Sunshine Act Meetings

Federal Register
Vol. 59, No. 116
Friday, June 17, 1994

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).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:27 a.m. on Tuesday, June 14, 1994, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate and supervisory activities.

In calling the meeting, the Board determined, on motion of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), seconded by Director Eugene A. Ludwig (Comptroller of the Currency), concurred in by Acting Chairman Andrew C. Hove, Jr., that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Dated: June 14, 1994.

Federal Deposit Insurance Corporation.

Patti C. Fox,

Acting Deputy Executive Secretary.

[FR Doc. 94–14972 Filed 6–15–94; 2:53 am]

BILLING CODE 6714–01–M

FEDERAL ENERGY REGULATORY COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: June 13, 1994, 59 FR 30384.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: June 15, 1994, 10:00 a.m.

CHANGE IN THE MEETING: The following Docket No. has been Item CAG–2 on the Agenda scheduled for June 15, 1994:

Item No., Docket No., and Company

CAG–2—RP94–96–000, Consolidated Natural Gas Company

Lois D. Cashell,

Secretary.

[FR Doc. 94–14929 Filed 6–15–94 1:05 pm]

BILLING CODE 6717–01–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Wednesday, June 22, 1994.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: June 14, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–14902 Filed 6–15–94; 8:45 am]

BILLING CODE 6210–01–P

NATIONAL CREDIT UNION ADMINISTRATION

TIME AND DATE; 11:00 a.m., Thursday, June 23, 1994.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, Virginia 22314–3428.

STATUS: Open.

BOARD BRIEFING:

1. Insurance Fund Report.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Open Meeting.
2. Final Rule: Amendments to Parts 701.6 and 741.11, NCUA's Rules and Regulations, NCUA's Fiscal Year and NCUSIF's Insurance Year to Calendar Year.
3. Proposed Rule: Amendments to Part 708, NCUA's Rules and Regulations, Mergers of Federally Insured Credit Unions.

RECESS: 11:30 a.m.

TIME AND DATE: 11:45 a.m., Thursday, June 23, 1994.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, Virginia 22314–3428.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Closed Meetings.
2. Administrative Action under Part 747, NCUA's Rules and Regulations. Closed pursuant to exemptions (6) and (8).
3. Appeal of Determination under Part 709, NCUA's Rules and Regulations. Closed pursuant to exemptions (6) and (8).
4. Administrative Action under Section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).
5. Administrative Action under Section 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).
6. Midsession Budget Review. Closed pursuant to exemptions (2), (6), and (9)(B).

FOR MORE INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (703) 518–6304.

Becky Baker,

Secretary of the Board.

[FR Doc. 94–14958 Filed 6–15–94; 2:32 pm]

BILLING CODE 7535–01–M

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of June 20, 1994.

A closed meeting will be held on Tuesday, June 21, 1994, at 3:00 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, 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), permit consideration of the scheduled matters at a closed meeting.

Commissioner Roberts, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the closed meeting scheduled for Tuesday, June 21, 1994, at 3:00 p.m., will be:

Institution of administrative proceedings of an enforcement nature.

Settlement of administrative proceedings of an enforcement nature.

Report of investigation.

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: Brian Lane (202) 942–0600.

Dated: June 14, 1994.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–14928 Filed 6–15–04; 1:05 pm]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: [59 FR 30097, June 10, 1994].

STATUS: Closed meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE PREVIOUSLY ANNOUNCED: June 10, 1994.

CHANGE IN THE MEETING: Additional Item.

The following item was considered at a closed meeting held on Tuesday, June 14, 1994, at 2:00 p.m.

Personnel matter.

Commissioner Roberts, as duty officer, determined that Commission business required the above change and that no earlier notice thereof was possible.

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 Ramsay at (202) 942–0700.

Dated: June 14, 1994.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–14977 Filed 6–15–94; 3:41 pm]

BILLING CODE 8010–01–M

Corrections

Federal Register
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This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis; Meeting

Correction

In notice document 94-13377 appearing on page 28553 in the issue of Thursday, June 2, 1994, make the following correction:

In the second column, in the first full paragraph, in the fifth line, "energy testing" should read "anergy testing".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts412, 413, 482, 485, and 489

[BPD-802-P]
RIN 0938-AG46

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rates

Correction

In proposed rule document 94-12516 beginning on page 27708 in the issue of Friday, May 27, 1994, make the following corrections:

1. On page 27771, in the 1st column, in the 23rd line, "was" should read "will be".

2. On page 27819, in Table 6B, in the fourth and fifth columns, remove "Pre" and "481".

3. On page 27896, remove the table and footnotes that appear at the bottom of the page.

4. On page 27897, remove lines one and two at the top of the page.

BILLING CODE 1505-01-D

Federal Register

Friday
June 17, 1994

Part II

Environmental Protection Agency

40 CFR Parts 9 and 89

Determination of Significance for Nonroad Sources and Emission Standards for New Nonroad Compression-Ignition Engine At or Above 37 Kilowatts; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 89

[FRL–4893–8]

RIN 2060–AD54

Control of Air Pollution; Determination of Significance for Nonroad Sources and Emission Standards for New Nonroad Compression-Ignition Engines At or Above 37 Kilowatts

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Section 213 of the Clean Air Act (CAA) as amended requires the Environmental Protection Agency (EPA) to make a determination of the significance of the contribution of nonroad sources to nonattainment of the National Ambient Air Quality Standards (NAAQS) for ozone and carbon monoxide (CO) in more than one nonattainment area. If the Agency makes a positive determination of significance, it must then promulgate regulations that will result in reductions in emissions from nonroad sources. In today's action, EPA is finalizing the determination of significance of emissions from nonroad engines. EPA is also promulgating standards for carbon monoxide (CO), hydrocarbon (HC), particulate matter (PM), oxides of nitrogen (NO_X) and smoke emissions from large nonroad compression-ignition (CI) engines at or above 37 kilowatts (kW) in power, with exclusions for certain types of engines. The NO_X standard is expected to reduce average per unit NO_X emissions from affected engines by 27 percent before the year 2010, with a 37 percent reduction by the year 2025.

EFFECTIVE DATE: This regulation is effective July 18, 1994. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 18, 1994. The information collection requirements contained in 40 CFR 89.114–96 through 89.120–96, 89.122–96 through 89.127–96, 89.129–96, 89.203–96 through 89.207–96, 89.209–96 through 89.211–96, 89.304–96 through 89.331–96, and 89.404–96 through 89.424–96 have not been approved by the Office of Management and Budget (OMB) and are not effective until OMB has approved them. A technical amendment will be published in the Federal Register when OMB has approved the information collection requirements.

ADDRESSES: Materials relevant to this final rule are contained in Docket No. A–91–24 and A–91–18, located at the Air Docket, 401 M Street SW., Washington, DC 20460, and may be reviewed in room M–1500 from 8 a.m. until noon and from 1:30 p.m until 3:30 p.m. Monday through Friday. As provided in 40 CFR part 2, a reasonable fee may be charged by EPA for photocopying docket materials.

FOR FURTHER INFORMATION CONTACT: Linda Hormes, Office of Mobile Sources, Certification Division, (313) 668–4502.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The preamble, regulatory language and regulatory support document are available electronically on the Technology Transfer Network (TTN). TTN is an electronic bulletin board system (BBS) operated by EPA's Office of Air Quality Planning and Standards. Users are able to access and download TTN files on their first call. After logging onto TTN BBS, to navigate through the BBS to the files of interest, the user must enter the appropriate command at each of a series of menus. The steps required to access information on this rulemaking are listed below. The service is free of charge, except for the cost of the phone call.

TTN BBS: 919–541–5742 (1200–14400 bps, no parity, 8 data bits, 1 stop bit)
Voice Helpline: 919–541–5384
Internet address: TELNET ttnbbs.rtpnc.epa.gov
Off-line: Mondays from 8:00 AM to 12:00 Noon ET

1. Technology Transfer Network Top Menu <T> GATEWAY TO TTN TECHNICAL AREAS (Bulletin Boards) Command: T
2. TTN Technical Information Areas <M> OMS—Mobile Sources Information Command: M
3. OMS BBS === MAIN MENU <K> Rulemaking & Reporting Command: K
4. Rulemaking Packages <6> Non-Road Command: 6
5. NON-Road Rulemaking Area File area #2 . . . Non-Road Engines Command: 2<CR>
6. Non-Road Engines

At this stage, the system will list all available nonroad engine files. To download a file, select a transfer protocol which will match the terminal software on your own computer, then set your own software to receive the file using that same protocol.

If unfamiliar with handling compressed (i.e. ZIP'ed) files, go to the TTN top menu, System Utilities (Command: 1) for information and the necessary program to download in order to unZIP the files of interest after downloading to your computer. After getting the files you want onto your computer, you can quit the TTN BBS with the <G>oodbye command.

I. Table of Contents

II. Legal Authority and Background

Authority for the actions in this notice is granted to EPA by sections 202, 203, 204, 205, 206, 207, 208, 209, 213, 215, 216, and 301 of the Clean Air Act as amended (42 U.S.C. 7521, 7522, 7523, 7524, 7525, 7541, 7542, 7543, 7547, 7549, 7550, 7601(a)).

On November 15, 1990, the Clean Air Act Amendments of 1990 (CAAA) were enacted in order to broaden and strengthen the CAA. While the CAA had long specifically authorized EPA regulation of on-highway vehicle and engine emissions, the 1990 amendments extended EPA's authority to regulate nonroad vehicles and engines. Specifically, revised section 213 directs EPA to: (1) Conduct a study of emissions from nonroad engines and vehicles; (2) determine whether emissions of CO, NO_X, and volatile

organic compounds (VOCs) from nonroad engines and vehicles are significant contributors to ozone or CO in more than one area which has failed to attain the NAAQS for ozone or CO; and (3) regulate those categories or classes of new nonroad engines and vehicles that contribute to such air pollution if nonroad emissions are determined to be significant. EPA may also regulate other emissions from new nonroad engines or vehicles if the Agency determines that they contribute to air pollution which may reasonably be anticipated to endanger public health or welfare. Finally, EPA is to regulate emissions from new locomotives by 1995.

The Nonroad Engine and Vehicle Emission Study required by section 213(a)(1) was completed in November 1991.[1] The purpose of this final rule is to implement section 213(a) (2), (3), (4), and (5) by determining that emissions from nonroad engines and vehicles are significant contributors to ozone and CO nonattainment and by promulgating regulations containing standards applicable to emissions from certain nonroad engines and vehicles.

III. Determination of Significance

Section 213(a)(2) of the CAA provides that after notice and public comment, EPA is to determine, based on the Nonroad Engine and Vehicle Emission Study (hereafter called the Nonroad Study), whether nonroad emissions are significant contributors to ozone or CO in more than one nonattainment area. Based on the results of the Nonroad Study and consideration of the public comments discussed below, EPA is finalizing its proposed affirmative significance determination in today's rulemaking.

The majority of commenters did not address EPA's proposed determination of significance. Of those who did, most were in opposition, including organizations representing equipment manufacturers and users. Expressing support for the determination were some engine manufacturers, state and local organizations and environmental groups. A summary of comments is found in the Response to Comments document contained in the docket for this rule. Major comments are discussed below, accompanied by EPA's response.

1. Use of the EKMA Model

Several commenters stated that EPA had not adequately demonstrated a significant contribution to ozone or CO nonattainment from nonroad engines or vehicles, as directed by the Act. These commenters argued that EPA had shown only the nonroad contribution to ozone precursor and CO emission inventories, and not the nonroad contribution to ozone formation or ozone and CO nonattainment. Some commenters questioned EPA's use of the Empirical Kinetic Modeling Approach (EKMA model) as the basis for its air quality analysis, and they suggested that EPA should have used a grid-based air quality model.

However, the Agency did conduct photochemical modeling. Using the EKMA model, the Agency analyzed the effects of nonroad engine emission controls on ozone concentrations. The results of this analysis, presented in more detail in the Notice of Proposed Rulemaking (NPRM) (ref. 58 FR 28809, May 17, 1993), showed that by eliminating nonroad engines in the studied areas, ozone levels would drop between four and 13 parts per billion (ppb) below current levels. This amounts to levels roughly three to eight percent lower than current levels in the 16 ozone nonattainment areas included in the analysis.

The EKMA model has been used by the Agency for a number of years. Although the decision to use this model was driven to some extent by time and resource constraints, the Agency maintains its position that this model is valid and appropriate for the nonroad analysis. The Agency may utilize grid-based air quality modeling in future analyses.

Furthermore, the Agency has traditionally based regulatory decisions on pollutant emission levels and the potential for their reduction. Because of the wide variability inherent in photochemical modeling (source emission levels, emission transport, and meteorological effects including ambient temperatures, cloud cover, sunlight intensity, wind patterns, and so forth), the Agency has typically relied on estimates of potential reductions in source emission inventories as the basis for regulatory analyses. These emission reduction estimates and the well established VOC/NO_X link with tropospheric ozone formation, in conjunction with ozone monitors showing unacceptably high ambient ozone levels, have formed the basis of the Agency's regulatory approach toward ozone control for many years. In addition, as discussed in the NPRM, the Senate Committee Report, in discussing the significance of the contribution of nonroad emissions to ozone problems, specifically discussed the percentage of nationwide NO_X and VOC emissions attributed to nonroad engines. Thus, the Senate clearly understood the relationship between emissions of NO_X and VOCs to the creation of ozone.

The NPRM discussed in detail the Nonroad Study's findings regarding the contribution from nonroad sources of summertime VOCs and NO_X. These findings clearly show that emissions from nonroad engines are a major source of VOCs and NO_X, as well as CO in most, if not all of the nonattainment areas studied. Given the clear link between VOCs and NO_X and the formation of ozone, there can be no question that emissions from nonroad engines are significant contributors to ozone formation in at least two ozone nonattainment areas. Therefore, the Agency has met the CAA mandate to "determine * * * whether emissions * * * from new and existing nonroad engines or nonroad vehicles * * * are significant contributors to ozone or carbon monoxide concentrations in more than one area which has failed to attain the national ambient air quality standards * * *"

2. NO_X Transport

Some commenters asserted that EPA failed to properly consider both the transport of ozone precursor emissions and the natural decay of NO_X concentrations, NO_X having a lifetime of only six to ten hours according to one commenter. One commenter suggested EPA had erroneously assumed that ozone precursors emitted in rural areas are transported toward, and never away from, urban areas. Some commenters suggested that equipment operated primarily in rural areas should be exempted from regulation since these areas do not have air quality problems. Another commenter argued that reducing NO_X can increase ozone, therefore EPA must first show that NO_X reductions will result in reduced ozone nonattainment before promulgating regulations.

Those commenters suggesting the Agency had erroneously assumed that NO_X always will be transported toward, rather than away from, the urban core, may have misunderstood the Agency's assumption. The Agency assumed only that pollution transport *can* occur toward the urban core, thereby contributing to high source emission inventories. It is obvious that different days will produce different transport patterns, and that the potential for rural NO_X and/or rural ozone to be transported toward the urban core exists.

As for the Agency's failure to account for the short lifetime of NO_X and its subsequent low likelihood of long-range

[1] The Nonroad Study is available in the docket for this rulemaking. It is also available through the National Technical Information Service, referenced as document PB 92-126960.

transport, the commenters failed to recognize NO_X sinks. A NO_X "sink" is a molecular compound which stores NO_X (NO and NO_2) for potential later release. Therefore, the NO_X itself may disappear, but it disappears into NO_X sinks, sometimes referred to as NOy, and can then be re-released at a later time. Examples of NO_X sinks include the nitrate radical (NO_3), which forms at night in the presence of ozone and nitrogen dioxide (NO_2) and then quickly photolyzes in the morning,[2] and nitrous acid (HONO), probably formed from NO_2 and water, which is a major source of the hydroxyl radical (OH), a primary constituent for tropospheric ozone formation.[3] Another NO_X sink is peroxyacetyl nitrate (PAN), which transports NO_X over relatively large distances through the atmosphere. The rate of PAN decomposition significantly increases with temperature, so that it can be formed in colder regions, transported, and then decomposed to deliver NO_2 to warmer regions. Another NO_X sink, methyl peroxynitrate (CH_3OONO_2) can last as many as two days in the upper troposphere and then quickly disassociate under surface level temperature conditions, thereby providing a source of NO_2.[4]

Regarding comments that EPA is required to show that NO_X reductions will not lead to actual ozone increases, the Agency disagrees. Most studies indicate that reductions of both VOC and NO_X will lead to reductions of ozone, except under specific circumstances.[5] The photochemical modeling of alternative emission control strategies contained in the ROMNET report[6] offers additional support: ROMNET found that reductions in both VOC and NO_X emissions beyond the minimum requirements of the CAA and across the northeastern U.S. would be required to bring the major East Coast cities into attainment of the ozone standard. In addition, a National Academy of Sciences Study[7] states that, "* * * ozone in rural areas of the eastern U.S. is limited by the availability of NO_X rather than hydrocarbons, and that reductions in NO_X probably will be necessary to reduce rural ozone values." This same study also states that, "Control of NO_X * * *, although it is predicted to lead to an increase in ozone in some places, such as downtown Los Angeles and New York City * * * will probably be necessary in addition to or instead of VOC control to alleviate the ozone problem in many cities and regions." Even under those circumstances where a NO_X decrease can result in an ozone increase, the ozone increase occurs only until a "ridgeline" is reached, after which further NO_X control results in reduced ozone concentrations. In areas with relatively high VOC/NO_X ratios, typical of suburban and rural areas, decreasing NO_X concentrations at constant VOC concentrations is very effective in ozone reduction.[8]

3. Defining Significance

Some commenters argued that EPA cannot make a significance determination without first defining a standard upon which to base that determination, the claim being that without first defining what is significant, any level of contribution could conceivably be deemed as significant. Some commenters argued that the legislative history found in a Senate report stating, "Emissions from off-road and non-road engines and vehicles now make up a *significant* portion of pollution * * * [E]missions inventories from EPA estimate that farm and construction equipment emit 3.7 percent of CO nationwide, four percent of nationwide NO_X, and 1.3 percent of total hydrocarbons * * *,"[9] does not provide guidance on significance, as the NPRM stated.

The Agency disagrees with the contention that a specific numerical standard for significance must be determined prior to considering whether nonroad emissions are significant. When Congress mandated that EPA determine the significance of nonroad emissions, Congress could have given EPA a specific numerical mandate for determining whether such emissions are significant contributors. Instead, Congress gave EPA wide discretion to determine whether the emissions of NO_X, VOCs and CO from nonroad engines and vehicles are significant contributors to ozone or CO concentrations. In any case, any reasonable indicator of significance would conclude that emissions from nonroad engines and vehicles were indeed significant contributors. As presented in the NPRM and discussed above, the Agency's photochemical modeling showed that without nonroad sources, the ozone levels of 16 of the 19 analyzed nonattainment areas would decrease from three to eight percent from their current levels and differences in excess of five percent were indicated in eight of the 16 areas. Additionally, NO_X emission levels from nonroad sources were found to be exceeded by only one other source: the generation of electrical power. Nonroad VOC emission levels were found to be exceeded by only two other sources: light-duty highway vehicles and solvent evaporation. Nonroad CO emission levels were found to be exceeded by only two other sources: light-duty highway vehicles and residential fuel use. In addition, emissions from nonroad engines and vehicles accounted for over ten percent of the inventory of:

(1) VOCs in 12 to 14 of the 19 nonattainment areas studied in the nonroad study;

(2) NO_X in 16 to 19 of the areas studied; and

(3) CO in six to seven of the areas studied.

As pointed out in the NPRM, in numerous nonattainment areas, other sources are regulated that have lower emissions than the total from nonroad engines in the area. Therefore, it is reasonable to conclude that the higher contributions from nonroad sources in those areas are also significant enough to justify the regulation of NO_X, VOC and CO emissions from nonroad engines and vehicles.

4. Operation in Rural Areas

Some commenters stated that some equipment covered by the proposed regulations operates primarily (almost 80 percent based on number of units) in areas already meeting federal clean air requirements; therefore, these commenters concluded that such equipment should not be regulated.

The Agency believes that these pieces of equipment can reasonably be expected to contribute to ozone nonattainment. Also, the Agency has determined that it should not regulate engines only in urban nonattainment areas. Most commenters made strong

[2] Finlayson-Pitts, B.J., and J.N. Pitts, Jr., "Atmospheric Chemistry of Tropospheric Ozone Formation: Scientific and Regulatory Implications," *Air & Waste*, Vol. 43, August 1993, p. 1091.

[3] *Rethinking the Ozone Problem in Urban and Regional Air Pollution*, National Research Council, 1991.

[4] *Rethinking the Ozone Problem in Urban and Regional Air Pollution*, National Research Council, 1991.

[5] *Rethinking the Ozone Problem in Urban and Regional Air Pollution*, National Research Council, 1991.

B.J. Finalyson-Pitts and J.N. Pitts, Jr., "Atmospheric Chemistry of Tropospheric Ozone Formation: Scientific and Regulatory Implications," *Air and Waste*, Vol. 43, August 1993.

[6] U.S. Environmental Protection Agency, "Regional Oxidant Modeling for Northeast Transport (ROMNET), EPA–450/4–91–002a, Research Triangle Park, NC: Office of Air Quality Planning and Standards, June 1991.

[7] *Rethinking the Ozone Problem in Urban and Regional Air Pollution*, National Research Council, 1991, pp. 363 and 377.

[8] B.J. Finlayson-Pitts and J.N. Pitts, Jr., "Atmospheric Chemistry of Tropospheric Ozone Formation: Scientific and Regulatory Implications," *Air and Waste*, Vol. 43, August 1993.

[9] S.R. Rept. No. 101–228, p. 104 (emphasis added).

arguments substantiating the need for national uniformity of treatment for all equipment incorporating regulated engines regardless of the intended geographic area of equipment use. Moreover, Title II of the Act generally requires national regulation of mobile sources, given the inherent ability of such sources to move from one area to another. Also, as discussed, nonroad sources have been clearly shown to contribute significantly to pollution in several nonattainment areas.

5. Significance Determination for Classes and Categories of Nonroad Engines

Some commenters stated that various subcategories of nonroad equipment (e.g., farm equipment, mining equipment) individually represent only a small contribution to national pollutant inventories and to nonattainment and that a significance determination should be made for each specific subcategory of nonroad engine, not for nonroad engines as a whole.

These comments have misinterpreted the clear language of section 213(a). Paragraphs one and two of section 213(a) make it clear that EPA's determination of significance should be based on whether emissions from all new and existing nonroad engines are significant contributors to ozone or CO concentrations. There is no indication that the significance determination should be based on contributions from various subcategories of nonroad engines or vehicles. By contrast, if the Administrator makes an affirmative decision regarding significance, then section 213(a)(3) requires the Administrator to promulgate regulations for those classes and categories of nonroad engines and vehicles "which in the Administrator's judgment cause, or contribute to, such air pollution." This mandate does not include any reference to a determination of significance for classes and categories. Thus, the Agency believes that Congress did not intend a showing of significant contribution to be required for regulation of classes or categories of nonroad engines and vehicles.

This interpretation is echoed by the language in section 213(a)(4) which allows the Agency to regulate new nonroad engine emissions that were not referred to in the Nonroad Study. Under this paragraph, if the Agency determines that any such emissions significantly contribute to air pollution which may reasonably be anticipated to endanger the public health or welfare, the Agency may promulgate regulations applicable to those classes or categories of new nonroad engines and vehicles which in the Administrator's judgment cause or contribute to such air pollution. Once again, there is a reference to significant contribution regarding the initial determination on emissions from all nonroad engines or vehicles, but there is no such reference to significance in the subsequent language regarding regulation of classes or categories of engines and vehicles. Therefore, it seems clear that Congress intended that a showing of significance is not required for regulation of classes or categories of nonroad engines and vehicles.

One commenter suggested that EPA had misinterpreted the statute's requirements based on a perceived inconsistency between that interpretation and the Agency's proposed consent decree settling several lawsuits.[10] This commenter stated that, in the proposed consent decree, EPA had implicitly acknowledged its obligation to make the significance determination for each category or class of products it intends to regulate by specifically reserving its "right" to determine that large gasoline and/or small diesel nonroad engines do not cause or contribute to air pollution within the meaning of section 213(a)(3). Such a reservation, this commenter argued, would be meaningless if EPA were permitted, as proposed in the NPRM, to regulate any category or class of nonroad engine or nonroad vehicle regardless of its contribution to ozone or CO concentrations in nonattainment areas.

The Agency disagrees with the assertion that there is an inconsistency between the Agency's proposed consent decree and the NPRM. In fact, the consent decree does not discuss any determination of "significant contribution" for classes or categories of nonroad engines. The decree only discusses "contribution". The Agency assumes this comment is meant to suggest that prior to regulating, EPA must first show that each equipment type (agricultural, construction, mining, and so forth) contributes significantly to nonattainment. As discussed above, the Agency interprets the Act to provide for regulation of any classes or categories of nonroad engines and vehicles that can be shown to cause or contribute to air pollution. The NPRM discussed the contribution to air pollution of the engine size and type being regulated today. The Agency reserves the right to use other class or category types in future nonroad emissions regulations.

[10] *Sierra Club* v. *Browner*, Civ. No. 93-0197 NHJ (D.D.C. 1993).

6. Equipment Distribution/Use of Consolidated Metropolitan Statistical Areas (CMSA)

Some commenters stated that EPA's use of CMSAs to define the urban areas was inappropriate. These commenters asserted that since many CMSAs encompass an area roughly equivalent to a 100 mile diameter, much of the CMSA is rural. Consequently, EPA has assumed a uniform distribution of nonroad equipment resulting in as many farm tractors in downtown New York City as in the surrounding countryside, according to comments.

Comments that EPA assumed a uniform distribution of equipment within areas evaluated in the Nonroad Study, thereby resulting in an equal number of farm tractors in both downtown New York City and the surrounding countryside, are incorrect. The equipment population distributions used in the Nonroad Study were derived from estimates of activity levels within specific counties of each CMSA. A county, such as that containing Manhattan, would presumably show an activity index for agricultural equipment presumably at or near zero. Therefore, the agricultural equipment population estimate for Manhattan would also be at or near zero.[11]

7. Support of the Agency's Determination of Significance

Some commenters supported the Agency's proposed significance determination. One engine manufacturer supported grouping the 80-plus types of nonroad equipment together instead of evaluating and regulating each type of equipment separately. This commenter also stated that it is not cost effective to build parallel regulated/unregulated engine families for the U.S. market to support regulated and unregulated applications.

A State commented that it is particularly important that any EPA regulation control emissions from construction and farm equipment, as those emissions cannot be controlled by state or local agencies. It cited its own estimates that agricultural equipment contributes over 90 tons per day of NO_x in the State of California. Much of these emissions occur in the San Joaquin valley and are a primary contributor to the nonattainment status of that overwhelmingly agricultural area.

In addition, a major city agreed with the Agency's significance

[11] The methodology is documented in the Energy and Environmental Analysis final report entitled "Methodology to Estimate Nonroad Equipment Populations by Nonattainment Areas," available for review in Docket #A-91-24, Item No. II-A-3.

determination, stating that further reductions in VOC, CO, and NO_x were essential to achieving attainment. A regional association of states also supported the Agency's determination of significance, stating that engines subject to the proposed standards are responsible for approximately 11 percent of all NO_x emitted in its region, making control of emissions from these sources critical to their efforts to meet the statutory requirements of the CAA. An environmental association stated that without significant reductions from nonroad engines, states will not be able to develop long-term plans for the attainment and maintenance of ambient air quality standards.

IV. Definition of Nonroad Engine

CAA section 216(10) defines the term "nonroad engine" as "an internal combustion engine (including the fuel system) that is not used in a motor vehicle or a vehicle used solely for competition, or that is not subject to standards promulgated under section 111 or 202." Section 111(a)(3) of the CAA notes, however, that "Nothing in Title II of this Act relating to nonroad engines shall be construed to apply to stationary internal combustion engines."

1. Original Proposed Definition of Nonroad Engine

In the May 17, 1993 NPRM, EPA proposed that the engines encompassed by the statutory definition of nonroad engine included internal combustion engines meeting one of the following criteria:

(1) Any internal combustion engine (including the fuel system) of any size which is used to propel any vehicle if the engine is not otherwise excluded from this definition (see below). This includes any internal combustion engine which serves a dual function (that is, to both propel a vehicle and operate a device while stationary), such as a mobile crane;

(2) Any internal combustion engine which is located in (or on) a nonroad vehicle and which is an integral part of the nonroad vehicle at the time of the nonroad vehicle's manufacture and which is not otherwise excluded from this definition (see below); or

(3) Any internal combustion engine or combination of internal combustion engines arranged to function together, regardless of application, with a combined output of less than 175 hp, unless otherwise excluded from this definition (see below).

Several specific exclusions were included in the proposed definition of nonroad engines. An internal combustion engine would not be considered a nonroad engine if:

(1) The engine is used to propel a motor vehicle or a vehicle used solely for competition;

(2) The engine is regulated under section 111 or section 202 of the Act, regardless of size; or

(3) The engine is located on a trailer or other platform attached to (not an integral part of) a nonroad vehicle or is otherwise not an integral part of a nonroad vehicle and the engine has an output greater than or equal to 175 hp.

EPA received numerous comments in response to this NPRM definition. The vast majority of commenters opposed all or part of the proposed definition.

The primary reason cited by commenters for their opposition to the proposed definition relates to the use of a horsepower (hp) cut-off point as the means for determining which internal combustion engines are classified as nonroad engines. The commenters asserted that the use of a horsepower cut-off point would allow engines used in mobile applications to be regulated as stationary sources, and would allow stationary engines to be regulated as mobile sources, solely on the basis of engine size. The commenters noted that this would result in identical sources being regulated in a different manner based solely on engine power. Commenters further indicated that the use of a horsepower cut-off point is arbitrary and not reflective of the realities of portable or transportable equipment, which can be and are moved from one area to another and, therefore, should be classified as nonroad regardless of horsepower.

According to these commenters, an engine should be classified on the basis of its use as mobile or stationary, rather than on its horsepower. In other words, the determination as to whether an engine is a nonroad engine should depend on whether the engine is either used in equipment that is mobile (that is, self-propelled, portable or transportable), or in equipment that is in fact used in a stationary manner at a particular location for an extended period of time.

Industry commenters indicated that to do otherwise could result in costly and unnecessary administrative burdens for manufacturers. According to these commenters, such administrative burdens would result from engines and equipment that would be wrongly subjected to a myriad of different mobile and stationary source regulations in states and local air quality management districts. The commenters also indicated that regulation by a multitude of regulatory agencies could result in restricting the geographic operating range of certain engines and equipment.

In addition, commenters indicated that it would be contrary to the intent of the Act. In support of this position, these commenters noted that Congress did not establish a horsepower cut-off point in the Act for distinguishing between nonroad and stationary engines, and did not require that nonroad vehicles be self-propelled to fall within the nonroad definition.

The comments from state and local air pollution control agencies also opposed the use of a horsepower cut-off point for determining whether internal combustion engines would be classified as nonroad engines. Local air pollution control agencies noted that they are currently regulating stationary engines under 175 hp and would lose the authority to continue regulating these engines under the proposed nonroad definition.

For a detailed discussion of the comments regarding the nonroad definition initially proposed see the Response to Comments in the docket.

2. Revised Definition of Nonroad Engine

In response to the comments received regarding the nonroad definition proposed in the May 17, 1993 NPRM, EPA revised the nonroad engine definition. The revised definition was published in the **Federal Register** on October 4, 1993 (58 FR 51595). The comment period was reopened until October 25, 1993, so that interested parties could provide comments on the following revised definition of nonroad engine:

(1) Except as discussed in (2) below, a nonroad engine is any internal combustion engine:

(i) In or on a piece of equipment that is self-propelled or serves a dual purpose by both propelling itself and performing another function (such as a mobile crane); or

(ii) In or on a piece of equipment that is intended to be propelled while performing its function (such as lawn mowers and string trimmers); or

(iii) That, by itself or in or on a piece of equipment, is portable or transportable, meaning designed to be and capable of being carried or moved from one location to another. Indicia of transportability include, but are not limited to, wheels, skids, carrying handles, dolly, trailer, platform or mounting.

(2) An internal combustion engine is not a nonroad engine if:

(i) The engine is used to propel a motor vehicle or a vehicle used solely for competition; or

(ii) The engine is regulated under section 111 or section 202 of the Act; or

(iii) The engine otherwise included in (1)(iii) remains or will remain at a location for more than 12 consecutive months, or a shorter period of time where such period is representative of normal annual source operation at a stationary source that resides at a fixed location for more than 12 months (e.g., seasonal operations such as canning facilities.) A location is any site at a building, structure, facility, or installation. Any engine (or engines) that replaces an engine at a location and that is intended to perform the same or similar function as the engine replaced will be included in calculating the consecutive time period.

A portable generator engine which functions as a permanent back-up generator and which is replaced by a different engine (or engines) that performs the same function would be an example of engines covered by (2)(iii). In such a case, the cumulative residence time of both generators, including the time between removal of the original engine and installation of the replacement, would be counted toward the consecutive residence time period.

EPA intended the revised definition of nonroad engines to address concerns expressed by the commenters in response to the definition originally proposed. Under the revised definition, an internal combustion engine would be a nonroad engine if it is used in equipment that is self-propelled or intended to be propelled while performing its function, or if it is portable or transportable. The revised definition specifically distinguishes between nonroad engines and stationary internal combustion engines on the basis of engine mobility and residence time, rather than on horsepower size.

EPA intended that stationary internal combustion engines be all internal combustion engines regulated by a federal New Source Performance Standard promulgated under section 111 of the Act and all internal combustion engines that are neither nonroad engines nor engines used to propel a motor vehicle or a vehicle used solely for competition. Moreover, the revised definition specifically states that portable and transportable engines remaining in a particular location for over 12 months are not nonroad engines (this excludes engines in self-propelled equipment and equipment intended to be propelled while performing its intended function), thus ensuring that engines that are actually used in a stationary manner are considered stationary engines.

The revised nonroad engine definition excluded from nonroad regulation those engines that are used for normal annual source operations at fixed stationary sources that only operate on a seasonal basis, such as canneries. This provision is designed to ensure that engines that operate as integral parts of these stationary sources are considered stationary.

The revised nonroad engine definition also included a provision that if an engine is replaced by another engine within the 12 month period, the replacement engine should be considered in calculating the consecutive time period. This provision is designed to ensure that where an internal combustion engine is necessary for the operation of a stationary facility, the replacement of one particular engine with another would not prevent the engines from being included as part of the stationary facility.

EPA included as a prohibited act any attempt to circumvent the residence time exclusion of a portable or transportable engine in (2)(iii) by means of removing the engine from its location for a period and then returning it to that same location. In such cases, the time between removal of the engine and its return to service (or replacement) would be counted towards the time period specified in (2)(iii).

3. Final Definition of Nonroad Engine

The majority of comments received on the revised definition supported the usage-based definition, as opposed to the initially proposed power-based definition. Still, most commenters requested that EPA make two modifications to the revised nonroad engine definition.

The first modification requested by the commenters relates to section (2)(ii) of the revised definition which stated that an engine is not a nonroad engine if it is regulated under section 111 or section 202 of the CAA. The commenters expressed concern that this portion of the definition would allow states to promulgate state regulations under the authority of section 111, creating a loophole in the state preemption framework, whereby states would be able to regulate preempted engines. They contended that this would result in dual standards for an engine, as both stationary and nonroad.

The second modification requested by the commenters relates to the application of the 12 month residence time limitation to seasonal operations. While most commenters agreed with the proposal to use a 12 month residence time limit to distinguish between mobile and stationary use of portable or transportable engines, several commenters opposed the proposal to consider residence time based on "seasonal" use. These commenters asserted that excluding an undefined group of engines for an indeterminate period of time, between one and 365 days, is neither reasonable nor enforceable. Moreover, the same commenters requested that EPA clarify that the 12 month residence time applies only to those portable and transportable engines which are integral parts of fixed stationary sources.

One commenter opposed the 12 month time limit on the grounds that it could create a regulatory vacuum which would result in some engines escaping all nonroad engine and stationary engine regulations. In support of the revised nonroad engine definition, another commenter stated that the equipment used on a military installation should be designed so emissions are reduced by the engine manufacturer and not by the end user. The commenter requested that EPA clarify the term "location" in a manner that would permit a "location" to exist within a stationary source.

The comments from a State agency supported the elimination of the horsepower criteria for nonroad engines, but expressed concern that the new definition would cause it to lose permitting authority for engines it was currently regulating as stationary engines. The commenter suggested that those states with permitting programs be allowed to maintain permitting authority over those engines which they had previously determined to be stationary.

One local air pollution agency disagreed with EPA's conclusion that portable engines are nonroad engines. In support of its position, the agency cited title V of the CAA as evidence that Congress recognized that some stationary sources were moveable. If EPA were to adopt a definition based on residence time, the agency requested that three months, rather than a year, be the cutoff point beyond which an engine would no longer be considered nonroad.

The Agency believes that the revised nonroad definition eliminates the potential for the arbitrary classification of internal combustion engines as nonroad or stationary sources based on engine size. Rather, as noted by the commenters, the revised definition is based on the use of the engine, which is a more appropriate and reliable indicator of its classification.

EPA has considered the modification requested by some commenters regarding that portion of the definition that provides an internal combustion

engine is not a nonroad engine if it is regulated under CAA section 111. The Agency has amended the revised definition to provide that an internal combustion engine is not a nonroad engine if "The engine is regulated by a federal New Source Performance Standard promulgated under section 111 of the Act." Thus, under provision (2)(ii), national emission standards for an internal combustion engine must be promulgated before it is classified as a stationary engine.

Contrary to the comments, EPA believes that it is appropriate to exclude from the nonroad definition engines that remain at sources that only operate on a seasonal basis. Although such sources, such as canning facilities, may operate for less than 12 months in any one year, they operate regularly for a similar time period year after year. Operations for a seasonal source generally occur at the same location, rather than traveling between different states or regions. Engines that are located at a seasonal source during the full annual operations period of that source should be considered a part of that source. They are clearly integral parts of these facilities. Moreover, as such sources produce emissions that can be calculated on a regular basis, a local air quality agency or other authority should be able to reasonably enforce stationary source regulations. As a result, the Agency has maintained the seasonal source exclusion. However, as requested by several commenters, EPA has revised the language for the exclusion to make it clearer. EPA believes that a seasonal source is a stationary source because it functions at only one location for its full annual operating period, even if that period is less than 12 months. EPA has specified in the final regulations that a seasonal source must remain at a single location on a permanent basis (that is, at least two years) and must operate approximately three months or more each year. EPA also clarified that an engine located at a seasonal source is an engine that remains at the source for the full annual operating period of the source. This should eliminate any confusion as to whether certain sources are considered to be seasonal sources.

EPA also disagrees with commenters who believe that only engines "fixed" in place for more than 12 months should be excluded from the nonroad definition. An internal combustion engine can be stationary without being "affixed" to the ground or other structures. To require otherwise could result in the improper classification of internal combustion engines. For example, an engine that is not bolted or otherwise attached to a structure but remains at one location for five years would be classified under the commenters' proposition as a nonroad engine, even though it operates in a stationary manner, as evidenced by its remaining at the same location for an extended period of time. Therefore, the Agency has decided that the fact that an engine is not "affixed" to the ground or other structure does not necessarily identify the internal combustion engine as a nonroad engine.

The Agency also believes that 12 months is the appropriate time limit for determining whether an internal combustion engine which is either portable or transportable is to be classified as a stationary engine. Generally, engines that remain at one site for more than 12 months will stay at that site either permanently or for an extended period of time. In such cases, local or state air quality agencies should be able to regulate the applicable engines as stationary sources, since the emissions impact is occurring over a period of time which is likely to have a measurable impact on an area's air quality.

The term "location" has been defined so as to permit a "location" to exist within a facility. Section (2)(iii) of the revised definition defines "location" as "any single site at a building, structure, facility or installation." This definition of "location" provides more precision in classifying an engine as nonroad if the engine is actually intended to be used in a mobile manner within a stationary source. In other words, an engine would be considered nonroad if it moves to different sites within a stationary source.

EPA does not agree with the assertion made by one commenter that title V of the CAA evidences Congress' recognition that some stationary sources are moveable. Title V of the CAA deals with the permitting of stationary sources and not with the determination as to which internal combustion engines are nonroad engines and which are stationary engines.

4. Nonroad Engines Manufactured Prior to the Effective Date of This Definition

In the initial NPRM, EPA noted that it interprets the exclusion in CAA section 302(z) to apply only to those internal combustion engines that are manufactured after the effective date of these regulations. EPA stated that this interpretation avoids a regulatory gap for engines manufactured between the promulgation of the CAA and the date that these regulations are promulgated. EPA received several comments opposing this interpretation. These commenters claimed that the language in section 302(z) applied to all nonroad engines at the time of the passage of the 1990 CAAA, even though that term had not yet been defined with any reasonable clarity. In addition, commenters asserted that nonroad engines are generally preempted from regulation by states under title II of the Act.

EPA continues to believe that internal combustion engines manufactured prior to the effective date of these regulations should not be considered preempted nonroad engines. First, EPA believes that until the regulations finalizing the definition of nonroad engine (as well as the regulations determining the scope of the term "new" as applied to nonroad engines) were complete, no state or other entity could be assured whether such engines would be defined as nonroad engines or as stationary internal combustion engines and the extent to which state regulations of such engines was preempted. Congress clearly intended EPA to determine which internal combustion engines should be defined as nonroad engines and which should be stationary internal combustion engines.[12] As has been discussed above, the final definition of nonroad engine promulgated today is substantially revised from the definition originally proposed. Moreover, as the comments reveal, numerous other definitions of nonroad engine have been suggested to the Agency, many of which are either significantly broader or significantly narrower than EPA's final definition. EPA believes that if the exclusionary language of section 302(z) were applied before EPA's definition of nonroad engine became final, states would have been frustrated from regulating any internal combustion engines manufactured during that time, given the uncertain nature of such engines. For example, a state would not know whether to include regulations of engines in its New Source Review program, or whether such engines should be regulated in a separate in-use operation program. Further, until the initial regulations regarding nonroad engines were finalized, states could not determine the extent to which their regulation of such engines would be preempted, and thus were hampered from going forward with specific programs to regulate such engines. EPA believes that Congress did not intend states to be prevented from regulating these engines before EPA defined what they were. In particular, EPA believes that permits for internal combustion

[12] See Report of House of Representatives Committee on Energy and Commerce, Rept. 101-490, at 272 (May 17, 1990).

engines issued prior to July 18, 1994, are not precluded under section 209 and 302(z) if the permits apply to internal combustion engines manufactured before July 18, 1994, even if those engines are of a type that has been defined by EPA to be nonroad engines.

Moreover, even to the extent such engines are defined to be nonroad engines in this final rule, such engines were not preempted from state regulations under section 209 prior to the effective date of these regulations. The two sections of the Act preempting state regulation of nonroad engines, section 209(e)(1) and section 209(a) (as incorporated by section 213(d)), refer to "nonroad engines subject to regulation under this Act" or to engines "subject to this part." EPA believes that, until EPA promulgated final regulations defining nonroad engines and subjecting such engines to regulation, these engines were not preempted from state regulation under the Act, nor were they subject to any regulation under title II of the Act.

Finally, some of the comments regarding the definition of nonroad engines and the issue of grandfathering examined whether grandfathering subjects an engine to dual regulation (i.e., regulation both by the state as a stationary source and by EPA as a nonroad engine). There is no such risk in this instance because EPA has not subjected any engines manufactured before the effective date of this regulation to regulation as new nonroad engines. Such engines, if they are regulated at all, are regulated under title I programs.

Moreover, it should be noted that the vast majority of these engines are no longer new nonroad engines. Thus, even if they are viewed as preempted nonroad engines, they are subject to in-use regulation by states.

As discussed below in section VI. U. (definition of new), states are not precluded from regulating the use of nonroad engines. Nothing in section 209 of the CAA prohibits local pollution control districts from regulating the operation of nonroad engines, such as the hours of usage, sulfur limits in fuel (state fuel restrictions may in some cases be precluded under section 211), daily mass emission limits, and title I operating permits. In addition, local districts can impose a permitting fee consistent with the costs incurred for various operational expenditures, such as monitoring usage and administrative functions. EPA believes that utilization of this option will assist local districts in achieving their targeted emission levels.

Moreover, states are not prevented from requiring retrofitting of nonroad engines, as long as such requirements do not amount to a standard relating back to the original design of the engine by the original engine manufacturer. As discussed below, EPA believes modest retrofit requirements may be required after a reasonable amount of time, such as at the time of reregistration or rebuilding. Moreover, after a sufficient time has passed after an engine ceases to be new, for example, after the end of the useful life of the engine, a state may institute more significant retrofit requirements. As the court stated in *Allway Taxi* v. *City of New York*, 340 F. Supp. 1120, 1124 (S.D.N.Y.), *aff'd*, 468 F. 2d 624 (2d Cir. 1972), section 209 "was made not to hamstring localities in their fight against air pollution but to prevent the burden on interstate commerce which would result if, instead of uniform standards, every state and locality were left free to impose different standards for exhaust emission control devices for the manufacture and sale of new cars." The Act does not intend preemption of regulations, like regulation of the use of nonroad engines or modest retrofit requirements after an engine is no longer new, that "would cause only minimal interference with interstate commerce, since they would be directed at intrastate activities and the burden of compliance would be on individual owners and not on manufacturers and distributors." *Id.*

EPA has added an interpretive rule in the form of an appendix to these regulations summarizing its views on these issues (see Appendix I to subpart A of part 89: Internal combustion engines manufactured prior to the effective date of the nonroad engine definition). This interpretive rule does not supersede, alter, replace, or change the scope of these regulations. The appendix is intended to be interpretive guidance and is not final agency action subject to judicial review.

Based on comments received from several of California's local air quality districts, the Agency is concerned about the impact of the nonroad definition on the unique situation that exists in these areas, that is, the current local regulation of certain engines as stationary sources which, as a result of the nonroad definition, will become nonroad engines subject to emission standards promulgated only by EPA. According to the commenters, classification of these engines as nonroad by EPA may negatively affect the ability of local districts to achieve targeted emission reduction levels. To some extent, the grandfathering in of certain engines, discussed above, addresses this concern by ensuring that engines regulated prior to the effective date of this rulemaking continue to be regulated in the same manner. Nevertheless, this may not, in all situations, allay concerns regarding the overall impact that classification of these engines as nonroad will have on an area. The Agency believes, however, that any additional concerns that may exist following the effective date of this rule can be addressed by local air quality districts through their regulation of nonroad engine operations.

5. Equating Nonroad Engines With Nonroad Vehicles and Equipment

EPA received one comment on the October 4, 1993 notice that opposed the revised definition of the term "nonroad engine" because, according to the commenter, the definition equated nonroad engines with nonroad equipment. This comment states that, by defining nonroad engines in terms of their use "in or on a piece of equipment," EPA exceeded its authority because, according to the commenter, the CAA only authorizes EPA to regulate nonroad engines and vehicles, not nonroad equipment. This comment argues that EPA does not have equal authority over off-highway mobile cranes, which are nonroad vehicles, and lawnmowers and string trimmers, which are nonvehicular nonroad equipment. This comment asks EPA to acknowledge that it lacks authority to regulate nonroad equipment.

First, EPA disagrees with the commenter's contention that the nonroad engine definition "equates" nonroad engines with nonroad equipment. The nonroad engine definition is written to include only engines, and cannot be read to include equipment. The definition clearly refers only to "engines used in" certain applications, not to the applications themselves. Moreover, this definition has been promulgated pursuant to numerous comments received by the Agency, discussed above, that assert that the most appropriate definition of nonroad engine is one that refers to the use or application of the engine.

EPA also notes that this rulemaking does not promulgate any standards for nonroad equipment, only for nonroad engines. The only restriction on nonroad equipment manufacturers in this rulemaking is a prohibition on the use of uncertified nonroad engines manufactured after the applicable implementation dates. This prohibition is necessary to enforce the engine-based standards and is authorized under the Clean Air Act.

In addition, EPA does not agree that it lacks authority to regulate nonroad equipment or particular applications of nonroad engines. CAA section 213, as well as section 301(a), provide EPA with authority to regulate both nonroad equipment and particular applications of nonroad engines, as well as nonroad engines and nonroad vehicles.

Congress used the terms "nonroad engine," "equipment," and "vehicle" interchangeably (see, e.g., S. Rep., Legislative History of the 1990 Amendments to the Clean Air Act, Committee on Environment and Public Works to accompany S. 1630, December 20, 1989, at 104–105). It is EPA's belief that Congress intended nonroad vehicles and engines to be inclusive terms covering all manner and types of equipment not defined as motor vehicles, vehicles for competition, or stationary sources (see, e.g., H. Rep., Legislative History of the 1990 Amendments to the Clean Air Act, Committee on Energy and Commerce to accompany H.R. 3030, May 17, 1990, at 310). There is no evidence that Congress intended to limit the reach of its nonroad mandate to self-propelled vehicles; on the contrary, it appears that Congress used the term vehicle to include any carrier for the engine.

Section 213 and the rest of the CAA provide EPA with authority to regulate nonroad equipment and particular applications of nonroad engines in nonroad equipment. The Act provides equal authority to regulate off-highway mobile cranes, which are nonroad vehicles, and lawnmowers, which are nonroad equipment.

Moreover, the interpretation of EPA's authority suggested by the commenter would undermine the environmental and public health benefits of the nonroad emission reduction program by creating a gaping loophole. EPA can find no evidence that Congress intended the regulation of certain nonroad engines, vehicles, and equipment that cause or contribute to air pollution, but not the regulation of others.

Finally, there is a practical interrelationship between an engine and the equipment that houses it or is powered by it. Equipment or vehicle characteristics may have a significant impact on the emissions associated with the operation of the engine. The nonroad engine definition relies to a great extent on this interrelationship between an engine and a piece of equipment to determine whether an engine is a mobile or stationary source. In the future development of the nonroad program, EPA may determine that it is most effective to test and certify a nonroad engine integrally with its related equipment, rather than separately. Additionally, it may become necessary and appropriate to regulate aspects of equipment to control fuel spillage, evaporative emissions, or refueling emissions. EPA believes that the CAA provides authority for such regulation. EPA does not believe Congress, in giving EPA the authority to regulate all nonroad engines, intended to create an artificial barrier between the engine and the equipment that houses it. Therefore, if EPA determines in future rulemakings that the most effective way to control emissions from nonroad engines is to regulate directly the nonroad equipment housing the engines, EPA shall do so using its authority under the Clean Air Act.

V. Requirements of the Final Rule

This section provides a general overview of the major elements of the final rule. A general discussion of comments submitted to EPA during the public comment periods is presented in section VI.

A. Applicability

The regulations of today's action apply to all new nonroad CI engines at or above 37 kW with certain exemptions and exclusions. Hereafter the engines included in this rule will be referred to as "large nonroad CI engines."

The vast majority of large nonroad CI engines currently being used and manufactured are diesel-fueled engines. The use of alternative fuels by nonroad engines will not be necessary to meet the emission standards. However, these regulations apply to large nonroad CI engines regardless of the fuel that is used (for example, diesel, compressed natural gas (CNG), rapeseed, methanol, ethanol, and blends). Provisions have been included which allow manufacturers to apply for Administrator approval of alternative test procedures if fuel other than diesel is to be used.

B. Standards

EPA is adopting the proposed NO_x emission and smoke standards for all large nonroad CI engines at or above 37 kW produced on or after the implementation dates presented below. Furthermore, EPA is adopting standards for HC, CO, and PM emissions for engines at or above 130 kW, consistent with those standards adopted by California in sections 2420–2427, chapter 11, title 13 of the California Code of Regulations, "California Regulation for New 1996 and Later Heavy-duty Off-road Diesel Cycle Engines."

All standards and units have been converted to metric in the final rule (discussed in more detail in section VI.A.). For ease of use, the tables below and in section V.C. show the English units parenthetically. The metric units, however, are the units used in the regulations and thus all affected parties must follow these units in complying with the standards promulgated today.

Net Power kW(Hp)	HC g/kW-hr (g/bH p-hr)	CO g/kW-hr (g/bH p-hr)	NO_x g/kW-hr (g/bH p-hr)	PM g/kW-hr (g/bH p-hr)	Smoke A/L/P[1] (Percent)
≥130 (≥175)	1.3 (1.0)	11.4 (8.5)	9.2 (6.9)	0.54 (0.4)	20/15/50
≥75 to =130 (≥100 to <175)	.....	.....	9.2 (6.9)	.....	20/15/50
≥37 to <75 (≥50 to <100)	.....	.....	9.2 (6.9)	.....	20/15/50

[1] Smoke Opacity Standards are reported in terms of percent opacity during an acceleration mode, a lug mode and the peak opacity on either the acceleration or lug modes.

In addition, EPA is prepared to propose and adopt additional standards for HC, CO, and PM emissions for engines from 37 kW to less than 130 kW consistent with those to be adopted by the European Community (EEC) and the United Nations Economic Commission for Europe (ECE) as soon as these groups finalize their requirements for HC, CO, and PM emissions. The European standards are currently projected to be as follows:

Net Power kW (Hp)	HC g/kW-hr (g/bHp-hr)	CO g/kW-hr (g/bHp-hr)	PM g/kW-hr (g/bHp-hr)
≥130	[1] 1.3	5.0	[1] 0.54
(≥175)	(1.0)	(3.7)	(0.40)
≥75 to <130	1.3	5.0	0.70
(≥100 to <175)	(1.0)	(3.7)	(0.52)
≥37 to <75	1.3	6.5	0.85
(≥50 to <100)	(1.0)	(4.8)	(0.63)

[1] Consistent with the current California standards.

Note that the adopted CO standard for engines at or above 130 kW may be changed from 11.5 g/kW-hr to 5.0 g/kW-hr when the European rules are final. This would ensure consistency between EPA and the more stringent European standard. This is also compatible with California since engines certified to the lower European CO standard would clearly be below the California CO standard.

C. Implementation Dates

All engines produced by an engine manufacturer on or after January 1 of the implementation year specified below by power category must be certified by the engine manufacturer according to the requirements in effect for that year. No nonroad vehicle or equipment manufacturer may install in its vehicles or equipment nonroad engines manufactured after January 1 of the implementation year specified below unless such engines are certified engines. EPA expects nonroad vehicle and equipment manufacturers to begin installing certified engines as soon as they become available from engine manufacturers, although EPA understands that some transition period may be necessary for vehicle and equipment manufacturers to deplete their inventory.

Early certification is allowed one year prior to the applicable implementation date for engines participating in the averaging, banking, and trading (ABT) program for NO_X.

Engine size, kW (Hp)	Implementation date
≥130 to ≤560 (≥175 to ≤750).	January 1, 1996.
≥75 to <130 (≥100 to <175).	January 1, 1997.
≥37 to <75 (≥50 to <100).	January 1, 1998.
>560 (>750)	January 1, 2000.

D. Certification and Test Procedures

1. Engine Family Selection

EPA is adopting the engine family definition as proposed. EPA had expressed some concern in its proposal that, should it adopt HC, CO and PM emission standards in the final rule, it was uncertain whether manufacturers should be allowed to include engines with different numbers of cylinders or cylinder orientations in the same engine family. EPA argued that it was uncertain whether deterioration of HC, CO and PM emission performance would proceed at different rates in-use for engines with different numbers of cylinders. One commenter expressed a strong desire to be able to consolidate engine families as much as practicable. The commenter also reminded EPA of the substantial enforcement liability program in this rule that would provide adequate incentive to ensure a manufacturer makes reasonable use of the engine family flexibilities.

The Agency is aware that additional built-in safeguards such as the manufacturers' burden to define engine families in such a way as to ensure all engine configurations have similar emission characteristics, and the manufacturers' recall liability if all engine configurations are not as durable as expected. The Agency has no additional data at this time to address its original concern. However, the Agency does believe that the enforcement provisions in this rule will provide incentive to manufacturers to ensure that their engines are properly grouped so that they can be appropriately represented by the selected test engines.

2. Exhaust Emission Test Procedures

The smoke test procedures are adopted as they were proposed.

The gaseous emission 8-mode test procedures are finalized as proposed with minor revisions. These procedures apply to HC and CO emissions as well as NO_X.

For PM emission measurement, EPA is adopting the California test procedures finalized in Sections 2420–2427, Title 13 of the California Code of Regulations, "California Regulation for New 1996 and Later Heavy-duty Off-road Diesel Cycle Engines," as amended by California Air Resources Board Resolution 92–2, described in CARB mailout #93–42 dated September 1, 1993. These procedures are incorporated by reference in the regulations.

Manufacturers of engines that are not able to operate properly over the 8-mode or smoke test cycles (such as engines with constant speed governors) may petition the Administrator prior to certification to allow use of an alternative test procedure. Upon adequate demonstration of need, the Administrator may allow use of alternative procedures. If an engine is unable to be operated over the smoke test procedure, the manufacturer must submit an alternative test plan to the Administrator for approval in advance of any testing performed for certification purposes. Use of alternative test procedures to demonstrate exhaust emission compliance is discussed in Section VI.H.

3. Certification Test Fuel

EPA is adopting the certification test fuel specifications as proposed. This is because the most common diesel fuel available to nonroad engines will have a higher sulfur content than that required for highway CI engines. Furthermore, to ensure that no commercially available fuel is inadvertently excluded by this rule, EPA has broadened the band of fuel sulfur content to include all fuels ranging from greater than .05 percent to .5 percent fuel sulfur. However, as a provision of harmonizing with California emission standards, and explained below, EPA will allow engine manufacturers the option to use test fuel specified by California, which contains lower sulfur content.

California's particulate standard is predicated on the use of low sulfur fuel, which is the State-wide fuel standard for both nonroad and highway engines. Therefore, the particulate standard EPA is adopting is likewise predicated on the use of low sulfur fuel. However, EPA cannot require testing on a fuel that is not widely available. To compensate for the effect of sulfur on particulate emissions, EPA is permitting two options for demonstrating compliance with those standards. First, EPA will allow testing on the low sulfur

California-specified test fuel for compliance with all emission standards because sulfur content does not impact HC, CO or NO_X emissions. Second, when testing is conducted with the higher sulfur federal certification fuel, the particulate measurement may be adjusted by using the following equation to reflect the effects of higher sulfur content of the fuel on particulate emissions:

$PM_{adj} = PM - [BSFC * 0.0917 * (FSF - USLF_{CA})]$

Where:

PM_{adj} = adjusted measured PM level [g/Kw-hr]

PM = measured weighted PM level [g/Kw-hr]

BSFC = measured brake specific fuel consumption [G/Kw-hr]

FSF = fuel sulfur weight fraction

$USLF_{CA}$ = upper sulfur level weight fraction of California specification.[13]

This adjustment only applies to engines with no exhaust gas aftertreatment. No adjustment is provided for engines with exhaust gas aftertreatment.

The test fuel option selected by the manufacturer will not affect enforcement testing for the HC, CO, NO_X and smoke standards. EPA may select either fuel, without constraints, for confirmatory or other compliance testing for all of the standards, except particulate. For particulate testing, EPA's options are constrained somewhat by the manufacturer's choice of test fuel. If a manufacturer chooses to test using low sulfur California test fuel, EPA would not use higher sulfur, with the associated adjustment factor, for official enforcement of the particulate standard. However, if a manufacturer chooses to test using the higher sulfur fuel, EPA will presume the manufacturer accepts the validity of the adjustment factor, in which case EPA could choose to do a particulate enforcement test using either the higher sulfur fuel with adjustment or the low sulfur fuel without adjustment. This issue is discussed further in section VI. I. below.

4. Certification Test Engine Selection

EPA has revised the proposed certification test engine selection criteria. The selection of an engine configuration within an engine family will be based on the most fuel injected per stroke of an injector at maximum power.

5. Labeling of Engines From Each Engine Family

EPA is adopting the proposed requirement to label each engine; some minor modifications have been made to the proposal.

6. Definition of "New"

EPA has added a definition of "new" as it pertains to nonroad engines, vehicles and equipment.

7. Other Requirements

EPA is adopting as proposed:

(a) The requirement to obtain a federal certificate for each engine family every model year;

(b) The recordkeeping and reporting requirements;

(c) Provisions for EPA confirmatory testing with minor technical revisions; and

(d) The averaging, banking and trading provisions.

8. Fees

As discussed in the NPRM for this rulemaking, EPA is authorized under section 217 of the CAA to establish fees to recover compliance program costs associated with sections 206 and 207. EPA will propose to establish fees for today's nonroad compliance program at some future time, after associated costs are determined.

E. Enforcement

1. Prohibited Acts

EPA is adopting provisions that will prohibit introducing engines into commerce in the U.S. which are not covered by a certificate of conformity issued by EPA. Additionally it will be a prohibited act to use a regulated but uncertified nonroad engine in nonroad vehicles or equipment.

2. Selective Enforcement Auditing (SEA)

With the exception of some revisions described below, the SEA program is being adopted as proposed. The large nonroad CI engine SEA program is an emission compliance program for new production nonroad engines and is authorized by CAA section 213. With this action EPA may issue a SEA test order for any engine family for which EPA has issued a certificate of conformity.

3. Emission Defect Warranty

EPA is adopting emission design and defect warranty requirements as proposed. Nonroad engine manufacturers will be required to warrant emission related components for a period of five years or 3,000 hours from the date of purchase by the ultimate purchaser. This warranty will help ensure the manufacturing of a durable emission system and will require the manufacturer to cover all repairs and replacements involving emission related components, at no cost to the ultimate purchaser, during the warranty period.

4. Tampering Prohibitions

EPA is adopting as proposed prohibitions against tampering with nonroad engines. Nonroad tampering provisions will help ensure that in-use engines remain in certified configurations and continue to comply with emission standards. All persons, will be prohibited from removing or rendering inoperative any device or element of design installed on or in a nonroad engine. The manufacturing, sale and installation of a part or component intended for use with a nonroad engine, where a principal effect of the part or component is to bypass, defeat, or render inoperative a device or element of design of the nonroad engine will also be prohibited.

5. Importation Restrictions

EPA is implementing the proposed restrictions on the importation of nonconforming nonroad engines. Today's action will permit independent commercial importers (ICIs) who hold valid certificates of conformity issued by EPA to import nonconforming nonroad engines. Under this program, the ICI must certify the engine to applicable U.S. regulations via the certification process before an engine is imported. ICIs will be responsible for assuring that subsequent to importation, the nonroad engines are properly modified and/or tested to comply with EPA's emission and other requirements over their useful lives. The ICIs will also be responsible for recalls, maintenance instructions, emission warranties, engine emission labeling, and maintaining adequate records in the same manner as an engine manufacturer.

Today's action also provides certain exceptions to the restrictions on importing nonconforming nonroad engines. These exceptions are similar to the existing regulations on importing nonconforming motor vehicles and motor vehicle engines and include

[13] Should European requirements be finalized using a different fuel sulfur level but maintaining the same PM emission standards as those adopted in this rule and allowing no adjustment for fuel sulfur content, EPA will consider revising its regulations to replace the upper sulfur level weight fractions from the California specification (that is, $USLF_{CA}$) with the upper sulfur level weight fraction from the final European test fuel specification (that is, $USLF_{ea}$).

exemptions for repairs and alterations, testing, precertification, display, national security, hardship, nonroad engines greater than 20 original production years old, and certain nonroad engines proven to be identical, in all material respects, to their corresponding U.S. versions. These exceptions also include the exclusion of nonconforming engines used solely for competition.

6. In-Use Enforcement

EPA is adopting the proposed regulations subjecting nonroad engine manufacturers to the requirements of section 207 of the CAA. Under the adopted regulations EPA has the authority to recall engines which do not comply with emission standards in-use. As proposed, the in-use testing liability period will be up to seven years or 6,000 hours, which ever occurs first. The actual repair period for which a manufacturer must remedy nonconformities would not be limited by actual years or hours, thus any resulting recall will apply to all engines of the recall family, regardless of the years or hours of an individual engine.

In-use compliance with emission standards will be determined based on test results using the same test procedure as that used in certification. EPA is modeling its large nonroad CI engine recall program after section 207 of the CAA and therefore the Administrator may require manufacturers to recall applicable engines if a substantial number of properly maintained and used engines are found to be out of conformity with the regulations issued under section 213 of the CAA.

7. Defect Reporting

EPA is adopting the proposed emission defect reporting regulations which require manufacturers to report to EPA emission-related defects that affect a given class or category of engines. The emission defect reporting regulations also specify procedural and reporting requirements for manufacturers that initiate voluntary emission recalls.

8. Exemptions

EPA is adopting the proposed regulations which allow manufacturers and other persons, where appropriate, to request exemptions from regulation for certain purposes. These purposes include testing, display, national security, export, and for manufacturer-owned and precertification nonroad engines.

VI. Public Participation and Discussion of Comments

EPA held a public hearing on June 25, 1993 at which testimony was given by 14 individuals, including representatives from equipment and engine manufacturers and states. The public comment period was open until July 27, 1993. EPA received over 80 written comments during this time. In addition, meetings were requested by two organizations and held during the comment period. As mentioned previously, the public comment period was reopened from October 4, 1993 through October 25, 1993. During this period, EPA received additional comments which were given further consideration in developing the final rule. The discussion of major comments and EPA's responses are divided into general categories. More detailed Agency responses to comments may be found in the "Response to Comments" document in the docket for this rulemaking.

In addition, a related rule concerning preemption of state nonroad regulations was proposed at 56 FR 45866, September 6, 1991. A public hearing was conducted on September 20, 1991. Many industries presented comments through an association or individually. Represented at the hearing and in written comments are the following: engine manufacturers; manufacturers and dealers of various types of equipment including agricultural, construction, mining, utility, and lawn and garden; manufacturers of emission controls; railroads; manufacturers of industrial trucks; the San Diego Country Air Pollution Control District; and the State of California. EPA considered these comments in promulgating this final rule.

A. Conversion of Standards and Measures to Metric Units

EPA's proposed regulation presented standards and measures in non-metric units, with metric units given parenthetically. Comments were received requesting that, for purposes of harmonization with Europe, EPA present all standards and measures in metric units, forgoing the non-metric units altogether. EPA has the authority to do so under the Metric Conversion Act of 1975 and Executive Order of July 25, 1991. Therefore, EPA is adopting metric units in the final rule.

In the final rule, the metric power equivalents (kilowatts (kW)) given for horsepower units in two cases are different from the proposed equivalents. The 131 kW category in the NPRM is now 130 kW, and the 559 kW category is now 560 kW. EPA was requested to adopt the 130 and 560 kW categories because they are in harmony with categories currently being developed by the European Community. An engine manufacturers' association stated that so doing would not include or exclude any engines that would not otherwise have been included or excluded in EPA's proposed rule. EPA agrees that a one kW change will not significantly affect the engine family implementation schedule.

The units in the tables of standards and implementation dates in this preamble show the non-metric equivalents. The regulatory language is exclusively metric.

B. Emission Standards

1. HC, CO, and PM Emission Standards

EPA proposed NO_X and smoke standards and did not propose standards for HC, CO, and PM. Since NO_X emission was demonstrated in the draft Regulatory Support Document to be largely unaffected by transient operation, EPA is confident that an emission standard based on the adopted steady-state 8-mode test procedures for NO_X will result in a sizable in-use emission reduction. Likewise for smoke, the adopted on-highway smoke test procedures have both transient and steady-state operating modes, giving EPA confidence that the necessary technologies will be applied to meet the smoke standards which will result in actual in-use emission reduction.

However, in its proposed rule, the Agency reasoned that sufficient data and analyses had not been generated to adequately demonstrate that the 8-mode test procedures are representative of potential transient operation occurring in actual use. Since HC, CO, and PM emissions typically increase during transient operation, the Agency was not confident that standards for these three pollutants on the adopted steady-state 8-mode test procedures would result in real emission reduction in actual use and, thus, proposed not to regulate them. However, EPA did request comment on the appropriateness of adopting standards for these pollutants. In particular, EPA requested comment on whether it should adopt California's standards for these pollutants.

State and local agencies, environmental groups, health agency officials, and engine industry representatives all requested that standards for HC, CO, and PM be included in the rule. The industry argued that, while adequate data may not have been generated to establish an emission reduction benefit of the additional standards, adoption of the

additional standards is critical to worldwide marketing strategies which require regulatory harmony between the U.S. and foreign government entities. The industry commenters claim, in this context, that by harmonizing with the California standards and the projected European standards presented in Section V.B., EPA would actually reduce the cost to an engine manufacturer which would not be compelled to build a different version of its engine for U.S. consumption than would be built for the rest of the world. Arguments were presented that in any case there would be no harm in regulating these additional pollutant emissions and there might be some consequential emission control or at least a capping effect on HC, CO, and PM emissions.

EPA is committed to providing regulatory harmonization when it can be done without compromising U.S. environmental goals. Since HC, CO, and PM emissions are typically higher during transient operation, EPA maintains its position that there is too much uncertainty about the ability of the existing steady state test procedures to accurately predict those emissions from in-use nonroad engines. Therefore, EPA believes it is technically incorrect to claim emission reduction benefits for HC, CO, and PM emissions as measured by the test procedure being adopted. However, at the same time, EPA believes that adopting these standards will not compromise U.S. nationally uniform environmental goals.

In reaching the decision to regulate HC, CO, and PM, EPA had to consider any additional costs which might be imposed, and queried the industry during the public comment period. Engine manufacturers responded that these additional standards would not result in added cost, or that any added costs would be offset by the efficiency gained by having harmonized standards. On the basis of these comments, EPA is concluding that adopting HC, CO, and PM standards will not result in increased cost burden.

EPA is not incorporating HC, CO, and PM into the averaging, banking and trading option. The flexibility provided by this option is desirable for NO_x compliance, where there are quantifiable environmental benefits to be gained. However, because HC, CO and PM standards have been promulgated solely for harmonization with California and Europe (neither of which allow ABT), and because the benefits for HC, CO, and PM are not similarly quantifiable, ABT is not appropriate for HC, CO, and PM. Moreover, the burden to the Agency and to industry of tracking and enforcing ABT for HC, CO, and PM would defeat the Agency's intent to minimize such burdens to the degree that the Agency would reconsider its decision to adopt those standards at all, an option the Agency is not willing to choose.

2. Smoke Standards

One commenter questioned EPA's authority to regulate smoke emissions, stating that EPA did not demonstrate as required in CAA section 213(a)(4) that smoke significantly contributes to air pollution that may reasonably be anticipated to endanger public health or welfare. EPA made a finding in the NPRM that smoke significantly contributes to air pollution, based on smoke's impact on visibility. As evidence of smoke's significant contribution to air pollution, EPA specifically cited in its draft Regulatory Support Document the agreement to reduce smoke from the Navajo Generating Station to improve visibility in the Grand Canyon. EPA discussed in the NPRM why smoke may reasonably be anticipated to endanger both public health and welfare. EPA stated that "there are indications that visible smoke may have an adverse effect on health" (58 FR 28809, 28845). The particles that make up smoke, about 2.5 microns in diameter, are of a size that reflects and refracts light. These particles are sufficiently small to be inhaled into the lower lung cavities, thus posing a potential health threat to the inhaler. See, for example, volume 329 of the New England Journal of Medicine (December 9, 1993, p. 1753) for a discussion of the association between particulate air pollution and mortality rates. EPA also cited damage through soiling of urban buildings, homes, cars and other property. EPA has met the statutory mandate of CAA section 213(a)(4) for smoke, and stands by its assessments presented in the NPRM and RSD for this rulemaking. Hence, EPA is retaining the smoke standards as proposed.

C. Lower Emission Standards

Environmentalists and states requested that EPA commit to a second phase of emission standards for new large nonroad CI engines on an "aggressive" timeline. They are satisfied with the level of the standard only on an interim basis and want to quickly move to a more stringent standard. One commenter expressed concern that, without specifying a deadline for promulgating a second phase of emission standards in this rule, manufacturers will be slow to cooperate with EPA in developing the new test procedures.

Engine manufacturers have asked for assurances that they will have from five to eight years of "regulatory stability" before more stringent standards are promulgated, in order to amortize their investment in the current standards.

EPA believes that more stringent emission standards should not be promulgated until the existing test cycle has been verified to be representative, or until a more representative test cycle has been developed. EPA is currently working with engine manufacturers to evaluate actual in-use operating conditions and the test procedures adopted in this rule. These data will be used to determine the necessary modifications to the test procedures to ensure that more stringent emission standards in the future result in actual in-use emission reductions.

EPA has every intention of moving forward to determine the most appropriate test procedures to use in future regulation of the engines covered in this rule. EPA has found that coordination with industry on clearly technical projects such as this is most beneficial since it allows the Agency to receive early input as procedures are being developed. Such early feedback creates an atmosphere of consensus-building and allows the Agency to promulgate rules that are more equitable, efficient and effective. At this point, however, EPA cannot make assurances that it will provide engine manufacturers "five to eight years of regulatory stability," and neither can it commit to promulgating more stringent standards on an "aggressive" timeline.

D. Exemptions

The American Mining Congress and other commenters in the mining industry requested that surface mining equipment be exempted from regulation since, according to the commenters, mining equipment operates well outside nonattainment areas. One commenter within the mining industry suggested that regulation of mining equipment should be on a case-by-case basis. In other words, if the mining equipment at a site is shown to contribute to ozone or CO nonattainment, the equipment at that site should be subject to regulation. As an alternative, these commenters suggested horsepower cutoffs ranging from 500 to 750 horsepower, above which nonroad equipment would be exempted from compliance. These commenters also took exception to EPA's inclusion of mining equipment in the construction equipment category, stating that mining equipment is larger and more specialized than construction

equipment. Further, they stated that while construction equipment may be used at a mine site, mining equipment is never used on a typical urban construction site. These commenters also questioned EPA's application of the proposed regulations to mining equipment since emissions from such equipment were not included in the analysis contained in the Nonroad Study.

The Agency sees no justifiable reason for exempting from regulation all mining equipment or mining equipment above certain horsepower cutoffs. The Agency is obliged to regulate all classes or categories of new nonroad engines that cause or contribute (without reference to significance) to ozone or CO pollution in more than one nonattainment area. The Agency believes that such equipment, even if operating outside nonattainment areas, is capable of contributing to ozone nonattainment and, therefore, the Agency cannot justify an exemption of mining equipment.

Regarding whether mining equipment is being inappropriately included in the construction equipment category, the Agency believes that mining equipment should not be treated as a separate class of equipment. There is acknowledged crossover of equipment used on construction and mining sites. For example, excavators, off-highway trucks, crushing equipment, rubber tired loaders and dozers, and crawler tractors are types of equipment commonly used by both mining and construction industries. While some equipment may currently be used only at mining sites, there is no way to predict future equipment use with certainty. Given the high degree of similarity between construction equipment and equipment used in mines, EPA believes that it is justified in treating equipment used in mining as a subcategory of construction equipment. EPA is not required, in determining classes and categories of nonroad engines or vehicles, to subdivide such engines into small subcategories of engines, each of which may have less of an impact on nonattainment than the broader category in which they are included.

Moreover, it should be noted that the American Mining Congress specifically stated in its comments in the recent EPA rulemaking on preemption of state standards for nonroad engines and vehicles that surface mining equipment should be considered "construction equipment" in the context of that rulemaking (EPA Docket No. A–91–18). In addition, EPA held a meeting with the American Mining Congress on July 22, 1993, and asked for specific information to support their request for exemption from the proposed regulations. Such information requests included specific dollar figures for the technology needed to comply, a component level breakdown of costs, annual equipment sales and horsepower ranges of mining equipment and other information specifically targeted toward the impacts of mining equipment on ozone and CO nonattainment.[14] As of October 25, 1993, the close of this rulemaking's second comment period, the Agency had not received this information.

Regarding the comment that mining equipment operates well outside of nonattainment areas, the American Mining Congress submitted as part of its public comment a report from the TRC Environmental Corporation which states that 40 mine sites are located in ozone nonattainment areas.[15] Moreover, EPA is not required to make determinations of nonroad contributions to air pollution on a site by site basis, or to regulate on a site by site basis; CAA section 213 requires a national program based on an aggregate significance determination.

Commenters suggested the Agency use varying horsepower cutoffs above which nonroad engines should not be regulated. The main rationale given by commenters was that the technology improvements and/or design changes to these larger engines would be too costly. EPA has received very little data directly addressing the actual costs anticipated for these changes, and no information was provided detailing the specific unique high cost technologies that these engines would need, even after the specific request by EPA discussed above. As discussed in section VII, EPA agrees that the cost of compliance for engines over 560 kW (750 horsepower) would be more than the average cost per engine estimated in this rule. EPA uses the net present value of the retail price increase per engine reported in this rule to estimate the cost of this regulation to society, not to predict the cost of any particular engine covered by this rule. While the Agency did not do a cost breakout by engine size, EPA's assessment of the limited cost data submitted by one manufacturer of engines greater than 560 kW suggests that the retail price of these larger engines could increase by approximately $100 per 75 kW due to this regulation. Therefore, in absolute terms, the cost is greater for larger engines. However, in relative terms, the price increase for larger engines only represents about one percent of the total cost of the equipment in which the engine is used. On average, this represents a slightly lower percentage price increase than for smaller engines covered by this rule. EPA has determined that this level of increase for extremely high cost machinery is reasonable.

EPA also received several comments stating that certain farm equipment, skid steer loaders in particular, should be exempted from regulation because they do not significantly contribute to ozone nonattainment. As discussed above, EPA is not required to make a significance determination for every category of nonroad engine it intends to regulate. The significance determination applies only to the initial determination regarding emissions from all nonroad engines and vehicles. Once that determination is made, the Agency shall promulgate regulations for all classes and categories that contribute (without reference to significance) to nonattainment in more than one area. The Nonroad Study clearly shows that farm equipment air pollution causes or contributes to nonattainment in several of the nonattainment areas studied.

With regard to specific subcategories of farm equipment, EPA is not required to make determinations regarding every subcategory of equipment that it intends to regulate. The Senate, in fact, instructed EPA not to disaggregate the universe of nonroad engines into small subcategories.[16] Therefore, given EPA's finding regarding farm equipment, skid steer loaders and other subcategories of farm equipment will not be exempted from the regulations promulgated in this notice.

E. Particulate Matter Test Procedures

EPA is adopting by reference the PM test procedures adopted by California in Sections 2420–2427, Chapter 11, title 13 of the California Code of Regulations, "California Regulation for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines." California developed its test procedures by combining portions of the June 2 and June 30, 1992 versions of the test procedures being developed by the International Standards Organization as ISO–8178 test procedures recommended practices.

In determining the PM test procedures to adopt in the final rule, EPA

[14] A complete breakdown of the information requested, as well as a summary of the meeting, is contained in Docket #A–91–24, Item No. IV–E–01.

[15] "Analysis of Nonroad Engine Emissions in the Mining Industry," TRC Environmental Corporation, July 1993, p. 1.

[16] Senate Report 101–228, p. 104. The Senate provisions regarding nonroad engines were ultimately rejected in favor of the House of Representatives' provisions, but the language in the Report indicates the intent of Congress in determining the breadth of categories.

considered the need for harmonization and enforceability. EPA determined that the California PM test procedures meet these two needs. First, this procedure ensures harmonization with the State of California, allowing manufacturers to design one engine for both the California and federal markets. The California procedures include the full range of the ISO–8178 recommended practices as published in June 1992, providing wide latitude for the conditions and methods used for PM measurement. EPA is not concerned with allowing the engine manufacturers to use the full latitude of ISO–8178 for certification testing because, as previously discussed, no PM emission reduction benefits are being claimed, and EPA has the ability to perform in-use compliance testing over the entire range of the ISO–8178 procedures.

EPA is confident that its ability to perform compliance testing using any procedure within the boundaries of ISO–8178 will ensure that engine manufacturers use good judgment in selecting their specific PM test procedures. At the same time, EPA recognizes the potential burden of liability for emission compliance over the entire range of conditions specified in ISO–8178. This burden results from an engine manufacturer's responsibility to comply with emission standards under any test conditions specified by the test procedures. Historically, when a range of test conditions exist, manufacturers choose to test with the conditions which are worst-case for emissions performance. To the extent that a manufacturer is unable to determine with certainty the worst-case conditions, it may be necessary to perform a number of emission tests which bracket the range of test condition combinations within the ISO–8178 procedures to ensure that the worst-case emissions are accounted for. Thus the burden to the manufacturer is increased testing dictated by the level of risk that a particular engine family would fail EPA testing (compliance or in-use) due to an unaccounted-for test condition specified in ISO–8178. However, EPA believes that the overriding concern expressed in the comments for harmonization outweighs the potential burden of liability to comply with a broad test procedure. Furthermore, the Agency does not have an alternative test procedure option that would ensure harmonization at this time.

EPA is satisfied that the adopted PM test procedures are implementable and enforceable. The Agency is prepared to review any proposals from the nonroad manufacturing industry to modify any portions of the PM test procedures that would narrow the scope of test conditions while maintaining the integrity of the procedures. EPA is not prepared to make its own proposal to tighten the test procedure specifications at this time as it might negatively impact harmonization for an emittant for which EPA is claiming no emission benefit in this rule.

EPA considered adopting a modified version of its current on-highway engine test procedures for particulate contained in 40 CFR part 86, subpart N. This would address the flexibility issues regarding the ISO–8178 procedure, because subpart N has tighter measurement tolerances and specific methodologies and procedures for emission measurement. However, EPA did not have an effective means to address the various needs of the different manufacturers (that originally led to the broad range of options in ISO–8178) in the time frame of this rule without adversely affecting some manufacturers more than others. Additionally, this approach presented some risk that the test procedures developed from EPA's current regulations would contain some elements not in harmony with California and Europe. Since EPA believes the California PM test procedures will meet its needs and ensure harmony, development of its own procedures based on subpart N was determined less desirable at this time.

Finally, EPA considered, but rejected, adoption of the most recent United Nation draft version of ISO–8178. This draft represents the most current development of these test procedures and is compatible with current European plans. However, the United Nation's draft version of ISO–8178 must still go through a review process that could result in a number of additional changes and will likely take one to two years before being adopted. If EPA adopted the draft United Nations version, the Agency could eventually find itself to be in harmony with neither the California version nor the final adopted European version of ISO–8178.

F. Smoke Test Procedures

Commenters requested that EPA revise the on-highway smoke procedures in 40 CFR 86, Subpart I, which were proposed for this rule. The same revisions were requested under a separate EPA action that specifically focuses on technical clarification on the subpart I procedures. Since part 89 regulations directly reference the part 86 subpart I procedures, EPA will not consider these comments in this rule. Any revisions adopted under the separate EPA action of technical amendments to part 86 subpart I procedures will likewise apply to engines certified under part 89.

