gas-fired space heater. To avoid confusion as to coverage of the certification, this label is to be separate and distinct from any use or operation labels provided by the manufacturer.

In deciding that certification for unvented gas-fired space heaters should be in the form of a permanent label rather than a separate certificate supplied to persons in the distribution chain, the Commission notes that the label will be visible to all in the distribution chain, and the certification will be immediately available if any questions concerning compliance with the standard arise about a particular heater. A permanent label will benefit consumers and industry, as well as the Commission, in the following ways:

1. For a period of time after the standard goes into effect, both complying and noncomplying heaters may be available on the retail market. A label affixed to the individual product will help consumers make an informed choice between complying and noncomplying products.

2. A permanent label will enable CPSC investigators screening products for compliance to distinguish between those manufactured before and those manufactured after the standard without examining retailers' or distributors' shipping records. Such an examination can be time-consuming and difficult.

3. A permanent label with an identification of the date and location of manufacture will be advantageous to manufacturers, importers, private labelers, distributors, retailers, and consumers in the event of a recall under section 15 of the CPSA.

Proposed Enforcement Policy

Compliance with a mandatory standard for unvented gas-fired space heaters would generally be established during on-site inspections at the manufacturing facility. The Commission plans to conduct such inspections during the second quarter of the calendar year, since that appears to be the peak production period for the heaters. During the inspection, the investigator would examine the product labeling and review the firm's records on testing and certification. If during any such inspection the investigator concluded that there was reason to believe that a particular heater did not meet the requirements of the standard, a sample heater would be collected for testing in accordance with the standard. In addition, before the first heating season after the effective date of the standard, a representative sample of heaters that have been manufactured to comply with the standard would be tested by or under Commission supervision to determine compliance with the standard.

Notice of Noncompliance

Section 15(b) of the CPSA (15 U.S.C. 2064(b)) provides that every manufacturer and importer of a consumer product distributed in commerce, and every distributor and retailer of that product who obtains information which reasonably supports the conclusion that the product is subject to and fails to comply with an applicable consumer product safety rule, shall immediately inform the Commission of such a failure. Thus, manufacturers, importers, distributors and retailers have a duty to report to the Commission any information they may have on the distribution in commerce of noncomplying unvented gas-fired space heaters. Commission regulations describing these requirements in detail can be found at Title 16 of the Code of Federal Regulations, Part 1115.

Failure to comply with the certification requirements in Subpart B below are not subject to the reporting requirements of section 15(b) since such requirements apply only to the standard itself at Subpart A, rather than to the procedures for certification and recordkeeping. Of course, failure to comply with the certification and recordkeeping requirements of Subpart B are subject other enforcement actions under the CPSA as appropriate, such as Civil penalties, criminal penalties or injunctive enforcement (sections 20–22 of the CPSA, 15 U.S.C. 2069–2071).

Since the reporting requirements of section 15(b) apply only to consumer products distributed in commerce, a test failure that occurs during a reasonable testing program for unvented gas-fired space heaters before the heater is distributed in commerce, is not subject to the reporting requirements.

J. Preliminary Statutory Findings

Section 9(c) of the Consumer Product Safety Act requires that prior to issuing a consumer product safety rule the Commission shall consider and make appropriate findings for inclusion in the rule. From information available to the Commission, as set forth in the bibliography to the proposed standard, the Commission has been able to draw preliminary conclusions which are set forth in § 1212.9 as proposed findings in the proposed standard. The proposed findings are subject to change by relevant information. Therefore, the Commission is particularly interested in obtaining information on the following matters:

(1) The degree and nature of the risk of injury which the rule is designed to eliminate or reduce;

(2) The approximate number of consumer products, or types or classes thereof, subject to such rule;

(3) The need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need;

(4) Any means of achieving the effect of the rule while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety;

(5) That the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk associated with unvented gas space heaters; and

(6) That promulgation of the rule is in the public interest (15 U.S.C. 2058 (b) and (c)).

Section 9(b) of the Act (15 U.S.C. 2058(b)) requires that in promulgating a consumer product safety rule, the Commission shall also consider and take into account the special needs of elderly and handicapped persons to determine the extent to which such persons may be adversely affected by the rule. Since it appears that many users of unvented gas-fired space heaters are elderly and possibly handicapped, the Commission solicits comments as to the potential effect of the proposed standard on this segment of the population.

Information currently available to the Commission on the degree and nature of the risk of injury from CO poisoning associated with unvented gas-fired space heaters, is mostly "death" data. A conservative estimate of 70 deaths a year is indicated by this data. Many of these deaths occur during sleep while

people are unaware and unprotected against CO emissions from these heaters. Since the symptoms of CO poisoning on a lesser scale such as headache, dizziness and nausea ((*2 D–4*) *9*) can be attributed to other illnesses, such symptoms are not generally reported.

The number of products that would be affected by the rule does not appear to be significant. Information from undustry indicates that the production of unvented gas-fired space heaters was stopped in 1978, although manufacture of this product has resumed.

Unvented gas-fired space heaters equipped with ODS devices will provide safe products to the primary users of these heaters who tend to be elderly, low-income residents of southern regions of the U.S. These unvented heaters have a high thermal efficiency, almost 100%, because the energy of the heater is not exhausted to the outside. When ODS systems are attached to such heaters, it would be reasonable to assume that their utility will be greatly enhanced by supplying safety while conserving energy. The retail price of a medium-sized unit of 25,000 BTU capacity was about $140 in 1978. Addition of the ODS would result in a minor price increase; it may range between $4 to $17.50 at retail depending on the ODS system used and the degree of modification needed to apply the ODS to the heater. Commission economists estimate that competitive pressures could result in a retail price increase of about $10 (*2E*).

The Commission is encouraged that industry is actively working toward incorporating ODS into unventd gas-fired space heaters although industry reports that additional research is needed before the product can be manufactured (*2 D–2*). The provisions concerning labeling as well as those concerning certification of compliance and recordkeeping required by the proposed standard are not expected to be a significant part of this price increase. The voluntary ANSI standard to which manufacturers now conform contains provisions on labeling and testing (*2 D–2*) which are required in order to obtain acceptance under many state and local building codes. Thus, since the requirements for certifiction, labeling, and recordkeeping of the proposed standard are not expected to significantly increase the usual administrative burdens on manufacturers for maintaining this kind of information, the Commission does not believe these factors are meaningfully involved in increased costs. The Commission believes that ODS equipped heaters will be available for use by the public in the near future.