Manufacturers point out that this test was specifically designed for on-highway truck engines and is less applicable to nonroad engine usage, but agree that this test is the best available at this time. In their comments, engine manufacturers agreed to use the on-highway smoke test procedures until more representative and globally harmonized smoke test procedures can be developed.

EPA is working closely with Europe and other government agencies as well as with voluntary standard-setting organizations to develop new smoke test procedures. These procedures are not sufficiently developed at this time to reference or adopt.

EPA is willing to use cooperatively developed and harmonized smoke test procedures that it determines meet its needs to control in-use smoke emissions. A mechanism has been provided in this rule to allow the use of such procedures via the alternative test procedures approval process. With this process, the manufacturer requests EPA approval to use the alternative test procedures in advance of certification. EPA has authority to grant such a request if the procedures are determined to be equivalent or better than the promulgated procedures.

In the absence of a "world-wide" smoke procedure, EPA is confident the adopted procedures will reduce smoke emissions and will ensure harmonization with California. California has pointed out it has modified its test procedures somewhat by allowing the use of an in-line smokemeter. EPA has included provisions by which a manufacturer may use alternative measuring equipment upon demonstration that it correlates with the current opacity meter.

G. Use of the On-highway Federal Test Procedure (FTP)

EPA has decided not to allow use of the on-highway FTP for any aspect of nonroad engine certification. Based on data received during the comment period and discussed in the Response to Comments document, the ability of the on-highway test cycle to predict nonroad NO_x emissions for some types of engines is uncertain. In addition, even those commenters in support of the on-highway FTP option stated that they would likely make minimal use of it. These reasons form the basis of EPA's decision not to adopt this option.

H. Alternate Test Procedures for Constant Speed Engines

A number of engine manufacturers requested that EPA allow use of an alternate test procedure for engines that use constant speed governors. These engines are typically used on applications such as generator sets that must be capable of holding one precise speed during operation. Commenters have stated that these engines are not properly represented by, and may not be capable of operating over, the 8-mode test procedures. Commenters recommended that EPA allow use of the ISO 8178–D2 test procedures (2-mode) for constant speed engines.

EPA has a mechanism in the regulations that would allow this request for alternate test procedures to be made with full technical justification. Insufficient data were presented for EPA to determine the need and appropriateness of adopting the specific ISO 8178–D2 test procedures for constant speed engines in this final rule. However, there may be adequate technical justification for such an alternate test procedure. EPA has made available in the regulations provisions by which an engine manufacturer may propose to the Administrator the use of an alternate test procedure with adequate demonstration. This would be the appropriate mechanism for manufacturers of constant speed engines should they determine that the 8-mode test procedures are unrepresentative for their engines.

I. Certification Test Fuel

EPA is adopting test fuel requirements which allow an engine manufacturer to submit data either using a test fuel that falls within the specification in the proposed regulations, modified to expand the fuel sulfur range to greater than .05 percent to .5 percent fuel sulfur, or a lower sulfur test fuel that is consistent with the test fuel to be used in California. EPA retains the right to perform confirmatory or in-use enforcement testing using either test fuel.

EPA modified the fuel sulfur concentration range of its proposed test fuel based on concerns that the range specified may inadvertently preclude the use of a fuel that could be available for use now or in the future. For example, the current proposal in Europe specifies a test fuel with sulfur content ranging from .1 percent to .2 percent. Should the final European requirements specify such a fuel in the future, EPA's proposal would not have allowed use of this fuel. As this is not EPA's intent, the Agency chose to broaden the range of fuel sulfur content specified in Table 4 to Appendix A of Subpart D in Part 89 of today's regulation.

EPA proposed that all nonroad engines be certified using test fuel with a sulfur content of 0.2 to 0.5 percent sulfur by weight. EPA reasoned that although federal on-highway and California state-wide sulfur specifications will be .03 to .05 percent sulfur by weight, some diesel fuel producers will continue to provide fuel with a higher sulfur content for 49-state nonroad use. EPA believes some producers will decide not to incur the cost of purchasing and operating hydrotreating equipment necessary for sulfur removal in the absence of a requirement to provide low sulfur fuel for the federal nonroad segment of the market. Therefore, it is likely that the fuel available to the majority of nonroad engines will be higher sulfur fuel.

Manufacturers requested to certify on low sulfur fuel because it will save them the cost of performing an extra test (that is, one on high sulfur fuel for the federal rule and one on low sulfur fuel for California). They argued that because the sulfur content of the fuel does not influence the production of NO_X emission and smoke, they should be allowed to use low sulfur fuel for certification testing.

EPA believes that using fuel specifications of commercially available fuel for certification testing is an important demonstration of emission performance of in-use nonroad engines. EPA acknowledges that, in this case, the sulfur content of the test fuel will not impact either NO_X or smoke emissions. However, EPA has agreed to adopt PM standards for the purposes of harmonization with California and Europe. It is generally accepted that fuel sulfur has a noticeable impact on PM emissions. The impact of fuel sulfur on PM, NO_X and smoke emissions is discussed further in the Response to Comments document. Since fuel sulfur does have an impact on PM emissions, PM emissions in the federal fleet will be higher in actual use than in the California fleet where the only available fuel will have low sulfur content. While this rationale would argue against allowing use of low sulfur certification fuel, at the same time, it is likely that the engines certified on low sulfur fuel will have no higher PM emission in actual use than would have resulted had EPA promulgated only NO_X and smoke emission standards. Because harmonization, rather than emission benefits, is the driving factor behind EPA's decision to impose the PM standard, EPA sees no need to increase the testing burden by requiring a different certification fuel specification to demonstrate compliance with the PM standard.

For these reasons, EPA will, at this time, allow engine manufacturers the option to use low sulfur test fuel as specified in the regulatory language and consistent with California regulations. EPA may not continue to allow this option in future regulations where emission benefits for PM reduction are claimed, unless EPA is satisfied that the low sulfur test fuel is the fuel generally used by the regulated engines. Manufacturers using the higher sulfur test fuel may normalize the PM emission results with the equation discussed in section V.D.3.

J. Certification Test Engine Selection

EPA proposed that the test engine selected to represent an engine family be a "worst case emitter." This proposal allowed each manufacturer to use its best technical judgment based on unique understanding of the specific engine design it is certifying. The flexibility of such a methodology could result in the most cost effective and most accurate selections, because the selection would be tailored to the specific engine family being considered.

Engine manufacturers were not comfortable taking on the uncertainty of choosing their own "worst case" test engine, pointing out that "worst case" is ambiguous. For example, what is worst case for NO_X may not be worst case for smoke.

EPA is aware of this tendency for "worst case" to be emission specific. For that reason, in the past, the federal on-highway rules and CARB's rule have specified that the engine selected for certification testing must be the one that injects the most fuel per stroke of an injector at maximum power. This approach generally results in the selection of the least efficient design within the engine family. While this approach is more prescriptive than the proposal, it generally results in more consistency and is more likely to assure the selection of worst case for at least some of the emittants. It gives manufacturers a more defined program and creates less administrative burden than the proposed method which required manufacturers and EPA to make determinations and evaluations for each engine family.

For the reasons discussed above, EPA is adopting this more traditional engine selection criteria—most fuel per stroke of an injector at maximum power—in the final rule.

K. Miscellaneous Certification Issues

1. Engine Labeling

Comments were received requesting that EPA modify some of the proposed engine labeling requirements to be consistent with California regulations. Some of the modifications requested were wording changes. Others involved deleting or changing labeling requirements. EPA's response to these requests is included in the Response to Comments document. One request for a modification had the potential for a more significant impact on industry. This request was to add a provision requiring "supplemental labels" to be installed by the equipment manufacturer should the original engine label be obscured after engine installation. EPA believes this provision would impose an additional burden on the equipment manufacturers (in the form of label costs and recordkeeping to ensure the correct label was placed on the equipment) and that no significant benefit would be gained. Thus, EPA is not requiring the use of supplemental labels, but will not prohibit equipment manufacturers from using such labels, provided the labels meet the labeling requirements set forth in the regulation.

2. Requiring Yearly Certification, Accepting California and European Certificates

Comments were received requesting that EPA not require yearly certification in cases where no changes to the engine family were made. EPA is retaining this requirement. It believes that the burden imposed on manufacturers in cases where no changes are made is minimal (no additional testing required and only the resubmission of paperwork from the previous year), and that yearly certification ensures continuity and equitable treatment among manufacturers.

A commenter also requested that EPA accept certification by California or Europe in lieu of federal certification for reasons of economy. EPA's on-highway certification program requires that every vehicle sold in the United States be covered by a federal certificate of conformity. On-highway manufacturers are permitted to "carry across" emission data from testing performed to demonstrate compliance with California regulations to satisfy federal requirements. This is possible because the test procedures are identical. For the nonroad certification program, EPA envisions that similar certification and carryover/carry across policies will be in effect, which will allow manufacturers to use the test data from a test performed for European or California certification to satisfy federal requirements as long as the manufacturer provides evidence that the procedures used comply with the federal regulations. It is EPA's responsibility to assure compliance with federal regulations. Manufacturers should be assured, however, that the consistency and quality of the California certification program is such that engine families certified by California will very likely receive federal certification. At this time, European regulations are not final, so EPA cannot yet officially harmonize its requirements with Europe. Therefore, EPA is finalizing its proposal to require an annual federal certificate for each engine family.

3. Technical Certification Test Procedure Revisions

Comments were provided on subparts D and E of the regulatory language, dealing with certification test equipment and test procedures. In some cases, the comments were corrections of typographical errors or inconsistencies within the regulatory language. In other cases, EPA was requested to modify technical aspects of its proposed procedure. EPA adopted some, but not all of, the requested changes. These are discussed in the Response to Comments Document.

L. Implementation Dates

EPA is adopting the implementation schedule as proposed.

Environmental and state organizations commented that EPA should shorten the total implementation period, stating that staggering implementation up to the year 2000 would delay important emissions benefits. On the other hand, engine manufacturers asked for one to two years additional time, citing costs and facility constraints. Equipment manufacturers also asked for one year to eighteen months to implement necessary equipment changes.

In addressing state and environmental concerns, EPA considered a number of factors in its phase-in schedule determination. First, the category of engines to be regulated in 1996 represents about 30 percent of the total population. This first group includes engines similar to existing on-highway engines which can directly utilize the on-highway emission control strategies and will produce a substantial early benefit. The other three categories of engines belong to a manufacturing segment of the nonroad industry that has, for the most part, not previously been subject to EPA emission standards. Manufacturers of these categories of engines have neither the facilities in place to collect required information nor staff with experience in the certification process. Further, the phase-in schedule was designed to allow time for the technical development which will be needed for the category of smaller-sized engines to comply with the standards. Finally, over 95 percent of the total engine population to be regulated will be in compliance by the 1998 model year. The final category (in the year 2000, engines at or above 560 kW) represents a small percentage of the yearly sales population.

EPA believes that engine and equipment manufacturers have been provided enough flexibility in this rule (through such features as ABT for NO_x and staggered schedules) to allow enough lead time for them to make any necessary changes or modifications by the implementation date. Engine manufacturers have stated that they intend to use the flexibilities of this rule to minimize the impact of these regulations on their equipment manufacturer customers. EPA designed the phase-in schedule so that smaller engines, which will be more difficult to control to the adopted NO_x standard, and equipment using these engines, which may require the most modification due to tighter packaging constraints, have an additional one to two years for development before regulation. Furthermore, early banking allows manufacturers to selectively forego modifying specific models by collecting credits one year in advance of implementation from engines that have been made to comply with the NO_x standards before the implementation date of the standard. Finally, ABT provides to manufacturers of that small percentage of engines requiring extensive modification the ongoing option to avoid situations where high cost or tight time constraints make modifications unreasonable. Therefore, EPA is retaining the implementation schedule as proposed. No additional time is being granted to engine, vehicle or equipment manufacturers. However, EPA will allow vehicle and equipment manufacturers a reasonable amount of time after the implementation dates for the different engine categories so that the equipment and vehicle manufacturers can clear their inventory of unregulated engines.

M. In-use Enforcement

EPA proposed an in-use recall program which included testing of in-use engines. EPA believes that a critical element in the success of its nonroad program is assuring that manufacturers build engines that continue to meet emission standards beyond the certification and production stages.

Under the adopted regulations, EPA has the authority to recall engines which do not comply with emission standards in-use. As proposed, the in-use testing liability period will be up to seven years or 6,000 hours, whichever occurs first. This represents 70 to 75 percent of the nonroad engine average expected useful life. The repair period for which a manufacturer must remedy nonconformities would not be limited by actual years or hours; thus any resulting recall may be required to be applied to all engines of the recall family, regardless of the years or hours of an individual engine. In-use compliance with emission standards will be determined based on test results using the same test procedure as that used in certification.

One commenter expressed concern that EPA's recall program carefully select in-use engines which have been properly maintained and used and that are representative of engines in-use. EPA acknowledges the concern of this commenter. The Agency conducts its on-highway recall program with careful attention to compliance with the requirements of the CAA concerning proper maintenance and use, and will continue to do so for the nonroad program, although differences between uses for on-highway and nonroad equipment may require certain deviations from the on-highway program. EPA is modeling its large nonroad CI engine recall program after section 207 of the CAA and therefore the Administrator may require manufacturers to recall applicable engines if a substantial number of properly maintained and used engines are found to be out of conformity with the regulations issued under section 213 of the CAA.

The recall regulations adopted today provide procedures and requirements for manufacturers of engines for which a determination of nonconformity has been made. Such requirements include notification to be sent to engine owners, the manufacturer's remedial plan and EPA approval of the plan, and procedures to be followed in the event that the manufacturer requests a public hearing to contest the Administrator's finding of nonconformity.

N. Useful Life

EPA is adopting the definition of useful life as proposed with additional conditions. The useful life of engines covered by this rule is ten years or 8,000 hours, whichever comes first. Further, the useful life ends when the engine is scrapped or rebuilt. EPA is adding a provision allowing the manufacturer to apply to the Administrator for a shorter useful life period for engines that are subject to severe service in seasonal equipment or that are designed specifically for lower useful life hours to match equipment life.

Engine useful life defines the period of time a manufacturer is liable for the emissions that the engine emits. In-use surveillance emission testing may be conducted at any time by EPA to determine if an engine family, after some time in use, is still meeting emission standards. EPA is adopting an in-use testing and recall program based on testing for a period of seven years or 6,000 hours, representing 70 to 75 percent of the average expected useful life for nonroad engines. Therefore, while the manufacturer's liability for its engines covers the full useful life, evaluation of an engine family's in-use compliance will be based on those engines within the engine family that have attained 70 to 75 percent or less of their expected useful life. This not only allows EPA to find more properly maintained and used engines, but also allows for variation in the durability of different engine configurations within the same engine family without selecting engines that are at the end of their useful life.

While generally agreeing with the ten year/8,000 hour useful life for most engines, manufacturers expressed their concern that some engine families are expected to have a useful life less than 8,000 hours. These engines are designed to be used in severe conditions, often in seasonal equipment, or equipment with a short useful life. Manufacturers are concerned that, should all engines be assumed to last for 8,000 hours, in-use testing of these severe application engines at 6,000 hours (that is, 75 percent of the useful life) would unfairly penalize severe application engines that could in fact be outside of their designed shorter useful life. EPA understands that such a situation could exist, and thus is providing means for the manufacturer to petition the Administrator for an alternative useful life as stated previously. Solid engineering data should accompany the request so that a reliable engineering judgment can be made.

Two commenters requested that EPA adopt a shorter useful life period for engine families with individual cylinder displacement below a specified volume. It appears that this suggestion was intended to provide a straightforward method to administer useful life at the time of certification. However, EPA is not aware of a supportable technical rationale that would suggest there is correlation between cylinder volume and useful life, or that engines with smaller cylinder volumes wear out faster than engines with larger cylinder volumes. Smaller engines are also installed in smaller equipment and the relative work expectation is no greater than larger engines in larger equipment. Most engines covered by this rule are built to operate at full load/rated speed most of the time. Therefore, in relative terms, engines are generally equally stressed during their lifetime regardless of their size or power. For these reasons, EPA does not believe it is appropriate to define a shorter useful life for all engines under a specified cylinder volume. EPA has provided a means for a manufacturer to provide evidence that would allow severe service engines to be held to a shorter useful life.

O. Locomotive Engines

EPA proposed to exclude engines used to propel locomotives from this rulemaking, as regulation of such engines is being undertaken separately. EPA did not, however, exclude other engines operated on locomotives from this rulemaking. EPA requested comment as to whether such other engines ("auxiliary engines") should be regulated in this or the later locomotives action.

EPA received several comments on this issue. The commenters all noted that auxiliary engines are appropriately regulated under section 213(a)(5) as "engines used in locomotives." EPA agrees with this determination and is promulgating a definition of "engines used in locomotives" that corresponds to this determination. While there was general agreement with the regulatory authority under which auxiliary engines used on locomotives can be regulated, comments were received both agreeing and disagreeing with EPA's proposal that the auxiliary engines should be regulated in today's rulemaking action. EPA believes that the statutory mandate of section 213(a)(5) allows EPA to regulate auxiliary engines in this rulemaking. Moreover, the standard under which such engines are to be regulated is virtually identical to the standard under section 213(a)(3). EPA also received comments indicating that auxiliary engines are similar in design and performance to other nonroad engines regulated in this rulemaking, and that such engines should therefore be regulated in this rulemaking.

Therefore, EPA is including auxiliary large CI engines operated on locomotives in this rulemaking. This issue is discussed further in the Response to Comments in the docket.

P. Vehicle and Equipment Manufacturer Requirements

EPA is finalizing the requirement that nonroad vehicle and equipment manufacturers and importers use certified nonroad engines. EPA believes that the most effective way to ensure that certified engines are used in nonroad vehicles and equipment is to require such engines to be used.

In the May 17, 1993 NPRM, EPA stated that CAA section 213 provides authority to require nonroad vehicle and equipment manufacturers to use certified nonroad engines. However, EPA did not propose such a requirement. Instead, EPA requested comment on how it might assure that only certified nonroad engines be used in nonroad vehicles and equipment. EPA received comments on this issue from a State and an environmental association. Both comments requested that nonroad vehicle and equipment manufacturers be required to use certified nonroad engines. One comment agreed that EPA has authority under CAA section 213 to establish such a requirement, and the other pointed out that the entire program would be undercut without such a requirement.

In the October 4, 1993 notice, EPA proposed requiring nonroad vehicle and equipment manufacturers and importers to use certified nonroad engines. EPA received 12 comments on this issue, from six companies, four industry associations, one State, and one environmental association.

Two commenters opposed the establishment of this requirement. One company argued that failure to require use of certified engines would not undercut the program because engine inventories are already kept to a minimum as their purchase is a significant investment. An association argued that without a technical support document and regulatory language, it could not comment meaningfully.

EPA disagrees that industry inventory control practices can take the place of a requirement that certified nonroad engines be used in nonroad vehicles and equipment. Without a requirement that certified engines be used, nonroad vehicle and equipment manufacturers would be free to use uncertified engines, thus undermining the environmental and public health benefits of the nonroad large CI engine emission reduction program. EPA is not requiring vehicle or equipment manufacturers to be responsible for certification or performance of nonroad engines; that is the responsibility of the engine manufacturer. The final regulations merely prohibit nonroad vehicle and equipment manufacturers from using uncertified nonroad engines in their nonroad vehicles and equipment. Violation of this prohibition would be a violation of CAA section 203(a), and would subject nonroad vehicle and equipment manufacturers to sanctions under sections 204 and 205. EPA does not agree that the October 4, 1993 notice was so lacking in specificity as to require reproposal. In fact, this prohibition was clearly discussed in the October 4 notice. EPA does not find regulatory language regarding prohibited acts to have been required in the October 4 notice because such language would have only restated the requirement that nonroad vehicle and equipment manufacturers must use certified nonroad engines. That requirement was clearly spelled out in the notice.

Several commenters agreed with the requirement. Of the two companies that supported the requirement, one stated that the responsibility of vehicle and equipment manufacturers should be limited to assuring that engines have emission compliance labels, and that engine manufacturers should be responsible for certification, testing, audits, warranty, and recall. A State that supported the requirement said it is the only way to ensure that certified engines are used. An environmental association said the requirement should improve the enforceability of the rule. EPA agrees with these comments. The nonroad vehicle and equipment manufacturer is responsible only for assuring that certified engines are used.

Several commenters neither agreed nor disagreed with the requirement but raised questions regarding it. Several commenters asked about the use of noncertified engines built prior to the implementation dates of this regulation. Several commenters requested implementation dates for vehicles and equipment, to provide sufficient lead time for engine manufacturers to produce certified engines for vehicle and equipment manufacturers to use. Two commenters stated that an implementation date for engine manufacturers was sufficient.

EPA is not establishing separate implementation dates for nonroad vehicle and equipment manufacturers. However, EPA recognizes that certified engines are not likely to be available in the numbers needed by nonroad vehicle and equipment manufacturers on the implementation date, and that vehicle and equipment manufacturers will continue to use noncertified engines built prior to the implementation date until noncertified engine inventories are used up and certified engines are available. As long as vehicle and equipment manufacturers do not inventory engines outside of normal business practices (that is, as long as they do not stockpile noncertified engines), vehicle and equipment manufacturers will be considered to be in compliance.

Another question raised by several commenters regards products intended for export. Commenters asked whether engine manufacturers can continue to produce noncertified engines for export, and whether noncertified engines may be imported for use in nonroad vehicles and equipment intended for export. One commenter requested an exemption from liability for engine and equipment manufacturers if nonroad vehicles or equipment sold for export are used in the U.S.

This regulation does not prohibit import of noncertified engines for use in nonroad vehicles and equipment intended for export. As originally proposed, the exemption for repair and alteration in 40 CFR 89.611–96(b)(1) will allow the import under bond of noncertified engines for use in vehicles and equipment intended for export. Further, this regulation does not prohibit the manufacture of noncertified engines intended for export. Manufacture of noncertified engines intended for export is allowed under the conditions specified in 40 CFR 89.909–96(a), as originally proposed. EPA is not providing a blanket exemption from liability for nonroad manufacturers whose products, intended for export, are used in the U.S. Such manufacturers may, in fact, be liable for sanctions. Each case must be determined on its own merits.

Q. Alternative Fuels

The Agency proposed that the use of alternative fuels would not be necessary to comply with the emission standards, but allowed any manufacturer wanting to use alternative fuels to petition the Administrator for approval of alternative test procedures appropriate for that fuel.

Two commenters addressed alternative fuels. One argued that alternative-fueled CI engines should be exempt from regulation because of increased costs and increased competition with non-CI alternative-fueled engines. The other commenter stated that EPA should include all natural gas engines in this regulation, establish better test procedures as soon as possible, and allow these engines to certify to the same standards.

EPA will adopt as proposed its provisions to include alternative fuel CI engines. No data were provided to

support any of the statements made by commenters. EPA still believes that including alternative fuel engines is appropriate. Any additional cost for these engines to certify is small and comparable to that of diesel fueled engines. EPA reserves the right to adjust standards when necessary, such as adjusting the HC standard to its non-methane equivalent, for certain alternative fuels.

R. Selective Enforcement Auditing

EPA received a number of comments on its proposed Selective Enforcement Auditing (SEA) program for large nonroad CI engines. The proposed nonroad SEA program was designed to be similar to the existing on-highway program for heavy-duty motor vehicle engines, with some modifications to accommodate differences between the two industries.

Comments indicate that industry understands EPA's need for the SEA program, but concern was expressed regarding EPA's proposed changes from the on-highway program to adapt to the large nonroad CI engine industry.

EPA proposed to determine annual limits for the number of SEAs a manufacturer would receive. Each passing audit counts as one toward a manufacturer's annual limit. EPA's on-highway light-duty vehicle (LDV), light-duty truck (LDT) and heavy-duty engine (HDE) programs determine annual limits by dividing a manufacturer's projected annual production by 300,000 for LDV and LDT manufacturers and 30,000 for HDE manufacturers, then rounding to the nearest whole number. If the calculated production factor is less than one, the figure is set at one for that manufacturer.

To compensate for differences between the on-highway and nonroad industries, EPA proposed that nonroad engine manufacturers' annual limits would be determined by first calculating two annual limit factors, the production factor and the family factor. These factors respectively represent the maximum number of audits based on yearly annual sales and on the number of engine families produced in that model year.

The production factor was derived from the annual limits currently used in the on-highway SEA programs and the relative contributions of emissions from on-highway and nonroad sources. EPA proposed that the production factor should be the projected annual nonroad engine sales of each manufacturer divided by 9,500 and rounded to the nearest whole number. If the calculated production factor is less than one, the figure is set at one for that manufacturer.

The family factor was proposed as an alternative method to compensate for situations where manufacturers may have low production but a large number of engine families. EPA proposed that the family factor would be determined by dividing the number of engine families certified by the manufacturer in a given model year by five and rounding to the nearest whole number.

EPA proposed to use whichever value is higher of either the production factor or the family factor as the annual limit of SEAs for a manufacturer.

Manufacturers commented that EPA was putting a larger SEA burden on nonroad manufacturers than on on-highway manufacturers. They recommended eliminating the family factor and that annual limits be determined, as in the on-highway HDE SEA program, by dividing by 30,000 and rounding to the nearest whole number.

Annual limits were also discussed at the public hearing for this rule on June 30, 1993. At that time EPA expressed concern that if a manufacturer were assigned an annual limit of one, and that manufacturer passed an SEA early in the model year, the incentive to maintain close control over emissions may decrease or the desire to establish very low emission limits to maximize credits in an averaging program might increase the risk of noncompliance. Similarly, the manufacturer could modify its production to increase emissions with the knowledge that no more SEAs would likely be assigned during that model year.

EPA has decided to revise its proposed production factor method for determining annual limits. As commented upon, EPA's proposed production factor analysis did not take into consideration projected emission reductions for large nonroad CI engines. EPA estimated that the emission contribution for large nonroad CI engines is approximately half of the contribution for on-highway sources. However, EPA estimates that NO_x emissions from nonroad engines will decrease by approximately 37 percent by the year 2025 or when a complete fleet turnover occurs. Therefore, EPA reevaluated its production factor analysis and determined that the production factor divisor should be 16,000.

EPA has decided to retain the family factor method for determining annual limits. This method was proposed to help compensate for the expected low annual production per engine family and for the possible multitude of engine families with relatively few SEAs per manufacturer to check compliance. EPA estimates that the average annual production per engine family for large nonroad CI engines, even with the expanded engine family definition, will be less than one tenth and less than one twentieth the average production of on-highway HDE and combined LDV/LDT engine families respectively. Consequently, EPA believes the family factor in combination with the production factor is necessary to assign annual limits to large nonroad CI engine manufacturers.

As in the on-highway program, a goal of the nonroad SEA program is to encourage manufacturers to perform self-auditing. Some manufacturers commented that EPA should develop specific guidelines for counting self-auditing against manufacturers' annual limits. Additionally, it was suggested that EPA should count audits conducted by CARB toward annual limits.

EPA recognizes the time, effort and cost manufacturers expend on self-audit testing and considers the quality, scope and effectiveness of such programs when assigning audits to a manufacturer. However, EPA's on-highway HDE SEA program has had audit failures even when a manufacturer's self-auditing showed that engines were in compliance with standards. Consequently, EPA believes that spot checks of manufacturer's self-audit programs by SEAs are necessary.

The criteria governing the assignment of audits are too numerous and interconnected to make specific guidelines relating self-auditing to annual limits useful. For instance, a manufacturer with a comprehensive self-audit program who is reluctant to remedy deficiencies and fails SEAs warrants continued attention by EPA just as a manufacturer with a minimal program is likely to receive few SEAs if it routinely designs and produces engines well below emission standards. Likewise, manufacturers who set unusually low FELs in averaging programs will be subject to extra scrutiny.

Substantial consideration will be given to assembly line testing required by CARB on engine families sold nationwide when the CARB test protocols (for example, sampling plan) are as stringent as EPA's. While EPA will not reduce its annual limits based on CARB audits, it will work together with CARB to exchange emission test data and consequently more efficiently assess compliance with applicable standards.

Manufacturers will be notified of SEAs by means of a test order. EPA proposed that the test order would specify the engine family to be audited, or EPA could specify an engine

configuration or range of configurations from a family to be audited. Manufacturers commented that, by auditing engine families, EPA could be significantly increasing the SEA burden on manufacturers. However, as indicated in the NPRM, EPA planned to consider requests by manufacturers to exclude particular engines or configurations from test samples for reasons such as urgent customer orders or to minimize test cell set-up time. EPA still plans to consider those requests.

EPA proposed that imported engines could be selected at ports of entry or storage locations in the U.S. SEA engines are typically selected from the point of final engine assembly or from a storage or shipping facility. Manufacturers commented that selecting foreign-produced engines at ports should be an option but not a requirement. Comments also indicated that port selections could significantly increase the manufacturers' SEA costs.

However, as indicated in the NPRM, manufacturers could designate selection locations to minimize disruption and shipping costs. EPA would not likely select engines for SEAs that are only imported installed in equipment; instead, SEAs of those engines would usually occur during foreign trips by SEA staff.

The total number of engines tested in an SEA will be dictated by the number of engines required to reach the statistically acceptable pass/fail decision within the sampling plan applied. As in the on-highway program, these sampling plans were designed to meet a 40 percent Acceptable Quality Level (AQL).

EPA proposed to use the same sampling plans used for the on-highway HDE SEA program with two revisions. The proposed revisions were to include a sampling plan (Plan AA) for lower production engines and to permit the use of the on-highway sampling plan A on families with projected production between 20 and 99 engines. Plan AA was proposed as an option for families with projected annual production between 20 and 50 engines and to permit an audit pass decision in as few as three tests with a maximum of 20 tests.

Manufacturers requested that EPA provide further flexibility in the use of sampling plans. It was requested that EPA make each sampling plan available for manufacturers regardless of the audited engine's projected annual production. It was also requested that EPA permit the use of CARB's low-volume sampling plan which permits a pass decision in as few as two tests and has a maximum test sample of ten engines.

EPA is not adopting CARB's low-volume sampling plan for the SEA program. EPA believes this sampling plan's consumer risk is too great to justify its use in a federal emission compliance program. However, EPA may consider requests by manufacturers to terminate testing early during SEAs of low production families when the audit results are significantly and consistently below each applicable standard or FEL, and selection of additional engines would be difficult or cause a delay in shipment of customer-ordered engines, or the manufacturer's test facility does not have sufficient capacity to expeditiously conclude the SEA.

As proposed, failure of an SEA may result in suspension or revocation of the certificate of conformity for that engine family. To have the certificate reinstated subsequent to a suspension, or reissued subsequent to a revocation, the manufacturer must demonstrate, by showing passing data that improvements, modifications, or replacement have brought the family into compliance. The regulations include hearing provisions which allow the manufacturer to challenge EPA's suspension or revocation decision based on application of the sampling plans or the manner in which tests were conducted.

S. Averaging, Banking and Trading (ABT)

1. Inclusion of ABT

EPA proposed ABT for NO_X emissions from large nonroad CI engines. This market-based incentive program is designed to provide manufacturers with flexibility in meeting the NO_X standard while achieving a target level of environmental benefits.

Many commenters supported the inclusion of ABT. Others opposed the program. One commenter believes that the program would be overly complex, difficult to enforce, and would decrease the effectiveness of the standard by increasing the overall emissions.

EPA disagrees. The target level of environmental benefits was proposed with ABT in mind. In EPA's opinion, and as discussed in the NPRM, the flexibilities afforded by ABT are appropriate to achieve the 9.2 g/kW-hr NO_X average emission standard and the resultant target 37 percent reduction in fleet emissions upon fleet turnover. EPA is confident that the target level of environmental benefits will be achieved by this regulation.

2. Participation of California-certified Engines in ABT

EPA proposed that engines sold in California and subject to California emissions standards would not be included in the federal ABT program. EPA also proposed that engines sold in California but preempted from California regulation or not subject to California emission standards (primarily construction and farm equipment below 130 kW (175 hp)) be eligible to participate in ABT.

One commenter preferred to have a 50-state credit exchange program which would include all engines shipped to all 50 states regardless of the state regulations. Other commenters believed that the engines subject to state regulations should be excluded from participation in the program. Also, one commenter preferred that all engines sent to California not be included in the federal ABT program and recommended the compromise of having a California-only averaging set.

EPA believes that to maintain the effectiveness of the separate California and national emission standards, any engines both sold in California and subject to California regulations (or both subject to regulations and sold in other states that adopt California's regulations under section 209(e)(2)(B)) should not be allowed to participate in the federal ABT program. Although a 50-state scenario would reduce the tracking burden on manufacturers, reduced tracking burden is not a sufficient reason in EPA's opinion to include California engines. Because California does not allow ABT, all engines both sold in the California market and subject to California regulations will be at or below the NO_X standard finalized by EPA today. Therefore, including these engines in the national average could cause the average emissions of engines in the other 49 states to exceed the standard. Finally, engines sold in California but not subject to California emission regulations are subject to federal regulations and, thus, may participate in ABT.

3. Power Ratings for Credit Calculations

EPA proposed to calculate credits by taking the difference between the standard and the FEL, times the sales volume of engines participating in the program, times the power rating. The power rating was proposed to be the largest power rating within an engine family for those families using credits, and the smallest rating within an engine family for families generating credits.

Some commenters claimed that the proposed method for determining the

power rating for credit calculations translates into a significant (greater than 50 percent) reduction in the number of credits generated and an increase in the number of credits used. They recommended that families be divided into subfamilies, and the most environmentally-safe power rating be drawn from each subfamily for credit calculations. An engine family would have to consist of a broad range of power ratings to realize either a 50 percent reduction in credit generation or a 50 percent increase in credit use. EPA stated in the NPRM that it would not allow multi-configuration engine families to be arbitrarily divided into multiple engine families to maximize credit generation or minimize credit usage.

However, in those specific cases where such a broad range of power ratings occur in one family, a manufacturer would likely be able to demonstrate, consistent with § 89.116–96(d) of the regulations, that the expected useful life emission characteristics of some configurations within a broad engine family warrant a separate engine family designation. This would mitigate the credit reduction caused by extremely broad engine families while maintaining EPA's intent that subcategories not be established for the sole purpose of maximizing credits.

4. Discounting of Credits

EPA's proposed ABT program did not include a discount on credits. The proposal did specify a first in, first out (FIFO) accounting system for credits used in averaging (see § 89.204–96(b)); this effectively extends FIFO to banking and trading because in order to ultimately use banked or traded credits, they must be averaged.

Some commenters approved of the absence of a discount on banked or traded credits. One commenter disapproved because discounting, which is included in the on-highway heavy duty averaging program, is viewed as ensuring that a tangible environmental benefit will accrue from a banking program. This commenter would prefer a reduction in available banked credits through discounting or the use of a last in, first out (LIFO) accounting system to mitigate this effect over time.

EPA determined that a discount was appropriate for the on-highway heavy duty ABT program.[17] The rationale for the credit discount was two-fold. First, additional environmental benefits were desired from banking and trading over and above the benefits produced from the averaging program already in place when banking and trading were added. Credit discounting was determined to be an appropriate method of providing a tangible environmental benefit, so that both manufacturers and the public would share the benefits created by the addition of banking and trading. Second, EPA believed that the amount of the discount would not be a disincentive toward participation in the program. Although a credit discount may be appropriate for the on-highway heavy duty ABT program, where banking and trading were promulgated separately from averaging, EPA is not promulgating a credit discount for today's action. The level of environmental benefits, the level of the emission standard, and the banking and trading components of the ABT program were determined in conjunction with one another. Therefore, a credit discount for today's action is not necessary.

One commenter requested that if EPA was not requiring discounting, the Agency should require the use of LIFO as a means to minimize the value of early banking and of banking in general. Under a FIFO accounting system, older banked credits must be used in the current year's average before credits generated in the current year. This potentially allows manufacturers to bank all the current year's credits, which will have a three year potential credit life, if manufacturers are able to use previously-banked credits or purchased credits to offset those engines with FELs above the standard. This encourages manufacturers to achieve more emissions reductions earlier, which may be beneficial for the environment. Mandating a LIFO accounting system may discourage early emission reductions and was not proposed by the Agency.

5. Allowing Early Banking of Emission Credits

Some commenters supported EPA's proposal to allow manufacturers to bank credits one year in advance of the implementation date in order to provide incentives to introduce clean technology a year early. One commenter suggested allowing early banking starting in 1995 regardless of the phase-in implementation date. One commenter believed that early banking should be excluded in order to prevent the generation of windfall credits.

The Agency believes that incentives should be provided for manufacturers to make early use of clean technology. This consideration outweighs the Agency's concerns regarding the minimal number of credits that may be generated a year in advance by the small percentage of engines which already meet the upcoming standard. EPA presented an analysis in the NPRM demonstrating that credits from this small percentage of engines did not represent significant windfall credits.

Although EPA supports early banking incentives for the introduction of clean technology, EPA does not support allowing early banking starting in 1995 regardless of the phase-in implementation date. EPA proposed the phase-in implementation dates because many manufacturers had informed EPA that additional leadtime is necessary for particular sizes of engines. Although it would be beneficial to the environment to have clean engines introduced earlier, EPA is not allowing early banking beyond one year because the larger number of engine families and the extended years of early banking would increase the potential of windfall credits.

6. Early Banking Credit Generation Level

EPA proposed to allow manufacturers to generate credits one model year prior to the implementation date of the standards. EPA proposed that engines banking early must have NO_x emissions below 9.2 g/kW-hr and could generate credits up to the 9.2 g/kW-hr according to § 89.207–96 and bank these credits for future use.

One commenter opposed the idea of early banking. However, several commenters disagreed on the credit generation level. Some commenters recommended that, to create an incentive for manufacturers to meet the standards early, they should be allowed to generate credits up to 11.9 g/kW-hr. Another commenter opposed the credit generation level of 11.9 g/kW-hr.

EPA believes that it is inappropriate to establish a credit generation level above 9.2 g/kW-hr due to the possibility of windfall credits. EPA did not receive data to indicate that emission credits granted to industry at the 11.9 g/kW-hr level would be, overall, less than or equal to the environmental benefits gained by the early banking program. Therefore, manufacturers participating in early banking may only generate credits up to 9.2 g/kW-hr.

7. Liability and Noncompliance

Several commenters were concerned about the enforcement of the ABT program. One commenter wanted assurance that strict penalties were in place for exceeding FELs and other commenters wanted assurance that adequate compliance demonstration methodologies were in place.

[17] 55 FR 30584, 30592–30593 (July 26, 1990).

EPA has substantial experience in enforcement of vehicle and engine emissions from the on-highway ABT program. This experience will be carried forward to the nonroad program. EPA will ensure that manufacturers are held responsible for meeting the FELs that they set, that the FELs are carefully monitored by means of the SEA program, and that overall compliance is effectively monitored. Further, manufacturers will not be allowed to use credits to remedy FEL exceedances detected by EPA enforcement.

8. Disclosure of Credit Information

Due to the connection between credit information and confidential sales information, EPA regulations concerning the release of confidential business information have restricted the public's opportunity to review manufacturers' submission of credit generation and usage. EPA is currently discussing with the participating manufacturers in the on-highway ABT program the possibility of implementing a means of allowing the public to access enough information to make general assessments about the effectiveness of the ABT program on a regular basis. The Engine Manufacturers Association concurs that it is important to provide an ongoing opportunity for the public to evaluate the overall progress of the program. EPA and EMA expect to finalize an agreement in the near future on the periodic release of credit data in a format that would be useful to the public.

T. Nonroad Equipment Definition

EPA is finalizing the following definition for the term nonroad equipment: "Nonroad equipment means equipment that is powered by nonroad engines." This definition follows Congress' format for defining "nonroad vehicles." EPA believes this definition will clarify use of the term nonroad equipment.

Defining the term nonroad equipment is a logical outgrowth of this rulemaking, is in keeping with the intent of Congress, and clarifies EPA's use of the term. EPA also notes that the definition of the term "nonroad vehicle" has been revised to match the statutory definition; instead of defining nonroad vehicles as vehicles propelled by nonroad engines, they are defined as vehicles powered by nonroad engines.

U. Definition of New

In the September 6, 1991 NPRM proposing regulations under section 209(e) of the CAA regarding preemption of state nonroad regulations, EPA proposed a definition of "new nonroad engine" and "new nonroad vehicle." In that NPRM, EPA defined "new nonroad engine" and "new nonroad vehicle" to mean a nonroad engine or a nonroad vehicle the equitable or legal title to which has never been transferred to an ultimate purchaser. EPA did not provide a definition of "new" in its May 17, 1993 NPRM because EPA expected that the definition of "new" promulgated in the context of the section 209(e) rulemaking would control how "new" would be defined in this rule. However, EPA has not yet promulgated its section 209(e) regulations. Therefore, EPA is finalizing a definition of "new" in this rulemaking relying in part on the definition proposed in the September 6, 1991 NPRM and the comments received in response to that NPRM.

Ultimate purchaser was proposed to be defined as the first person who in good faith purchases such a new nonroad vehicle or nonroad engine for purposes other than resale. Additionally, with respect to imported nonroad engines, EPA proposed to define "new" nonroad engine to be a nonroad engine manufactured after the effective date of a regulation issued under section 213 which would be applicable to such engine had it been manufactured for importation into the United States. These definitions also applied to "new locomotives" and "new engines used in locomotives."

Comments on EPA's proposed definition of "new" were several. First, CARB, the San Diego Air Pollution Control Board (SDAPCB), and the Manufacturers of Emissions Controls Association (MECA) supported EPA's definition. CARB asked that EPA clarify which regulatory activities states may perform; for example, whether states may require in-use testing and impose add-on or retrofit requirements. On the other hand, many commenters, including U.S. Representative Terry Bruce, the Equipment Manufacturers Institute (EMI), the Engine Manufacturers Association (EMA), and the Portable Power Equipment Manufacturers Association (PPEMA), opposed EPA's proposed definition and proposed that "new" should mean manufactured after either the effective date of the Clean Air Act Amendments, November 15, 1990, or after federal regulations take effect. These commenters believe that Congress intended an "absolute" preemption. That is, the nonroad engines and vehicles in the preempted categories manufactured after November 15, 1990 would never be subject to any kind of state emission regulation. EMA commented that if EPA does not accept the latter definition, it should expand its proposed definition so that engines remain "new" until they have exceeded their useful life.

Commenters in the railroad industry also supported a definition of "new" as "manufactured after November 1990" and stated further that the railroad industry has traditionally been preempted from state regulation, such as in the area of safety. The same commenters indicated that they believe that state control of locomotive emissions or state enforcement of federal standards would interfere with interstate commerce. Railroad commenters also stated that any standards for rebuilt or remanufactured engines or locomotives should be uniform federal standards—not state standards. Furthermore, if remanufactured engines were rebuilt to comply with such federal standards, they should be considered "new".

Commenters also opposed the proposed definition regarding imported vehicles and engines because the definition of "new" was different depending upon whether the nonroad engine was produced domestically or abroad.

These proposed definitions for "new nonroad vehicles" and "new nonroad engines" parallel the definitions of "new motor vehicles" and "new motor vehicle engines" in section 216 of the Clean Air Act. The definition of "new" proposed for imported nonroad engines was intended to address nonconforming engines which may become subject to federal emission requirements at the time the engine or vehicle is imported into the United States. The Agency has decided to delete this definition of "new" for imported engines. EPA agrees with the commenters that imports and domestic products should generally be treated alike for regulatory purposes. Today's rule treats domestic and imported nonroad engines the same way for purposes of determining whether they are new.

This final rule establishes for the purpose of these federal regulations, a definition of "new" as it applies to all domestically manufactured and imported "new nonroad engines," "new nonroad vehicles," and "new nonroad equipment." [18] New nonroad engines, vehicles, and equipment are defined as engines, vehicles, and equipment the equitable or legal title to which has not been transferred to an ultimate purchaser. The ultimate purchaser is

[18] This final rule does not provide a final definition of "new" for the purposes of determining the scope of preemption of state nonroad regulations under section 209(e). EPA shall finalize its definition of "new" as applied to preemption of state regulations in a later rulemaking.

defined as the first person who in good faith purchases such engine, vehicle, or equipment for purposes other than resale. For some engines, vehicles, or equipment the passage of title in the United States may not formally occur or manufacturers may retain title and lease the engines or equipment. In these cases, a domestic or imported nonroad engine, nonroad vehicle, or nonroad equipment will retain its status as "new" until such engine or vehicle is "placed into service." An engine, vehicle, or equipment is considered "placed into service" when the engine, vehicle, or equipment is used for its functional purposes. EPA believes that the definition of new should include the "placed into service" addition to the motor vehicle definition of new found in section 216 of the Act because of the nature of the nonroad market. Nonroad engines, nonroad vehicles and nonroad equipment are often leased and maintained by the manufacturer well into the useful life of the nonroad equipment. A piece of equipment, the title of which has passed to the ultimate purchaser, should not be treated differently than a piece of equipment which is being used but has not yet passed to an ultimate purchaser.

The Agency believes that this definition of "new" comports with the language, intent and structure of the Clean Air Act and is a permissible construction of the statute. Contrary to the assertion of some commenters, EPA's definition of "new" is consistent with the dictionary definition of the word as "having existed or been made but a short time." Webster's Ninth New Collegiate Dictionary, 1990. Generally speaking, manufactured products are sold soon after they are made and are considered new until they are sold or used. The commenters' definition of new—anything manufactured after the Clean Air Act Amendments' enactment or an applicable regulation's promulgation—would mean, by contrast, that any engine manufactured after a certain date would be new forever. This is certainly not the plain meaning of "new." Congress could have stated that the federal preemption applied to certain equipment manufactured after a certain date, but Congress did not do so. Elsewhere in title II, Congress specified that a provision only applied to products manufactured after a certain date (see, section 218 requiring a ban on engines manufactured after the 1992 model year that require leaded gasoline) or first introduced into commerce after a certain date (see, section 211(f) regarding prohibition on fuels that are not substantially similar to fuels used to certify vehicles as meeting emission standards). The lack of such a date here further supports that Congress intended "new" to mean newly manufactured and not yet sold.

The legislative record also shows Congressional intent that "new" should refer to newly manufactured products. In his colloquy with Senator Wilson explaining the final version of section 209(e), Senator Chafee notes that "because the preemption is limited to new engine standards only, States can continue to require existing *and in-use* nonroad engines to reduce emissions * * *" [Emphasis added] 136 Cong. Rec. S17237 (October 26, 1990). This language is echoed by similar language from Senator Baucus in his report to the Senate on the conference bill. 136 Cong. Rec. S16976 (October 27, 1990). If Congress intended the definition of new nonroad engines or equipment, and as a result the preemption, to apply to an engine for its entire life, then it would appear that there would be no distinction between new and in-use nonroad engines, as an engine manufactured after a certain date would always be new. Yet the statements of Senator Chafee and Senator Baucus clearly contemplate such a distinction.

The Agency's definition of new is also consistent with the way the Act approaches motor vehicle emission control. As noted earlier, section 216 defines new in the context of motor vehicles as "a motor vehicle the equitable or legal title to which has never been transferred to an ultimate purchaser." The Act applies federal emissions standards to "new" vehicles. These federal standards are enforced through certification, assembly line, and recall testing. States, on the other hand, have a role in motor vehicle emission control through inspection/maintenance programs and are not restricted from controlling used vehicles. The section 209(a) prohibition of state regulation of motor vehicles addresses only "new" motor vehicles and engines and prohibits state regulation that occurs before sale, titling, or registration of the vehicle.[19]

The Clean Air Act Amendments of 1990 take a parallel approach to nonroad standards and enforcement. Section 213 provides EPA with authority to set standards for "new" engines and provides for federal enforcement of such standards in the same manner as motor vehicle enforcement. Furthermore, nothing on the face of section 209(e) or section 213 indicates that Congress intended "new" to be interpreted differently in the nonroad and motor vehicle contexts.[20] Given that the preemption provisions for new motor vehicles and new nonroad engines appear in the same section of the Clean Air Act, it is reasonable to believe that Congress did not intend for the word "new" to be defined differently within the same section without stating this intent explicitly.[21]

There is not a compelling policy or factual justification for defining new differently in the nonroad and motor vehicle contexts. State regulation of nonroad engines does not generally present any greater degree of disruption of the movement of products, engines or equipment between states than does regulation of motor vehicles. The comments provide little if any justification, in terms of relevant distinctions between motor vehicles and nonroad engines, to justify such a significant departure from EPA's established practice for regulating mobile sources.

The Agency's definition of new is also consistent with case law. In *Allway Taxi, Inc.* v. *City of New York*,[22] the court held that where the exercise of local police power serves the purpose of a federal act—the Clean Air Act in that case—the preemptive effect of the act should be narrowly construed. In keeping with that principle, EPA believes that the definition of "new" should be construed narrowly in order

[19] Section 209(a) provides, in part, ". . . No State shall require certification, inspection, or any other approval relating to the control of emissions from any new motor vehicle or new motor vehicle engine as condition precedent to the initial retail sale, titling (if any), or registration of such motor vehicle, motor vehicle engine, or equipment."

[20] Much of the argument below discusses the definition of "new" as applied to section 209 of the statute. However, these arguments are equally valid for the purposes of defining "new" under section 213, especially given the integrated nature of Part A of Title II, the legislative and statutory history, and practical necessity. For example, consistent definitions of new under sections 209 and 213 are likely to ensure that there are no unintended gaps in regulation or unintended dual regulation. Also, the statutory definition of "new motor vehicle" and "new motor vehicle engine" are applicable equally to federal regulations and preemption of state regulations. EPA generally sees no logical reason to treat nonroad engines differently. However, see the discussion in footnote 21.

[21] EPA recognizes that regulation of locomotives presents unique circumstances, including questions regarding interstate commerce, that require special attention. EPA therefore believes that the definition of "new" as used in "new locomotive" and "new engine used in a locomotive" may need to be treated differently for the purposes of determining preemption of state regulation under section 209(e) than it is treated for the purpose of federal regulation under section 213(a). This issue will be addressed in a later rulemaking.

[22] *Allway Taxi, Inc.* v. *City of New York*, 340 F. Supp. 1120 (S.D.N.Y.), *aff'd*, 468 F.2d 624 (2d Cir. 1972).

to protect states' rights, particularly in an area such as public health in which states traditionally exercise control. California's nonroad regulations will serve the purpose of the federal act by improving air quality.

In *Allway Taxi*, the court discussed the federal preemption of new motor vehicles and interpreted the meaning of new motor vehicle as defined in Section 216 of the Act. The court noted that this definition "reveals a clear congressional intent to preclude states and localities from setting their own exhaust emission control standards only with respect to the manufacture and distribution of new automobiles."[23] The court stated further that the narrow purpose in the definition is reinforced by prohibiting states and localities from setting emission standards before the initial sale or registration of an automobile. Congress specifically declared that section 209 did not preempt states from regulation of the use or movement of motor vehicles after they have reached their ultimate purchasers.[24]

EPA believes that the further a state requirement is removed in time from the manufacture and distribution of new engines, the less interstate commerce is likely to be burdened. Furthermore, the legality of particular regulatory controls that a state may impose on nonroad vehicles or engines that are no longer new will depend upon the burden that such controls place on interstate commerce. In fact, the court in *Allway Taxi* stated that a state or locality is not free to impose its own emission control measures the moment after a new car is bought and registered. "That would be an obvious circumvention of the Clean Air Act and would defeat the congressional purpose of preventing obstruction to interstate commerce."[25] The court further stated that federal preemption does not, however, preclude a state from imposing its own exhaust emission control standards upon the resale or reregistration of the automobile. Furthermore, states are not precluded from setting standards for licensing of vehicles for commercial use. These types of regulations, which are more removed, "would cause only minimal interference with interstate commerce, since they would be directed primarily to intrastate activities and the burden of compliance would be on individual owners and in-state users and not on manufacturers and distributors."[26]

[23] *Id.* at 1124.

[24] *Id.*

[25] *Id.*

[26] *Id.*

EPA expects that the principles articulated in *Allway Taxi* will be applied by the courts to any State adoption of in-use controls. For example, manufacturers have voiced a concern that California would attempt to impose in-use emission control measures that would apply immediately after a new vehicle or engine were purchased. As the *Allway Taxi* court said, such standards applied to almost-new vehicles would be an attempt to circumvent section 209 preemption and would obstruct interstate commerce.[27]

It should be noted that section 209(e)(2) of the Act does not prevent California or other states from regulating nonroad engines and vehicles in use.[28] EPA believes that the requirements of section 209(e)(2) apply only to new nonroad engines and vehicles. The requirements of section 209(e)(2) are only required for nonroad engines and vehicles the regulation of which has been preempted. The language of section 209(e)(2) does not state any clear preemption, either for new or in use vehicles. The only clear preemption of state regulation of nonroad engines occurs in section 209(e)(1) and section 209(a).[29] Both of these subsections are limited to new engines and vehicles. Given the general legal presumption against reading a preemption more broadly than explicitly required, as discussed in *Allway Taxi*, a preemption of state regulation of nonroad engines and vehicles in use should not be readily implied.

Another indication that section 209(e)(2) was not intended to apply to most in-use regulations of nonroad engines is the fact that neither the Senate nor the House version of the 1990 Act amendments would have preempted state regulation of anything but new nonroad engines. Neither version would have expressly preempted regulation in use. It would be unusual for a bill to come out of conference with a broader preemption than existed in either house and without any mention in the legislative history that such broader preemption had been mandated. In fact, both Senators Chafee and Baucus believed that the scope of the preemption had been narrowed from the House bill, not widened.[30]

In fact, as the legislative history indicates, it appears that Congress intended the preemption provisions of section 209, as applied to nonroad engines, to be analogous to the preemption provisions as applied to motor vehicles, except that California cannot request any waiver of the Federal preemption of state regulation of new small farm and construction equipment and locomotives.

Further indication that section 209(e)(2) was not intended to apply to in-use regulations is the fact that, if the subsection were applied to in-use regulations, then California would be the only government (local, state or federal) that could directly set regulations for nonroad engines in use. EPA's mandate under section 213 applies only to new engines. Therefore, EPA will not promulgate standards for in-use regulation of nonroad engines under section 213, beyond in-use regulations normally associated with new certified engines (*e.g.* in-use testing and recall requirements under section 207). States other than California would not be able to regulate nonroad engines in use (*e.g.* operation controls under section 209(d)) until California regulates them and could only regulate them in a manner identical to California's regulations. Nothing in the legislative history indicates such a dramatic departure from the current ability of states and local authorities to regulate emissions of mobile sources in use.

[27] *Id.* EPA expects the reasoning and policy outlined above in the *Allway Taxi* discussion to apply to locomotives although its implementation is dependent upon the ultimate definition of new locomotive.

[28] In-use testing and recall programs of the type set forth in section 207 ensure compliance with standards required to be met by manufacturers at the time of certification of the engine. Because these in-use standards relate to the original manufacture of the engine and place the burden of compliance upon the manufacturer, they are deemed to be standards affecting a new motor vehicle or a new nonroad engine and thus require a waiver under the criteria of section 209(b) or 209(e)(2) respectively.

[29] Section 209(a) applies to nonroad vehicles because of the language of section 213(d) of the Act, which specifically requires that EPA's standards regulating nonroad engines and vehicles be subject to sections 206, 207, 208 and 209 of the Act, with such modifications of the applicable regulations as the Administrator deems appropriate. Thus, Congress clearly anticipated that all of section 209 would be applicable to nonroad engines. Subsections (a) through (d) of section 209 do not specifically reference nonroad engines, nor do sections 206, 207 or 208. However, the language of section 213(d) clearly is intended to apply such provisions to nonroad engines. Further indication of Congress' intent is the language of the last sentence of section 209(e)(1), which states that subsection 209(b) does not apply for purposes of subsection (e)(1). (Section 209(b) provides the procedure under which California can receive a waiver of section 209(a) preemption for motor vehicles.) This sentence would not have been necessary unless subsection 209(a) through (d) otherwise applied.

[30] Both Senators declare that state preemption is limited to new locomotives and new small farm and construction equipment. Both mention that states may still regulate other new nonroad equipment, presumably after receiving EPA approval. Finally, each declare that states also fully retain existing authority to regulate emissions from all types of existing or in-use nonroad engines by specifying fuel quality specifications, operational modes or characteristics or measures that limit the use of nonroad engines or equipment.

Therefore, if section 209(e)(2) is determined to apply to in-use regulations, the entire United States regulatory scheme for regulation of nonroad engines in use would be dependent on the actions of one state, California. Congress could not have meant to grant such plenary power to a single state.

This is especially true given the location-specific nature of in-use regulations. In-use regulations, such as time of use or place of use restrictions (*e.g.* high occupancy vehicle lanes) are typically very site specific. An in-use regulation suitable for California, or in part of California, may have little or no relevance or practicality to the type of in-use regulation suitable for another area. Such regulations which primarily effect local users are more appropriately controlled and implemented by local and state governments.

Moreover, section 209(d) of the Act clearly limits the preemption of state regulation in use. It states that "nothing in this part shall preclude or deny to any other State or political subdivision thereof the right otherwise to control, regulate, or restrict the use, operation or movement of registered or licensed motor vehicles." As was stated above, section 209 as a whole applies equally to nonroad engines. Thus, section 209(d) should be interpreted to mean that, unless state regulation of use of nonroad engines is specifically preempted, section 209 should not be interpreted to grant any implicit preemption, except within the framework of *Allway Taxi*.

Given the language of section 209 and the lack of any express preemption, the legislative history of these provisions, and the general presumption against providing broad preemption where such preemption is not made explicit, EPA believes that it is clear that section 209(e)(2) does not apply to in use regulation of nonroad engines.

While EPA recognizes the important principle of narrowly construing the preemptive effect of the Act as explained in *Allway Taxi*, EPA also notes that certain state regulations that may be characterized as "in-use" regulations may be preempted because they are effectively regulations on the design of new engines rather than on the use of "in-use" engines. Industry has expressed concern that states might impose retrofit requirements on nonroad engines and vehicles as soon as they are introduced into commerce, or when such engines are being rebuilt, or at a date after which nonroad engines are typically rebuilt.[31] EPA recognizes that CARB does not envision a retrofit requirement and that, because of the nature of the nonroad market, it is unlikely that other states would adopt such a requirement.[32] However, given EPA's definition of new and the scope of the definition within this rulemaking, this issue could arise when other states plan their in-use emission strategy. In such a case, EPA believes that a retrofit requirement mandating a retrofit of a nonroad engine immediately after the engine is no longer new is adverse to the Congressional intent of section 209(e) and the principles laid out in *Allway Taxi*. Therefore, in this scenario, such a retrofit requirement would be deemed an in-use emission standard relating back to the original design of the new engine by the original engine manufacturer (OEM) and would be subject to the waiver criteria of section 209(e)(2). Within this same scenario, only California could adopt such a requirement and other states could only adopt California's requirement if California subsequently was granted a waiver. However, after a reasonable amount of time has passed and the engine is no longer new (most likely when an engine is being rebuilt), modest retrofit requirements would most likely not be deemed to significantly affect the OEM and thus such requirements would not be subject to subsection 209(e)(2). In this second scenario, the modest retrofit requirements would still be subject to challenge in court under the *Allway Taxi* criteria.[33]

Therefore, the Agency has determined that nonroad engines and nonroad vehicles will be "new" for purposes of the Act until the equitable or legal title passes to the ultimate purchaser, or if title passage does not occur, then the engine or vehicle will be new until placed into service.

V. Definition of Locomotive

The September 6, 1991 NPRM to the California nonroad preemption regulation defined locomotive as a self-propelled piece of on-track equipment (other than equipment designed for operation both on highways and rails, specialized maintenance equipment, and other similar equipment) designed for moving other equipment or carrying freight or passenger traffic or both. As with the definition of "new," EPA did not propose a definition of locomotive in its May 17th NPRM, but is finalizing a definition is this rulemaking, relying in part on the definition proposed in the September 6, 1991 NPRM and the comments received in response to that NPRM. The comments discussed below are contained in Docket # A–91–18.

EMA noted a difference between the NPRM definition and the definition given in the Locomotive Inspection Act (LIA) upon which the EPA definition was based, but did not recommend EPA use the LIA definition in the definition EMA provided. The only difference between the EPA definition and the LIA definition is that the LIA definition of locomotive includes a piece of equipment without propelling motors but with one or more control stands. This item was not included by EPA since if it has no propelling motors it will not be of concern for purposes of engine emissions regulations. It is noted that neither the Association of American Railroads (AAR) nor any railroad companies that commented on the NPRM, such as Union Pacific and Southern Pacific, had any specific comments on the definition of locomotive.

EMA provided definitions for "locomotive" and "locomotive engine".[34] Under this definition, the regulation of any engine mounted on a locomotive (such as an engine driving a crane or winch) would be preempted. The dictionary definition of "locomotive" is a "self-propelled vehicle, usually diesel or electric, that travels on rails and moves railroad cars."[35] EMA's definition of locomotive engine goes beyond the specific purpose of locomotion to include any other engine that might be placed on a

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[31] See Oral Statement of the Engine Manufacturers Association, Docket entry IV-F–7, which states "The ultimate purchaser must have the assurance that the engine * * * she might purchase, and which properly meets EPA requirements * * * is 'good' until that engine is ready to be rebuilt. No state should be allowed to impose retrofit standards on engines which otherwise conform to EPA requirements."

[32] See Letter from Mr. Ceckette, CARB to Mr. Mandel, EMA, dated July 20, 1993, Docket entry IV–I–55.

[33] EPA's definition of "new" does not present a problem for engines or equipment that do not sell relatively quickly (*e.g.*, within a year of being made) in California. If California's regulation set standards applicable to "new" engines, *i.e.* as of the date title passed, regardless of when the engine was produced, then an engine manufactured in 1990 but not sold until 1994 would be subject to 1994 emission standards. This problem is avoided since California's Utility Engine Rule ties the date of manufacture to the standard, therefore a 1990 engine would be subject to a 1990 standard and a 1994 engine subject to a 1994 standard.

[34] EMA recommended the following definitions: "Locomotive" means a self-propelled piece of on-track railroad equipment (other than equipment designed for operation both on-highway and on-track) and "Locomotive engine" means an engine included in a locomotive. See Statement of Engine Manufacturers Association, Docket entry IV-G–19.

[35] Websters II, New Riverside University Dictionary, 1988.

locomotive. EPA believes that the term "locomotive engine" is limited to the engine used to propel the locomotive and other railroad cars. However, EPA does believe that the term "engines used in locomotives," as found in section 209(e)(1)(B), can be defined to include other engines which are mounted on a locomotive regardless of whether they are used for purposes of self-propulsion. EPA notes that under this definitional framework the "locomotive" is only that piece of on-track equipment which is self-propelling and is designed for moving other cars containing equipment, freight, or passengers. "Engines used in locomotives" thus includes an engine placed in the locomotive to propel the train and also includes other engines mounted on the locomotive for auxiliary power generation for the train, but does not include engines mounted on the train elsewhere than the locomotive. An engine providing power for a crane or winch, for example, would only be considered preempted from state regulation (if it otherwise met the requirements for "new") as "an engine used in [a] locomotive" if such engine were mounted on the locomotive. EPA believes these definitions reflect the intent of Congress to reduce the burden on interstate commerce for the railroad industry, and address EMA's concerns regarding auxiliary engines.[36]

EPA has stricken the word "carrying" from the definition of locomotive. This was done to avoid implying that any persons or property that were moved by the engine had to be located directly on the locomotive. The word "moving" in the definition is all that is needed to give the correct meaning.

For the final rule, EPA has decided that a "locomotive" means a self-propelled piece of on-track equipment (other than equipment designed for operation both on highways and rails, specialized maintenance equipment, and other similar equipment) designed for moving other equipment, freight or passenger traffic. EPA has also decided that the term "engines used in locomotives" means either an engine placed in the locomotive to move other equipment, freight , or passenger traffic, or an engine mounted on the locomotive to provide auxiliary power.

VII. Cost Analysis

EPA has adjusted its estimate of the average annual cost of this rule upward from approximately $29 million to $70 million. EPA has decided to make the adjustment after analyzing new information provided by commenters with respect to the engine modifications required to meet the adopted emission standards and updated cost information provided confidentially by manufacturers. Based on EPA's revised analysis (see the final version of the Regulatory Support Document in the docket), the Agency has adjusted the present value of the per engine increase in retail price of a 1996 model year engine upward from approximately $110 per engine to approximately $220 per engine (in 1992 dollars).

To maintain acceptable performance throughout the engine speed band, some manufacturers commented that they will choose to use waste-gate technology in lieu of smoke limiters on some of their engine models. These manufacturers stated that, for their engine designs, applying a smoke limiter to control smoke could cause a performance discontinuity that could present a safety concern under certain operating conditions. While the cost of waste-gate technology was not accounted for in EPA's proposed cost impact, the Agency believes it is reasonable for manufacturers to use a costlier solution in those cases where there is a potential performance or safety impact. EPA estimates that half of the turbocharged engines could be fitted with this technology. That represents approximately 30 percent of all engines covered by this rule with a parallel 30 percent reduction in use of smoke limiter technology. Based on average per piece cost figures submitted by manufacturers, EPA has calculated that the addition of waste-gate technology in the technology mix would result in a per engine weighted hardware cost increase of approximately $35 per engine, while the weighted cost due to use of smoke limiter technology will be revised to $3 per engine.

EPA also assumed in its estimate of hardware cost that there would be little or no cost involved with upgrading fuel pumps to increased injection pressures (as opposed to changing pump type, rotary to in-line, in-line to unit injector). During the comment period, manufacturers provided concrete evidence that there is a significant cost increment to increasing injection pressures. Based on manufacturers' data an average weighted cost of $73 per engine will be assessed to account for modifications that will allow in-line fuel pumps and unit fuel injection systems to accommodate incremental increases in injection pressure.

Manufacturers also provided information on additional hardware costs. Electronic control systems and low sac fuel injectors were two strategies mentioned. While electronic control will reduce NO_x emission, EPA maintains that is not the most cost effective method to meet the requirements of this rule. A number of marketing and performance reasons unrelated to emission performance, such as fuel economy and versatility, make such strategies attractive to manufacturers. These reasons in and of themselves may cause manufacturers to convert a portion of their fleets to electronic controls. Because EPA's cost estimate is based on the necessary cost to meet this rule and to maintain current performance and fuel economy characteristics, the extra cost incurred by a manufacturer to install electronic control will not be added to EPA cost estimates.

Similarly, manufacturers requested that EPA include the cost of low sac injectors. Low sac injectors are an effective HC control strategy. However, EPA's proposal did not contain HC standards, and the HC standard adopted in the final rule can be expected to do no better than cap the current HC levels. Furthermore, EPA requested that manufacturers provide information on the cost ramifications of adopting additional standards. Industry comments have stated that EPA's adoption of the HC standard will not increase the cost of this rule.

EPA believes it has adequately accounted for costs of low sac injectors in its fuel system cost estimates and will not report a separate cost line to account for the limited usage of low sac injectors caused by this rulemaking. A percentage of the engine production volume by the 1996 model year will be using low sac injectors whether regulations are in place or not. An additional percentage of regulated engines that undergo fuel system modifications will incorporate low sac injectors at that time. Manufacturers that intend to do this have reported fuel system modification costs that include the low sac injector costs. These costs are already included in the EPA hardware cost estimate under the "Fuel System Improvements" section of the RSD.

Several manufacturers suggested that their engine model prices would increase more than the proposed EPA per engine retail price increase. It should be noted that the EPA present value per engine retail price estimate is a relative estimate aggregated across engines on a sales-weighted basis. Thus the estimate cannot be directly translated into the price increase a consumer should expect to pay for a particular piece of equipment. For engines greater than 130 kW, the disaggregated data generally indicate

[36] See Letter from Glenn Keller, EMA to Joanne Goldhand, EPA, Docket entry IV–I–54.

that an engine purchaser can expect a price increase of approximately $100 per 75 kW, which represents less than one percent of the equipment price in most cases. Price increases for engines between 37 kW and 130 kW will generally increase between zero to two percent of the equipment price. These are general estimates and there will be exceptions that do not show in EPA's reported aggregate value. In any event, relative industry level estimates calculated for regulatory analysis purposes would not be expected to match the retail price of a particular engine design. However, based on all data available (including confidential manufacturers' submissions), EPA believes that its final adjusted estimate reported in the rulemaking is accurate in the aggregate and is consistent with accepted regulatory costing methodology.

Some comments suggested that the proposed rule would cause a significant increase in fuel consumption. EPA maintains that the impact of this rule on fleet average fuel consumption will be minimal. EPA's experience with on-highway engines is that fuel consumption decreases when the various technologies to control emissions are added. From 1988 to 1991, fuel consumption decreased one percent, while NO_X and smoke decreased about 40 percent for the average on-highway engine. Specific power also increased four percent. EPA's on-highway findings are consistent with an analysis presented by Caterpillar at the American Petroleum Institute Off-Highway Forum in September, 1993 in Milwaukee, Wisconsin (see the RSD for details of this analysis).

EPA's estimate of hardware costs accounts for those additional costs needed to control fuel consumption beyond what is necessary to reduce NO_X emission levels to meet the standard. These methods to both reduce NO_X emissions and maintain current fuel consumption and performance have been used for a number of years in the on-highway fleet.

Since fuel economy and power are important criteria for the consumers of these engines, most manufacturers commented that they are going to add hardware to their engines in an effort to maintain current levels of performance. Some manufacturers commented that while they would do their best to fully maintain the baseline fuel economy levels, selected engine models would incur a small fuel economy penalty despite their efforts. While a small number of engine families may not be capable, for either technical or cost reasons, to fully retain current fuel consumption and power levels, EPA's past experience with the on-highway program has shown that most engine models will be able to attain the emission standards without compromising fuel consumption or power. One manufacturer stated that it expected fuel efficiency to increase over time as manufacturers optimize their engine designs. EPA has strong evidence from its historical database suggesting that is the case.

EPA maintains that the impact of this rule on equipment in which regulated engines are installed will be minimal. EPA has accounted for the cost of applying the range of engine technologies required to maintain engine efficiency so that equipment modifications will not be required. Furthermore, the added program flexibilities, such as the later implementation date for lower power engines and the implementation of the ABT program, provide means for manufacturers to minimize any negative impacts. Based on EPA's analysis in the RSD and further discussed in the Response to Comments document in the docket, EPA believes that the adopted rules provide the means to avoid equipment modifications in all but the most severe cases. These cases will not affect the aggregate cost analysis presented in this rule.

Comments received with respect to equipment impacts centered around the need to redesign the engine cooling system and increase maintenance to offset an expected loss in engine efficiency. A number of commenters disagreed with EPA's assessment of no impact on equipment.

EPA provided analysis in the draft RSD supporting minimal loss in engine efficiency. Manufacturers did not provide data demonstrating efficiency losses and did not refute the data provided by EPA. Four equipment manufacturers and their association did provide average cost figures. These cost figures were based on anticipated equipment modifications and increased maintenance due to engine efficiency loss estimates that were not supported with data. Furthermore, projections and costs for equipment modification and maintenance were highly aggregated and thus provided insufficient resolution to establish the need for the projected equipment changes. Requests from EPA for additional data from specific manufacturers were not responded to with sufficient detail. Based on the information available to EPA (and discussed further in the Response to Comments in the docket), the Agency concludes that equipment modifications will rarely be needed to accommodate certified engines.

VIII. Environmental Benefits

National Ambient Air Quality Standards (NAAQS) have been set for criteria pollutants which adversely affect human health, vegetation, materials, and visibility. Three criteria pollutants (nitrogen dioxide (NO_2), ozone (O_3), and particles smaller than 10 microns (PM_{10})), are impacted by NO_X emissions. EPA has determined the standards set in this rule will reduce NO_X emissions and help nonattainment areas come into compliance with the NAAQS for ozone. The following provides a summary of the reduction expected of NO_X emissions. The underlying analysis is described in greater detail in the Regulatory Support Document.

The Agency believes the adopted standards should reduce average per-unit NO_X emission from large nonroad CI engines by 27 percent before the year 2010, with a fleet-wide 37 percent reduction once a complete fleet turnover occurs or by the year 2025. This will result in annual nationwide reductions of roughly 800,000 tons of NO_X by the year 2010 and over 1,200,000 tons of NO_X by the year 2025. Based on EPA projections of future emission levels, these reductions represent four percent of total nationwide annual NO_X emissions expected in 2010.[37]

IX. Cost Effectiveness

In evaluating various pollution control options, EPA considers the cost effectiveness of the control. The cost effectiveness of a pollution control measure is typically expressed as the cost per ton of pollutant emissions reduced. Other things being equal, Agency guidance directs that the regulatory option selected should, for a given level of effectiveness, cost less per ton of emissions reduced.

A. Cost Per Ton of NO_X Reduction

EPA has revised its cost effectiveness estimate of the NO_X standard upward to $188 per ton of NO_X removed from the exhaust of the affected engines. This figure is based on the ratio of the present value of the stream of projected costs to the present value of the stream of projected emission reduction benefits, and it reflects the revised cost estimates presented in section VII.

[37] U.S. Environmental Protection Agency, *National Air Pollutant Emission Estimates: 1940–1990*, EPA–450/4–91–026, November, 1991, p. 46.

B. Comparison to Cost Effectiveness of Other Emission Control Strategies

The cost-effectiveness of the nonroad NO_X standards may be compared to other CAA measures that reduce NO_X emissions. title I of the 1990 CAAA requires certain areas to provide for reductions in VOC and NO_X emissions as necessary to attain the NAAQS for ozone. Title I specifically outlines provisions for the application of reasonably available control technology (RACT) and new source review (NSR) for major NO_X emitters. In addition, EPA anticipates that more stringent reductions in NO_X emissions will be necessary in certain areas. Such reductions will be identified through dispersion modeling analyses required under title I. The cost-effectiveness of these measures is generally estimated to be in the range of $100 to $5,000 per ton of NO_X reduced.[38]

In addition to applying NO_X control technologies to meet requirements under CAA title I, many point sources will also be required to meet NO_X emission rate limits set forth in other programs, including those established under CAA title IV, which addresses acid deposition (that is, acid rain). EPA anticipates that the cost of complying with regulations required under section 407 of the CAA (Nitrogen Oxides Emission Reduction Program), which proposes nationwide limits applicable to NO_X emission from coal-fired power plants, will be between $200 and $250 per ton.

The cost effectiveness of controlling NO_X emissions from on-highway mobile sources has also been estimated. The 1998 heavy-duty highway engine NO_X standard is estimated to cost between $210 and $260 per ton of NO_X reduced, and the recently promulgated on-board diagnostics regulation is estimated to cost $1974 per ton of NO_X reduced from malfunctioning in-use light-duty vehicles.

In summary, the revised cost effectiveness of the NO_X standard included in this rule remains favorable relative to the cost effectiveness of several other NO_X control measures required under the Clean Air Act. To the extent that cost effective nationwide controls are applied to large nonroad CI engines, the need to apply in the future more expensive additional controls to mobile and stationary sources that also contribute to acid deposition, as well as ozone nonattainment, nutrient loading, visibility, and PM nonattainment may be reduced.

[38] U.S. Environmental Protection Agency, The Clean Air Act Section 183(d) Guidance on Cost-Effectiveness, EPA–450/2–91–008, November 1991

X. Administrative Requirements

A. Administrative Designation and Regulatory Analysis

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it may adversely affect in a material way that sector of the economy involved with the production of nonroad large CI engines and nonroad vehicles and equipment using those engines, previously unregulated by EPA. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The information collection requirements pertaining to certification and ABT in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by EPA (ICR No. 1684.01) and a copy may be obtained from Sandy Farmer, Information Policy Branch, EPA/OPPE/ORME, 401 M Street SW., Washington, DC 20460 (Mail Code 2136) or by calling (202) 260–2740. These requirements are not effective until OMB approves them and a technical amendment to that effect is published in the **Federal Register**.

This collection of information has an estimated reporting burden averaging 5,800 hours annually for a typical engine manufacturer. However, the hours spent annually on information collection activities by a given manufacturer depends upon manufacturer-specific variables, such as the number of engine families, production changes, emissions defects, and so forth. This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch; EPA/OPPE/ORME; 401 M Street SW., (Mail Code 2136); Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: EPA Desk Officer."

All other information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and have been assigned the following control numbers:

EPA ICR No.	Type of information	OMB control No.
ICR No. 11	Selective Enforcement Auditing.	2060–0064
ICR No. 282	Emission Defect Reporting.	2060–0048
ICR No. 10	Importation of Nonconforming Vehicles.	2060–0095
ICR No. 12	Exclusions ...	2060–0124
ICR No. 95	Exemptions .	2060–0007

C. Impact on Small Entities

The Regulatory Flexibility Act of 1980 requires federal agencies to identify potentially adverse impacts of federal regulations upon small entities. In instances where significant impacts are possible on a substantial number of these entities, agencies are required to perform a Regulatory Flexibility Analysis (RFA).

EPA has determined that this rule will not have a significant effect on a substantial number of small entities. This regulation will affect manufacturers of large nonroad CI engines, a group that does not contain a substantial number of small entities. Manufacturers will be able to take advantage of the flexibility afforded by the averaging, banking, and trading program.

Therefore, as required under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, I certify that this regulation does not have a significant impact on a substantial number of small entities.

List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 89

Environmental protection, Administrative practice and procedure, Air pollution control, Confidential business information, Imports, Incorporation by reference, Labeling, Nonroad source pollution, Reporting and recordkeeping requirements.

Dated: May 31, 1994.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1321, 1326, 1330, 1334, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3,300j–4, 300j–9, 1857 *et. seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Section 9.1 is amended by adding a new heading and entries to the table in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citations	OMB control No.
Control of Emissions From New and In-Use Nonroad Engines	
89.611	2060–0007
89.905	
89.906	
89.801	2060–0048
89.803	
85.1903 through 85.1906	
85.1908	
85.1909	
89.505 through 89.509	2060–0064
89.511	
89.512	
89.603 through 89.605	2060–0095
89.607 through 89.612	
89.903	2060–0124
89.1	
89.2	

* * * * *

3. Part 89 is added to read as follows:

PART 89—CONTROL OF EMISSIONS FROM NEW AND IN-USE NONROAD ENGINES

Subpart A—General

Sec.

Authority: Sections 202, 203, 204, 205, 206, 207, 208, 209, 213, 215, 216, and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7521, 7522, 7523, 7524, 7525, 7541, 7542, 7543, 7547, 7549, 7550, and 7601(a)).

Subpart A—General

§ 89.1 Applicability.

(a) This part applies to nonroad compression-ignition engines that have a gross power output at or above 37 kilowatts (kW) and that are used for any purpose.

(b) The following nonroad engines are not subject to the provisions of this part:

(1) Engines used in aircraft as defined in § 87.1(a) of this chapter;

(2) Engines used in underground mining or engines used in underground mining equipment and regulated by the Mining Safety and Health Administration (MSHA) in 30 CFR parts 7, 31, 32, 36, 56, 57, 70, and 75;

(3) Engines used to propel a locomotive; and

(4) Engines used in marine vessels as defined in the General Provisions of the United States Code, 1 U.S.C. 3 (1992).

§ 89.2 Definitions.

The following definitions apply to part 89. All terms not defined herein have the meaning given them in the Act.

Act means the Clean Air Act, as amended, 42 U.S.C. 7401 *et.seq.*

Adjustable parameter means any device, system, or element of design which is physically capable of being adjusted (including those which are difficult to access) and which, if adjusted, may affect emissions or engine performance during emission testing.

Administrator means the Administrator of the Environmental Protection Agency or his or her authorized representative.

Auxiliary emission control device (AECD) means any element of design that senses temperature, vehicle speed, engine RPM, transmission gear, or any other parameter for the purpose of activating, modulating, delaying, or deactivating the operation of any part of the emission control system.

Certification means, with respect to new nonroad engines, obtaining a certificate of conformity for an engine family complying with the nonroad engine emission standards and requirements specified in this part.

Emission control system means any device, system, or element of design which controls or reduces the emission of substances from an engine.

Engine, as used in this part, refers to nonroad engine.

Engine manufacturer means any person engaged in the manufacturing or assembling of new nonroad engines or importing such engines for resale, or who acts for and is under the control of any such person in connection with the distribution of such engines. Engine manufacturer does not include any dealer with respect to new nonroad engines received by such person in commerce.

Engine used in a locomotive means either an engine placed in the locomotive to move other equipment, freight, or passenger traffic, or an engine mounted on the locomotive to provide auxiliary power.

EPA enforcement officer means any officer or employee of the Environmental Protection Agency so designated in writing by the Administrator (or by his or her designee).

Family emission limit (FEL) means an emission level that is declared by the manufacturer to serve in lieu of an emission standard for certification purposes and for the averaging, banking, and trading program. A FEL must be expressed to the same number of decimal places as the applicable emission standard.

Gross power means the power measured at the crankshaft or its equivalent, the engine being equipped only with the standard accessories (such as oil pumps, coolant pumps, and so forth) necessary for its operation on the test bed. Alternators must be used, if necessary, to run the engine. Fans, air conditioners, and other accessories may be used at the discretion of the manufacturer, but no power adjustments for these accessories may be made.

Identification number means a specification (for example, model number/serial number combination) which allows a particular nonroad engine to be distinguished from other similar engines.

Locomotive means a self-propelled piece of on-track equipment (other than equipment designed for operation both on highways and rails, specialized maintenance equipment, and other similar equipment) designed for moving other equipment, freight or passenger traffic.

Model year (MY) means the manufacturer's annual new model production period which includes January 1 of the calendar year, ends no later than December 31 of the calendar year, and does not begin earlier than January 2 of the previous calendar year. Where a manufacturer has no annual new model production period, model year means calendar year.

New, for the purposes of this part, means a domestic or imported nonroad engine, nonroad vehicle, or nonroad equipment the equitable or legal title to which has never been transferred to an ultimate purchaser. Where the equitable or legal title to the engine, vehicle, or equipment is not transferred to an ultimate purchaser until after the engine, vehicle or equipment is placed into service, then the engine, vehicle, or equipment will no longer be new after it is placed into service. A nonroad engine, vehicle, or equipment is placed into service when it is used for its functional purposes.

Nonroad compression-ignition engine means a nonroad engine which utilizes the compression-ignition combustion cycle.