In considering this information, the Commission weighed the factors of cost, utility and availability of unvented gas-fired space heaters and compared them with the hazards from CO emissions associated with the product. The factors of unknowing exposure to an atmosphere made life-threatening by CO buildup, particularly during sleep, and the consequent lack of opportunity for people to take steps to remove themselves from the harzard, causes the Commission to preliminarily conclude that the hazard of CO poisoning associated with unvented gas-fired space heaters outweighs the anticipated effect of the rule on the cost, utility and availability of these heaters. Therefore, the Commission preliminarily concludes that these heaters present an unreasonable risk of injury to the public.

Although the voluntary ANSI standard provides for an ODS system for unvented gas-fired space heaters, that provision is not currently required by the industry's certification program which is the basis of acceptance of gas appliances by state and local building and code officials. Further, although maufacturers are diligently engaged in efforts to apply ODS systems to unvented gas-fired space heaters, they are also currently producing and marketing unvented gas-fired space heaters that do not contain ODS systems. Based on statements by industry spokesmen (*2 J–3, I–5*), the Commission believes that production of such heaters, without ODS systems, would continue in the absence of a mandatory standard. Therefore, the Commission concludes that the proposed standard requiring unvented gas-fired space heaters to be equipped with ODS systems is reasonably necessary to eliminate or reduce the unreasonable risk, and that the proposed standard is in the public interest.

K. Possible Preemption

Section 26(a) of the CPSA (15 U.S.C. 2075(a)) provides that when a Commission standard is in effect, it preempts state and local standards or other regulations which apply to the same risk of injury associated with a consumer product—in this case the risk of CO poisoning associated with unvented gas-fired space heaters. An exception to preemption is provided in section 26(b) for state and local standards concerning products for a state or locality's own use, if those standards provide a higher degree of protection than the CPSA standard. In addition, section 26(c) provides that upon application by a state or locality, the Commission may, by rule, exempt from preemption a state or local regulation addressed to the same risk of injury from a consumer product where the Commission determines that such a regulation provides a significantly higher degree of protection than does the federal standard, and that the state/local regulation does not unduly burden interstate commerce.

The Commission believes that a discussion on preemption in the preamble to any final rule issued for this product could be helpful to the numerous jurisdictions that enforce rules on unvented gas-fired space heaters, as well as to consumers and industry members. The Commission recognizes that there may be a wide variety of different rules among state and local jurisdictions. In order to provide guidance concerning rules and regulations that are in effect, the Commission solicits responses to the questions set forth below from persons associated with administering state and municipal regulations, including building codes that would apply to unvented gas-fired space heaters. The questions are for guidance in gathering this information and should not be considered as limiting the kinds of information state and local official believe should be provided:

(1) Name of political entity.
(2) Title of rule.
(3) When was the rule adopted?
(4) Why was the rule adopted?
(5) Please provide the text of the rule.
(6) What potential injury or injuries are addressed by the rule and how are they addressed?
(7) Please state any provisions for enforcing the rule.
(8) If the Commission issues a final standard on unvented gas-fired space heaters, would you expect that your rule would continue in effect?
(9) If the Commission issues a final standard, would you expect your jurisdication to issue an identical rule that could be locally enforced?
(10) Please state the position, title and address of a person who could be contacted for further information.

In addition to soliciting comments on this subject by this notice, the Commission also intends to contact directly those state and local officials whose names are known to Commission staff members.

L. Extension of Time To Publish Final Rule

Section 9(a)(2) of the CPSA (15 U.S.C. 2058(a)(2)) requires the Commission to publish a notice of proposed rulemaking and to provide interested persons with

an opportunity to participate in the rulemaking through submission of written data, views, or arguments. In addition to these written comments, interested persons must also be given an opportunity to make oral presentations of data, views, or arguments.

Section 9(a)(1) of the CPSA provides that within 60 days after publication of a proposed rule, the Commission shall promulgate a final rule or withdraw the proposal. The Commission may extend the 60-day period for good cause and must publish its reasons for extension.

In order to encourage wide dissemination of the proposed rule on unvented gas-fired space heaters and to afford sufficient time for persons to submit written comments, the Commission is permitting a 60-day comment period. The Commission believes that additional time will be needed for staff analysis, Commission evaluation, and publication of any final rule. Therefore, the Commission believes that the 60-day time period provided in section 9(a) between publication of a proposed standard and publication of a final rule should be extended. To conserve the resources that would be needed to issue an extension of time during the comment period, the Commission announces the extension in this proposal, and finds that the need for additional time constitutes good cause for this extension. Therefore, the Commission extends for five months from March 18, 1980 to August 18, 1980 the period in which it must either issue a final rule for unvented gas-fired space heaters containing ODS systems or withdraw the proposed consumer product safety standard. This period may be further extended for good cause published in the **Federal Register.**

M. Date of Promulgation

Section 9 of the CPSA (15 U.S.C. 2058) sets forth the administrative procedures applicable to promulgation of consumer product safety rules and provides guidance concerning the time period for a rule to take effect after the date it has been promulgated by the Commission. However, the CPSA does not define the date of promulgation. In the absence of statutory direction or Commission guidance, therefore, there is an element of uncertainty as to when a rule is considered to be promulgated. Promulgation could take place when the Commission, at a public meeting, votes to issue a rule or when the **Federal Register** notice announcing the rule is signed by the Commission's Secretary, or at another time.

The uncertainty of date of promulgation may be important to those who believe they are adversely affected by a rule issued by the Commission. Section 11 of the CPSA (15 U.S.C. 2060) provides that such persons or groups may petition a U.S. Court of Appeals in the circuit of their residence or principal place of business for judicial review of the rule. In such a case, the Commission is required to respond by filing the record of the rule in the court chosen by the first person or group to file for judicial review.

Thus, persons or groups that are represented at a public meeting where the Commission votes to issue a rule and believe they are adversely affected by the rule, may properly try to be first to file for judicial review in a circuit of their own choosing. Persons or groups unable to be represented at such public meetings, whether for reasons of geographical or financial inconvenience, or otherwise, may also believe they are adversely affected by a Commission decision to issue a rule and yet not have an opportunity to file for judicial review in a forum of their own choosing.

The Commission believes it is important to remove the elements of uncertainty and possible unfairness that may occur concerning opportunity for judicial review of this proposed standard on unvented gas-fired space heaters by promulgating the rule on a date certain after its publication. The Commission observes that courts have traditionally approved a great deal of discretion to agencies in determining the manner in which their actions are promulgated; courts have deferred to the agency's choice as long as the choice is reasonable.

Accordingly, in order to provide the maximum amount of guidance possible to the courts and interested persons, the Commission proposes that this standard be promulgated at noon, Eastern Time, ten days after it is published as a final rule in the **Federal Register.** The Commission believes this choice of promulgation date is reasonable in that it provides sufficient time for interested persons to learn about the rule before a court can be petitioned for judicial review.

N. Conclusion and Proposal

Based on the foregoing information, the Commission preliminarily determines that unvented gas-fired space heaters present an unreasonable risk of injury due to CO poisoning, and that a consumer product safety rule is reasonably necessary to eliminate or reduce this risk. Therefore, the Commission proposes to issue a consumer product safety standard that addresses this risk by requiring that unvented gas-fired space heaters contain ODS systems and specified labeling, and that manufacturers certify compliance and maintain test and certification records.

Accordingly, the Consumer Product Safety Commission proposes to amend Title 16, Chapter II, Subchapter B, of the Code of Federal Regulations, by adding Part 1212, as follows:

PART 1212—SAFETY STANDARD REQUIRING OXYGEN DEPLETION SAFETY SHUTOFF SYSTEMS (ODS) FOR UNVENTED GAS-FIRED SPACE HEATERS

Subpart A—Safety Standard

Sec.
1212.1 Scope and purpose of the standard.
1212.2 Effective date.
1212.3 Definitions.
1212.4 Exclusions.
1212.5 Requirements for ODS.
1212.6 Test equipment and procedures.
1212.7 Certification and recordkeeping.
1212.8 Labeling.
1212.9 Findings.

Subpart B—Certification

Sec.
1212.20 Purpose of certification.
1212.21 Reasonable testing program.
1212.22 Certification of compliance.
1212.23 Records.

Authority: Secs. 2, 3, 7, 9, 14, 16, 27, Pub. L. 92–573, as amended, Pub. L. 94–284, Pub. L. 95–631; 86 Stat. 1207, 1208, 1212, 1220, 1228 as amended 90 Stat. 503, 92 Stat. 3742; 15 U.S.C. 2051, 2052, 2056, 2058, 2063, 2065, 2076.

Subpart A—Safety Standard

§ 1212.1 Scope and purpose of the standard.

(a) *Scope.* This part requires an oxygen depletion safety shutoff system (ODS) and specified labeling for unvented gas-fired space heaters that are customarily produced or distributed for sale to or for the personal use or enjoyment of consumers in or around a household or residence, a school, in recreation or otherwise. Manufacturers (including importers) are responsible for certifying that their products comply with the requirements of the standard and for maintaining records which describe the testing performed as the basis for such certification. Manufacturers are in the best position to provide for testing and certifying compliance with the standard and it is not necessary to also have private labelers certify compliance or maintain testing records. Therefore, private labelers are not required to certify that products comply or to maintain records of testing. (Unvented gas-fired space heaters are defined at § 1212.3; exclusions from this definition are provided at § 1212.4.)

(b) *Purpose.* This standard is intended to reduce the unreasonable risk of injury associated with unvented gas-fired space heaters due to carbon monoxide (CO) poisoning. The standard addresses only the risks arising from carbon monoxide and does not deal with any other possible safety aspects of unvented gas-fired space heaters. The proposed ODS standard does not replace any other voluntary standards or parts of such standards that may apply to other performance or construction characteristics of the heaters for addressing any other potential hazards such as thermal burns or fires. However, to help ensure the quality of the entire product, manufacturers are encouraged to adhere to customary good manufacturing practices for their products such as may be needed to ensure that the products would be generally acceptable under state and local building codes.

§ 1212.2 Effective date.

All unvented gas-fired space heaters defined at § 1212.3 that are manufactured or imported after midnight December 30, 1980 are subject to the requirements of Subpart A and, as provided by Subpart B, shall be certified as complying with Subpart A.

§ 1212.3 Definitions.

In addition to the definitions provided in section 3(a) of the Consumer Product Safety Act (15 U.S.C. 2052(a)), the following definitions apply to this Part. (Metric equivalents appear in parentheses where appropriate.)

(a) BTU. Abbreviation for British Thermal Unit. The quantity of heat required to raise the temperature of 1 pound ( ) of water 1°F. ( )

(b) Burner. A device for the final conveyance of the gas, or a mixture of gas and air, to the combustion zone.

(c) Cubic foot of gas. The amount of gas which would occupy 1 cubic foot ( ) when at a temperature of 60°F ( ) if saturated with water vapor and under a pressure equivalent to that of 30 inches of mercury. ( )

(d) Field adjustment means. A part, device or mechanism which allows a change in setting by the user.

(e) Heating value. The number of British Thermal Units ( ) produced by the combustion at constant pressure, of 1 cubic foot ( ) of gas when the products of combustion are cooled to the initial temperature of the gas and air, when the water vapor formed during combustion is condensed, and when corrected to a temperature of 60°F ( ) at a pressure equivalent to 30 inches of mercury. ( )

(f) Input rating. The maximum gas-burning capacity of an appliance in BTU per hour ( ) as specified on the nameplate by the manufacturer.

(g) Integral marking. Marking that is embossed, cast, stamped or otherwise formed in the part.

(h) Liquefied petroleum gases. Any material which is composed predominantly of any of the following hydrocarbons, or mixtures of them: propane, propylene, butanes (normal butane or isobutane), and butylenes.

(i) LP gas-air mixtures. Liquefied petroleum gas distributed at relatively low pressures and normal atmospheric temperatures, which have been diluted with air to produce desired heating value and utilization characteristics.

(j) Manufactured gas. A gas produced from coal, coke, or oil, or by reforming of natural or liquefied petroleum gases or any mixtures thereof, and including any natural or liquefied petroleum gas if used for enriching.

(k) Mixed gas. A gas in which manufactured gas is comingled with natural or liquefied petroleum gas in such a manner that the resulting product has a BTU value higher than that previously produced by the utility prior to the time of the introduction of natural or liquefied petroleum gas.

(l) Natural gas. A naturally occurring mixture of hydrocarbon and nonhydrocarbon gases found in porous formation beneath the earth's surface, ofter in association with crude petroleum. The natural gas or commerce, supplied to fuel gas markets, usually contains from 80 to 95 percent methane and lesser amounts of ethane and propane. Most of the remainder is nitrogen.

(m) Normal butane (N-butane), technical grade. a liquefied petroleum gas composed of a minimum of 95 percent n-butane (C_4H_{10}) which may contain other impurities such as isobutane, butylenes and propane not in excess of 5 percent.

(n) Oxygen depletion safety shutoff system (ODS). A system designed to act to shut off the gas supply to the main and pilot burners if the oxygen in the surrounding atmosphere is depleted to a specified value (see § 1212.5(b)). (The system shall depend primarily on lack of oxygen for actuation and not on other phenomena in the surrounding atmosphere such as temperature or CO concentration.)

(o) Permanent plate marking. Marking that is made of metal of a minimum thickness of 0.012 inch ( ) and that is securely attached so that it will remain with the heater throughout its life expectancy.

(p) Pilot. A small flame which is utilized to ignite the gas at the main burner(s).