Nonroad engine means:

(1) Except as discussed in paragraph (2) of this definition, a nonroad engine is any internal combustion engine:

(i) in or on a piece of equipment that is self-propelled or serves a dual purpose by both propelling itself and performing another function (such as garden tractors, off-highway mobile cranes and bulldozers); or

(ii) in or on a piece of equipment that is intended to be propelled while performing its function (such as lawnmowers and string trimmers); or

(iii) that, by itself or in or on a piece of equipment, is portable or transportable, meaning designed to be and capable of being carried or moved from one location to another. Indicia of transportability include, but are not limited to, wheels, skids, carrying handles, dolly, trailer, or platform.

(2) An internal combustion engine is not a nonroad engine if:

(i) the engine is used to propel a motor vehicle or a vehicle used solely for competition, or is subject to standards promulgated under section 202 of the Act; or

(ii) the engine is regulated by a federal New Source Performance Standard promulgated under section 111 of the Act; or

(iii) the engine otherwise included in paragraph (1)(iii) of this definition remains or will remain at a location for more than 12 consecutive months or a shorter period of time for an engine located at a seasonal source. A location is any single site at a building, structure, facility, or installation. Any engine (or engines) that replaces an engine at a location and that is intended to perform the same or similar function as the engine replaced will be included in calculating the consecutive time period. An engine located at a seasonal source is an engine that remains at a seasonal source during the full annual operating period of the seasonal source. A seasonal source is a stationary source that remains in a single location on a permanent basis (i.e., at least two years) and that operates at that single location approximately three months (or more) each year. This paragraph does not apply to an engine after the engine is removed from the location.

Nonroad equipment means equipment that is powered by nonroad engines.

Nonroad vehicle means a vehicle that is powered by a nonroad engine as defined in this section and that is not a motor vehicle or a vehicle used solely for competition.

Nonroad vehicle or nonroad equipment manufacturer means any person engaged in the manufacturing or assembling of new nonroad vehicles or equipment or importing such vehicles or equipment for resale, or who acts for and is under the control of any such person in connection with the distribution of such vehicles or equipment. A nonroad vehicle or equipment manufacturer does not include any dealer with respect to new nonroad vehicles or equipment received by such person in commerce.

Opacity means the fraction of a beam of light, expressed in percent, which fails to penetrate a plume of smoke.

Operating hours means:

(1) For engine storage areas or facilities, all times during which personnel other than custodial personnel are at work in the vicinity of the storage area or facility and have access to it.

(2) For all other areas or facilities, all times during which an assembly line is in operation or all times during which testing, maintenance, service accumulation, production or compilation of records, or any other procedure or activity related to certification testing, to translation of designs from the test stage to the production stage, or to engine manufacture or assembly is being carried out in a facility.

Presentation of credentials means the display of the document designating a person as an EPA enforcement officer or EPA authorized representative.

Test fleet means the engine or group of engines that a manufacturer uses during certification to determine compliance with emission standards.

Ultimate purchaser means, with respect to any new nonroad engine, new nonroad vehicle, or new nonroad equipment, the first person who in good faith purchases such new nonroad engine, nonroad vehicle, or nonroad equipment for purposes other than resale.

Used solely for competition means exhibiting features that are not easily removed and that would render its use other than in competition unsafe, impractical, or highly unlikely.

§ 89.3 Acronyms and abbreviations.

The following acronyms and abbreviations apply to part 89.

AECD	Auxiliary emission control device.
ASME	American Society of Mechanical Engineers.
ASTM	American Society for Testing and Materials.
CAA	Clean Air Act.
CAAA	Clean Air Act Amendments of 1990.
CI	Compression-ignition.
CO	Carbon monoxide.
CO_2	Carbon dioxide.
EPA	Environmental Protection Agency.
FEL	Family emission limit.
FTP	Federal Test Procedure.
g/kW-hr	Grams per kilowatt hour.
HC	Hydrocarbons.
ICI	Independent Commercial Importer.
kW	Kilowatt.
NIST	National Institute for Standards and Testing.

NTIS	National Technical Information Service.
NO	Nitric oxide.
NO_2	Nitrogen dioxide.
NO_x	Oxides of nitrogen.
O_2	Oxygen.
OEM	Original equipment manufacturer.
SAE	Society of Automotive Engineers.
SEA	Selective Enforcement Auditing.
SI	Spark-ignition.
U.S.C.	United States Code.
VOC	Volatile organic compounds.

§ 89.4 Section numbering.

(a) Sections are numbered sequentially by subpart.

(b) Where two different standards or requirements are concurrently applicable, the model year of applicability is indicated by the number following the main section number. The two digits following the hyphen designate the first model year for which a section is effective.

Example: Section 89.304–96 applies to the 1996 and subsequent model years until superseded. If a § 89.304–98 is promulgated, it would take effect beginning with the 1998 model year; § 89.304–96 would apply to model years 1996 through 1997. Therefore, in calendar year 1997, a manufacturer may be certifying both 1997 and 1998 model year engines, requiring the use of different requirements concurrently.

Note: Model year 2000 and later will appear sequentially with 1999 and earlier based on the order of the last two digits of the year, not in calendar year order; that is, § 89.304–03 will appear before § 89.304–99.

(c) A section without the model year designation is applicable to all model years as designated in the applicability section for the subpart or part or in the text of the section.

§ 89.5 Table and figure numbering; position.

(a) Tables for each subpart appear in an appendix at the end of the subpart. Tables are numbered consecutively by order of appearance in the appendix. The table title will indicate the model year (if applicable) and the topic.

(b) Figures for each subpart appear in an appendix at the end of the subpart. Figures are numbered consecutively by order of appearance in the appendix. The figure title will indicate the model year (if applicable) and the topic.

§ 89.6 Reference materials.

(a) *Incorporation by reference.* The documents in paragraph (b) of this section have been incorporated by reference. The incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at US EPA, OAR, 401 M Street SW., Washington, DC 20460, or at the Office of the Federal Register, 800 N. Capitol Street NW., Suite 700, Washington, DC.

(b) The following paragraphs and tables set forth the material that has been incorporated by reference in this part.

(1) *ASTM material.* The following table sets forth material from the American Society for Testing and Materials which has been incorporated by reference. The first column lists the number and name of the material. The second column lists the section(s) of this part, other than § 89.6, in which the matter is referenced. The second column is presented for information only and may not be all inclusive. Copies of these materials may be obtained from American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103.

Document number and name	40 CFR part 89 reference
ASTM D86–90: Standard Test Method for Distillation of Petroleum Products	Appendix A to Subpart D.
ASTM D93–90: Standard Test Methods for Flash Point by Pensky-Martens Closed Tester	Appendix A to Subpart D.
ASTM D129–91: Standard Test Method for Sulfur in Petroleum Products (General Bomb Method)	Appendix A to Subpart D.
ASTM D287–92: Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method)	Appendix A to Subpart D.
ASTM D445–88: Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and the Calculation of Dynamic Viscosity).	Appendix A to Subpart D.
ASTM D613–86: Standard Test Method for Ignition Quality of Diesel Fuels by the Cetane Method	Appendix A to Subpart D.
ASTM D1319–89: Standard Test Method for Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption.	Appendix A to Subpart D.
ASTM D2622–92: Standard Test Method for Sulfur in Petroleum Products by X-ray Spectrometry	Appendix A to Subpart D.
ASTM E29–90: Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications	89.207–96; 89.509–96.

(2) *SAE material.* The following table sets forth material from the Society of Automotive Engineers which has been incorporated by reference. The first column lists the number and name of the material. The second column lists the section(s) of this part, other than § 89.6, in which the matter is referenced. The second column is presented for information only and may not be all inclusive. Copies of these materials may be obtained from Society of Automotive Engineers International, 400 Commonwealth Dr., Warrendale, PA 15096–0001.

Document number and name	40 CFR part 89 reference
SAE J244 June 83: Recommended Practice for Measurement of Intake Air or Exhaust Gas Flow of Diesel Engines	89.416–96
SAE J1937 November 89: Recommended Practice for Engine Testing with Low Temperature Charge Air Cooler Systems in a Dynamometer Test Cell	89.327–96

Document number and name	40 CFR part 89 reference
SAE Paper 770141: Optimization of a Flame Ionization Detector for Determination of Hydrocarbon in Diluted Automotive Exhausts, Glenn D. Reschke	89.319–96

(3) *California Air Resources Board Test Procedure.* The following table sets forth material from the Title 13, California Code of Regulations, Sections 2420–2427, as amended by California Air Resources Board Resolution 92–2 and published in California Air Resources Board mail out #93–42, September 1, 1993) which has been incorporated by reference. The first column lists the number and name of the material. The second column lists the section(s) of this part, other than § 89.6, in which the matter is referenced. The second column is presented for information only and may not be all inclusive. Copies of these materials may be obtained from California Air Resources Board, Haagen-Smit Laboratory, 9528 Telstar Avenue, El Monte, CA 91731–2990.

Document number and name	40 CFR part 89 reference
California Regulations for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines	89.112–96 89.119–96 89.508–96

§ 89.7 Treatment of confidential information.

(a) Any manufacturer may assert that some or all of the information submitted pursuant to this part is entitled to confidential treatment as provided by part 2, subpart B of this chapter.

(b) Any claim of confidentiality must accompany the information at the time it is submitted to EPA.

(c) To assert that information submitted pursuant to this part is confidential, a manufacturer must indicate clearly the items of information claimed confidential by marking, circling, bracketing, stamping, or otherwise specifying the confidential information. Furthermore, EPA requests, but does not require, that the submitter also provide a second copy of its submittal from which all confidential information has been deleted. If a need arises to publicly release nonconfidential information, EPA will assume that the submitter has accurately deleted the confidential information from this second copy.

(d) If a claim is made that some or all of the information submitted pursuant to this part is entitled to confidential treatment, the information covered by that confidentiality claim will be disclosed by the Administrator only to the extent and by means of the procedures set forth in part 2, subpart B of this chapter.

(e) Information provided without a claim of confidentiality at the time of submission may be made available to the public by EPA without further notice to the submitter, in accordance with § 2.204(c)(2)(i)(A) of this chapter.

Appendix A to Subpart A—Internal Combustion Engines Manufactured Prior to July 18, 1994

This appendix sets forth the Environmental Protection Agency's (EPA's) interpretation of the Clean Air Act regarding the status of certain internal combustion engines manufactured before July 18, 1994, (the effective date of the final rulemaking promulgating EPA's definition of nonroad engine). This interpretation does not alter, replace, supersede, or change the scope of subpart A. It is not final agency action subject to judicial review.

1. EPA interprets the Clean Air Act as not precluding state regulation of internal combustion engines manufactured prior to July 18, 1994, except that state regulation of such engines that are used in motor vehicles or vehicles used solely for competition is precluded. EPA believes that the language of Clean Air Act section 302(z) generally excluding emissions resulting directly from nonroad engines and nonroad vehicles from the definition of stationary source could not be applied until after the definition of nonroad engine was specified in final regulations promulgated by EPA. EPA believes that if the exclusionary language of section 302(z) were applied before EPA's definition of nonroad engine became final, states would have been frustrated from regulating internal combustion engines manufactured during that time, given the uncertain nature of the definition of such engines. EPA believes that Congress did not intend states to be prevented from regulating these engines before a final EPA definition was promulgated. EPA does not believe that Congress intended the exclusionary language of section 302(z) regarding nonroad engines and vehicles to be applied retroactively to engines, vehicles, and equipment regulated pursuant to a permit issued before the date that the terms nonroad engine and nonroad vehicle were defined.

2. EPA further believes that internal combustion engines manufactured prior to July 18, 1994 are not preempted, under Clean Air Act section 209, from state regulation. The two sections of the Act preempting state regulation of nonroad engines, section 209(e)(1) and section 209(a) (as incorporated by section 213(d)), refer to "nonroad engines subject to regulation under this Act" or to engines "subject to this part" (i.e., part A of title II of the Act). EPA believes that, until EPA promulgated final regulations defining nonroad engines and subjecting such engines to regulation, these engines were not preempted from state regulation under the Act, as the engines were not yet defined as nonroad engines, nor were they subject to any regulation under title II of the Act. In the regulations with an effective date of July 18, 1994, EPA has issued final rules defining nonroad engines and, thus, subjecting nonroad engines to regulation under part A of title II of the Act. Accordingly, EPA believes that pursuant to Clean Air Act section 209, state regulation of new nonroad engines is preempted for engines manufactured on or after that date, and is not preempted as to engines manufactured before that date.

3. Moreover, EPA believes that states are not precluded under section 209 from regulating the use and operation of nonroad engines, such as regulations on hours of usage, daily mass emission limits, or sulfur limits on fuel; nor are permits regulating such operations precluded once the engine is placed into service or once the equitable or legal title to the engine or vehicle is transferred to an ultimate purchaser, as long as no certification, inspection, or other approval related to the control on emissions is required as a condition precedent to the initial retail sale, titling, or registration of the engine or equipment. EPA believes that states are not prevented by section 209 from requiring retrofitting of nonroad engines in certain circumstances once a reasonable time has passed after the engine is no longer new, as long as the requirements do not amount to a standard relating back to the original manufacturer. Therefore, EPA believes that modest retrofit requirements may be required after a reasonable amount of time (e.g., at the time of reregistration or rebuilding) and more significant retrofit requirements may be

required after a more significant period of time (e.g., after the end of the useful life of the engine).

Subpart B—Emission Standards and Certification Provisions

§ 89.101–96 Applicability.

The requirements of subpart B are applicable to all new nonroad compression-ignition engines subject to the provisions of subpart A of part 89, pursuant to the schedule delineated in § 89.102–96.

§ 89.102–96 Effective dates, optional inclusion.

(a) This subpart applies to all engines described in § 89.101–96 with the following gross power output and manufactured after the following dates:

(1) Greater than or equal to 37 kW but less than 75 kW and manufactured on or after January 1, 1998;

(2) Greater than or equal to 75 kW but less than 130 kW and manufactured on or after January 1, 1997;

(3) Greater than or equal to 130 kW but less than or equal to 560 kW and manufactured on or after January 1, 1996;

(4) Greater than 560 kW and manufactured on or after January 1, 2000.

(b) A manufacturer can optionally certify engines manufactured up to one calendar year prior to the effective date of mandatory certification to earn emission credits under the averaging, banking, and trading program. Such optionally certified engines are subject to all provisions relating to mandatory certification and enforcement described in this part.

§ 89.103–96 Definitions.

The definitions in subpart A of part 89 apply to this subpart. All terms not defined herein or in subpart A have the meaning given them in the Act.

§ 89.104–96 Useful life, recall, and warranty periods.

(a) The useful life is a period of 8,000 hours of operation or ten years of use, whichever first occurs.

(b) Engines are subject to recall testing for a period of 6,000 hours of operation or seven years of use, whichever first occurs. However, in a recall, engines in the subject class or category must be recalled regardless of actual years or hours of operation.

(c) Warranties imposed by the Clean Air Act are for 3,000 hours of operation or five years of use, whichever first occurs.

(d) Manufacturers may apply to the Administrator for approval for a shorter useful life period for engines that are subject to severe service in seasonal equipment, or are designed specifically for lower useful life hours to match equipment life. Such an application must be made prior to certification.

§ 89.105–96 Certificate of conformity.

Every manufacturer of a new nonroad compression-ignition engine must obtain a certificate of conformity covering the engine family, as described in § 89.116–96. The certificate of conformity must be obtained from the Administrator prior to selling, offering for sale, introducing into commerce, or importing into the United States the new nonroad compression-ignition engine for each model year.

§ 89.106–96 Prohibited controls.

(a) An engine may not be equipped with an emission control system for the purpose of complying with emission standards if such system will cause or contribute to an unreasonable risk to public health, welfare, or safety in its operation or function.

(b) An engine with an emission control system may not emit any noxious or toxic substance which would not be emitted in the operation of such engine in the absence of such system except as specifically permitted by regulation.

§ 89.107–96 Defeat devices.

(a) An engine may not be equipped with a defeat device.

(b) For purposes of this section, "defeat device" means any device, system, or element of design which senses operation outside normal emission test conditions and reduces emission control effectiveness.

(1) Defeat device includes any auxiliary emission control device (AECD) that reduces the effectiveness of the emission control system under conditions which may reasonably be expected to be encountered in normal operation and use unless such conditions are included in the test procedure.

(2) Defeat device does not include such items which either operate only during engine starting or are necessary to protect the engine (or equipment in which it is installed) against damage or accident during its operation.

§ 89.108–96 Adjustable parameters, requirements.

(a) Nonroad engines equipped with adjustable parameters must comply with all requirements of this subpart for any adjustment in the physically adjustable range.

(b) An operating parameter is not considered adjustable if it is permanently sealed or otherwise not normally accessible using ordinary tools.

(c) The Administrator may require that adjustable parameters be set to any specification within its adjustable range for certification, selective enforcement audit, or in-use testing to determine compliance with the requirements of this subpart.

§ 89.109–96 Maintenance instructions.

The manufacturer must furnish or cause to be furnished to the ultimate purchaser of each new nonroad engine written instructions for the maintenance needed to assure proper functioning of the emission control system.

§ 89.110–96 Emission control information label.

(a) The manufacturer must affix at the time of manufacture a permanent and legible label identifying each nonroad engine. The label must meet the following requirements:

(1) Be attached in such a manner that it cannot be removed without destroying or defacing the label;

(2) Be durable and readable for the entire engine life;

(3) Be secured to an engine part necessary for normal engine operation and not normally requiring replacement during engine life;

(4) Be written in English; and

(5) Be located so as to be readily visible to the average person after the engine is installed in the equipment. A supplemental label meeting all the requirements of this section may be attached to a location other than the engine, in cases where the required label must be obscured after the engine is installed in the equipment.

(b) The label must contain the following information:

(1) The heading "Important Engine Information;"

(2) The full corporate name and trademark of the manufacturer;

(3) EPA standardized engine family designation;

(4) Engine displacement;

(5) Advertised power;

(6) Engine tuneup specifications and adjustments. These should indicate the proper transmission position during tuneup, and accessories (for example, air conditioner), if any, that should be in operation;

(7) Fuel requirements;

(8) Date of manufacture (month and year). The manufacturer may, in lieu of including the date of manufacture on the engine label, maintain a record of the engine manufacture dates. The manufacturer shall provide the date of manufacture records to the Administrator upon request;

(9) Family emission limits (FELs) if applicable; and

(10) The statement: "This engine conforms to [model year] U.S. EPA regulations large nonroad compression-ignition engines."

(c) Other information concerning proper maintenance and use or indicating compliance or noncompliance with other standards may be indicated on the label.

(d) Each engine must have a legible unique engine identification number permanently affixed to or engraved on the engine.

§ 89.111–96 Averaging, banking, and trading of exhaust emissions.

Regulations regarding the availability of an averaging, banking, and trading program along with applicable record-keeping requirements are found in subpart C of this part. Participation in the averaging, banking, and trading program is optional.

§ 89.112–96 Oxides of nitrogen, carbon monoxide, hydrocarbon, and particulate matter exhaust emission standards.

(a) Nonroad engines to which this subpart is applicable must meet the following exhaust emission standards:

(1) Exhaust emissions of oxides of nitrogen shall not exceed 9.2 grams per kilowatt hour (g/kW-hr).

(2) Exhaust emissions of carbon monoxide shall not exceed 11.4 g/kW-hr for engines at and above 130 kW.

(3) Exhaust emissions of hydrocarbon shall not exceed 1.3 g/kW-hr for engines at and above 130 kW.

(4) Exhaust emissions of particulate matter shall not exceed 0.54 g/kW-hr for engines at and above 130 kW.

(b) Exhaust emission of oxides of nitrogen, carbon monoxide, and hydrocarbon is measured using the procedures set forth in subpart E of this part.

(c) Exhaust emission of particulate matter is measured using the California Regulations for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines. This procedure is incorporated by reference. See § 89.6.

(d) In lieu of the standard specified in paragraph (a)(1) of this section, manufacturers may elect to include engine families in the averaging, banking, and trading program, the provisions of which are specified in subpart C of this part. The manufacturer must set a family emission limit (FEL) not to exceed 14.6 grams per kilowatt hour. This FEL serves as the standard for that family.

§ 89.113–96 Smoke emission standard.

(a) Exhaust opacity from compression-ignition nonroad engines for which this subpart is applicable must not exceed:

(1) 20 percent during the acceleration mode;

(2) 15 percent during the lugging mode; and

(3) 50 percent during the peaks in either the acceleration or lugging modes.

(b) Opacity levels are to be measured and calculated as set forth in part 86, subpart I.

§ 89.114–96 Special test procedures.

(a) *Use of special test procedures by EPA.* The Administrator may, on the basis of written application by a manufacturer, establish special test procedures other than those set forth in this part, for any nonroad engine that the Administrator determines is not susceptible to satisfactory testing under the specified test procedures set forth in subpart E of this part or part 86, subpart I.

(b) *Use of alternate test procedures by manufacturer.*

(1) A manufacturer may elect to use an alternate test procedure provided that it yields equivalent results to the specified procedures, its use is approved in advance by the Administrator, and the basis for equivalent results with the specified test procedures is fully described in the manufacturer's application.

(2) The Administrator may reject data generated under alternate test procedures which do not correlate with data generated under the specified procedures.

§ 89.115–96 Application for certificate.

(a) For each engine family that complies with all applicable standards and requirements, the engine manufacturer must submit to the Administrator a completed application for a certificate of conformity.

(b) The application must be approved and signed by the authorized representative of the manufacturer.

(c) The application will be updated and corrected by amendment as provided for in § 89.123–96 to accurately reflect the manufacturer's production.

(d) *Required content.* Each application must include the following information:

(1) A description of the basic engine design including, but not limited to, the engine family specifications, the provisions of which are contained in § 89.116–96;

(2) An explanation of how the emission control system operates, including a detailed description of all emission control system components, each auxiliary emission control device (AECD), and all fuel system components to be installed on any production or test engine(s);

(3) Proposed test fleet selection and the rationale for the test fleet selection;

(4) Special or alternate test procedures, if applicable;

(5) The description of the operating cycle and the period of operation necessary to accumulate service hours on test engines and stabilize emission levels;

(6) A description of all adjustable operating parameters (including, but not limited to, injection timing and fuel rate), including the following:

(i) The nominal or recommended setting and the associated production tolerances;

(ii) The intended physically adjustable range;

(iii) The limits or stops used to establish adjustable ranges;

(iv) Production tolerances of the limits or stops used to establish each physically adjustable range; and

(v) Information relating to why the physical limits or stops used to establish the physically adjustable range of each parameter, or any other means used to inhibit adjustment, are effective in preventing adjustment of parameters to settings outside the manufacturer's intended physically adjustable ranges on in-use engines;

(7) For families participating in the averaging, banking, and trading program, the information specified in subpart C of this part;

(8) A description of the test equipment and fuel proposed to be used;

(9) All test data obtained by the manufacturer on each test engine;

(10) An unconditional statement certifying that all engines in the engine family comply with all requirements of this part and the Clean Air Act.

(b) At the Administrator's request, the manufacturer must supply such additional information as may be required to evaluate the application including, but not limited to, projected nonroad engine production.

§ 89.116–96 Engine families.

(a) A manufacturer's product line is divided into engine families that are comprised of engines expected to have similar emission characteristics throughout their useful life periods.

(b) The following characteristics distinguish engine families:

(1) Fuel;

(2) Cooling medium;

(3) Method of air aspiration;

(4) Method of exhaust aftertreatment (for example, catalytic converter or particulate trap);
(5) Combustion chamber design;
(6) Bore;
(7) Stroke;
(8) Number of cylinders, (engines with aftertreatment devices only); and
(9) Cylinder arrangement (engines with aftertreatment devices only).

(c) Upon a showing by the manufacturer that the useful life period emission characteristics are expected to be similar, engines differing in one or more of the characteristics in paragraph (b) of this section may be grouped in the same engine family.

(d) Upon a showing by the manufacturer that the expected useful life period emission characteristics will be different, engines identical in all the characteristics of paragraph (b) of this section may be divided into separate engine families.

§ 89.117–96 Test fleet selection.

(a) The manufacturer must select for testing, from each engine family, the engine with the most fuel injected per stroke of an injector at maximum power.

(b) Each engine in the test fleet must be constructed to be representative of production engines.

(c) After review of the manufacturer's test fleet, the Administrator may select from the available fleet one additional test engine from each engine family.

§ 89.118–96 Service accumulation.

(a)(1) Each test engine in the test fleet must be operated with all emission control systems operating properly for a period sufficient to stabilize emissions.

(2) A manufacturer may elect to consider as stabilized emission levels from engines with no more than 125 hours of service.

(b) No maintenance, other than recommended lubrication and filter changes, may be performed during service accumulation without the Administrator's approval.

(c) Service accumulation should be performed in a manner using good engineering judgment to ensure that emissions are representative of in-use engines.

(d) The manufacturer must maintain, and provide to the Administrator if requested, records stating the rationale for selecting the service accumulation period and records describing the method used to accumulate service hours on the test engine(s).

§ 89.119–96 Emission tests.

(a) *Manufacturer testing.* (1) Upon completion of service accumulation, the manufacturer must test each test engine using the specified test procedures, except as provided in § 89.114–96. The procedures to be used are set forth in:

(i) Subpart E of this part;

(ii) The California Regulations for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines. This procedure has been incorporated by reference. See § 89.6; and

(iii) Part 86, subpart I of this chapter.

(2) Each test engine must be configured to be representative of actual in-use operation. The Administrator may specify the adjustment of any adjustable parameter. All test results must be reported to the Administrator.

(b) *Confirmatory testing.* The Administrator may conduct confirmatory testing or other testing on any test engine. The manufacturer must deliver test engines as directed by the Administrator. When the Administrator conducts confirmatory testing or other testing, those test results are used to determine compliance with emission standards.

(c) *Use of carryover test data.* In lieu of testing to certify an engine family for a given model year, the manufacturer may submit, with the Administrator's approval, emission test data used to certify that engine family in previous years. This "carryover" data is only allowable if the submitted test data show that the test engine would comply with the emission standard(s) for the model year for which certification is being sought.

(d) *Test fuels.* EPA may use the fuel specified in either Table 4 or Table 5 of appendix A to subpart D of this part in confirmatory testing or other testing on any test engine. Emission test results based on use of Table 5 fuel will be used to confirm compliance with HC, CO, NO_X, PM, and smoke standards. Emission test results based on Table 4 fuel will be used to confirm compliance with HC, CO, NO_X, and smoke standards; when a manufacturer uses the fuel specified in Table 4 of appendix A to subpart D of this part for its certification testing, EPA has the option to use the PM emission result, corrected using the PM correction factor specified in § 89.425–96, to confirm compliance with the PM standard.

§ 89.120–96 Compliance with emission standards.

(a) If all test engines representing an engine family have emissions less than or equal to each emission standard, that family complies with the emission standards.

(b) If any test engine representing an engine family has emissions greater than each emission standard, that family will be deemed not in compliance with the emission standard(s).

(c) If aftertreatment is employed by an engine family, then a deterioration factor must be determined and applied.

(d) For engine families included in the averaging, banking, and trading program, the families' emission limits (FELs) are used in lieu of the applicable federal emission standard.

§ 89.121–96 Certificate of conformity effective dates.

The certificate of conformity is valid from the date of issuance by EPA until 31 December of the model year or calendar year for which it is issued.

§ 89.122–96 Certification.

(a) If, after a review of the manufacturer's application, request for certificate, information obtained from any inspection, and such other information as the Administrator may require, the Administrator determines that the application is complete and that the engine family meets the requirements of this part and the Clean Air Act, the Administrator shall issue a certificate of conformity.

(b) If, after a review of the information described in paragraph (a) of this section, the Administrator determines that the requirements of this part and the Clean Air Act have not been met, the Administrator will deny certification. The Administrator must give a written explanation when certification is denied. The manufacturer may request a hearing on a denial.

§ 89.123–96 Amending the application and certificate of conformity.

(a) The manufacturer of nonroad compression-ignition engines must notify the Administrator when changes to information required to be described in the application for certification are to be made to a product line covered by a certificate of conformity. This notification must include a request to amend the application or the existing certificate of conformity. Except as provided in paragraph (e) of this section, the manufacturer shall not make said changes or produce said engines prior to receiving approval from EPA.

(b) A manufacturer's request to amend the application or the existing certificate of conformity shall include the following information:

(1) A full description of the change to be made in production or of the engine to be added;

(2) Engineering evaluations or data showing that engines as modified or added will comply with all applicable emission standards; and

(3) A determination whether the manufacturer's original test fleet selection is still appropriate, and if the original test fleet selection is determined not to be appropriate, proposed test fleet selection(s) representing the engines changed or added which would have been required if the engines had been included in the original application for certification.

(c) The Administrator may require the manufacturer to perform tests on the engine representing the engine to be added or changed.

(d) *Decision by Administrator.* (1) Based on the description of the proposed amendment and data derived from such testing as the Administrator may require or conduct, the Administrator will determine whether the proposed change or addition would still be covered by the certificate of conformity then in effect.

(2) If the Administrator determines that the change or new engine(s) meets the requirements of this subpart and the Act, the appropriate certificate of conformity is amended.

(3) If the Administrator determines that the changed or new engine(s) does not meet the requirements of this subpart and the Act, the certificate of conformity will not be amended. The Administrator shall provide a written explanation to the manufacturer of the decision not to amend the certificate. The manufacturer may request a hearing on a denial.

(e) A manufacturer may make changes in or additions to production engines concurrently with notifying the Administrator as required by paragraph (a) of this section, if the manufacturer complies with the following requirements:

(1) In addition to the information required in paragraph (b) of this section, the manufacturer must supply supporting documentation, test data, and engineering evaluations as appropriate to demonstrate that all affected engines will still meet applicable emission standards.

(2) If, after a review, the Administrator determines additional testing is required, the manufacturer must provide required test data within 30 days or cease production of the affected engines.

(3) If the Administrator determines that the affected engines do not meet applicable requirements, the Administrator will notify the manufacturer to cease production of the affected engines and to recall and correct at no expense to the owner all affected engines previously produced.

(4) Election to produce engines under this paragraph will be deemed to be a consent to recall all engines which the Administrator determines do not meet applicable standards and to cause such nonconformity to be remedied at no expense to the owner.

§ 89.124–96 Record retention, maintenance, and submission.

(a) The manufacturer of any nonroad compression-ignition engine must maintain the following adequately organized records:

(1) Copies of all applications filed with the Administrator.

(2) A detailed history of each test engine used for certification including the following:

(i) A description of the test engine's construction, including a general description of the origin and buildup of the engine, steps taken to ensure that it is representative of production engines, description of components specially built for the test engine, and the origin and description of all emission-related components;

(ii) A description of the method used for service accumulation, including date(s) and the number of hours accumulated;

(iii) A description of all maintenance, including modifications, parts changes, and other servicing performed, and the date(s) and reason(s) for such maintenance;

(iv) A description of all emission tests performed (except tests performed by the EPA directly) including routine and standard test documentation, as specified in subpart E of this part, date(s) and the purpose of each test;

(v) A description of all tests performed to diagnose engine or emission control performance, giving the date and time of each and the reason(s) for the test; and

(vi) A description of any significant event(s) affecting the engine during the period covered by the history of the test engine but not described by an entry under one of the previous paragraphs of this section.

(b) Routine emission test data, such as those reporting test cell temperature and relative humidity at start and finish of test and raw emission results from each mode or test phase, must be retained for a period of one year after issuance of all certificates of conformity to which they relate. All other information specified in paragraph (a) of this section must be retained for a period of eight years after issuance of all certificates of conformity to which they relate.

(c) Records may be kept in any format and on any media, provided that at the Administrator's request, organized, written records in English are promptly supplied by the manufacturer.

(d) The manufacturer must supply, at the Administrator's request, copies of any engine maintenance instructions or explanations issued by the manufacturer.

§ 89.125–96 Production engines, annual report.

(a) Upon the Administrator's request, the manufacturer must supply a reasonable number of production engines for testing and evaluation. These engines must be representative of typical production and must be supplied for testing at such time and place and for such reasonable periods as the Administrator may require.

(b) The manufacturer must annually, within 30 days after the end of the model year, notify the Administrator of the number of engines produced by engine family, by gross power, by displacement, by fuel system, or by other categories as the Administrator may require.

§ 89.126–96 Denial, revocation of certificate of conformity.

(a) If, after review of the manufacturer's application, request for certification, information obtained from any inspection, and any other information the Administrator may require, the Administrator determines that one or more test engines do not meet applicable standards (or family emission limits, as appropriate), then the Administrator will notify the manufacturer in writing, setting forth the basis for this determination.

(b) Notwithstanding the fact that engines described in the application may comply with all other requirements of this subpart, the Administrator may deny the issuance of, suspend, or revoke a previously issued certificate of conformity if the Administrator finds any one of the following infractions to be substantial:

(1) The manufacturer submits false or incomplete information;

(2) The manufacturer denies an EPA enforcement officer or EPA authorized representative the opportunity to conduct authorized inspections;

(3) The manufacturer fails to supply requested information or amend its application to include all engines being produced;

(4) The manufacturer renders inaccurate any test data which it submits or otherwise circumvents the intent of the Act or this part;

(5) The manufacturer denies an EPA enforcement officer or EPA authorized representative reasonable assistance (as defined in § 89.129–96(e)).

(c) If a manufacturer knowingly commits an infraction specified in

paragraph (b)(1) or (b)(4) of this section, knowingly commits any other fraudulent act which results in the issuance of a certificate of conformity, or fails to comply with the conditions specified in §§ 89.203–96(f), 89.206–96(d), 89.209–96(c) or 89.210–96(g), the Administrator may deem such certificate void ab initio.

(d) When the Administrator denies, suspends, revokes, or voids ab initio a certificate of conformity the manufacturer will be provided a written determination. The manufacturer may request a hearing under § 89.127–96 on the Administrator's decision.

(e) Any suspension or revocation of a certificate of conformity shall extend no further than to forbid the introduction into commerce of engines previously covered by the certification which are still in the hands of the manufacturer, except in cases of such fraud or other misconduct that makes the certification invalid ab initio.

§ 89.127–96 Request for hearing.

(a) A manufacturer may request a hearing on the Administrator's denial, suspension, voiding ab initio or revocation of a certificate of conformity.

(b) The manufacturer's request must be filed within 30 days of the Administrator's decision, be in writing, and set forth the manufacturer's objections to the Administrator's decision and data to support the objections.

(c) If, after review of the request and supporting data, the Administrator finds that the request raises a substantial and factual issue, the Administrator will grant the manufacturer's request for a hearing.

§ 89.128–96 Hearing procedures.

(a)(1) After granting a request for a hearing the Administrator shall designate a Presiding Officer for the hearing.

(2) The hearing will be held as soon as practicable at a time and place determined by the Administrator or by the Presiding Officer.

(3) The Administrator may, at his or her discretion, direct that all argument and presentation of evidence be concluded within a specified period established by the Administrator. Said period may be no less than 30 days from the date that the first written offer of a hearing is made to the manufacturer. To expedite proceedings, the Administrator may direct that the decision of the Presiding Officer (who may, but need not, be the Administrator) shall be the final EPA decision.

(b)(1) Upon appointment pursuant to paragraph (a) of this section, the Presiding Officer will establish a hearing file. The file shall consist of the following:

(i) The determination issued by the Administrator under § 89.126–96(d);

(ii) The request for a hearing and the supporting data submitted therewith;

(iii) All documents relating to the request for certification and all documents submitted therewith; and

(iv) Correspondence and other data material to the hearing.

(2) The hearing file will be available for inspection by the applicant at the office of the Presiding Officer.

(c) An applicant may appear in person or may be represented by counsel or by any other duly authorized representative.

(d)(1) The Presiding Officer, upon the request of any party or at his or her discretion, may arrange for a prehearing conference at a time and place he/she specifies. Such prehearing conference will consider the following:

(i) Simplification of the issues;

(ii) Stipulations, admissions of fact, and the introduction of documents;

(iii) Limitation of the number of expert witnesses;

(iv) Possibility of agreement disposing of any or all of the issues in dispute; and

(v) Such other matters as may aid in the disposition of the hearing, including such additional tests as may be agreed upon by the parties.

(2) The results of the conference shall be reduced to writing by the Presiding Officer and made part of the record.

(e)(1) Hearings shall be conducted by the Presiding Officer in an informal but orderly and expeditious manner. The parties may offer oral or written evidence, subject to the exclusion by the Presiding Officer of irrelevant, immaterial, and repetitious evidence.

(2) Witnesses will not be required to testify under oath. However, the Presiding Officer shall call to the attention of witnesses that their statements may be subject to the provisions of 18 U.S.C. 1001 which imposes penalties for knowingly making false statements or representations or using false documents in any matter within the jurisdiction of any department or agency of the United States.

(3) Any witness may be examined or cross-examined by the Presiding Officer, the parties, or their representatives.

(4) Hearings shall be reported verbatim. Copies of transcripts of proceedings may be purchased by the applicant from the reporter.

(5) All written statements, charts, tabulations, and similar data offered in evidence at the hearings shall, upon a showing satisfactory to the Presiding Officer of their authenticity, relevancy, and materiality, be received in evidence and shall constitute a part of the record.

(6) Oral argument may be permitted at the discretion of the Presiding Officer and shall be reported as part of the record unless otherwise ordered by the Presiding Officer.

(f)(1) The Presiding Officer shall make an initial decision which shall include written findings and conclusions and the reasons or basis regarding all the material issues of fact, law, or discretion presented on the record. The findings, conclusions, and written decision shall be provided to the parties and made a part of the record. The initial decision shall become the decision of the Administrator without further proceedings, unless there is an appeal to the Administrator or motion for review by the Administrator within 20 days of the date the initial decision was filed. If the Administrator has determined under paragraph (a) of this section that the decision of the Presiding Officer is final, there is no right of appeal to the Administrator.

(2) On appeal from or review of the initial decision, the Administrator shall have all the powers which he or she would have in making the initial decision, including the discretion to require or allow briefs, oral argument, the taking of additional evidence, or the remanding to the Presiding Officer for additional proceedings. The decision by the Administrator may adopt the original decision or shall include written findings and conclusions and the reasons or basis therefor on all the material issues of fact, law, or discretion presented on the appeal or considered in the review.

§ 89.129–96 Right of entry.

(a) Any manufacturer who has applied for certification of a new engine or engine family subject to certification testing under this subpart shall admit or cause to be admitted to any of the following facilities during operating hours any EPA enforcement officer or EPA authorized representative on presentation of credentials.

(1) Any facility where any such certification testing or any procedures or activities connected with such certification testing are or were performed;

(2) Any facility where any new engine which is being, was, or is to be tested is present;

(3) Any facility where any construction process or assembly process used in the modification or buildup of such an engine into a certification engine is taking place or has taken place; and

(4) Any facility where any record or other document relating to any of the above is located.

(b) Upon admission to any facility referred to in paragraph (a)(1) of this section, any EPA enforcement officer or EPA authorized representative shall be allowed:

(1) To inspect and monitor any part or aspect of such procedures, activities, and testing facilities, including, but not limited to, monitoring engine preconditioning, emission tests and service accumulation, maintenance, and engine storage procedures, and to verify correlation or calibration of test equipment;

(2) To inspect and make copies of any such records, designs, or other documents; and

(3) To inspect and photograph any part or aspect of any such certification engine and any components to be used in the construction thereof.

(c) To allow the Administrator to determine whether production engines conform in all material respects to the design specifications applicable to those engines, as described in the application for certification for which a certificate of conformity has been issued, any manufacturer shall admit any EPA enforcement officer or EPA authorized representative on presentation of credentials to:

(1) Any facility where any document, design, or procedure relating to the translation of the design and construction of engines and emission-related components described in the application for certification or used for certification testing into production engines is located or carried on; and

(2) Any facility where any engines to be introduced into commerce are manufactured or assembled.

(d) On admission to any such facility referred to in paragraph (c) of this section, any EPA enforcement officer or EPA authorized representative shall be allowed:

(1) To inspect and monitor any aspects of such manufacture or assembly and other procedures;

(2) To inspect and make copies of any such records, documents or designs; and

(3) To inspect and photograph any part or aspect of any such new engines and any component used in the assembly thereof that are reasonably related to the purpose of his or her entry.

(e) Any EPA enforcement officer or EPA authorized representative shall be furnished by those in charge of a facility being inspected with such reasonable assistance as he or she may request to help the enforcement officer or authorized representative discharge any function listed in this paragraph. Each applicant for or recipient of certification is required to cause those in charge of a facility operated for its benefit to furnish such reasonable assistance without charge to EPA whether or not the applicant controls the facility.

(1) Reasonable assistance includes, but is not limited to, clerical, copying, interpretation and translation services; the making available on request of personnel of the facility being inspected during their working hours to inform the EPA enforcement officer or EPA authorized representative of how the facility operates and to answer the officer's questions; and the performance on request of emission tests on any engine which is being, has been, or will be used for certification testing. Such tests shall be nondestructive, but may require appropriate service accumulation.

(2) A manufacturer may be compelled to cause any employee at a facility being inspected to appear before an EPA enforcement officer or EPA authorized representative. The request for the employee's appearance shall be in writing, signed by the Assistant Administrator for Air and Radiation, and served on the manufacturer. Any employee who has been instructed by the manufacturer to appear will be entitled to be accompanied, represented, and advised by counsel.

(f) The duty to admit or cause to be admitted any EPA enforcement officer or EPA authorized representative applies whether or not the applicant owns or controls the facility in question and applies both to domestic and to foreign manufacturers and facilities. EPA will not attempt to make any inspections which it has been informed that local law forbids. However, if local law makes it impossible to do what is necessary to ensure the accuracy of data generated at a facility, no informed judgment that an engine is certifiable or is covered by a certificate can properly be based on those data. It is the responsibility of the manufacturer to locate its testing and manufacturing facilities in jurisdictions where this situation will not arise.

(g) Any entry without 24 hours prior written or oral notification to the affected manufacturer shall be authorized in writing by the Assistant Administrator for Enforcement.

Subpart C—Averaging, Banking, and Trading Provisions

§ 89.201–96 Applicability.

Nonroad compression-ignition engines subject to the provisions of subpart A of this part are eligible to participate in the averaging, banking, and trading program described in this subpart.

§ 89.202–96 Definitions.

The definitions in subpart A of this part apply to this subpart. The following definitions also apply to this subpart:

Averaging for nonroad engines means the exchange of emission credits among engine families within a given manufacturer's product line.

Banking means the retention of nonroad engine emission credits by the manufacturer generating the emission credits for use in future model year averaging or trading as permitted by these regulations.

Emission credits represent the amount of emission reduction or exceedance, by a nonroad engine family, below or above the emission standard, respectively. Emission reductions below the standard are considered as "positive credits," while emission exceedances above the standard are considered as "negative credits." In addition, "projected credits" refer to emission credits based on the projected applicable production/sales volume of the engine family. "Reserved credits" are emission credits generated within a model year waiting to be reported to EPA at the end of the model year. "Actual credits" refer to emission credits based on actual applicable production/sales volume as contained in the end-of-year reports submitted to EPA. Some or all of these credits may be revoked if EPA review of the end-of-year reports or any subsequent audit action(s) uncovers problems or errors.

Trading means the exchange of nonroad engine emission credits between manufacturers.

§ 89.203–96 General provisions.

(a) The averaging, banking, and trading program for NO_x emissions from eligible nonroad engines is described in this subpart. Participation in this program is voluntary.

(b) A nonroad engine family is eligible to participate in the averaging, banking, and trading program for NO_x emissions if it is subject to regulation under subpart B of this part with certain exceptions specified in subsection (c) of this section. No averaging, banking, and trading program is available for meeting the HC, CO, PM, or smoke emission standards specified in subpart B of this part.

(c) Nonroad engines may not participate in the averaging, banking, and trading program if they are subject to state engine emission standards, are exported, or use an alternate or special test procedure under § 89.114–96.

(d) A manufacturer may certify one or more nonroad engine families at family emission limits (FELs) above or below the applicable emission standard, provided the summation of the manufacturer's projected balance of all credit transactions in a given model year is greater than or equal to zero, as determined under § 89.207–96.

(1) FELs for NO_x may not exceed 14.6 grams per kilowatt hour.

(2) An engine family certified to an FEL is subject to all provisions specified in subparts B, D, E, G, H, I, J, and K of this part, except that the applicable FEL replaces the NO_x emission standard for the family participating in the averaging, banking, and trading program.

(3) A manufacturer of an engine family with an FEL exceeding the applicable emission standard must obtain emission credits sufficient to address the associated credit shortfall via averaging, banking, or trading.

(4) An engine family with an FEL below the applicable standard may generate emission credits for averaging, banking, trading, or a combination thereof. Emission credits may not be used to offset an engine family's emissions that exceed its applicable FEL. Credits may not be used to remedy nonconformity determined by a Selective Enforcement Audit (SEA) or by recall (in-use) testing. However, in the case of an SEA failure, credits may be used to allow subsequent production of engines for the family in question if the manufacturer elects to recertify to a higher FEL.

(e) Credits generated in a given model year may be used in the following three model years. Credits not used by the end of the third model year after being generated are forfeited. Credits generated in one model year may not be used for prior model years.

(f) Manufacturers must demonstrate compliance under the averaging, banking, and trading program for a particular model year by 270 days after the model year. Engine families without an adequate amount of emission credits will violate the conditions of the certificates of conformity. The certificates of conformity may be voided ab initio under § 89.126–96(c) for those engine families.

§ 89.204–96 Averaging.

(a) A manufacturer may use averaging to offset an emission exceedance of a nonroad engine family caused by an FEL above the applicable emission standard. Credits used in averaging may be obtained from credits generated by another engine family in the same model year, credits banked in the three previous model years, or credits obtained through trading.

(b) Credits scheduled to expire in the earliest model year must be used first, before using other available credits.

§ 89.205–96 Banking.

(a) A manufacturer of a nonroad engine family with an FEL below the applicable standard for a given model year may bank credits in that model year for use in averaging and trading in the following three model years. Credits not withdrawn within the three model years after they are banked are forfeited.

(b) A manufacturer of a nonroad engine family may bank credits up to one calendar year prior to the effective date of mandatory certification. Such engines must meet the requirements of subparts A, B, D, E, F, G, H, I, J, and K of this part.

(c) A manufacturer may bank actual credits only after the end of the model year and after EPA has reviewed the manufacturer's end-of-year reports. During the model year and before submittal of the end-of-year report, credits originally designated in the certification process for banking will be considered reserved and may be redesignated for trading or averaging in the end-of-year report and final report.

(d) Credits declared for banking from the previous model year that have not been reviewed by EPA may be used in averaging or trading transactions. However, such credits may be revoked at a later time following EPA review of the end-of-year report or any subsequent audit actions.

§ 89.206–96 Trading.

(a) A nonroad engine manufacturer may exchange emission credits with other nonroad engine manufacturers in trading.

(b) Credits for trading can be obtained from credits banked in the three previous model years or credits generated during the model year of the trading transaction. Traded credits expire if they are not used in averaging within three model years following the model year in which they were generated.

(c) Traded credits can be used for averaging, banking, or further trading transactions.

(d) In the event of a negative credit balance resulting from a transaction, both the buyer and the seller are liable, except in cases involving fraud. Certificates of all engine families participating in a negative trade may be voided ab initio under § 89.126–96(c).

§ 89.207–96 Credit calculation.

For each participating engine family, emission credits (positive or negative) are to be calculated according to one of the following equations and rounded, in accordance with ASTM E29–90, to the nearest one-tenth of a megagram per hour (Mg/hr). ASTM E29–90 has been incorporated by reference. See § 89.6. Consistent units are to be used throughout the equation.

(a) For determining credit availability from all engine families generating credits:

$$\text{Emission credits} = (\text{Std} - \text{FEL}) \times (\text{Volume}) \times (\text{MinPR}) \times (10^{-6})$$

(b) For determining credit usage for all engine families requiring credits to offset emissions in excess of the standard:

$$\text{Emission credits} = (\text{Std} - \text{FEL}) \times (\text{Volume}) \times (\text{MaxPR}) \times (10^{-6})$$

Where:

Std=the current and applicable nonroad engine emission standard in grams per brake horsepower hour.

FEL=the family emission limit for the engine family in grams per brake horsepower hour.

Volume=the number of nonroad engines eligible to participate in the averaging, banking, and trading program within the given engine family during the model year. Quarterly production projections are used for initial certification. Actual applicable production/sales volumes is used for end-of-year compliance determination.

MinPR=the power rating of the configuration within an engine family with the lowest power rating.

MaxPR=the power rating of the configuration within an engine family with the highest power rating.

§ 89.208–96 Labeling.

For all nonroad engines included in the averaging, banking, and trading program, the family emission limit to which the engine is certified must be included on the label required in § 89.110–96.

§ 89.209–96 Certification.

(a) In the application for certification a manufacturer must:

(1) Declare its intent to include specific engine families in the averaging, banking, and trading program.

(2) Submit a statement that the engines for which certification is requested will not, to the best of the manufacturer's belief, cause the manufacturer to have a negative credit balance when all credits are calculated for all the manufacturer's engine families participating in the averaging, banking, and trading program.

(3) Declare an FEL for each engine family participating in averaging, banking, and trading.

(i) The FEL must be to the same number of significant digits as the emission standard.

(ii) In no case may the FEL exceed the upper limit prescribed in § 89.203–96(d).

(4) Indicate the projected number of credits generated/needed for this family; the projected applicable production/sales volume, by quarter; and the values required to calculate credits as given in § 89.207–96.

(5) Submit calculations in accordance with § 89.207–96 of projected emission credits (positive or negative) based on quarterly production projections for each participating family.

(6) (i) If the engine family is projected to have negative emission credits, state specifically the source (manufacturer/engine family or reserved) of the credits necessary to offset the credit deficit according to quarterly projected production.

(ii) If the engine family is projected to generate credits, state specifically (manufacturer/engine family or reserved) where the quarterly projected credits will be applied.

(b) All certificates issued are conditional upon manufacturer compliance with the provisions of this subpart both during and after the model year of production.

(c) Failure to comply with all provisions of this subpart will be considered to be a failure to satisfy the conditions upon which the certificate was issued, and the certificate may be deemed void ab initio.

(d) The manufacturer bears the burden of establishing to the satisfaction of the Administrator that the conditions upon which the certificate was issued were satisfied or waived.

(e) Projected credits based on information supplied in the certification application may be used to obtain a certificate of conformity. However, any such credits may be revoked based on review of end-of-year reports, follow-up audits, and any other verification steps deemed appropriate by the Administrator.

§ 89.210–96 Maintenance of records.

(a) The manufacturer of any nonroad engine that is certified under the averaging, banking, and trading program must establish, maintain, and retain the following adequately organized and indexed records for each such engine produced:

(1) EPA engine family;

(2) Engine identification number;

(3) Engine model year and build date,

(4) Power rating;

(5) Purchaser and destination; and

(6) Assembly plant.

(b) The manufacturer of any nonroad engine family that is certified under the averaging, banking, and trading program must establish, maintain, and retain the following adequately organized and indexed records for each such family:

(1) EPA engine family;

(2) Family emission limit (FEL);

(3) Power rating for each configuration tested;

(4) Projected applicable production/sales volume for the model year; and

(5) Actual applicable production/sales volume for the model year.

(c) Any manufacturer producing an engine family participating in trading reserved credits must maintain the following records on a quarterly basis for each engine family in the trading program:

(1) The engine family;

(2) The actual quarterly and cumulative applicable production/sales volume;

(3) The value required to calculate credits as given in § 89.207–96;

(4) The resulting type and number of credits generated/required;

(5) How and where credit surpluses are dispersed; and

(6) How and through what means credit deficits are met.

(d) The manufacturer must retain all records required to be maintained under this section for a period of eight years from the due date for the end-of-model-year report. Records may be retained as hard copy or reduced to microfilm, ADP diskettes, and so forth, depending on the manufacturer's record retention procedure; provided, that in every case all information contained in the hard copy is retained.

(e) Nothing in this section limits the Administrator's discretion in requiring the manufacturer to retain additional records or submit information not specifically required by this section.

(f) Pursuant to a request made by the Administrator, the manufacturer must submit to the Administrator the information that the manufacturer is required to retain.

(g) EPA may void ab initio under § 89.126–96(c) a certificate of conformity for an engine family for which the manufacturer fails to retain the records required in this section or to provide such information to the Administrator upon request.

§ 89.211–96 End-of-year and final reports.

(a) End-of-year and final reports must indicate the engine family, the actual applicable production/sales volume, the values required to calculate credits as given in § 89.207–96, and the number of credits generated/required. Manufacturers must also submit how and where credit surpluses were dispersed (or are to be banked) and/or how and through what means credit deficits were met. Copies of contracts related to credit trading must be included or supplied by the broker, if applicable. The report shall include a calculation of credit balances to show that the summation of the manufacturer's use of credits results in a credit balance equal to or greater than zero.

(b) The applicable production/sales volume for end-of-year and final reports must be based on the location of the point of first retail sale (for example, retail customer, dealer, secondary manufacturer) also called the final product purchase location.

(c)(1) End-of-year reports must be submitted within 90 days of the end of the model year to: Director, Manufacturers Operations Division (6405–J), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

(2) Final reports must be submitted within 270 days of the end of the model year to: Director, Manufacturers Operations Division (6405–J), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

(d) Failure by a manufacturer participating in the averaging, banking, or trading program to submit any end-of-year or final reports in the specified time for all engines is a violation of sections 203(a)(1) and 213 of the Clean Air Act for each engine.

(e) A manufacturer generating credits for deposit only who fails to submit end-of-year reports in the applicable specified time period (90 days after the end of the model year) may not use the credits until such reports are received and reviewed by EPA. Use of projected credits pending EPA review is not permitted in these circumstances.

(f) Errors discovered by EPA or the manufacturer in the end-of-year report, including errors in credit calculation, may be corrected in the final report up to 270 days from the end of the model year.

(g) If EPA or the manufacturer determines that a reporting error occurred on an end-of-year or final report previously submitted to EPA under this section, the manufacturer's credits and credit calculations will be recalculated. Erroneous positive credits will be void except as provided in paragraph (h) of this section. Erroneous negative credit balances may be adjusted by EPA.

(h) If within 270 days of the end of the model year, EPA review determines a reporting error in the manufacturer's favor (that is, resulting in an increased

credit balance) or if the manufacturer discovers such an error within 270 days of the end of the model year, the credits shall be restored for use by the manufacturer.

§ 89.212–96 Notice of opportunity for hearing.

Any voiding of the certificate under §§ 89.203–96(f), 89.206–96(d), 89.209–96(c) and 89.210–96(g) will be made only after the manufacturer concerned has been offered an opportunity for a hearing conducted in accordance with §§ 89.512 and 89.513 and, if a manufacturer requests such a hearing, will be made only after an initial decision by the Presiding Officer.

Subpart D—Emission Test Equipment Provisions

§ 89.301–96 Scope; applicability.

(a) This subpart describes the equipment required in order to perform exhaust emission tests on new nonroad compression-ignition engines subject to the provisions of subpart B of part 89.

(b) Exhaust gases, either raw or dilute, are sampled while the test engine is operated using an 8-mode test cycle on an engine dynamometer. The exhaust gases receive specific component analysis determining concentration of pollutant, exhaust volume, the fuel flow, and the power output during each mode. Emission is reported as grams per kilowatt hour (g/kw-hr). See subpart E of this part for a complete description of the test procedure.

(c) General equipment and calibration requirements are given in § 89.304–96 through 89.324–96. Sections 89.325–96 through 89.331–96 set forth general test specifications.

(d) Additional information about system design, calibration methodologies, and so forth, for raw gas sampling can be found in part 86, subpart D of this chapter. Examples for system design, calibration methodologies, and so forth, for dilute exhaust gas sampling can be found in part 86, subpart N of this chapter.

§ 89.302–96 Definitions.

The definitions in subpart A of part 89 apply to this subpart. For terms not defined in part 89, the definitions in part 86, subparts A, D, I, and N apply to this subpart. The following definition also applies to this subpart.

Specific emissions, g/kW-hr, is expressed on the basis of observed gross brake power. When it is not possible to test the engine in the gross conditions, for example, if the engine and transmission form a single integral unit, the engine may be tested in the net condition. Power corrections from net to gross conditions will be allowed with prior approval of the Administrator.

§ 89.303–96 Symbols/abbreviations.

(a) The abbreviations in § 86.094–3 or part 89.3 of this chapter apply to this subpart.

(b) The abbreviations in Table 1 in appendix A of this subpart apply to this subpart. Some abbreviations from § 89.3 have been included for the convenience of the reader.

(c) The symbols in Table 2 in appendix A of this subpart apply to this subpart.

§ 89.304–96 Equipment required for gaseous emissions; overview.

(a) All engines subject to this subpart are tested for exhaust emissions. Engines are operated on dynamometers meeting the specification given in § 89.306–96.

(b) The exhaust is tested for gaseous emissions using a raw gas sampling system as described in § 89.412–96 or a constant volume sampling (CVS) system as described in § 89.419–96. Both systems require analyzers (see paragraph (c) of this section) specific to the pollutant being measured.

(c) Analyzers used are a non-dispersive infrared (NDIR) absorption type for carbon monoxide and carbon dioxide analysis; paramagnetic (PMD), zirconia (ZRDO), or electrochemical type (ECS) for oxygen analysis; a heated flame ionization (HFID) type for hydrocarbon analysis; and a chemiluminescent detector (CLD) or heated chemiluminescent detector (HCLD) for oxides of nitrogen analysis. Sections 89.309–96 through 89.324–96 set forth a full description of analyzer requirements and specifications.

§ 89.305–96 Equipment measurement accuracy/calibration frequency.

The accuracy of measurements must be such that the maximum tolerances shown in Table 3 in appendix A of this subpart are not exceeded. Calibrate all equipment and analyzers according to the frequencies shown in Table 3 in Appendix A of this subpart.

§ 89.306–96 Dynamometer specifications and calibration weights.

(a) *Dynamometer specifications.* The dynamometer test stand and other instruments for measurement of power output must meet the accuracy and calibration frequency requirements shown in Table 3 in appendix A of this subpart. The dynamometer must be capable of performing the test cycle described in § 89.410–96.

(b) *Dynamometer calibration weights.* A minimum of six calibration weights for each range used are required. The weights must be spaced to reflect good engineering judgement such that they cover the range of weights required and must be traceable to within 0.5 percent of NIST weights. Laboratories located in foreign countries may certify calibration weights to local government bureau standards.

§ 89.307–96 Dynamometer calibration.

(a) If necessary, follow the dynamometer manufacturer's instructions for initial start-up and basic operating adjustments.

(b) Check the dynamometer torque measurement for each range used by the following method:

(1) Warm up the dynamometer following the dynamometer manufacturer's specifications.

(2) Determine the dynamometer calibration moment arm (a distance/weight measurement). Dynamometer manufacturer's data, actual measurement, or the value recorded from the previous calibration used for this subpart may be used.

(3) When calibrating the engine flywheel torque transducer, any lever arm used to convert a weight or a force through a distance into a torque must be in a horizontal position (±5 degrees).

(4) Calculate the indicated torque (IT) for each calibration weight to be used by:

IT = calibration weight (N) × calibration moment arm (m)

(5) Attach each calibration weight specified in § 89.306–96 to the moment arm at the calibration distance determined in paragraph (b)(2) of this section. Record the power measurement equipment response (N – m) to each weight.

(6) For each calibration weight, compare the torque value measured in paragraph (b)(5) of this section to the calculated torque determined in paragraph (b)(4) of this section.

(7) The measured torque must be within 2 percent of the calculated torque.

(8) If the measured torque is not within 2 percent of the calculated torque, adjust or repair the system. Repeat steps in paragraphs (b)(1) through (b)(6) of this section with the adjusted or repaired system.

(c) Optional. A master load-cell or transfer standard may be used to verify the torque measurement system.

(1) The master load-cell and read out system must be calibrated with weights at each test weight specified in § 89.306–96. The calibration weights must be traceable to within 0.1 percent of applicable national standards.

(2) Warm up the dynamometer following the equipment manufacturer's specifications.

(3) Attach the master load-cell and loading system.

(4) Load the dynamometer to a minimum of 6 equally spaced torque values as indicated by the master load-cell for each in-use range used.

(5) The in-use torque measurement must be within 2 percent of the torque measured by the master system for each load used.

(6) If the in-use torque is not within 2 percent of the master torque, adjust or repair the system. Repeat steps in paragraphs (c)(2) through (c)(5) of this section with the adjusted or repaired system.

(d) Calibrated resistors may not be used for engine flywheel torque transducer calibration, but may be used to span the transducer prior to engine testing.

(e) Perform other engine dynamometer system calibrations as dictated by good engineering practice.

§ 89.308–96 Sampling system requirements for gaseous emissions.

(a) For each component (pump, sample line section, filters, and so forth) in the heated portion of the sampling system that has a separate source of power or heating element, use engineering judgment to locate the coolest portion of that component and monitor the temperature at that location. If several components are within an oven, then only the surface temperature of the component with the largest thermal mass and the oven temperature need be measured.

(b) If water is removed by condensation, the sample gas temperature or sample dewpoint must be monitored either within the water trap or downstream. It may not exceed 7 °C.

§ 89.309–96 Analyzers required for gaseous emissions.

(a) *Analyzers.* The following instruments are required for analyzing the measured gases:

(1) *Carbon Monoxide (CO) analysis.* (i) The carbon monoxide analyzer must be of the non-dispersive infrared (NDIR) absorption type.

(ii) The use of linearizing circuits is permitted.

(2) *Carbon Dioxide (CO_2) analysis.* (i) The carbon dioxide analyzer must be of the non-dispersive infrared (NDIR) absorption type.

(ii) The use of linearizing circuits is permitted.

(3) *Oxygen (O_2) analysis.* Oxygen (O_2) analyzers may be of the paramagnetic (PMD), zirconia (ZRDO) or electrochemical type (ECS).

(4) *Hydrocarbon (HC) analysis.* (i) The hydrocarbon analyzer must be of the heated flame ionization (HFID) type.

(ii) If the temperature of the exhaust gas at the sample probe is below 190 °C, the temperature of the valves, pipework, and so forth, must be controlled so as to maintain a wall temperature of 190 °C ± 11 °C. If the temperature of the exhaust gas at the sample probe is above 190 °C, the temperature of the valves, pipework, and so forth, must be controlled so as to maintain a wall temperature greater than 180 °C.

(iii) The oven must be capable of maintaining temperature within 2 °C of the set point.

(iv) Fuel and burner air must conform to the specifications in § 89.312–96.

(v) The percent of oxygen interference must be less than 3 percent, as specified in § 89.319–96(d).

(5) *Oxides of nitrogen (NO_X) analysis.* (i) This analysis device must consist of the subsequent items, following the sample probe, in the given order:

(A) Pipework, valves, and so forth, controlled so as to maintain a wall temperature above 60 °C.

(B) A NO_2 to NO converter. The NO_2 to NO converter efficiency must be at least 90 percent.

(C) An ice bath or other cooling device located after the NO_X converter.

(D) A chemiluminescent detector (CLD).

(ii) The quench interference must be less than 3.0 percent as measured in § 89.318–96.

(b) Other gas analyzers yielding equivalent results may be used with advance approval of the Administrator.

(c) The following requirements must be incorporated in each system used for testing under this subpart.

(1) Carbon monoxide and carbon dioxide measurements must be made on a dry basis (for raw exhaust measurement only). Specific requirements for the means of drying the sample can be found in § 89.309–96(e).

(2) Calibration or span gases for the NO_X measurement system must pass through the NO_2 to NO converter.

(d) The electromagnetic compatibility (EMC) of the equipment must be on a level as to minimize additional errors.

(e) *Gas drying.* Chemical dryers are not an acceptable method of removing water from the sample. Water removal by condensation is acceptable. A water trap performing this function and meeting the specifications in § 89.308–96(b) is an acceptable method. Means other than condensation may be used only with prior approval from the Administrator.

§ 89.310–96 Analyzer accuracy and specifications.

(a) *Measurement accuracy—general.* The analyzers must have a measuring range which allows them to measure the concentrations of the exhaust gas sample pollutants with the accuracies shown in Table 3 in Appendix A of this subpart.

(1) *Response time.* The analyzer response time must be measured and accounted for before recording of data begins.

(2) *Precision.* The precision of the analyzer must be, at worst, ±1 percent of full-scale concentration for each range used at or above 100 ppm (or ppmC) or ±2 percent for each range used below 100 ppm (or ppmC). The precision is defined as 2.5 times the standard deviation(s) of 10 repetitive responses to a given calibration or span gas.

(3) *Noise.* The analyzer peak-to-peak response to zero and calibration or span gases over any 10-second period must not exceed 2 percent of full-scale chart deflection on all ranges used.

(4) *Zero drift.* The analyzer zero-response drift during a 1-hour period must be less than 2 percent of full-scale chart deflection on the lowest range used. The zero-response is defined as the mean response including noise to a zero-gas during a 30-second time interval.

(5) *Span drift.* The analyzer span drift during a 1-hour period must be less than 2 percent of full-scale chart deflection on the lowest range used. The analyzer span is defined as the difference between the span-response and the zero-response. The span-response is defined as the mean response including noise to a span gas during a 30-second time interval.

(b) *Operating procedure for analyzers and sampling system.* Follow the start-up and operating instructions of the instrument manufacturer. Adhere to the minimum requirements given in § 89.314–96 to § 89.323–96.

(c) *Emission measurement accuracy—Bagged sampling.* (1) Good engineering practice dictates that exhaust emission sample analyzer readings below 15 percent of full-scale chart deflection should generally not be used.

(2) Some high resolution read-out systems, such as computers, data loggers, and so forth, can provide sufficient accuracy and resolution below 15 percent of full scale. Such systems may be used provided that additional calibrations are made to ensure the accuracy of the calibration curves. If a gas divider is used, the gas divider must conform to the accuracy requirements specified in § 89.312–96(c). The

following procedure for calibration below 15 percent of full scale may be used:

(i) Span the full analyzer range using a top range calibration gas meeting the accuracy requirements of § 89.312–96(c).

(ii) Generate a calibration curve according to, and meeting the requirements of, §§ 89.319–96 through 89.323–96.

(iii) Select a calibration gas (a span gas may be used for calibrating the CO_2 analyzer) with a concentration midway between the two lowest calibration gases or non-zero gas divider increments. This gas must be "named" to an accuracy of ±2.0 percent of NIST gas standards, or other standards approved by the Administrator.

(iv) Using the calibration curve fitted to the points generated in paragraphs (c)(2)(i) and (ii) of this section, check the concentration of the gas selected in paragraph (c)(2)(iii) of this section. The concentration derived from the curve must be within ±2.3 percent (±2.8 percent for CO_2 span gas) of the original named gas concentration.

(v) Provided the requirements of paragraph (c)(2)(iv) of this section are met, use the gas divider with the gas selected in paragraph (c)(2)(iii) of this section and determine the remainder of the calibration points. Fit a calibration curve per §§ 89.319–96 through 89.322–96 of this chapter for the entire analyzer range.

(d) *Emission measurement accuracy—continuous sampling.* Analyzers used for continuous analysis must be operated such that the measured concentration falls between 15 and 100 percent of full-scale chart deflection. Exceptions to these limits are:

(1) The analyzer's response may be less than 15 percent or more than 100 percent of full scale if automatic range change circuitry is used and the limits for range changes are between 15 and 100 percent of full-scale chart deflection;

(2) The analyzer's response may be less than 15 percent of full scale if:

(i) Alternative (c)(2) of this section is used to ensure that the accuracy of the calibration curve is maintained below 15 percent; or

(ii) The full-scale value of the range is 155 ppm (or ppmC) or less.

§ 89.311–96 Analyzer calibration frequency.

(a) Prior to initial use and after major repairs, bench check each analyzer (see § 89.315–96).

(b) Calibrations are performed as specified in §§ 89.319–96 through 89.324–96.

(c) At least monthly, or after any maintenance which could alter calibration, the following calibrations and checks are performed.

(1) Leak check the vacuum side of the system (see § 89.316–96).

(2) Check that the analysis system response time has been measured and accounted for.

(3) Verify that the automatic data collection system (if used) meets the requirements found in Table 3 in Appendix A of this subpart.

(4) Check the fuel flow measurement instrument to insure that the specifications in Table 3 in appendix A of this subpart are met.

(d) Verify that all NDIR analyzers meet the water rejection ratio and the CO_2 rejection ratio as specified in § 89.318–96.

(e) Verify that the dynamometer test stand and power output instrumentation meet the specifications in Table 3 in Appendix A of this subpart.

§ 89.312–96 Analytical gases.

(a) The shelf life of all calibration gases must not be exceeded. The expiration date of the calibration gases stated by the gas manufacturer shall be recorded.

(b) *Pure gases.* The required purity of the gases is defined by the contamination limits given below. The following gases must be available for operation:

(1) Purified nitrogen (Contamination ≤ 1 ppm C, ≤ 1 ppm CO, ≤ 400 ppm CO_2, ≤ 0.1 ppm NO)

(2) Purified oxygen (Purity 99.5 percent vol O_2)

(3) Hydrogen-helium mixture (40 ± 2 percent hydrogen, balance helium) (Contamination ≤ 31 ppm C, ≤ 400 ppm CO)

(4) Purified synthetic air (Contamination ≤ 1 ppm C, ≤ 1 ppm CO, ≤ 400 ppm CO_2, ≤ 0.1 ppm NO) (Oxygen content between 18–21 percent vol.)

(c) *Calibration and span gases.* (1) Calibration gas values are to be derived from NIST Standard Reference Materials (SRM's) or other standardized gas samples and are to be single blends as listed in the following paragraph.

(2) Mixtures of gases having the following chemical compositions shall be available:

C_3H_8 and purified synthetic air (dilute measurements);

C_3H_8 and purified nitrogen (raw measurements);

CO and purified nitrogen;

NO_X and purified nitrogen (the amount of NO_2 contained in this calibration gas must not exceed 5 percent of the NO content);

CO_2 and purified nitrogen

(3) The true concentration of a span gas must be within ±2 percent of the NIST gas standard. The true concentration of a calibration gas must be within ±1 percent of the NIST gas standard. The use of precision blending devices (gas dividers) to obtain the required calibration gas concentrations is acceptable, provided that the blended gases are accurate to within ±1.5 percent of NIST gas standards, or other gas standards which have been approved by the Administrator. This accuracy implies that primary gases used (or blending) must be "named" to an accuracy of at least ±1 percent, traceable to NIST or other approved gas standards. All concentrations of calibration gas shall be given on a volume basis (volume percent or volume ppm).

(4) The gas concentrations used for calibration and span may also be obtained by means of a gas divider, either diluting with purified N_2 or diluting with purified synthetic air. The accuracy of the mixing device must be such that the concentration of the diluted gases may be determined to within ±2 percent.

(d) Oxygen interference check gases shall contain propane with 350 ppmC ±75 ppmC hydrocarbon. The concentration value shall be determined to calibration gas tolerances by chromatographic analysis of total hydrocarbons plus impurities or by dynamic blending. Nitrogen shall be the predominant diluent with the balance oxygen.

(e) Fuel for the FID shall be a blend of 40 percent ±2 percent hydrogen with the balance being helium. The mixture shall contain less than 1 ppm equivalent carbon response; 98 to 100 percent hydrogen fuel may be used with advance approval of the Administrator.

(f) *Hydrocarbon analyzer burner air.* The concentration of oxygen must be within 1 mole percent of the oxygen concentration of the burner air used in the latest oxygen interference check (%O_2I). If the difference in oxygen concentration is greater than 1 mole percent, then the oxygen interference must be checked and, if necessary, the analyzer adjusted to meet the %O_2I requirements. The burner air must contain less than 2 ppmC hydrocarbon.

§ 89.313–96 Initial calibration of analyzers.

(a) *Warming-up time.* The warming-up time should be according to the recommendations of the manufacturer. If not specified, a minimum of two hours shall be allowed for warming up the analyzers.

(b) *NDIR and HFID analyzer.* The NDIR analyzer shall be tuned and maintained according to the instrument manufacturer's instructions. The combustion flame of the HFID analyzer shall be optimized in order to meet the specifications in § 89.319–96(b)(2).

(c) *Zero setting and calibration.* (1) Using purified synthetic air (or nitrogen), the CO, CO_2, NO_X, and HC analyzers shall be set at zero.

(2) Introduce the appropriate calibration gases to the analyzers and the values recorded. The same gas flow rates shall be used as when sampling exhaust.

(d) *Rechecking of zero setting.* The zero setting shall be rechecked and the procedure described in paragraph (c) of this section repeated, if necessary.

§ 89.314–96 Pre- and post-test calibration of analyzers.

Each operating range used during the test shall be checked prior to and after each test in accordance with the following procedure. (A chronic need for parameter adjustment can indicate a need for instrument maintenance.):

(a) The calibration is checked by using a zero gas and a span gas whose nominal value is between 80 percent and 100 percent of full-scale, inclusive, of the measuring range.

(b) After the emission test a zero gas and the same span gas will be used for rechecking. The analysis will be considered acceptable if the difference between the two measuring results is less than 2 percent of full scale.

§ 89.315–96 Analyzer bench checks.

(a) Prior to initial use and after major repairs verify that each analyzer complies with the specifications given in Table 3 in appendix A of this subpart.

(b) If a stainless steel NO_2 to NO converter is used, condition all new or replacement converters. The conditioning consists of either purging the converter with air for a minimum of 4 hours or until the converter efficiency is greater than 90 percent. The converter must be at operational temperature while purging. Do not use this procedure prior to checking converter efficiency on in-use converters.

§ 89.316–96 Analyzer leakage and response time.

(a) *Vacuum side leak check.* (1) Any location within the analysis system where a vacuum leak could affect the test results must be checked.

(2) The maximum allowable leakage rate on the vacuum side is 0.5 percent of the in-use flow rate for the portion of the system being checked. The analyzer flows and bypass flows may be used to estimate the in-use flow rates.

(3) The sample probe and the connection between the sample probe and valve V2 (see Figure 1 in appendix B of this subpart) may be excluded from the leak check.

(b) *Pressure side leak check.* The maximum allowable leakage rate on the pressure side is 5 percent of the in-use flow rate.

(c) The response time shall be accounted for in all emission measurement and calculations.

§ 89.317–96 NO_X converter check.

(a) Prior to its introduction into service, and monthly thereafter, the chemiluminescent oxides of nitrogen analyzer shall be checked for NO_2 to NO converter efficiency. Figure 2 in appendix B of this subpart is a reference for the following paragraphs.

(b) Follow good engineering practices for instrument start-up and operation. Adjust the analyzer to optimize performance.

(c) Zero the oxides of nitrogen analyzer with zero-grade air or zero-grade nitrogen.

(d) Connect the outlet of the NO_X generator to the sample inlet of the oxides of nitrogen analyzer which has been set to the most common operating range.

(e) Introduce into the NO_X generator analyzer-system an NO-in-nitrogen (N_2) mixture with an NO concentration equal to approximately 80 percent of the most common operating range. The NO_2 content of the gas mixture shall be less than 5 percent of the NO concentration.

(f) With the oxides of nitrogen analyzer in the NO mode, record the concentration of NO indicated by the analyzer.

(g) Turn on the NO_X generator O_2 (or air) supply and adjust the O_2 (or air) flow rate so that the NO indicated by the analyzer is about 10 percent less than indicated in paragraph (b)(5) of this section. Record the concentration of NO in this $NO+O_2$ mixture.

(h) Switch the NO_X generator to the generation mode and adjust the generation rate so that the NO measured on the analyzer is 20 percent of that measured in paragraph (b)(5) of this section. There must be at least 10 percent unreacted NO at this point. Record the concentration of residual NO.

(i) Switch the oxides of nitrogen analyzer to the NO_X mode and measure total NO_X. Record this value.

(j) Switch off the NO_X generator but maintain gas flow through the system. The oxides of nitrogen analyzer will indicate the NO_X in the $NO+O_2$ mixture. Record this value.

(k) Turn off the NO_X generator O_2 (or air) supply. The analyzer will now indicate the NO_X in the original NO-in-N_2 mixture. This value should be no more than 5 percent above the value indicated in paragraph (b)(4) of this section.

(l) Calculate the efficiency of the NO_X converter by substituting the concentrations obtained into the following equation:

$$\text{percent efficiency} = \left(1 + \frac{a-b}{c-d}\right) \times 100$$

Where:

a=concentration obtained in paragraph (i),

b=concentration obtained in paragraph (j),

c=concentration obtained in paragraph (g),

d=concentration obtained in paragraph (h).

If converter efficiency is not greater than 90 percent, corrective action will be required.

§ 89.318–96 Analyzer interference checks.

(a) Gases present in the exhaust other than the one being analyzed can interfere with the reading in several ways. Positive interference occurs in NDIR and PMD instruments when the interfering gas gives the same effect as the gas being measured, but to a lesser degree. Negative interference occurs in NDIR instruments by the interfering gas broadening the absorption band of the measured gas and in CLD instruments by the interfering gas quenching the radiation. The interference checks described in this section are to be made initially and after any major repairs that could affect analyzer performance.

(b) *CO analyzer water and CO_2 interference checks.* Prior to its introduction into service and annually thereafter, the NDIR carbon monoxide analyzer shall be checked for response to water vapor and CO_2:

(1) Follow good engineering practices for instrument start-up and operation. Adjust the analyzer to optimize performance on the most sensitive range to be used.

(2) Zero the carbon monoxide analyzer with either zero-grade air or zero-grade nitrogen.

(3) Bubble a mixture of 3 percent CO_2 in N_2 through water at room temperature and record analyzer response.

(4) An analyzer response of more than 1 percent of full scale for ranges above 300 ppm full scale or more than 3 ppm on ranges below 300 ppm full scale requires corrective action. (Use of conditioning columns is one form of corrective action which may be taken.)

(c) *NO_X analyzer quench check.* The two gases of concern for CLD (and HCLD) analyzers are CO_2 and water vapor. Quench responses to these two gases are proportional to their concentrations and, therefore, require test techniques to determine quench at the highest expected concentrations experienced during testing.

(1) *NO_X analyzer CO_2 quench check.* A CO_2 span gas having a concentration of 80 percent to 100 percent of full scale of the maximum operating range used during testing shall be passed through the CO_2 NDIR analyzer and the value recorded as *a*. It is diluted approximately 50 percent with NO span gas and then passed through the CO_2 NDIR and CLD (or HCLD), with the CO_2 and NO values recorded as *b* and *c* respectively. The CO_2 shall then be shut off and only the NO span gas passed through the CLD (or HCLD) and the NO value recorded as *d*. Percent CO_2 quench shall be calculated as follows and shall not exceed 3 percent:

$$\%\,CO_2\ \text{quench} = 100 \times \left(1 - \frac{(c \times a)}{(d \times a) - (d \times b)}\right) \times (a / b)$$

Where:

a=Undiluted CO_2 concentration (percent)

b=Diluted CO2 concentration (percent)

c=Diluted NO concentration (ppm)

d=Undiluted NO concentration (ppm)

(2) *NO_X analyzer water quench check.*

(i) This check applies to wet measurements only. An NO span gas having a concentration of 80 percent to 100 percent of full scale of a normal operating range shall be passed through the CLD (or HCLD) and the response recorded as *D*. The NO span gas shall then be bubbled through water at room temperature and passed through the CLD (or HCLD) and the analyzer response recorded as *AR*. Determine and record the analyzer absolute operating pressure and the bubbler water temperature. (It is important that the NO span gas contains minimal NO_2 concentration for this check. No allowance for absorption of NO_2 in water has been made in the following quench calculations.)

(ii) Calculations for water quench must consider dilution of the NO span gas with water vapor and scaling of the water vapor concentration of the mixture to that expected during testing. Determine the mixture's saturated vapor pressure (designated as *Pwb*) that corresponds to the bubbler water temperature. Calculate the water concentration (Z1, percent) in the mixture by the following equation:

$$Z1 = 100 \times \frac{Pwb}{GP}$$

where GP = analyzer operating pressure (Pa)

(iii) Calculate the expected dilute NO span gas and water vapor mixture concentration (designated as *D1*) by the following equation:

$$D1 = D \times \left(1 - \frac{Z1}{100}\right)$$

(iv) For diesel (compression-ignition) exhaust, the maximum raw or dilute exhaust water vapor concentration expected during testing (designated as *Wm*) can be estimated from the CO_2 span gas (designated as *A*) criteria in paragraph (c)(1) of this section and the assumption of a fuel atom H/C ratio of 1.8:1 as:

$$Wm(\%) = 0.9 \times A(\%)$$

Where:

A = undiluted CO_2 concentration.

Percent water quench shall not exceed 3 percent and shall be calculated by:

$$\%\,\text{Water Quench} = 100 \times \frac{D1 - AR}{D1} \times \frac{Wm}{Z1}$$

§ 89.319–96 Hydrocarbon analyzer calibration.

(a) The FID hydrocarbon analyzer shall receive the initial and periodic calibration as described in this section. The HFID used with petroleum-fueled diesel (compression-ignition) engines shall be operated to a set point ±5.5 °C between 185 and 197 °C.

(b) *Initial and periodic optimization of detector response.* Prior to introduction into service and at least annually thereafter, adjust the FID hydrocarbon analyzer for optimum hydrocarbon response as specified in this paragraph. Alternate methods yielding equivalent results may be used, if approved in advance by the Administrator.

(1) Follow good engineering practices for initial instrument start-up and basic operating adjustment using the appropriate fuel (see § 89.312–96(e)) and zero-grade air.

(2) One of the following procedures is required for FID or HFID optimization:

(i) The procedure outlined in Society of Automotive Engineers (SAE) paper No. 770141, "Optimization of a Flame Ionization Detector for Determination of Hydrocarbon in Diluted Automotive Exhausts"; author, Glenn D. Reschke. This procedure has been incorporated by reference. See § 89.6.

(ii) The HFID optimization procedures outlined in § 86.331–79 of this chapter.

(iii) Alternative procedures may be used if approved in advance by the Administrator.

(3) After the optimum flow rates have been determined, record them for future reference.

(c) *Initial and periodic calibration.* Prior to introduction into service and monthly thereafter, the FID or HFID hydrocarbon analyzer shall be calibrated on all normally used instrument ranges using the steps in this paragraph. Use the same flow rate and pressures as when analyzing samples. Calibration gases shall be introduced directly at the

analyzer, unless the "overflow" calibration option of § 86.1310–90(b)(3)(i) of this chapter for the HFID is taken.

(1) Adjust analyzer to optimize performance.

(2) Zero the hydrocarbon analyzer with zero-grade air.

(3) Calibrate on each used operating range with propane-in-air (dilute) or propane-in-nitrogen (raw) calibration gases having nominal concentrations starting between 10–15 percent and increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

(d) *Oxygen interference optimization.* Choose a range where the oxygen interference check gases will fall in the upper 50 percent. Conduct the test, as outlined in this paragraph, with the oven temperature set as required by the instrument manufacturer. Oxygen interference check gas specifications are found in § 89.312–96(d).