(q) Propane HD–5. A special grade of liquefied petroleum gas composed of a minimum of 90 percent liquid volume of propane (C_3H_8) and a maximum of 5 percent liquid volume of propylene (C_3H_6).

(r) Specific gravity. As applied to gas, specific gravity is the ratio of the weight of a given volume to that of the same volume of air, both measured at the same temperature and pressure.

(s) Stoichiometric combustion. The rapid oxidation of fuel gases, having the exact proportions of fuel and air required for theoretically complete chemical reaction.

(t) Unvented gas-fired space heater. A self-contained, free-standing or recessed, gas-burning appliance which furnishes warm air to the surrounding or adjacent living space by gravity convection, fan circulation or radiation directly from the heater and without duct connections, and which discharges combustion products such as carbon monoxide, carbon dioxide, and water vapor directly into the heated space. The term includes the following:

(1) *Unvented circulator.* A room heater that coverts the energy in the fuel to convected and radiant heat by direct mixing of air to be heated with the combustion products and excess air inside the jacket. Unvented circulators have an external jacket surrounding the burner and may be equipped with radiants with the jacket open in front of the radiants.

(2) *Wall heater, unvented, closed front.* An unvented circulator having a closed front for insertion in or attachment to a wall or partition.

(3) *Radiant heater.* An open-front unvented room heater designed primarily to convert the energy in the fuel to radiant heat by means of refractory radiants or similar radiating materials. A radiant heater has not external jacket.

§ 1212.4 Exclusions.

The following categories of products are excluded from this standard:

(a) *Kitchen range and oven.* An appliance which provides a source of localized heat for food preparation.

(b) *Decorative gas appliance.* An appliance generally used in a vented fireplace to simulate the appearance of a natural burning material such as wood or coal. The term includes but is not limited to "gas logs", "coal baskets" and "fireplace inserts."

(c) *Catalytic camp heater.* An open faced, unvented heating appliance which utilizes a catalyst in the

combustion process. An existing voluntary standard addresses this product.

(d) *Non-catalytic camp heater.* An unvented portable heating appliance of other than the catalytic type. A voluntary standard addresses this product.

(e) *Infrared heater.* An appliance which directs a substantial amount of its energy in the form of infrared energy into the area to be heated and is generally used for heating of outdoor spaces or non-residential indoor spaces.

§ 1212.5 Requirements for ODS.

(a) Each heater shall be equipped with an oxygen depletion sensor (ODS) safety shutoff system capable of shutting off the gas supply to the heater when oxygen in the surrounding atmosphere is depleted.

(b) The concentration of oxygen in the surrounding atmosphere at time of shutoff shall not be less than 18% when corrected to 70 degrees Fahrenheit ( ) at a barometric pressure equivalent to 30 inches of mercury ( ), when tested in accordance with the procedures at § 1212.6. (The system shall depend primarily on lack of oxygen for actuation and not on other phenomena in the surrounding atmosphere such as temperature or CO concentration.)

(c) The ODS system shall not incorporate field adjustment means capable of changing the set point at which the system acts to shut off the gas supply to the heater.

§ 1212.6 Test equipment and procedures.

This section describes the equipment and procedures to be used by CPSC for evaluating the shutdown performance of unvented gas-fired space heaters fitted with oxygen depletion sensors.

(a) *Facilities, equipment and conditions*—(1) *Test room or chamber size.* The test shall be conducted in a room or chamber of sufficient size to hold the necessary equipment for conducting the test, but no larger than 1000 cubic feet ( ) in volume.

(2) *Air infiltration.* The room, including the door, shall be constructed so that air infiltration into the room shall not exceed 0.25 volume changes per hour when determined under the following conditions:

Heater input rate=40,000 Btu/hr ( ). Room temperature=70°F ( ). Temperature external to test room=70°F ( ). Wind velocity external to test room=Zero mph ( ).

These restrictions are specified to establish a base for determining air infiltration rate only and are not conditions for the test.

(3) *Provisions for remote measurement.* Provisions shall be made for the remote measurement and recording of the room air temperature, oxygen or carbon dioxide concentration and barometric pressure. Room air temperature shall be measured with at least five thermocouples at different levels and plan locations to provide an average room air temperature. The oxygen or carbon dioxide concentration in the room atmosphere shall be measured at a minimum of five locations, the same as the thermocouples above. Five separate measurements or a single measurement through the use of a manifold may be used. Barometric pressure may be measured at any location in the test room.

(4) *Air temperature.* During the conduct of this test the room air temperature shall not exceed 80°F ( ) nor fall below 60°F ( ). The temperature shall be measured and recorded during the entire test to the nearest 1°F (°C). The correction for conversion to the standard condition of 70 degrees Fahrenheit and 30 inches of mercury is:

$$\left(\begin{matrix}\text{Corrected oxygen}\\ \text{at shutdown}\end{matrix}\right)=\left(\begin{matrix}\text{measured oxygen}\\ \text{at shutdown}\end{matrix}\right)\times\left(\frac{460+70}{460+{}^{\circ}F_R}\right)\times\frac{{}^{\circ}F_B}{30}$$

Where

$^{\circ}F_R$ = ambient temperature (°F) in test room at shutdown.

$^{\circ}F_B$ = barometric pressure (inches Hg) in test room at shutdown.

(5) *Oxygen/carbon dioxide concentration.* The oxygen or carbon dioxide concentration in the room atmosphere shall be measured during the entire test and recorded to the nearest 0.1 percent. When carbon dioxide is measured the following equation will be used to calculate the relative value of oxygen in the room atmosphere for a specific test gas.

$$x=20.93-y\frac{(20.93)}{y_1}$$

Where;

x = percent 02 in room,

y = percent CO_2 measured in room,

y_1 = ultimate percent CO_2 resulting from stoichiometric combustion of the specific test gas,

20.93 = maximum percent oxygen content of air.

(6) *Air circulation.* The atmosphere of the room shall be evenly mixed and shall not interfere with the operation of the heater under test. Air circulation shall be provided so that sufficient mixing is attained without causing movement of the main burner, pilot burner or oxygen depletion sensor flame. A fan or blower with a discharge capacity of 320 cubic feet per minute shall be used for a 1000 cubic foot room. (Smaller test rooms will require a lower discharge capacity in the same proportion to the reduction in room size.)

(b) *Test gases.* The tests shall be conducted with the type(s) of gas for which the heater is deisgned, as specified by the manufacturer, except that heaters for use with natural gas shall be tested with natural gas and butane-air. Gases with characteristics approximately as shown below shall be used.

Characteristics of Test Gases

	Heating value (Btu per Ft³)	Specific gravity (Air=1.0)	Ultimate CO_2 (%)
Natural	1075	0.65	12.2
Manufactured	535	0.38	11.82
Mixed	800	0.50	11.82
n-Butane	3200	2.00	14.0
Propane HD-5	2500	1.55	14.0
Propane-Air	700	1.16	14.0
Butane-Air	1400	1.42	14.0
Propane-Air	1400	1.30	14.0

(c) *Procedures.* The heater shall be assembled and adjusted in accordance with any instructions provided by the manufacturer. It shall be installed near the geometric center of the test room floor. The heater shall be started and set at maximum input. The door of the room shall then be closed. The heater shall be operated at maximum input until the oxygen depletion sensor shuts off the heater. When the oxygen depletion sensor acts to shut off the gas supply to the heater the following shall be determined and recorded:

(1) Oxygen (or carbon dioxide) concentration of the room atomosphere;

(2) Average room temperature;

(3) Barometric pressure.

The necessary corrections and conversions shall be made and the test results recorded.

§ 1212.7 Certification and enforcement.

(a) *Testing required for certification.* The test procedures described at § 1212.6 will be used for enforcement purposes by the Commission to determine whether unvented gas-fired space heaters subject to this standard actually meet its requirements. Although the standard does not require that a manufacturer or importer perform these tests, section 14 of the CPSA (15 U.S.C. 2063) requires them to certify that their products conform with all applicable consumer product safety standards. The certificate must be based on either a test of each product or on a reasonable testing program. Subpart B below prescribes the requirements that manufacturers and importers shall follow to certify that their unvented gas-fired space heaters comply with the requirements of the standard.

(b) *Reporting of noncompliance.* Every manufacturer and importer of unvented gas-fired space heaters that have been distributed in commerce and every distributor and retailer of such products who obtains information which reasonably supports the conclusion that the product is subject to and fails to comply with the requirements of Subpart A, shall immediately inform the Commission of the failure to comply, in accordance with the reporting provisions of section 15(b) of the CPSA (15 U.S.C. 2064(b), 16 CFR Part 1115). (A test failure that occurs during a reasonable testing program before distribution of any such units is not subject to the reporting requirements of section 15(b). Failure to comply with the certification and recordkeeping requirements of Subpart B is not subject to the reporting requirements of Section 15(b) of the CPSA.)

§ 1212.8 Labeling.

(a) Each heater shall bear an integral marking or permanent plate marking which shall be conspicuous and clearly legible when the heater is in an installed position and shall be separate from any use or operation label supplied by the manufacturer. The marking shall contain the following statement:

Warning

When used without fresh air this heater may give off CARBON MONOXIDE, an odorless, poisonous gas. Open a window an inch or two for fresh air.

This heater has a pilot light safety system that turns off the heater if not enough fresh air is available.

Do not tamper with this safety system. If the heater shuts off, do not relight until you provide fresh air.

If the heater keeps shutting off, have it serviced. Keep the burner and control compartment clean.

Carbon monoxide poisoning may lead to death. Early signs of carbon monoxide poisoning resemble the flu, with headache, dizziness and/or nausea. If you have these signs, the heater may not be working properly. Get fresh air *at once,* and have the heater serviced.

Some people—pregnant women, persons with heart or lung disease, anemia, those under the influence of alcohol, those at high altitudes—are more affected by carbon monoxide than others.

(b) The word "WARNING" shall be in capital letters at least ¼ inch high and the remainder of the wording in letters at least ⅛ inch high.

§ 1212.9 Findings.

(a) *General.* Section 9(c) of the CPSA (15 U.S.C. 2058(c)) provides that to issue a rule, the Commission must make certain findings for inclusion in the rule. (The findings discussed here are preliminary and are subject to change, by subsequent events, or by information and comments received from the public during the comment period permitted after publication of this proposal.)

(b) *The degree and nature of the risk of injury the proposed standard is designed to eliminate or reduce.* (1) The risk of injury addressed by this standard is from the poisonous gas, carbon monoxide (CO) entering the human respiratory system due to the CO hazard associated with unvented gas-fired space heaters. Where room oxygen is sufficiently depleted due to inadequate ventilation or maladjustment of the heater's burner, a dangerous buildup of CO may occur. CO combines readily with hemoglobin in the blood thereby reducing the capability of the blood to carry oxygen needed to maintain body tissues. The dangers of CO poisoning may be higher for certain sensitive persons such as those suffering heart/lung impairments, for pregnant women, and smokers, for examples. There is also the possibility of chronic health effects from prolonged exposure to low concentrations of CO. Depending on the degree to which CO results in the lowering of blood oxygen, and the period for which it is lowered, tissue damage or death can occur. The degree of risk is a direct function of the concentration of CO, the duration of exposure and individual sensitivity. Information available to the Commission on the hazard of CO poisoning associated with unvented gas-fired space heaters is predominantly death data. The information suggests that the primary risk is from a high, one-time (acute) exposure to CO emissions. Such acute exposure is of particular concern during sleeping hours. Lack of data other than death data may be related to the fact that symptoms of CO poisoning such as headache, dizziness, and nausea resemble those of other illnesses.

(2) The Commission has information on 200 deaths for the period from October 1973 to March 1979. This may represent a conservative estimate because the effects of CO poisoning impact strongly on the cardiovascular and neurological systems of the body and this factor may cause CO deaths to be misdiagnosed and attributed to other physiological causes. Commission data indicate that about 70 deaths a year can be attributed to CO poisoning associated with unvented gas-fired space heaters.

(3) A 1979 Commission study of CO blood levels (COHb) describing 22 autopsy reports of CO poisoning associated with unvented gas-fired space heaters, indicates that if the heaters involved in the incidents had been equipped with oxygen depletion systems as required by the proposed standard, the gas supply to the heaters would probably have been shut off before the fatal COHb blood levels could have been reached in 20 of the 22 cases. On this basis, the Commission estimates that the proposed standard can be expected to reduce the annual estimated death figure of 70 by about 90%.

(c) *Products subject to the rule.* The production of unvented gas-fired space heaters defined at § 1212.3(t) declined about 70% between 1967 and 1976. This decline may have been due to rising consumer affluence, preference for central heating, or higher purchase prices. In 1976, 182,000 units were produced. In 1977, production was down to about 82,000, possibly in expectation of CPSC regulation. No unvented gas-fired space heaters were produced in 1978. Production began again in 1979 and is estimated to number 120,000 for the year. For 1980, in light of possible increased demand due to the rapid increase in energy costs and the relatively low operating costs of unvented gas-fired space heaters, industry estimates that another 120,000 units would be produced.