(1) Zero the analyzer.

(2) Span the analyzer with the purified synthetic air specified in § 89.312–96(b)(4).

(3) Recheck zero response. If it has changed more than 0.5 percent of full scale repeat paragraphs (d)(1) and (d)(2) of this section to correct problem.

(4) Introduce the 5 percent and 10 percent oxygen interference check gases.

(5) Recheck the zero response. If it has changed more ±1 percent of full scale, repeat the test.

(6) Calculate the percent of oxygen interference (designated as *percent O_2I*) for each mixture in paragraph (d)(4) of this section.

$$\text{percent } O_2I = \frac{(B-C)}{B}(100)$$

A=hydrocarbon concentration (ppmC) of the span gas used in paragraph (d)(2) of this section.

B=hydrocarbon concentration (ppmC) of the oxygen interference check gases used in paragraph (d)(4) of this section.

$$C = \text{analyzer response (ppmC)} = \frac{A}{D}$$

D=percent of full-scale analyzer response due to *A*.

(7) The percent of oxygen interference (designated as *$\%O_2I$*) must be less than ± 3.0 percent for all required oxygen interference check gases prior to testing.

(8) If the oxygen interference is greater than the specifications, incrementally adjust the air flow above and below the manufacturer's specifications, repeating paragraphs (d)(1) through (d)(7) of this section for each flow.

(9) If the oxygen interference is greater than the specification after adjusting the air flow, vary the fuel flow and thereafter the sample flow, repeating paragraphs (d)(1) through (d)(7) of this section for each new setting.

(10) If the oxygen interference is still greater than the specifications, repair or replace the analyzer, FID fuel, or burner air prior to testing. Repeat this section with the repaired or replaced equipment or gases.

§ 89.320–96 Carbon monoxide analyzer calibration.

(a) Calibrate the NDIR carbon monoxide as described in this section.

(b) *Initial and periodic interference check.* Prior to its introduction into service and annually thereafter, the NDIR carbon monoxide analyzer shall be checked for response to water vapor and CO_2 in accordance with § 318.96(b).

(c) *Initial and periodic calibration.* Prior to its introduction into service and monthly thereafter, the NDIR carbon monoxide analyzer shall be calibrated.

(1) Adjust the analyzer to optimize performance.

(2) Zero the carbon monoxide analyzer with either zero-grade air or zero-grade nitrogen.

(3) Calibrate on each used operating range with carbon monoxide-in-N_2 calibration gases having nominal concentrations starting between 10 and 15 percent and increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

(d) The initial and periodic interference, system check, and calibration test procedures specified in part 86, subpart D of this chapter may be used in lieu of the procedures specified in this section.

§ 89.321–96 Oxides of nitrogen analyzer calibration.

(a) The chemiluminescent oxides of nitrogen analyzer shall receive the initial and periodic calibration described in this section.

(b) Prior to its introduction into service, and monthly thereafter, the chemiluminescent oxides of nitrogen analyzer is checked for NO_2 to NO converter efficiency according to § 89.317–96.

(c) *Initial and periodic calibration.* Prior to its introduction into service, and monthly thereafter, the chemiluminescent oxides of nitrogen analyzer shall be calibrated on all normally used instrument ranges. Use the same flow rate as when analyzing samples. Proceed as follows:

(1) Adjust analyzer to optimize performance.

(2) Zero the oxides of nitrogen analyzer with zero-grade air or zero-grade nitrogen.

(3) Calibrate on each normally used operating range with NO-in-N_2 calibration gases with nominal concentrations starting at between 10 and 15 percent and increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

(d) The initial and periodic interference, system check, and calibration test procedures specified in part 86, subpart D of this chapter may be used in lieu of the procedures specified in this section.

§ 89.322–96 Carbon dioxide analyzer calibration.

(a) Prior to its introduction into service, and monthly thereafter, the NDIR carbon dioxide analyzer shall be calibrated as follows:

(1) Follow good engineering practices for instrument start-up and operation. Adjust the analyzer to optimize performance.

(2) Zero the carbon dioxide analyzer with either zero-grade air or zero-grade nitrogen.

(3) Calibrate on each normally used operating range with carbon dioxide-in-N_2 calibration or span gases having nominal concentrations starting between 10 and 15 percent and

increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

(b) The initial and periodic interference, system check, and calibration test procedures specified in part 86, subpart D of this chapter may be used in lieu of the procedures in this section.

§ 89.323–96 NDIR analyzer calibration.

(a) *Detector optimization.* If necessary, follow the instrument manufacturer's instructions for initial start-up and basic operating adjustments.

(b) *Calibration curve.* Develop a calibration curve for each range used as follows:

(1) Zero the analyzer.

(2) Span the analyzer to give a response of approximately 90 percent of full-scale chart deflection.

(3) Recheck the zero response. If it has changed more than 0.5 percent of full scale, repeat the steps given in paragraphs (b)(1) and (b)(2) of this section.

(4) Record the response of calibration gases having nominal concentrations starting between 10 and 15 percent and increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice.

(5) Generate a calibration curve. The calibration curve shall be of fourth order or less, have five or fewer coefficients. If any range is within 2 percent of being linear a linear calibration may be used. Include zero as a data point. Compensation for known impurities in the zero gas can be made to the zero-data point. The calibration curve must fit the data points within 2 percent of point.

(6) Optional. A new calibration curve need not be generated if:

(i) A calibration curve conforming to paragraph (b)(5) of this section exists; or

(ii) The responses generated in paragraph (b)(4) of this section are within 1 percent of full scale or 2 percent of point, whichever is less, of the responses predicted by the calibration curve for the gases used in paragraph (b)(4) of this section.

(7) If multiple range analyzers are used, the lowest range used must meet the curve fit requirements below 15 percent of full scale.

§ 89.324–96 Calibration of other equipment.

Other test equipment used for testing shall be calibrated as often as required by the instrument manufacturer or as necessary according to good practice.

§ 89.325–96 Engine intake air temperature measurement.

(a) Engine intake air temperature measurement must be made within 122 cm of the engine. The measurement location must be made either in the supply system or in the air stream entering the supply system.

(b) The temperature measurements shall be accurate to within ±2 °C.

§ 89.326–96 Engine intake air humidity measurement.

(a) *Humidity conditioned air supply.* Air that has had its absolute humidity altered is considered humidity-conditioned air. For this type of intake air supply, the humidity measurements must be made within the intake air supply system and after the humidity conditioning has taken place.

(b) *Nonconditioned air supply procedure.* Humidity measurements in nonconditioned intake air supply systems must be made in the intake air stream entering the supply system. Alternatively, the humidity measurements can be measured within the intake air supply stream.

§ 89.327–96 Charge cooling.

For engines with an air-to-air intercooler (or any other low temperature charge air cooling device) between the turbocharger compressor and the intake manifold, follow SAE J1937. This procedure has been incorporated by reference. See § 89.6. The temperature of the cooling medium and the temperature of the charge air shall be monitored and recorded.

§ 89.328–96 Inlet and exhaust restrictions.

(a) The manufacturer is liable for emission compliance over the full range of restrictions that are specified by the manufacturer for that particular engine.

(b) Perform testing at the following inlet and exhaust restriction settings.

(1) Equip the test engine with an air inlet system presenting an air inlet restriction at the upper limit at maximum air flow, as specified by the engine manufacturer for a clean air cleaner. A system representative of the installed engine may be used. In other cases a test shop system may be used.

(2) The exhaust backpressure must be at the upper limit at maximum declared power, as specified by the engine manufacturer. A system representative of the installed engine may be used. In other cases a test shop system may be used.

§ 89.329–96 Engine cooling system.

An engine cooling system is required with sufficient capacity to maintain the engine at normal operating temperatures as prescribed by the engine manufacturer.

§ 89.330–96 Lubricating oil and test fuels.

(a) *Lubricating oil.* Use the engine lubricating oil for testing that meets the requirements as specified by the manufacturer for a particular engine and intended usage. Record the specifications of the lubricating oil used for the test.

(b) *Test fuels.* (1) Use diesel fuels for testing which are clean and bright, with pour and cloud points adequate for operability. The diesel fuel may contain nonmetallic additives as follows: Cetane improver, metal deactivator, antioxidant, dehazer, antirust, pour depressant, dye, dispersant, and biocide.

(2) Use only petroleum fuel meeting the specifications in Table 4 in appendix A of this subpart, or substantially equivalent specifications approved by the Administrator, for exhaust emission testing. Alternatively, petroleum fuel meeting the specifications in Table 5 in appendix A of this subpart may be used in exhaust emission testing. The grade of diesel fuel used must be commercially designated as "Type 2–D" grade diesel fuel and recommended by the engine manufacturer. If the fuel specified in Table 4 in Appendix A of this subpart is used, the adjustment factor specified in § 89.425–96 may be applied to particulate emission values to account for the impact of sulfur in fuel on particulate emissions.

(c) Other fuels may be used for testing provided they meet the following qualifications:

(1) They are commercially available;

(2) Information acceptable to the Administrator is provided to show that only the designated fuel would be used in customer service;

(3) Use of a fuel listed under paragraph (b) of this section would have a detrimental effect on emissions or durability; and

(4) Fuel specifications are approved in writing by the Administrator prior to the start of testing.

(d) Report the specification range of the fuel to be used under paragraphs

(b)(2) and (c)(1) through (c)(4) of this section in the application for certification in accordance with §89.115–96 (a)(8).

§89.331–96 Test conditions.

(a) *General requirements.* Calculate all volumes and volumetric flow rates at standard conditions for temperature and pressure (0 °C and 101.3 kPa), and these conditions must be used consistently throughout all calculations.

(b) *Engine test conditions.* Measure the absolute temperature (designated as T and expressed in Kelvin) of the engine air at the inlet to the engine, and the dry atmospheric pressure (designated as p and expressed in kPa), and determine the parameter f according to the following provisions:

(1) Naturally aspirated and mechanically supercharged engines:

$$f = \frac{99}{p_s} \times \left(\frac{T}{298}\right)^{0.7}$$

(2) Turbocharged engine with or without cooling of inlet air:

$$f = \left(\frac{99}{p_s}\right)^{0.7} \times \left(\frac{T}{298}\right)^{1.5}$$

(c) For a test to be recognized as valid, the parameter f shall be between the limits as shown below:

$$0.98 < f < 1.02$$

Appendix A to Subpart D—Tables

TABLE 1.—ABBREVIATIONS USED IN SUBPART D

CLD	Chemiluminescent detector.
CO	Carbon monoxide.
CO_2	Carbon dioxide.
HC	Hydrocarbons.
HCLD	Heated chemiluminescent detector.
HFID	Heated flame ionization detector.
NDIR	Non-dispersive infra-red analyzer.
NIST	National Institute for Standards and Testing.
NO	Nitric Oxide.
NO_2	Nitrogen Dioxide.
NOx	Oxides of nitrogen.
O_2	Oxygen.
PMD	Paramagnetic detector.
ZROD	Zirconiumdioxyde sensor.

TABLE 2.—SYMBOLS USED IN SUBPART D

Symbol	Term	Unit
Conc	Concentration (ppm by volume)	ppm
f	Engine specific parameter considering atmospheric conditions	
F_{FCB}	Fuel specific factor for the carbon balance calculation	
F_{FD}	Fuel specific factor for exhaust flow calculation on dry basis	
F_{FH}	Fuel specific factor representing the hydrogen to carbon ratio	
F_{FW}	Fuel specific factor for exhaust flow calculation on wet basis	
G_{AIRW}	Intake air mass flow rate on wet basis	kg/h
G_{AIRD}	Intake air mass flow rate on dry basis	kg/h
G_{EXHW}	Exhaust gas mass flow rate on wet basis	kg/h
G_{Fuel}	Fuel mass flow rate	kg/h
H	Absolute humidity (water content related to dry air)	g/kg
i	Subscript denoting an individual mode	
K_H	Humidity correction factor	
L	Percent torque related to maximum torque for the test mode	%
Mass	Pollutant mass flow	g/h
$n_{d,i}$	Engine speed (average at the i'th mode during the cycle)	1/min
P_s	Dry atmospheric pressure	kPa
P_d	Test ambient saturation vapor pressure at ambient temperature	kPa
P	Gross power output uncorrected	kW
P_{AUX}	Declared total power absorbed by auxiliaries fitted for the test	kW
P_M	Maximum power measured at the test speed under test conditions	kW
P_i	$P_i = P_{M,i} + P_{AUX,i}$	
P_B	Total barometric pressure (average of the pre-test and post-test values)	kPa
R_a	Relative humidity of the ambient air	%
S	Dynamometer setting	kW
T	Absolute temperature at air inlet	K
T_{be}	Air temperature after the charge air cooler (if applicable) (average)	K
T_{clout}	Coolant temperature outlet (average)	K
T_{Dd}	Absolute dewpoint temperature	K
$T_{d,i}$	Torque (average at the i'th mode during the cycle)	N-m
T_{SC}	Temperature of the intercooled air	K
$T_{ref.}$	Reference temperature	K
V_{EXHD}	Exhaust gas volume flow rate on dry basis	m^3/h
V_{AIRW}	Intake air volume flow rate on wet basis	m^3/h
P_B	Total barometric pressure	kPa
V_{EXHW}	Exhaust gas volume flow rate on wet basis	m^3/h
WF	Weighing factor.	
WF_E	Effective weighing factor.	

TABLE 3.—MEASUREMENT ACCURACY CALIBRATION FREQUENCY (MY96 AND LATER)

No.	Item	Permissible deviation from reading [1]		Calibration frequency
		Nonidle	Idle	
1	Engine speed	±2%	±2%	30 days.

TABLE 3.—MEASUREMENT ACCURACY CALIBRATION FREQUENCY (MY96 AND LATER)—Continued

No.	Item	Permissible deviation from reading [1]		Calibration frequency
		Nonidle	Idle	
2	Torque	±2%	±5%	30 days.
3	Fuel consumption	±1%	±5%	30 days.
4	Air consumption	±2%	±5%	As required.
5	Coolant temperature	±2 °K	Same	As required.
6	Lubricant temperature	±2 °K	Same	As required.
7	Exhaust backpressure	±5%	Same	As required.
8	Inlet depression	±5%	Same	As required.
9	Exhaust gas temperature	±15 °K	Same	As required.
10	Air inlet temperature (combustion air)	±2 °K	Same	As required.
11	Atmospheric pressure	±0.5%	Same	As required.
12	Humidity (combustion air) (relative)	±3.0%	Same	As required.
13	Fuel temperature	±2 °K	Same	As required.
14	Temperature with regard to dilution tunnel	±2 °K	Same	As required.
15	Dilution air humidity	±3% absolute.	Same	As required.
16	HC analyzer	±2% [2]	Same	30 days.
17	CO analyzer	±2% [2]	Same	30 days.
18	NO_X analyzer	±2% [2]	Same	30 days.
19	NO_X converter efficiency check	90%	Same	30 days.
20	CO_2 analyzer	±2% [2]	Same	30 days.

[1] All accuracy requirements pertain to the final recorded value which is inclusive of the data acquisition system.
[2] If reading is under 100 ppm then the accuracy shall be ±2 ppm.

TABLE 4. TEST FUEL SPECIFICATIONS FOR MY96 AND LATER:FEDERAL SPECIFICATIONS

Item	Procedure (ASTM) [1]	Value (type 2–D)
Cetane	D613–86	42–50
Distillation range:		
IBP, °C	D86–90	171–204
10% point, °C	D86–90	204–235
50% point, °C	D86–90	243–283
90% point, °C	D86–90	293–332
EP, °C	D86–90	321–366
Gravity, API	D287–92	33–37
Total sulfur, %mass	D129–91 or D2622–92	>0.05—0.5
Hydrocarbon composition:		
Aromatics, %vol.	D1319–89	[2]10
Parafins,	D1319–89	[3]
Napthenes,		
Olefins,		
Flashpoint, °C (minimum)	D93–90	54
Viscosity @ 38 °C, Centistokes	D445–88	2.0–3.2

[1] All ASTM procedures in this table have been incorporated by reference. See § 89.6.
[2] Minimum.
[3] Remainder.

TABLE 5.—TEST FUEL SPECIFICATIONS FOR MY96 AND LATER: CALIFORNIA SPECIFICATIONS

Item	Procedure (ASTM) [1]	Value (type 2–D)
Cetane	D613–86	40–48
Distillation range:		
IBP, °C	D86–90	171–204
10% point, °C	D86–90	204–235
50% point, °C	D86–90	243–283
90% point, °C	D86–90	293–332
EP, °C	D86–90	321–366
Gravity, API	D287–92	33–37
Total sulfur, %mass	D129–91 or D2622–92	.03–.05
Hydrocarbon composition:		
Aromatics %vol.	D1319–89	[2]10
Parafins	D1319–89	[3]
Napthenes		
Olefins		
Flashpoint, °C (minimum)	D93–90	54

TABLE 5.—TEST FUEL SPECIFICATIONS FOR MY96 AND LATER: CALIFORNIA SPECIFICATIONS—Continued

Item	Procedure (ASTM) [1]	Value (type 2–D)
Viscosity @ 38 °C, centistokes	D445–88	2.0–3.2

[1] All ASTM procedures in this table have been incorporated by reference. See § 89.6.
[2] Minimum.
[3] Remainder.

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Appendix B to Subpart D—Figures

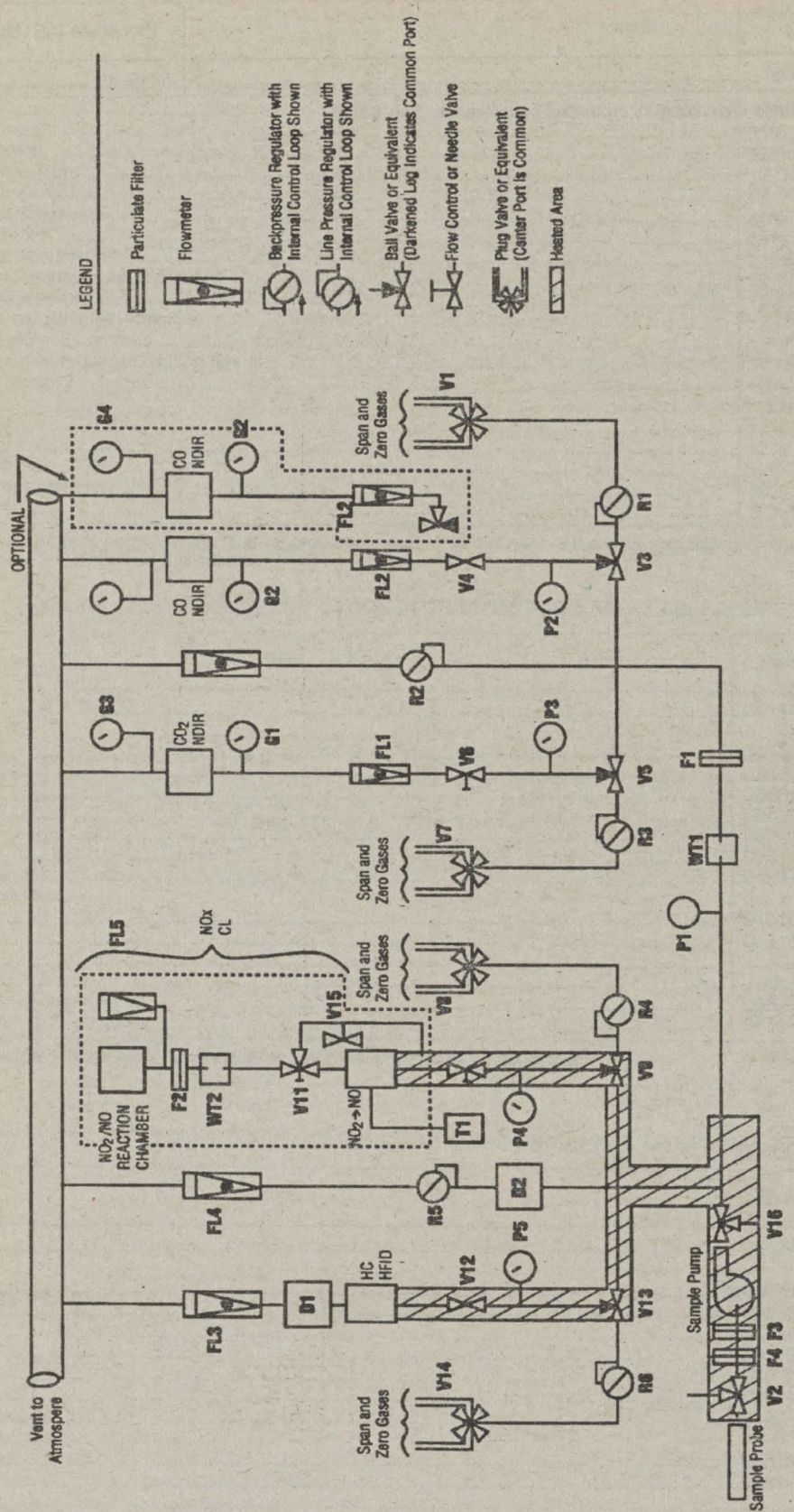

Figure 1. — Exhaust Gas Sampling and Analytical Train

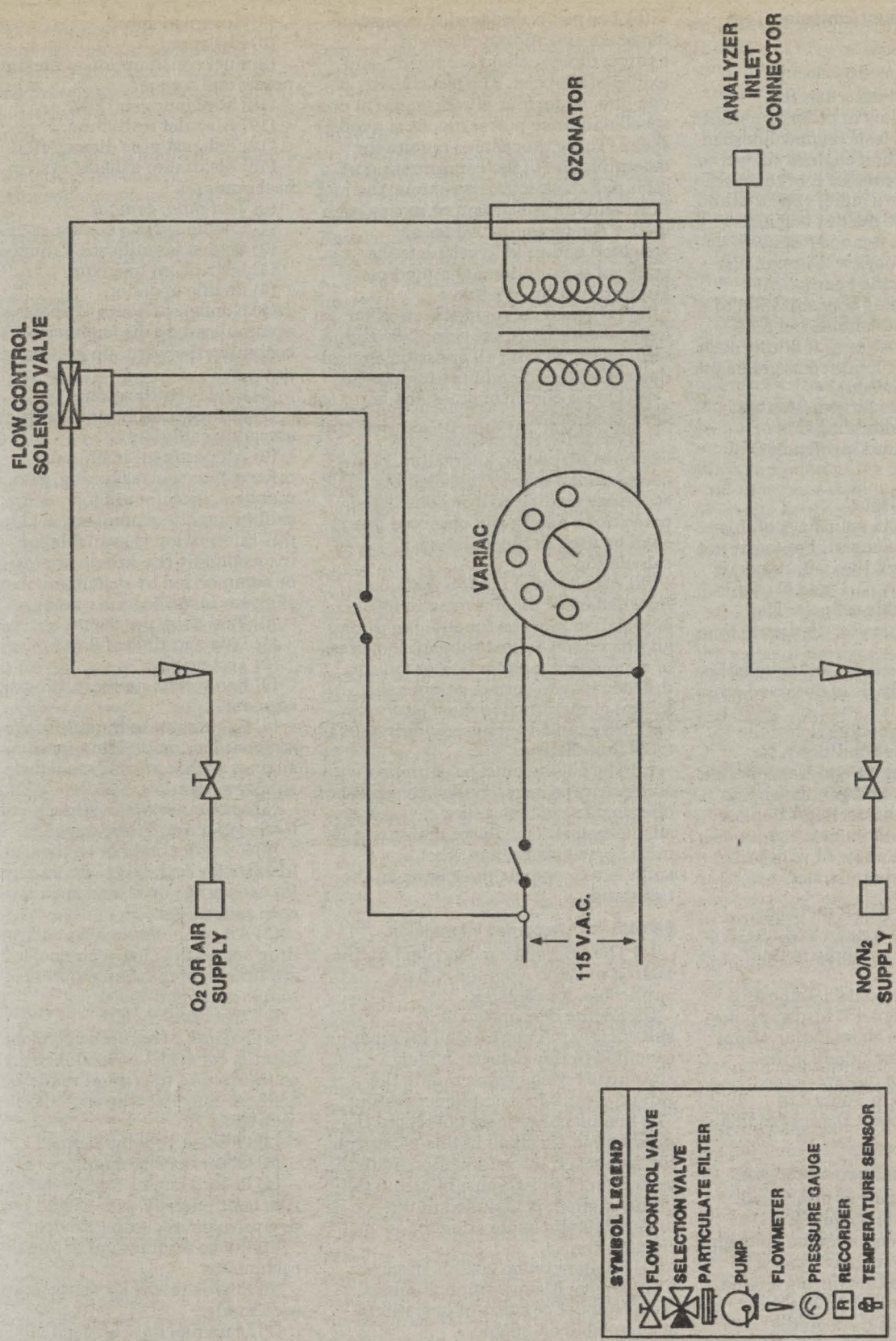

Figure 2. — NOx Converter Efficiency Detector

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Subpart E—Exhaust Emission Test Procedures

§ 89.401–96 Scope; applicability.

(a) This subpart describes the procedures to follow in order to perform exhaust emission tests on new nonroad compression-ignition engines subject to the provisions of subpart B of this part.

(b) Exhaust gases, either raw or dilute, are sampled while the test engine is operated using an 8-mode test cycle on an engine dynamometer. The exhaust gases receive specific component analysis determining concentration of pollutant, exhaust volume, the fuel flow, and the power output during each mode. Emission is reported as grams per kilowatt hour (g/kW-hr).

(c) Requirements for emission test equipment and calibrating this equipment are found in subpart D of this part.

§ 89.402–96 Definitions.

The definitions in subpart A of this part apply to this subpart. For terms not defined in this part, the definitions in part 86, subparts A, D, I, and N of this chapter apply to this subpart. The following definition also applies to this subpart.

Specific emissions, (g/kW-hr), shall be expressed on the basis of observed gross power.

When it is not possible to test the engine in the gross conditions, for example, if the engine and transmission form a single integral unit, the engine may be tested in the net condition. Power corrections from net to gross conditions will be allowed with prior approval of the Administrator.

§ 89.403–96 Symbols/abbreviations.

(a) The abbreviations in § 86.094–3 or § 89.3 of this chapter apply to this subpart.

(b) The abbreviations in Table 1 in appendix A to subpart D also apply to this subpart. Some abbreviations from § 89.3 have been included for the convenience of the reader.

(c) The symbols in Table 2 in appendix A to subpart D apply to this subpart.

§ 89.404–96 Test procedure overview.

(a) The test consists of prescribed sequences of engine operating conditions to be conducted on an engine dynamometer. The exhaust gases, generated raw or dilute during engine operation, are sampled for specific component analysis through the analytical train. The test is applicable to engines equipped with catalytic or direct-flame afterburners, induction system modifications, or other systems, or to uncontrolled engines.

(b) The test is designed to determine the brake-specific emissions of hydrocarbons, carbon monoxide, and oxides of nitrogen. The test consists of one idle mode, four power modes at one speed and three power modes at another speed. These procedures require the determination of the concentration of each pollutant, exhaust volume, the fuel flow, and the power output during each mode. The measured values are weighted and used to calculate the grams of each pollutant emitted per kilowatt hour (g/kW-hr).

(c) (1) When an engine is tested for exhaust emissions, the complete engine shall be tested with all emission control devices installed and functioning.

(2) On air-cooled engines, the fan shall be installed.

(3) Additional accessories (for example, oil cooler, alternators, or air compressors) may be installed but such accessory loading will be considered parasitic in nature and observed power shall be used in the emission calculation.

(d) All emission control systems installed on or incorporated in the application must be functioning during all procedures in this subpart. In cases of component malfunction or failure, maintenance to correct component failure or malfunction must be authorized in accordance with § 86.094–25 of this chapter.

(e) The engine must be equipped with an electrical generation device typical of one used in customer service (such as an alternator). The power drain from it must be no greater than what is sufficient to operate the engine on the test stand.

§ 89.405–96 Recorded information.

(a) The information described in this section must be recorded, where applicable, for each test.

(b) *Engine description and specification.* A copy of the information specified in this paragraph must accompany each engine sent to the Administrator for compliance testing. The manufacturer need not record the information specified in this paragraph for each test if the information, with the exception of paragraphs (b)(3) and (b)(9) of this section, is included in the manufacturer's application for certification.

(1) Engine-system combination.

(2) Engine identification numbers.

(3) Number of hours of operation accumulated on engine.

(4) Rated maximum horsepower and torque.

(5) Maximum horsepower and torque speeds.

(6) Engine displacement.

(7) Governed speed.

(8) Idle rpm.

(9) Fuel consumption at maximum power and torque.

(10) Maximum air flow.

(11) Air inlet restriction.

(12) Exhaust pipe diameter(s).

(13) Maximum exhaust system backpressure.

(c) *Test data; general.*

(1) Engine-system combination.

(2) Engine identification number.

(3) Instrument operator.

(4) Engine operator.

(5) Number of hours of operation accumulated on the engine prior to beginning the warm-up portion of the test.

(6) Fuel identification.

(7) Date of most recent analytical assembly calibration.

(8) All pertinent instrument information such as tuning, gain, serial numbers, detector number, and calibration curve numbers. As long as this information is available for inspection by the Administrator, it may be summarized by system number or analyzer identification numbers.

(d) *Test data; pre-test.*

(1) Date and time of day.

(2) Test number.

(3) Barometric pressure, pre-test segment.

(4) Engine intake humidity, pre-test segment for compression-ignition engines with non-conditioned air supply systems.

(5) Maximum observed torque for intermediate and rated speeds.

(6) Recorder chart or equivalent. Identify for each test segment zero traces for each range used, and span traces for each range used.

(7) Air temperature after and pressure drop across the charge air cooler (if applicable) at maximum observed torque and rated speed.

(e) *Test data; modal.*

(1) Recorder chart or equivalent. Identify for each test mode the emission concentration traces and the associated analyzer range(s). The start and finish of each test.

(2) Observed engine torque.

(3) Observed engine rpm.

(4) Record engine torque and engine rpm continuously with a chart recorder or equivalent recording device.

(5) Intake air flow and depression for each mode.

(6) Engine intake air temperature for each mode.

(7) Mass fuel flow for each mode.

(8) Engine intake humidity.

(9) Coolant temperature outlet.

(10) Engine fuel inlet temperature, location to be representative of in-use as specified by each manufacturer.

(f) *Test data; post-test.*

(1) Recorder chart or equivalent. Identify the zero traces for each range used and the span traces for each range used. Identify hangup check, if performed.

(2) Total number of hours of operation accumulated on the engine.

(3) Barometric pressure, post-test segment.

(4) Engine intake humidity, post-test segment for compression-ignition engines with non-conditioned air supply systems.

§ 89.406–96 Pre-test procedures.

(a) Allow a minimum of 30 minutes warmup in the standby or operating mode prior to spanning the analyzers.

(b) Replace or clean the filter elements and then vacuum leak check the system per § 89.316–96(a). A pressure leak check is also permitted per § 89.316–96(b). Allow the heated sample line, filters, and pumps to reach operating temperature.

(c) Perform the following system checks:

(1) Check the sample-line temperature (see § 86.310–79 of this chapter for raw test procedures or § 86.1310–90 of this chapter for dilute test procedures).

(2) Check that the system response time has been accounted for prior to sample collection data recording.

(3) A hang-up check is permitted, but is optional.

(d) Check analyzer zero and span at a minimum before and after each test. Further, check analyzer zero and span any time a range change is made or at the maximum demonstrated time span for stability for each analyzer used.

(e) Check system flow rates and pressures.

§ 89.407–96 Engine dynamometer test run.

(a) Measure and record the temperature of the air supplied to the engine, the fuel temperature at the pump inlet, and the observed barometric pressure.

(b) The governor and fuel system shall have been adjusted to provide engine performance at the levels reported in the application for certification required under § 89.115–96.

(c) The following steps are taken for each test:

(1) Install instrumentation and sample probes as required.

(2) Perform the pre-test procedure as specified in § 89.406–96.

(3) Read and record the general test data as specified in § 89.405–96(c).

(4) Start cooling system.

(5) Precondition (warm up) the engine in the following manner:

(i) Operate the engine at idle for 2 to 3 minutes;

(ii) Operate the engine at approximately 50 percent power at the peak torque speed for 5 to 7 minutes;

(iii) Operate the engine at rated speed and maximum horsepower for 25 to 30 minutes;

(iv) Optional. It is permitted to precondition the engine at rated speed and maximum horsepower until the oil and water temperatures are stabilized. The temperatures are defined as stabilized if they are maintained within ±2 °C for 2 minutes. The engine must be operated a minimum of 10 minutes for this option. This optional procedure may be substituted for the procedure in paragraph (c)(5)(iii) of this section;

(v) Optional. If the engine has been operating on service accumulation for a minimum of 40 minutes, the service accumulation may be substituted for the procedure in paragraphs (c)(5)(i) through (iii) of this section.

(6) Read and record all pre-test data specified in § 89.405–96(d).

(7) Start the test cycle (see § 89.410–96) within 20 minutes of the end of the warmup. (See paragraph (c)(13) of this section.)

(8) During the first mode calculate the torque corresponding to 75, 50, and 10 percent of the maximum observed torque for the rated speed.

(9) During the fifth mode calculate the torque corresponding to 75 and 50 percent of the maximum observed torque for the intermediate speed.

(10) Record all modal data specified in § 89.405–96(e) during a minimum of the last 60 seconds of each mode.

(11) Record the analyzer(s) response to the exhaust gas during the a minimum of the last 60 seconds of each mode.

(12) Test modes may be repeated, as long as the engine is preconditioned by running the previous mode.

(13) If a delay of more than 20 minutes occurs between the end of one mode and the beginning of another mode, the test is void. If the delay is under four hours, the test may be restarted without preconditioning (begin at the point in the procedure described at paragraph (c)(6) of this section). If the delay exceeds 4 hours, the test shall include preconditioning (begin at paragraph (c)(2) of this section).

(14) The engine speed and torque must be measured within the accuracy requirements of Table 3 (in appendix A to subpart D), and maintained within the requirements of Table 1 (in appendix B to this subpart) during a minimum of the last 60 seconds of each mode.

(15) If at any time during a test mode, the test equipment malfunctions or the specifications in paragraph (c)(14) of this section are not met, the test mode is void and may be aborted. The test mode may be restarted without preconditioning (begin with paragraph (c)(6) of this section).

(16) Fuel flow and air flow during the idle load condition may be determined just prior to or immediately following the dynamometer sequence, if longer times are required for accurate measurements.

(d) *Exhaust gas measurements.* (1) Measure HC, CO, CO_2, and NO_x concentration in the exhaust sample.

(2) Each analyzer range that may be used during a test mode must have the zero and span responses recorded prior to the execution of that test mode. Only the zero and span for the range(s) used to measure the emissions during a test mode are required to be recorded after the completion of the test mode.

(3) It is permissible to change filter elements between test modes.

(4) A leak check is permitted between test segments.

(5) A hangup check is permitted between test segments.

(6) If, during the emission measurement portion of a test segment, the value of the gauges downstream of the NDIR analyzer(s) *G3* or *G4* (see Figure 1 in appendix B to subpart D) differs by more than ±0.5 kPa from the pretest value, the test segment is void.

§ 89.408–96 Post-test procedures.

(a) A hangup check is recommended at the completion of the last test mode using the following procedure:

(1) Within 30 seconds introduce a zero-grade gas or room air into the sample probe or valve *V2* (see Figure 1 in appendix B to subpart D) to check the "hangup zero" response. Simultaneously start a time measurement.

(2) Select the lowest HC range used during the test.

(3) Within four minutes of beginning the time measurement in paragraph (a)(1) of this section, the difference between the span-zero response and the hangup zero response shall not be greater than 5.0 percent of full scale or 10 ppmC whichever is greater.

(b) Begin the analyzer span checks within 6 minutes after the completion of the last mode in the test. Record for each analyzer the zero and span response for each range used during the preceding test or test segment.

(c) If during the test, the filter element(s) were replaced or cleaned, a vacuum check must be performed per § 89.316–96(a) immediately after the span checks. If the vacuum side leak check does not meet the requirements of § 89.316–96(a), the test is void.

(d) Record the post-test data specified in § 89.405–96(f).

(e) For a valid test, the analyzer drift between the before-mode and after-mode span checks for each analyzer must meet the following requirements:

(1) The span drift (defined as the change in the difference between the zero response and the span response) must not exceed 2 percent of full-scale chart deflection for each range used.

(2) The zero response drift must not exceed 2 percent of full-scale chart deflection for each range used above 155 ppm (or ppmC) or 3 percent of full-scale chart deflection for each range below 155 ppm (or ppmC).

§ 89.409–96 Data logging.

(a) A computer or any other automatic data processing device(s) may be used as long as the system meets the requirements of this subpart.

(b) Determine from the data collection records the analyzer responses corresponding to the end of each mode.

(c) Record data at a minimum of once every 5 seconds.

(d) Determine the final value for CO_2, CO, HC, and NO_x concentrations by averaging the concentration of each point taken during the sample period for each mode.

(e) For purposes of this section, calibration data includes calibration curves, linearity curves, span-gas responses, and zero-gas responses.

§ 89.410–96 Engine test cycle.

(a) The 8-mode cycle (see Table 1 in Appendix B to this subpart) shall be followed in dynamometer operation tests of compression-ignition nonroad engines.

(b) During each non-idle mode, hold the specified speed and load to within ±2 percent of point. During each idle mode, speed must be held within the manufacturer's specifications for the engine, and the throttle must be in the fully closed position and torque must not exceed 5 percent of the peak torque value of mode 5.

(c) If the operating conditions specified in paragraph (b) of this section for modes 2, 3, 4, 6, and 7 cannot be maintained, the Administrator may authorize deviations from the specified load conditions. Such deviations shall not exceed 10 percent of the maximum torque at the test speed. The minimum deviations, above and below the specified load, necessary for stable operation shall be determined by the manufacturer and approved by the Administrator prior to the test run.

(d) Power generated during the idle mode may not be included in the calculation of emission results.

§ 89.411–96 Exhaust sample procedure—gaseous components.

(a) *Automatic data collection equipment requirements.* The analyzer response may be read by automatic data collection (ADC) equipment such as computers, data loggers, and so forth. If ADC equipment is used, the following is required:

(1) For bag sample analysis, the analyzer response must be stable at greater than 99 percent of the final reading for the dilute exhaust sample bag. A single value representing the average chart deflection over a 10-second stabilized period shall be stored.

(2) For continuous analysis systems, a single value representing the average integrated concentration over a cycle shall be stored.

(3) The chart deflections or average integrated concentrations required in paragraphs (a)(1) and (a)(2) of this section may be stored on long-term computer storage devices such as computer tapes, storage discs, punch cards, and so forth, or they may be printed in a listing for storage. In either case a chart recorder is not required and records from a chart recorder, if they exist, need not be stored.

(4) If ADC equipment is used to interpret analyzer values, the ADC equipment is subject to the calibration specifications of the analyzer as if the ADC equipment is part of analyzer system.

(b) Data records from any one or a combination of analyzers may be stored as chart recorder records.

(c) *Bag sample analysis.* For bag sample analysis perform the following sequence:

(1) Warm up and stabilize the analyzers; clean and/or replace filter elements, conditioning columns (if used), and so forth, as necessary.

(2) Obtain a stable zero reading.

(3) Zero and span the analyzers with zero and span gases. The span gases must have concentrations between 75 and 100 percent of full-scale chart deflection. The flow rates and system pressures during spanning shall be approximately the same as those encountered during sampling. A sample bag may be used to identify the required analyzer range.

(4) Recheck zero response. If this zero response differs from the zero response recorded in paragraph (c)(3) of this section by more than 1 percent of full scale, then paragraphs (c)(2), (c)(3), and (c)(4) of this section must be repeated.

(5) If a chart recorder is used, identify and record the most recent zero and span response as the pre-analysis values.

(6) If ADC equipment is used, electronically record the most recent zero and span response as the pre-analysis values.

(7) Measure HC, CO, CO_2, and NO_x background concentrations in the sample bag(s) with approximately the same flow rates and pressures used in paragraph (c)(3) of this section. (Constituents measured continuously do not require bag analysis.)

(8) A post-analysis zero and span check of each range must be performed and the values recorded. The number of events that may occur between the pre- and post-analysis checks is not specified. However, the difference between pre-analysis zero and span values (recorded in paragraph (c)(5) or (c)(6) of this section) versus those recorded for the post-analysis check may not exceed the zero drift limit or the span drift limit of 2 percent of full-scale chart deflection for any range used. Otherwise the test is void.

(d) *Continuous sample analysis.* For continuous sample analysis perform the following sequence:

(1) Warm up and stabilize the analyzers; clean and/or replace filter elements, conditioning columns (if used), and so forth, as necessary.

(2) Leak check portions of the sampling system that operate at negative gauge pressures when sampling, and allow heated sample lines, filters, pumps, and so forth to stabilize at operating temperature.

(3) Optional: Perform a hangup check for the HFID sampling system:

(i) Zero the analyzer using zero air introduced at the analyzer port.

(ii) Flow zero air through the overflow sampling system. Check the analyzer response.

(iii) If the overflow zero response exceeds the analyzer zero response by 2 percent or more of the HFID full-scale deflection, hangup is indicated and corrective action must be taken.

(iv) The complete system hangup check specified in paragraph (e) of this section is recommended as a periodic check.

(4) Obtain a stable zero reading.

(5) Zero and span each range to be used on each analyzer operated prior to the beginning of the test cycle. The span gases shall have a concentration between 75 and 100 percent of full-scale chart deflection. The flow rates and system pressures shall be approximately the same as those encountered during sampling. The HFID analyzer shall be zeroed and spanned through the overflow sampling system.

(6) Re-check zero response. If this zero response differs from the zero response recorded in paragraph (d)(5) of this

section by more than 1 percent of full scale, then paragraphs (d)(4), (d)(5), and (d)(6) of this section must be repeated.

(7) If a chart recorder is used, identify and record the most recent zero and span response as the pre-analysis values.

(8) If ADC equipment is used, electronically record the most recent zero and span response as the pre-analysis values.

(9) Collect background HC, CO, CO_2, and NO_X in a sample bag (for dilute exhaust sampling only, see § 89.420–96).

(10) Perform a post-analysis zero and span check for each range used at the conditions specified in paragraph (d)(5) of this section. Record these responses as the post-analysis values.

(11) Neither the zero drift nor the span drift between the pre-analysis and post-analysis checks on any range used may exceed 3 percent for HC, or 2 percent for NO_X, CO, and CO_2, of full scale chart deflection, or the test is void. (If the HC drift is greater than 3 percent of full-scale chart deflection, hydrocarbon hangup is likely.)

(12) Determine background levels of NO_X, CO, or CO_2 (for dilute exhaust sampling only) by the bag sample technique outlined in paragraph (c) of this section.

(e) *Hydrocarbon hangup.* If HC hangup is indicated, the following sequence may be performed:

(1) Fill a clean sample bag with background air.

(2) Zero and span the HFID at the analyzer ports.

(3) Analyze the background air sample bag through the analyzer ports.

(4) Analyze the background air through the entire sample probe system.

(5) If the difference between the readings obtained is 2 ppm or more, clean the sample probe and the sample line.

(6) Reassemble the sample system, heat to specified temperature, and repeat the procedure in paragraphs (e)(1) through (e)(6) of this section.

§ 89.412–96 Raw gaseous exhaust sampling and analytical system description.

(a) *Schematic drawing.* An example of a sampling and analytical system which may be used for testing under this subpart is shown in Figure 1 in appendix B to subpart D. All components or parts of components that are wetted by the sample or corrosive calibration gases shall be either chemically cleaned stainless steel or inert material, for example, polytetrafluoroethylene resin. The use of "gauge savers" or "protectors" with nonreactive diaphragms to reduce dead volumes is permitted.

(b) *Sample probe.* (1) The sample probe shall be a straight, closed-end, stainless steel, multi-hole probe. The inside diameter shall not be greater than the inside diameter of the sample line plus 0.03 cm. The wall thickness of the probe shall not be greater than 0.10 cm. The fitting that attaches the probe to the exhaust pipe shall be as small as practical in order to minimize heat loss from the probe.

(2) The probe shall have a minimum of three holes. The spacing of the radial planes for each hole in the probe must be such that they cover approximately equal cross-sectional areas of the exhaust duct. See Figure 1 in appendix A to this subpart. The angular spacing of the holes must be approximately equal. The angular spacing of any two holes in one plane may not be 180° ±20° (that is, section view C-C of Figure 1 in appendix A to this subpart). The holes should be sized such that each has approximately the same flow. If only three holes are used, they may not all be in the same radial plane.

(3) The probe shall extend radially across the exhaust duct. The probe must pass through the approximate center and must extend across at least 80 percent of the diameter of the duct.

(c) *Sample transfer line.* (1) The maximum inside diameter of the sample line shall not exceed 1.32 cm.

(2) If valve *V2* is used, the sample probe must connect directly to valve *V2*. The location of optional valve *V2* may not be greater than 1.22 m from the exhaust duct.

(3) The location of optional valve *V16* may not be greater than 61 cm from the sample pump. The leakage rate for this section on the pressure side of the sample pump may not exceed the leakage rate specification for the vacuum side of the pump.

(d) *Venting.* All vents, including analyzer vents, bypass flow, and pressure relief vents of regulators, should be vented in such a manner to avoid endangering personnel in the immediate area.

(e) Any variation from the specifications in this subpart including performance specifications and emission detection methods may be used only with prior approval by the Administrator.

(f) Additional components, such as instruments, valves, solenoids, pumps, switches, and so forth, may be employed to provide additional information and coordinate the functions of the component systems.

(g) The following requirements must be incorporated in each system used for raw testing under this subpart.

(1) The sample for all components shall be taken with one sample probe, except as allowed under § 89.413–96, and internally split to the different analyzers.

(2) The sample transport system from the engine exhaust pipe to the HC analyzer and the NO_X analyzer must be heated as indicated in Figure 1 in appendix B of subpart D.

§ 89.413–96 Raw sampling procedures.

Follow these procedures when sampling for gaseous emissions.

(a) The gaseous emission sampling probe must be installed at least 0.5 m or 3 times the diameter of the exhaust pipe—whichever is the larger—upstream of the exit of the exhaust gas system.

(b) In the case of a multi-cylinder engine with a branched exhaust manifold, the inlet of the probe shall be located sufficiently far downstream so as to ensure that the sample is representative of the average exhaust emissions from all cylinders.

(c) In multi-cylinder engines having distinct groups of manifolds, such as in a "Vee" engine configuration, it is permissible to:

(1) Sample after all exhaust pipes have been connected together into a single exhaust pipe.

(2) For each mode, sample from each exhaust pipe and average the gaseous concentrations to determine a value for each mode.

(3) Sample from all exhaust pipes simultaneously with the sample lines connected to a common manifold prior to the analyzer. It must be demonstrated that the flow rate through each individual sample line is ±4 percent of the average flow rate through all the sample lines.

(4) Use another method, if it has been approved in advance by the Administrator.

(d) All heated sampling lines shall be fitted with a heated filter to extract solid particles from the flow of gas required for analysis. The sample line for CO, CO_2, and O_2 analysis may be heated or unheated.

(e) If the composition of the exhaust gas is influenced by any treatment such as heat exchanger or air injection (except catalysts and soot filters) then the exhaust probe must be taken upstream of this device.

§ 89.414–96 Air flow measurement specifications.

(a) The air flow measurement method used must have a range large enough to accurately measure the air flow over the engine operating range during the test. Overall measurement accuracy must be

±2 percent of the reading for all modes except the idle mode. For the idle mode, the measurement accuracy shall be ±5 percent or less of the reading. The Administrator must be advised of the method used prior to testing.

(b) When an engine system incorporates devices that affect the air flow measurement (such as air bleeds) that result in understated exhaust emission results, corrections to the exhaust emission results shall be made to account for such effects.

§ 89.415–96 Fuel flow measurement specifications.

The fuel flow rate measurement instrument must have a minimum accuracy of ±1 percent of full-scale flow rate for each measurement range used. An exception is allowed at the idle point. For this mode (idle), the minimum accuracy is ±2 percent of full-scale flow rate for the measurement range used. The controlling parameters are the elapsed time measurement of the event and the weight or volume measurement.

§ 89.416–96 Raw exhaust gas flow.

The exhaust gas flow shall be determined by one of the methods described in this section and conform to the tolerances of Table 3 in appendix A to subpart D:

(a) Measurement of the air flow and the fuel flow by suitable metering systems (for details see SAE J244. This procedure has been incorporated by reference. See § 89.6.) and calculation of the exhaust gas flow as follows:

$G_{EXHW}=G_{AIRW}+G_{FUEL}$ (for wet exhaust mass)

or

$V_{EXHD}=V_{AIRD}+(-.767)\times G_{FUEL}$ (for dry exhaust volume)

or

$V_{EXHW}=V_{AIRW}+.749\times G_{FUEL}$ (for wet exhaust volume)

(b) Exhaust mass calculation from fuel consumption (see § 89.415–96) and exhaust gas concentrations using the method found in § 89.418–96.

§ 89.417–96 Data evaluation for gaseous emissions.

For the evaluation of the gaseous emission recording, the last 60 seconds of each mode are recorded, and the average values for HC, CO, CO_2, and NO_X during each mode are determined from the average concentration readings determined from the corresponding calibration data.

§ 89.418–96 Raw emission sampling calculations.

(a) The final test results shall be derived through the steps described in this section.

(b) The exhaust gas flow rate G_{EXHW} and V_{EXHW} shall be determined (see § 89.416–96) for each mode.

(c) When applying G_{EXHW} the measured concentration shall be converted to a wet basis according to the following formula, if not already measured on a wet basis.

$$K_W=\left[1-F_{FH}\times\frac{G_{fuel}}{G_{air}}\right]-K_{W1}\ \text{only applicable for raw exhaust}$$

F_{FH}=1.783 if air/fuel ratio is 1.00
1.865 if air/fuel ratio is 1.35
1.920 if air/fuel ratio is 3.50

(d) As the NO_X emission depends on ambient air conditions, the NO_X concentration shall be corrected for ambient air temperature and humidity with the factor K_H given in the following formulas. Equation (1) of this paragraph is to be used when testing in uncontrolled dynamometer rooms or at other sites with uncontrolled temperatures and humidities. Equation (2) of this paragraph is to be used for all testing when performed in controlled condition rooms. For engines operating on alternative combustion cycles, other correction formulas may be used if they can be justified or validated.

(1) For compression-ignition engines operating in uncontrolled conditions:

$$K_H=\frac{1}{1+A(H-10.71)+B(T-298)}$$

Where:
A=0.309 (f/a) − 0.0266
B=-0.209 (f/a)+0.00954
T=temperature of the air in K
H=humidity of the inlet air in grams of water per kilogram of dry air in which:

$$H=\frac{6.220\times R_a\times p_d}{(p_B-p_d)\times R_a\times 10^{-2}}$$

(2) For compression-ignition engines operating in controlled conditions:

$$K_H=\frac{1}{(1-0.0182(H-10.71))}$$

If required the dry fuel/air ratio may be calculated from the following equation:
Where:

$$(f/a)\ Stoich=\frac{M_c+aM_H}{138.18(1+a/4)}$$

$$X=\frac{DCO_2}{10^2}+\frac{DCO}{10^6}+\frac{DHC}{10^6}$$

$K=3.5$

(e) The pollutant mass flow for each mode shall be calculated as follows:

Gas mass = u×Gas conc.×G_{EXHW}
Gas mass = v×Gas conc.×V_{EXHD}
Gas mass = w×Gas conc.×V_{EXHW}

The coefficients u (wet), v (dry), and w (wet) are to be used according to the following table:

Gas	u	v	w	Conc.
NO_X	0.001587	0.00205	0.00205	ppm.
CO	0.000966	0.00125	0.00125	ppm.
HC	0.000478		0.000618	ppm.
CO_2	15.19	19.64	19.64	percent.
O_2	11.05	14.29	14.29	percent.

Note: The given coefficients u, v, and w are calculated for 273.15 °K (0 °C) and 101.3 kPa. In cases where the reference conditions vary from those stated, an error may occur in the calculations.

(f) The following equations may be used to calculate the coefficients u, v, and w in paragraph (e) of this section for other conditions of temperature and pressure.

(1) For ideal gases at 273.15 °K (0 °C) and 101.3 kPa:

For the calculation of u, v, and w for NO_X (as NO_2), CO, HC (in paragraph (e) of this section as $H_{1.85}$; CO_2; O_2

w=4.4615.10^{-5} * M if conc. in ppm

w=4.4615.10^{-1} * M if conc. in percent

v=w

u=w/p_{Air}

M=Molecular weight

p_{Air}=Density of dry air at 273.15 °K (0 °C), 101.3 kPa=1.293 kg/m³

(2) For real gases at 273.15 °K (0 °C) and 101.3 kPa: For the calculation of u, v, and w

w=gas×10^{-6} if conc. in ppm

v=w

u = w/p_{Air}

$$\text{conc}\frac{g}{m_3} = \frac{M}{M_v} \times \frac{T_o}{T_o + T} \times \frac{P}{P_o} \quad \frac{\text{Conc(ppm)}}{10^6}$$

—for real gases

$$\text{conc}\frac{g}{m_3} = \rho_{Gas} \times \frac{T_o}{T_o + T} \times \frac{P}{P_o} \quad \frac{\text{Conc(ppm)}}{10^6}$$

with:

1% = 10⁴ ppm

M = Molecular weight in g/Mol

M_v = Molecular Volume = 22.414 × 10^{-3} m³/Mol for ideal gases

T_o = reference temperature 273.15 K

p_o = reference pressure 101.3 kPa

T = Temperature in °C

p = pressure in kPa

p_{Gas} = Density of the measured gas at 0 °C, 101.3 kPa

Conc. = Gas concentration

(g) The emission shall be calculated for all individual components in the following way:

$$\text{individual gas} = \frac{\sum_{i=1}^{i=n} \text{Gas Mass}_i \times WF_i}{\sum_{i=1}^{i=n-1} P_i \times WF_i}$$

The weighting factors and the number of modes (n) used in the above calculation are according to § 89.410–96.

§ 89.419–96 Dilute gaseous exhaust sampling and analytical system description.

(a) *General.* The exhaust gas sampling system described in this section is designed to measure the true mass of gaseous emissions in the exhaust of petroleum-fueled nonroad compression-ignition engines. This system utilizes the CVS concept (described in § 86.1310–90 of this chapter) of measuring mass emissions of HC, CO, and CO_2. A continuously integrated system is required for HC and NO_X measurement and is allowed for all CO and CO_2 measurements. The mass of gaseous emissions is determined from the sample concentration and total flow over the test period. As an option, the measurement of total fuel mass consumed over a cycle may be substituted for the exhaust measurement of CO_2. General requirements are as follows:

(1) This sampling system requires the use of a PDP–CVS and a heat exchanger or a CFV–CVS with either a heat exchanger or electronic flow compensation. Figure 2 in appendix A to this subpart is a schematic drawing of the PDP–CVS system. Figure 3 in appendix A to this subpart is a schematic drawing of the CFV–CVS system.

(2) The HC analytical system for petroleum-fueled compression-ignition engines requires a heated flame ionization detector (HFID) and heated sample system (191 ±11 °C).

(i) The HFID sample must be taken directly from the diluted exhaust stream through a heated probe and integrated continuously over the test cycle. Unless compensation for varying flow is made, the HFID must be used with a constant flow system to ensure a representative sample.

(ii) The heated probe shall be located in the primary dilution tunnel and far enough downstream of the mixing chamber to ensure a uniform sample distribution across the CVS duct at the point of sampling.

(3) The CO and CO_2 analytical system requires:

(i) Bag sampling (see § 86.1309–90 of this chapter) and analytical capabilities (see § 86.1311–90 of this chapter), as shown in Figure 2 and Figure 3 in appendix A to this subpart; or

(ii) Continuously integrated measurement of diluted CO and CO_2 meeting the minimum requirements and technical specifications contained in paragraph (b)(4) of this section. Unless compensation for varying flow is made, a constant flow system must be used to ensure a representative sample.

(4) The NO_X analytical system requires a continuously integrated measurement of diluted NO_X meeting the minimum requirements and technical specifications contained in paragraph (b)(4) of this section. Unless compensation for varying flow is made, a constant flow system must be used to ensure a representative sample.

(5) Since various configurations can produce equivalent results, exact conformance with these drawings is not required. Additional components such as instruments, valves, solenoids, pumps, and switches may be used to provide additional information and coordinate the functions of the component systems. Other components, such as snubbers, which are not needed to maintain accuracy on some systems, may be excluded if their exclusion is based upon good engineering judgment.

(6) Other sampling and/or analytical systems may be used if shown to yield equivalent results and if approved in advance by the Administrator.

(b) *Component description.* The components necessary for exhaust sampling shall meet the following requirements:

(1) *Exhaust dilution system.* The PDP–CVS shall conform to all of the requirements listed for the exhaust gas PDP–CVS in § 86.1309–90(b) of this chapter. The CFV–CVS shall conform to all of the requirements listed for the exhaust gas CFV–CVS in § 86.1309–90(c) of this chapter. In addition, the CVS must conform to the following requirements:

(i) The flow capacity of the CVS must be sufficient to maintain the diluted exhaust stream at or below the temperature required for the measurement of hydrocarbon emissions noted in the following paragraph and to

prevent condensation of water at any point in the dilution tunnel.

(ii) The flow capacity of the CVS must be sufficient to maintain the diluted exhaust stream in the primary dilution tunnel at a temperature of 191 °C or less at the sampling zone for hydrocarbon measurement and as required to prevent condensation at any point in the dilution tunnel. Gaseous emission samples may be taken directly from this sampling point.

(iii) For the CFV–CVS, either a heat exchanger or electronic flow compensation is required (see Figure 3 in appendix A to this subpart).

(iv) For the CFV–CVS when a heat exchanger is used, the gas mixture temperature, measured at a point immediately ahead of the critical flow venturi, shall be within ±11 °C) of the average operating temperature observed during the test with the simultaneous requirement that condensation does not occur. The temperature measuring system (sensors and readout) shall have an accuracy and precision of ±2 °C. For systems utilizing a flow compensator to maintain proportional flow, the requirement for maintaining constant temperature is not necessary.

(v) The primary dilution air shall have a temperature of 25 °C ±5 °C.

(2) *Continuous HC measurement system.* (i) The continuous HC sample system (as shown in Figure 2 or 3 in appendix A to this subpart) uses an "overflow" zero and span system. In this type of system, excess zero or span gas spills out of the probe when zero and span checks of the analyzer are made. The "overflow" system may also be used to calibrate the HC analyzer per § 86.1321–90(b) of this chapter, although this is not required.

(ii) No other analyzers may draw a sample from the continuous HC sample probe, line or system, unless a common sample pump is used for all analyzers and the sample line system design reflects good engineering practice.

(iii) The overflow gas flow rates into the sample line shall be at least 105 percent of the sample system flow rate.

(iv) The overflow gases shall enter the heated sample line as close as practical to the outside surface of the CVS duct or dilution tunnel.

(v) The continuous HC sampling system shall consist of a probe (which must raise the sample to the specified temperature) and, where used, a sample transfer system (which must maintain the specified temperature). The continuous hydrocarbon sampling system (exclusive of the probe) shall:

(A) Maintain a wall temperature of 191 °C ±11 °C as measured at every separately controlled heated component (that is, filters, heated line sections), using permanent thermocouples located at each of the separate components.

(B) Have a wall temperature of 191 °C ±11 °C over its entire length. The temperature of the system shall be demonstrated by profiling the thermal characteristics of the system where possible at initial installation and after any major maintenance performed on the system. The profiling shall be accomplished using the insertion thermocouple probing technique. The system temperature will be monitored continuously during testing at the locations and temperature described in § 86.1310–90(b)(3)(v).

(C) Maintain a gas temperature of 191 °C ±11 °C immediately before the heated filter and HFID. These gas temperatures will be determined by a temperature sensor located immediately upstream of each component.

(vi) The continuous hydrocarbon sampling probe shall:

(A) Be defined as the first 25 cm to 76 cm of the continuous hydrocarbon sampling system.

(B) Have a 0.48 cm minimum inside diameter.

(C) Be installed in the primary dilution tunnel at a point where the dilution air and exhaust are well mixed (that is, approximately 10 tunnel diameters downstream of the point where the exhaust enters the dilution tunnel).

(D) Be sufficiently distant (radially) from other probes and the tunnel wall so as to be free from the influence of any wakes or eddies.

(E) Increase the gas stream temperature to 191 °C ±11 °C at the exit of the probe. The ability of the probe to accomplish this shall be demonstrated using the insertion thermocouple technique at initial installation and after any major maintenance. Compliance with the temperature specification shall be demonstrated by continuously recording during each test the temperature of either the gas stream or the wall of the sample probe at its terminus.

(vii) The response time of the continuous measurement system shall be no greater than:

(A) 1.5 seconds from an instantaneous step change at the port entrance to the analyzer to within 90 percent of the step change.

(B) 20 seconds from an instantaneous step change at the entrance to the sample probe or overflow span gas port to within 90 percent of the step change. Analysis system response time shall be coordinated with CVS flow fluctuations and sampling time/test cycle offsets if necessary.

(C) For the purpose of verification of response times, the step change shall be at least 60 percent of full-scale chart deflection.

(3) *Primary dilution tunnel.* (i) The primary dilution tunnel shall be:

(A) Small enough in diameter to cause turbulent flow (Reynolds Number greater than 4000) and of sufficient length to cause complete mixing of the exhaust and dilution air;

(B) At least 46 cm in diameter; (engines below 110 kW may use a dilution tunnel that is 20 cm in diameter or larger)

(C) Constructed of electrically conductive material which does not react with the exhaust components; and

(D) Electrically grounded.

(ii) The temperature of the diluted exhaust stream inside of the primary dilution tunnel shall be sufficient to prevent water condensation.

(iii) The engine exhaust shall be directed downstream at the point where it is introduced into the primary dilution tunnel.

(4) *Continuously integrated NO_X, CO, and CO_2 measurement systems.* (i) The sample probe shall:

(A) Be in the same plane as the continuous HC probe, but shall be sufficiently distant (radially) from other probes and the tunnel wall so as to be free from the influences of any wakes or eddies.

(B) Heated and insulated over the entire length, to prevent water condensation, to a minimum temperature of 55 °C. Sample gas temperature immediately before the first filter in the system shall be at least 55 °C.

(ii) The continuous NO_X, CO, or CO_2 sampling and analysis system shall conform to the specifications of part 86, subpart D of this chapter with the following exceptions and revisions:

(A) The system components required to be heated by part 86, subpart D of this chapter need only be heated to prevent water condensation, the minimum component temperature shall be 55 °C.

(B) The system response shall be no greater than 20 seconds. Analysis system response time shall be coordinated with CVS flow fluctuations and sampling time/test cycle offsets, if necessary.

(C) Alternative NO_X measurement techniques outlined in § 86.346–79 of this chapter are not permitted for NO_X measurement in this subpart.

(D) All analytical gases must conform to the specifications of § 89.312–96.

(E) Any range on a linear analyzer below 155 ppm must have and use a calibration curve conforming to § 89.310–96.

(iii) The chart deflections or voltage output of analyzers with non-linear calibration curves shall be converted to concentration values by the calibration curve(s) specified in § 89.323–96 before flow correction (if used) and subsequent integration takes place.

§ 89.420–96 Background sample.

(a) Background samples are produced by drawing a sample of the dilution air during the 60 second exhaust collection phase of each test cycle mode.

(1) Individual background samples may be produced and analyzed for each mode. Hence, a unique background value will be used for the emission calculations for each mode.

(2) Alternatively, a single background sample may be produced by drawing a sample during the collection phase of each of the test cycle modes. Hence, a single cumulative background value will be used for the emission calculations for each mode.

(b) For analysis of the individual sample described in paragraph (a)(1) of this section, a single value representing the average chart deflection over a 10-second stabilized period is stored. All readings taken during the 10-second interval must be stable at the final value to within ±1 percent of full scale.

(c) Measure HC, CO, CO_2, and NO_x exhaust and background concentrations in the sample bag(s) with approximately the same flow rates and pressures used during calibration.

§ 89.421–96 Exhaust gas analytical system; CVS bag sample.

(a) *Schematic drawings.* Figure 4 in appendix A to this subpart is a schematic drawing of the exhaust gas analytical system used for analyzing CVS bag samples from compression-ignition engines. Since various configurations can produce accurate results, exact conformance with the drawing is not required. Additional components such as instruments, valves, solenoids, pumps and switches may be used to provide additional information and coordinate the functions of the component systems. Other components such as snubbers, which are not needed to maintain accuracy in some systems, may be excluded if their exclusion is based upon good engineering judgment.

(b) *Major component description.* The analytical system, Figure 4 in appendix A to this subpart, consists of a flame ionization detector (FID) (heated for petroleum-fueled compression-ignition engines to 191 °C ±6 °C) for the measurement of hydrocarbons, nondispersive infrared analyzers (NDIR) for the measurement of carbon monoxide and carbon dioxide, and a chemiluminescence detector (CLD) (or HCLD) for the measurement of oxides of nitrogen. The exhaust gas analytical system shall conform to the following requirements:

(1) The CLD (or HCLD) requires that the nitrogen dioxide present in the sample be converted to nitric oxide before analysis. Other types of analyzers may be used if shown to yield equivalent results and if approved in advance by the Administrator.

(2) If CO instruments are used which are essentially free of CO_2 and water vapor interference, the use of the conditioning column may be deleted. (See §§ 86.1322–84 and 86.1342–90 of this chapter.)

(3) A CO instrument will be considered to be essentially free of CO_2 and water vapor interference if its response to a mixture of 3 percent CO_2 in N2, which has been bubbled through water at room temperature, produces an equivalent CO response, as measured on the most sensitive CO range, which is less than 1 percent of full scale CO concentration on ranges above 300 ppm full scale or less than 3 ppm on ranges below 300 ppm full scale. (See § 86.1322–84 of this chapter.)

(c) *Alternate analytical systems.* Analysis systems meeting the specifications of part 86, subpart D of this chapter (with the exception of §§ 86.346–79 and 86.347–79) may be used for the testing required under this subpart. Heated analyzers may be used in their heated configuration.

(d) Other analyzers and equipment. Other types of analyzers and equipment may be used if shown to yield equivalent results and if approved in advance by the Administrator.

§ 89.422–96 Dilute sampling procedures—CVS calibration.

(a) The CVS is calibrated using an accurate flowmeter and restrictor valve.

(1) The flowmeter calibration must be traceable to NIST measurements, and will serve as the reference value (NIST "true" value) for the CVS calibration. (Note: In no case should an upstream screen or other restriction which can affect the flow be used ahead of the flowmeter unless calibrated throughout the flow range with such a device.)

(2) The CVS calibration procedures are designed for use of a "metering venturi" type flowmeter. Large radius or ASME flow nozzles are considered equivalent if traceable to NIST measurements. Other measurement systems may be used if shown to be equivalent under the test conditions in this section and traceable to NIST measurements.

(3) Measurements of the various flowmeter parameters are recorded and related to flow through the CVS.

(4) Procedures used by EPA for both PDP–CVS and CFV–CVS are outlined below. Other procedures yielding equivalent results may be used if approved in advance by the Administrator.

(b) After the calibration curve has been obtained, verification of the entire system may be performed by injecting a known mass of gas into the system and comparing the mass indicated by the system to the true mass injected. An indicated error does not necessarily mean that the calibration is wrong, since other factors can influence the accuracy of the system (for example, analyzer calibration, leaks, or HC hangup). A verification procedure is found in paragraph (e) of this section.

(c) *PDP–CVS calibration.* (1) The following calibration procedure outlines the equipment, the test configuration, and the various parameters which must be measured to establish the flow rate of the PDP–CVS pump.

(i) All the parameters related to the pump are simultaneously measured with the parameters related to a flowmeter which is connected in series with the pump.

(ii) The calculated flow rate, in (cm^3/s), (at pump inlet absolute pressure and temperature) can then be plotted versus a correlation function which is the value of a specific combination of pump parameters.

(iii) The linear equation which relates the pump flow and the correlation function is then determined.

(iv) In the event that a CVS has a multiple speed drive, a calibration for each range used must be performed.

(2) This calibration procedure is based on the measurement of the absolute values of the pump and flowmeter parameters that relate the flow rate at each point. Two conditions must be maintained to assure the accuracy and integrity of the calibration curve:

(i) The temperature stability must be maintained during calibration. (Flowmeters are sensitive to inlet temperature oscillations; this can cause the data points to be scattered. Gradual changes in temperature are acceptable as long as they occur over a period of several minutes.)

(ii) All connections and ducting between the flowmeter and the CVS pump must be absolutely void of leakage.

(3) During an exhaust emission test the measurement of these same pump parameters enables the user to calculate the flow rate from the calibration equation.

(4) Connect a system as shown in Figure 5 in appendix A to this subpart. Although particular types of equipment are shown, other configurations that yield equivalent results may be used if approved in advance by the Administrator. For the system indicated, the following measurements and accuracies are required:

CALIBRATION DATA MEASUREMENTS

Parameter	Symbol	Units	Sensor-readout tolerances
Barometric pressure (corrected)	P_B	kPa	±.34 kPa
Ambient temperature	T_A	°C	±.3 °C
Air temperature into metering venturi	*ETI*	°C	±1.1 °C
Pressure drop between the inlet and throat of metering venturi	*EDP*	kPa	±.01 kPa
Air flow	Q_S	m³/min	±.5% of NIST value.
Air temperature at CVS pump inlet	*PTI*	°C	±1.1 °C
Pressure depression at CVS pump inlet	*PPI*	kPa	±.055 kPa
Pressure head at CVS pump outlet	*PPO*	kPa	±.055 kPa
Air temperature at CVS pump outlet (optional)	*PTO*	°C	±1.1 °C
Pump revolutions during test period	*N*	Revs	±1 Rev.
Elapsed time for test period	*t*	s	±.5 s.

(5) After the system has been connected as shown in Figure 5 in appendix A to this subpart, set the variable restrictor in the wide open position and run the CVS pump for 20 minutes. Record the calibration data.

(6) Reset the restrictor valve to a more restricted condition in an increment of pump inlet depression that will yield a minimum of six data points for the total calibration. Allow the system to stabilize for 3 minutes and repeat the data acquisition.

(7) Data analysis:

(i) The air flow rate, Q_s, at each test point is calculated in standard cubic meters per minute (0 °C, 101.3 kPa) from the flowmeter data using the manufacturer's prescribed method.

(ii) The air flow rate is then converted to pump flow, V_o, in cubic meter per revolution at absolute pump inlet temperature and pressure:

$$V_o = \frac{Q_s}{n} \times \frac{T_p}{273} \times \frac{101.3}{P_p}$$

Where:

V_o=Pump flow, (m³/rev) at T_p, P_p.

Q_s=Meter air flow rate in standard cubic meters per minute, standard conditions are 0 °C, 101.3 kPa.

n=Pump speed in revolutions per minute.

T_p=Pump inlet temperature °K=P_{ti}+273 °K, P_{ti}=Pump inlet temp °C

P_p=Absolute pump inlet pressure, (kPa) $=P_B - P_{PI}$

Where:

P_B=barometric pressure, (kPa).

P_{PI}=Pump inlet depression, (kPa).

(iii) The correlation function at each test point is then calculated from the calibration data:

$$X_o = \frac{1}{n}\sqrt{\left(\frac{\Delta p}{P_e}\right)}$$

X_o=correlation function.

Δp=The pressure differential from pump inlet to pump outlet, (kPa). $=P_e - P_p$.

P_e=Absolute pump outlet pressure, (kPa) $=P_B + P_{PO}$

Where:

P_{PO}=Pressure head at pump outlet, (kPa).

(iv) A linear least squares fit is performed to generate the calibration equation which has the form:

$V_o = D_o - M(X_o)$

D_o and M are the intercept and slope constants, respectively, describing the regression line.

(8) A CVS system that has multiple speeds must be calibrated on each speed used. The calibration curves generated for the ranges will be approximately parallel and the intercept values, D_o, will increase as the pump flow range decreases.

(9) If the calibration has been performed carefully, the calculated values from the equation will be within ±0.50 percent of the measured value of V_o. Values of M will vary from one pump to another, but values of D_o for pumps of the same make, model, and range should agree within ±3 percent of each other. Calibrations should be performed at pump start-up and after major maintenance to assure the stability of the pump slip rate. Analysis of mass injection data will also reflect pump slip stability.

(d) *CFV–CVS calibration.* (1) Calibration of the CFV is based upon the flow equation for a critical venturi. Gas flow is a function of inlet pressure and temperature:

$$Q_s = \frac{K_v P}{\sqrt{T}}$$

Where:

Q_s=flow.

K_v=calibration coefficient.

P=absolute pressure.

T=absolute temperature.

The calibration procedure described in paragraph (d)(3) of this section establishes the value of the calibration coefficient at measured values of pressure, temperature, and air flow.

(2) The manufacturer's recommended procedure shall be followed for calibrating electronic portions of the CFV.

(3) Measurements necessary for flow calibration are as follows:

CALIBRATION DATA MEASUREMENTS

Parameter	Symbol	Units	Tolerances
Barometric Pressure (corrected)	P_B	kPa	±.34 kPa
Air temperature, into flowmeter	*ETI*	°C	(±.3 °C
Pressure drop between the inlet and throat of metering venturi	*EDP*	kPa	±.01 kPa
Air flow	Q_S	m³/min.	±.5% of NIST value.
CFV inlet depression	*PPI*	kPa	±.055 kPa
Temperature at venturi inlet	T_V	°C	±2.2 °C

(4) Set up equipment as shown in Figure 6 in Appendix A to subpart and eliminate leaks. (Leaks between the flow measuring devices and the critical flow venturi will seriously affect the accuracy of the calibration.)

(5) Set the variable flow restrictor to the open position, start the blower, and allow the system to stabilize. Record data from all instruments.

(6) Vary the flow restrictor and make at least eight readings across the critical flow range of the venturi.

(7) *Data analysis.* The data recorded during the calibration are to be used in the following calculations:

(i) The air flow rate (designated as Q_s) at each test point is calculated in standard cubic feet per minute from the flow meter data using the manufacturer's prescribed method.

(ii) Calculate values of the calibration coefficient for each test point:

$$K_v = \frac{Q_s\sqrt{T_v}}{P_v}$$

Where:

Q_s = Flow rate in standard cubic meter per minute, at the standard conditions of 0 °C, 101.3 kPa.

T_v = Temperature at venturi inlet, °K.

P_v = PB - PPI (= Pressure at venturi inlet, kPA)

Where:

P_{PI} = Venturi inlet pressure depression, (kPa).

(iii) Plot K_v as a function of venturi inlet pressure. For choked flow, K_v will have a relatively constant value. As pressure decreases (vacuum increases), the venturi becomes unchoked and K_v decreases. (See Figure 7 in appendix A to this subpart.)

(iv) For a minimum of eight points in the critical region calculate an average K_v and the standard deviation.

(v) If the standard deviation exceeds 0.3 percent of the average K_v, take corrective action.

(e) *CVS system verification.* The following "gravimetric" technique can be used to verify that the CVS and analytical instruments can accurately measure a mass of gas that has been injected into the system. (Verification can also be accomplished by constant flow metering using critical flow orifice devices.)

(1) Obtain a small cylinder that has been charged with 99.5 percent or greater propane or carbon monoxide gas (Caution—carbon monoxide is poisonous).

(2) Determine a reference cylinder weight to the nearest 0.01 grams.

(3) Operate the CVS in the normal manner and release a quantity of pure propane into the system during the sampling period (approximately 5 minutes).

(4) The calculations are performed in the normal way except in the case of propane. The density of propane (0.6109 kg/m³/carbon atom)) is used in place of the density of exhaust hydrocarbons.

(5) The gravimetric mass is subtracted from the CVS measured mass and then divided by the gravimetric mass to determine the percent accuracy of the system.

(6) Good engineering practice requires that the cause for any discrepancy greater than ±2 percent must be found and corrected.

§ 89.423–96 CVS calibration frequency.

The CVS positive displacement pump or critical flow venturi shall be calibrated following initial installation, major maintenance or as necessary when indicated by the CVS system verification (described in § 89.352–96(e)).

§ 89.424–96 Dilute emission sampling calculations.

(a) The final reported emission test results are computed by use of the following formula:

$$A_{WM} = \frac{\sum_{i=1}^{i=n}(g_i \times WF_i)}{\sum_{i=n-1}^{i=1}(kW - hr_i \times WF_i)}$$

Where:

A_{wm} = Weighted mass emission level (HC, CO, CO_2, or NO_X) in grams per kilowatt-hour.

g_i = Mass emission level in grams, measured during the mode.

WF_i = Effective weighing factor.

$kW\text{-}hr_i$ = Total kilowatt-hours (kilowatts integrated over time) for the mode.

(b) The mass of each pollutant for each mode for bag measurements and diesel heat exchanger system measurements is determined from the following equations:

(1) Hydrocarbon mass:

$HC_{mass} = V_{mix} \times Density_{HC} \times (HC_{conc}/10^6)$

(2) Oxides of nitrogen mass:

$NO_{Xmass} = V_{mix} \times Density_{NO2} \times KH \times (NO_{Xconc}/10^6)$

(3) Carbon monoxide mass:

$CO_{mass} = V_{mix} \times Density_{CO} \times (CO_{conc}/10^6)$

(4) Carbon dioxide mass:

$CO_{2mass} = V_{mix} \times Density_{CO2} \times (CO_{2conc}/10_2)$

(c) The mass of each pollutant for the mode for flow compensated sample systems is determined from the following equations:

$$HC_{mass} = V_{mix} \times Density_{HC} \frac{HC_e - HC_d\left(1 - \frac{1}{DF}\right)}{10^6}$$

$$NOX_{mass} = K_H \frac{NOX_e - NOX_d\left(1 - \frac{1}{DF}\right)}{10^6} V_{mix} \times Density_{NO_2}$$

$$CO_{mass} = V_{mix} \times Density_{CO} \frac{CO_e - CO_d\left(1 - \frac{1}{DF}\right)}{10^6}$$

$$CO_{2_{mass}} = V_{mix} \times Density_{CO_2} \frac{CO_{2_e} - CO_{2_d}\left(1 - \frac{1}{DF}\right)}{10^6}$$

(d) Meaning of symbols:

(1) For hydrocarbon equations:

HC_{mass} = Hydrocarbon emissions, in grams per test mode.

$Density_{HC}$ = Density of hydrocarbons is (.5800 kg/m³) for #1 diesel, and (0.5746 kg/m³) for #2 diesel, assuming an average carbon to hydrogen ratio of 1:1.93 for #1 diesel, and 1:1.80 for #2 diesel at 20 °C and 101.3 kPa pressure.

HC_{conc} = Hydrocarbon concentration of the dilute exhaust sample corrected for background, in ppm carbon equivalent (that is, equivalent propane times 3).

$$HC_{conc} = HC_e - HC_d\left(1 - \frac{1}{DF}\right)$$

Where:

HC_e = Hydrocarbon concentration of the dilute exhaust bag sample or, for diesel heat exchanger systems, average hydrocarbon concentration of the dilute exhaust sample as calculated from the integrated HC traces, in ppm carbon equivalent. For flow compensated sample systems $(HC_e)_i$ is the instantaneous concentration.

HC_d = Hydrocarbon concentration of the dilution air as measured, in ppm carbon equivalent.

(2) For oxides of nitrogen equations:

NO_{Xmass} = Oxides of nitrogen emissions, in grams per test mode.

$Density\ NO_2$ = Density of oxides of nitrogen is 1.913 kg/m³, assuming they are in the form of nitrogen dioxide, at 20 °C and 101.3 kPa pressure.

NO_{Xconc} = Oxides of nitrogen concentration of the dilute exhaust sample corrected for background, in ppm:

$$NOx_{conc} = NOx_e - NOx_d\left(1 - \frac{1}{DF}\right)$$

Where:

NO_{Xe} = Oxides of nitrogen concentration of the dilute exhaust bag sample as measured, in ppm. For flow compensated sample systems $(NO_{Xe})_i$ is the instantaneous concentration.

NO_{Xd} = Oxides of nitrogen concentration of the dilute air as measured, in ppm.

(3) For carbon monoxide equations:

CO_{mass}=Carbon monoxide emissions, grams per test mode.

$Density_{CO}$=Density of carbon monoxide (1.164 kg/m³ at 20 °C and 101.3 kPa pressure).

CO_{conc}=Carbon monoxide concentration of the dilute exhaust sample corrected for background, water vapor, and CO_2 extraction, ppm.

$$CO_{conc} = CO_e - CO_d\left(1 - \frac{1}{DF}\right)$$

Where:

CO_e=Carbon monoxide concentration of the dilute exhaust bag sample volume corrected for water vapor and carbon dioxide extraction, ppm. For flow compensated sample systems, $(CO_e)_i$ is the instantaneous concentration.

The following calculation assumes the carbon to hydrogen ratio of the fuel is 1:1.85. As an option the measured actual carbon to hydrogen ratio may be used:

$$CO_e = [1 - 0.01925CO_{2e} - 0.000323R]CO_{em}$$

Where:

CO_{em}=Carbon monoxide concentration of the dilute exhaust sample as measured, ppm.

CO_{2e}=Carbon dioxide concentration of the dilute exhaust bag sample, in percent, if measured. For flow compensated sample systems, $(CO_{2e})_i$ is the instantaneous concentration. For cases where exhaust sampling of CO_2 is not performed, the following approximation is permitted:

$$CO_{2_e} = \frac{44.010}{12.011 + 1.008\alpha} \frac{M^1\ 453.6}{Density_{CO_2}} \frac{100}{V_{mix}}$$

^{a}=Average carbon to hydrogen ratio.

M^1=Fuel mass consumed during the test cycle.

R=Relative humidity of the dilution air, percent.

CO_d=Carbon monoxide concentration of the dilution air corrected for water vapor extraction, ppm.

$$CO_d = (1 - 0.000323R)CO_{dm}$$

Where:

CO_{dm}=Carbon monoxide concentration of the dilution air sample as measured, ppm.

Note: If a CO instrument which meets the criteria specified in § 86.1311–90 of this chapter is used and the conditioning column has been deleted, CO_{em} must be substituted directly for CO_e and CO_{dm} must be substituted directly for CO_d.

(4) For carbon dioxide equation:

CO_{2mass}=Carbon dioxide emissions, in grams per test mode.

$Density\ CO_2$=Density of carbon dioxide is 1.830 kg/m³, at 20 °C and 760 mm Hg pressure.

CO_{2conc}=Carbon dioxide concentration of the dilute exhaust sample corrected for background, in percent.

$$CO_{2_{mass}} = CO_{2_e} - CO_{2_d}\left(1 - \frac{1}{DF}\right)$$

Where:

CO_{2d}=Carbon dioxide concentration of the dilution air as measured, in percent.

(5) $$DF = \frac{13.4}{CO_{2_e} + \left(HC_e + CO_e \times 10^{-4}\right)}, \text{ or } DF = \frac{13.4}{CO_{2_e}}.$$

(6) KH=Humidity correction factor. For compression-ignition engines:

$KH = 1/[1 - 0.0182\,(H - 10.71)]$.

Where:

H=Absolute humidity of the engine intake air in grams of water per kilogram of dry air and

$H = (6.211)R_i \times P_d)/(P_b - (P_d \times R_i/100))$

Where:

R_i=Relative humidity of the engine intake air, in percent.

P_d=Saturated vapor pressure (kPa) at the engine intake air dry bulb temperature.

P_B=Barometric pressure (kPa).

(e) The final reported brake-specific fuel consumption (*BSFC*) shall be computed by use of the following formula:

$$BSFC = \frac{M}{kW - hr}$$

Where:

BSFC=brake-specific fuel consumption in grams of fuel per kilowatt-hr (kW-hr)

M=mass of fuel in grams, used by the engine during a mode

kW-hr=total kilowatts integrated with respect to time for a mode

(f) The mass of fuel for the mode is determined from mass fuel flow measurements made during the mode, or from the following equation:

$$M = \left(\frac{G_S}{R_2}\right)\left(\frac{1}{273.15}\right)$$

Where:

M=Mass of fuel, in grams, used by the engine during the mode.

G_s=Grams of carbon measured during the mode:

$$G_S = \left[\frac{12.011}{12.011 + \alpha\,(1.008)}\right] HC_{mass} + 0.429CO_{mass} + 0.273CO_{2_{mass}}$$

R_2=Grams C in fuel per gram of fuel

Where:

HC_{mass}=hydrocarbon emissions, in grams for the mode

CO_{2mass}=carbon monoxide emissions, in grams for the mode

CO_{2mass}=carbon dioxide emissions, in grams for the mode

α=The atomic hydrogen to carbon ratio of the fuel.

§ 89.425–96 Particulate adjustment factor.

The following equation may be used to adjust the particulate measurement when the test fuel specified in Table 4 of Subpart D of this Part is used:

$PM_{adj} = PM - [BSFC * 0.0917 * (FSF - USLF_{CA})]$

Where:

PM_{adj}=adjusted measured PM level [g/Kw-hr]

PM=measured weighted PM level [g/Kw-hr]

BSFC=measured brake specific fuel consumption [G/Kw-hr]

FSF=fuel sulfur weight fraction

$USLF_{CA}$=upper sulfur level weight fraction of California specification.

This adjustment only applies to engines with no exhaust gas after treatment. No adjustment is provided for engines with exhaust gas after treatment.

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Appendix A to Subpart E—Figures

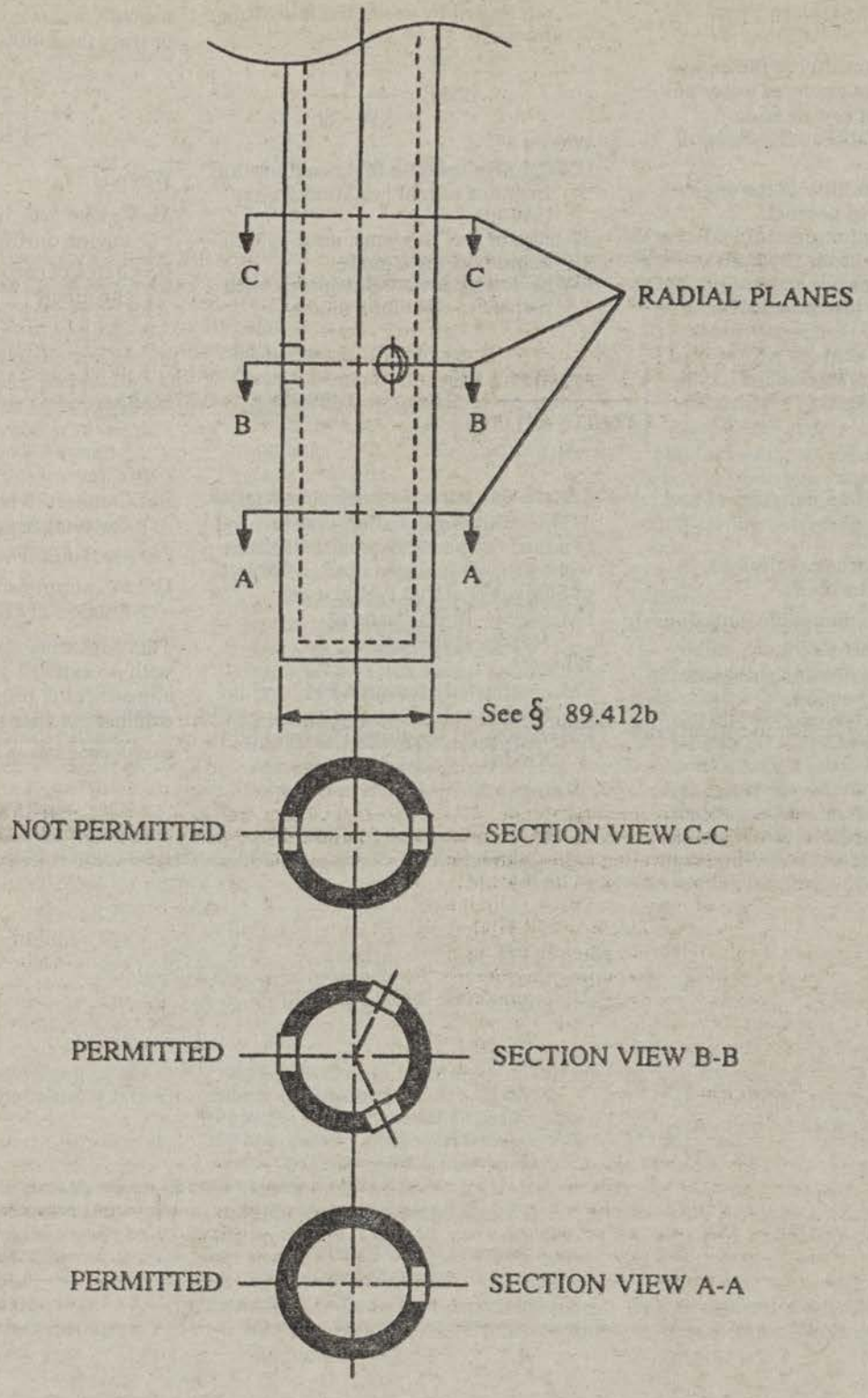

Figure 1.--SAMPLE PROBE AND TYPICAL HOLE SPACING

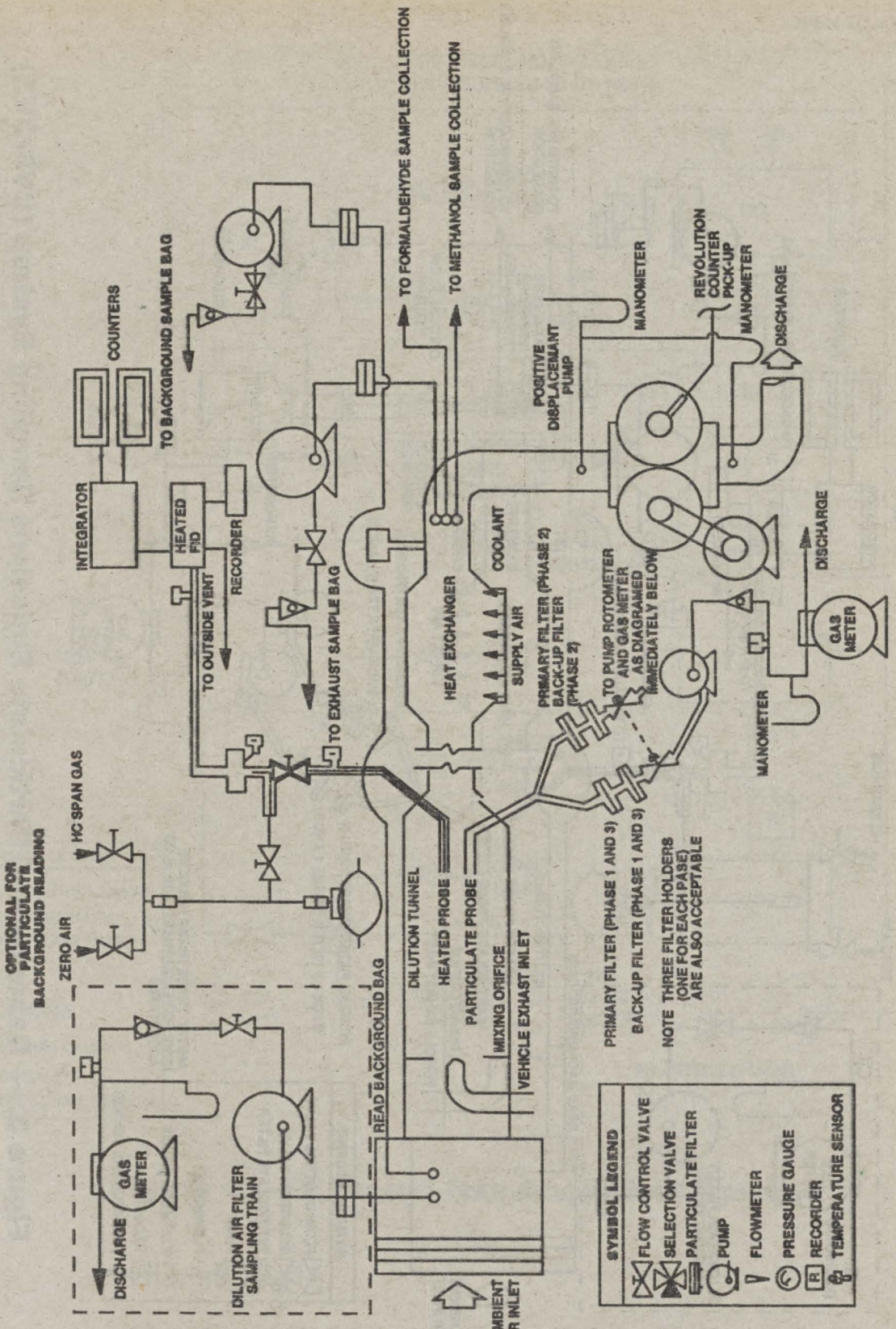

Figure 2 — Gaseous & Particulate Emissions Sampling System (PDP-CVS)

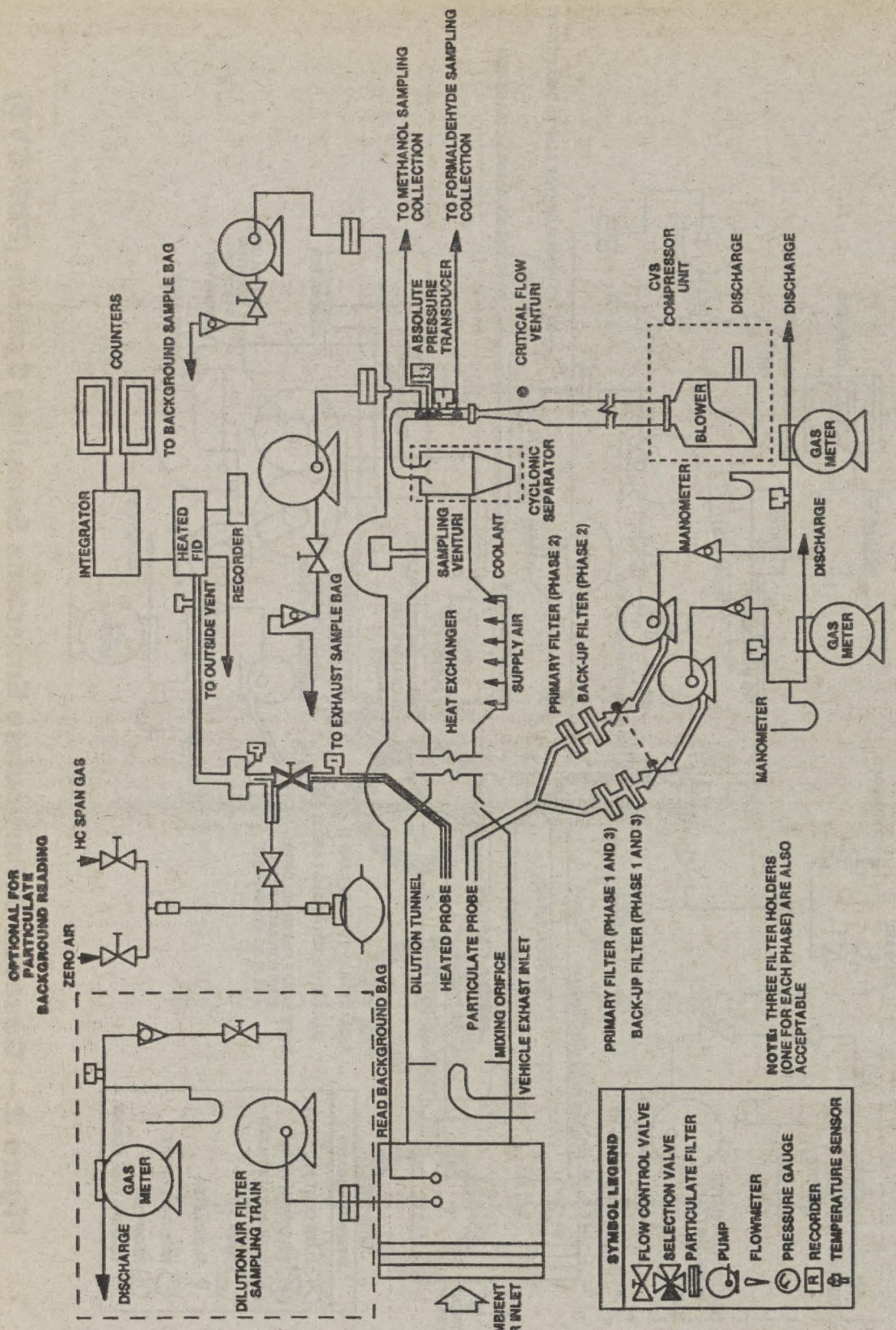

Figure 3. — Gaseous and Particulate Emissions Sampling System (CVF-CVS)

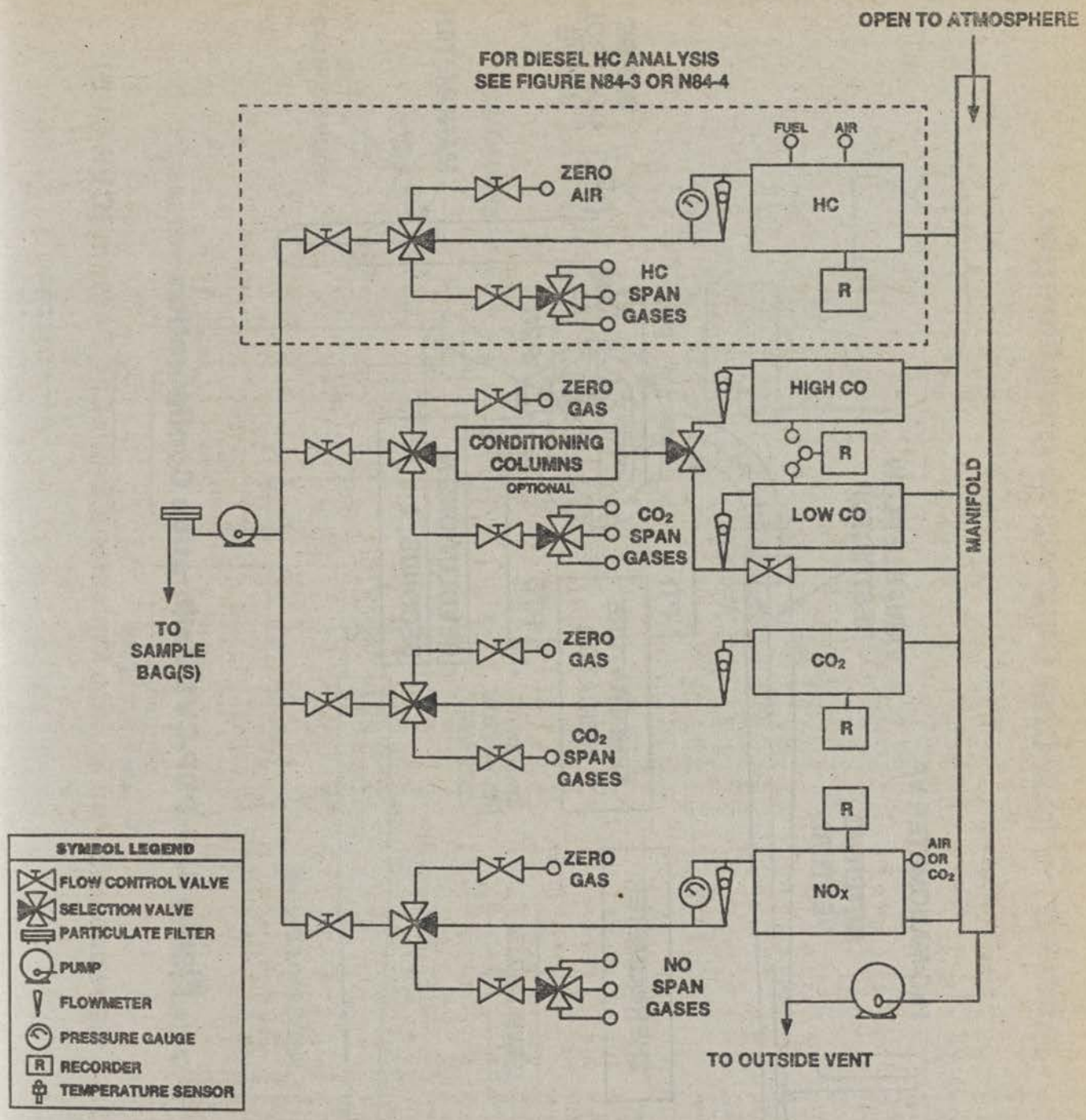

Figure 4. — Exhaust Gas Analytical System

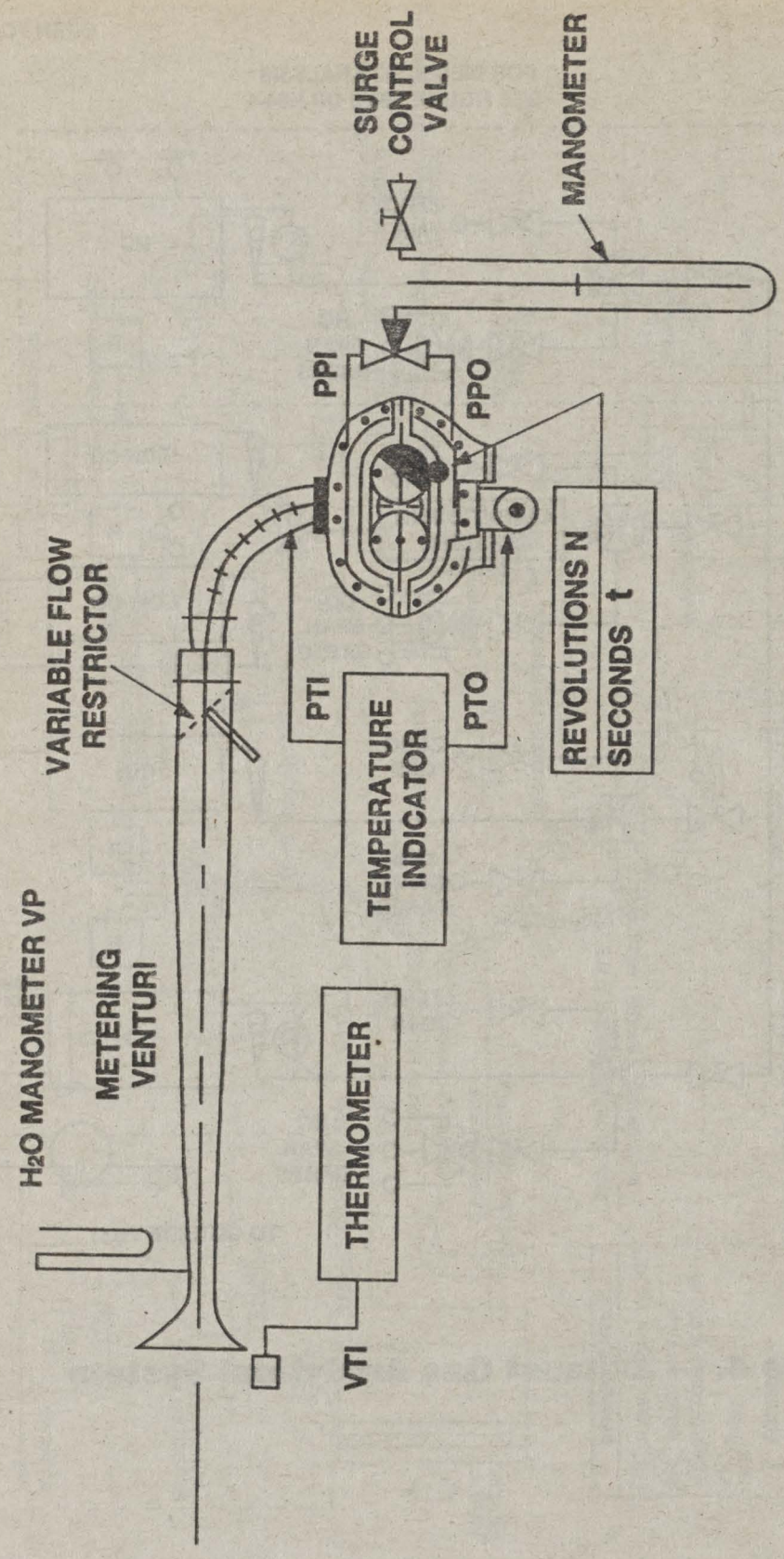

Figure 5. — PDP-CVS Calibration Configuration

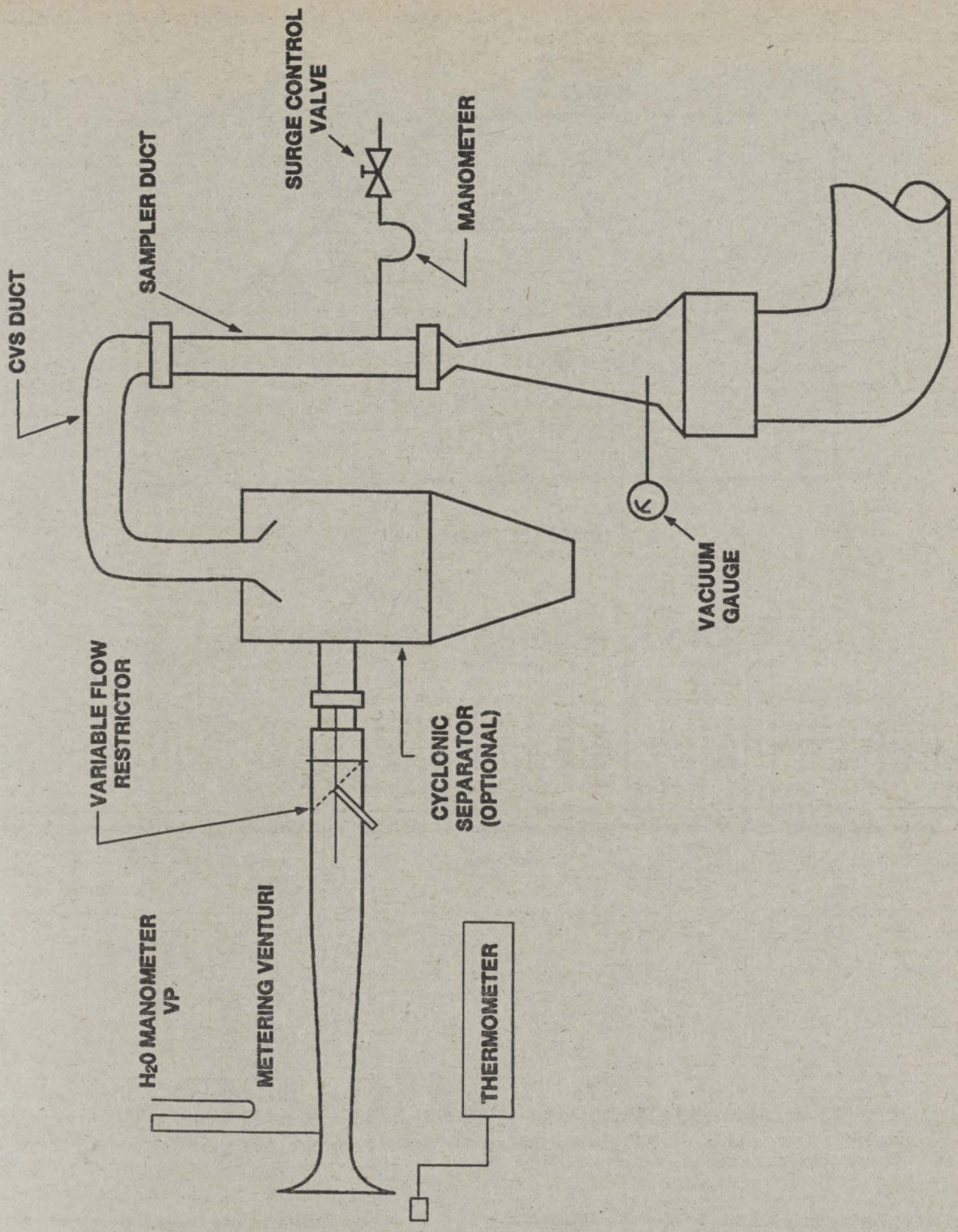

Figure 6. — CFV-CVS Calibration Configuration

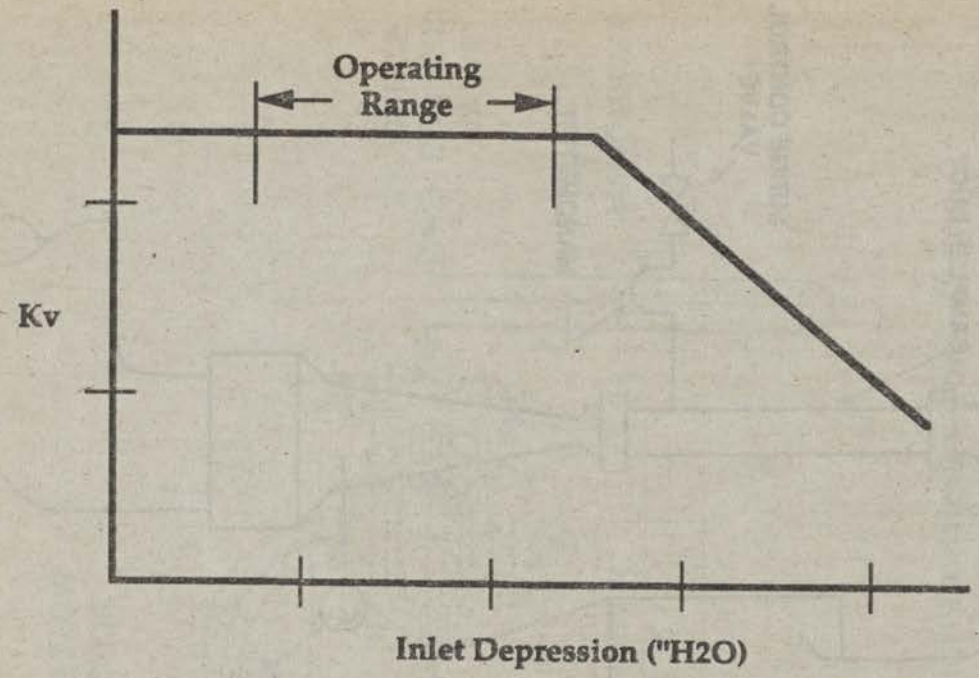

Figure 7.—Sonic Flow Choking

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Appendix B to Subpart E—Table 1

TABLE 1.—8. MODE TEST CYCLE (MY96 AND LATER)

Test segment	Mode No.	Engine speed (1)	Observed torque (2) (percent of maximum observed)	Time in mode (minutes)		Weighting factors
				Min	Max	
1	1	Rated	100	5.0	20.0	0.15
1	2	Rated	75	5.0	20.0	0.15
1	3	Rated	50	5.0	20.0	0.15
1	4	Rated	10	5.0	20.0	0.10
2	5	Int	100	5.0	20.0	0.10
2	6	Int	75	5.0	20.0	0.10
2	7	Int	50	5.0	20.0	0.10
2	8	Idle	0	5.0	20.0	0.15

(1) Engine speed (non-idle): ±1 percent of rated or ±3 rpm, which ever is greater. Engine speed (idle): Within manufacturer's specifications. Rated speed, intermediate speed, and idle speed are specified by the manufacturer. If no intermediate speed is stated, 60 percent of rated speed shall be used.

(2) Torque (non-idle): Throttle fully open for 100 percent points. Other non-idle points: ±2 percent of set point. Torque (idle): Throttle fully closed. Load less than 5 percent of peak torque.

Subpart F—Selective Enforcement Auditing

§ 89.501–96 Applicability.

The requirements of subpart F are applicable to all nonroad engines subject to the provisions of subpart A of part 89.

§ 89.502–96 Definitions.

The definitions in subpart A of this part apply to this subpart. The following definitions also apply to this subpart.

Acceptable quality level (AQL) means the maximum percentage of failing engines that can be considered a satisfactory process average for sampling inspections.

Configuration means any subclassification of an engine family which can be described on the basis of gross power, emission control system, governed speed, injector size, engine calibration, and other parameters as designated by the Administrator.

Inspection criteria means the pass and fail numbers associated with a particular sampling plan.

Test engine means an engine in a test sample.

Test sample means the collection of engines selected from the population of an engine family for emission testing.

§ 89.503–96 Test orders.

(a) A test order addressed to the manufacturer is required for any testing under this subpart.

(b) The test order is signed by the Assistant Administrator for Air and Radiation or his or her designee. The test order must be delivered in person by an EPA enforcement officer or EPA authorized representative to a company representative or sent by registered mail, return receipt requested, to the manufacturer's representative who signed the application for certification submitted by the manufacturer, pursuant to the requirements of the applicable section of subpart B of this part. Upon receipt of a test order, the manufacturer must comply with all of the provisions of this subpart and instructions in the test order.

(c) *Information included in test order.* (1) The test order will specify the engine family to be selected for testing, the manufacturer's engine assembly plant or associated storage facility or port facility (for imported engines) from which the engines must be selected, the time and location at which engines must be selected, and the procedure by which engines of the specified family must be selected. The test order may specify the configuration to be audited and/or the number of engines to be selected per day. Engine manufacturers are required to select a minimum of four engines per day unless an alternate selection procedure is approved pursuant to § 89.507–96(a), or unless total production of the specified configuration is less than four engines per day. If total production of the specified configuration is less than four engines per day, the manufacturer selects the actual number of engines produced per day.

(2) The test order may include alternate families to be selected for testing at the Administrator's discretion in the event that engines of the specified family are not available for testing because those engines are not being manufactured during the specified time or are not being stored at the specified assembly plant, associated storage facilities, or port of entry.

(3) If the specified family is not being manufactured at a rate of at least two engines per day in the case of manufacturers specified in § 89.508–96(g)(1), or one engine per day in the case of manufacturers specified in § 89.508–96(g)(2), over the expected duration of the audit, the Assistant Administrator or her or his designated representative may select engines of the alternate family for testing.

(4) In addition, the test order may include other directions or information essential to the administration of the required testing.

(d) A manufacturer may submit a list of engine families and the corresponding assembly plants, associated storage facilities, or (in the case of imported engines) port facilities from which the manufacturer prefers to have engines selected for testing in response to a test order. In order that a manufacturer's preferred location be considered for inclusion in a test order for a particular engine family, the list must be submitted prior to issuance of the test order. Notwithstanding the fact that a manufacturer has submitted the list, the Administrator may order selection at other than a preferred location.

(e) Upon receipt of a test order, a manufacturer must proceed in accordance with the provisions of this subpart.

(f)(1) During a given model year, the Administrator may not issue to a manufacturer more Selective Enforcement Auditing (SEA) test orders than an annual limit determined to be the larger of the following factors:

(i) Production factor, determined by dividing the projected nonroad engine sales in the United States for that model year, as declared by the manufacturer under § 89.505- 96(c)(1), by 16,000 and rounding to the nearest whole number. If the projected sales are less than 8,000, this factor is one.

(ii) Family factor, determined by dividing the manufacturer's total number of certified engine families by five and rounding to the nearest whole number.

(2) If a manufacturer submits to EPA in writing prior to or during the model year a reliable sales projection update or adds engine families or deletes engine families from its production, that information is used for recalculating the manufacturer's annual limit of SEA test orders.

(3) Any SEA test order for which the family fails under § 89.510–96 or for which testing is not completed is not counted against the annual limit.

(4) When the annual limit has been met, the Administrator may issue additional test orders to test those families for which evidence exists indicating noncompliance. An SEA test order issued on this basis will include a statement as to the reason for its issuance.

§ 89.504–96 Testing by the Administrator.

(a) The Administrator may require by test order under § 89.503–96 that engines of a specified family be selected in a manner consistent with the requirements of § 89.507–96 and submitted to the Administrator at the place designated for the purpose of conducting emission tests. These tests will be conducted in accordance with § 89.508–96 to determine whether engines manufactured by the manufacturer conform with the regulations with respect to which the certificate of conformity was issued.

(b) *Designating official data.* (1) Whenever the Administrator conducts a test on a test engine or the Administrator and manufacturer each conduct a test on the same test engine, the results of the Administrator's test comprise the official data for that engine.

(2) Whenever the manufacturer conducts all tests on a test engine, the manufacturer's test data is accepted as the official data, provided that if the Administrator makes a determination based on testing conducted under paragraph (a) of this section that there is a substantial lack of agreement between the manufacturer's test results and the Administrator's test results, no manufacturer's test data from the manufacturer's test facility will be accepted for purposes of this subpart.

(c) If testing conducted under § 89.503–96 is unacceptable under paragraph (b)(2) of this section, the Administrator must:

(1) Notify the manufacturer in writing of the Administrator's determination that the test facility is inappropriate for conducting the tests required by this subpart and the reasons therefor; and

(2) Reinstate any manufacturer's data upon a showing by the manufacturer that the data acquired under § 89.503–96 was erroneous and the manufacturer's data was correct.

(d) The manufacturer may request in writing that the Administrator reconsider the determination in paragraph (b)(2) of this section based on data or information which indicates that changes have been made to the test facility and these changes have resolved the reasons for disqualification.

§ 89.505–96 Maintenance of records; submittal of information.

(a) The manufacturer of any new nonroad engine subject to any of the provisions of this subpart must establish, maintain, and retain the following adequately organized and indexed records:

(1) *General records.* A description of all equipment used to test engines in

accordance with § 89.508–96 pursuant to a test order issued under this subpart, specifically, the equipment requirements specified in §§ 86.884–8 and 86.884–9 of this chapter and the equipment requirements specified in §§ 89.306–96, 89.308–96, 89.309–96, and 89.312–96.

(2) *Individual records.* These records pertain to each audit conducted pursuant to this subpart and include:

(i) The date, time, and location of each test;

(ii) The number of hours of service accumulated on the engine when the test began and ended;

(iii) The names of all supervisory personnel involved in the conduct of the audit;

(iv) A record and description of any repairs performed prior to and/or subsequent to approval by the Administrator, giving the date, associated time, justification, name(s) of the authorizing personnel, and names of all supervisory personnel responsible for the conduct of the repair;

(v) The date the engine was shipped from the assembly plant, associated storage facility or port facility, and date the engine was received at the testing facility;

(vi) A complete record of all emission tests performed pursuant to this subpart (except tests performed directly by EPA), including all individual worksheets and/or other documentation relating to each test, or exact copies thereof, to be in accordance with the record requirements specified in § 89.404–96 or § 86.884–10 of this chapter.

(vii) A brief description of any significant audit events not described under paragraph (a)(2) of this section, commencing with the test engine selection process and including such extraordinary events as engine damage during shipment.

(3) The manufacturer must record test equipment description, pursuant to paragraph (a)(1) of this section, for each test cell that can be used to perform emission testing under this subpart.

(b) The manufacturer must retain all records required to be maintained under this subpart for a period of one year after completion of all testing in response to a test order. Records may be retained as hard copy or reduced to microfilm, floppy disc, and so forth, depending upon the manufacturer's record retention procedure; provided, that in every case, all the information contained in the hard copy is retained.

(c) The manufacturer must, upon request by the Administrator, submit the following information with regard to engine production:

(1) Projected production for each engine configuration within each engine family for which certification is requested;

(2) Number of engines, by configuration and assembly plant, scheduled for production for the time period designated in the request;

(3) Number of engines, by configuration and by assembly plant, storage facility or port facility, scheduled to be stored at facilities for the time period designated in the request; and

(4) Number of engines, by configuration and assembly plant, produced during the time period designated in the request that are complete for introduction into commerce.

(d) Nothing in this section limits the Administrator's discretion in requiring the manufacturer to retain additional records or submit information not specifically required by this section.

(e) All reports, submissions, notifications, and requests for approvals made under this subpart are addressed to: Director, Manufacturers Operations Division, U.S. Environmental Protection Agency, 6405–J, 401 M Street SW, Washington, DC 20460.

§ 89.506–96 Right of entry and access.

(a) To allow the Administrator to determine whether a manufacturer is complying with the provisions of this subpart and a test order issued thereunder, EPA enforcement officers or EPA authorized representatives may enter during operating hours and upon presentation of credentials any of the following places:

(1) Any facility where any engine to be introduced into commerce, including ports of entry, or any emission-related component is manufactured, assembled, or stored;

(2) Any facility where any tests conducted pursuant to a test order or any procedures or activities connected with these tests are or were performed;

(3) Any facility where any engine which is being tested, was tested, or will be tested is present; and

(4) Any facility where any record or other document relating to any of the above is located.

(b) Upon admission to any facility referred to in paragraph (a) of this section, EPA enforcement officers or EPA authorized representatives are authorized to perform the following inspection-related activities:

(1) To inspect and monitor any aspects of engine manufacture, assembly, storage, testing and other procedures, and the facilities in which these procedures are conducted;

(2) To inspect and monitor any aspect of engine test procedures or activities, including, but not limited to, engine selection, preparation, service accumulation, emission test cycles, and maintenance and verification of test equipment calibration;

(3) To inspect and make copies of any records or documents related to the assembly, storage, selection, and testing of an engine in compliance with a test order; and

(4) To inspect and photograph any part or aspect of any engine and any component used in the assembly thereof that is reasonably related to the purpose of the entry.

(c) EPA enforcement officers or EPA authorized representatives are authorized to obtain reasonable assistance without cost from those in charge of a facility to help the officers perform any function listed in this subpart and they are authorized to request the recipient of a test order to make arrangements with those in charge of a facility operated for the manufacturer's benefit to furnish reasonable assistance without cost to EPA whether or not the recipient controls the facility.

(1) Reasonable assistance includes, but is not limited to, clerical, copying, interpretation and translation services; the making available on an EPA enforcement officer's or EPA authorized representative's request of personnel of the facility being inspected during their working hours to inform the EPA enforcement officer or EPA authorized representative of how the facility operates and to answer the officer's or representative's questions; and the performance on request of emission tests on any engine which is being, has been, or will be used for SEA testing.

(2) A manufacturer may be compelled to cause the personal appearance of any employee at such a facility before an EPA enforcement officer or EPA authorized representative by written request for his appearance, signed by the Assistant Administrator for Air and Radiation, served on the manufacturer. Any such employee who has been instructed by the manufacturer to appear will be entitled to be accompanied, represented, and advised by counsel.

(d) EPA enforcement officers or EPA authorized representatives are authorized to seek a warrant or court order authorizing the EPA enforcement officers or EPA authorized representatives to conduct activities related to entry and access as authorized in this section, as appropriate, to execute the functions specified in this section. EPA enforcement officers or

authorized representatives may proceed ex parte to obtain a warrant whether or not the EPA enforcement officers or EPA authorized representatives first attempted to seek permission of the recipient of the test order or the party in charge of the facilities in question to conduct activities related to entry and access as authorized in this section.

(e) A recipient of a test order must permit an EPA enforcement officer(s) or EPA authorized representative(s) who presents a warrant or court order to conduct activities related to entry and access as authorized in this section and as described in the warrant or court order. The recipient must also cause those in charge of its facility or a facility operated for its benefit to permit entry and access as authorized in this section pursuant to a warrant or court order whether or not the recipient controls the facility. In the absence of a warrant or court order, an EPA enforcement officer(s) or EPA authorized representative(s) may conduct activities related to entry and access as authorized in this section only upon the consent of the recipient of the test order or the party in charge of the facilities in question.

(f) It is not a violation of this part or the Clean Air Act for any person to refuse to permit an EPA enforcement officer(s) or EPA authorized representative(s) to conduct activities related to entry and access as authorized in this section if the officer(s) or representative(s) appears without a warrant or court order.

(g) A manufacturer is responsible for locating its foreign testing and manufacturing facilities in jurisdictions where local law prohibits an EPA enforcement officer(s) or EPA authorized representative(s) from conducting the entry and access activities specified in this section. EPA will not attempt to make any inspections which it has been informed that local foreign law prohibits.

§ 89.507–96 Sample selection.

(a) Engines comprising a test sample will be selected at the location and in the manner specified in the test order. If a manufacturer determines that the test engines cannot be selected in the manner specified in the test order, an alternative selection procedure may be employed, provided the manufacturer requests approval of the alternative procedure prior to the start of test sample selection, and the Administrator approves the procedure.

(b) The manufacturer must assemble the test engines of the family selected for testing using its normal mass production process for engines to be distributed into commerce. If, between the time the manufacturer is notified of a test order and the time the manufacturer finishes selecting test engines, the manufacturer implements any change(s) in its production processes, including quality control, which may reasonably be expected to affect the emissions of the engines selected, then the manufacturer must, during the audit, inform the Administrator of such changes. If the test engines are selected at a location where they do not have their operational and emission control systems installed, the test order will specify the manner and location for selection of components to complete assembly of the engines. The manufacturer must assemble these components onto the test engines using normal assembly and quality control procedures as documented by the manufacturer.

(c) No quality control, testing, or assembly procedures will be used on the test engine or any portion thereof, including parts and subassemblies, that have not been or will not be used during the production and assembly of all other engines of that family, unless the Administrator approves the modification in assembly procedures pursuant to paragraph (b) of this section.

(d) The test order may specify that an EPA enforcement officer(s) or authorized representative(s), rather than the manufacturer, select the test engines according to the method specified in the test order.

(e) The order in which test engines are selected determines the order in which test results are to be used in applying the sampling plan in accordance with § 89.510–96.

(f) The manufacturer must keep on hand all untested engines, if any, comprising the test sample until a pass or fail decision is reached in accordance with § 89.510–96(e). The manufacturer may ship any tested engine which has not failed the requirements as set forth in § 89.510–96(b). However, once the manufacturer ships any test engine, it relinquishes the prerogative to conduct retests as provided in § 89.508–96(i).

§ 89.508–96 Test procedures.

(a)(1) For nonroad engines subject to the provisions of this subpart, the prescribed test procedures are the nonroad engine 8-mode test procedure as described in subpart E of this part, the federal smoke test as described in part 86, subpart I of this chapter, and the particulate test procedure as adopted in the California Regulations for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines. This procedure is incorporated by reference. See § 89.6.

(2) The Administrator may, on the basis of a written application by a manufacturer, prescribe test procedures other than those specified in paragraph (a)(1) of this section for any nonroad engine he or she determines is not susceptible to satisfactory testing using the procedures specified in paragraph (a)(1) of this section.

(b)(1) The manufacturer may not adjust, repair, prepare, or modify the engines selected for testing and may not perform any emission tests on engines selected for testing pursuant to the test order unless this adjustment, repair, preparation, modification, and/or tests are documented in the manufacturer's engine assembly and inspection procedures and are actually performed or unless these adjustments and/or tests are required or permitted under this subpart or are approved in advance by the Administrator.

(2) The Administrator may adjust or cause to be adjusted any engine parameter which the Administrator has determined to be subject to adjustment for certification and Selective Enforcement Audit testing in accordance with § 89.108–96, to any setting within the physically adjustable range of that parameter, as determined by the Administrator in accordance with § 89.108–96, prior to the performance of any tests. However, if the idle speed parameter is one which the Administrator has determined to be subject to adjustment, the Administrator may not adjust it to any setting which causes a lower engine idle speed than would have been possible within the physically adjustable range of the idle speed parameter if the manufacturer had accumulated 125 hours of service on the engine under paragraph (c) of this section, all other parameters being identically adjusted for the purpose of the comparison. The manufacturer may be requested to supply information needed to establish an alternate minimum idle speed. The Administrator, in making or specifying these adjustments, may consider the effect of the deviation from the manufacturer's recommended setting on emission performance characteristics as well as the likelihood that similar settings will occur on in-use engines. In determining likelihood, the Administrator may consider factors such as, but not limited to, the effect of the adjustment on engine performance characteristics and surveillance information from similar in-use engines.

(c) *Service Accumulation.* Prior to performing exhaust emission testing on an SEA test engine, the manufacturer

may accumulate on each engine a number of hours of service equal to the greater of 125 hours or the number of hours the manufacturer accumulated during certification on the emission data engine corresponding to the family specified in the test order.

(1) Service accumulation must be performed in a manner using good engineering judgment to obtain emission results representative of normal production engines. This service accumulation must be consistent with the new engine break-in instructions contained in the applicable owner's manual.

(2) The manufacturer must accumulate service at a minimum rate of 16 hours per engine during each 24-hour period, unless otherwise approved by the Administrator.

(i) The first 24-hour period for service begins as soon as authorized checks, inspections, and preparations are completed on each engine.

(ii) The minimum service or mileage accumulation rate does not apply on weekends or holidays.

(iii) If the manufacturer's service or target is less than the minimum rate specified (16 hours per day), then the minimum daily accumulation rate is equal to the manufacturer's service target.

(3) Service accumulation must be completed on a sufficient number of test engines during consecutive 24-hour periods to assure that the number of engines tested per day fulfills the requirements of paragraphs (g)(1) and (g)(2) of this section.

(d) The manufacturer may not perform any maintenance on test engines after selection for testing, nor may the Administrator allow deletion of any engine from the test sequence, unless requested by the manufacturer and approved by the Administrator before any engine maintenance or deletion.

(e) The manufacturer must expeditiously ship test engines from the point of selection to the test facility. If the test facility is not located at or in close proximity to the point of selection, the manufacturer must assure that test engines arrive at the test facility within 24 hours of selection. The Administrator may approve more time for shipment based upon a request by the manufacturer accompanied by a satisfactory justification.

(f) If an engine cannot complete the service accumulation or an emission test because of a malfunction, the manufacturer may request that the Administrator authorize either the repair of that engine or its deletion from the test sequence.

(g) Whenever a manufacturer conducts testing pursuant to a test order issued under this subpart, the manufacturer must notify the Administrator within one working day of receipt of the test order as to which test facility will be used to comply with the test order. If no test cells are available at a desired facility, the manufacturer must provide alternate testing capability satisfactory to the Administrator.

(1) A manufacturer with projected nonroad engine sales for the United States market for the applicable year of 7,500 or greater must complete emission testing at a minimum rate of two engines per 24-hour period, including each voided test and each smoke test.

(2) A manufacturer with projected nonroad engine sales for the United States market for the applicable year of less than 7,500 must complete emission testing at a minimum rate of one engine per 24-hour period, including each voided test and each smoke test.

(3) The Administrator may approve a lower daily rate of emission testing based upon a request by a manufacturer accompanied by a satisfactory justification.

(h) The manufacturer must perform test engine selection, shipping, preparation, service accumulation, and testing in such a manner as to assure that the audit is performed in an expeditious manner.

(i) *Retesting.* (1) The manufacturer may retest any engines tested during a Selective Enforcement Audit once a fail decision for the audit has been reached in accordance with § 89.510–96(e).

(2) The Administrator may approve retesting at other times based upon a request by the manufacturer accompanied by a satisfactory justification.

(3) The manufacturer may retest each engine a total of three times. The manufacturer must test each engine or vehicle the same number of times. The manufacturer may accumulate additional service before conducting a retest, subject to the provisions of paragraph (c) of this section.

(j) A manufacturer must test engines with the test procedure specified in subpart E of this part to demonstrate compliance with the exhaust emission standard (or applicable FEL) for oxides of nitrogen. If alternate procedures were used in certification pursuant to § 89.114–96, then those alternate procedures must be used.

§ 89.509–96 Calculation and reporting of test results.

(a) Initial test results are calculated following the applicable test procedure specified in paragraph (a) of § 89.508–96. The manufacturer rounds these results, in accordance with ASTM E29–90, to the number of decimal places contained in the applicable emission standard expressed to one additional significant figure. This procedure has been incorporated by reference. See § 89.6.

(b) Final test results are calculated by summing the initial test results derived in paragraph (a) of this section for each test engine, dividing by the number of tests conducted on the engine, and rounding in accordance with ASTM E29–90 to the same number of decimal places contained in the applicable standard expressed to one additional significant figure.

(c) Within five working days after completion of testing of all engines pursuant to a test order, the manufacturer must submit to the Administrator a report which includes the following information:

(1) The location and description of the manufacturer's exhaust emission test facilities which were utilized to conduct testing reported pursuant to this section;

(2) The applicable standards and/or FEL against which the engines were tested;

(3) A description of the engine and its associated emission-related component selection method used;

(4) For each test conducted;

(i) Test engine description, including:

(A) Configuration and engine family identification;

(B) Year, make, and build date;

(C) Engine identification number; and

(D) Number of hours of service accumulated on engine prior to testing;

(ii) Location where service accumulation was conducted and description of accumulation procedure and schedule;

(iii) Test number, date, test procedure used, initial test results before and after rounding, and final test results for all exhaust emission tests, whether valid or invalid, and the reason for invalidation, if applicable;

(iv) A complete description of any modification, repair, preparation, maintenance, and/or testing which was performed on the test engine and has not been reported pursuant to any other paragraph of this subpart and will not be performed on all other production engines;

(v) Where an engine was deleted from the test sequence by authorization of the Administrator, the reason for the deletion;

(vi) Any other information the Administrator may request relevant to the determination as to whether the new engines being manufactured by the

manufacturer do in fact conform with the regulations with respect to which the certificate of conformity was issued; and

(5) The following statement and endorsement:

This report is submitted pursuant to sections 213 and 208 of the Clean Air Act. This Selective Enforcement Audit was conducted in complete conformance with all applicable regulations under 40 CFR part 89 *et seq.* and the conditions of the test order. No emission-related changes to production processes or quality control procedures for the engine family tested have been made between receipt of the test order and conclusion of the audit. All data and information reported herein is, to the best of (Company Name) knowledge, true and accurate. I am aware of the penalties associated with violations of the Clean Air Act and the regulations thereunder. (Authorized Company Representative.)

§ 89.510–96 Compliance with acceptable quality level and passing and failing criteria for selective enforcement audits.

(a) The prescribed acceptable quality level is 40 percent.

(b) A failed engine is one whose final test results pursuant to § 89.509–96(b), for one or more of the applicable pollutants, exceed the applicable emission standard or family emission level.

(c) The manufacturer must test engines comprising the test sample until a pass decision is reached for all pollutants or a fail decision is reached for one pollutant. A pass decision is reached when the cumulative number of failed engines, as defined in paragraph (b) of this section, for each pollutant is less than or equal to the pass decision number, as defined in paragraph (d) of this section, appropriate to the cumulative number of engines tested. A fail decision is reached when the cumulative number of failed engines for one or more pollutants is greater than or equal to the fail decision number, as defined in paragraph (d) of this section, appropriate to the cumulative number of engines tested.

(d) The pass and fail decision numbers associated with the cumulative number of engines tested are determined by using the tables in appendix A to this subpart, "Sampling Plans for Selective Enforcement Auditing of Nonroad Engines," appropriate to the projected sales as made by the manufacturer in its report to EPA under § 89.505–96(c)(1). In the tables in appendix A to this subpart, sampling plan "stage" refers to the cumulative number of engines tested. Once a pass or fail decision has been made for a particular pollutant, the number of engines with final test results exceeding the emission standard for that pollutant shall not be considered any further for the purposes of the audit.

(e) Passing or failing of an SEA occurs when the decision is made on the last engine required to make a decision under paragraph (c) of this section.

(f) The Administrator may terminate testing earlier than required in paragraph (c) of this section.

§ 89.511–96 Suspension and revocation of certificates of conformity.

(a) The certificate of conformity is suspended with respect to any engine failing pursuant to paragraph (b) of § 89.510–96 effective from the time that testing of that engine is completed.

(b) The Administrator may suspend the certificate of conformity for a family which does not pass an SEA, pursuant to paragraph § 89.510–96(c), based on the first test or all tests conducted on each engine. This suspension will not occur before ten days after failure of the audit, unless the manufacturer requests an earlier suspension.

(c) If the results of testing pursuant to these regulations indicate that engines of a particular family produced at one plant of a manufacturer do not conform to the regulations with respect to which the certificate of conformity was issued, the Administrator may suspend the certificate of conformity with respect to that family for engines manufactured by the manufacturer at all other plants.

(d) Notwithstanding the fact that engines described in the application may be covered by a certificate of conformity, the Administrator may suspend such certificate immediately in whole or in part if the Administrator finds any one of the following infractions to be substantial:

(1) The manufacturer refuses to comply with the provisions of a test order issued by the Administrator under § 89.503–96.

(2) The manufacturer refuses to comply with any of the requirements of this subpart.

(3) The manufacturer submits false or incomplete information in any report or information provided to the Administrator under this subpart.

(4) The manufacturer renders inaccurate any test data submitted under this subpart.

(5) An EPA enforcement officer(s) or EPA authorized representative(s) is denied the opportunity to conduct activities related to entry and access as authorized in this subpart and a warrant or court order is presented to the manufacturer or the party in charge of a facility in question.

(6) An EPA enforcement officer(s) or EPA authorized representative(s) is unable to conduct activities related to entry and access as authorized in § 89.506–96 because a manufacturer has located a facility in a foreign jurisdiction where local law prohibits those activities.

(e) The Administrator must notify the manufacturer in writing of any suspension or revocation of a certificate of conformity in whole or in part; a suspension or revocation is effective upon receipt of the notification or ten days, except that the certificate is immediately suspended with respect to any failed engines as provided for in paragraph (a) of this section.

(f) The Administrator may revoke a certificate of conformity for a family when the certificate has been suspended pursuant to paragraph (b) or (c) of this section if the proposed remedy for the nonconformity, as reported by the manufacturer to the Administrator, is one requiring a design change or changes to the engine and/or emission control system as described in the application for certification of the affected family.

(g) Once a certificate has been suspended for a failed engine, as provided for in paragraph (a) of this section, the manufacturer must take the following actions before the certificate is reinstated for that failed engine:

(1) Remedy the nonconformity.

(2) Demonstrate that the engine conforms to applicable standards or family emission levels by retesting the engine in accordance with these regulations.

(3) Submit a written report to the Administrator, after successful completion of testing on the failed engine, which contains a description of the remedy and test results for each engine in addition to other information that may be required by this part.

(h) Once a certificate for a failed family has been suspended pursuant to paragraph (b) or (c) of this section, the manufacturer must take the following actions before the Administrator will consider reinstating the certificate:

(1) Submit a written report to the Administrator which identifies the reason for the noncompliance of the engines, describes the proposed remedy, including a description of any proposed quality control and/or quality assurance measures to be taken by the manufacturer to prevent future occurrences of the problem, and states the date on which the remedies will be implemented.

(2) Demonstrate that the engine family for which the certificate of conformity has been suspended does in fact comply with these regulations by testing engines selected from normal production runs of

that engine family, at the plant(s), port facility(ies) or associated storage facility(ies) specified by the Administrator, in accordance with the conditions specified in the initial test order. If the manufacturer elects to continue testing individual engines after suspension of a certificate, the certificate is reinstated for an engine actually determined to be in conformance with the applicable standards or family emission levels through testing in accordance with the applicable test procedures, provided that the Administrator has not revoked the certificate pursuant to paragraph (f) of this section.

(i) Once the certificate for a family has been revoked under paragraph (f) of this section and the manufacturer desires to continue introduction into commerce of a modified version of that family, the following actions must be taken before the Administrator may consider issuing a certificate for that modified family:

(1) If the Administrator determines that the proposed change(s) in engine design may have an effect on emission performance deterioration, the Administrator will notify the manufacturer, within five working days after receipt of the report in paragraph (g) of this section, whether subsequent testing under this subpart is sufficient to evaluate the proposed change or changes or whether additional testing is required; and

(2) After implementing the change or changes intended to remedy the nonconformity, the manufacturer must demonstrate that the modified engine family does in fact conform with these regulations by testing engines selected from normal production runs of that modified engine family in accordance with the conditions specified in the initial test order. If the subsequent audit results in passing of the audit, the Administrator will reissue the certificate or issue a new certificate, as the case may be, to include that family, provided that the manufacturer has satisfied the testing requirements of paragraph (i)(1) of this section. If the subsequent audit is failed, the revocation remains in effect. Any design change approvals under this subpart are limited to the family affected by the test order.

(j) At any time subsequent to an initial suspension of a certificate of conformity for a test engine pursuant to paragraph (a) of this section, but not later than 15 days (or such other period as may be allowed by the Administrator) after notification of the Administrator's decision to suspend or revoke a certificate of conformity in whole or in part pursuant to paragraph (b), (c), or (f) of this section, a manufacturer may request a hearing as to whether the tests have been properly conducted or any sampling methods have been properly applied.

(k) Any suspension of a certificate of conformity under paragraph (d) of this section:

(1) will be in writing and will include the offer of an opportunity for a hearing conducted in accordance with §§ 89.512–96, 89.513–96, and 89.514–96 and

(2) need not apply to engines no longer in the hands of the manufacturer.

(l) After the Administrator suspends or revokes a certificate of conformity pursuant to this section and prior to the commencement of a hearing under § 89.512–96, if the manufacturer demonstrates to the Administrator's satisfaction that the decision to suspend, revoke, or void the certificate was based on erroneous information, the Administrator will reinstate the certificate.

(m) To permit a manufacturer to avoid storing non-test engines when conducting an audit of a family subsequent to a failure of an SEA and while reauditing of the failed family, it may request that the Administrator conditionally reinstate the certificate for that family. The Administrator may reinstate the certificate subject to the condition that the manufacturer consents to recall all engines of that family produced from the time the certificate is conditionally reinstated if the family fails the subsequent audit at the level of the standard and to remedy any nonconformity at no expense to the owner.

§ 89.512–96 Request for public hearing.

(a) If the manufacturer disagrees with the Administrator's decision under § 89.511–96 (b), (c), (d), or (f) to suspend or revoke a certificate or disputes the basis for an automatic suspension pursuant to § 89.511–96 (a), the manufacturer may request a public hearing.

(b) The manufacturer's request must be filed with the Administrator not later than 15 days after the Administrator's notification of the decision to suspend or revoke, unless otherwise specified by the Administrator. The manufacturer must simultaneously serve two copies of this request upon the Director of the Manufacturers Operations Division and file two copies with the Hearing Clerk of the Agency. Failure of the manufacturer to request a hearing within the time provided constitutes a waiver of the right to a hearing. Subsequent to the expiration of the period for requesting a hearing as of right, the Administrator may, at her or his discretion and for good cause shown, grant the manufacturer a hearing to contest the suspension or revocation.

(c) The manufacturer's request for a public hearing must include:

(1) A statement as to which engine configuration(s) within a family is to be the subject of the hearing;

(2) A concise statement of the issues to be raised by the manufacturer at the hearing, except that in the case of the hearing requested under § 89.511–96(j), the hearing is restricted to the following issues:

(i) Whether tests have been properly conducted, specifically, whether the tests were conducted in accordance with applicable regulations under this part and whether test equipment was properly calibrated and functioning;

(ii) Whether sampling plans have been properly applied, specifically, whether sampling procedures specified in Appendix A of this subpart were followed and whether there exists a basis for distinguishing engines produced at plants other than the one from which engines were selected for testing which would invalidate the Administrator's decision under § 89.511–96(c);

(3) A statement specifying reasons why the manufacturer believes it will prevail on the merits of each of the issues raised; and

(4) A summary of the evidence which supports the manufacturer's position on each of the issues raised.

(d) A copy of all requests for public hearings will be kept on file in the Office of the Hearing Clerk and will be made available to the public during Agency business hours.

§ 89.513–96 Administrative procedures for public hearing.

(a) The Presiding Officer is an Administrative Law Judge appointed pursuant to 5 U.S.C. 3105 (see also 5 CFR part 930 as amended).

(b) The Judicial Officer is an officer or employee of the Agency appointed as a Judicial Officer by the Administrator, pursuant to this section, who meets the qualifications and performs functions as follows:

(1) *Qualifications.* A Judicial Officer may be a permanent or temporary employee of the Agency who performs other duties for the Agency. The Judicial Officer may not be employed by the Office of Enforcement or have any connection with the preparation or presentation of evidence for a hearing held pursuant to this subpart. The Judicial Officer must be a graduate of an accredited law school and a member in good standing of a recognized Bar

Association of any state or the District of Columbia.

(2) *Functions.* The Administrator may consult with the Judicial Officer or delegate all or part of the Administrator's authority to act in a given case under this section to a Judicial Officer, provided that this delegation does not preclude the Judicial Officer from referring any motion or case to the Administrator when the Judicial Officer determines such referral to be appropriate.

(c) For the purposes of this section, one or more Judicial Officers may be designated. As work requires, a Judicial Officer may be designated to act for the purposes of a particular case.

(d) *Summary decision.* (1) In the case of a hearing requested under § 89.511–96(j), when it clearly appears from the data and other information contained in the request for a hearing that no genuine and substantial question of fact or law exists with respect to the issues specified in § 89.512–96(c)(2), the Administrator may enter an order denying the request for a hearing and reaffirming the original decision to suspend or revoke a certificate of conformity.

(2) In the case of a hearing requested under § 89.512–96 to challenge a suspension of a certificate of conformity for the reasons specified in § 89.511–96(d), when it clearly appears from the data and other information contained in the request for the hearing that no genuine and substantial question of fact or law exists with respect to the issue of whether the refusal to comply with the provisions of a test order or any other requirement of § 89.503–96 was caused by conditions and circumstances outside the control of the manufacturer, the Administrator may enter an order denying the request for a hearing and suspending the certificate of conformity.

(3) Any order issued under paragraph (d)(1) or (d)(2) of this section has the force and effect of a final decision of the Administrator, as issued pursuant to § 89.515–96.

(4) If the Administrator determines that a genuine and substantial question of fact or law does exist with respect to any of the issues referred to in paragraphs (d)(1) and (d)(2) of this section, the Administrator will grant the request for a hearing and publish a notice of public hearing in the **Federal Register** or by such other means as the Administrator finds appropriate to provide notice to the public.

(e) *Filing and service.* (1) An original and two copies of all documents or papers required or permitted to be filed pursuant to this section and § 89.512–96(c) must be filed with the Hearing Clerk of the Agency. Filing is considered timely if mailed, as determined by the postmark, to the Hearing Clerk within the time allowed by this section and § 89.512–96(b). If filing is to be accomplished by mailing, the documents must be sent to the address set forth in the notice of public hearing referred to in paragraph (d)(4) of this section.

(2) To the maximum extent possible, testimony will be presented in written form. Copies of written testimony will be served upon all parties as soon as practicable prior to the start of the hearing. A certificate of service will be provided on or accompany each document or paper filed with the Hearing Clerk. Documents to be served upon the Director of the Manufacturers Operations Division must be sent by registered mail to: Director, Manufacturers Operations Division, U.S. Environmental Protection Agency, 6405–J, 401 M Street SW, Washington, DC 20460. Service by registered mail is complete upon mailing.

(f) *Computation of Time.* (1) In computing any period of time prescribed or allowed by this section, except as otherwise provided, the day of the act or event from which the designated period of time begins to run is not included. Saturdays, Sundays, and federal legal holidays are included in computing the period allowed for the filing of any document or paper, except that when the period expires on a Saturday, Sunday, or federal legal holiday, the period is extended to include the next following business day.

(2) A prescribed period of time within which a party is required or permitted to do an act is computed from the time of service, except that when service is accomplished by mail, three days will be added to the prescribed period.

(g) *Consolidation.* The Administrator or the Presiding Officer in his discretion may consolidate two or more proceedings to be held under this section for the purpose of resolving one or more issues whenever it appears that consolidation will expedite or simplify consideration of these issues. Consolidation does not affect the right of any party to raise issues that could have been raised if consolidation had not occurred.

(h) *Hearing Date.* To the extent possible hearings under § 89.512–96 will be scheduled to commence within 14 days of receipt of the application in § 89.512–96.

§ 89.514–96 Hearing procedures.

The procedures provided in § 86.1014–84 (i) to (s) apply for hearings requested pursuant to § 89.512–96, suspension, revocation, or voiding of a certificate of conformity.

§ 89.515–96 Appeal of hearing decision.

The procedures provided in § 86.1014–84 (t) to (aa) apply for appeals filed with respect to hearings held pursuant to § 89.514–96.

§ 89.516–96 Treatment of confidential information.

The provisions for treatment of confidential information as described in § 89.7 apply.

Appendix A to Subpart F of Part 89—Sampling Plans for Selective Enforcement Auditing of Nonroad Engines

TABLE 1.—SAMPLING PLAN CODE LETTER

Annual engine family sales	Code letter
20–50	AA[1]
20–99	A
100–299	B
300–299	C
500 or greater	D

[1] A manufacturer may optionally use either the sampling plan for code letter "AA" or sampling plan for code letter "A" for Selective Enforcement Audits of engine families with annual sales between 20 and 50 engines. Additionally, the manufacturer may switch between these plans during the audit.

TABLE 2.—SAMPLING PLAN FOR CODE LETTER "AA"

[Sample inspection criteria]

Stage	Pass No.	Fail No.
1	([1])	([2])
2	([1])	([2])
3	0	([2])
4	0	([2])
5	1	5
6	1	6
7	2	6
8	2	7
9	3	7
10	3	8
11	4	8
12	4	9
13	5	9
14	5	10
15	6	10
16	6	10
17	7	10
18	8	10
19	8	10
20	9	10

[1] Test sample passing not permitted at this stage.

[2] Test sample failure not permitted at this stage.

TABLE 3.—SAMPLING PLAN FOR CODE LETTER "A"

[Sample inspection criteria]

Stage	Pass No.	Fail No.
1	(1)	(2)
2	(1)	(2)
3	(1)	(2)
4	0	(2)
5	0	(2)
6	1	6
7	1	7
8	2	7
9	2	8
10	3	8
11	3	8
12	4	9
13	5	10
14	5	10
15	6	11
16	6	11
17	7	12
18	7	12
19	8	13
20	8	13
21	9	14
22	10	14
23	10	15
24	11	15
25	11	16
26	12	16
27	12	17
28	13	17
29	14	17
30	16	17

[1] Test sample passing not permitted at this stage.
[2] Test sample failure not permitted at this stage.

TABLE 4.—SAMPLING PLAN FOR CODE LETTER "B"

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
1	(1)	(2)
2	(1)	(2)
3	(1)	(2)
4	(1)	(2)
5	0	(2)
6	1	6
7	1	7
8	2	7
9	2	8
10	3	8
11	3	9
12	4	9
13	4	10
14	5	10
15	5	11
16	6	12
17	6	12
18	7	13
19	8	13
20	8	14
21	9	14
22	9	15
23	10	15
24	10	16
25	11	16
26	11	17
27	12	17

TABLE 4.—SAMPLING PLAN FOR CODE LETTER "B"—Continued

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
28	12	18
29	13	18
30	13	19
31	14	19
32	14	20
33	15	20
34	16	21
35	16	21
36	17	22
37	17	22
38	18	22
39	18	22
40	21	22

[1] Test sample passing not permitted at this stage.
[2] Test sample failure not permitted at this stage.

TABLE 5.—SAMPLING PLAN FOR CODE LETTER "C"

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
1	(1)	(2)
2	(1)	(2)
3	(1)	(2)
4	(1)	(2)
5	0	(2)
6	0	6
7	1	7
8	2	7
9	2	8
10	3	9
11	3	9
12	4	10
13	4	10
14	5	11
15	5	11
16	6	12
17	6	12
18	7	13
19	7	13
20	8	14
21	8	14
22	9	15
23	10	15
24	10	16
25	11	16
26	11	17
27	12	17
28	12	18
29	13	18
30	13	19
31	14	19
32	14	20
33	15	20
34	15	21
35	16	21
36	16	22
37	17	22
38	18	23
39	18	23
40	19	24
41	19	24
42	20	25
43	20	25
44	21	26

TABLE 5.—SAMPLING PLAN FOR CODE LETTER "C"—Continued

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
45	21	27
46	22	27
47	22	27
48	23	27
49	23	27
50	26	27

[1] Test sample passing not permitted at this stage.
[2] Test sample failure not permitted at this stage.

TABLE 6.—SAMPLING PLAN FOR CODE LETTER "D"

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
1	(1)	(2)
2	(1)	(2)
3	(1)	(2)
4	(1)	(2)
5	0	(2)
6	0	6
7	1	7
8	2	8
9	2	8
10	3	9
11	3	9
12	4	10
13	4	10
14	5	11
15	5	11
16	6	12
17	6	12
18	7	13
19	7	13
20	8	14
21	8	14
22	9	15
23	9	15
24	10	16
25	11	16
26	11	17
27	12	17
28	12	18
29	13	19
30	13	19
31	14	20
32	14	20
33	15	21
34	15	21
35	16	22
36	16	22
37	17	23
38	17	23
39	18	24
40	18	24
41	19	25
42	19	26
43	20	26
44	21	27
45	21	27
46	22	28
47	22	28
48	23	29
49	23	29
50	24	30
51	24	30

TABLE 6.—SAMPLING PLAN FOR CODE LETTER "D"—Continued

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
52	25	31
53	25	31
54	26	32
55	26	32
56	27	33
57	27	33
58	28	33
59	28	33
60	32	33

[1] Test sample passing not permitted at this stage.

[2] Test sample failure not permitted at this stage.

Subpart G—Importation of Nonconforming Nonroad Engines

§ 89.601–96 Applicability.

(a) Except where otherwise indicated, this subpart is applicable to nonroad engines for which the Administrator has promulgated regulations under this part prescribing emission standards and nonroad vehicles and equipment containing such nonroad engines that are offered for importation or imported into the United States, but which engines, at the time of conditional importation, are not covered by certificates of conformity issued under section 213 and section 206(a) of the Clean Air Act as amended (that is, which are nonconforming nonroad engines as defined in § 89.602–96), and this part. Compliance with regulations under this subpart does not relieve any person or entity from compliance with other applicable provisions of the Clean Air Act.

(b) Regulations prescribing further procedures for the importation of nonroad engines and nonroad vehicles and equipment into the customs territory of the United States, as defined in 19 U.S.C. 1202, are set forth in U.S. Bureau of Customs regulations.

(c) For the purposes of this subpart, the term "nonroad engine" includes all nonroad engines incorporated into nonroad equipment or nonroad vehicles at the time they are imported or offered for import into the United States.

§ 89.602–96 Definitions.

The definitions in subpart A of this part apply to this subpart. The following definitions also apply to this subpart.

Certificate of conformity. The document issued by the Administrator under section 213 and section 206(a) of the Act.

Currently valid certificate of conformity. A certificate of conformity for which the current date is within the effective period as specified on the certificate of conformity, and which has not been withdrawn, superseded, voided, suspended, revoked, or otherwise rendered invalid.

Fifteen working day hold period. The period of time between a request for final admission and the automatic granting of final admission (unless EPA intervenes) for a nonconforming nonroad engine conditionally imported pursuant to § 89.605–96 or § 89.609–96. Day one of the hold period is the first working day (see definition below) after the Manufacturers Operations Division of EPA receives a complete and valid application for final admission.

Independent commercial importer (ICI). An importer who is not an original engine manufacturer (OEM) (see definition below), but is the entity in whose name a certificate of conformity for a class of nonroad engines has been issued.

Model year for imported engines. The manufacturer's annual production period (as determined by the Administrator) which includes January 1 of the calendar year; provided, that if the manufacturer has no annual production period, the term "model year" means the calendar year in which a nonroad engine is modified. An independent commercial importer (ICI) is deemed to have produced a nonroad engine when the ICI has modified (including labeling) the nonconforming nonroad engine to meet applicable emission requirements.

Nonconforming nonroad engine. A nonroad engine which is not covered by a certificate of conformity prior to final or conditional admission (or for which such coverage has not been adequately demonstrated to EPA) and which has not been finally admitted into the United States under the provisions of § 89.605–96 or § 89.609–96.

Original engine manufacturer (OEM). The entity which originally manufactured the nonroad engine.

Original production (OP) year. The calendar year in which the nonroad engine was originally produced by the OEM.

Original production (OP) years old. The age of a nonroad engine as determined by subtracting the original production year of the nonroad engine from the calendar year of importation.

Production changes. Those changes in nonroad engine configuration, equipment, or calibration which are made by an OEM or ICI in the course of nonroad engine production and required to be reported under § 89.123–96.

United States. United States includes the customs territory of the United States as defined in 19 U.S.C. 1202, and the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Useful life. A period of time as specified in subpart B of this part which for a nonconforming nonroad engine begins at the time of resale (for a nonroad engine owned by the ICI at the time of importation) or release to the owner (for a nonroad engine not owned by the ICI at the time of importation) of the nonroad engine by the ICI after modification and/or testing pursuant to § 89.605–96 or § 89.609–96.

Working day. Any day on which federal government offices are open for normal business. Saturdays, Sundays, and official federal holidays are not working days.

§ 89.603–96 General requirements for importation of nonconforming nonroad engines.

(a) A nonconforming nonroad engine offered for importation into the United States is to be imported only by an Independent Commercial Importer (ICI) who is a holder of a currently valid certificate of conformity unless an exemption or exclusion is granted by the Administrator under § 89.611–96 of this subpart. For a nonroad engine imported pursuant to § 89.605–96, the ICI must hold a currently valid certificate of conformity for that specific nonroad engine model.

(b) Any nonroad engine imported into the United States must have a legible unique engine identification number permanently affixed to or engraved on the engine.

(c) Final admission may not be granted unless:

(1) The nonroad engine is covered by a certificate of conformity issued under subpart B of this part in the name of the ICI and the ICI has complied with all requirements of § 89.605–96; or

(2) The nonroad engine is modified and emission tested in accordance with the provisions of § 89.609–96 and the ICI has complied with all other requirements of § 89.609–96; or

(3) The nonroad engine is exempted or excluded under § 89.611–96.

(d) The ICI must submit to the Manufacturers Operations Division of EPA a copy of all approved applications for certification used to obtain certificates of conformity for the purpose of importing nonconforming nonroad engines pursuant to § 89.605–96 or § 89.609–96. In addition, the ICI must submit to the Manufacturers Operations Division a copy of all approved production changes implemented pursuant to § 89.605–96 or subpart B of this part. Documentation

submitted pursuant to this paragraph must be provided to the Manufacturers Operations Division within 10 working days of approval of the certification application (or production change) by the Certification Division of EPA.

§ 89.604–96 Conditional admission.

(a) A nonroad engine offered for importation under § 89.605–96 or § 89.609–96 may be conditionally admitted into the United States. These engines are refused final admission, unless at the time of conditional admission the importer has submitted to the Administrator a written report that the subject nonroad engine has been permitted conditional admission pending EPA approval of its application for final admission under § 89.605–96 or § 89.609–96. This written report is to contain the following:

(1) Identification of the importer of the nonroad engine and the importer's address, telephone number, and taxpayer identification number;

(2) Identification of the nonroad engine owner, the owner's address, telephone number, and taxpayer identification number;

(3) Identification of the nonroad engine including make, model, identification number, and original production year;

(4) Information indicating under what provision of these regulations the nonroad engine is to be imported;

(5) Identification of the place where the subject nonroad engine is to be stored until EPA approval of the importer's application to the Administrator for final admission;

(6) Authorization for EPA enforcement officers to conduct inspections or testing otherwise permitted by the Act or regulations thereunder;

(7) Identification of the Independent Commercial Importer's (ICI) certificate of conformity that permits the ICI to import that nonroad engine (for importation under § 89.605–96 or § 89.609–96); and

(8) Such other information as is deemed necessary by the Administrator.

(b) EPA will not require a U.S. Customs Service bond for a nonconforming nonroad engine which is imported under § 89.605–96 or § 89.609–96. The period of conditional admission may not exceed 120 days. Nonroad engines imported under § 89.605–96 or § 89.609–96 may not be operated during the period of conditional admission except for that operation necessary to comply with the requirements of this subpart. During the period of conditional admission applicable to § 89.605–96 or § 89.609–96, the importer must store the nonroad engine at a location where the Administrator has reasonable access to the nonroad engine for inspection.

(c) During the period of conditional admission under § 89.605–96 or § 89.609–96, an ICI may transfer responsibility of a nonroad engine to another qualified ICI for the purposes of complying with this subpart.

(1) The transferee ICI must be a holder of a currently valid certificate of conformity for the specific nonroad engine being transferred or be authorized to import the nonroad engine pursuant to § 89.609–96 as of the transfer date. The transferee ICI must comply with all the requirements of § 89.603–96, § 89.604–96, and either § 89.605–96 or § 89.609–96, as applicable.

(2) For the purpose of this subpart, the transferee ICI has "imported" the nonroad engine as of the transfer date as designated in a written record that is signed by both ICIs.

(3) The ICI that originally imported the nonroad engine is responsible for all requirements of this subpart from the actual date of importation until the date of transfer as designated in the written record. The transferee ICI is responsible for all requirements of this subpart beginning on the date of transfer.

(4) A copy of the written record is to be submitted to the Manufacturers Operations Division of EPA within five working days of the transfer date.

(d) Notwithstanding any other requirement of this subpart or U.S. Customs Service regulations, an ICI may also assume responsibility for the modification and testing of a nonconforming nonroad engine which was previously imported by another party. The ICI must be a holder of a currently valid certificate of conformity for that specific nonroad engine or authorized to import it pursuant to § 89.609–96 at the time of assuming such responsibility. The ICI must comply with all the requirements of § 89.603–96, § 89.604–96, and either § 89.605–96 or § 89.609–96, as applicable. For the purposes of this subpart, the ICI has "imported" the nonroad engine as of the date the ICI assumes responsibility for the modification and testing of the nonroad engine. The ICI must submit written notification to the Manufacturers Operations Division of EPA within 10 working days of the assumption of that responsibility.

§ 89.605–96 Final admission of certified nonroad engines.

(a) A nonroad engine may be finally admitted into the United States upon approval of the ICI's application to the Administrator. The application is made by completing EPA forms in accordance with EPA instructions. The application contains:

(1) The information required in § 89.604–96(a);

(2) Information demonstrating that the nonroad engine has been modified in accordance with a valid certificate of conformity. Demonstration is made in one of the following ways:

(i) The ICI attests that the nonroad engine has been modified in accordance with the provisions of the ICI's certificate of conformity; presents to EPA a statement written by the applicable Original Engine Manufacturer (OEM) that the OEM must provide to the ICI, and to EPA, information concerning production changes to the class of nonroad engines described in the ICI's application for certification; delivers to the Manufacturers Operations Division of EPA notification by the ICI of any production changes already implemented by the OEM at the time of application and their effect on emissions; and obtains from EPA written approval to use this demonstration option; or

(ii) The ICI attests that the nonroad engine has been modified in accordance with the provisions of the ICI's certificate of conformity. The ICI also attests that it has conducted, within 120 days of entry, an applicable and valid emission test on every third nonroad engine imported under that certificate of conformity to demonstrate compliance with federal emission requirements. The test is to be conducted at a laboratory located within the United States. Sequencing of the tests is determined by the date of importation of each nonroad engine beginning with the prototype nonroad engine used to obtain the applicable certificate of conformity. Should the ICI exceed a threshold of 300 nonroad engines imported under the certificate of conformity without adjustments or other changes in accordance with paragraph (a)(3) of this section, the amount of required testing is reduced to every fifth nonroad engine.

(3) The results of every emission test which the ICI conducted on the nonroad engine pursuant to paragraph (a)(2)(ii) of this section. Should a subject nonroad engine fail an emission test at any time, the following procedures are applicable:

(i) The ICI may either:

(A) Conduct one retest that involves no adjustment of the nonroad engine from the previous test (for example, adjusting the RPM, timing, air-to-fuel ratio, and so forth) other than adjustments to adjustable parameters

that, upon inspection, were found to be out of tolerance. When such an allowable adjustment is made, the parameter may be reset only to the specified (that is, nominal) value (and not any other value within the tolerance band); or

(B) Initiate a change in production (production change) under the provisions of subpart B of this part that causes the nonroad engine to meet federal emission requirements.

(ii) If the ICI chooses to retest in accordance with paragraph (a)(3)(i)(A) of this section:

(A) The retests are to be completed no later than five working days subsequent to the first emission test;

(B) Should the subject nonroad engine fail the second emission test, then the ICI must initiate a change in production (a production change) under the provisions of subpart B of this part that causes the nonroad engine to meet federal emission requirements.

(iii) If the ICI chooses to initiate a change in production (a production change) under the provisions of subpart B of this part that causes the nonroad engine to meet federal requirements, a change involving adjustments of adjustable nonroad engine parameters (for example, adjusting the RPM, timing, air/fuel ratio) represents a change in the specified (that is, nominal) value to be deemed acceptable by EPA.

(iv) A production change made in accordance with this section is to be implemented on all subsequent nonroad engines imported under the certificate of conformity after the date of importation of the nonroad engine which gave rise to the production change.

(v) Commencing with the first nonroad engine receiving the production change, every third nonroad engine imported under the certificate of conformity is to be emission tested to demonstrate compliance with federal emission requirements until, as in paragraph (a)(2)(ii) of this section, a threshold of 300 nonroad engines imported under the certificate of conformity is exceeded without adjustments or other changes in accordance with paragraph (a)(3)(i)(A) of this section, at which time the amount of required emission testing is reduced to every fifth nonroad engine.