(d) *The need of the public for consumer products subject to the rule.* Owners of unvented gas-fired space heaters are concentrated in southern areas of the United States where the climate may make central heating systems uneconomical for certain households. These owners tend to be the elderly and low income groups of this area. The energy efficiency of unvented gas-fired space heaters means fairly low operating costs. Therefore, this product is particularly important for those in the lower socio-economic brackets for whom substitute heaters such as vented gas heaters or electric heaters may be too costly because of higher operating costs.

(e) *Probable effect of the rule on the utility of the product.* The Commission believes that the utility of the product will be greatly increased by the proposed rule. Those who have historically used this form of heating could be assured that heaters equipped with ODS systems are safer than those not so equipped. In addition to safer products for the replacement market, an ODS-equipped heater may appeal to those who may have hesitated to use unvented heaters because of the CO hazard.

(f) *Probable effect of the rule on the cost of the product.* (1) Cost estimates are made on the basis of two known

ODS devices. The cost of one of the devices to the heater manufacturers is estimated to be about $2; the other is estimated at no more than $5.00. In 1978, the retail price of a medium size unvented gas-fired space heater of 25,000 BTU capacity was about $140. Competitive pressures should keep the retail price increase down. The Commission estimates, on the basis of information submitted by industry, that the retail price could increase in a range between $4 and $17.50. The proposed provisions concerning labeling as well as those concerning certification of compliance and recordkeeping are not expected to be a significant part of this price increase. The voluntary standard to which U.S. manufacturers now conform contains provisions on labeling and testing which are generally needed for acceptance by many state and local jurisdictions. In addition, manufacturers currently maintain production records. Thus, since the proposed requirements for certification labeling and recordkeeping are not expected to significantly increase the usual administrative burdens a manufacturer may incur in maintaining this kind of business information, the Commission believes that the certification, labeling and recordkeeping requirements of the proposed standard are not meaningfully involved in any possible increased costs of this product.

(2) Commission economists estimated, on the basis of the industry-projected 1980 output of 120,000 unvented gas-fired space heaters, that the addition of the least expensive ODS (American) currently know, $2, would add an additional $240,000 to the manufacturers' cost of producing the entire year's output. To the consumer, the increased cost would be $4 to $7 per unit or $480,000 to $840,000 total price increase. For the European device, the added cost for manufacturers to apply the device to the 1980 projected output, $5.00, could be about $600,000. The consumers' increased cost for the European device would be $10 to $17.50 per heater or a total increase of $1.2 million to $2.1 million.

(3) By using an equation based primarily on the number of unvented gas-fired space heaters produced in the past, the expected usage life of the units, the expected production for the year 1980, and the estimate of 70 deaths a year derived from a Commission study of autopsy reports of CO poisoning deaths from these products, the staff calculated that the number of deaths likely to occur during the 25-year usage span of the 120,000 heaters produced in 1980, would be 16. On the assumption, discussed in paragraph (b) of this section that the ODS would be 90% effective in preventing CO deaths, Commission staff estimates that the addition of ODS could have saved 14 of the 16 lives.

(4) If the cost estimate of $480,000 to $840,000 for the American ODS is divided by the number of lives expected to be saved, 14, the ODS device would cost approximately $33,300 to $40,000 per life saved. If the cost estimates of $1.2 million to $2.1 million of the European device are used, the cost for a life saved would range from $83,300 to $146,000. Value-of-life estimates, based on the methodology of discounted future earnings start at about ¼ million dollars per life, the willingness-to-pay theory ranges upward to 2 million dollars per life. In the area of product safety and consumer health, however, the Commission believes it is inappropriate and unnecessary to assign a monetary value to human life. Nevertheless, the Commission observes that these value-of-life estimates are considerably higher than $146,000, the highest estimated increased cost for equipping a year's production of unvented gas-fired space heaters with ODS systems. On this basis, the increased cost can be considered minimal. (For a dicussion of the methodology of cost/benefit analysis and estimates of the value of life, refer to "Suggested Readings for Cost-Benefit Analysis, Value of Life and Discount Rates", a summary of readings on these subjects suggested by Commission economists, on file at the Office of the Secretary. Also on file there is the Commission staff's October 1979 Preliminary Report on the Economic Impact of this proposed standard, which provides further details on the cost/benefit study summarized briefly in this subsection.)

(g) *The probable effect of the rule on the availability of the product.* The Commission believes that the standard would not have a significant effect on the availability of unvented gas-fired space heaters. Historically, the availability of this product declined over the last decade; none appear to have been manufactured in 1978. Production of the heater in 1979 is estimated to be about 120,000. This figure is considerably less than the total of 182,000 manufactured in the last full production year of 1976. Further the three known manufacturers of the product are actively engaged in measures to equip their heaters with ODS devices. The Commission believes there will be only a short period of time before ODS-equipped unvented gas-fired heaters will be ready for the market, and that manufacturers will be better able to make production plans when they are certain of their obligations under the standard.

(h) *Other means of achieving the objective of the proposed standard.* The Commission considered other means of attaining the objective of the standard—that is, to eliminate or reduce the hazard of CO poisoning associated with unvented gas-fired space heaters. Among the means considered was a CO detector and shutoff device, but the Commission found this to be technically impracticable and economically unfeasible. The Commission also considered banning manufacture and distribution of unvented gas-fired space heaters before learning of the ODS and its capability to respond to oxygen depletion and thereby help avoid exposure to high concentrations of CO emissions.

(i) *Unreasonable risk of injury.* (1) The term "unreasonable risk of injury" is not defined in the CPSA; however, the term "risk of injury" is defined at section 3(a)(3) to mean a risk of death, personal injury or serious or frequent illness. The legislative history of the CPSA (H.R. Rep. No. 92–1153, 92d Cong., 2d Sess., 1972, p. 33) states that determining unreasonable hazards (risks) involves balancing the probability that risk will result in harm and the gravity of such harm against the effect of regulation on the product's utility, cost, and availability to the consumer. The primary risk of CO poisoning associated with unvented gas-fired space heaters is death. The hazard of CO poisoning is particularly insidious since CO is colorless and odorless, as well as poisonous. Thus even people who are awake and active, and move in and out of the space where CO buildup may be occurring from an unvented gas-fired space heater in an oxygen-deficient atmosphere, would generally be unaware of CO emissions. During sleeping hours, this lack of awareness can mean death. The ODS system required for unvented gas-fired space heaters in this standard functions as a detector and monitor of oxygen depletion and its accompanying condition of CO buildup. The ODS acts to shut off the gas supply to the heater if oxygen is depleted to less than 18%. The Commission estimates (see item (f)) above that the ODS can effect a death reduction of 90% for a cost increase that is small for the industry and for consumers. Since assigning a monetary value to human life is difficult, it is also difficult to estimate the benefits of this potential death reduction. In reviewing the possible increased costs, the

Commission concludes that the benefits in death reduction far outweigh the costs of incorporating ODS system in unvented gas-fired space heaters.