(vi) A report concerning these production changes is to be made to both the Manufacturers Operations and Certification Divisions of EPA within ten working days of initiation of the production change. The cause of any failure of an emission test is to be identified, if known;

(4) The applicable deterioration factor, if any;

(5) The emission test results adjusted by the deterioration factor;

(6) Other information that may be specified by applicable regulations or on the certificate of conformity under which the nonroad engine has been modified in order to assure compliance with requirements of the Act;

(7) All information required under § 89.610–96 related to maintenance, warranties, and labeling;

(8) An attestation by the ICI that the ICI is responsible for the nonroad engine's compliance with federal emission requirements, regardless of whether the ICI owns the nonroad engine imported under this section;

(9) The name, address, and telephone number of the person who the ICI prefers to receive EPA notification under § 89.605–96(c);

(10) An attestation by the ICI that all requirements of § 89.607–96 and § 89.610–96 have been met; and

(11) Other information as is deemed necessary by the Administrator.

(b) EPA approval for final admission of a nonroad engine under this section is to be presumed not to have been granted if a requirement of this subpart has not been met. This includes, but is not limited to, properly modifying the nonroad engine to be in conformity in all material respects with the description in the application for certification or not complying with the provisions of § 89.605–96(a)(2) or if the final emission test results, adjusted by the deterioration factor, if applicable, do not comply with applicable emission standards.

(c) Except as provided in paragraph (b) of this section, EPA approval for final admission of a nonroad engine under this section is presumed to have been granted if the ICI does not receive oral or written notice from EPA to the contrary within 15 working days of the date that the Manufacturers Operations Division of EPA receives the ICI's application under paragraph (a) of this section. EPA notice of nonapproval may be made to any employee of the ICI. It is the responsibility of the ICI to ensure that the Manufacturers Operations Division of EPA receives the application and to confirm the date of receipt. During this 15 working day hold period, the nonroad engine is to be stored at a location where the Administrator has reasonable access to the nonroad engine for the Administrator's inspection. The storage is to be within 50 miles of the ICI's testing facility to allow the Administrator reasonable access for inspection and/or testing. A storage facility not meeting this criterion must be approved in writing by the Administrator prior to the submittal of the ICI's application under paragraph (a) of this section.

§ 89.606–96 Inspection and testing of imported nonroad engines.

(a) In order to allow the Administrator to determine whether an ICI's production nonroad engines comply with applicable emission requirements or requirements of this subpart, an EPA enforcement officer or authorized representative is authorized to conduct inspections and/or tests of nonroad engines imported by the ICI. The ICI must admit an EPA enforcement officer or authorized representative during operating hours to any of the following places upon demand and upon presentation of credentials:

(1) Any facility where any nonroad engine imported by the ICI under this subpart was or is being modified, tested, or stored and

(2) Any facility where any record or other document relating to modification, testing, or storage of the nonroad engine, or required to be kept by § 89.607–96, is located. EPA may require inspection or testing of nonroad engines at the test facility used by the ICI or at an EPA-designated testing facility, with transportation and/or testing costs to be borne by the ICI.

(b) Upon admission to any facility referred to in paragraph (a) of this section, an EPA enforcement officer or authorized representative is allowed during operating hours:

(1) To inspect and monitor any part or aspect of activities relating to the ICI's modification, testing, and/or storage of nonroad engines imported under this subpart;

(2) To inspect and make copies of record(s) or document(s) related to modification, testing, and storage of a nonroad engine, or required by § 89.607–96; and

(3) To inspect and photograph any part or aspect of the nonroad engine and any component used in the assembly thereof.

(c) An EPA enforcement officer or authorized representative is to be furnished, by those in charge of a facility being inspected, with such reasonable assistance as the officer or representative may request to help discharge any function listed in this subpart. An ICI must make arrangements with those in charge of a facility operated for its benefit to furnish such reasonable assistance without charge to EPA. Reasonable assistance includes, but is not limited to, clerical, copying, interpretation and translation services, and the making available on

request of personnel of the facility being inspected during their working hours to inform the EPA enforcement officer or authorized representative of how the facility operates and to answer any questions.

(d) The requirements of paragraphs (a), (b), and (c) of this section apply whether or not the ICI owns or controls the facility in question. It is the ICI's responsibility to make such arrangements as may be necessary to assure compliance with paragraphs (a), (b), and (c) of this section. Failure to do so, or other failure to comply with paragraphs (a), (b), or (c), may result in sanctions as provided for in the Act or § 89.612–96(e).

(e) Duly designated enforcement officers are authorized to proceed ex parte to seek warrants authorizing the inspection or testing of the nonroad engines described in paragraph (a) of this section whether or not the enforcement officers first attempted to seek permission from the ICI or facility owner to inspect such nonroad engines.

(f) The results of the Administrator's test under this section comprise the official test data for the nonroad engine for purposes of determining whether the nonroad engine should be permitted final entry under § 89.605–96 or § 89.609–96.

§ 89.607–96 Maintenance of independent commercial importer's records.

(a) The Independent Commercial Importer (ICI) subject to any of the provisions of this subpart must establish and maintain adequately organized and indexed records, correspondence and other applicable documents relating to the certification, modification, test, purchase, sale, storage, registration, and importation of that nonroad engine. The ICI must retain such records for 8 years from the date of final admission or exportation of a nonconforming nonroad engine imported by the ICI. These records include, but are not limited to:

(1) The declaration required by U.S. Bureau of Customs regulations.

(2) Any documents or other written information required by a federal government agency to be submitted or retained in conjunction with the certification, importation or emission testing (if applicable) of nonroad engines;

(3) All bills of sale, invoices, purchase agreements, purchase orders, principal or agent agreements, and correspondence between the ICI and the ultimate purchaser of each nonroad engine and between any agents of the above parties;

(4) For nonroad engines imported by an ICI pursuant to § 89.605–96 or § 89.609–96, documents providing parts identification data (including calibration changes and part numbers and location of such parts on each nonroad engine) associated with the emission control system installed on each nonroad engine demonstrating that such emission control system was properly installed on such nonroad engine;

(5) For nonroad engines imported by an ICI pursuant to § 89.605–96 or § 89.609–96, documents demonstrating that, where applicable, each nonroad engine was emission tested in accordance with subpart E of this part and part 86, subpart I of this chapter;

(6) Documents providing evidence that the requirements of § 89.610–96 have been met;

(7) Documents providing evidence of compliance with all relevant requirements of the Clean Air Act;

(8) Documents providing evidence of the initiation of the 15 working day hold period (that is, evidence that the application submitted pursuant to § 89.605–96(a) or § 89.609–96(b) was received by EPA) for each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96;

(9) For nonroad engines owned by the ICI at the time of importation, documents providing evidence of the date of sale and date of delivery to the ultimate purchaser, together with the name, address, and telephone number of the ultimate purchaser for each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96;

(10) For nonroad engines not owned by the ICI at the time of importation, documents providing evidence and date of release to the owner (including owner's name, address, and telephone number) for each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96;

(11) Documents providing evidence of the date of original manufacture of the nonroad engine. The importer may substitute an alternate date in lieu of the date of original manufacture, provided that the substitution of such alternate date is approved in advance by the Administrator.

(b) The ICI is responsible for ensuring the maintenance of records required by this section, regardless of whether or not facilities used by the ICI to comply with requirements of this subpart are under the control of the ICI.

§ 89.608–96 "In Use" inspections and recall requirements.

(a) Nonroad engines which have been imported by an Independent Commercial Importer (ICI) pursuant to § 89.605–96 or § 89.609–96 and finally admitted by EPA may be inspected and emission tested by EPA for the recall period specified in § 89.104–96(b).

(b) ICIs must maintain for eight years, and provide to EPA upon request, a list of owners or ultimate purchasers of all nonroad engines imported by the ICI under this subpart.

(c) The Administrator must notify the ICI whenever the Administrator has determined that a substantial number of a class or category of the ICI's nonroad engines, although properly maintained and used, do not conform to the regulations prescribed under section 213 of the Act when in actual use throughout their useful lives. After such notification, the recall regulations at subpart H of this part govern the ICI's responsibilities. References to a manufacturer in the recall regulations apply to the ICI.

§ 89.609–96 Final admission of modification nonroad engines and test nonroad engines.

(a) A nonroad engine may be imported under this section by an Independent Commercial Importer (ICI) possessing a currently valid certificate of conformity only if:

(1) The nonroad engine is six original production years old or older; and

(2) The ICI's name has not been placed on a currently effective EPA list of ICIs ineligible to import such modification/test nonroad engines, as described in paragraph (e) of this section; and

(3) The ICI has a currently valid certificate of conformity for the same nonroad engine class and fuel type as the nonroad engine being imported.

(b) A nonroad engine conditionally imported under this section may be finally admitted into the United States upon approval of the ICI's application by the Administrator. The application is to be made by completing EPA forms, in accordance with EPA instructions. The ICI includes in the application:

(1) The identification information required in § 89.604–96;

(2) An attestation by the ICI that the nonroad engine has been modified and tested in accordance with the applicable emission tests as specified in Subpart B § 89.119–96(a) of this part at a laboratory within the United States;

(3) The results of all emission tests;

(4) The applicable deterioration factor assigned by EPA, if any;

(5) The emission test results adjusted by the applicable deterioration factor;

(6) All information required under § 89.610–96 related to maintenance, warranties, and labeling;

(7) An attestation by the ICI that the ICI is responsible for the nonroad

engine's compliance with federal emission requirements, regardless of whether the ICI owns the nonroad engine imported under this section;

(8) The applicable address and telephone number of the ICI, or the name, address, and telephone number of the person who the ICI prefers to receive EPA notification under § 89.609–96(d);

(9) An attestation by the ICI that all requirements of § 89.607–95 and § 89.610–96 have been met; and

(10) Such other information as is deemed necessary by the Administrator.

(c) EPA approval for final admission of a nonroad engine under this section is presumed not to have been granted if any requirement of this subpart has not been met.

(d) Except as provided in paragraph (c) of this section, EPA approval for final admission of a nonroad engine under this section is presumed to have been granted if the ICI does not receive oral or written notice from EPA to the contrary within 15 working days of the date that the Manufacturers Operations Division of EPA receives the ICI's application under paragraph (b) of this section. Such EPA notice of nonapproval may be made to any employee of the ICI. It is the responsibility of the ICI to ensure that the Manufacturers Operations Division of EPA receives the application and to confirm the date of receipt. During this 15 working day hold period, the nonroad engine is stored at a location where the Administrator has reasonable access to the nonroad engine for the Administrator's inspection. The storage is to be within 50 miles of the ICI's testing facility to allow the Administrator reasonable access for inspection and/or testing. A storage facility not meeting this criterion must be approved in writing by the Administrator prior to the submittal of the ICI's application under paragraph (b) of this section.

(e) *EPA list of ICIs ineligible to import nonroad engines for modification/test.* EPA maintains a current list of ICIs who have been determined to be ineligible to import nonroad engines under this section. The determination of ineligibility is made in accordance with the criteria and procedures in § 89.612–96(e) of this subpart.

(f) *Inspections.* Prior to final admission, a nonroad engine imported under this section is subject to special inspections as described in § 89.606–96 with these additional provisions:

(1) If, in the judgment of the Administrator, a significant number of nonroad engines imported by an ICI fail to comply with emission requirements upon inspection or retest or if the ICI fails to comply with a provision of these regulations that pertain to nonroad engines imported pursuant to § 89.609–96, the ICI may be placed on the EPA list of ICIs ineligible to import nonroad engines under this section as specified in paragraph (e) of this section and § 89.612–96(e).

(2) An individual nonroad engine which fails a retest or inspection is to be repaired and retested, as applicable, to demonstrate compliance with emission requirements before final admission is granted by EPA.

(3) Unless otherwise specified by EPA, the ICI bears the costs of all retesting under this subsection, including transportation.

(g) *In-use inspection and testing.* A nonroad engine imported under this section may be tested or inspected by EPA at any time during the recall period specified in § 89.104–96(b), in accordance with § 89.608–96(a). If, in the judgment of the Administrator, a significant number of properly maintained and used nonroad engines imported by the ICI pursuant to this section fail to meet emission requirements, the name of the ICI may be placed on the EPA list of ICIs ineligible to import nonroad engines under the modification/test provision as specified in paragraph (e) of this section and § 89.612–96(e).

§ 89.610–96 Maintenance instructions, warranties, emission labeling.

The provisions of this section are applicable to all nonroad engines imported under the provisions of § 89.605–96 or § 89.609–96.

(a) *Maintenance Instructions.* (1) The Independent Commercial Importer (ICI) must furnish to the purchaser, or to the owner of each nonroad engine imported under § 89.605–96 or § 89.609–96 of this subpart, written instructions for the maintenance and use of the nonroad engine by the purchaser or owner. Each application for final admission of a nonroad engine is to provide an attestation that such instructions have been or will be (if the ultimate purchaser is unknown) furnished to the purchaser or owner of such nonroad engine at the time of sale or delivery. The ICI must maintain a record of having furnished such instructions.

(2) For each nonroad engine imported under § 89.609–96, a copy of the maintenance and use instructions is to be maintained in a file containing the records for that nonroad engine.

(3) The maintenance and use instructions are not to contain requirements more restrictive than those set forth in § 89.109–96 (Maintenance Instructions) and are to be in sufficient detail and clarity that a mechanic of average training and ability can maintain or repair the nonroad engine.

(4) For each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96, ICIs must furnish with each nonroad engine a list of the emission control parts, emission-related parts added by the ICI, and the emission control and emission-related parts furnished by the Original Engine Manufacturer (OEM).

(5) The information required in this section to be furnished to the ultimate purchaser or owner is to be copied and maintained in a file containing the records for that nonroad engine prior to submitting each application for final admission pursuant to § 89.605–96(a) or § 89.609–96(b).

(b) *Warranties.* (1) ICIs must submit to the Manufacturers Operations Division of EPA sample copies (including revisions) of any warranty documents required by this section prior to importing nonroad engines under this subpart.

(2) ICIs must provide to nonroad engine owners emission warranties identical to those required by sections 207(a) of the Act. The warranty period for each nonroad engine is to commence on the date the nonroad engine is delivered by the ICI to the ultimate purchaser or owner.

(3) ICIs must provide warranty insurance coverage by a prepaid mandatory service insurance policy underwritten by an independent insurance company. The policy is to:

(i) Be subject to the approval of the Administrator if the insurance coverage is less than the required warranty;

(ii) At a minimum, provide coverage for emission-related components installed or modified by the ICI and, to the maximum extent possible, the emission-related components installed by the OEM;

(iii) Be transferable to each successive owner for the periods specified in § 89.104–96(c); and

(iv) Provide that in the absence of an ICI's facility being reasonably available (that is, within 50 miles) for performance of warranty repairs, the warranty repairs may be performed anywhere.

(4) ICIs must attest in each application for final admission that the warranty requirements have been met, that the mandatory insurance has been paid and is in effect, and that certificates and statements of the warranties have been or will be provided to the owner or ultimate purchaser. A copy of the warranties and evidence that the warranties are paid and in effect is to be maintained in a file containing the records for each nonroad engine prior to

submitting each application for final admission pursuant to § 89.605–96(a) or § 89.609–96(b).

(c) *Emission labeling.* (1) For each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96, the ICI must affix a permanent legible label which identifies each nonroad engine and also satisfies the following:

(i) The label meets all the requirements of § 89.110–96 and contains the following statement "This nonroad engine was originally produced in (month and year of original production). It has been imported and modified by (ICI's name, address, and telephone number) to conform to United States emission regulations applicable to the (year) model year."

(ii) If the nonroad engine is owned by the ICI at the time of importation, the label also states "This nonroad engine is warranted for five years or 3000 hours of operation from the date of purchase, whichever first occurs."

(iii) If the nonroad engine is not owned by the ICI at the time of importation, the label states "This nonroad engine is warranted for five years or 3000 hours of operation from the date of release to the owner, whichever first occurs."

(iv) For nonroad engines imported under § 89.609–96, the label clearly states in bold letters that "This nonroad engine has not been manufactured under a certificate of conformity but conforms to United States emission regulations under a modification/test program." For all nonroad engines imported pursuant to § 89.605–96 or § 89.609–96, the label contains the vacuum hose routing diagram applicable to the nonroad engines.

(2) As part of the application to the Administrator for final admission of each individual nonroad engine under § 89.609–96, the ICI must maintain a copy of the labels for each nonroad engine in a file containing the records for that nonroad engine prior to submitting each application for final admission. ICIs importing under § 89.605–96 or § 89.609–96 must attest to compliance with the preceding labeling requirements of this section in each application for final admission.

§ 89.611–96 Exemptions and exclusions.

(a) Individuals, as well as ICIs, are eligible for importing nonroad engines into the United States under the provisions of this section, unless otherwise specified.

(b) Notwithstanding other requirements of this subpart, a nonroad engine entitled to one of the temporary exemptions of this paragraph may be conditionally admitted into the United States if prior written approval for the conditional admission is obtained from the Administrator. Conditional admission is to be under bond. The Administrator may request that the U.S. Customs Service require a specific bond amount to ensure compliance with the requirements of the Act and this subpart. A written request for approval from the Administrator is to contain the identification required in § 89.604–96(a) (except for § 89.604–96(a)(5)) and information that demonstrates that the importer is entitled to the exemption. Noncompliance with provisions of this section may result in the forfeiture of the total amount of the bond or exportation of the nonroad engine. The following temporary exemptions are permitted by this paragraph:

(1) *Exemption for repairs or alterations.* Upon written approval by EPA, an owner of nonroad engines may conditionally import under bond such nonroad engines solely for purpose of repair(s) or alteration(s). The nonroad engines may not be operated in the United States other than for the sole purpose of repair or alteration. They may not be sold or leased in the United States and are to be exported upon completion of the repair(s) or alteration(s).

(2) *Testing exemption.* A test nonroad engine may be conditionally imported by a person subject to the requirements of § 89.905. A test nonroad engine may be operated in the United States provided that the operation is an integral part of the test. This exemption is limited to a period not exceeding one year from the date of importation unless a request is made by the appropriate importer concerning the nonroad engine in accordance with § 89.905(f) for a subsequent one-year period.

(3) *Precertification exemption.* A prototype nonroad engine for use in applying to EPA for certification pursuant to this subpart may be conditionally imported subject to applicable provisions of § 89.906 and the following requirements:

(i) No more than one prototype nonroad engine for each engine family for which an importer is seeking certification is to be imported.

(ii) The granting of precertification exemptions by the Administrator is discretionary. Normally, no more than three outstanding precertification exemptions are allowed for each importer. No precertification exemption is allowed if the importer requesting the exemption is in noncompliance with any requirement of this subpart until the noncompliance is corrected.

(iii) Unless a certificate of conformity is issued for the prototype nonroad engine and the nonroad engine is finally admitted pursuant to the requirements of § 89.605 within 180 days from the date of entry, the total amount of the bond is to be forfeited or the nonroad engine exported unless an extension is granted by the Administrator. A request for an extension is to be in writing and received by the Administrator prior to the date that the precertification exemption expires.

(iv) Such precertification nonroad engine may not be operated in the United States other than for the sole purpose of the precertification exemption.

(4) *Display exemptions.* (i) A nonroad engine intended solely for display may be conditionally imported subject to the requirements of § 89.907.

(ii) A display nonroad engine may be imported by any person for purposes related to a business or the public interest. Such purposes do not include collections normally inaccessible or unavailable to the public on a daily basis, display of a nonroad engine at a dealership, private use, or other purpose that the Administrator determines is not appropriate for display exemptions. A display nonroad engine may not be sold in the United States and may not be operated in the United States except for the operation incident and necessary to the display purpose.

(iii) A temporary display exemption is granted for 12 months or for the duration of the display purpose, whichever is shorter. Two extensions of up to 12 months each are available upon approval by the Administrator. In no circumstances, however, may the total period of exemption exceed 36 months. The U.S. Customs Service bonds a temporary display exemption.

(c) Notwithstanding any other requirement of this subpart, a nonroad engine may be finally admitted into the United States under this paragraph if prior written approval for such final admission is obtained from the Administrator. Conditional admission of these nonroad engines under this subpart is not permitted for the purpose of obtaining such written approval from the Administrator. A request for approval is to contain the identification information required in § 89.604–96(a) (except for § 89.604–96(a)(5)) and information that demonstrates that the importer is entitled to the exemption or exclusion. The following exemptions or exclusions are permitted by this paragraph:

(1) *National security exemption.* A nonroad engine may be imported under the national security exemption found at § 89.908.

(2) *Hardship exemption.* The Administrator may exempt on a case-by-case basis a nonroad engine from federal emission requirements to accommodate unforeseen cases of extreme hardship or extraordinary circumstances.

(3) *Exemption for nonroad engines identical to United States certified versions.*

(i) A person (including businesses) is eligible for importing a nonroad engine into the United States under the provisions of this paragraph. An exemption will be granted if the nonroad engine:

(A) is owned by the importer;

(B) is not offered for importation for the purpose of resale; and

(C) is proven to be identical, in all material respects, to a nonroad engine certified by the Original Engine Manufacturer (OEM) for sale in the United States or is proven to have been modified to be identical, in all material respects, to a nonroad engine certified by the OEM for sale in the United States according to complete written instructions provided by the OEM's United States representative, or his/her designee.

(ii) *Proof of Conformity.* (A) Documentation submitted pursuant to this section for the purpose of proving conformity of individual nonroad engines is to contain sufficiently organized data or evidence demonstrating that the nonroad engine identified pursuant to § 89.604–96(a) is identical, in all material respects, to a nonroad engine identified in an OEM's application for certification.

(B) If the documentation does not contain all the information required by this part, or is not sufficiently organized, EPA notifies the importer of any areas of inadequacy, and that the documentation does not receive further consideration until the required information or organization is provided.

(C) If EPA determines that the documentation does not clearly or sufficiently demonstrate that a nonroad engine is eligible for importation, EPA notifies the importer in writing.

(D) If EPA determines that the documentation clearly and sufficiently demonstrates that a nonroad engine is eligible for importation, EPA grants approval for importation and notifies the importer in writing. Notwithstanding any other requirement of this subpart, the notice constitutes approval for final admission into the United States.

(d) Foreign diplomatic and military personnel may import a nonconforming nonroad engine without bond. At the time of admission, the importer must submit to the Administrator the written report required in § 89.604–96(a) (except for information required by § 89.604–96(a)(5)) and a statement from the U.S. Department of State confirming qualification for this exemption. The nonroad engine may not be sold in the United States and must be exported if the individual's diplomatic status is no longer applicable, as determined by the Department of State, unless subsequently brought into conformity in accordance with §§ 89.605–96, 89.609–96, or 89.611–96(c)(3).

(e) *Competition exclusion.* A nonconforming engine may be imported by any person provided the importer demonstrates to the Administrator that the engine is used to propel a vehicle used solely for competition and obtains prior written approval from the Administrator. A nonconforming engine imported pursuant to this paragraph may not be operated in the United States except for that operation incident and necessary for the competition purpose, unless subsequently brought into conformity with United States emission requirements in accordance with §§ 89.605–96, 89.609–96, or 89.611–96(c)(3).

(f) *Exclusions/exemptions based on date of original manufacture.* (1) Notwithstanding any other requirements of this subpart, the following nonroad engines are excluded, as determined by the engine's gross power output, from the requirements of the Act in accordance with section 213 of the Act and may be imported by any person:

(i) All nonroad engines greater than or equal to 37 kW but less than 75 kW originally manufactured prior to January 1, 1998.

(ii) All nonroad engines greater than or equal to 75 kW but less than 130 kW originally manufactured prior to January 1, 1997.

(iii) All nonroad engines greater than or equal to 130 kW but less than or equal to 560 kW originally manufactured prior to January 1, 1996.

(iv) All nonroad engines greater than 560 kW originally manufactured prior to January 1, 2000.

(2) Notwithstanding other requirements of this subpart, a nonroad engine not subject to an exclusion under § 89.611–96(f)(1) but greater than 20 original production (OP) years old is entitled to an exemption from the requirements of the Act, provided that it has not been modified in those 20 OP years and it is imported into the United States by an ICI. At the time of admission, the ICI must submit to the Administrator the written report required in § 89.604–96(a) (except for information required by § 89.604–96(a)(5)).

(g) An application for exemption and exclusion provided for in paragraphs (b), (c), and (e) of this section is to be mailed to: U.S. Environmental Protection Agency, Office of Mobile Sources, Manufacturers Operations Division (6405–J), 401 M Street, SW, Washington, DC 20460, Attention: Imports.

§ 89.612–96 Prohibited acts; penalties.

(a) The importation of a nonroad engine, including a nonroad engine incorporated into a nonroad vehicle or nonroad equipment, which is not covered by a certificate of conformity other than in accordance with this subpart and the entry regulations of the U.S. Customs Service is prohibited. Failure to comply with this section is a violation of section 213(d) and section 203 of the Act.

(b) Unless otherwise permitted by this subpart, during a period of conditional admission, the importer of a nonroad engine may not:

(1) Register, license, or operate the nonroad engine in the United States;

(2) Sell or offer the nonroad engine for sale;

(3) Store the nonroad engine on the premises of a dealer (unless approved by the Administrator), owner, or purchaser;

(4) Relinquish control of the nonroad engine to the owner or purchaser; or

(5) Cause a nonroad engine to be altered in any manner subsequent to modification and testing, if applicable, for which an application for final admission is based and submitted to the Administrator, unless approved in advance by the Administrator.

(c) A nonroad engine conditionally admitted pursuant to § 89.604–96 and not granted final admission within 120 days of such conditional admission, or within such additional time as the Administrator and the U.S. Customs Service may allow, is deemed to be unlawfully imported into the United States in violation of section 213(d) and section 203 of the Act, unless the nonroad engine has been delivered to the U.S. Customs Service for export or other disposition under applicable Customs laws and regulations. A nonroad engine not so delivered is subject to seizure by the U.S. Customs Service.

(d) An importer who violates section 213(d) and section 203 of the Act is subject to the provisions of section 209 of the Act and is also subject to a civil penalty under section 205 of the Act of not more than $25,000 for each nonroad engine subject to the violation. In addition to the penalty provided in the Act, where applicable, a person or entity

who imports an engine under the exemption provisions of § 89.611–96(b) and, who fails to deliver the nonroad engine to the U.S. Customs Service is liable for liquidated damages in the amount of the bond required by applicable Customs laws and regulations.

(e)(1) An ICI whose nonroad engines imported under § 89.605–96 or § 89.609–96 fail to conform to federal emission requirements after modification and/or testing or who fails to comply with applicable provisions of this subpart, may, in addition to any other applicable sanctions and penalties, be subject to any, or all, of the following sanctions:

(i) The ICI's currently held certificates of conformity may be revoked or suspended;

(ii) The ICI may be deemed ineligible to apply for new certificates of conformity for up to three years; and

(iii) The ICI may be deemed ineligible to import nonroad engines under § 89.609–96 in the future and be placed on a list of ICIs ineligible to import nonroad engines under the provisions of § 89.609–96.

(2) Grounds for the actions described in paragraph (e)(1) of this section include, but are not limited to, the following:

(i) Action or inaction by the ICI or the laboratory performing the emission test on behalf of the ICI, which results in fraudulent, deceitful, or grossly inaccurate representation of any fact or condition which affects a nonroad engine's eligibility for admission to the United States under this subpart;

(ii) Failure of a significant number of imported nonroad engines to comply with federal emission requirements upon EPA inspection or retest; or

(iii) Failure by an ICI to comply with requirements of this subpart.

(3) The following procedures govern any decision to suspend, revoke, or refuse to issue certificates of conformity under this subpart:

(i) When grounds appear to exist for the actions described in paragraph (e)(1) of this section, the Administrator must notify the ICI in writing of any intended suspension or revocation of a certificate of conformity, proposed ineligibility to apply for new certificates of conformity, or intended suspension of eligibility to conduct modification/testing under § 89.609–96, and the grounds for such action.

(ii) Except as provided by paragraph (e)(3)(iv), the ICI must take the following actions before the Administrator will consider withdrawing notice of intent to suspend or revoke the ICI's certificate of conformity or to deem the ICI ineligible to apply for new certification or to deem the ICI ineligible to perform modification/testing under § 89.609–96:

(A) Submit a written report to the Administrator which identifies the reason for the noncompliance of the nonroad engine, describes the proposed remedy, including a description of any proposed quality control and/or quality assurance measures to be taken by the ICI to prevent the future occurrence of the problem, and states the date on which the remedies are to be implemented or

(B) Demonstrate that the nonroad engine does in fact comply with applicable regulations in this chapter by retesting, if applicable, the nonroad engine in accordance with the applicable emission test specified in subpart E of this part.

(iii) An ICI may request, within 15 calendar days of the Administrator's notice of intent to suspend or revoke the ICI's certificate of conformity or to deem the ICI ineligible to apply for new certificates or to deem the ICI ineligible to perform modification/testing under § 89.609- 96, that the Administrator grant such ICI a hearing:

(A) As to whether the tests, if applicable, have been properly conducted,

(B) As to any substantial factual issue raised by the Administrator's proposed action.

(iv) If, after the Administrator notifies an ICI of the intent to suspend or revoke the ICI's certificate of conformity or to deem the ICI ineligible to apply for new certificates or to deem the ICI ineligible to perform modification/testing under § 89.609–96 and prior to any final suspension or revocation, the ICI demonstrates to the Administrator's satisfaction that the decision to initiate suspension or revocation of the certificate of conformity or eligibility to perform modification/testing under § 89.609- 96 was based on erroneous information, the Administrator will withdraw the notice of intent.

(4) Hearings on suspensions and revocations of certificates of conformity or of eligibility to apply for new certificates or of eligibility to perform modification/testing under § 89.609–96 will be held in accordance with the following:

(i) The procedures prescribed by this section will apply whenever an ICI requests a hearing pursuant to paragraph (e)(3)(iii) of this section.

(ii) Hearings under paragraph (e)(3)(iii) will be held in accordance with the procedures outlined in § 86.614 of this chapter, where applicable, provided that where § 86.612 is referred to in § 86.614: § 86.612(a) is replaced by § 89.612–96(e)(2); and § 86.612(i) is replaced by § 89.612–96(e)(3)(iii).

(5) When a hearing is requested under this section and it clearly appears from the data or other information contained in the request for a hearing, or submitted at the hearing, that no genuine and substantial question of fact exists with respect to the issue of whether the ICI failed to comply with this subpart, the Administrator will enter an order denying the request for a hearing, or terminating the hearing, and suspending or revoking the certificate of conformity and/or deeming the ICI ineligible to apply for new certificates or to perform modification/testing under § 89.609–96.

(6) In lieu of requesting a hearing under paragraph (e)(3)(iii) of this section, an ICI may respond in writing to EPA's charges in the notice of intent to suspend or revoke. An ICI's written response must be received by EPA within 30 days of the date of EPA's notice of intent. No final decision to suspend or revoke will be made before that time.

§ 89.613–96 Treatment of confidential information.

The provisions for treatment of confidential information as described in § 89.7 apply.

Subpart H—Recall Regulations

§ 89.701 Applicability.

The requirements of subpart H are applicable to all nonroad engines subject to the provisions of subpart A of part 89.

§ 89.702 Definitions.

The definitions in subpart A of this part apply to this subpart.

§ 89.703 Applicability of part 85, subpart S.

(a) Nonroad engines subject to provisions of subpart B of this part are subject to recall regulations specified in part 85, subpart S of this title, except for the items set forth in this section.

(b) Reference to section 214 of the Clean Air Act in § 85.1801 is replaced by reference to section 216 of the Clean Air Act.

(c) Reference to section 202 of the Act in § 85.1802(a) is replaced by reference to section 213 of the Act.

(d) Reference to "family particulate emission limits as defined in Part 86 promulgated under section 202 of the Act" in § 85.1803(a) and § 85.1805(a)(1) is replaced by reference to family emission limits as defined in part 89 promulgated under section 213 of the Act.

(e) Reference to "vehicles or engines" throughout the subpart is replaced by reference to "engines."

Subpart I—Emission Defect Reporting Requirements

§ 89.801 Applicability.

The requirements of subpart I are applicable to all nonroad engines subject to the provisions of subpart A of part 89. The requirement to report emission-related defects affecting a given class or category of engines remains applicable for five years from the end of the model year in which such engines were manufactured.

§ 89.802 Definitions.

The definitions in subpart A of this part apply to this subpart.

§ 89.803 Applicability of part 85, subpart T.

(a) Nonroad engines subject to provisions of subpart B of this part are subject to emission defect reporting requirements specified in part 85, subpart T of this chapter, except for the items set forth in this section.

(b) Section 85.1901 is replaced by § 89.801.

(c) Reference to the Clean Air Act, 42 U.S.C. 1857 in § 85.1902(a) is replaced by reference to the Clean Air Act, 42 U.S.C. 7401.

(d) Reference to the "approved Application for Certification required by 40 CFR 86.077–22 and like provisions of Part 85 and Part 86 of Title 40 of the Code of Federal Regulations" in § 85.1902(b) is replaced by reference to the approved application for certification required by § 89.115–96 and like provisions of part 89 of this chapter.

(e) Reference to section 202(d) of the Act in § 85.1902(c) is replaced by reference to section 202(d) and section 213 of the Act.

(f) Reference to section 214 of the Act in § 85.1902 (e) and (f) is replaced by reference to section 216 of the Act.

(g) Reference to "vehicles or engines" throughout the subpart is replaced by reference to "engines."

Subpart J—Exemption Provisions

§ 89.901 Applicability.

The requirements of subpart J are applicable to all nonroad engines subject to the provisions of subpart A of part 89.

§ 89.902 Definitions.

The definitions in subpart A of this part apply to this subpart. The following definitions also apply to this subpart.

Exemption means exemption from the prohibitions of § 89.1006.

Export exemption means an exemption granted under § 89.1004(b) for the purpose of exporting new nonroad engines.

National security exemption means an exemption which may be granted under § 89.1004(b) for the purpose of national security.

Manufacturer-owned nonroad engine means an uncertified nonroad engine owned and controlled by a nonroad engine manufacturer and used in a manner not involving lease or sale by itself or in a vehicle or piece of equipment employed from year to year in the ordinary course of business for product development, production method assessment, and market promotion purposes.

Testing exemption means an exemption which may be granted under § 89.1004(b) for the purpose of research investigations, studies, demonstrations or training, but not including national security.

§ 89.903 Application of section 216(10) of the Act.

(a) For the purpose of determining the applicability of section 216(10) of the Act, an internal combustion engine (including the fuel system) that is not used in a motor vehicle is deemed a nonroad engine if it meets the definition in subpart A of this part.

(b) EPA will maintain a list of nonroad engines that have been determined to be excluded because they are used solely for competition. This list will be available to the public and may be obtained by writing to the following address: Chief, Selective Enforcement Auditing Section, Manufacturers Operations Division (6405–J), Environmental Protection Agency, 401 M Street SW, Washington, DC 20460.

(c) Upon written request, EPA will make written determinations as to whether certain engines are or are not nonroad engines. Engines that are determined not to be nonroad engines are excluded from regulations under this part.

§ 89.904 Who may request an exemption.

(a) Any person may request a testing exemption under § 89.905.

(b) Any nonroad engine manufacturer may request a national security exemption under § 89.908.

(c) For nonroad engine manufacturers, nonroad engines manufactured for export purposes are exempt without application, subject to the provisions of § 89.909.

(d) For eligible manufacturers, as determined by § 89.906, manufacturer-owned nonroad engines are exempt without application, subject to the provisions of § 89.906.

(e) For any person, display nonroad engines are exempt without application, subject to the provisions of § 89.907.

§ 89.905 Testing exemption.

(a) Any person requesting a testing exemption must demonstrate the following:

(1) That the proposed test program has a purpose which constitutes an appropriate basis for an exemption in accordance with this section;

(2) That the proposed test program necessitates the granting of an exemption;

(3) That the proposed test program exhibits reasonableness in scope; and

(4) That the proposed test program exhibits a degree of control consonant with the purpose of the test program and EPA's monitoring requirements.

(5) Paragraphs (b), (c), (d), and (e) of this section describe what constitutes a sufficient demonstration for each of the four identified elements.

(b) With respect to the purpose of the proposed test program, an appropriate purpose would be research, investigations, studies, demonstrations, or training, but not national security. A concise statement of purpose is a required item of information.

(c) With respect to the necessity that an exemption be granted, necessity arises from an inability to achieve the stated purpose in a practicable manner without performing or causing to be performed one or more of the prohibited acts under § 89.1003. In appropriate circumstances, time constraints may be a sufficient basis for necessity, but the cost of certification alone, in the absence of extraordinary circumstances, is not a basis for necessity.

(d) With respect to reasonableness, a test program must exhibit a duration of reasonable length and affect a reasonable number of engines. In this regard, required items of information include:

(1) An estimate of the program's duration, and

(2) The maximum number of nonroad engines involved.

(e) With respect to control, the test program must incorporate procedures consistent with the purpose of the test and be capable of affording EPA monitoring capability. As a minimum, required items of information include:

(1) The technical nature of the test;

(2) The site of the test;

(3) The time or mileage duration of the test;

(4) The ownership arrangement with regard to the engines involved in the test;

(5) The intended final disposition of the engines;

(6) The manner in which the engine identification numbers will be identified, recorded, and made available; and

(7) The means or procedure whereby test results will be recorded.

(f) A manufacturer of new nonroad engines may request a testing exemption to cover nonroad engines intended for use in test programs planned or anticipated over the course of a subsequent one-year period. Unless otherwise required by the Director, Manufacturers Operations Division, a manufacturer requesting such an exemption need only furnish the information required by paragraphs (a)(1) and (d)(2) of this section along with a description of the record-keeping and control procedures that will be employed to assure that the engines are used for purposes consistent with paragraph (a) of this section.

§ 89.906 Manufacturer-owned exemption and precertification exemption.

(a) Except as provided in paragraph (b) of this section, any manufacturer-owned nonroad engine, as defined by § 89.902, is exempt from § 89.1003, without application, if the manufacturer complies with the following terms and conditions:

(1) The manufacturer must establish, maintain, and retain the following adequately organized and indexed information on each exempted engine:

(i) Engine identification number,

(ii) Use of the engine on exempt status and

(iii) Final disposition of any engine removed from exempt status; and

(2) The manufacturer must provide right of entry and access to these records to EPA authorized representatives as outlined in § 89.506–96.

(3) Unless the requirement is waived or an alternate procedure is approved by the Director, Manufacturers Operations Division, the manufacturer must permanently affix a label to each nonroad engine on exempt status. This label should

(i) Be affixed in a readily visible portion of the engine,

(ii) Be attached in such a manner that cannot be removed without destruction or defacement,

(iii) State in the English language and in block letters and numerals of a color that contrasts with the background of the label, the following information:

(A) The label heading "Emission Control Information;"

(B) Full corporate name and trademark of manufacturer;

(C) Engine displacement, engine family identification, and model year of engine; or person of office to be contacted for further information about the engine;

(D) The statement "This nonroad engine is exempt from the prohibitions of 40 CFR section 90.1003."

(4) No provision of paragraph (a)(3) of this section prevents a manufacturer from including any other information it desires on the label.

(b) Any independent commercial importer that desires a precertification exemption pursuant to § 89.611(b)(3) and is in the business of importing, modifying, or testing uncertified nonroad engines for resale under the provisions of § 89.611 et seq., must apply to the Director, Manufacturers Operations Division. The Director may require such independent commercial importer to submit information regarding the general nature of the fleet activities, the number of nonroad engines involved, and a demonstration that adequate record-keeping procedures for control purposes will be employed.

§ 89.907 Display exemption.

Where an uncertified nonroad engine is a display engine to be used solely for display purposes, will only be operated incident and necessary to the display purpose, and will not be sold unless an applicable certificate of conformity has been received or the engine has been finally admitted pursuant to subpart G of this part, no request for exemption of the engine is necessary.

§ 89.908 National security exemption.

A manufacturer requesting a national security exemption must state the purpose for which the exemption is required and the request must be endorsed by an agency of the federal government charged with responsibility for national defense.

§ 89.909 Export exemptions.

(a) A new nonroad engine intended solely for export, and so labeled or tagged on the outside of the container and on the engine itself, is subject to the provisions of § 89.1003, unless the importing country has new nonroad engine emission standards which differ from EPA standards.

(b) For the purpose of paragraph (a) of this section, a country having no standards, whatsoever, is deemed to be a country having emission standards which differ from EPA standards.

(c) EPA will maintain a list of foreign countries that have in force nonroad emission standards identical to EPA standards and have so notified EPA. This list may be obtained by writing to the following address: Chief, Selective Enforcement Auditing Section, Manufacturers Operations Division (6405–J), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. New nonroad engines exported to such countries must comply with EPA certification regulations.

(d) It is a condition of any exemption for the purpose of export under paragraph (a) of this section, that such exemption is void ab initio with respect to a new nonroad engine intended solely for export, where such nonroad engine is sold, or offered for sale, to an ultimate purchaser or otherwise distributed or introduced into commerce in the United States for purposes other than export.

§ 89.910 Granting of exemptions.

(a) If upon completion of the review of an exemption request made pursuant to § 89.905 or § 89.908, EPA determines it is appropriate to grant such an exemption, a memorandum of exemption is to be prepared and submitted to the person requesting the exemption. The memorandum is to set forth the basis for the exemption, its scope, and such terms and conditions as are deemed necessary. Such terms and conditions generally include, but are not limited to, agreements by the applicant to conduct the exempt activity in the manner described to EPA, create and maintain adequate records accessible to EPA at reasonable times, employ labels for the exempt engines setting forth the nature of the exemption, take appropriate measures to assure that the terms of the exemption are met, and advise EPA of the termination of the activity and the ultimate disposition of the engines.

(b) Any exemption granted pursuant to paragraph (a) of this section is deemed to cover any subject engine only to the extent that the specified terms and conditions are complied with. A breach of any term or condition causes the exemption to be void ab initio with respect to any engine. Consequently, the causing or the performing of an act prohibited under § 89.1003(a)(1) or (a)(3), other than in strict conformity with all terms and conditions of this exemption, renders the person to whom the exemption is granted, and any other person to whom the provisions of § 89.1003(a) are applicable, liable to suit under sections 204 and 205 of the Act.

§ 89.911 Submission of exemption requests.

Requests for exemption or further information concerning exemptions and/or the exemption request review procedure should be addressed to: Chief, Selective Enforcement Auditing

Section, Manufacturers Operations Division (6405–J), Environmental Protection Agency, 401 M Street SW, Washington, DC 20460.

§ 89.912 Treatment of confidential information.

The provisions for treatment of confidential information as described in § 89.7 apply.

Subpart K—General Enforcement Provisions and Prohibited Acts

§ 89.1001 Applicability.

The requirements of subpart K are applicable to all nonroad engines subject to the provisions of subpart A of part 89, and to all nonroad vehicles and equipment that contain such nonroad engines.

§ 89.1002 Definitions.

The definitions in subpart A of this part apply to this subpart.

§ 89.1003 Prohibited acts.

(a) The following acts and the causing thereof are prohibited:

(1)(i) In the case of a manufacturer of new nonroad engines, vehicles, or equipment for distribution in commerce, the sale, or the offering for sale, or the introduction, or delivery for introduction, into commerce, of any new nonroad engine manufactured after the applicable effective date under this part, or any nonroad vehicle or equipment containing such engine, unless such engine is covered by a certificate of conformity issued (and in effect) under regulations found in this part.

(ii) In the case of any person, except as provided in subpart G of this part, the importation into the United States of any new nonroad engine manufactured after the applicable effective date under this part, or any nonroad vehicle or equipment containing such engine, unless such engine is covered by a certificate of conformity issued (and in effect) under regulations found in this part.

(2)(i) For a person to fail or refuse to permit access to or copying of records or to fail to make reports or provide information required under § 89.1004.

(ii) For a person to fail or refuse to permit entry, testing, or inspection authorized under §§ 89.129–96, 89.506–96 or 89.1004.

(iii) For a person to fail or refuse to perform tests, or to have tests performed as required under §§ 89.119–96 or 89.1004.

(iv) For a person to fail to establish or maintain records as required under § 89.1004.

(3)(i) For a person to remove or render inoperative a device or element of design installed on or in a nonroad engine, vehicle or equipment in compliance with regulations under this part prior to its sale and delivery to the ultimate purchaser, or for a person knowingly to remove or render inoperative such a device or element of design after the sale and delivery to the ultimate purchaser; or

(ii) For a person to manufacture, sell or offer to sell, or install, a part or component intended for use with, or as part of, a nonroad engine, vehicle or equipment, where a principal effect of the part or component is to bypass, defeat, or render inoperative a device or element of design installed on or in a nonroad engine in compliance with regulations issued under this part, and where the person knows or should know that the part or component is being offered for sale or installed for this use or put to such use.

(4) For a manufacturer of a new nonroad engine subject to standards prescribed under this part:

(i) To sell, offer for sale, or introduce or deliver into commerce, a nonroad engine unless the manufacturer has complied with the requirements of § 89.1007.

(ii) To sell, offer for sale, or introduce or deliver into commerce, a nonroad engine unless a label or tag is affixed to the engine in accordance with § 89.110–96.

(iii) To fail or refuse to comply with the requirements of § 89.1008.

(iv) Except as provided in § 89.109–96, to provide directly or indirectly in any communication to the ultimate purchaser or a subsequent purchaser that the coverage of a warranty under the Act is conditioned upon use of a part, component, or system manufactured by the manufacturer or a person acting for the manufacturer or under its control, or conditioned upon service performed by such persons.

(v) To fail or refuse to comply with the terms and conditions of the warranty under § 89.1007.

(5) For a person to circumvent or attempt to circumvent the residence time requirements of subsection (b)(2)(iii) of the nonroad engine definition in § 89.2.

(6) For a manufacturer of nonroad vehicles or equipment to distribute in commerce, sell, offer for sale, or introduce into commerce nonroad vehicles or equipment which contain an engine not covered by a certificate of conformity.

(b) For the purposes of enforcement of this part, the following apply:

(1) Nothing in paragraph (a)(3) of this section is to be construed to require the use of manufacturer parts in maintaining or repairing a nonroad engine.

(2) Actions for the purpose of repair or replacement of a device or element of design or any other item are not considered prohibited acts under § 89.1003(a) if the action is a necessary and temporary procedure, the device or element is replaced upon completion of the procedure, and the action results in the proper functioning of the device or element of design.

(3) Actions for the purpose of a conversion of a nonroad engine for use of a clean alternative fuel (as defined in Title II of the Act) are not considered prohibited acts under § 89.1003(a) if:

(i) the vehicle complies with the applicable standard when operating on the alternative fuel, and the device or element is replaced upon completion of the conversion procedure, and

(ii) in the case of engines converted to dual fuel or flexible use, the action results in proper functioning of the device or element when the nonroad engine operates on conventional fuel.

(4) Certified nonroad engines shall be used in all vehicles and equipment that are self-propelled, portable, transportable, or are intended to be propelled while performing their function unless the manufacturer of the vehicle or equipment can prove that the vehicle or equipment will be used in a manner consistent with paragraph (2) of the definition of nonroad engine in § 89.2 of this part. Nonroad vehicle and equipment manufacturers may continue to use noncertified nonroad engines built prior to the effective date until noncertified engine inventories are depleted; however, stockpiling of noncertified nonroad engines will be considered a violation of this section.

§ 89.1004 General enforcement provisions.

(a) *Information collection provisions.* (1) Every manufacturer of new nonroad engines and other persons subject to the requirements of this part must establish and maintain records, perform tests where such testing is not otherwise reasonably available under this part, make reports and provide information the Administrator may reasonably require to determine whether the manufacturer or other person has acted or is acting in compliance with this part or to otherwise carry out the provisions of this part, and must, upon request of an officer or employee duly designated by the Administrator, permit the officer or employee at reasonable times to have access to and copy such records. The manufacturer shall comply in all

respects with the requirements of Subpart I of this part.

(2) For purposes of enforcement of this part, an officer or employee duly designated by the Administrator, upon presenting appropriate credentials, is authorized:

(i) to enter, at reasonable times, any establishment of the manufacturer, or of any person whom the manufacturer engaged to perform any activity required under paragraph (a) (1) of this section, for the purposes of inspecting or observing any activity conducted pursuant to paragraph (a)(1) of this section, and

(2) to inspect records, files, papers, processes, controls, and facilities used in performing an activity required by paragraph (a)(1) of this section, by the manufacturer or by a person whom the manufacturer engaged to perform the activity.

(b) *Exemption provision.* The Administrator may exempt a new nonroad engine from § 89.1003 upon such terms and conditions as the Administrator may find necessary for the purpose of export, research, investigations, studies, demonstrations, or training, or for reasons of national security.

(c) *Importation provision.* (1) A new nonroad engine, vehicle, or equipment offered for importation or imported by a person in violation of § 89.1003 is to be refused admission into the United States, but the Secretary of the Treasury and the Administrator may, by joint regulation, provide for deferring a final determination as to admission and authorizing the delivery of such a nonroad engine offered for import to the owner or consignee thereof upon such terms and conditions (including the furnishing of a bond) as may appear to them appropriate to insure that the nonroad engine will be brought into conformity with the standards, requirements, and limitations applicable to it under this part.

(2) If a nonroad engine is finally refused admission under this paragraph, the Secretary of the Treasury shall cause disposition thereof in accordance with the customs laws unless it is exported, under regulations prescribed by the Secretary, within 90 days of the date of notice of the refusal or additional time as may be permitted pursuant to the regulations.

(3) Disposition in accordance with the customs laws may not be made in such manner as may result, directly or indirectly, in the sale, to the ultimate consumer, of a new nonroad engine that fails to comply with applicable standards of the Administrator under this part.

(d) *Export provision.* A new nonroad engine intended solely for export, and so labeled or tagged on the outside of the container and on the engine itself, shall be subject to the provisions of § 89.1003, except that if the country that is to receive the engine has emission standards that differ from the standards prescribed under subpart B of this part, then the engine must comply with the standards of the country that is to receive the engine.

§ 89.1005 Injunction proceedings for prohibited acts.

(a) The district courts of the United States have jurisdiction to restrain violations of § 89.1003(a).

(b) Actions to restrain violations of § 89.1003(a) must be brought by and in the name of the United States. In an action, subpoenas for witnesses who are required to attend a district court in any district may run into any other district.

§ 89.1006 Penalties.

(a) *Violations.* A violation of the requirements of this subpart is a violation of the applicable provisions of the Act, including sections 213(d) and 203, and is subject to the penalty provisions thereunder.

(1) A person who violates § 89.1003(a)(1), (a)(4), or (a)(6), or a manufacturer or dealer who violates § 89.1003(a)(3)(i), is subject to a civil penalty of not more than $25,000 for each violation.

(2) A person other than a manufacturer or dealer who violates § 89.1003(a)(3)(i) or any person who violates § 89.1003(a)(3)(ii) is subject to a civil penalty of not more than $2,500 for each violation.

(3) A violation with respect to § 89.1003 (a)(1), (a)(3)(i), (a)(4), or (a)(6) constitutes a separate offense with respect to each nonroad engine.

(4) A violation with respect to § 89.1003(a)(3)(ii) constitutes a separate offense with respect to each part or component. Each day of a violation with respect to § 89.1003(a)(5) constitutes a separate offense.

(5) A person who violates § 89.1003(a)(2) or (a)(5) is subject to a civil penalty of not more than $25,000 per day of violation.

(b) *Civil actions.* The Administrator may commence a civil action to assess and recover any civil penalty under paragraph (a) of this section.

(1) An action under this paragraph may be brought in the district court of the United States for the district in which the defendant resides or has the Administrator's principal place of business, and the court has jurisdiction to assess a civil penalty.

(2) In determining the amount of a civil penalty to be assessed under this paragraph, the court is to take into account the gravity of the violation, the economic benefit or savings (if any) resulting from the violation, the size of the violator's business, the violator's history of compliance with Title II of the Act, action taken to remedy the violation, the effect of the penalty on the violator's ability to continue in business, and such other matters as justice may require.

(3) In any such action, subpoenas for witnesses who are required to attend a district court in any district may run into any other district.

(c) *Administrative assessment of certain penalties*—(1) *Administrative penalty authority.* In lieu of commencing a civil action under paragraph (b) of this section, the Administrator may assess any civil penalty prescribed in paragraph (a) of this section, except that the maximum amount of penalty sought against each violator in a penalty assessment proceeding shall not exceed $200,000, unless the Administrator and the Attorney General jointly determine that a matter involving a larger penalty amount is appropriate for administrative penalty assessment. Any such determination by the Administrator and the Attorney General is not subject to judicial review. Assessment of a civil penalty shall be by an order made on the record after opportunity for a hearing held in accordance with the procedures found at part 22 of this chapter. The Administrator may compromise, or remit, with or without conditions, any administrative penalty which may be imposed under this section.

(2) *Determining amount.* In determining the amount of any civil penalty assessed under this paragraph, the Administrator shall take into account the gravity of the violation, the economic benefit or savings (if any) resulting from the violation, the size of the violator's business, the violator's history of compliance with Title II of the Act, action taken to remedy the violation, the effect of the penalty on the violator's ability to continue in business, and such other matters as justice may require.

(3) *Effect of administrator's action.*

(i) Action by the Administrator under this paragraph does not affect or limit the Administrator's authority to enforce any provisions of the Act; except that any violation with respect to which the Administrator has commenced and is diligently prosecuting an action under this paragraph, or for which the Administrator has issued a final order

not subject to further judicial review and for which the violator has paid a penalty assessment under this paragraph shall not be the subject of a civil penalty action under paragraph (b) of this section.

(ii) No action by the Administrator under this paragraph shall affect a person's obligation to comply with a section of this part.

(4) *Finality of order.* An order issued under this subsection is to become final 30 days after its issuance unless a petition for judicial review is filed under paragraph (c)(5) of this section.

(5) *Judicial review.* A person against whom a civil penalty is assessed in accordance with this subsection may seek review of the assessment in the United States District Court for the District of Columbia or for the district in which the violation is alleged to have occurred, in which such person resides, or where the person's principal place of business is located, within the 30-day period beginning on the date a civil penalty order is issued. The person shall simultaneously send a copy of the filing by certified mail to the Administrator and the Attorney General. The Administrator shall file in the court within 30 days a certified copy, or certified index, as appropriate, of the record on which the order was issued. The court is not to set aside or remand any order issued in accordance with the requirements of this paragraph unless substantial evidence does not exist in the record, taken as a whole, to support the finding of a violation or unless the Administrator's assessment of the penalty constitutes an abuse of discretion, and the court is not to impose additional civil penalties unless the Administrator's assessment of the penalty constitutes an abuse of discretion. In any proceedings, the United States may seek to recover civil penalties assessed under this section.

(6) *Collection.* (i) If any person fails to pay an assessment of a civil penalty imposed by the Administrator as provided in this part after the order making the assessment has become final or after a court in an action brought under paragraph (c)(5) of this section has entered a final judgment in favor of the Administrator, the Administrator shall request that the Attorney General bring a civil action in an appropriate district court to recover the amount assessed (plus interest at rates established pursuant to section 6621(a)(2) of the Internal Revenue Code of 1986 from the date of the final order or the date of final judgment, as the case may be). In such an action, the validity, amount, and appropriateness of the penalty is not subject to review.

(ii) A person who fails to pay on a timely basis the amount of an assessment of a civil penalty as described in paragraph (c)(6)(i) of this section shall be required to pay, in addition to that amount and interest, the United States' enforcement expenses, including attorney's fees and costs for collection proceedings, and a quarterly nonpayment penalty for each quarter during which the failure to pay persists. The nonpayment penalty is an amount equal to ten percent of the aggregate amount of that person's penalties and nonpayment penalties which are unpaid as of the beginning of such quarter.

§ 89.1007 Warranty provisions.

(a) The manufacturer of each nonroad engine must warrant to the ultimate purchaser and each subsequent purchaser that the engine is designed, built, and equipped so as to conform at the time of sale with applicable regulations under section 213 of the Act, and is free from defects in materials and workmanship which cause such engine to fail to conform with applicable regulations for its warranty period (as determined under § 89.104–96).

(b) In the case of a nonroad engine part, the manufacturer or rebuilder of the part may certify according to § 85.2112 that use of the part will not result in a failure of the engine to comply with emission standards promulgated in this part.

(c) For the purposes of this section, the owner of any nonroad engine warranted under this part is responsible for the proper maintenance of the engine. Proper maintenance includes replacement and service, at the owner's expense at a service establishment or facility of the owner's choosing, such items as spark plugs, points, condensers, and any other part, item, or device related to emission control (but not designed for emission control) under the terms of the last sentence of section 207(a)(3) of the Act, unless such part, item, or device is covered by any warranty not mandated by this Act.

§ 89.1008 In-use compliance provisions.

(a) Effective with respect to nonroad vehicles, equipment, and engines manufactured during model years 1996 and after:

(1) If the Administrator determines that a substantial number of any class or category of engines, although properly maintained and used, do not conform to the regulations prescribed under section 213 of the Act when in actual use throughout their recall period (as defined under § 89.104–96(b)), the Administrator shall immediately notify the manufacturer of such nonconformity and require the manufacturer to submit a plan for remedying the nonconformity of the engines with respect to which such notification is given.

(i) The manufacturer's plan shall provide that the nonconformity of any such engines which are properly used and maintained will be remedied at the expense of the manufacturer.

(ii) If the manufacturer disagrees with such determination of nonconformity and so advises the Administrator, the Administrator shall afford the manufacturer and other interested persons an opportunity to present their views and evidence in support thereof at a public hearing. Unless, as a result of such hearing, the Administrator withdraws such determination of nonconformity, the Administrator shall, within 60 days after the completion of such hearing, order the manufacturer to provide prompt notification of such nonconformity in accordance with paragraph (a)(2) of this section. The manufacturer shall comply in all respects with the requirements of subpart G of this part.

(2) Any notification required to be given by the manufacturer under paragraph (a)(1) of this section with respect to any class or category of engines shall be given to dealers, ultimate purchasers, and subsequent purchasers (if known) in such manner and containing such information as required in subparts H and I of this part.

(3)(i) The manufacturer shall furnish with each new nonroad engine written instructions for the proper maintenance and use of the engine by the ultimate purchaser as required under § 89.109–96. The manufacturer shall provide in boldface type on the first page of the written maintenance instructions notice that maintenance, replacement, or repair of the emission control devices and systems may be performed by any nonroad engine repair establishment or individual using any nonroad engine part which has been certified as provided in § 89.1007(a).

(ii) The instruction under paragraph (3)(i) of this section must not include any condition on the ultimate purchaser's using, in connection with such engine, any component or service (other than a component or service provided without charge under the terms of the purchase agreement) which is identified by brand, trade, or corporate name. Subject instructions also must not directly or indirectly distinguish between service performed by the franchised dealers of such manufacturer, or any other service establishments with which such manufacturer has a commercial relationship, and service performed by

independent nonroad engine repair facilities with which such manufacturer has no commercial relationship.

(iii) The prohibition of paragraph (a)(3)(ii) of this section may be waived by the Administrator if:

(A) The manufacturer satisfies the Administrator that the engine will function properly only if the component or service so identified is used in connection with such engine, and

(B) The Administrator finds that such a waiver is in the public interest.

(iv) In addition, the manufacturer shall indicate by means of a label or tag permanently affixed to the engine that the engine is covered by a certificate of conformity issued for the purpose of assuring achievement of emission standards prescribed under section 213 of the Act. This label or tag shall also contain information relating to control of emissions as prescribed under § 89.110–96.

(b) The manufacturer bears all cost obligation a dealer incurs as a result of a requirement imposed by paragraph (a) of this section. The transfer of any such cost obligation from a manufacturer to a dealer through franchise or other agreement is prohibited.

(c) If a manufacturer includes in an advertisement a statement respecting the cost or value of emission control devices or systems, the manufacturer shall set forth in the statement the cost or value attributed to these devices or systems by the Secretary of Labor (through the Bureau of Labor Statistics). The Secretary of Labor, and his or her representatives, has the same access for this purpose to the books, documents, papers, and records of a manufacturer as the Comptroller General has to those of a recipient of assistance for purposes of section 311 of the Act.

(d) Any inspection of a nonroad engine for purposes of paragraph (a)(1) of this section, after its sale to the ultimate purchaser, is to be made only if the owner of such vehicle or engine voluntarily permits such inspection to be made, except as may be provided by any state or local inspection program.

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June 17, 1994

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 333 and 369

Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 333 and 369

[Docket No. 75N–183H]

RIN 0905–AA06

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of an amended tentative final monograph that would establish conditions under which over-the-counter (OTC) topical health-care antiseptic drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking to amend the previous notice of proposed rulemaking on topical antimicrobial drug products (see the **Federal Register** of January 6, 1978, 43 FR 1210) after considering the public comments on that notice and other information in the administrative record for this rulemaking. FDA is also requesting data and information concerning the safety and effectiveness of topical antimicrobials for use as hand sanitizers or dips. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for an oral hearing on the proposed regulation before the Commissioner of Food and Drugs by December 14, 1994. Because of the length and complexity of this proposed regulation, the agency is allowing a period of 180 days for comments and objections instead of the normal 60 days. New data by June 19, 1995. Comments on the new data by August 17, 1995. Written comments on the agency's economic impact determination by December 14, 1994.

ADDRESSES: Written comments, objections, new data, or requests for an oral hearing to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 13, 1974 (39 FR 33103), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Antimicrobial I Drug Products (Antimicrobial I Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by November 12, 1974. Reply comments in response to comments filed in the initial comment period could be submitted by December 12, 1974. In response to numerous requests, the agency issued a notice in the **Federal Register** of October 17, 1974 (39 FR 37066) granting an extension of the deadline for comments until December 12, 1974, and for reply comments until January 13, 1975.

In the **Federal Register** of January 6, 1978 (43 FR 1210), FDA published, under § 330.10(a)(7), a notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products, based on the recommendations of the Antimicrobial I Panel and the agency's response to comments submitted following publication of the advance notice of proposed rulemaking. Interested persons were invited to submit objections or requests for oral hearing by February 6, 1978. In response to numerous requests to extend the time period for submitting objections or requests for oral hearing, the agency issued a notice in the **Federal Register** of February 3, 1978 (43 FR 4637) granting an extension of the deadline to March 6, 1978. During this time period, the agency received 6 petitions that requested reopening the administrative record and 11 requests for an oral hearing. In a notice published in the **Federal Register** of March 9, 1979 (44 FR 13041), the agency deferred action on the requests for a hearing, but granted the petitions to reopen the record to allow interested persons to submit comments and any new or additional data by June 7, 1979, and reply comments by July 9, 1979. FDA also stated its intent to publish an updated (amended) tentative final monograph based on the review and evaluation of new submissions and a reevaluation of existing data.

In a notice published in the **Federal Register** of October 26, 1979 (44 FR 61609), the agency again reopened the administrative record for the submission of new data by March 26, 1980, and for comments on the new data by May 27, 1980. This action was taken to permit manufacturers to submit the results of testing to FDA as expeditiously as possible prior to establishment of a final monograph.

Subsequent to the June 7, 1979, closing date for the submission of new data, and prior to the October 26, 1979, reopening of the administrative record, data and information were submitted to FDA. In a notice published in the **Federal Register** of March 21, 1980 (45 FR 18398), the agency advised that it had reopened the administrative record for OTC topical antimicrobial drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the date the administrative record on the tentative final monograph had officially closed on March 6, 1978. The agency concluded that any new data and information filed prior to March 21, 1980, should be available to the agency in developing a proposed regulation in the form of a tentative final monograph.

In a notice published in the **Federal Register** on January 5, 1982 (47 FR 436), the agency advised that it had again reopened the administrative record for OTC topical antimicrobial drug products to allow for consideration of the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel) on mercury-containing drug products. Interested persons were invited to submit comments by April 5, 1982, and reply comments by May 5, 1982. FDA stated that the proceeding to develop a monograph for mercury-containing drug products would be merged with the general proceeding to establish a monograph for OTC topical antimicrobial drug products.

In a notice published in the **Federal Register** on May 21, 1982 (47 FR 22324), the agency advised that it had again reopened the administrative record for OTC topical antimicrobial drug products to allow for consideration of the recommendations of the Miscellaneous External Panel on alcohol drug products. Interested persons were invited to submit comments by August 19, 1982, and reply comments by September 20, 1982. The notice stated that the proceeding to develop a monograph for alcohol drug products would be merged with the general proceeding to establish a monograph for OTC topical antimicrobial drug products.

In the **Federal Register** of September 7, 1982 (47 FR 39406), FDA issued a notice to reopen the administrative record for OTC topical antimicrobial drug products to allow for consideration

of the Miscellaneous External Panel's recommendations on topical antimicrobial drug products used for the treatment of diaper rash. The agency discussed topical antimicrobial active ingredients for this use in the **Federal Register** of June 20, 1990 (55 FR 25246).

In accordance with § 330.10(a)(10), the data and information considered by the Panels were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information. In response to the previous tentative final monograph and the advance notice of proposed rulemaking for mercury-containing drug products and the advance notice of proposed rulemaking for alcohol drug products, 4 drug manufacturers' associations, 44 drug manufacturers, 1 medical device manufacturer, 1 drug distributor, 2 medical schools, 2 research laboratories, 1 law firm, and 1 consulting firm submitted comments. Copies of the comments received are also on public display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the **Federal Register** of September 13, 1974 (39 FR 33103), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (§ 330.10). Similarly, the notice of proposed rulemaking, which was published in the **Federal Register** of January 6, 1978 (43 FR 1210), was designated as a "tentative final monograph." The present document is also designated as a "tentative final monograph." The legal status of each tentative final monograph, however, is that of a proposed rule. The present document is a reproposal regarding health-care antiseptic drug products.

This antimicrobial rulemaking is broad in scope, encompassing products that may contain the same active ingredients, but are labeled and marketed for different intended uses. For example, one group of products is primarily used by consumers for "first aid" and includes skin antiseptics, skin wound cleansers, and skin wound protectants. Another group of products, antiseptic handwashes, are used by consumers on a more frequent, even daily, basis and includes products for personal use in the home, such as when caring for invalids and during family illness. A third group of products is generally intended for use by health professionals and includes health-care personnel handwashes, patient preoperative skin preparations, and surgical hand scrubs.

In order to expedite the completion of the first aid section of the antimicrobial monograph, the agency published a separate tentative final monograph for these products in the **Federal Register** of July 22, 1991 (56 FR 33644). The non-first aid uses of topical antimicrobials, now identified as "health-care antiseptics," are addressed in this document. Although the amended tentative final monographs for first-aid antiseptics and health-care antiseptics are being published separately, both categories will eventually be included under part 333 (21 CFR part 333).

The agency also has decided that OTC topical antimicrobial and topical antibiotic drug products should be included within the same monograph. Although an advance notice of proposed rulemaking to establish a monograph for OTC topical antibiotic drug products was published under part 342 (21 CFR part 342) on April 1, 1977 (42 FR 17642), the final monograph for those products was issued on December 11, 1987 (52 FR 47312) as a new subpart of the OTC topical antimicrobial monograph, part 333, subpart B—Topical First Aid Antibiotic Drug Products. Subpart A will cover first aid antiseptic drug products; subpart C will cover antifungal drug products; subpart D covers acne drug products; and new subpart E will cover health-care antiseptic drug products.

In this tentative final monograph (proposed rule) to establish subpart E of part 333, FDA states its position on the establishment of a monograph for OTC health-care antiseptic drug products. This document addresses only those comments and data concerning the previous antimicrobial tentative final monograph that are related to "non-first aid uses," including products for personal use in the home and products used by health-care professionals.

This proposal constitutes FDA's reevaluation of the January 6, 1978 tentative final monograph based on the comments received and the agency's independent evaluation of the Miscellaneous External Panel's reports on OTC alcohol and mercury-containing drug products and the comments received. The following sections of the January 6, 1978 tentative final monograph for topical antimicrobial drug products are being addressed in this document: §§ 333.1, 333.3, 333.30, 333.50, 333.85, 333.87, 333.97, and 333.99. The following sections of the advance notice of proposed rulemaking for alcohol drug products are being addressed in this document: §§ 333.55 and 333.98. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them. (See section I.)

The OTC drug procedural regulations (21 CFR 330.10) provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA does not use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage. In place of Category I, the term "monograph conditions" is used; in place of Categories II and III, the term "nonmonograph conditions" is used. This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application or abbreviated application (hereinafter called application). Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC topical antimicrobial drug products (39 FR 33103), the agency suggested that the conditions included in the monograph

(Category I) be effective 30 days after the date of publication of the final monograph in the **Federal Register** and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture. The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace. If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the **Federal Register** of January 7, 1972 (37 FR 235) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments and Reply Comments

A. General Comments

1. Two comments contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. One comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464 at 9471 to 9472), and in paragraph 3 of the preamble to the tentative final monograph for OTC antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696 to 698 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), aff'd, 637 F.2d 887 (2d Cir. 1981).)

2. One comment pointed out that under "Subpart B—Active Ingredients" of the tentative final monograph, no CFR part number was assigned to the category "skin antiseptic." However, part numbers were assigned to other categories without any Category I ingredients, with the term "reserved" in parentheses. The comment requested that this omission be corrected in the amended tentative final monograph.

The omission pointed out by the comment was an oversight. However, it is no longer necessary to assign a CFR part number to the category "skin antiseptic," because skin antiseptics have been included in broader categories identified as first aid antiseptics in the amended tentative final monograph for first aid antiseptics (56 FR 33644) and as health-care antiseptics in this tentative final monograph. (See section I.B., comment 3.) All Category I first aid antiseptic and health-care antiseptic active ingredients have been listed in the amended tentative final monograph under subpart A and subpart E, respectively.

B. General Comments on Antimicrobials

3. A number of comments objected to the Panel's recommendation for separate statements of identity in the labeling of products containing the same antimicrobial active ingredient. As an example, several comments noted that povidone-iodine has several professional uses (health-care personnel handwash, skin antiseptic, and surgical hand scrub) and marketing a product in conformance with two or more product categories becomes difficult because there are different labeling requirements for each drug product category. Some comments requested FDA to combine the drug product category designations or to add a new multipurpose product category that allows the combining of labeling indications now included in several product categories. One comment specifically recommended that the agency consider changing product class designations and/or adding a new product class "Multi Purpose Skin Prep" or "Skin Prep," with the indications for use including those listed under § 333.85 (health-care personnel hand wash), § 333.87 (patient preoperative skin preparation), § 333.90 (skin antiseptic), and § 333.97 (surgical hand scrub).

Another comment stated that the word "skin" was superfluous because all OTC antiseptics are intended only for use on the skin; still another comment contended that the statement of identity "antiseptic" is preferable to "skin antiseptic" because these products are used on cuts, scratches, and mucous membranes as well as skin.

In response to the advance notice of proposed rulemaking and reopening of the administrative record for alcohol drug products for topical antimicrobial OTC use published in the **Federal Register** of May 21, 1982 (47 FR 22324), one comment objected to the statement of identity in proposed § 333.98(a) which read, "alcohol for topical antimicrobial use," (47 FR 22324 at 22332). The comment stated that this term would be confusing to the consumer and suggested the term "antiseptic for the skin."

The agency agrees that OTC topical antimicrobial drug products need not have multiple statements of identity. In reviewing the statements of identity recommended by the Antimicrobial I Panel (39 FR 33103), i.e., health-care personnel handwash, patient preoperative skin preparation, skin antiseptic, surgical hand scrub, and the statement of identity recommended by the Miscellaneous External Panel (47 FR 22324), i.e., alcohol for topical antimicrobial use, the agency has determined that the general term "antiseptic" broadly describes all proposed product categories and reflects the basic intended uses of these

products. The agency believes that the statement of identity of "multiple purpose skin prep" or "skin prep" recommended by one comment would not as clearly and succinctly describe the use of these products as the statement of identity "antiseptic." As discussed in section I.B., comment 5, the agency is also proposing an additional term "antiseptic handwash" as a statement of identity to describe products for home use.

As discussed in the first aid antiseptic segment of this rulemaking (56 FR 33644 at 33647), the term "skin" has been deleted from the previously proposed statement of identity "skin antiseptic." Although several comments felt that the word "skin" was superfluous, the agency has no objection to the statement "antiseptic for the skin" or "skin antiseptic" appearing elsewhere in the labeling of these products as additional information to the consumer or health-care professional, provided it does not appear in any portion of the labeling required by the monograph and does not detract from such required information. (See section I.I., comment 19.)

As stated in the first aid antiseptic segment of this rulemaking (56 FR 33644 at 33647), the agency believes that the term "antiseptic" is readily understood by consumers. The agency also finds this to be true for health professionals. The agency is therefore proposing the term "antiseptic" as the general statement of identity for all OTC topical antimicrobial ingredients included in this tentative final monograph. Further, FDA is also proposing that manufacturers may have an option to provide an alternate statement of identity describing only the specific intended use(s) of the product. Specifically, the agency is proposing that the statement of identity for antiseptic drug products in § 333.450(a) read as follows: "The labeling of a single-use product contains the established name of the drug, if any, and identifies the product as an 'antiseptic' and/or with the appropriate statement of identity described in §§ 333.455(a), 333.460(a), or 333.465(a). The labeling of a multiple-use product contains the established name of the drug, if any, and may use the single statement of identity 'antiseptic' and/or the appropriate statements of identity described in §§ 333.455(a), 333.460(a), and 333.465(a). When 'antiseptic' is used as the only statement of identity on a single-use or a multiple-use product, the intended use(s), such as patient preoperative skin preparation, is to be included under the indications. For multiple-use products, a statement of the intended use should also precede the specific directions for each use."

The agency believes that the proposed labeling for these multiple-use products is flexible and provides manufacturers with a number of options. However, the agency recognizes that some manufacturers may wish to label their antiseptic drug products with all of the allowable indications for a particular active ingredient and that this may give rise to difficulties in incorporating all of the information on a product's various uses in the limited space on an OTC label. The agency wishes to point out that some portions of the proposed indications are optional, i.e., the examples included in both the antiseptic and health-care personnel handwash indications, and need not be incorporated in the labeling at all. In addition, manufacturers are free to design ways of incorporating all the information on the various uses of their drug product through the use of flap labels, redesigned packages, or package inserts.

The agency is providing several examples of labeling for an antiseptic product containing povidone-iodine when labeled as a single-use or as a multiple-use product, as follows:

1. When labeled as a single-use product, i.e., patient preoperative skin preparation.

a. Established name: povidone-iodine.

b. Statement of identity (any of these is acceptable):

(1) "antiseptic";

(2) "patient preoperative skin preparation";

(3) "antiseptic/patient preoperative skin preparation."

c. Indications:

(1) When only "antiseptic" is used in the statement of identity:

"Patient preoperative skin preparation:

Helps to reduce bacteria that potentially can cause skin infection."

(2) When patient preoperative skin preparation is used as or included as part of the statement of identity: "Helps to reduce bacteria that potentially can cause skin infection."

d. Directions: (Insert directions in § 333.460(d).)

2. When labeled as a multiple-use product, i.e., patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub.

a. Established name: povidone-iodine.

b. Statement of identity (any of these is acceptable):

(1) "antiseptic";

(2) "patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub";

(3) "antiseptic/patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub."

c. Indications: Irrespective of which statement of identity is used, the following is required: "Patient preoperative skin preparation: Helps to reduce bacteria that potentially can cause skin infection. Antiseptic handwash: For handwashing to reduce bacteria on the skin (which may be followed by one or more of the following: after changing diapers, after assisting ill persons, or before contact with a person under medical care or treatment). Health-care personnel handwash: Handwash to help reduce bacteria that potentially can cause disease or For handwashing to reduce bacteria on the skin (which may be followed by one or more of the following: after changing diapers, after assisting ill persons, or before contact with a person under medical care or treatment). Surgical hand scrub: Significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care."

d. Directions: The following is required: Patient preoperative skin preparation: (Insert directions in § 333.460(d).) Antiseptic handwash or health-care personnel handwash: (Insert directions in § 333.455(c).) Surgical handscrub: (Insert directions in § 333.465(c).)

4. One comment requested that scrubbing devices such as brushes or sponges that are impregnated with approved antimicrobial ingredients be included in the monograph. Another comment requested clarification of the agency's views on trays or kits that contain povidone-iodine and disposable instruments (scissors, forceps, and hemostats) packed in a sterile package, which are designed to reduce the incidence of cross-infection in hospitals.

This tentative final monograph does not provide for the use of devices such as brushes or sponges impregnated with antimicrobials, or of trays or kits that contain povidone-iodine and disposable instruments, because the monograph is intended to regulate only OTC drug active ingredients. Since these comments were submitted, the agency has established procedures (see 21 CFR part 3) describing how it determines which agency component has primary jurisdiction for the premarket review and regulation of products comprised of any combination of a drug and a device. In addition, interested parties are encouraged to read the following document (Ref. 1) for guidance: "Intercenter Agreement Between the

Center for Drug Evaluation and Research and the Center for Devices and Radiological Health." (See § 3.5 (21 CFR 3.5).) This agreement is on file in the Dockets Management Branch (address above).

(1) Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

5. One comment expressed concern that the tentative final monograph failed to provide consumers with an antibacterial skin cleanser for home use. The comment noted that, in addition to professional health care personnel, many consumers have a need for cleansing products containing antibacterial agents for the purpose of promoting good individual and family hygiene. Uses for such products include the following: (1) To reduce bacteria on the hands and face to a greater extent than can be accomplished with ordinary soap, and to prevent accumulation of bacteria from potential sources of contamination. The following examples were cited: Cleansing oneself after changing a baby's diaper, or after assisting aged or ill members of the household with their toilet needs, and before preparing a family meal. (2) The added benefit of an antibacterial cleanser for the minute cuts and abrasions from shaving and other minor traumas. (3) The need for an antibacterial cleanser other than bar soap on local parts of the body such as the face because soap (alkali salts of fatty acids) can be irritating or too drying for some individuals' needs. The comment recommended a new product class under proposed § 333.90(a) (skin antiseptic) to be identified as "Antimicrobial (or Antibacterial) Personal Cleanser" with claims such as "decreases bacteria on the skin" and "contains an antibacterial agent." The comment also suggested that the 10-day maximum use limitation would not be appropriate for this product class, but use could be restricted to 5 or 10 times daily.

Another comment recommended that antimicrobial soaps be allowed to make claims relating to general health care and personal hygiene similar to the claims allowed for health-care personnel handwashes. The comment stated that an antimicrobial soap will reduce bacteria or the transfer of potentially pathogenic micro-organisms in the home and, therefore, serves as a preventive health care aid in controlling diseases.

A third comment requested the addition of a fourth indication for alcohol active ingredients in proposed § 333.98(b) to allow use as an antibacterial handwash to avoid cross-contamination from one individual to another. The comment argued that products containing alcohols are often used as handwashes by athletic trainers to help prevent the spread of skin infections from one individual to another in situations in which soap and water are not available, e.g., on the playing field.

A fourth comment asserted that numerous other meaningful and truthful indications can be used which enhance the safe and effective use of a health-care personnel handwash. For example, the terms "microbicidal cleanser" or "antiseptic germicidal skin cleanser" are appropriate and meaningful terminology describing this use indication.

The agency agrees that antibacterial or antiseptic personal cleanser products are practical for home use, to help prevent cross contamination from one person to another, especially after diaper changing and caring for invalids or ill family members. The agency also agrees with one comment that claims relating to general health-care and personal hygiene similar to the claims allowed for health-care personnel handwashes may be suitable because such claims explain the uses of these products in lay terms.

In the **Federal Register** of July 22, 1991 (56 FR 33644), the agency separated the first aid antiseptic uses of OTC topical antimicrobial drug products from the "non-first aid uses." In that document, the agency proposed that the following terms and categories be deleted: skin antiseptics, skin wound protectants, and skin wound cleansers; and the agency proposed that the appropriate labeling, instead, be included in a new category called "first aid antiseptics" (56 FR 33644 at 33649). Several uses proposed by one comment, i.e., "minute cuts and abrasions from shaving and other minor traumas," are considered as describing "first aid uses" and are adequately covered by the labeling provided for "first aid antiseptics" in proposed § 333.50(b) (56 FR 33677), which contains the following: "First aid to help" (select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against") (select one of the following: "infection," "bacterial contamination," or "skin infection") "in minor cuts, scrapes, and burns." The agency believes that the first aid indication is sufficiently broad to cover minute cuts and abrasions from shaving and that it is not necessary to include the words "other minor traumas" in the indications statement.

Beyond the first aid uses described in the first comment, the agency recognizes a need for an OTC "antiseptic handwash" product for repeated or daily use over an extended period of time for some of the other uses described by the comment. The agency agrees with the comments that health-care personnel handwashes are appropriate for such use because submitted data from effectiveness studies, for uses subject to this rulemaking, were derived from handwashing tests similar to or the same as tests described in the agency's previously proposed testing guidelines (see 43 FR 1210 at 1240), i.e., "Modified Cade Procedure," "Glove Juice Test," and "Test for Health-Care Personnel Handwash Effectiveness." The agency is proposing in this tentative final monograph in § 333.455(a) that a health-care personnel handwash can also bear a statement of identity of "antiseptic handwash." (See section I.B., comment 3.) For products labeled for multiple uses including both antiseptic handwash and first aid labeling claims, the general statement of identity would be "antiseptic" as described in section I.B., comment 3. The product would then need to incorporate the monograph labeling for both antiseptic handwash as well as first aid antiseptic.

The term "cleanser" included in claims requested by the comments is not appropriate in this rulemaking because it is considered to be a cosmetic claim in view of the fact that the Federal Food, Drug, and Cosmetic Act (the act) defines a cosmetic as "articles intended to be * * * applied to the human body * * * for cleansing * * *" (21 U.S.C. 321(i)(1)) and thus may be misleading to consumers. As discussed in section I.I., comment 19, the terms "microbicidal" and "germicidal" may appear in the labeling of OTC antiseptic drug products under certain conditions.

Accordingly, the agency is proposing as the indication for products bearing the statement of identity "antiseptic handwash" a general claim similar to one recommended by one of the comments, i.e., "for handwashing to decrease bacteria on the skin." The agency has determined that this claim may, at the manufacturer's option, be followed by one or more of the following examples: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment."

Descriptive statements such as "contains antibacterial ingredients" and "for the purpose of promoting good

individual and family hygiene" are considered to be examples of statements not significantly related to the safe and effective use of the product and thus are outside the scope of the rulemaking. Such statements may be included in the labeling of these OTC drug products subject to the statutory provisions against false or misleading labeling.

The agency has determined that the indication proposed for antiseptic handwash drug products is also appropriate for health-care personnel handwashes and is also proposing the following indication for health-care personnel handwashes. "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.") In addition to the indication proposed above, the agency is proposing that health-care personnel handwashes may also bear the following indication: "Handwash to help reduce bacteria that potentially can cause disease." The agency is proposing the statement "recommended for repeated use" as an "other allowable indication" for antiseptic or health-care personnel handwash drug products (see below).

The agency sees no reason to continue to include "antimicrobial soap" as a separate product category. Soap is considered to be a dosage form, and specific dosage forms are not being included in the monograph unless there is a particular safety or efficacy reason for doing so. Antimicrobial ingredients may be formulated as soaps for some of the uses discussed in this document, e.g., handwash; however, the designation "antimicrobial soap" is no longer being proposed for inclusion in the monograph. In addition, the agency considers the other product categories that are being proposed to be more informative to the users of these products.

Based upon the comments, the agency is proposing labeling appropriate for professional or consumer uses as follows:

Section 333.455 Labeling of Antiseptic Handwash or Health-Care Personnel Handwash Drug Products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiseptic," as stated above under § 333.450(a), and/or "antiseptic handwash," or "health-care personnel handwash."

(b) *Indications.* * * *

(1) *For products labeled as a health-care personnel handwash.* "Handwash to help reduce bacteria that potentially can cause disease" or "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.")

(2) *For products labeled as an antiseptic handwash.* "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.")

(3) *Other allowable indications for products labeled as either antiseptic or health-care personnel handwash.* The labeling of the product may also contain the following phrase: "Recommended for repeated use."

Other labeling claims requested by the comments for first aid antiseptics are not being included in the tentative final monograph. The agency believes that the general claim "for handwashing to decrease bacteria on the skin" encompasses the variety of uses for promoting good individual and family hygiene. The agency tentatively concludes that the labeling statements proposed above express the same concepts as the labeling suggested by the comments in language that can be more readily understood by the consumer.

C. Comments on Definitions

6. One comment objected to a portion of the definition for health-care personnel handwash in § 333.3(d) of the tentative final monograph that states that the antimicrobial agent is "broad-spectrum" and "if possible, persistent." The comment argued that, because these handwashes are used 50 to 100 times daily, persistence of effect is unnecessary. The comment also questioned the need for a broad-spectrum antimicrobial, stating that *Staphylococcus epidermidis* (*S. epidermidis*) generally is the only natural resident bacteria on the skin, and other transient micro-organisms are more likely to be removed mechanically by washing than by antimicrobial action. The comment suggested that the choice to use or not to use a broad-spectrum antimicrobial ingredient should be left to the manufacturer.

Another comment pointed out that the requirement for "broad spectrum" activity is inconsistently applied in the definitions for health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub (§ 333.3(d), (e), and (i), respectively) because "broad spectrum" activity is mandatory for the first two classes and only "desirable" for surgical hand scrubs. The comment cited comment 93 (43 FR 1210 at 1224) and the testing guidelines for safety and effectiveness of OTC topical antimicrobials (43 FR 1239) to show the agency's awareness of possible shifts in microbial flora due to a lack of broad spectrum activity. The comment urged that all three product classes include the requirement for each product to at least demonstrate in vitro "cidal" activity against gram-negative bacteria, fungi, and lipophilic and hydrophilic viruses in addition to the gram-positive activity.

In § 333.3(d) of the previous tentative final monograph, a health-care personnel handwash was defined as an "* * * antimicrobial-containing preparation designed for frequent use; it reduces the number of transient micro-organisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying, and it is broad-spectrum, fast acting, and, if possible, persistent." In the tentative final monograph, the agency agreed with the Panel that persistence, defined as prolonged activity, is a valuable attribute that assures antimicrobial activity during the interval between washings and is important to a safe and effective health-care personnel handwash (43 FR 1215). The Panel explained that a property such as persistence, which acts to prevent the growth or establishment of transient micro-organisms as part of the normal baseline or resident flora, would be an added benefit (39 FR 33103 at 33115). Although the Panel did not propose persistence as a mandatory requirement for a health-care personnel handwash, the agency is retaining the words "if possible, persistent" in the definition in this amended tentative final monograph because this is a desirable trait for these products.

Regarding the comment's objection to the broad-spectrum requirement, the Panel in its discussion of the normal skin flora stated that the predominant members of the normal flora are gram positive cocci and diptheroids and not *S. epidermidis*, as the comment indicates. The Panel stated further that a small number of gram negative species, such as coliforms and related micro-organisms, as well as higher forms such as yeast may also be residents of the skin of healthy individuals (39 FR 33103 at 33107). In its discussion of health-care personnel handwash drug products, the Panel acknowledged that, in all likelihood, the specified effect of these products (i.e., removal of transient micro-organisms) can be achieved with a well formulated

nonantimicrobial soap or detergent product. However, the Panel concluded that transient micro-organisms may become part of the established "resident" flora with time, and stated that in a health-care situation, the fast, effective removal of transient micro-organisms is a requirement because they may be pathogenic (39 FR 33103 at 33115). The Panel recommended that health-care personnel handwash drug products containing an antimicrobial ingredient should be broad spectrum. The Panel defined "broad spectrum" in reference to microbiological activity as meaning the antimicrobial has activity against more than one type of micro-organism, that is, activity against gram positive and gram negative bacteria, fungi, and viruses (39 FR 33115). Because transient micro-organisms present on the skin may include widely diverse species, resulting from contact with contaminated persons and materials, the agency concludes that a greater reduction of transient micro-organisms on the skin can be achieved if the antimicrobial containing drug product used as a health-care personnel handwash provides broad spectrum activity.

In addition, because the principal intended use of these professional use products is the prevention of nosocomial (hospital acquired) infections, the agency believes that these drug products should have demonstrable antimicrobial activity against a microbial spectrum that includes the micro-organisms associated with these infections. As discussed in section I.N., comment 28, the agency is proposing, in § 333.470(a)(1)(ii) of the testing requirements, a list of micro-organisms that reflects a spectrum of antimicrobial activity pertinent to the intended use of these drug products and against which the products must be tested. The agency is proposing the following definition of broad spectrum activity in § 333.403(b) of this amended tentative final monograph: "*Broad spectrum activity.* A properly formulated drug product, containing an ingredient included in the monograph, that possesses in vitro activity against the micro-organisms listed in § 333.470(a)(1)(ii), as demonstrated by in vitro minimum inhibitory concentration determinations conducted according to methodology in § 333.470(a)(1)(ii)." This methodology has been developed by the National Committee for Clinical Standards (NCCLS) (Ref. 1). Although micro-organisms in addition to those listed may also be used for testing, the agency will use the test micro-organisms identified in § 333.470(a)(1)(ii) for any necessary compliance testing.

The agency wants to emphasize that in this amended tentative final monograph the broad-spectrum criterion applies to final-formulated drug products used as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub. Although the Category I active ingredients currently included in this amended tentative final monograph are broad spectrum independent of formulation, some Category III antiseptic ingredients have limited spectra (activity against only gram positive bacteria; for example, chloroxylenol (see section I.G., comment 12) and triclosan (see section I.L., comment 23)), but when properly formulated in a final product the spectrum can be broadened to include additional activity against the test micro-organisms, thereby possibly enabling these ingredients to become Category I. Although the agency agrees with the first comment that the manufacturer may use or not use a broad-spectrum ingredient in a particular health-care antiseptic drug product, the finished product must demonstrate in vitro activity against the specific micro-organisms listed in proposed § 333.470(a)(1)(ii).

In response to the second comment, that broad spectrum was inconsistently applied in the definitions of the three product classes, the agency has reevaluated the issue and believes that all product classes should be broad spectrum. As stated in the tentative final monograph (43 FR 1210 at 1212), maintaining the balance among species of micro-organisms constituting the normal skin flora is more likely to be threatened by use of antimicrobial products with a limited spectrum. Also much of the data concerning the spread of infections in hospitals indicates that the use of an antimicrobial with broad spectrum activity would help prevent this (see section I.D., comment 9). Based on the reasons mentioned above, the agency is proposing to include "broad spectrum" in the definitions of the three product classes included in this tentative final monograph.

Reference

(1) National Committee for Clinical Laboratory Standards, "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically—2d ed.; Approved Standard," NCCLS Document M7–A2, 10:8, 1990.

D. Comments on Labeling

7. Several comments contended that FDA does not have the authority to restrict OTC labeling claims to exact wording, to the exclusion of what the comments described as other "equally truthful claims for the products." One comment pointed out that numerous other meaningful and truthful statements will provide useful information and will enhance the safe and effective use of these products. Several comments maintained that manufacturers have a constitutional right to use any truthful, nonmisleading labeling under the first amendment. To support their position, the comments cited *Bigelow* v. *Virginia*, 421 U.S. 809 (1975); *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); *Linmark Associates, Inc.* v. *Willingboro*, 431 U.S. 85 (1977); *Bates* v. *State Bar of Arizona*, 433 U.S. 350 (1977); *Federal Trade Commission* v. *Beneficial Corp.*, 542 F.2d 611, 97 S. Ct. 1679 (1977); and *Warner-Lambert Co.* v. *Federal Trade Commission*, 562 F.2d 749 at 768 (D.C. Cir. 1977).

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g).

In the previous tentative final monograph, supplemental language relating to indications had been proposed and captioned as *Other Allowable Statements* in §§ 333.85, 333.87 and 333.97. Under FDA's revised labeling policy (51 FR 16258), such statements are included at the tentative final stage as examples of other truthful

and nonmisleading language that would be allowed elsewhere in the labeling. In accordance with the revised labeling policy, such statements would not be included in a final monograph.

In preparing this amended tentative final monograph, the agency has reevaluated these "other allowable statements" to determine whether they should be incorporated, wherever possible, as part of the indications developed under the monograph.

The agency has reviewed the "*Other Allowable Statements*" proposed in the previous tentative final monograph in § 333.85 for health-care personnel handwash, in § 333.87 for patient preoperative skin preparation, and in § 333.97 for surgical hand scrub. The statement "recommended for repeated use" proposed for a health-care personnel handwash has been included in this amended tentative final monograph as an "other allowable indication" in proposed § 333.455 for antiseptic handwash or health-care personnel handwash drug products. (See section I.B., comment 5.)

The terms "broad spectrum" and "fast-acting" (if applicable) were proposed as "*Other Allowable Statements*" for all three of these product classes in the previous tentative final monograph. As discussed in section I.C., comment 6, the agency is proposing to include "broad spectrum" in the definition of the three product classes included in this amended tentative final monograph. Although the term "broad spectrum" is included in the definitions of these product classes, the agency does not see a need to include this information in the "indications" for these products. Likewise, the term "fast-acting" is included in the definitions of these product classes, but the agency does not see a need to include this information in the indications for these products. This type of information may appear elsewhere in the labeling of these products as additional information to the health-care professional, provided it does not appear in any portion of the labeling required by the monograph and does not detract from such required information. Other previously proposed "*Other Allowable Statements*," i.e., "contains antibacterial ingredient(s)," "contains antimicrobial ingredient(s)," and "nonirritating," are not related in a significant way to the safe and effective use of these products. The agency does not believe that statements such as "contains antibacterial ingredient(s)" or "contains antimicrobial ingredient(s)" are necessary on products intended primarily for health professionals, but has no objection to such statements appearing in the labeling as other information not intertwined with any portion of the labeling required by the monograph. Likewise, the term "nonirritating" may appear as additional information to the health-care professional, provided it does not appear in any portion of the labeling required by the monograph and does not detract from such required information. However, such statements are subject to the provisions of section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Such statements will be evaluated on a product-by-product basis, under the provisions of section 502 of the act relating to labeling that is false or misleading.

8. Several comments requested that certain warnings required in the labeling of OTC drug products marketed for the general public should not be required on such products distributed only to health professionals and labeled primarily for use in health-care facilities as in proposed § 333.99 "Professional labeling" (43 FR 1210 at 1248 and 1249). Examples cited were the cautionary statements for "skin antiseptic" and "skin wound protectant" in proposed §§ 333.90(c)(3) and 333.93(c)(3) "Do not use this product for more than 10 days. If the infection (condition) worsens or persists, see your physician," and for "skin wound protectant" in proposed § 333.93(c)(7) "Do not use on chronic skin conditions such as leg ulcers, diaper rash, or hand eczema." The comments stated that the professional use of these products sometimes differs from consumer use and that products which are marketed only to health-care institutions and are dispensed and administered by professionals should only contain warnings that apply to professional use. One comment concluded that requiring professional labeling to contain a caution such as in proposed § 333.93(c)(7) could possibly subject the health-care facility and the physician to unwarranted product liability claims, although the particular use of the product under medical supervision is entirely justified and necessary for proper treatment of the patient. One of the comments stated that flexibility should be provided so that manufacturers can utilize only those warnings that are appropriate for professional personnel when packages are restricted to health-care facilities or where a topical antimicrobial product is used as part of a course of treatment selected by the clinician.

In the **Federal Register** of November 12, 1973 (38 FR 31260), the agency published the tentative final monograph for OTC antacid drug products, in which the concept of ethical labeling for OTC drug products was first discussed in comment 56 at 38 FR 31264. There, the agency stated that the warning statements appearing on OTC drug products should be included in ethical (professional) labeling.

Subsequently, in the previous tentative final monograph for OTC topical antimicrobial drug products, published in the **Federal Register** of January 6, 1978 (43 FR 1210), the agency proposed § 333.99 ("Professional labeling") which stated that the labeling of products (covered by the monograph) that is provided only to health professionals and the labeling for those products primarily used in health-care facilities shall include all of the warnings required in each subsection of the monograph, e.g., those in § 333.90 for "skin antiseptic" or § 333.93 for "skin wound protectant."

As described in the first aid antiseptic segment of the tentative final monograph for OTC antimicrobial drug products, published in the **Federal Register** of July 22, 1991 (56 FR 33644), the agency has proposed deletion of the categories cited by the comments, i.e., "skin antiseptic" and "skin wound protectant," as separate drug categories and included them in a single drug product category identified as "first aid antiseptic." The cautionary statements referred to by the comments are addressed in that document.

In this document, the agency is addressing the uses other than first-aid, i.e., health-care antiseptic uses, of topical antimicrobial drug products. These products may contain the same antiseptic active ingredient(s) as the first aid antiseptic drug products, but they are labeled and marketed for different uses. The cautionary statements previously proposed in §§ 333.90(c)(3) and 333.93(c)(3) addressed short-term first aid uses of products primarily proposed as "consumer products." These products were not principally intended to be marketed for hospital or professional use. Therefore, the agency agrees with the comments that such cautionary statements do not apply to professional use of antiseptic drug products and need not appear in the labeling of antiseptic products marketed as antiseptic handwashes or health-care personnel handwashes, patient preoperative skin preparations, and surgical hand scrubs. Likewise the agency believes that health-care antiseptic drug products, marketed principally to health-care professionals, do not need to bear a cautionary statement not to use the product on chronic skin conditions such as leg ulcers, diaper rash, or hand eczema. As

the comment pointed out, professional use of these products is different than consumer use and, in some instances, use of the product on the above-mentioned skin conditions under medical supervision may be justified and necessary for proper treatment of the patient. Therefore, this cautionary statement is not being included in this tentative final monograph.

This tentative final monograph addresses specifically the use of these topical antiseptic drug products by health-care professionals and in health-care facilities. The labeling proposed for those products in this document represents that labeling which the agency believes health-care professionals need to properly use these products. Therefore, the agency believes that the warnings proposed in § 333.450(c) of this tentative final monograph should appear in the labeling of these products that are directed to health-care professionals and health-care facilities, even if the product is marketed principally to these sources only. However, the agency believes that one of these warnings can be modified if the product is labeled "For Hospital and Professional Use Only." In such cases, the second sentence of the warning proposed in § 333.450(c)(3), regarding consulting a doctor, can be deleted. This concept is being included in this tentative final monograph. (See § 333.450(d).)

In responding to the comments regarding the warnings in the "Professional labeling" section (§ 333.99) of the previous tentative final monograph, the agency has determined that these warnings are no longer necessary. Accordingly, § 333.99 is not being included in this amended tentative final monograph. (See section I.D., comment 9 for discussion of § 333.99(a), and section I.J., comment 21 for discussion of § 333.99(b). Also, see section II.B., paragraph 14 in the first aid antiseptic segment of this tentative final monograph (56 FR 33644 at 33675) for discussion of § 333.99(c).)

9. Several comments made recommendations regarding the requirement that professional labeling for all classes of OTC topical antimicrobial drug products must contain the caution statement in proposed § 333.99(a), "Caution: Overuse of this and other antimicrobial products may result in an overgrowth of gram-negative micro-organisms, particularly *Pseudomonas*." Some of the comments stated that this caution statement should be required only for antimicrobials where there is valid scientific evidence to show that such caution is appropriate, for example, quaternary ammonium compounds and triclosan, which have been associated with the overgrowth of gram-negative micro-organisms, specifically *Pseudomonas*. Three comments contended that reports of contamination of benzalkonium chloride solutions with *Pseudomonas* and *Enterobacteria* species were basically the result of misuse, improper storage and dilution, poor technique, and contamination with neutralizing chemicals. One comment recommended that the proposed caution statement in § 333.99(a) should be changed to read: "Improper use or overuse * * *." and cited the discussion of the proposed warning for quaternary ammonium compounds by the agency at 43 FR 1237 where the phrase "misuse or overuse" was included. Another comment objected to the caution, arguing that it is based on theoretical considerations only and there is no published clinical evidence implicating quaternary ammonium compounds. Still another comment stated that its quaternary ammonium compound product passed the commonly used test for *Pseudomonas* activity.

In defense of triclosan's implication in *Pseudomonas* overgrowth, one comment argued that overgrowth was just an unproven hypothesis and submitted the "Summary for Basis of Approval" from an approved new drug application (NDA) for chlorhexidine gluconate (Ref. 1) which included data on a skin flora study that indicated an increasing, continuous gram-negative growth only in the axillary area over a 6-month period, even though chlorhexidine is active against gram-negative micro-organisms. The comment referred to FDA's Division of Anti-Infective Drug Products as having recognized that gram-negative overgrowth can be adequately controlled by restricting use to indications provided in the labeling of a product.

Several comments pointed out that data on povidone-iodine have proven broad spectrum effectiveness, referring to the Centers for Disease Control and Prevention's (CDC) recommendation (Ref. 2) for using this ingredient for skin preparation before intravenous catheter insertion and other procedures to reduce infection. The comments also noted that in a study by Houang et al. (Ref. 3), in which 20 transfers of 7 gram-negative micro-organisms (including *Pseudomonas aeruginosa* (*P. aeruginosa*)) were made, the minimum inhibitory concentration did not change, supporting the fact that repeated use of povidone-iodine would not result in resistant micro-organisms. For these reasons, these comments recommended that § 333.99(a) should be revised to exclude povidone-iodine.

After a thorough review and evaluation of the available data, the agency concludes that the professional labeling caution that overuse of an antimicrobial drug product may cause an overgrowth of gram-negative micro-organisms is not necessary. In the previous tentative final monograph (43 FR 1210 at 1212), the agency stated its awareness of the theory that gram-negative bacteria will replace gram-positive bacteria that are reduced in number or eliminated by use of antimicrobials and encouraged research to test the validity of the theory. The agency also recalled the Panel's highlighting the need for research on microbial ecology of the skin and its concern about the effect of overuse of antimicrobial drug products, especially products with a limited spectrum, in hospitals and other closed populations. Therefore, the agency proposed the professional labeling caution in § 333.99(a) "for certain antimicrobial ingredients approved for OTC drug use * * * used in health-care facilities" (43 FR 1213). However, the agency concluded that the limited consumer use of these products in the population at large did not constitute a risk that would warrant such a label warning. Although benzalkonium chloride has been frequently implicated in *Pseudomonas* hospital infections, the agency's review of numerous reports and studies on quaternary ammonium compounds and other antimicrobials (Refs. 4 through 10) indicates that specific causes for contamination, such as lack of aseptic technique when applying intravenous infusions and sterilization failure of the items used (bottles, tubing, distilled water used in diluting benzalkonium chloride), were the problem and not overuse of benzalkonium chloride. The agency discussed this problem in the previous tentative final monograph and stated that it appears that practices in the health-care facility environments where quaternary ammonium compounds are commonly used often fall short of the minimum necessary to prevent outbreaks of infection. (See comment 51 43 FR 1210 at 1218.) Benzalkonium chloride is more prone to become contaminated for several reasons that were brought out in the studies: (1) *Pseudomonas* species are among the bacteria most resistant to surface-active agents like quaternary ammonium compounds. (2) The usual quaternary ammonium compound concentration appears to be ineffective against some species, such as *Pseudomonas cepacia*,

an organism which has been reported to have been associated with hospital infections. One study showed that this organism survived 14 years in a salt solution preserved with 0.05 percent benzalkonium chloride. (3) Organic materials (gauze, cotton, cork in stoppers, soaps), inorganic matter, protein, and anionic substances inactivate quaternary ammonium compounds. (4) Hospital personnel are unfamiliar with these problems and with procedures for using quaternary ammonium compounds safely and effectively. Based on these reports, the agency agrees with the comments that "improper" use, not "overuse," is the cause of benzalkonium chloride being implicated in *Pseudomonas* contamination and that there is a lack of data demonstrating "overuse" to be the cause.

The agency also agrees with the comment which stated that it was an unproven hypothesis that overuse of an antiseptic causes *Pseudomonas* overgrowth. The "Summary for Basis of Approval" from an approved NDA for chlorhexidine gluconate (Ref. 1) cites a skin flora study that indicated that the axilla was an area where gram-negative micro-organisms continued to be isolated even though chlorhexidine gluconate has shown gram-negative effectiveness. The comment cited FDA's Division of Anti-Infective Drug Products' recognition that for health-care uses, such as surgical scrub and health-care personnel handwash, there would be no problem with *Pseudomonas* overgrowth because the hands are an area of the body not likely to support the growth of *Pseudomonas* because of the lack of moisture. In defending triclosan, the comment contended that this ingredient is bacteriostatic and does not eliminate all gram-positive bacteria; therefore, it would not predispose for gram-negative overgrowth. Triclosan has been implicated in *Pseudomonas* contamination because it is primarily effective against gram-positive bacteria, has limited in vitro and in vivo activity against gram-negative bacteria, and no activity against *Pseudomonas* (43 FR 1210 at 1232). One report showed that triclosan was effective against some gram-negative micro-organisms, but not effective against *Serratia* and *Pseudomonas* (Ref. 11). *Pseudomonas* and *Serratia* resistance caused the contamination, not overuse of the antiseptic.

The agency agrees with the comments that quaternary ammonium compounds and triclosan have been implicated in *Pseudomonas* hospital infections more frequently than povidone-iodine, but studies indicate that 'overuse' of these or any antimicrobial has not been the cause. *Pseudomonas* species may become dominant because of inherent resistant factors which enable them to survive the effects of many antibiotics and antiseptics (Refs. 12, 13, and 14). In addition, this genus is ubiquitous, found in both soil and water, and can multiply in almost any moist environment with even a trace of organic material (Ref. 15).

The agency believes that the data and reports have not provided specific evidence that repeated use of health-care antiseptics, including benzalkonium chloride and triclosan, have brought about overgrowth of gram-negative bacteria, particularly *Pseudomonas*. The agency agrees with the comments that improper use, failure of hospital personnel to use according to labeling indications, nonaseptic technique in diluting and handling, and lack of good quality control to ensure sterility of items in contact with antiseptics, such as sterile distilled water, hosing, and receptacles, are responsible.

The study by Houang et al. (Ref. 3) shows that repeated in vitro exposure of seven gram-negative micro-organisms, including *P. aeruginosa*, in povidone-iodine dilutions did not result in the development of resistance. The agency notes that CDC previously recommended povidone-iodine for use in intravenous catheter and other procedures (Ref. 2). However, there has been one report from CDC (Ref. 16) which described *Pseudomonas* hospital infections caused by intrinsically contaminated povidone-iodine (contaminated during manufacture, indicating failure of control of microbiological contamination). Compliance with the agency's regulations governing current good manufacturing practice for finished pharmaceuticals (21 CFR part 211) should prevent intrinsic contamination.

Accordingly, the agency concludes that a cautionary statement against overuse is not needed in the professional labeling of health-care antiseptic drug products. Therefore, the previously proposed caution in § 333.99(a) is not being included in this tentative final monograph. If new information indicates a need for a cautionary statement, the agency will consider appropriate action at that time.

References

(1) "Summary for Basis of Approval, Chlorhexidine Gluconate," NDA 17–768, Comment No. SUP022, Docket No. 75N–0183, Dockets Management Branch.

(2) "Recommendations for the Insertion and Maintenance of Plastic Intravenous Catheters," Paper for Training Purpose, Hospital Infections and Microbiological Control Sections, Bacterial Diseases Branch, Epidemiology Program, Centers for Disease Control, 1972.

(3) Houang, E.T. et al., "Absence of Bacterial Resistance to Povidone Iodine," *Journal of Clinical Pathology*, 29:752–755, 1976.

(4) Mitchell, R.G., and A.C. Hayward, "Postoperative Urinary-Tract Infections Caused by Contaminated Irrigating Fluid," *The Lancet*, 1:793–795, 1966.

(5) Geftic, S.G., H. Heymann, and F. W. Adair, "Fourteen-Year Survival of *Pseudomonas cepacia* in a Salts Solution Preserved with Benzalkonium Chloride," *Applied and Environmental Microbiology*, 37:505–510, 1979.

(6) Rapkin, R.H., "*Pseudomonas cepacia* in an Intensive Care Nursery," *Pediatrics*, 57:239–243, 1976.

(7) Plotkin, S.A., and R. Austrian, "Bacteremia Caused by *Pseudomonas* Sp. Following the Use of Materials Stored in Solutions of a Cationic Surface-Active Agent," *The American Journal of the Medical Sciences*, 235:621–627, 1958.

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(9) Kaslow, R.A., D.C. Mackel, and G.F. Maillison, "Nosocomial Pseudobacteremia. Positive Blood Cultures Due to Contaminated Benzalkonium Antiseptic," *Journal of the American Medical Association*, 236:2407–2409, 1976.

(10) Burdon, D.W., and J.L. Whitby, "Contamination of Hospital Disinfectants with *Pseudomonas* Species," *British Medical Journal*, 2:153–155, 1967.

(11) Barry, M.A. et al., "*Serratia marcescens* Contamination of Antiseptic Soap Containing Triclosan: Implications for Nosocomial Infection," *Infection Control*, 5:427–430, 1984.

(12) Dailey, R.H., and E.J. Benner, "Necrotizing Pneumonitis Due to the Pseudomonad 'Eugonic Oxidizer-Group I'," *New England Journal of Medicine*, 279:361–2, 1968.

(13) Weinstein, A.J. et al., "Case Report: *Pseudomonas cepacia* Pneumonia," *American Journal of the Medical Sciences*, 265:491–494, 1973.

(14) Richards, R.M.E., and J.M. Richards, "*Pseudomonas cepacia* Resistance to Antibacterials," *Journal of Pharmaceutical Sciences*, 68:1436–1438, 1979.

(15) Sonnenwirth, A.C., "*Pseudomonas*," *in* "Microbiology," 2d ed., edited by Davis, B.D. et al, Harper and Row, Hagerstown, MD, New York, Evanston, San Francisco, London, p. 783, 1973.

(16) "Contaminated Povidone-Iodine Solution—Northeastern United States," Morbidity and Mortality Weekly Report, Public Health Service, Centers for Disease Control, HHS Publication No. (CDC) 81–8017, 29:553–555, 1980.

E. Comment on Alcohol

10. One comment submitted data on the safety and effectiveness of 62

percent alcohol formulated in an emolliented vehicle and dispensed as a foam (Ref. 1) and requested that alcohol be included in the topical antimicrobial monograph as a surgical hand scrub, health-care personnel handwash, and hand degermer.

Data on the safety and effectiveness of alcohol formulated in an emolliented vehicle for use as a surgical hand scrub, health-care personnel handwash, and hand degermer were submitted to the Miscellaneous External Panel (Refs. 2 and 3). However, the data were not reviewed or categorized for these uses during that rulemaking. In reviewing alcohol for short-term uses, that Panel stated, "ethyl alcohol acts relatively quickly to decrease the number of micro-organisms on the skin surface. Each minute that scrubbed hands and arms were immersed in approximately 77 percent ethyl alcohol by volume was found to be equivalent to 6.5 minutes of scrubbing in water; if the skin was scrubbed with the alcohol, the rate was further increased" (47 FR 22324 at 22328). The Panel found ethyl alcohol safe and effective for use as a topical antimicrobial preparation in concentrations of 60 to 95 percent by volume in an aqueous solution. The following indications were proposed:

(1) "For first aid use to decrease germs in minor cuts and scrapes."

(2) "To decrease germs on the skin prior to removing a splinter or other foreign object."

(3) "For preparation of the skin prior to an injection." (See the advance notice of proposed rulemaking for OTC alcohol drug products for topical antimicrobial use, in the **Federal Register** of May 21, 1982, 47 FR 22324.)

The submissions (Refs. 1 and 2) included effectiveness data and labeling for a currently marketed product containing 62 percent ethyl alcohol formulated in an emolliented vehicle and dispensed as a foam used "* * * to degerm hands * * *." The agency has reviewed these data, derived from effectiveness testing as a surgical hand scrub (glove juice test) and health-care personnel handwash, and finds that they meet the procedures in the testing guidelines in the previous tentative final monograph (43 FR 1210 at 1242). Statistical analyses showed microbial reduction to be highly significant. A glove juice test showed that alcohol foam reduced the baseline number of bacteria present in normal skin flora, after first use, by 1.87 logs, and, after continued use for 5 days, by 2.36 logs. The reduction of the baseline number of bacteria was maintained for up to 6 hours under surgical gloves. A health-care personnel handwash effectiveness test showed microbial reduction on test subjects' hands, artificially contaminated with *Serratia marcescens* (*S. marcescens*). Microbial reduction averaged 3.3 logs after 5 treatments and 3.63 logs after 25 treatments. In vitro data, derived from studies using *S. marcescens* as the test bacteria, showed that alcohol properly formulated in an emolliented vehicle and dispensed as a foam, significantly reduced the number of test bacteria, in 10 percent serum, within 15 seconds.

Based on these data and the conclusions of the Miscellaneous External Panel (47 FR 22324), the agency concludes that alcohol, when properly formulated, is effective for use as a surgical hand scrub and antiseptic handwash or health-care personnel handwash. Because it is well established that alcohol alone does not provide persistence, the agency notes that a preservative agent in the vehicle provided the persistent effect to maintain reduction in the baseline number of bacteria for 6 hours as required to demonstrate efficacy as a surgical hand scrub drug product.

The agency is including alcohol in proposed § 333.410(a) (antiseptic handwash or health-care personnel handwash), § 333.412(a) (patient preoperative skin preparation), and § 333.414(a) (surgical hand scrub), as follows: "Alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR part 20." Further, the agency finds the Miscellaneous External Panel's proposed Category I indication for OTC alcohol drug products, i.e., "for preparation of the skin prior to an injection" to be an appropriate indication for patient preoperative skin preparation drug products. Based on that Panel's recommendations, the agency is including this indication as an additional claim for alcohol drug products in § 333.460(b)(2) of the proposed monograph. In addition, based on that Panel's similar recommendations for isopropyl alcohol (47 FR 22324 at 22329 and 22332), the agency is proposing this indication for OTC isopropyl alcohol drug products in § 333.460(b)(3). As discussed in section I.N., comment 28, the agency is proposing new effectiveness criteria for drug products labeled for this use.

The monograph will also state that an alcohol drug product must be properly formulated, such as the product in an emolliented vehicle dispensed as a foam discussed above, to meet the test requirements in § 333.470. This means that alcohol when intended for certain uses must be able to demonstrate effectiveness by certain tests proposed in this tentative final monograph, as follows: (1) Antiseptic or health-care personnel handwash—§ 333.470(b)(2), (2) patient preoperative skin preparation—§ 333.470(b) (3), and (3) surgical hand scrub—§ 333.470(b)(1). As discussed in section I.B., comment 5, the term "antiseptic handwash" in lieu of "hand degermer" is being proposed in the monograph as the statement of identity for this type of product.

The labeling for the alcohol product (Ref. 1) provides directions for use without water rinsing, where water is not readily available, as follows: "A 'palmful' (5 grams) is dispensed in one hand. It is spread on both hands and rubbed into the skin until dry (approximately 1 to 2 minutes). A smaller amount (2.5 grams) is then dispensed into one hand, spread over both hands to wrist, and rubbed into the skin until dry (approximately 30 seconds)." The agency concurs with these directions and is incorporating them into its proposed directions for use for OTC topical antiseptic drug products, including alcohol, formulated for use without water in this tentative final monograph. See proposed § 333.455(c) and § 333.465(c).

References

(1) Unpublished studies on emolliented alcohol foam (62 percent alcohol), Comments No. C105, C144, and CR7, Docket No. 75N–0183, Dockets Management Branch.

(a) Microbiological evaluation of "Alcare Hand Degermer" on personnel in a newborn intensive care unit, May 12, 1977.

(b) Results of a study of efficacy against experimental contamination of human skin, June 20, 1978.

(c) Efficacy study with Vestal Foam results of a glove fluid study, January 27, 1975.

(d) *Serratia marcescens* efficacy data for Alcare, February 20, 1978.

(e) Amended labeling for Alcare Foamed Alcohol, August 19, 1982.

(2) OTC Vol. 160377.

(3) OTC Vol. 160382.

F. Comments on Chlorhexidine Gluconate

11. Several comments requested that the agency include chlorhexidine gluconate as a Category I ingredient in any amended tentative final monograph. The comments submitted references and data to establish general recognition of safety and effectiveness (Ref. 1), and stated that chlorhexidine gluconate solution is recognized in the "British Pharmacopeia" (Ref. 2) and is formulated in a wide range of products that have been successfully marketed to a material extent and for a material length of time in other countries. The comments asserted that when

formulated in compliance with FDA's current good manufacturing practice regulations (21 CFR part 211), chlorhexidine products are safe and effective for use as skin wound cleansers, skin wound protectants, patient preoperative skin preparations, skin antiseptics, surgical hand scrubs, and health-care personnel handwashes.

A reply comment argued that chlorhexidine gluconate, currently marketed in the United States under approved new drug applications (NDA's), is not eligible for an OTC drug monograph because the ingredient has not been marketed within this country to a material extent and for a material length of time. The comment added that variations in final formulations may alter the safety and effectiveness of the ingredient. The comment submitted data (Ref. 3) to support this viewpoint and requested that chlorhexidine gluconate be classified in Category II.

In the previous tentative final monograph (43 FR 1210), chlorhexidine gluconate (4 percent solution) was neither addressed nor categorized as Category I, II, or III. However, subsequent to the tentative final monograph, the agency granted a petition (Ref. 4) and in the **Federal Register** of March 9, 1979, reopened the administrative record to allow interested persons an opportunity to submit data and information (44 FR 13041). The comments (Ref. 1) and reply comment (Ref. 2) were submitted in response to that notice. However, since that time a majority of the comments on chlorhexidine submitted in response to the notice have been withdrawn (Ref. 5). While the withdrawn comments remain on public display as part of the administrative record, they are no longer being considered in this rulemaking.

The agency has reviewed the marketing history of chlorhexidine gluconate and finds that although it has been marketed for professional or hospital use under NDA's, insufficient data remain in the public administrative record for this rulemaking to support general recognition of safety and effectiveness for OTC use. Accordingly, chlorhexidine gluconate 4 percent aqueous solution as a health-care antiseptic is a new drug and is not included in this tentative final monograph.

References

(1) Comments No. C110, C116, C120, C130, C131, C136, C137, EXT18, RC2, RC5, CP3, LET12, LET14, LET16, SUP30, SUP33, SUP38, and SUP40, Docket No. 75N–0183, Dockets Management Branch.

(2) "British Pharmacopeia," Vol. I, Her Majesty's Stationery Office, London, pp. 100–101, 1980.

(3) Comments No. RC1 and RC4, Docket No. 75N–0183, Dockets Management Branch.

(4) Comment No. CP3, Docket No. 75N–0183, Dockets Management Branch.

(5) Comments No. WDL3, WDL4, and WDL5, Docket No. 75N–0183, Dockets Management Branch.

G. Comments on Chloroxylenol

12. A number of comments disagreed with the agency's Category III classification of chloroxylenol in the tentative final monograph. They argued that a reevaluation of the data previously submitted to the agency along with new data that have been submitted (Refs. 1 through 16) would provide adequate justification for classifying chloroxylenol in Category I for safety and effectiveness for use in antimicrobial soaps, health-care personnel handwashes, patient preoperative skin preparations, skin antiseptics, skin wound cleansers, skin wound protectants, and surgical hand scrubs. Several comments pointed out that the Antimicrobial II Panel unanimously concluded that chloroxylenol is generally recognized as safe for topical use in athlete's foot and jock-itch preparations.

Based upon the submitted data (Refs. 1 through 16) and other information reviewed by the Antimicrobial Panels, the agency concluded in the amended tentative final monograph for OTC first aid antiseptic drug products that chloroxylenol (0.24 percent to 3.75 percent) was safe but not effective for short-term use as an OTC topical first aid antiseptic (54 FR 33644 at 33658). These data (Refs. 1 through 16) and new data submitted under the agency's "feedback" procedures (Refs. 17 through 30) are insufficient to support a Category I classification of the safety and effectiveness of the ingredient for other long-term uses, e.g., antiseptic handwash or health-care personnel handwash and surgical hand scrub. The agency concludes that chloroxylenol remains classified in Category III as an active ingredient for these uses. However, the ingredient would be considered safe for short-term use as a patient preoperative skin preparation but remains in Category III due to a lack of effectiveness data for this use.

In the previous tentative final monograph (43 FR 1210 at 1222 and 1238), the agency stated that the data were insufficient to reclassify chloroxylenol into Category I, and the ingredient remained in Category III for safety and effectiveness. Indicating concern about the absorption of topically applied antimicrobial drug products used repeatedly by consumers over a number of years, the agency stated the following regarding the safety of the ingredient:

> Only the most superficial toxicity data in animals were submitted to and reviewed by the Panel. The Commissioner concurs with the Panel that toxicity in rodent and nonrodent species, substantivity, blood levels, distribution and metabolism, as well as any subsequent systemic absorption studies must be characterized * * *. The degree of absorption of PCMX following topical administration has not been established. The target organ for PCMX toxicity in animals also remains unidentified and should be shown in a long-term animal toxicity study.

While safety data (Refs. 1, 2, 6, and 7) are sufficient to establish safety for short-term use such as for a patient preoperative skin preparation drug product, these data do not resolve concerns about long-term chronic toxicity. Conclusions on these data, which were also reviewed by the Advisory Review Panel on OTC Antimicrobial II Drug Products (Antimicrobial II Panel) in conjunction with its review of OTC topical antifungal drug products, were published in the **Federal Register** of March 23, 1982 (47 FR 12480). That Panel, which evaluated the safety of the ingredient for use in OTC topical antifungal drug products, categorized chloroxylenol (0.5 to 3.75 percent) as safe (Category I) for short-term use (up to 13 weeks) and advised, "* * * relatively low doses of chloroxylenol can be systemically tolerated, at least over a 13-week period. The Panel is concerned about the effect of chronic administration on the liver, but does not consider that topical application of chloroxylenol to small areas of the skin over short periods of time would result in liver damage." (47 FR 12480 at 12534). The agency subsequently agreed with the Panel's conclusions concerning the safety of using the ingredient in OTC topical antifungal drug products for the treatment of athlete's foot, jock itch, and ringworm (maximum treatment duration 4 weeks) in its tentative final monograph for these OTC drug products, published in the **Federal Register** of December 12, 1989 (54 FR 51136 at 51139). The agency subsequently finalized these conclusions in the final rule for OTC topical antifungal drug products published in the **Federal Register** of September 23, 1993 (58 FR 49890).

Regarding long-term chronic toxicity, data and information provided by one manufacturer included final reports of completed studies and interim reports

of incomplete studies (Ref. 2). The information also contained a protocol of a planned preclinical study (projected starting and completion dates for experiments) which identified a 2-year rat feeding study. Because this study might resolve concerns about long-term chronic toxicity, the agency requested the raw data (Ref. 31); however, the manufacturer declined to submit the data, explaining that it is no longer interested in marketing chloroxylenol, that its study had not been completed, and that the study was conducted prior to establishment of the Good Laboratory Practices regulations (Ref. 32).

In response to the agency's determination that data from a 2-year rat feeding study were essential (Ref. 33), another manufacturer submitted additional information along with copies of already available safety data (Ref. 34). The manufacturer explained that it believes that long-term safety data, i.e., 2-year oral feeding study, while not currently available, may not be a necessity. Citing statements made by the Panel, that its recommended guidelines for the safety testing of these drug products were developed primarily for antimicrobial agents applied to the entire body surface and that appropriate tests should be chosen to reflect the intended use of the antimicrobial drug product (39 FR 33103 at 33135), the manufacturer contended that the guidelines were developed to address the most extreme exposure to an antimicrobial ingredient rather than to describe the minimal requirements for safety data that the Panel would find acceptable. Noting the contrast between the use of surgical hand scrub drug products (products used by adults in a limited area of the body for a specified time span) with lifetime application to the entire body in bar soaps, the manufacturer contended that while the use of a surgical hand scrub is considered chronic use, the exposure to the antimicrobial ingredient during such use is limited to the hand and half the distance to the elbow. The manufacturer further suggested that one might simply regard the use of health-care antiseptic ingredients in handwashes and surgical scrubs as repeated daily use in a limited area of the body.

The manufacturer contended that data from a 2-year feeding study would not contribute any information on the long-term safety of chloroxylenol that is not already available from subchronic studies (Ref. 35). In support of its contention, the manufacturer submitted data from subchronic animal toxicity and human bathing studies (Ref. 18) previously submitted in response to the tentative final monograph for OTC topical antimicrobial drug products and to the Antimicrobial II Panel. The data also included computer simulation models (Ref. 36) of plasma levels of chloroxylenol that might occur after dermal applications of varying concentrations of the ingredient. The simulations, based on urinary excretion data from human bathing studies, predict a lack of potential for accumulation of the ingredient in humans. Subsequent submissions from the same manufacturer included a review article on the toxicity of chloroxylenol (Ref. 19), a retrospective analysis of the value of chronic animal toxicology studies of pharmaceutical compounds (Ref. 20), and copies of all available toxicity data for chloroxylenol (Ref. 21). Included in the toxicity data was a kinetic analysis (Ref. 37) of data from human and animal studies of the ingredient previously submitted to the agency that also predicts that accumulation in humans is not likely to occur at reasonable exposure levels. Based on the above data and information, the manufacturer requested that the agency reconsider the necessity of a long-term animal study. In response to the manufacturer's request, a public meeting was held to discuss the available toxicity data for chloroxylenol. At that meeting, the agency noted that many of the subchronic studies of the ingredient are of limited usefulness because they were conducted using a formulated product that contained isopropyl alcohol, turpineols, and castor oil soap in addition to chloroxylenol. The kinetic model used in the studies was considered inappropriate. A one-compartment model, as used in the analysis, is not relevant to chloroxylenol due to its lipophilic nature. The agency's detailed comments are on file in the Dockets Management Branch (Refs. 38 and 39).

After considering the manufacturer's comments and evaluating the data available at the time, the agency concluded that the information was not adequate to characterize the level of absorption, the distribution, the metabolism, and the excretion of chloroxylenol following topical administration. In a 1988 letter to the manufacturer (Ref. 40), the agency stated: (1) That data from the human bathing studies reviewed are highly variable (absorption 0.5 to 15.7 percent), (2) the analytical methodology used in the studies had not been validated and (3) that the small number of subjects included in the studies made it difficult to draw meaningful conclusions from the reported results. The agency commented further that submitted accumulation predictions were not adequate to define the toxicity that might occur with repeated exposure to the ingredient because no data have been submitted to support or validate the model's assumptions in characterizing exposure and stated that additional data are needed to justify, support, and verify the assumptions and data used in the predictions. Pointing out that accumulation is not the sole issue of long-term toxicity, the agency asserted that long-term toxicity may be related to repeated daily exposure to low levels of the ingredient over a lifetime.

In that same letter, the agency stated that it had reexamined the necessity for a long-term animal study based on the manufacturer's assertion that use of the ingredient as an antiseptic handwash and surgical scrub should be regarded as repeated use to a limited area of the body, and had concluded that data from additional short-term studies conducted under actual use conditions (i.e., where abrasion is followed by occlusion, with the level of absorption, distribution, metabolism, and elimination of the ingredient being shown under these conditions) could provide adequate information to determine whether or not a long-term animal study is necessary. Protocols for a pharmacokinetic surgical scrub study to develop such data were submitted to the agency (Refs. 41 and 42); however, to date the agency has not received any data from such a study. The agency's detailed comments are on file in the Dockets Management Branch (Refs. 43 and 44).

More recently, the agency received additional data pertaining to the safety of chloroxylenol from another manufacturer (Ref. 30). The data included an assessment of the ingredient's mutagenic potential by a series of in vitro and in vivo assays (Ames test, unscheduled DNA synthesis in rat primary hepatocytes, chromosomal aberrations in Chinese hamster ovary cells, and an in vivo mouse micronucleus assay). The data also included a dose range-finding study for a teratology study of the ingredient in rats and the subsequent teratology study.

Two of the four mutagenicity assays included in the submission yielded suspect or equivocal results. The in vitro administration of 19, 38, 75, and 150 micrograms per milliliter (µg/mL) doses of chloroxylenol to Chinese hamster ovary cells produced a statistically significant increase relative to the solvent control in the mean number of chromosome aberrations per cell at the 75 and 150 µg/mL dose level both in the presence and absence of

metabolic activation. Statistically significant increases in the percent of aberrant cells were also seen at the 75 µg/mL dose in the absence of metabolic activation and at the 75 and 150 µg/mL doses in the presence of metabolic activation. No dose response was apparent in either the activated or nonactivated systems. The investigator concluded that the results were equivocal in the nonactivated test system and suspect in the activated test system.

The results of the in vivo mouse micronucleus assay demonstrated a statistically significant increase in micronucleated polychromatic erythrocytes in female mice 24 and 72 hours after oral dosing with 250 and 833 milligrams per kilogram (mg/kg) doses of chloroxylenol. However, no dose response was apparent. The investigator considered the results to be a statistical anomaly based on unusually low mean micronucleus values in the negative control group and the lack of a dose response. However, the agency believes that because the observed increases were significantly elevated over those of the negative controls ($p \leq 0.01$) and were reproducible at two dose levels, these results should be considered equivocal. The manufacturer has provided additional information (Ref. 45) in response to the agency's interpretation of the results of the mouse micronucleus assay. However, the agency continues to believe that reliance on data from historical controls is inappropriate and has not changed its position on the data. The agency's detailed comments are on file in the Dockets Management Branch (Refs. 46 and 47).

In light of the new data (Ref. 30) and the issues that they raise, the agency has again reexamined the data requirements necessary to support the safe chronic use of this ingredient. The agency finds it necessary to broaden the additional testing requirements in order to clearly assess potential risks associated with chronic use of chloroxylenol. Therefore, data obtained from the following are necessary: (1) Human studies conducted under maximal use conditions, i.e., repeated use as a surgical scrub use where abrasion is followed by occlusion, characterizing the level of absorption, the distribution, metabolism, and elimination of the ingredient, (2) a lifetime dermal carcinogenicity study (up to 2 years) in mice, and (3) an appropriate human epidemiological study performed to determine the effects on health-care professionals in countries, such as England, where the ingredient has been used extensively for a long period of time are necessary. Further, in order to relate the data derived from the chronic animal study to humans, the lifetime dermal carcinogenicity study should also include concomitant absorption, distribution, metabolism, and excretion studies. A protocol for an 18-month dermal carcinogenicity study has been submitted to the agency (Ref. 48). The agency's detailed comments and evaluation of the data and protocol are on file in the Dockets Management Branch (Ref. 47).

Regarding the effectiveness of chloroxylenol, the agency stated the following in the previous tentative final monograph: "Claims for broad spectrum activity have been made * * *; however, the Commissioner finds that inadequate effectiveness data were submitted. Many studies were old and not performed with modern antiseptic testing procedures. * * * effectiveness testing both in vitro and in vivo should be done in accordance with the Guidelines" (43 FR 1238).

The applicable effectiveness data submitted by the comments were derived from in vivo and in vitro studies (Refs. 1 through 7 and 13 through 16), along with data subsequently submitted under the "feedback" procedures (Refs. 22 through 28 and 50).

Data from in vivo glove juice studies (Refs. 1, 2, 19, and 50) demonstrated the antiseptic activity of chloroxylenol in a range of 3 to 3.75 percent when formulated in an aqueous surfactant vehicle. Chloroxylenol formulations are substantive in their activity, i.e., they do not produce an initial high reduction in the number of bacteria but after repeated use (routine use), they reduce the baseline number of bacteria and suppress bacterial growth for 6 hours. In vivo data for surgical hand scrub products containing chloroxylenol at concentrations lower than 3 percent are insufficient. Aqueous solutions of chloroxylenol in a pine oil vehicle (1:40 dilution of Dettol®) consistently reduced more than 99 percent *Staphylococcus aureus* (*S. aureus*) from the hands of test subjects (Ref. 25).

In vivo cup scrubbing and other appropriate data (Refs. 22, 23, and 24) indicate that chloroxylenol, in 70 percent alcohol, is fast acting as a patient preoperative skin preparation. However, alcohol itself meets the criteria for a preoperative skin preparation and is a significant contributor for fast acting contaminant reduction. The data are not sufficient to demonstrate that chloroxylenol in this formulation contributes to the total antimicrobial effect.

In vitro study data (Refs. 1, 3, 4, 5, 13, 14, 16, and 26) show that chloroxylenol in various vehicles is effective against gram-negative bacteria, i.e., *Escherichia coli* (*E. coli*), *P. aeruginosa*, *Proteus vulgaris*, and *Klebsiella aerogenes* (*K. aerogenes*). This anti-gram-negative activity is formulation dependent. Tested aqueous solutions of pure chloroxylenol with no other additives show that low concentrations (0.3 mg/mL) reduced 95 percent of some *Pseudomonas* in 10 minutes.

Data regarding the antiseptic activity of chloroxylenol itself are not adequate. While the data are considered sufficient to support in vitro effectiveness for the finished products, the available data are inadequate to show the contribution of the chloroxylenol. Because these finished products contain several additional ingredients, e.g., surfactants, isopropanol, pine oil, or ethylenediaminetetraacetic acid (EDTA), which contributed substantial germicidal activity, conclusions regarding chloroxylenol's active contribution to the product's efficacy cannot be supported. The agency's detailed comments and evaluations of the submitted data are on file in the Dockets Management Branch (Refs. 51 and 52). One manufacturer has responded to FDA's concern and provided additional data (Ref. 53). These data are currently being reviewed by the agency and will be discussed in the final rule for these drug products. In summary, the data are sufficient to support the in vitro and in vivo effectiveness of the formulations tested. However, additional data are needed to demonstrate that chloroxylenol contributes to the activity of these formulations. In addition, data from glove juice studies indicate that the antimicrobial activity of chloroxylenol is substantive in nature and does not produce an initial high reduction of bacteria, but that repeated use of the ingredient will produce a reduction in bacteria as well as a suppression of the baseline number of bacteria of the normal skin flora for 6 hours. As discussed in section I.N., comment 28, the agency is proposing that all antimicrobial products indicated for use as a surgical scrub or health-care personnel handwash be able to demonstrate an immediate reduction in bacteria and is inviting comment on the use of substantive antimicrobials in health-care antiseptic drug products.

The agency, therefore, is proposing that chloroxylenol at the concentrations evaluated (0.24 percent to 3.75 percent) be classified as Category I for safety and Category III for effectiveness for short-term use as a patient preoperative skin preparation and in Category III for safety and effectiveness for long-term uses, i.e., antiseptic handwash or health-care

personnel handwash and surgical hand scrub. The existing data are not adequate to extrapolate and assess the chronic toxicity of chloroxylenol for long-term use. Before chloroxylenol may be generally recognized as effective, the agency recommends that appropriate in vitro and in vivo effectiveness data be submitted. The data should include results obtained from both in vitro and in vivo tests as described in the testing procedures below. (See section I.N., comment 28.)

References

(1) Unpublished Clinical Safety and Effectiveness Studies on Aqueous Soap Formulations, Comment No. 0B7, Docket No. 75N–0183, Dockets Management Branch.

(a) Controlled Clinical Study Comparing the Activity of Fresh, Camay Soap, and Phisohex Against the Natural Bacterial Flora of the Hand.

(b) Antimicrobial Activity of PCMX, Triclosan, and TCC.

(c) Repeated Insult Patch Testing of Fresh Soap.

(2) Unpublished Nonclinical and Clinical Studies, and Protocols, Comment No. C96, Docket No. 75N–0183, Dockets Management Branch.

(a) Part I: PCMX Toxicosis, final reports of completed studies, interim reports of incomplete studies, and Preclinical Testing Protocol.

(b) Part II: Complete Reports on Clinical Safety and Efficacy and In Vitro Efficacy Studies.

(3) Unpublished Clinical Effectiveness Studies on Aqueous Soap Formulations, Comment No. C122, Docket No. 75N–0183, Dockets Management Branch.

(a) Protocol and Results of a Glove Juice Hand Washing Test Performed with PHLO Antimicrobial Skin Cleanser.

(b) Results of a Zone of Inhibition and Assay Performed on Aged Samples of PHLO Antimicrobial Skin Cleanser.

(4) Unpublished Clinical Safety and Effectiveness Studies on Aqueous Soap Formulations, Comment No. C123, Docket No. 75N–0183, Dockets Management Branch.

(a) Bactericidal Activity of Envair Antiseptic Hand Soap.

(b) Dermal Irritation Study.

(c) Insult Patch Test.

(d) Bacterial Kill Test.

(e) Hand-wash Effectiveness Test.

(5) Unpublished In Vitro Effectiveness Studies Performed on Aqueous Soap Solutions, Comment No. C125, Docket No. 75N–0183, Dockets Management Branch.

(a) AOAC Available Chlorine Germicidal Equivalent Concentration Test.

(b) The Antimicrobial Activity of a Sample.

(6) Published and Unpublished Nonclinical and Clinical Safety Studies, Comment No. SUP11, Docket No. 75N–0183, Dockets Management Branch.

(7) Comment No. SUP12, Docket No. 75N–0183, Dockets Management Branch.

(8) Unpublished Clinical Safety an Effectiveness Studies, Comment No. SUP10, Docket No. 75N–0183, Dockets Management Branch.

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(b) The Effect of Vaseline Petroleum Jelly and Vaseline First Aid Carbolated Petroleum Jelly on Healing of Experimental Skin Wounds, January 13, 1977.

(9) Bradbury, S. J., and J. Hayden, "Effect of Dettol® Wound Healing in Rats," Report No. RC 76132, unpublished study, Comment No. SUP5, Docket No. 75N–0183, Dockets Management Branch.

(10) Bradbury, S.J., and E.J. Hayden, "Dettol® Wound Healing," unpublished study, Project No. RC 1081, 1978, Comment No. SUP12, Docket No. 75N–0183, Dockets Management Branch.

(11) Maibach, H.I., "The Effects of Vaseline® Petroleum Jelly and Vaseline® First Aid Carbolated Petroleum Jelly on Epidermal Wound Healing—A Controlled Clinical Laboratory Study," unpublished study, Comment No. SUP10, Docket No. 75N–0183, Dockets Management Branch.

(12) Maibach, H.I., "The Effect of Vaseline® Petroleum Jelly and Vaseline® First Aid Carbolated Petroleum Jelly on Healing of Experimental Skin Wounds," unpublished study, Comment No. SUP10, Docket No. 75N–0183, Dockets Management Branch.

(13) Munton, T.J., and J. Prince, "The Bacteriostatic and Bactericidal Activity of Dettol® Against a Range of Recently Isolated Mesophilic Strains Including Members of the Normal Flora and Cutaneous Pathogens of the Skin," unpublished study, No. BL 75/4, 1975, Comment No. SUP3, Docket No. 75N–0183, Dockets Management Branch.

(14) Prince, J., and K.A. Barker, "A Comparison of the In-Vitro Activity of Dettol®, Hexylresorcinol, and Benzalkonium Chloride," unpublished study, No. BL 76/28, 1976, Comment No. SUP3, Docket No. 75N–0183, Dockets Management Branch.

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(17) Comment No. LET65, Docket No. 75N–0183, Dockets Management Branch.

(18) Comment No. SUP47, Docket No. 75N–0183, Dockets Management Branch.

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(27) Comment No. SUP48, Docket No. 75N–0183, Dockets Management Branch.

(28) Comment No. RPT3, Docket No. 75N–0183, Dockets Management Branch.

(29) Comment No. RC6, Docket No. 75N–0183, Dockets Management Branch.

(30) Comment No. C171, Docket No. 75N–0183, Dockets Management Branch.

(31) Letter from W.E. Gilbertson, FDA, to C. Rose, Pennwalt Corp., coded LET54, Docket No. 75N–0183, Dockets Management Branch.

(32) Letter from C. Rose, Pennwalt Corporation, to W.E. Gilbertson, FDA, coded LET59, Docket No. 75N–0183, Dockets Management Branch.

(33) Letters from W.E. Gilbertson, FDA, to J. Nalls, Ferro Corp., C. Rose, Pennwalt Corp., M.E. Garabedian, Dexide, Inc., M. Berdick, Chesebrough-Ponds, Inc., W.F. Stephen, Scientific and Regulatory Services, H.S. Chapman, Chemical Specialties, Inc., C.A. Wiseman, Sani-Fresh, Division of Envair, Inc., J. Rowan, Seagull Chemical, Inc., coded LET70, LET71, LET72, LET73, LET74, LET75, LET76, and LET77, respectively, in Docket No. 75N–0183, Dockets Management Branch.

(34) Comment No. LET65, volumes 1 through 3, Docket No. 75N–0183, Dockets Management Branch.

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(39) Memorandum of meeting between representatives of Dexide, Inc., Ferro Corp., and FDA, coded MM11, Docket No. 75N–0183, Dockets Management Branch.

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(41) Comment No. C165, Docket No. 75N–0183, Dockets Management Branch.

(42) Comment No. SUP51, Docket No. 75N–0183, Dockets Management Branch.

(43) Letter from W. E. Gilbertson, FDA, to M. K. Bruch, Dexide, Inc., coded LET93, Docket No. 75N–0183, Dockets Management Branch.

(44) Memorandum of meeting between representatives of Dexide, Inc., Ferro Corp., and FDA, coded MM15, Docket No. 75N–0183, Dockets Management Branch.

(45) Comment No. C172, Docket No. 75N–0183, Dockets Management Branch.

(46) Letter from W. E. Gilbertson, FDA, to G. R. Kramzar, NIPA Laboratories, Inc., coded LET97, Docket No. 75N–0183, Dockets Management Branch.

(47) Letter from W. E. Gilbertson, FDA to G. R. Kramzar, NIPA Laboratories, Inc., coded C174, Docket No. 75N–0183, Dockets Management Branch.

(48) Comment No. C173, Docket No. 75N-0183, Dockets Management Branch.

(49) Comment No. LET65, vol. 4, 5, and 6, Docket No. 75N–0183, Dockets Management Branch.

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(52) Letter from W. E. Gilbertson, FDA, to M. K. Bruch, Dexide, Inc., coded LET90, Docket No. 75N–0183, Dockets Management Branch.

(53) Letter from M. K. Bruch, Dexide, Inc., to W. E. Gilbertson, FDA, coded LET91, Docket No. 75N–0183, Dockets Management Branch.

H. Comment on Hexachlorophene

13. One comment urged reconsideration of hexachlorophene as an OTC "handwashing agent and antimicrobial skin cleanser for use in the hospital, doctor's office, and by adult consumers." The comment stated that adequate data to support Category I status were submitted in response to the advance notice of proposed rulemaking, but were only superficially discussed by the agency in comment 61 of the tentative final monograph. (See the **Federal Register** of January 6, 1978, 43 FR 1210 at 1220.) The comment submitted additional data to support the safety of hexachlorophene, including a retrospective study on 3 percent hexachlorophene in baby bathing (Ref. 1) and a study of hexachlorophene blood levels in infants receiving routine antiseptic skin care (Ref. 2). The comment also included a comprehensive review article on the safety and effectiveness of hexachlorophene (Ref. 3).

The agency has reevaluated the data discussed in comment 61 in the tentative final monograph (43 FR 1220) and evaluated the new data, and has determined that the data do not warrant changing the classification of hexachlorophene as a prescription drug. The infant data (Refs. 1 and 2) were discussed in detail in the tentative final monograph for OTC antimicrobial diaper rash drug products (55 FR 25246 at 25261 to 25263).

Summaries of handwash studies were also submitted, but no data were included. In one study, 3 percent hexachlorophene was tested as a surgical scrub under exaggerated use conditions (Ref. 4). Subjects (number not specified) washed their hands and forearms in 20 mL hexachlorophene for 10 minutes, 5 times daily, 6 days a week for a total of 58 days. No signs of toxicity were reported. The blood levels of hexachlorophene reached a plateau within 3 days at mean levels of 0.07 µg/mL.

The agency believes that it would be necessary to test a very large group of subjects (the number of subjects required to obtain a statistically significant result) with a variety of skin conditions to determine the true degree of absorption. A similar study reviewed by the Panel (39 FR 33103 at 33118) reported blood levels of 0.5 µg/mL or higher.

In the other study, subjects washed their hands and face three times daily for 3 weeks with either 2 or 5 mL of 3 percent hexachlorophene (Ref. 4). Blood concentrations reached a plateau within 7 days at mean levels of 0.21 µg/mL for the 2-mL group and 0.22 µg/mL for the 5-mL group.

Other additional data contained only a brief summary of the historical use of hexachlorophene and primarily cited publications in the medical literature (Ref. 5). The references provided no new information. Consequently, the agency has determined that hexachlorophene will continue on prescription status subject to the existing regulation in 21 CFR 250.250.

In order for hexachlorophene to be switched to OTC status, the concerns expressed by the Antimicrobial I Panel that hexachlorophene does not have an adequate margin of safety for OTC use (39 FR 33103 at 33117) should be addressed. After reviewing the submitted data, the agency concludes that the safety of this ingredient for OTC use on infants has not been demonstrated. For OTC status for use by adults, any further submission of data should specifically address the safe OTC use of hexachlorophene in adults.

Based upon the discussion above, the agency is proposing that hexachlorophene remain available by prescription only, except when used as a preservative at concentrations of 0.1 percent or less.

The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 6).

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(4) Comment No. SUP13, Docket No. 75N–0183, Dockets Management Branch.

(5) Comment No. C116, Docket No. 75N–0183, Dockets Management Branch.

(6) Letter from W. E. Gilbertson, FDA, to G. S. Goldstein, Sterling Drug Inc., coded LET63, Docket No. 75N–0183, Dockets Management Branch.

I. Comments on Iodine and Iodophors

14. One comment pointed out that poloxamer-iodine complex appeared to be incorrectly included in the Category II list under "health-care personnel handwash" (43 FR 1210 at 1227), while it is properly listed in Category III for use as a "health-care personnel handwash" (43 FR 1210 at 1229). The comment stated that deletion from the Category II list would correct the error.

The agency concurs with the comment that poloxamer-iodine complex for use as a health-care personnel handwash was incorrectly listed as Category II (43 FR 1227) and that the listing as Category III (43 FR 1229) was correct.

15. One comment submitted data on the safety and effectiveness of a "mixed iodophor" consisting of iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate (Ref. 1). The comment stated that this information had been previously submitted in May 1974, but that the ingredient had not been mentioned in the Panel's report or in the agency's proposed monograph and requested that the agency include it in the monograph. The comment pointed out that the iodophor, formulated as a liquid hand scrub, is intended for use by surgeons, food handlers, and others for whom reduced bacterial skin flora is of public health significance.

Regarding the comment's statement that the data were previously submitted,

the agency has no record of any submission of these data in 1974. Because this hand scrub was not previously reviewed or categorized as an OTC topical antimicrobial drug product, the agency reviewed the product's marketing history and considers it appropriate to include this product in the OTC drug review. The agency has evaluated the data submitted by the comment (Ref. 1) and determined that iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate is safe for use as a surgical hand scrub and health-care personnel handwash, but that there are insufficient data available to determine its effectiveness for these uses. Therefore, the ingredient is being classified in Category III.

The data included several studies on the absorption of the iodine complex, blood levels of iodine, and the systemic toxicity of the iodine complex. Protein-bound iodine (PBI) and iodine blood levels in rabbits were determined following two studies of acute dermal applications. In the first study, either 2 or 5 mL/kilogram (kg) of the test iodine complex was applied to the shaved backs of rabbits in one experiment. The method of occlusion, if any, was not stated, but the test material was washed off after 24 hours. In another experiment, 2 mL/kg of the test iodine complex was compared with a povidone-iodine complex and both were applied as in the first experiment. PBI and total iodine in blood were determined at 0, 24, and 48 hours in both experiments. In all treated animals, the level of PBI was extremely high at certain times, primarily at 24 hours. Animals receiving the higher dose of iodine complex in the first experiment seemed to return to normal sooner than those receiving the lower dose. All animals returned to normal by 14 days. For purposes of comparison, the second experiment showed that serum total iodine increased from 1.4 to 30.7 milligrams/deciliter (mg/dL) in the test iodine complex group compared to from 1.23 to 37.9 mg/dL in the povidone-iodine group in the 24 hours that the application remained on. In the second study, 5 mL/kg of the test iodine complex was applied to the shaved backs of two groups of five rabbits each. In one group the shaved backs were occluded for 24 hours and in the other group, the shaved backs were scrubbed for 10 minutes followed by rinsing and occlusion. An additional group served as an untreated control group. Blood samples for iodine determinations were taken at 0, 24, and 48 hours and at 14 days. All five animals in the group in which the iodine complex remained occluded on intact skin for 24 hours had markedly elevated levels of PBI and iodine at both 24 and 48 hours, but were only slightly above normal at 14 days. For the 10-minute scrub animals, the PBI levels were increased in two of five animals at 24 hours, slightly in all five animals at 48 hours, and were normal at 14 days.

A study to determine the effect on blood PBI levels of a routine scrubbing procedure in which exposure to the iodine complex exceeded normal use showed no alteration in PBI levels in four humans who scrubbed twice daily (each scrub consisting of two 5 minute hand washes with 5 mL) for 26 consecutive days. Also, no irritation was observed. In a similar study in which the subjects wore gloves for 2 hours after each scrub, PBI levels were not increased, but total iodine was slightly increased. In two subjects, this increase was greater in the middle of the study, but the total iodine blood levels were near normal by the end of the study.

A dermal absorption study in which the shaved backs of four monkeys were rubbed with 0.17 mL/kg of radioactive iodine complex for 10 minutes, rinsed, wrapped for 2 hours, and the animals sacrificed after 24 hours, revealed that less than 0.1 percent of the application was recovered in the thyroid, the target organ for iodine.

A 90-day sub-acute dermal toxicity study was conducted in three groups of monkeys divided into one control group and two test groups. One test group was scrubbed once for 10 minutes daily with 0.17 mL/kg of the iodine surgical scrub detergent product and the second group was scrubbed three times with 0.34 mL/kg (once for 10 minutes and twice for 3 minutes each day). To simulate the wearing of surgical gloves, the treated area of each animal, which consisted of a shaved area of the back equivalent to about 10 percent of the body area, was wrapped with a rubber dam for 30 to 90 minutes. The study lasted 13 weeks during which the animals were monitored. Neither test group showed any effects of iodophor treatment except elevated PBI levels in the high dose group, which peaked at one month. Also, there was no significant effect on the thyroid in the treated groups.

The agency believes this iodine complex is safe for humans based on the data from human, rabbit, and monkey studies. Test data showed very little iodine absorption when the product was used as a scrub, negligible uptake (following acute dermal application of radioactive iodine complex) by the thyroid in monkeys, and an unchanged thyroid weight in test groups of monkeys following 90 days of sub-acute applications of the iodine complex.

The comment submitted data from one clinical study for evaluating effectiveness as a surgical hand scrub but did not provide the testing protocol used. Five subjects scrubbed three times daily for 5 days with the iodophor formulation (containing 1.1 percent iodine). Four subjects completed the study. Surgical gloves were worn for 2 hours after the first wash of the day. Subjects' hands were sampled once each day at the end of the 2-hour gloved period using a single-basin Cade method. The initial sampling was used to establish a baseline microbial count for each subject. Study results were reported as the number of organisms per mL of basin water and the percent reduction in the number of organisms recovered. The reduction in the bacterial population ranged from 89 to 98 percent on the first day. By the fifth day, the reduction ranged from 99 to 100 percent. Similar results were obtained in a comparative study on six subjects using povidone-iodine.

Although it is clear that the test used was not the glove juice test which is described in the antimicrobial tentative final monograph (43 FR 1210 at 1242), alternative methods may be acceptable. However, because of the small number of subjects included in the study, the data are not sufficient to support the Category I classification of this ingredient for use as a surgical hand scrub. Additional studies, of the type described in § 333.470(b)(1) of this amended tentative final monograph, are necessary to support the effectiveness of this surfactant iodine complex for this use.

In the previous tentative final monograph (43 FR 1235), the agency recognized that elemental iodine complexed with a surfactant type "carrier" molecule reduces the amount of immediate "free" iodine, because most of the formulated iodine is bound in the complex. Effectiveness of all iodophors is dependent on the release of free iodine as the active agent from the complexing molecule which acts only as a carrier. The agency acknowledges that iodine complexed with a surfactant is an acceptable way of presenting iodine as an antimicrobial agent to the skin. However, because most of the formulated iodine may be tied up in the complex and because the information submitted by the comment to support in vitro efficacy (Ref. 2) dealt only with aqueous and/or tincture solutions of free iodine, testing of the complete formulation is necessary to judge the importance of formulation on the release of the active ingredient and,

thus, its influence on aspects of effectiveness.

Based on the data submitted, the agency concludes that iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate is safe but additional data from appropriate studies are needed to establish general recognition of effectiveness for use as a surgical hand scrub and health-care personnel handwash. The data should include results obtained from both in vitro and in vivo testing procedures. (See section I.N., comment 28.)

References

(1) Unpublished Nonclinical and Clinical Studies on V.I.S., Vestal Iodine Scrub (iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate), Comment No. C106, Docket No. 75N–0183, Dockets Management Branch.

(a) Acute Dermal Toxicity in Rabbits.

(b) Acute Dermal Application—Rabbits.

(c) Determination of the Influence of Scrubbing with Vestal Iodine Surgical Scrub Detergent on the Protein Bound Iodine Level of the Blood.

(d) Determination of the Influence of Scrubbing with Vestal Iodine Surgical Scrub Detergent on the Protein Bound Iodine and Total Serum Iodine Levels in the Blood.

(e) Percutaneous Absorption of Iodine in Monkeys from the Dermal Application of an Iodine Surgical Scrub Detergent.

(f) Three Month Sub-Acute Dermal Toxicity Study in Monkeys with Vestal Iodine Scrub Detergent.

(g) Iodine Surgical Scrub Detergent, Surgical Hand Scrub Study in Five Human Test Subjects.

(2) Gershenfeld, L., "Iodine," in "Disinfection, Sterilization, and Preservation" 1st ed., Lee and Febiger, Philadelphia, pp. 329–347, 1968.

16. Several comments objected to the warning proposed for the professional labeling for povidone-iodine and iodophor-surfactant products: "Caution: Do not use this product in the presence of starch-containing products. Starch can adsorb iodophors and the resulting complex can cause serosal adhesions (abnormal union of the serous membranes) and other undesirable effects in the body" (43 FR 1210 at 1221). The comments pointed out that the study by Goodrich, Prine, and Wilson (Ref. 1) on which the warning is based is not well controlled, is rudimentary, and lacks rigorous testing that produces evidence which can be statistically analyzed. The comments contended that this article is not sufficient basis for the warning. The comments requested that the impact of the article by Goodrich, Prine, and Wilson on the labeling of nonsurfactant iodophors be reevaluated and that povidone-iodine be exempt from the required warning relating to contact of starch and iodophors. One comment stated that there are numerous papers in the literature describing the antiadhesive effect of povidone and povidone-iodine and submitted nine references dealing with humans and animals that support an antiadhesive effect when povidone or povidone-iodine is used in intraperitoneal surgery (Ref. 2). Another comment explained that starch is well known for producing granuloma and that every package of surgeons' gloves carries a warning statement to the effect that the outside of the gloves must be cleansed of starch powder prior to use. The comment concluded that FDA should require a warning label on the gloves, but not on products containing the drug.

FDA has reevaluated the article by Goodrich et al. (Ref. 1), considered the additional cited references (Ref. 2), and examined current policy on the labeling of United States Pharmacopeia (U.S.P.) Absorbable Dusting Powder (cornstarch). Goodrich, Prine, and Wilson (Ref. 1) provide data from observations and arbitrary scoring of adhesions after intraperitoneal injection into 4 groups of 13 adult female mice with: (1) Powdered starch suspended in 1.5 mL of normal saline, (2) powdered starch treated with 5 mL of an iodophor and washed three times in saline before resuspension in 1.5 mL normal saline, (3) powdered starch treated with 5 mL of a 10-percent solution of surfactant washed three times in saline and resuspended in 1.5 mL of normal saline and (4) normal saline (control animals). The data do not indicate any significant difference between suspensions of the surfactant mixed with starch and the surfactant-iodophor mixed with starch. The agency's policy on the labeling of surgical gloves treated with Absorbable Dusting Powder U.S.P., determined upon evidence presented during the Drug Efficacy Study Implementation, was published in the **Federal Register** of May 25, 1971 (36 FR 9475). The agency requires the following statement on surgical gloves treated with Absorbable Dusting Powder U.S.P.: "Caution: after donning, remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method." Products containing Absorbable Dusting Powder U.S.P. for lubricating surgical gloves were formerly classified as new drugs, but are now regarded as transitional devices, for which premarket approval is required under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (42 FR 63472 at 63474). FDA's Center for Devices and Radiological Health is establishing categories for all surgical devices, including surgical gloves lubricated with powdered starch. Any changes in the labeling for this class of products will be dealt with in a separate rulemaking procedure and separate **Federal Register** notice.

The agency believes that the user's removal of dusting powder from surgical medical devices (rubber goods) treated with Absorbable Dusting Powder U.S.P. decreases the incidence of adhesions and is not persuaded that the data in the article by Goodrich, Prine, and Wilson provide a sufficient scientific basis for a warning label. Therefore, the warning about the interaction of iodophors and starch-containing products proposed in comment 66 of the previous tentative final monograph is not included in this amended tentative final monograph.

References

(1) Goodrich, E. O., J. R. Prine, and J. S. Wilson, "Iodized Starch Granules as a Cause of Starch Peritonitis," *Surgical Forum*, 25:372–374, 1974.

(2) Nonclinical and Clinical Safety Studies on Postoperative Observations of Abrasions, Comment No. C111, vol. 4, tabs 6–14, Docket No. 75N–0183, Dockets Management Branch.

17. A number of comments submitted new data (Ref. 1) to establish that povidone-iodine is safe and effective as a topical antimicrobial drug. The comments requested that povidone-iodine be reclassified from Category III to Category I as a topical antimicrobial ingredient for use as an antimicrobial soap, health-care personnel handwash, surgical hand scrub, patient preoperative skin preparation, skin antiseptic, skin wound cleanser, and skin wound protectant.

As discussed earlier in this document, this amended tentative final monograph addresses only topical antiseptics for health-care antiseptic uses as a surgical hand scrub, antiseptic handwash or health-care personnel handwash, and patient preoperative skin preparation. As discussed in section I.B., comment 5, antimicrobial soaps are no longer included in this rulemaking. The agency addressed the other use categories mentioned in the comment in a separate **Federal Register** notice for OTC first aid antiseptic drug products (56 FR 33644). As discussed in comment 38 of that document (56 FR 33660), FDA has tentatively concluded that povidone-iodine should be classified in Category I for use as a first aid antiseptic (formerly designated skin antiseptic, skin wound cleanser, and skin wound protectant).

The agency has considered the new data submitted and other information in

support of the request to reclassify povidone-iodine from Category III to Category I. On the basis of these data and information, the agency tentatively concludes that povidone-iodine should be reclassified from Category III to Category I as a topical antiseptic ingredient for use in surgical hand scrub, patient preoperative skin preparation, and health-care personnel or antiseptic handwash drug products.

The general safety aspects of povidone-iodine that concerned the agency in the previous tentative final monograph (43 FR 1210 at 1234 to 1236) are addressed elsewhere as follows: (1) The effect of povidone-iodine on wound healing. Based upon submitted data, the agency concluded in the first aid antiseptic segment of this rulemaking that non-surfactant iodophor products (povidone-iodine) do not delay wound healing. See comment 42 of that document (56 FR 33644 at 33662). Also, the Advisory Review Panel on OTC Antimicrobial II Drug Products reviewed povidone-iodine's effect on wound healing in its report on topical antifungal drug products and concluded that the drug did not affect wound healing (47 FR 12480 at 12545). (2) The effect of povidone-iodine on thyroid function. In comment 41 of the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33661), the agency discusses studies that indicate that topically applied povidone-iodine does not cause thyroid dysfunction. (3) The proposed warning about the interaction of starch-containing products with iodophors resulting in serosal adhesions and other undesirable effects, i.e., "Caution: Do not use this product in the presence of starch-containing products. Starch can adsorb iodophors and the resulting complex can cause serosal adhesions (abnormal union of the serous membranes) and other undesirable effects in the body" (43 FR 1210 at 1221). The agency has reevaluated the proposal and decided that the warning is not supported by the data. (See section I.I., comment 16.) (4) The agency's concern regarding molecular weights of povidone-iodine greater than 35,000 daltons not being excreted by the kidney and causing lymph node changes. In section I.I., comment 18, the agency discusses a previously proposed warning regarding this subject and determines, based on more recent data, that larger povidone-iodine molecules are not a risk when the product is limited to the topical uses included in this tentative final monograph.

The agency's concern about the need for expiration dates (not to exceed 2 years after manufacture) because of the lack of stability data for several iodophor preparations, which relates to the effectiveness of the product, can be satisfied by compliance with the current good manufacturing practices regulations (21 CFR parts 210 and 211). These regulations include, among other things, requirements regarding stability testing and expiration dating (see §§ 211.137 and 211.166). Therefore, as discussed in comment 40 of the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33661), data on the stability of povidone-iodine and the proposed 2-year expiration date are no longer considered needed in this rulemaking proceeding.

A second agency concern relating to effectiveness was the rate of release of "free" iodine from the complex and whether there was evidence of germicidal activity over a period of time in clinical application (43 FR 1210 at 1235). As discussed in the tentative final monograph for OTC topical acne drug products (comment 5, 50 FR 2172 at 2173), iodine is released from the povidone-iodine complex within milliseconds, thus resolving this concern.

With regard to the effectiveness of health-care antiseptic uses subject to this rulemaking, the agency has reviewed the data and information on povidone-iodine's germicidal in vitro and antiseptic in vivo effectiveness (Refs. 1 through 19) and concludes that the data are sufficient to reclassify this ingredient from Category III to Category I.

A series of in vitro controlled studies (Ref. 1–C133, Volume 1) included a broad spectrum of test micro-organisms which were associated with between 40 to 60 percent of the nosocomial infections in the urinary tract, surgical wounds, pneumonia, and bloodstream, reported by the National Nosocomial Infections Surveillance System (NNIS) for the period from January 1985 to August 1988 (Ref. 2). In most instances, these test micro-organisms, as proposed in § 333.470(a)(1)(ii) (see section I.C., comment 6), were killed after 0.5 to 5 minutes exposure to povidone-iodine. A minimum inhibitory concentration (MIC) study (Ref. 1–C133) using 30 cultures, both American Type Culture Collection (ATCC) and recent skin isolates, was also included in this series of in vitro studies. The results indicated a range for MIC from 87 parts per million (ppm) to 492 ppm for dilutions of povidone-iodine solution and 83 ppm to 476 ppm for dilutions of povidone-iodine surgical scrub depending on the test micro-organism. Tests with controls, neutralizer, and organic load using a serial dilution method were included in the study.

Gocke, Ponticas, and Pollack (Ref. 3) evaluated the susceptibility of 230 clinical isolates from blood, urine, sputum, and wound cultures to the bacteriocidal activity of povidone-iodine. These clinical isolates contained over half the organisms included in § 333.470(a)(1)(ii). Results indicated that 106 of the 230 organisms tested (46 percent) were killed when 1 mL of a standardized suspension containing 10^8 organisms was exposed to a 10 percent povidone-iodine solution for 15 seconds. Povidone-iodine showed its highest activity against gram-negative isolates, with 72 of the 94 isolates (75 percent) being killed after a 15-second exposure. Only 34 of the 134 (25 percent) gram-positive isolates were killed under the same conditions. However, further testing of organisms not killed after a 15-second exposure indicated that increases in exposure time to 120 seconds killed all of the previously "resistant" isolates. The study design incorporated the use of a neutralizer and controls.

The effectiveness of a povidone-iodine formulation on micro-organisms in a clinical setting was demonstrated by Michael (Ref. 4). The study included 100 subjects with decubitus ulcers following a spinal cord injury. Cultures of the wounds were taken prior to, during, and upon completion of a once-a-day povidone-iodine treatment. Prior to treatment, subjects had positive cultures for the following organisms: *S. aureus* (60 subjects), *Klebsiella/Enterobacter* species (20 subjects), *E. coli* (15 subjects), and *Pseudomonas* species (15 species). Following an 8-to-10 week period of treatment with povidone-iodine, cultures revealed that 90 of the 110 subjects no longer had positive cultures for these organisms.

Pereira, Lee, and Wade (Ref. 5) conducted an in vivo gloved hand test that is supportive of the effectiveness of povidone-iodine as a surgical hand scrub. They examined the effects of surgical scrub duration and type of antiseptic on the reduction of resident microbial flora. Thirty-four subjects scrubbed with a 7.5 percent povidone-iodine formulation or another antiseptic formulation using either a 5 minute initial/3 minute consecutive scrub procedure or a 3 minute initial/30 second scrub procedure. Subjects were assigned to one of four groups, and each group was assigned to one of the four treatments. Sampling was done by the glove juice method using a sampling solution containing a neutralizer. Glove juice samples were taken from both hands immediately before scrubbing

(baseline), from the nondominant hand immediately after the initial scrub, 2 hours after the initial surgical scrub but before the consecutive scrub (dominant hand), and 2 hours after one consecutive surgical scrub (dominant hand). No significant difference was found between the two durations of scrubbing with povidone-iodine. Povidone-iodine produced an immediate 1.2 $\log_{10}$ reduction on the dominant hand after an initial 5 minute scrub and a 1.0 $\log_{10}$ reduction on the dominant hand immediately after the 3 minute initial scrub. Baseline was not exceeded 2 hours after either the 5 or 3 minute scrub.