(2) An ancillary benefit of the ODS system is that it may help reduce any chronic health effects from CO poisoning associated with unvented gas-fired space heaters, because the ODS would reduce CO levels that may present a chronic hazard to susceptible individuals such as smokers, persons with heart or lung impairment, and pregnant women. The Commission believes, in addition, that the utility of unvented gas-fired space heaters would be increased by the addition of ODS systems. Persons who may not formerly have purchased this product because of safety considerations, may now do so because of assurance that the ODS would protect them from an atmosphere hazardous to human life. Other benefits of possibly increased use of ODS-equipped unvented gas-fired space heaters are energy conservation because no energy is exhausted through flue openings, and therefore generally lower operating costs for consumers who wish to purchase these now safer products. The Commission anticipates that ODS-equipped unvented gas-fired space heaters will be available on the market by the 1981 heating season because manufacturers of this product, their trade associations and related testing laboratories are actively engaged in expediting application of ODS systems to their products.

(j) *Conclusion.* In considering the anticipated costs of equipping unvented gas-fired space heaters with ODS systems, discussed in paragraph (f) of this section, the Commission concluded that they are not substantial when weighted against the gravity of the harm from unvented gas-fired space heaters not so equipped. Because CO is colorless and odorless as well as toxic, individuals can be unknowingly exposed; these characteristics present extreme danger during sleeping hours. Therefore, the Commission preliminarily determines that the hazards of CO poisoning associated with unvented gas-fired space heaters present an unreasonable risk of injury to the public. On the basis that unvented gas-fired space heaters continue to be manufactured, notwithstanding this hazard, the Commission also concludes that a standard requiring such products to be equipped with ODS systems is reasonably necessary to eliminate or reduce the unreasonable risk, and that the proposed standard is in the public interest.

Subpart B—Certification

§ 1212.20 Purpose of Subpart B.

The purpose of this Subpart B is to establish requirements that manufacturers and importers must follow to certify that their products comply with the requirements in Subpart A. This Subpart B includes testing, certification labeling and recordkeeping requirements.

§ 1212.21 Certification based on testing.

(a) *Requirements.* Certification by manufacturers and importers, as described in § 1212.22 shall be based either on a test of each individual unvented gas-fired space heater equipped with an ODS system or on a reasonable testing program.

(b) *Reasonable testing program.* A reasonable testing program for unvented gas-fired space heaters equipped with ODS systems is one which provides reasonable assurance that the products comply with the standard. Manufacturers and importers may establish their own reasonable testing programs. At the option of the manufacturer or importer the reasonable testing program may be performed by an independent third party qualified to conduct such testing programs.

§ 1212.22 Certification of compliance.

(a) *Certification requirements for manufacturers.* Manufacturers shall issue a certification of compliance for unvented gas-fired space heaters that are subject to the standard in the form of a lable that is permanently affixed to the heater and can reasonably be expected to last for the lifetime of the product. Such labeling shall be considered a certificate of compliance as that term is used in section 14 of the CPSA.

(1) *Placement of the certification.* The certification required by this section shall be placed at the end of the permanent plate marking label described in § 1212.8(a).

(2) *Contents of label certification.*

(i) The certification required by this section shall be visible and legible to the ultimate consumer and contain the following information:

(A) the statement, "Meets CPSC requirements for oxygen depletion safety shutoff systems";

(B) the name of the person or firm issuing the certificate, unless permanently affixed elsewhere on the heater in a place easily visible to the consumer; and

(C) the month, year, and place of manufacture.

(ii) The information required in paragraph (a)(2)(i)(B) of this section may be in code when the product bears a private label provided the code mark permits the seller of such a product to identify the manufacturer thereof to the purchaser upon his request.

(iii) The information required in paragraph (a)(2)(i)(C) of this section may be in code provided the person or firm issuing the certificate retains a written record of the meaning of each symbol used in the code that can be made available upon request by consumers, persons in the distribution chain and CPSC.

(b) *Certification requirements for importers.* The importer of any unvented gas-fired space heater that is subject to the standard must issue the certificate of compliance required by section 14(a) of the CPSA and paragraph (a) of this section. If the testing or reasonable testing program required by § 1212.21(b) of this section has been performed by or for the overseas manufacturer of the heater, the importer may rely on any such tests to support the certificate of compliance if the importer is a resident of the United States or has a resident agent in the U.S. and the records are maintained in the United States in accordance with § 1212.23. The importer bears responsibility for assuring that all testing required to support the certificate of compliance has been performed properly with passing or acceptable results and that all records of such tests are accurate and complete.

§ 1212.23 Records.

Every person issuing certificates of compliance for heaters subject to this standard is responsible for maintaining records of tests or testing programs that are the basis for the certification of compliance, whether the tests are performed by the person issuing the certificate of compliance or an independent laboratory. The records shall describe the test the heaters have been subjected to and the test results. The records shall also identify the heater or group of heaters that are certified as a result of the test data and establish that the heaters which are being marketed and certified to comply with the standard, are identical in every respect that relates to compliance with the standard, to the heaters that were tested for conformance with the standard. The records may be in any format that clearly provides this information. Records shall be maintained for a period of at least three years and shall be made available to CPSC for inspection upon request by a CPSC officer or employee, in accordance with section 16(b) of the CPSA (15 U.S.C. 2065(b)).

Dated: January 9, 1980.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

Bibliography

(1) ANSI: Gas-Fired Room Heaters, Vol. II—Unvented Room Heaters. 1978.

(2) CPSC: Staff briefing package to Commission. (November 5, 1979. Includes briefing memorandum and tabs A through O as follows):

Tab A—Draft Proposed Rules: Safety Standard Requiring Sensing Systems (ODS) for Unvented Gas-Fired Space Heaters.

Tab B—**Federal Register** Notices.

B–1 Unvented Gas-fired Space Heaters—Proposed Withdrawal of Proposed Rule, November 29, 1978.

B–2 Unvented Gas-Fired Space Heaters—Withdrawal of Proposed Rule, March 28, 1979.

Tab C—Staff Memoranda on Injury Data.

C–1 Unvented Gas Space Heater Related Deaths, Tyrrell/Kale, HIEA, February 1, 1979. (An investigation to determine COHb levels of victims.)

C–2 Carbon Monoxide Deaths from Unvented Gas Space Heaters, Bea Harwood, HIEA, October 12, 1979. (An estimate of deaths each year.)

Tab D—Staff Memoranda on Performance of ODS and Hazards of Carbon Monoxide.

D–1 Engineering and Sciences Position on CO Emission from unvented Gas Space Heaters, April 26, 1979, Don Clay, ES.

D–2 Rationale for 18% Oxygen Cut-off and Feasibility of ODS, August 22, 1979, Talentino, ESEP.

D–3 Safety of Performance Requirements of ODS Addressing Acute Hazard of Death by Carbon Monoxide Poisoning; and Discussion of Chronic Exposure to Carbon Monoxide, April 13, 1979, Talentino, ESEP/Ulasmer, ESHC.

D–4 Medical Aspects of Carbon Monoxide, April 10, 1979, M. Driggs, M.D., ESHT.

D–5 Toxic Effects of Low Levels of Carbon Monoxide, February 14, 1979, A. Ulsamer, ESHC.

D–6 Health Aspects of Carbon Monoxide Inhalation, March 16, 1979, Gale Wyer, ESH.

D–7 Table of Physiological Effects of Exposure to Increasing Atmospheric Concentrations of Carbon Monoxide, for Commission FR February 14, 1979 Proposing Ban of Unvented Gas-Fired Space Heaters.

Tab E—Preliminary Economic Impact Report and Environmental Assessment, Roy Sammarco, HICP, October 1979.

Tab F—Staff Memoranda on Economic Aspects of ODS Device.

F–1 Meeting with Jade Control on June 14, 1979, Roy Sammarco, HICP.

F–2 Stockpiling on Unvented Gas Space Heaters, August 17, 1979, Roy Sammarco, HICP.

Tab G—Staff Memoranda on Labeling Discussion of the Adequacy of Cautionary Labeling in the ANSI Gas-Fired Room Heater Standard, Warren Mathers, HIEH, March 9, 1979.

Tab H—Staff Memoranda on Certification and Enforcement Strategy.

H–1 Certification Requirements for Unvented Gas-fired Space Heaters, September 21, 1979, Jones, CERM/Buxbaum, CEEE.

H–2 Enforcement Strategy for Unvented Gas Space Heaters, June 5, 1979, Jones, CERM.

Tab I—Correspondence

I–1 Letter from ANSI Z 21 Committee to James Talentino, E&S, Concerning Status of Committee Actions, March 30, 1979.

I–2 Letter from AGA to Commissioner Sloan concerning AGA Certification, April 25, 1979.

I–3 Notice from AGA Laboratories to Manufacturers of Unvented Room Heaters Concerning Revisions to the ANSI Standard and Their Effective Dates, April 18, 1979.

I–4 Notice from AGA Laboratories to Manufacturers of Unvented Room Heaters Concerning the Effective Date of the Revision in ANSI Standard, August, 9, 1979.

I–5 Letter from Martin Industries to Commissioners Sloan and Pittle, Concerning Status of Martin Industry Position on Unvented Heaters, May 8, 1979.

Tab J—Logs of Meetings & Phone Conversations

J–1 Meeting between AGA, Manufacturers to Unvented Gas Heaters, Sourdillon Co. and Commission staff, March 3, 1979.

J–2 Meeting between Commissioners Sloan and Pittle and Representatives of AGA, GAMA, and Unvented Space Heater Manufacturers, April 24, 1979.

J–3 Meeting between Manufacturers of Unvented Gas Heaters, GAMA, AGA, Commission staff, August 14, 1979.

J–4 Phone Conservation between Mr. Cridland, Sourdillon Representative, and Stan Morrow, September 12, 1979.

TAB K—Staff Memorandum on Program Addressing Chronic Hazard of CO

K–1 Health Science Review of Briefing Package, July 3, 1979, Peter Preuss, HS.

K–2 Consideration of HS Comments, August 1, 1979, George Anikis, OPM.

TAB L—Addenda to American National Standard Z21.11.2—1978 for Gas-fired Room Heaters—Unvented.

TAB M—American National Standard for Gas-Fired Room Heaters—Unvented, ANSI Z21.11.2—1978.

TAB N—Sample of Labels as Drafted by Staff in Proposed Rule.

TAB O—Examples of Warning Labels and Instruction Books Currently Used by Unvented Gas Space Heater Manufacturers.

(3) CPSC: Hazard Analysis of Unvented Gas-Fired Space Heaters. 1978.

(4) CPSC: 42 FR 46072, Sept. 14, 1977. (Notice that it is not necessary at this time to address any hazards that may be associated with vented gas-fired space heaters.)

(5) CPSC: 40 FR 4112, Sept. 5, 1975. (Partial denial of petition CP 74–10).

(6) CPSC: 42 FR 6253, Feb. 14, 1978. (Proposed ban of unvented gas-fired space heaters.)

(7) Mo. Public Interest Research Group. Petition CP 74–10, to develop mandatory standard for space heaters. Jan. 10, 1974.

(8) CPSC: Transcript. Public Meeting on unvented Gas-Fired Space Heaters. Washington, D.C. March 6, 1978.

(9) Davis, Joseph H. M.D.: Carbon Monoxide and Space Heaters: An overview (Prepared for Public Meeting on Unvented Gas-Fired Space Heaters, Miami Beach, Fla., Mar. 28–29, 1978).

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(11) Kweller, E., and Cuthrell, W.: Testing of an Oxygen Depletion Detecting Device for Unvented Gas-Fueled Heaters. June 1978.

(12) Kweller, E.: Unvented Heater Tests and Analysis of Standards for a Temperature Sensitive Limit Device. National Bureau of Standards, Nov. 1978.

(13) CPSC: Survey on Unvented Gas-Fired Space Heaters. January 1977.

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(15) Roughton, F. J. W. The Equilibration of Carbon Monoxide with Human Hemoglobin in Whole Blood. An. N.Y. Acad. Sci. *174* 177 (1970).

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(21) LEAA: Relative Contribution of Carbon Monoxide and Heart Diseases to the Death of Public Safety Officers. (43 FR 41302, September 15, 1978.)

(22) CPSC: Comments from Public on Proposed Ban of Unvented Gas-Fired Space Heaters. 1978.

(23) CPSC: Transcript. Public Meeting on Unvented Gas-Fired Space Heaters. Dallas, Texas, March 28, 29, 1978.

(24) Kearney Management Consultants. Socio-Economic Impacts of a Ban on Unvented Gas-Fired Space Heaters, Feb. 1977.

(25) American Gas Association: AGA Certification Program. Undated.

(26) CPSC ODS Related Provisions of the ANSI, French and British Standards for Unvented Gas-Fired Space Heaters. Undated.

(27) American Gas Association; Letter from S. L. Blachman to G. Anikis, CPSC, discusses testing gases. Nov. 29, 1979.

(28) CPSC: Memo A. Thomas to G. Anikis, discusses testing gases. Nov. 30, 1979.

[FR Doc. 80–1281 Filed 1–17–80; 8:45 am]

BILLING CODE 6355–01–M