Aly and Maibach (Ref. 6) evaluated the characteristics of two antimicrobial impregnated surgical hand scrub sponge/brush drug products. The study, which included a widely used povidone-iodine impregnated surgical hand scrub sponge/brush, evaluated both the immediate and persistent effect on the resident bacterial flora of the hands plus the effect of blood on the persistent antimicrobial activity of the surgical hand scrub drug products. In the first phase of the study, 13 subjects with left and right hand baseline counts of $>10^6$ organisms were randomly assigned to perform a total of 11 scrubs with the povidone-iodine impregnated sponge/brush. Glove juice samples were taken from the right hand of each subject immediately following the first scrub of the day and from the left hand at either 3 or 6 hours. The entire procedure was repeated on test days 2 and 5. A similar procedure was used in phase two of the study, except that 2 mL of bacteriologically sterile blood was spread over the hands of 6 subjects following the initial scrub, and sampling occurred only at 3 and 6 hours. Neutralizers were incorporated into the stripping solution, diluent, and culture media. On day 1, povidone-iodine produced an immediate mean $\log_{10}$ reduction of 1.2, and baseline was not exceeded at 3 hours. On days 2 and 5, povidone-iodine produced immediate mean $\log_{10}$ reductions of 2.2 and 2.8, respectively, and bacterial counts did not exceed baseline at 6 hours. While counts for povidone-iodine approached baseline in the presence of blood, counts did not exceed baseline at 6 hours on any day.

Another study (Ref. 1–C104), employing a method similar to the effectiveness testing procedures described in proposed § 333.470(b)(2) of this amended tentative final monograph, demonstrated the effectiveness of povidone-iodine 5 percent as a health-care personnel handwash. Twenty-five consecutive handwashings were done in 10 human subjects with a 5 minute rest between washings. Before each washing the hands were dipped in broth culture containing 2.0×10^9 organisms (*Bacillus subtilis* var. *niger* ATCC 9372) per mL; the contaminant was spread up over the wrists to the forearms. Bacterial counts were done at the completion of every fifth washing by the glove juice sampling method. Both the dilution fluid and growth media incorporated a neutralizer. The transient microbial flora of the hands was reduced by an average of 5.8 logs from baseline.

Dineen (Ref. 7) used a 7.5 percent povidone-iodine formulation as a reference antiseptic in an open crossover evaluation of a health-care personnel handwash drug product. Participation in the study followed a 1-week prewash period in which study subjects used only a bland nonantiseptic soap. On day 1 of the study, samples were taken prior to contamination and again after a second contamination followed by a 15-second wash with a bland nonantiseptic soap, using the glove juice sampling method. Following the post-wash sampling, subjects washed for 5 minutes with povidone-iodine to remove any remaining inoculum. The hands of the first three subjects were contaminated with a 1 mL inoculum containing 1×10^{14} *S. marcescens, E. coli, P. aeruginosa,* and *Providentia stuartii* (*P. stuartii*). The hands of the seven other subjects were contaminated with a 1 mL inoculum containing 8×10^{14} to 2×10^{15} *S. marcescens* and *P. stuartii*. Inocula concentrations were determined each test day in a parallel experiment. On days 3 or 4 and 5, the procedure was repeated except that subjects were randomly assigned to wash with either (1) the reference antiseptic or the test preparation or (2) were crossed over to the preparation not used the previous day. In the interim between test days, subjects followed the wash and sampling procedure using only the nonantiseptic soap. The number of organisms included in the 1 mL inoculum was taken as the baseline, and all reductions were calculated on this basis. Neutralizers were incorporated in both the diluent and the culture medium. When corrected for the average log reduction produced by the nonantiseptic soap (4-$\log_{10}$), the reductions produced by povidone-iodine ranged from 7 to 9 $\log_{10}$.

Studies conducted by Ulrich (Ref. 8) and Newsom and Matthews (Ref. 9) are supportive of the effectiveness of povidone-iodine for this indication. Ulrich (Ref. 8) conducted a study using povidone-iodine 7.5 percent in 25 subjects. Both hands of each subject were contaminated with a stock culture of *Micrococcus roseus* (2.75×10^8 organisms per hand, the baseline count) and allowed to air dry for 60 seconds. This artificial hand contamination was followed by a 15-second wash with 5 mL of the povidone-iodine preparation, and this same procedure was repeated until 25 contaminations/washes had been performed. Glove fluid samples were taken after every fifth contamination/wash. Dilutions of the glove fluid were made in a sterile diluent that included a neutralizer. A neutralizer was also incorporated into the culture medium. Based on the average of both hands, the povidone-iodine preparation produced a 4.9 and a 5.2 log reduction of the transient micro-organisms from baseline by the 5th and 10th wash, respectively. By the end of the 25th wash the povidone-iodine preparation demonstrated a 5.5 $\log_{10}$ reduction from the baseline bacterial count.

Newsom and Matthews (Ref. 9) studied test solutions containing 5 or 10 percent povidone-iodine on hands artificially contaminated with an overnight culture of *E. coli*. The numbers of micro-organisms were measured before and immediately after hand disinfection with the test solution in 15 subjects. Sampling of the hands was accomplished by kneading the fingertips in a "recovery" broth that included a neutralizer. A mean 4.4 log reduction from baseline was reported for the bacterial counts taken immediately after the antiseptic wash.

Ayliffe, Babb, and Quoraishi (Ref. 10) evaluated the effect of various detergent and alcoholic antiseptic formulations (including a 7.5 percent povidone-iodine formulation) on the removal of *S. aureus, Staphylococcus saprophyticus* (*S. saprophyticus*), *P. aeruginosa,* or *E. coli* from contaminated fingertips. In one set of experiments, six subjects performed an initial wash with an unmedicated soap, followed by the inoculation of the tips of the subjects' fingers and thumbs with 0.02 mL of a broth culture containing either *S. aureus* or *P. aeruginosa*. Following contamination, subjects performed either a 30-second wash with 5 mL of a detergent or alcoholic antiseptic preparation, a 30-second wash with an unmedicated soap, or no wash at all. Bacterial sampling was accomplished by rubbing the fingers and thumbs on glass beads immersed in 100 mL of nutrient broth containing neutralizers. All treatments were tested against each organism. Results were reported as the log of the average number of viable organisms recovered from each subject. Against *S. aureus*, povidone-iodine

produced a 3.2 log reduction, which was significantly superior to the reduction achieved by the unmedicated soap. Against *P. aeruginosa*, povidone-iodine produced a 2.7 log reduction. However, this was not significantly different from the 2.2 log reduction demonstrated by the unmedicated soap.

In a second set of experiments (Ref. 10), the same authors assessed the effectiveness of three antiseptic formulations, including povidone-iodine, and an unmedicated soap in the removal of *S. aureus*, *S. saprophyticus*, or *E. coli* from contaminated fingertips. Under conditions similar to those in the previous study, povidone-iodine demonstrated a 3-log reduction in the baseline number of *S. aureus*, which was significantly superior to the log reduction demonstrated by the unmedicated soap. Povidone-iodine produced an average 2.1 log reduction in the number of *S. saprophyticus* and a 2.8 reduction in the number of *E. coli*. However, neither of these reductions was significantly different from the reductions produced by the unmedicated soap.

Rotter (Ref. 11) evaluated the influence of differences in two testing methodologies on the demonstration of the effectiveness of povidone-iodine. One test method used is the standard test method (Vienna) for the evaluation of drug products for hygienic disinfection adopted by the Austrian and German Societies for Hygiene and Microbiology. In this test model, the release of *E. coli* from the finger tips of artificially contaminated hands was determined before and after a 1-minute wash with povidone-iodine. The second model, based on agency recommendations for the testing of health-care personnel handwashes, evaluated the release of the *E. coli* from all surfaces of artificially contaminated hands by the glove juice sampling method before and after a 1 minute wash with the ingredient. These comparisons showed no significant difference in the reduction factor produced by povidone-iodine when tested with the two methods. Povidone-iodine when tested by the Vienna test method produced a 3.3 $\log_{10}$ reduction from the baseline count. When tested by the second method, the ingredient produced a 3.2 $\log_{10}$ reduction.

Rotter (Ref. 11) also used the Vienna test method to assess the effectiveness of rubbing antiseptics onto the hands versus washing with an antiseptic. Two povidone-iodine containing formulations were included in the assessment. A watery solution of povidone-iodine with 1 percent available free iodine rubbed onto the skin produced a 4 $\log_{10}$ reduction. Washing with a detergent formulation of the ingredient produced a 3.2 $\log_{10}$ reduction. However, this reduction was not statistically different from the reduction produced by washing with a nonantiseptic soap.

Rotter, Koller, and Wewalka (Ref. 12) used the Vienna test model to assess the effectiveness of a povidone-iodine liquid soap preparation (containing 0.75 percent available free iodine) for hygienic hand disinfection. The subjects' hands were contaminated by immersing them up to the mid-metacarpals in a broth culture of *E. coli*. The hands were allowed to air dry for 3 minutes prior to a pretreatment sampling. Sampling was accomplished by rubbing the finger tips of each hand for 1 minute on the bottom of a Petri dish containing a phosphate buffer sampling solution with neutralizers. After a 2-minute wash with the povidone-iodine or liquid soap followed by a 20-second rinse, the hands were again sampled. Average log values of the counts from the right and left hands of each subject were calculated, and the difference (log reduction factor) was determined. The povidone-iodine liquid soap formulation produced a 3.2 $\log_{10}$ reduction in the transient organisms.

Wade and Casewell (Ref. 13) evaluated the residual effectiveness of povidone-iodine against two clinical isolates associated with hospital outbreaks of infection. An initial determination of the survival of the test organisms on untreated hands of three subjects was made by contaminating the subjects' finger tips with either of the test organisms and sampling the individual fingers immediately after contamination and at 1, 3, 10, and 30 minutes. The subjects' hands were then pretreated by performing three 30-second washes at 5 minute intervals with various alcoholic and aqueous antiseptic test formulations, including a 7.5 percent povidone-iodine formulation and an unmedicated bar soap. The contamination and sampling procedure was repeated as before. All formulations were tested against both organisms. The median value of the log counts for the three subjects as each sampling was plotted against time. The survival curves for both organisms on hands pretreated by washing with an unmedicated soap and on hands with no pretreatment were similar. Pretreatment with povidone-iodine resulted in counts that were consistently less than for the untreated hands and for the hands pretreated by washing with an unmedicated soap and water for both organisms. After 30 minutes, hands pretreated with the povidone-iodine formulation demonstrated a 2.5 $\log_{10}$ reduction in the number of viable *Enterococcus faecium* and a 3.9 reduction in the number of viable *Enterobacter cloacae*.

The agency concludes that these data demonstrate the effectiveness of povidone-iodine 5 to 10 percent for use as a health-care personnel handwash.

Many *published* studies referenced in the submitted data and in the published literature (Refs. 1 and 14 through 19) have evaluated the effectiveness of povidone-iodine for use as a patient preoperative skin preparation. Although the procedures followed are different from those in the previous FDA testing procedures (43 FR 1210 at 1244) and from those proposed in § 333.470 of this amended tentative final monograph, the essential criteria have been met.

Georgiade et al. (Ref. 15) evaluated the effectiveness of two povidone-iodine formulations for use in the preoperative skin preparation of 150 subjects scheduled for elective surgical procedures. An initial sample for culture was taken from the unbroken skin of the operation site prior to the use of the formulations, and a baseline bacterial count was determined. Sampling was by a cup scrubbing method, using a sterile wash solution that incorporated a neutralizer. The operative site was then gently treated for 5 minutes with a povidone-iodine surgical scrub formulation and allowed to dry. Following the initial disinfection, a povidone-iodine antiseptic solution was evenly applied to the site and allowed to dry. The sample site was rinsed with sterile water and a second sample for culture was done. Upon completion of surgical procedures lasting from 30 to 180 minutes, the sample site was again cultured and sterile dressings were applied. The reported mean post-scrub reduction in the baseline number of bacteria of the sample site was 30,599 (4.5 $\log_{10}$ reduction). This reduction was maintained through the surgery as evidenced by the reported post-operative mean reduction of 30,613 organisms.

Vorherr, Vorherr, and Moss (Ref. 16) compared three antiseptic preparations (including 10 percent povidone-iodine), in 150 female subjects (50 to each preparation) for effectiveness in reducing the numbers of bacteria in the perineum and groin. The mean log reductions in bacteria after skin preparation with povidone-iodine at 10 minutes and 3 hours, respectively, were reported as 3.65/3.09 for the perineum and 3.42/2.85 for the groin. Another study by Dzubow et al. (Ref. 17) evaluated three antiseptic skin

preparations frequently used for dermatologic surgical procedures. A 60-second wipe with 1-percent povidone-iodine was performed in 14 subjects after which aerobic and anaerobic cultures were taken at 5 and 60 minutes. The aerobic flora were reduced by 2.8 and 2.5 log at 5 and 60 minutes, respectively. The reduction in anaerobic flora was reported to be 1.7 log at 5 minutes and 1.2 log at 60 minutes.

Leaper, Lewis, and Speller (Ref. 18) compared the effectiveness of povidone-iodine impregnated drapes, povidone-iodine with a sterile drape, and conventional preoperative skin preparation with povidone-iodine for the reduction of skin bacteria. Forty-five subjects scheduled to undergo elective groin surgery were randomized to one of the three treatments. Impression plates and skin swabs were taken immediately before and after surgery, and swabs were taken before and after skin incision and closure. Conventional preoperative skin prepping with povidone-iodine produced the greatest reduction of the bacterial flora (240 colony counts to 34 colony counts, 2.3 $\log_{10}$ reduction).

Duignan and Lowe (Ref. 19) studied the effectiveness of povidone-iodine for reducing pathogenic bacteria in the vagina. A 1:10 solution of a povidone-iodine formulation containing 0.75 percent available free iodine was instilled into the vagina of 35 subjects and left in situ for 1 to 3 minutes. Aspirate cultures were taken from the vagina before and after preoperative disinfection and subcultured into thioglycollate broth containing neutralizers. Povidone-iodine removed 92 percent of the bacteroides species, anaerobic streptococci, gram negative bacilli, and *Streptococcus pyogenes* present prior to the preoperative disinfection.

A surveillance report (Ref. 1–C132) of hospital infections showed that the use of povidone-iodine in preparing patients for catheterization significantly reduced the rate of urinary tract infections. A 5-year study showed that the rate of urinary tract infections before October 1977 ranged from 5.2 percent to 11.5 percent (mean 7.8 percent), but beginning in October 1977 when povidone-iodine was the antiseptic solution in use, the rate ranged from 1.0 percent to 4.0 percent (mean 2.4 percent). At the 95 percent confidence level this is statistically significant. No method data accompanied the report except that the urethral meatus was cleansed with cotton dipped in the antiseptic solution before catheterization.

The agency believes that these studies and other published and publicly available medical and scientific data demonstrate that povidone-iodine is effective for use as a patient preoperative skin preparation. Although all of the trials were not done the same way, and thus they are not strictly comparable, the weight of the evidence shows that povidone-iodine is effective both as a preoperative skin preparation and surgical hand scrub, reducing the normal microbial flora by more than 90 percent and not showing any significant qualitative selection among the normal species found on the skin. In conclusion, povidone-iodine was effective against a wide spectrum of pathogenic and normal skin micro-organisms and maintained some suppressive effect on skin counts after the initial use.

In addition to the data reviewed supporting the safety and effectiveness of povidone-iodine for these professional uses, the agency classified povidone-iodine 5 to 10 percent as Category I as a first aid antiseptic in the tentative final monograph published in the **Federal Register** on July 22, 1991 (56 FR 33644). Accordingly, the agency is reclassifying povidone-iodine 5 to 10 percent from Category III to Category I for use as a topical antiseptic ingredient for use in surgical hand scrub, patient preoperative skin preparation, and antiseptic handwash or health-care personnel handwash drug products.

References

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(17) Dzubow, L. M. et al., "Comparison of Preoperative Skin Preparations for the Face," *Journal of the American Academy of Dermatology*, 19:737–741, 1988.

(18) Leaper, D. J., D. A. Lewis, and D. C. E. Spiller, "Prophylaxis of Wound Sepsis Using Povidone-Iodine Skin Preparation or 'Ioban' Incise Drapes After Clean Inguinal Surgery," *Journal of Hospital Infection*, 6(supplement):215–218, 1985.

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18. Several comments objected to the agency's proposal that the professional labeling of povidone-iodine products containing molecules greater than 35,000 daltons should include warnings against parenteral use and against exposure of open surgical wounds or deep wounds to the product. (See comment 71, 43 FR 1210 at 1221.) Some of the comments contended that the Panel recommended such warnings because it felt there was widespread misuse (unapproved use) of povidone-iodine solution by surgeons bathing the peritoneal cavity with povidone-iodine during major surgery and then cleansing the area by rinsing. Another comment stated that because health-care personnel handwashes or surgical hand scrubs require a surfactant, such products so formulated would never be

considered for peritoneal lavage by surgeons. One comment argued that labeling to warn against parenteral use is clearly beyond the scope of the OTC drug review and FDA's regulatory authority. Another comment stated that it is unnecessary to establish an arbitrary molecular weight limit for povidone-iodine because no parenteral use of povidone-iodine is permitted in any of the approved labeling in the new drug applications for those products.

One comment stated that povidone-iodine is generally recognized as safe and effective for use in open wounds and a warning against such use would be contrary to clinical experience with this drug. In support of this position, the comment submitted a controlled study in which the surgical incisions of one group were irrigated before closure with 10 percent povidone-iodine solution, and the surgical incisions of the control group were irrigated before closure with saline solution (Ref. 1). The comment stated that the results of this study showed a significant decrease in infections when povidone-iodine was used, and there were no allergic, adverse, or other deleterious effects following this use of povidone-iodine.

In response to the Commissioner's recommendation for research data (43 FR 1210 at 1235), one comment submitted an extensive review of the extent of scavenging of residual povidone-iodine molecules by the reticuloendothelial system and possible lymph node involvement following use in the abdominal cavity or in large wounds (Ref. 2). The comment stated that, based on these data, povidone-iodine with medium molecular weights should not be limited to use on intact skin, nor should a warning be required. Another comment stated that the average molecular weight of povidone in the povidone-iodine that has been used exclusively in topical antimicrobial products for almost a quarter of a century is 37,900 daltons, and it presents no risk for any of the topical antimicrobial uses covered by the tentative final monograph.

The Panel recognized a relationship between molecular size and nodular lymphatic changes accompanying exposure to povidone-iodine, but made no decision on limiting the molecular size causing such pathology. (See 39 FR 33103 at 33130.) In the previous tentative final monograph, FDA evaluated data provided in a comment (Ref. 3) that contended there should be restrictions on the use of povidone-iodine according to molecular size. Published research cited in that comment indicated that povidone molecules larger than 40,000 daltons cannot be excreted by the kidneys, can cause nodules to appear in the lymphatic system, and may induce cosmetic deformities in the area of healing skin wounds. Based on expert opinion and the data provided in the comment (Ref. 3), the agency proposed that a molecular weight of 35,000 daltons be established as the safe upper limit for povidone-iodine products used parenterally. This calculation assumed that a povidone-iodine molecule with this molecular weight would be too large to pass through the kidney. (See comment 71, 43 FR 1210 at 1221.) FDA also noted its awareness of the inappropriate use of povidone-iodine products in open wounds and in the abdominal cavity during surgery. (See 43 FR 1235.) To promote proper use of povidone-iodine products, FDA proposed to recognize two categories of such products. Products with povidone-iodine molecular weights less than 35,000 daltons would be permitted for general use. Appropriate labeling would place each product in its proper category of use. The professional labeling of povidone-iodine products containing molecules greater than 35,000 daltons would also include warnings against parenteral use of, and exposure of open surgical wounds or deep wounds to, the product.

In this current tentative final monograph, the agency recognizes that the professional uses of povidone-iodine that are proposed as safe and effective are limited to a patient preoperative skin preparation, health-care personnel handwash, and surgical hand scrub. Further examination of the reference cited in the previous tentative final monograph (Ref. 3) reveals that the reported adverse effects were due to intravenous or parenteral use of povidone. Based on the more recent data and comments, the agency now believes that neither medium nor larger molecular weight povidone-iodine molecules present risks when limited to the topical uses included in this tentative final monograph. Larger molecules of povidone-iodine would not be absorbed if the drug is used for these professional uses in accordance with the monograph. Thus, there is no need for the professional labeling to limit the molecular weight of povidone-iodine products or to require special warnings related to the molecular weight of povidone-iodine. Accordingly, such labeling is not being included in this tentative final monograph.

References

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(2) Unpublished review of published and unpublished studies regarding lymph node changes and effect on the reticuloendothelial system resulting from use of PVP-iodine on intact skin, mucous membranes, and open wounds, Comment No. C111 (vol. III A), Docket No. 75N–0183, Dockets Management Branch.

(3) Unpublished review of published studies regarding intravenous or parenteral use of polyvinylpyrrolidone (PVP), Comment No. C40, Docket No. 75N–0183, Dockets Management Branch.

19. Several comments contended that there are numerous professional uses for povidone-iodine, particularly uses that involve medical devices, that were not discussed by the Panel or by the agency in the tentative final monograph. These professional uses include catheter care, ostomy hygiene, patient skin scrubbing prior to preoperative prepping, surgical site cleansing after stitching, mouth and throat swabbing, treatment of the skin before covering a fracture with a cast, antiseptic treatment of various scalp problems, and intravenous site preparation. One comment added that a pharmacist or other health professional may recommend the use of povidone-iodine as a douche, perianal wash, or whirlpool concentrate. The comments requested that special labeling be added to the monograph to cover all of these uses, but did not submit data regarding these uses.

One comment also provided professional labeling for povidone-iodine used for urinary or intravenous catheter care procedures. The suggested labeling included the following terms: "antiseptic," "germicide," "microbicidal," and "for hospital and professional use."

Several of the professional uses mentioned by the comments are not covered by this rulemaking, but they will be addressed under other OTC drug rulemakings. For example, the use of povidone-iodine for mouth and throat swabbing is included in the advance notice of proposed rulemaking for OTC oral health care drug products, published in the **Federal Register** of May 25, 1982 (47 FR 22760). The use of povidone-iodine for the treatment of scalp problems is addressed in the final rule for OTC dandruff, seborrheic dermatitis, and psoriasis drug products, published in the **Federal Register** of December 4, 1991 (56 FR 63554). The use of povidone-iodine as a douche is addressed in the advance notice of proposed rulemaking for OTC vaginal drug products, published in the **Federal Register** of October 13, 1983 (48 FR 46694).

The Advisory Review Panel on OTC Hemorrhoidal Drug Products stated that the inclusion of antiseptics in OTC anorectal drug products "is useful in concept," but "that proof of any significant clinical benefit of claimed antiseptic ingredients must be demonstrated in clinical trials" (45 FR 35576 at 35659). That Panel believed that, because of the large numbers of micro-organisms present in feces, there is little likelihood that effective antisepsis could be obtained in the anorectal area with antiseptics any more than with soap and water. Because no data were submitted on povidone-iodine as a perianal wash, the agency did not address this ingredient in the discussion of antiseptics in the tentative final monograph for OTC anorectal drug products when the agency evaluated the Panel's conclusions. Similarly, the ingredient was not included in the final rule for OTC anorectal drug products, published in the **Federal Register** of August 3, 1990 (55 FR 31766). Parties interested in this use of povidone-iodine can submit data and information as part of a citizen petition to amend the final rule for OTC anorectal drug products. (See 21 CFR 10.30.)

Several of the uses suggested by the comments are related to the general category of patient preoperative skin preparation that was discussed by the Panel. (See the **Federal Register** of September 13, 1974, 39 FR 33103 and 33114.) One example is the use "patient skin scrubbing prior to preoperative prepping." The agency believes that this use can more simply be described by the indication "for preparation of the skin prior to surgery," which is being proposed in § 333.460(b)(1)(i) of this tentative final monograph. Other uses are catheter care, ostomy hygiene, and intravenous site preparation. Some uses mentioned by the comments involve postoperative situations (surgical site cleansing after stitching) or do not even involve a surgical procedure (treatment of skin prior to covering a fracture with a cast or use as a whirlpool concentrate). The agency believes that instead of trying to identify in the product's labeling every possible situation where use of the product would reduce the risk of skin infection, this use of the product can best be described by the general indication "Helps to reduce bacteria that potentially can cause skin infection," which is being proposed in § 333.460(b)(1)(ii).

The agency has considered the term "for hospital and professional use only" suggested by one comment and finds it acceptable for professional labeling. (See section I.D., comment 8.) Likewise, the agency has no objection to terms such as "germicide," "germicidal," and "microbicidal" being used in professional labeling because health professionals understand the meaning of these terms. However, the agency does not believe there is a need to include in the monograph every one of these terms that might be used in the professional labeling of these products. These terms will be evaluated by the agency on a product-by-product basis, under the provision of section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading.

J. Comments on Quaternary Ammonium Compounds

20. One comment requested that benzalkonium chloride be placed in Category I as a skin antiseptic, a patient preoperative skin preparation, and a skin wound protectant, in addition to its present Category I classification as a skin wound cleanser. In support of its request, the comment cited several surgery textbooks and other references that recommend use of benzalkonium chloride at concentrations ranging from 1:750 to 1:5,000 as a preoperative skin preparation, surgical scrub, skin antiseptic for venipuncture, and in urinary tract procedures, especially in catheterized patients (Ref. 1). The comment also submitted two studies on a product containing benzalkonium chloride at a concentration of 1:1,000: (1) An in vitro study to demonstrate that this product formulation acts as a physical chemical barrier against contamination by micro-organisms, and (2) a study on induced wounds on the arms of 10 healthy subjects to present evidence that this product is nonirritating and neither delays healing nor favors the growth of micro-organisms (Ref. 2).

The agency determined in the tentative final monograph for OTC first aid antiseptic drug products that the safe and effective concentration range for using benzalkonium chloride as a first aid antiseptic has been established as 0.1 percent to 0.13 percent. (See 56 FR 33644 and 33663.) Data submitted to the Antimicrobial I Panel and by the comment were sufficient to establish safety for products intended for short-term use, such as a first aid antiseptic drug product. The data submitted also support safety for use as a patient preoperative skin preparation, based on the short-term use of the drug for this purpose. However, the data reviewed by the Panel and supplemented by the comments to establish the efficacy of benzalkonium chloride for use as a topical antiseptic ingredient in patient preoperative skin preparations are not sufficient. The Antimicrobial I Panel placed this ingredient in Category III for this use. (See 39 FR 33103 and 33115.) The agency finds that the surgery textbooks and other references cited by the comment (Ref. 1) do not contain sufficient information about quantitative and qualitative changes in the microbial flora of the treated skin areas. Before benzalkonium chloride may be generally regarded as effective for use as a patient preoperative skin preparation, additional in vitro and in vivo effectiveness data are needed. The data should include results obtained from both in vitro and in vivo testing procedures as described for patient preoperative skin preparation drug products. (See section I.N., comment 28.)

Accordingly, benzalkonium chloride remains classified in Category III as a topical antiseptic ingredient for use as a patient preoperative skin preparation.

References

(1) Comment No. C116, Docket No. 75N–0183, Dockets Management Branch.

(a) Review of Scientific Literature on the Safety and Effectiveness of Zephiran Chlorideé as a "Skin Antiseptic" and "Patient Preoperative Skin Preparation" for the Preoperative Cleansing and Degerming Before Surgery and Use of Medical Devices.

(2) Unpublished Clinical Wound Healing Studies on Medi-Quiké, Comment No. SUP13, Docket No. 75N–0183, Dockets Management Branch.

(a) Statistical Analysis of Data from Efficacy Study of Medi-Quik as a Skin Wound Protectant in Humans.

(b) Studies on Medi-Quik as a Wound Protectant.

21. Two comments objected to the proposed warning statement in § 333.92(c)(6) for concentrated products containing quaternary ammonium compounds, which states, "Dilute with distilled water before use because acidic or hard water may render the product inactive." One comment contended that this proposed warning is prejudicial to the quaternary ammonium products that can act in acidic or hard water and noted that the existence of quaternary ammonium compounds that can act as antimicrobials in acidic or hard water was recognized in the tentative final monograph (43 FR 1210 at 1219). The comment recommended that the labeling of products containing quaternary ammonium compounds include a statement, based on appropriate laboratory tests, about the ability of the product to perform in acidic solutions and the amount of water hardness (described as parts per million (ppm) calcium carbonate) in which the product will continue to be effective.

The other comment stated that several concentrated quaternary ammonium compounds (e.g., 50 percent benzalkonium chloride, U.S.P.) registered with the Environmental Protection Agency (EPA) conform with the hard-water tolerance requirements and therefore can maintain activity at a water-hardness level of 600 ppm. The comment also stated that pH must be reduced below 3.5 before the effectiveness of quaternary ammonium compounds is decreased to any significant extent (Ref. 1). The comment concluded that, because normal potable water supplies do not approach these levels for either hardness or acidity, the requirement in proposed § 333.92(c)(6) for diluting only with distilled water is inappropriate and needless.

In the tentative final monograph, the agency acknowledged that hard water and acidity reduce the antimicrobial activity of quaternary ammonium compounds, but that there are some newer synthesized quaternary ammonium compounds that are not adversely affected by hard water and acidity (43 FR 1210 at 1218, 1219, and 1236). However, these newer quaternary ammonium compounds (e.g., a mixture of three benzalkonium halide compounds with varying chain lengths), while structurally related to benzalkonium chloride, benzethonium chloride, and methylbenzethonium chloride (the quaternary ammonium compounds which the Antimicrobial I Panel reviewed and which the agency proposed as Category III), were not reviewed or categorized by the Panel or the agency and are not included in this rulemaking. (See comment 58, 43 FR 1210 at 1219.) Further, the agency notes that the 50 percent quaternary ammonium concentrates that conform with EPA standards are intended for germicidal uses and not for the antiseptic uses that are being considered in this rulemaking.

The agency is aware that studies have shown that effects of acidic water on quaternary ammonium compounds occur only at dilutions containing less than the dosage concentration proposed in the tentative final monograph (Ref. 2). Higher concentrations minimize quaternary ammonium compound inactivation due to pH change (Ref. 3). However, it is well known that natural water supplies in different areas differ in acidity and hardness. As a precautionary measure, FDA believes that concentrates of the ingredients considered in this rulemaking should be diluted in distilled water by consumers and health-care professionals, because information about water pH or hardness in any given area is not usually known. Diluting the concentrated quaternary ammonium compound products addressed in this rulemaking with distilled water ensures that inactivating factors are not encountered. Therefore, the agency proposes to retain the warning statement, "Dilute with distilled water before use because acidic or hard water may render the product inactive," for diluting any Category I quaternary ammonium concentrate. However, because all the quaternary ammonium compounds remain in Category III at this time, the warning statement is not being included in this tentative final monograph.

References

(1) Lawrence, C. A., "Surface-Active Quaternary Ammonium Germicides," Academic Press Inc., New York, pp. 76–79, 1950.

(2) Kundsin, R. B., "Investigations on Dynamics of Bactericidal Action of Two Quaternary Ammonium Salts," *Archives of Surgery*, 81:789–797, 1960.

(3) Soike, K. F., D. D. Miller, and P. R. Ellikerr, "Effect of pH of Solution on Germicidal Activity of Quaternary Ammonium Compounds," *Journal of Dairy Science*, 35:764–771, 1952.

K. Comment on Sodium Oxychlorosene

22. One comment requested that sodium oxychlorosene be included in the monograph for use as a topical antiseptic for treating localized infections, to remove necrotic debris in massive infections, as a patient preoperative skin preparation and postoperative irrigant, and for the cleansing and disinfection of fistulae, sinus tracts, empyemas, and wounds. The comment included a number of references that recommended usage of sodium oxychlorosene (Ref. 1). The comment stated that "* * * the 25 years of marketing experience, the almost total absence of complaints, the number of published articles, the unusual spectrum of organisms reported on, all attest to the safety and efficacy of this product."

The agency has reviewed the data submitted and concludes that the available information does not contain any well-controlled clinical studies on the effectiveness of sodium oxychlorosene. In addition, no meaningful scientific information was presented in regard to safety. Clinical use for a period of years may provide corroborative evidence but is inadequate to support safe use. A good example is hexachlorophene; this drug had been used OTC for many years before more thorough safety studies in animals showed that the drug was not as safe as had been assumed. The agency concludes that the data are insufficient to demonstrate the safety and effectiveness of sodium oxychlorosene for OTC topical antiseptic use and therefore places this ingredient in Category III for both safety and effectiveness.

The agency's detailed evaluation of the data and information is on file in the Dockets Management Branch (Ref. 2).

References

(1) Published in vivo and in vitro studies, submitted by Guardian Chemical Corporation, Comment No. C126, Docket No. 75N–0183, Dockets Management Branch.

(2) Letter from W. E. Gilbertson, FDA, to R. Rubinger, Guardian Chemical Corporation, Comment No. ANS3, Docket No. 75N–0183, Dockets Management Branch.

L. Comments on Triclosan

23. A number of comments submitted data and information from microbiological, mutagenicity, metabolism, cross-sensitization, photosensitization, and drug experience studies on triclosan (Ref. 1). The comments stated that the data and information show that triclosan (up to 1.0 percent) is safe and effective and that triclosan should be placed in Category I for use in the categories that were defined in the previous tentative final monograph, i.e., skin antiseptic, skin wound cleanser, skin wound protectant, antimicrobial soap, health-care personnel handwash, patient preoperative skin preparations, and surgical hand scrub. In addition, one comment submitted information on triclosan (0.1 percent) for the treatment of diaper rash and on triclosan (0.1 percent) combined with benzocaine for the treatment of sunburn (Ref. 2).

One comment from the manufacturer of triclosan objected to the agency's expressed concern, as stated in the tentative final monograph (43 FR 1210 at 1231 and 1233), that there is a proliferation of products containing triclosan marketed to the American consumer (Ref. 3). The comment argued that the agency's concerns were without factual basis and submitted sales data, held confidential under 21 CFR 10.20(j)(2)(i)(*d*), showing that overall sales of triclosan in the U.S. have in fact decreased from 1973 to 1977 and that sales for use in bar soaps and deodorants have also declined from 1973 to 1977. The comment pointed out that it has exclusive U.S. patent rights for triclosan and that no license has been, or will be, granted under these patents. The comment added that to the best of its knowledge triclosan is not used in infant clothing, a use mentioned in the tentative final monograph at 43 FR 1231. The comment stated that if triclosan is placed in Category I for use

in antimicrobial soaps, it would limit sales of triclosan to OTC use in antimicrobial and deodorant soaps, underarm deodorants, and registered Environmental Protection Agency (EPA) pesticide products. In the future, sales might be extended to include approved new drug applications. The comment also pointed out that the statement at 43 FR 1233 about the EPA's Office of Special Pesticide Review preparing a report on the proliferation of triclosan-containing products is in error, and that the erroneous statement apparently resulted from a miscommunication between FDA and EPA staff. The comment concluded that the concerns about proliferation raised by the agency in the tentative final monograph should not prevent triclosan from being placed in Category I.

Another comment from the manufacturer of triclosan submitted validation reports and raw data from a 2-year chronic oral toxicity study in rats, and carcinogenicity and reproduction studies conducted in mice, rats, rabbits, and monkeys by Industrial Bio-Test Laboratories (IBT) (Refs. 4, 5, and 6) and asserted that its validation of the studies shows that triclosan is safe.

Several comments objected to the agency's restriction at 43 FR 1229 that antimicrobial soaps containing triclosan can only be formulated in a bar soap to be used with water (Ref. 1). The comments argued that such a restriction was not applied to the other Category III uses of triclosan, *i.e.*, skin antiseptic, skin wound cleanser, and skin wound protectant, and that such a restriction was not recommended by the Panel in the advance notice of proposed rulemaking. The comments suggested that the footnote under "antimicrobial soaps" limiting triclosan to bar soap was probably intended to apply to cloflucarban, which, like triclocarban, is known for its "physical and/or chemical incompatibility."

With regard to safety, the agency evaluated the validation reports to support long-term use of the ingredient (Refs. 4, 5, and 6) and advised the manufacturer of triclosan that the IBT studies were invalid because of numerous problems. The agency's detailed comments and evaluation on the data are on file in the Dockets Management Branch (Ref. 7).

The manufacturer subsequently stated its intent to no longer rely on the 2-year chronic oral toxicity IBT study (Ref. 8), and submitted a final report from a new 2-year chronic oral toxicity study in rats (Ref. 9). The agency has determined that the study data are unacceptable as the sole evidence of the safety of the long-term use of triclosan as a health-care personnel handwash or surgical handscrub based on the marginal survival of the animals in both the control and treated groups and uncertainties about the dose and study conduct. Therefore, data from another chronic exposure study are necessary to assess the safety of the long-term use of triclosan. The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 10). A subsequent submission from the same manufacturer contained the final report of a two-generation study of the reproductive toxicity of triclosan in rats (Ref. 11). These data are currently being reviewed by the agency and will be discussed in the final rule for these drug products. Triclosan remains classified as Category III for safety for long-term use.

The agency concluded in the amended tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33665) that triclosan (in concentrations up to 1.0 percent) is safe for short term use as a first aid antiseptic (formerly designated as skin antiseptic, skin wound cleanser, and skin wound protectant). The data reviewed (Ref. 1) also support the safety of triclosan (up to 1.0 percent) for use as a patient preoperative skin preparation. However, with regard to safety for use as an antiseptic handwash or health-care personnel handwash and surgical hand scrub, triclosan remains classified in Category III for safety for long-term use, as stated above.

With regard to effectiveness, in the previous tentative final monograph the agency classified triclosan as Category II for use as a health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub because triclosan has limited activity against gram-negative bacteria. For example, triclosan is the subject of a patent (patent No. 3,616,256) for use in culture media for isolating *Pseudomonas*. Because human skin is regarded as a superb "culture medium," the possibility was raised (43 FR 1210 at 1232) that triclosan might selectively promote overgrowth of *Pseudomonas* on the hands of health-care personnel. Based upon data reviewed, the agency advised that in vitro data demonstrate that triclosan's antibacterial spectrum can be broadened, to be effective against *Pseudomonas* when triclosan is properly formulated with anionic surfactants to form a "synergistic mixture." Therefore, FDA reclassified triclosan (up to 1.0 percent, with the lower limit to be determined) from Category II to Category III for effectiveness. The agency further advised that additional studies are needed before triclosan can be generally recognized as effective for specific uses, *i.e.*, surgical hand scrub, health-care personnel handwash, patient preoperative skin preparation, and first aid uses (formerly designated as skin antiseptic, skin wound cleanser, and skin wound protectant). The agency's detailed comments are on file in the Dockets Management Branch (Ref. 12).

In response to the agency's comments (Ref. 12), the manufacturer of triclosan requested further guidance, and asserted, "The overall antimicrobial effectiveness of a topically applied product is a function of the total formulation rather than a single ingredient. Although it is impossible to anticipate and test all possible formulations, adequate in vivo evaluations of triclosan-containing formulations for specific end uses are available to fully justify Category I status for triclosan as an active ingredient in surgical hand scrubs, health-care personnel handwashes, and antimicrobial soaps." The comment submitted effectiveness data from four in vivo studies on formulations of triclosan (Ref. 13). These data included three previously unsubmitted studies (RDP/19/23 (June 24, 1981), RDP/19/21 (February 2, 1981), and CAB/AVD (February 2, 1982)), and one previously submitted study (66–D15–W221, OTC Volume 020038) that had been reviewed by the Panel (39 FR 33128). In study *RDP/19/23 (June 24, 1981)*, following modified glove juice test procedures, a test product (0.5 percent triclosan in 60 percent n-propyl alcohol) and a control (60 percent n-propyl alcohol) were compared for reduction of normal baseline flora and persistence of that reduction for 3 hours on the hands of 15 test subjects. The test product (0.5 percent triclosan in 60 percent n-propyl alcohol) and the control (60 percent n-propyl alcohol) immediately reduced approximately 99.5 percent of the baseline number of bacteria. After 3 hours, 0.5 percent triclosan in 60 percent n-propyl alcohol suppressed the baseline count better than the vehicle control; for example the test product allowed about a onefold increase in bacterial count within 3 hours, while the vehicle control (60 percent n-propyl alcohol) allowed an approximately twelvefold increase. Although the test used was not the glove juice test described in the antimicrobial tentative final monograph, alternative methods are acceptable, provided criteria meet those of the glove juice test procedures described in the guidelines. (See "Effectiveness Testing of Surgical Hand Scrub (Glove Juice Test)," 43 FR 1210 at

1242.) The agency has the following comments regarding the protocol for the study: only 15 subjects (an insufficient number) were tested; a baseline count from 3 samplings was not established before the test; the $\log_{10}$ reduction in bacteria from baseline was determined after 3 hours, but not after 6 hours; and the results of the test were not analyzed statistically.

In study *RDP/19/21 (February 2, 1981)*, 2 percent triclosan in a liquid soap vehicle reduced baseline counts of test bacteria *E. coli* ATCC 11229, *P. aeruginosa* ATCC 15442, and Staphylococcus species on the hands of human test subjects by 1 log greater than the water control after 2 minutes of handwashing. In study *CAB/AVD (February 2, 1982)*, triclosan (unknown concentrations) in a liquid soap formulation, compared to a vehicle control, maintained reduction of baseline counts (within 10, 30, 60, 90, and 120 minutes) after artificial contamination with *K. aerogenes*. In study *66–D15–W221 (in OTC Volume 020038)*, 0.5 percent, 1 percent, and 2 percent triclosan in Ivory^R soap was compared to Ivory^R soap without triclosan, as a control, to show reduction of baseline counts on the hands of five human test subjects after 5 days. Using the Quinn Split-Use Modification of the Price-Cade Method, increased skin-degerming activity was shown after 3 days of repeated (10) applications of triclosan as compared to the control. However, the number of test subjects (5) is not adequate to demonstrate general recognition of effectiveness. (See the "Modified Cade Procedure," 43 FR 1210 at 1243.)

The agency concludes that the data (Ref. 13) discussed above indicate that formulations of triclosan significantly reduce the baseline count of bacterial skin flora. However, before triclosan may be generally recognized as an effective health-care antiseptic for use in antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub drug products, additional in vivo data, i.e., glove juice test data, are needed. The in vivo data should correlate with data obtained from in vitro studies. Because of the nature of the intended uses of health-care antiseptic drug products, the agency believes it is essential to assure the effectiveness of the active ingredient, triclosan, in final formulations. To demonstrate effectiveness in vitro, information is needed on the germicidal activity of the vehicle alone, so that the germicidal contribution of triclosan attributed to the total effectiveness of the finished formulation can be determined. (See section I.N., comment 28.)

Accordingly, triclosan (up to 1 percent, with the lower limit to be determined) is being classified as Category III for use in health-care antiseptic drug products as a patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub. The agency's conclusions are summarized below:

Short-term use	Long-term (repeated/daily) uses
Patient Preoperative Skin Preparation IIIE.	Antiseptic Handwash or Health-Care Personnel Handwash IIISE. Surgical Hand Scrub IIISE.

S=Safety.
E=Effectiveness.

The agency has communicated further with EPA and has ascertained that there is no specific report on the proliferation of triclosan (Ref. 14). Regarding exclusive patent rights, the agency advises that these are not among the determining criteria to establish general recognition of safety and effectiveness, and therefore cannot be used in the evaluation. However, having reviewed the new data along with the previously submitted data, the agency concludes that there is no proliferation problem with triclosan.

Finally, the agency did not intend to restrict formulations of triclosan to bar soap. The agency has reviewed the Panel's recommendations and the footnotes in the previous tentative final monograph (43 FR 1210 at 1229) and finds that triclosan under "antimicrobial soaps" was erroneously marked with the reference to the footnote "Category III only when formulated in a bar soap to be used with water."

The use of triclosan in products for the treatment of diaper rash was discussed in the tentative final monograph for antimicrobial diaper rash drug products published on June 20, 1990 (55 FR 25246 at 25277 to 25278). The use of triclosan in products for treating sunburn will be addressed in the **Federal Register** at a later date in another OTC drug rulemaking for drug products for this use.

References

(1) Comments No. CP1, SUP19, SUP23, C103, C109, SUP31, SUP39, and C134, Docket No. 75N–0183, Dockets Management Branch.

(2) Comment No. SUP20, Docket No. 75N–0183, Dockets Management Branch.

(3) Comment No. OB15, Docket No. 75N–0183, Dockets Management Branch.

(4) "Two Year Chronic Oral Toxicity Study With Fat 80′ 023/A in Albino Rats," Comment No. C109, vol. 1, appendix E, and Comment No. C139, vol. 1–8, Docket No. 75N–0183, Dockets Management Branch.

(5) "Eighteen Month Carcinogenicity Study with Fat 80′ 023/A in Albino Mice," Comment No. C109, vol. 3, appendix I, and Comment No. C139, vol. 9, Docket No. 75N–0183, Dockets Management Branch.

(6) "Three Phase Reproduction Study Albino Rats and Rabbits, Bacteriostat CH 3565," Comment No. C134, tab 7, and Comment No. C139, vol. 10–11, Docket No. 75N–0183, Dockets Management Branch.

(7) Letter from W. E. Gilbertson, FDA, to R. Bernegger, Ciba-Geigy Corp., coded LET28/ANS, Docket No. 75N–0183, Dockets Management Branch.

(8) Memorandum of meeting between representatives of Ciba-Geigy Corp. and FDA, Comment No. MM7, Docket No. 75N–0183, Dockets Management Branch.

(9) "FAT 80′ 023 2–Year Oral Administration in Rats," vol. XLI, XLII, and XLIII and "Determination of FAT 80′ 023 in Blood and Tissue Samples Taken During a Two-Year Chronic Oral Toxicity/Oncogenicity Study in Albino Rats," vol. XLIV, Comment No. RPT2, Docket No. 75N–0183, Dockets Management Branch.

(10) Letter from W. E. Gilbertson, FDA, to Per Stensby, Ciba-Geigy Corp., coded LET100, Docket No. 75N–0183, Dockets Management Branch.

(11) Comment No. RPT7, Docket No. 75N–0183, Dockets Management Branch.

(12) Letter from W. E. Gilbertson, FDA, to R. Bernegger, Ciba-Geigy Corp., coded LET34, Docket No. 75N–0183, Dockets Management Branch.

(13) Comments No. MM3 and C157, Docket No. 75N–0183, Dockets Management Branch.

(14) Letter from A. E. Castillo, EPA, to W. E. Gilbertson, FDA, coded LET33, Docket No 75N–0183, Dockets Management Branch.

M. Comments on Combinations of Active Ingredients

24. One comment stated that the Panel did not review safety and effectiveness data submitted to it on mercufenol chloride (orthohydroxyphenylmercuric chloride) 0.1 percent and secondary amyltricresols 0.1 percent as single ingredients and in combination for use as a patient preoperative skin preparation, skin antiseptic, and skin wound protectant (Ref. 1). The comment added that the agency did not discuss these ingredients alone or in combination in the previous tentative final monograph.

The comment asserted that secondary amyltricresols, mentioned in the previous tentative final monograph under phenol (43 FR 1210 at 1238), is not equivalent to phenol because of chemical differences and differing antimicrobial properties, formulation concentrations, and patterns of use. The comment requested the agency to make decisions on the safety and effectiveness of this ingredient when used alone, or

in combination, as a patient preoperative skin preparation, a skin antiseptic, or a skin wound protectant.

The agency has previously reviewed data for first aid antiseptic uses of 0.1 percent mercufenol chloride and 0.1 percent secondary amyltricresols and found the evidence insufficient to support their safety and effectiveness either as single ingredients or in combination (56 FR 33644 at 33668). Only safety data on animals were submitted by the comment (Ref. 1); in general, these studies were conducted on a very small number of animals, did not detail methodology, and did not adequately describe results (physical condition of the animals). The submitted in vitro studies also lack sufficient detail to establish the effectiveness of mercufenol chloride.

Secondary amyltricresols is a mixture of isomeric secondary amyltricresols, which are derivatives of phenol, and has pharmacological properties similar to phenol. The agency agrees with the comment that the mixture of secondary amyltricresols is not equivalent to phenol and should be categorized separately from phenol. The submitted safety data included a study by Broom (Ref. 2), who reported that amylmetacresol is relatively nontoxic and less toxic than hexylresorcinol in rats and mice.

No toxicity studies in humans were included in the information provided by the comment. However, in the tentative final monograph for OTC external analgesic drug products, published in the Federal Register of February 8, 1983 (48 FR 5852 at 5858), the agency proposed that metacresol up to a 3.6-percent concentration be considered safe when combined with camphor and that a 3-to-1 ratio of camphor to metacresol reduces the irritating properties of metacresol. Although cresols may cause some irritation when applied to minor wounds, the agency believes that secondary amyltricresols at the concentration requested (0.1 percent) would not present any safety concerns, particularly considering the short-term use of antiseptics as patient preoperative skin preparation drug products. The submitted data are, however, inadequate to establish the efficacy of secondary amyltricresols.

Data are also needed to determine the safety and effectiveness of the combination of mercufenol chloride and secondary amyltricresols. Only animal safety data are available, and these studies were limited to determinations of the minimum lethal dose by various routes of administration (Ref. 1). The submitted information on marketing history is not sufficient to provide general recognition of the safety of these ingredients. The data contained isolated reports of the combination of mercufenol chloride and secondary amyltricresols causing occasional skin irritation, such as burning and blistering (Ref. 1), adverse effects that need to be more fully studied.

Most of the effectiveness work on the combination of mercufenol chloride and secondary amyltricresols has been in vitro. The combination is reported to combine the antibacterial activity of the single ingredients, that is, mercufenol chloride which is primarily active against gram-negative organisms and secondary amyltricresols which is primarily active against gram-positive organisms (Ref. 3). One in vivo study on the effectiveness of the combination as a patient preoperative skin preparation showed a substantial reduction in the skin microflora (Ref. 4). However, because neutralizers were not used, bacteriocidal activity cannot be differentiated from residual bacteriostatic activity. In addition, the effect of the 50-percent alcohol in the alcohol-acetone vehicle was not taken into consideration. Alcohol, 60 to 95 percent, is in Category I for antiseptic health-care uses.

Under the agency's guidelines for OTC drug combination products (Ref. 5), Category I active ingredients from the same therapeutic category that have different mechanisms of action may be combined to treat the same symptoms or condition if the combination meets the OTC combination policy in all respects and the combination is on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose. Accordingly, both mercufenol chloride and secondary amyltricresols and the combination of these ingredients are placed in Category III. The combination needs further testing of the combined ingredients compared to each individual active ingredient to establish effectiveness of the combination as a patient preoperative skin preparation.

The agency recommends that in vivo and in vitro effectiveness data be submitted. The data should be based on both in vitro and in vivo testing procedures as described for patient preoperative skin preparation drug products. (See section I.N., comment 28.)

References

(1) OTC Vol. 020093.

(2) Broom, W. A., "A Note on the Toxicity of Amyl-meta-cresol," *British Journal of Experimental Pathology*, 12:327–331, 1931.

(3) Dunn, C. G., "Germicidal Properties of Phenolic Compounds," *Industrial and Engineering Chemistry*, 28:609–612, 1936.

(4) Maddock, W. G., and L. K. Georg, "Further Experience with Mercresin," *American Journal of Surgery*, 45:72–75, 1939.

(5) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D–0322, Dockets Management Branch.

25. One comment submitted data on a combination drug product containing calomel (mercurous chloride) 30 percent, oxyquinoline benzoate, and trolamine (triethanolamine) combined with fatty acids to form a soap compound, plus a phenol derivative that is currently marketed over-the-counter and is indicated for use in the prevention of venereal disease (syphilis and gonorrhea) (Ref. 1). The comment included a historical review and information on in vitro activity of one of the ingredients. According to the comment, in 1905 the discovery was made that calomel in combination with fats is an effective germicide against *Treponema pallidum* (*T. pallidum*), the causative organism of syphilis. Later, calomel was stated to be active against *Neisseria gonorrhoeae* (*N. gonorrhoeae*) (the causative organism of gonorrhea).

This combination of ingredients and the indication of prevention of syphilis and gonorrhea have not been reviewed by any OTC advisory review panel. However, because a claim is made indicating antimicrobial activity and the product contains calomel, which is already included in the rulemaking for OTC topical antimicrobial drug products, the agency believes it is appropriate to review this combination and labeling claim in this amended tentative final monograph.

The in vitro effectiveness test described in the comment (Ref. 1) is a zone of inhibition test comparing the germicidal activity of calomel, phenol, and organic silver salts against *S. aureus* as an indicator of activity against syphilis (*T. pallidum*) and gonorrhea (*N. gonorrhoeae*). According to the submission, the causative organisms are not viable in vitro and were not used in the testing. The agency points out that it is possible to isolate and subculture isolates of *N. gonorrhoeae* for in vitro antimicrobial testing (Ref. 2), but *T. pallidum* cannot be grown in vitro (Ref. 3). The agency does not consider the in vitro test against *S. aureus* to be adequate to support a claim of prevention of syphilis and gonorrhea.

In a separate rulemaking for mercury-containing drug products for topical antimicrobial use, calomel was reviewed by the Miscellaneous External Panel (47 FR 436 at 440). That Panel did note that calomel "has been used in the past by inunction (rubbing into the skin)

as a prophylactic against venereal disease * * *" but placed the ingredient in Category II because "calomel may be safe as a topical antimicrobial agent, but it is not effective for this purpose."

Although it is apparent that calomel 30 percent would be considered an active ingredient, it is not clear from the available information whether the other ingredients in the combination (oxyquinoline benzoate, trolamine, and phenol derivative) are also considered active ingredients, nor are the concentrations of these other ingredients stated in the submission and no data have been submitted to the OTC drug review on these ingredients in relation to the prevention of venereal disease. In the absence of any data, none of these ingredients are considered safe and effective for this use.

The comment did not submit any in vivo data from clinical studies to demonstrate that the combination of calomel, oxyquinoline benzoate, trolamine, and phenol derivative is safe and effective for use in the prevention of syphilis and gonorrhea. Preliminary in vitro testing against *N. gonorrhoeae* should be conducted before any human clinical trials are done. Then, favorable results from two well-controlled clinical studies in humans conducted by qualified investigators in two geographic locations (at least one should be within the United States of America) are needed before any drug product can be recognized to be safe and effective in preventing syphilis and gonorrhea. Interested individuals should consult with the agency before initiating any testing. In conclusion, the agency is proposing that this combination of ingredients indicated for the prevention of syphilis and gonorrhea be classified Category II in this amended tentative final monograph.

The agency's detailed comments and evaluation on the data are on file in the Dockets Management Branch (Ref. 4).

References

(1) Comment No. C158, Docket No. 75N–0183, Dockets Management Branch.

(2) Morello, J. A., and M. Bohnhoff, "*Neisseria* and *Branhamella*," in "Manual of Clinical Microbiology," 3rd ed., edited by E. H. Lennette, *American Society for Microbiology*, Washington, pp. 111–122, 1980.

(3) Buchanan, R. E., and N. E. Gibbons, "Bergey's Manual of Determinative Bacteriology," 8th ed., Williams and Wilkins Co., Baltimore, p. 176, 1974.

(4) Letter from W. E. Gilbertson, FDA, to M. Lowenstein, The Sanitube Co., coded LET68, Docket No. 75N–0183, Dockets Management Branch.

N. Comments on Testing

26. Numerous comments addressed the agency's modifications in the Panel's proposed testing guidelines (43 FR 1210 at 1239 to 1240), the agency's statements on final formulation testing (43 FR 1211, 1224, and 1240), and specific protocols for upgrading an antimicrobial ingredient from Category III to Category I (43 FR 1242 to 1246). Stating that the testing guidelines were unclear in some places and pointing out inconsistencies between the guidelines and the agency's responses to comments at 43 FR 1211 and 1223 to 1227, a number of comments requested clarification or proposed modifications of a number of items in the guidelines.

Several comments requested specific information or submitted protocols for testing Category III ingredients. One comment requested that manufacturers be permitted to determine which protocol to follow to establish safety or effectiveness of an ingredient. A number of comments objected to the agency's consideration of the testing guidelines as final, and urged revisions in the guidelines for publication in the **Federal Register**.

The agency acknowledges that there were some inconsistencies in the testing guidelines for safety and effectiveness proposed in the previous tentative final rule. The agency does not consider the previous testing guidelines as final. The agency is clarifying in this amended tentative final monograph that all final formulations will be required to meet the specifications in the final monograph. As stated in section I.N., comment 28, the agency is proposing testing procedures in § 333.470 for evaluating the active ingredient in pure form as well as in the complete formulation. The agency recommends that manufacturers use these procedures for testing the final formulations of products intended for health-care antiseptic use. Manufacturers may propose other appropriate testing procedures subject to agency evaluation, as requested. The data from these tests are not required to be submitted to FDA by the manufacturer. However, the agency intends to use these procedures for any necessary compliance testing.

27. Two comments pointed out an apparent conflict in the agency's statements concerning safety factor calculations as follows: At 43 FR 1240, the agency concluded that a minimum of a 100-fold safety factor should apply to the exposure dose for ingredients labeled for repeated daily use; at 43 FR 1241, the agency stated that if the safety factor is extrapolated from an animal species to man, considering surface area, the highest no-effect dose should be used for the multiplier, and in the absence of complete data, a 100-fold safety factor should be applied when translating the animal highest no-effect dose to man; and at 43 FR 1213 (see comment 19), the agency stated that modifications of the safety factor will be allowed for specific ingredients where justified by risk-benefit considerations. One comment suggested that a safety factor of less than 100-fold be acceptable when scientific investigation of good quality shows that the test animals used in establishing the no-effect dose are similar to humans with respect to metabolism (biotransformation and pharmacokinetics) and/or tissue susceptibility. Another comment stated that a more reasoned and practical approach would be to require calculation of certain safety factors as recommended, and indicate in a general guideline that risk-benefit ratios based on these factors would determine the relative merits of the product.

The agency does not find any conflict in the various statements included in the previous tentative final monograph. The safety factor calculations were included merely as a general guideline. The agency's response to comment 19 at 43 FR 1213 indicated that the agency would retain a minimum of a 100-fold safety factor applied to the exposure dose for ingredients in products labeled for repeated daily use. However, the agency will consider modifications of the safety factor for specific ingredients where justified by risk-benefit considerations and where requests are based on submitted data. While the 100-fold safety factor was a general guideline in the previous tentative final monograph, the agency does not find a need to include a general guideline in this amended tentative final monograph.

28. Numerous comments requested clarification of the criteria required to establish effectiveness for each antimicrobial product class. One comment stated that the "Testing Guidelines" section seems to indicate that it may be necessary to determine the effect of the vehicle on the active ingredient. The comment contended that this provision is confusing because the preamble discussion in the tentative final monograph indicates that vehicle testing will not be necessary "* * * where adequate data are available on the active ingredients alone." (See 43 FR 1210 at 1224.) Another comment stated that the Cade handwashing test can only be conducted if the antimicrobial is placed in a vehicle and noted that the antimicrobial is never used by consumers in its raw form; therefore, efficacy testing on the raw antimicrobial

ingredient should not be required. A third comment stated that the overall antimicrobial effectiveness of a topically applied product is a function of the total formulation rather than a single ingredient. Another comment added that if an individual product formulation must be tested, and/or the testing of a product vehicle is considered essential, then such testing requirements must be specifically described. Citing the definition of an antiseptic in section 201(o) of the act (21 U.S.C. 321(o)), one comment asserted that the definition requires that the antimicrobial product kill or inhibit the growth of micro-organisms on the skin. The comment proposed that efficacy can be demonstrated by showing that the preparation produces a quantitative reduction in the levels of normal skin flora and/or inhibition of bacterial growth in vitro. Two comments pointed out that the "Modified Cade Procedure" handwashing test (43 FR 1210 at 1243) specifies a one-log reduction of bacteria, but the procedure fails to indicate how many uses or days of use of test product should produce the reduction. Other comments requested that no upper limit be set for bacterial hand counts, that the lower limit of 1.5×10^6 per hand be the only criteria for subject selection, and that minimal hand count reduction be defined in the test protocols for surgical hand scrub and health-care personnel handwash products. Another comment suggested that modification of the "Sampling technique and times" (paragraph 6) of the protocol "Effectiveness Testing of Surgical Hand Scrub (Glove Juice Test)" (43 FR 1243) was needed because the protocol did not indicate the volume of sampling solution but only stated that the volume * * * should be "kept constant" for all tests. The comment recommended that the agency specify a range of 50 to 100 mL of sampling solution in order to provide consistent and reproducible results.

The agency has carefully reviewed the comments, existing data, and other information, and is clarifying the effectiveness criteria for health-care antiseptics in this tentative final monograph.

In order for an antiseptic ingredient to be generally recognized as effective for use as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and/or surgical hand scrub, it must have existing data from well designed clinical studies demonstrating effectiveness. The agency believes that it is important to correlate effectiveness data from clinical studies with effectiveness data from in vitro studies on the activity of the vehicle and active ingredient individually, so that the germicidal contribution of the antiseptic ingredient to the total formulation can be fully characterized. As stated in the testing guidelines in the previous tentative final monograph, at 43 FR 1240, "* * * there should be demonstration that the formulated product is better than the vehicle alone. Testing of the complete formulation of Category III ingredients * * * is necessary to judge the importance of the vehicle in the release of the active ingredient as well as the influence of formulation on aspects of effectiveness * * *." The agency believes that information on the in vitro activity of the active ingredient alone helps to characterize its antiseptic activity independent of formulation and helps to further define formulation effects on the antimicrobial ingredient. Therefore, the agency is proposing that in vitro studies of the antimicrobial activity of health-care antiseptic drug products covered by § 333.470(a)(1)(i) and (a)(1)(ii) be conducted on the active ingredient, the vehicle, and the final formulation. Manufacturers are to have such data in their files for products containing ingredients included in the monograph.

In this amended tentative final monograph, the agency is proposing that the in vitro antimicrobial activity of the antiseptic ingredient, the vehicle, and the formulated product be characterized by the determination of their antimicrobial spectrum and by minimal inhibitory concentration determinations performed against selected organisms using methodology established by the National Committee for Clinical Laboratories Standards (NCCLS) (Ref. 1). Because the principal intended use of these health-care antiseptic drug products is the prevention of nosocomial or hospital acquired infections, the agency concludes that these products should be able to demonstrate in vitro activity against a microbial spectrum that reflects this use. Since 1970, the National Nosocomial Infection Surveillance System (NNIS) has collected and analyzed data on nosocomial pathogens reported to the Centers for Disease Control by a number of hospitals who perform prospective surveillance on nosocomial infections. These data provide an indication of the most frequently occurring pathogens at four major sites of nosocomial infection—the urinary tract, surgical wounds, lungs (pneumonia), and bloodstream. The agency believes that health-care personnel handwash, surgical hand scrub, and patient preoperative skin preparations should be able to demonstrate in vitro effectiveness against these pathogens as well as the normal resident skin flora. Therefore, the agency is proposing that micro-organisms associated with the most commonly occurring nosocomial infections and those found most often in nosocomial infections of high risk patients as reported by the NNIS, for the period from January 1985 through August 1988 (Ref. 2), be included in the list of micro-organisms to be tested in § 333.470(a)(1)(ii). The agency further concludes that this proposed list identifies a broad spectrum of antimicrobial activity that is also appropriate for home use antiseptic handwash products.

The agency notes that neither filamentous dermatophytic fungi or viruses are included in the NNIS report. More recent studies (Refs. 3 and 4) have reported small numbers of nosocomial infections associated with both of these organisms. However, the new studies do not provide sufficient information to assess the relative importance of these organisms as a cause of nosocomial infection. Therefore, the agency is not proposing to include filamentous dermatophytic fungi in the list of micro-organisms to be tested, as proposed in the previous in vitro effectiveness testing guidelines (43 FR 1210 at 1241) and is continuing to propose that viruses also not be included. The agency recognizes that the list of organisms to be tested may need updating to assure that it remains reflective of current trends in the microbial etiology of nosocomial infections. The agency intends to update the list as new information becomes available. Further, the agency invites the submission of comments and specifically data on the role of other organisms, particularly viruses and filamentous dermatophytic fungi, in nosocomial infections.

In addition to the characterization of the in vitro spectrum of activity, the agency believes that information on how rapidly these antimicrobial drug products achieve their antimicrobial effect is necessary. As a means of indicating how quickly these products achieve their antimicrobial effect, the agency is proposing in vitro time-kill curves of the formulated drug product as part of the testing requirements. The agency acknowledges that there is currently no accepted or standardized method that may be used in conducting this type of study and invites the submission of proposed methods that may be considered as applicable to this test. In § 333.470(a)(1)(iv) of the proposed testing regulations, the agency provides guidance on the development

of such methods. However, any time-kill studies submitted to the agency are to be conducted on a 10-fold dilution of the formulated product against the ATCC strains identified in § 333.470(a)(1)(ii) of the proposed testing regulations and are to include enumeration at times at 0, 3, 6, 9, 12, 15, and 30 minutes.

With regard to proof of clinical effectiveness, the agency is proposing specific criteria for final formulations of antiseptic handwashes or health-care personnel handwashes, patient preoperative skin preparations, and surgical hand scrubs that are based on the recommendations of the Panel and agency experience in evaluating the effectiveness of these types of drug products, as follows.

For antiseptic handwash or health-care personnel handwash products, the agency is proposing the following criteria: (1) A 2-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the first wash and (2) a 3-$\log_{10}$ reduction in the indicator organism on each hand within 5 minutes after the tenth wash, when tested by a modification of the standard procedure for the evaluation of health-care personnel handwash formulations published by the American Society for Testing and Materials (ASTM) (Ref. 5).

For patient preoperative skin preparations, the agency is proposing the following criteria: (1) A 2-$\log_{10}$ reduction of the microbial flora per square centimeter of an abdominal test site, (2) a 3-$\log_{10}$ reduction of the microbial flora per square centimeter of a groin test site within 10 minutes from a matched control area, and (3) the suppression of bacterial growth below baseline for 6 hours, when tested by a modification of the standard procedure for the evaluation of patient preoperative skin preparations published by the ASTM (Ref. 6). The agency believes that the revised effectiveness criteria more closely reflect the conditions of product use, *i.e.*, on a number of different body sites, each supporting different numbers of resident skin flora. In addition, although persistence of effect was not recommended by the Panel as a requirement for these drug products, the agency believes that persistence of antimicrobial effect would suppress the growth of residual skin flora not removed by preoperative prepping as well as transient micro-organisms inadvertently added to the operative field during the course of surgery and reduce the risk of surgical wound infection. Based on the proposed effectiveness criteria for this product class, the agency is proposing a revised definition of a patient preoperative skin preparation drug product in § 333.403(c)(2) of this amended tentative final monograph as follows: "A fast-acting broad-spectrum persistent antiseptic-containing preparation that significantly reduces the number of micro-organisms on intact skin."

As discussed in section I.E., comment 10, the agency is proposing the indication "for the preparation of the skin prior to an injection" for OTC alcohol and isopropyl alcohol drug products. The agency is further proposing that products labeled for such use demonstrate effectiveness by testing according to the same procedure used to demonstrate the effectiveness of patient preoperative skin preparation drug products not labeled for this use. Based on this intended use of alcohol drug products, the agency is proposing a 1-$\log_{10}$ reduction in the microbial flora per square centimeter of a dry skin test site within 30 seconds of product use as the effectiveness criteria for these products.

For surgical hand scrub products, the agency is proposing the following criteria: (1) A 1-$\log_{10}$ reduction of the microbial flora of each hand from the baseline count within 1 minute, (2) suppression of bacterial growth on each hand below baseline for 6 hours on the first day, (3) a 2-$\log_{10}$ reduction of the microbial flora on each hand within 1 minute of product use by the end of the second day, and (4) a 3-$\log_{10}$ reduction of the microbial flora on each hand within 1 minute of product use by the end of the fifth day, when tested by a modification of the standard procedure for the evaluation of surgical hand scrub products published by the ASTM (Ref. 7).

Based on glove juice test data for surgical hand scrub use of povidone-iodine (section I.I., comment 17), alcohol (section I.E., comment 10), chloroxylenol (section I.G., comment 12), and triclosan (section I.L., comment 23), the agency concludes that formulated products containing certain ingredients, *i.e.*, chloroxylenol and triclosan, are substantive in their action and do not produce a high (1-$\log^{10}$) initial reduction, but after repeated use for up to 5 days do reduce the baseline count and suppress the count in the user's glove. In a separate final rule, the agency stated that any product indicated for use as a surgical scrub should meet a standard for initial reduction. A one-log reduction was found acceptable as the minimal level of reduction suitable for a surgical scrub in a handwashing test. (See "New Drugs Containing Hexachlorophene," published in the **Federal Register** of December 20, 1977; 42 FR 63771.)

In that same final rule, the agency acknowledged that hexachlorophene containing surgical scrub drug products are substantive in their action and do not produce an initial high reduction but with repeated use are effective in reducing the resident skin flora and suppressing bacterial growth in the user's glove for up to 6 hours. Based on a lack of available products capable of producing both an initial high reduction in the resident skin flora and a prolonged microbial suppression marketed at the time of the agency's action on the ingredient in 1972, the agency agreed with the recommendations of its Antimicrobial I Panel and concluded that the ingredient should continue to be marketed for use as a surgical scrub and for handwashing as part of patient care. The agency stated its intention to reconsider its criteria for evaluating such products in light of risk-benefit judgments as new products containing both attributes become available (42 FR 63771).

Since that final rule was issued in 1977, data have been submitted to the agency demonstrating the effectiveness of surgical hand scrub formulations capable of producing an initial 1-$\log_{10}$ reduction and a suppression of microbial growth in the wearer's glove for up to 6 hours. (See section I.E., comment 10 on alcohol and section I.I., comment 17 on povidone-iodine.) The agency notes that the persistence of the antimicrobial effect demonstrated by an alcohol-containing surgical hand scrub formulation was provided by a preservative agent in the vehicle. Based on the new data, the agency has concerns about the risk associated with the initial use of substantive surgical hand scrub formulations, and with the use of these formulations after extended lapses in their routine use. Therefore, the agency is proposing that all surgical hand scrub formulations must demonstrate an initial one-log reduction in the bacterial flora. The agency invites comment on the use of substantive antimicrobials in health-care antiseptic drug products. Based on the revised effectiveness criterion for these drug products, the agency is proposing a revised definition of a surgical hand scrub drug product in § 333.403(c)(3) as follows: "An antiseptic containing preparation that significantly reduces the number of micro-organisms on intact skin; it is broad spectrum, fast acting, and persistent."

The agency believes that the modified ASTM procedures for the testing of health-care or antiseptic handwashes, surgical hand scrubs, and patient preoperative skin preps being proposed for inclusion in the testing requirements

provide protocols that are appropriate for the final formulation testing of these drug products. The proposed protocols describe, in detail, study conditions and materials to be used and address the concerns raised by the comments. For instance, the proposed protocol for the testing of surgical hand scrub products includes a baseline criterion for subject selection of equal to, or greater than, 1.5 $\times 10^5$ bacteria per hand and specifies that a 50 to 100 mL volume of sampling is to be used. The proposed protocols also specify requirements for a number of areas not addressed by the testing guidelines proposed in the previous tentative final monograph. For example, they address statistical aspects of study design and data analysis, and the use of neutralizers. A positive control is included in the protocols as a means of validating the testing procedure, equipment, and facilities. The agency believes that the proposed protocols for the testing of these products provide a consistent approach to the effectiveness testing of health-care personnel handwashes, surgical hand scrubs, and patient preoperative skin preparations. The agency is incorporating the above criteria and testing requirements in proposed § 333.470 of this tentative final monograph and invites specific comment on them at this time. After reviewing any submitted comments or data, the agency may revise the testing requirements and procedures prior to establishing a final monograph. The agency also recognizes that the test procedures may need to be revised periodically to reflect new information and newer techniques that are developed and proven adequate.

References

(1) National Committee for Clinical Laboratory Standards, "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically—2d ed.; Approved Standard," NCCLS Document M7–A2, 10:8, 1990.

(2) Horan, T. *et al.*, "Pathogens Causing Nosocomial Infections," *The Antimicrobic Newsletter*, 5:65–67, 1988.

(3) Andersen, L. J., "Major Trends in Nosocomial Viral Infections," *The American Journal of Medicine*, 91:107S–111S, 1991.

(4) Jarvis, W. R. *et al.*, "Nosocomial Outbreaks: The Centers for Disease Control's Hospital Infections Program Experience," *The American Journal of Medicine*, 91:101S–106S, 1991.

(5) American Society for Testing and Materials, "Standard Test Method for Evaluation of Health Care Personnel Handwash Formulation, Designation E 1174," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 209–212, 1987.

(6) American Society for Testing and Materials, "Standard Test Method for Evaluation of a Preoperative Skin Preparation, Designation E 1173," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 205–208, 1987.

(7) American Society for Testing and Materials, "Standard Test Method for Evaluation of Surgical Hand Scrub Formulation, Designation 1115," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 201–204, 1986.

II. The Agency's Amended Tentative Final Monograph

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of Ingredient Categories

The agency has carefully reviewed the claimed active ingredients submitted to this administrative record (Docket No. 75N–0183), which includes the following: the advance notice of proposed rulemaking (39 FR 33103) and previous tentative final monograph (43 FR 1210) for OTC topical antimicrobial drug products, the advance notice of proposed rulemaking for OTC topical alcohol drug products (47 FR 22324), and the advance notice of proposed rulemaking for OTC topical mercury-containing drug products (47 FR 436). Based upon the available information, including clinical and marketing history, as well as the recommendations of the Miscellaneous External Panel, the agency is proposing a tentative classification for OTC health-care antiseptic active ingredients.

Many of the ingredients included in the tabulation below are in Category II and Category III because of no data or a lack of data on use as a health-care antiseptic. However, all the ingredients have been included as a convenience to the reader. The agency specifically invites comment and additional data on these ingredients.

The advance notice of proposed rulemaking for alcohol drug products for topical antimicrobial OTC human use (47 FR 22324, May 21, 1982) is being incorporated into this amended tentative final monograph. In that proposed monograph, the Miscellaneous External Panel recommended that alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco, and Firearms regulations at 27 CFR part 21 and isopropyl alcohol 50 to 91.3 percent by volume in an aqueous solution be classified as Category I for topical antimicrobial use. The following indications were proposed:

(1) "For first aid use to decrease germs in minor cuts and scrapes."

(2) "To decrease germs on the skin prior to removing a splinter or other foreign object."

(3) "For preparation of the skin prior to an injection." (See the advance notice of proposed rulemaking for OTC alcohol drug products for topical antimicrobial use, in the **Federal Register** of May 21, 1982, 47 FR 22324.)

Based upon submitted data and the conclusions of the Miscellaneous External Panel, the agency is including alcohol as a Category I surgical hand scrub, patient preoperative skin preparation, and antiseptic handwash or health-care personnel handwash (see section I.E., comment 10). While no comments submitted data on health-care uses of isopropyl alcohol, the agency notes that one comment (Ref. 1) from a manufacturer requested that the OTC alcohol drug products monograph provide the labeling indication, "antibacterial handwash." The same manufacturer provided a submission (Ref. 2) to the Miscellaneous External Panel on a combination product containing isopropyl alcohol 50 percent and oxyquinoline sulfate 0.125 percent for use as a germicidal-fungicidal wash. However, the Panel disbanded before it was able to review the submission, which contained labeling for a currently marketed product and in vitro studies of the product's bacteriocidal activity. No in vivo effectiveness data were submitted for the use of isopropyl alcohol as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, or surgical hand scrub.

Based on the lack of data for the use of isopropyl alcohol as an antiseptic handwash or health-care personnel handwash and surgical hand scrub, the agency is placing the ingredient in Category III for these uses. The agency invites data on these uses of isopropyl alcohol. As discussed in section I.E., comment 10, the agency is including the Panel's recommended indication "for the preparation of the skin prior to an injection" as an additional Category I indication for patient preoperative skin preparations containing alcohol. Based on the Panel's recommendations, the agency is also proposing isopropyl alcohol as a Category I patient preoperative skin preparation for this indication. However, based on the lack of data on the use of isopropyl alcohol for more general patient preoperative skin preparation use, the agency is not proposing isopropyl alcohol as Category I for the other patient preoperative skin preparation indications included in § 333.460(b)(1), *i.e.*, "for the preparation of the skin prior to surgery" and "helps

to reduce bacteria that potentially can cause skin infection."

The agency has evaluated standard textbooks and published data on the effectiveness of isopropyl alcohol used topically on the area prior to an injection (Refs. 3, 4, and 5). The minimum effective concentration of isopropyl alcohol for this use is 70 percent. Further, the agency is not aware of any information concerning the use of isopropyl alcohol below 70 percent for this indication. Therefore, the agency is proposing to include isopropyl alcohol 70 to 91.3 percent in Category I for use as a patient preoperative skin preparation for the limited indication "for the preparation of the skin prior to an injection".

The Miscellaneous External Panel recommended that drug products containing alcohol and isopropyl alcohol bear the following warning: "Flammable, keep away from fire or flame," (47 FR 22324 at 22330). The agency concurs with the Panel's recommended warning and is proposing this warning in § 333.450(c)(4) of this tentative final monograph. In order to ensure the warning's prominence, the agency is further proposing that it appear in boldface type and as the first warning immediately following the heading "WARNINGS".

The agency is aware of ten reports (Refs. 6 and 7) of first and second degree burns occurring in patients undergoing electrocautery procedures. The burns were caused by the ignition of the isopropyl alcohol in patient preoperative skin preparations containing chlorhexidine gluconate or povidone-iodine in 70 percent isopropyl alcohol. The reports indicate that these incidents have occurred despite the presence of detailed warnings in the products' labeling cautioning that the products are flammable until dry and should not be allowed to pool on body surfaces or should not be used in conjunction with electrocautery procedures until dry (Refs. 8 and 9). Based on these reports, the agency tentatively concludes that patient preoperative skin preparations containing isopropyl alcohol in concentrations of 70 percent or more cannot be adequately labeled to allow the safe use of these drug products in conjunction with electrocautery procedures. Therefore, the agency is proposing that patient preoperative skin preparations containing isopropyl alcohol in concentrations of 70 percent or more bear the following label warning: "Do not use with electrocautery procedures." The agency is further proposing that the proposed warning immediately follow the flammable warning being proposed in § 333.450(c)(4).

The agency is not currently aware of any similar incidence occurring with other nonemollient patient preoperative skin preparations containing alcohol in similar concentrations. Therefore, at this time the agency is not proposing that patient preoperative skin preparations containing alcohol identified in § 333.412(a) bear a warning concerning the use of these products in conjunction with electrocautery procedures. However, the agency will consider extending the warning to patient preoperative skin preparations containing alcohol if new information indicates that this is necessary. The agency invites specific comment and data on the safety of both alcohol and isopropyl alcohol containing patient preoperative skin preparations in conjunction with electrocautery procedures.

References

(1) Comment No. C00148, Docket No. 75N–0183, Dockets Management Branch.

(2) OTC Vol. 160251.

(3) Lee, S., I. Schoen, and A. Malkin, "Comparison of Use of Alcohol with that of Iodine for Skin Antisepsis in Obtaining Blood Cultures," *American Journal of Clinical Pathology*, 47:646–648, 1967.

(4) Harvey, S.C., "Isopropanol," in "The Pharmacological Basis of Therapeutics," 7th ed., Macmillan Publishing Co., New York, p. 962, 1985.

(5) Harvey, S.C., "Isopropyl Alcohol," in "Remington's Pharmaceutical Sciences," 16th ed., Mack Publishing Co., Easton, PA, pp. 1103–1104, 1980.

(6) Drug Experience Reports No. 184970, 190547, 190548, 190549, 807471, and 851772 in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

(7) Transcripts of consumer complaints regarding DuraPrep™ Surgical Solution dated January 31, 1991, April 8, 1992, and April 9, 1992 in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

(8) Labeling for DuraPrep Surgical Solution, in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

(9) Physicians' Desk Reference, 38th ed., Medical Economics Company, Oradell, NJ, p. 1956, 1984.

The Panel also stated that benzyl alcohol and chlorobutanol were safe, but recommended that the ingredients be categorized as Category II for effectiveness. However, in the first aid antiseptic segment of this rulemaking these alcohol ingredients were reclassified from Category II to Category III for effectiveness as first aid antiseptic ingredients. (See 56 FR 33644 at 33673.) Because no comments, data, or information were received, and because the agency is not aware of any health-care antiseptic uses for these ingredients, benzyl alcohol and chlorobutanol are not being classified in this rulemaking for health-care antiseptic drug products.

The agency published an advance notice of proposed rulemaking for mercury-containing drug products on January 5, 1982 (47 FR 436). That notice, based upon the recommendations of the Miscellaneous External Panel, proposed to classify OTC mercury-containing drug products for topical antimicrobial use as not generally recognized as safe and effective and as being misbranded. The agency received no comments. The Panel classified the mercurial ingredients, as a group, in Category II; some for lack of safety, some for lack of efficacy, and others due to a lack of both safety and efficacy. However, in the first aid antiseptic segment of this amended tentative final monograph, several mercury-containing OTC topical antimicrobials have been reclassified from Category II to Category III for effectiveness. Mercurial ingredients placed in Category II for safety were not reclassified. The ingredients reclassified are calomel, merbromin, mercufenol chloride, and phenylmercuric nitrate. This change was made in keeping with the revised effectiveness criteria for the drug product category "first aid antiseptic," which were not available at the time the Miscellaneous External Panel evaluated the effectiveness of mercurial ingredients. (See 56 FR 33644 at 33672.) The agency is unaware of any clinical data or marketing history for the use of mercury-containing drug products as health-care antiseptics. Consequently, these drugs have not been classified as health-care antiseptics. In addition, the agency has reviewed submitted data on two combinations containing mercurial ingredients and proposes a Category II classification for these combinations. (See section I.M., comments 24 and 25.)

In the previous tentative final monograph, the agency concluded that cloflucarban and triclocarban are not generally recognized as safe and effective for use as a patient preoperative skin preparation, surgical hand scrub, and health-care personnel handwash. The Panel reviewed safety and effectiveness data on these ingredients formulated as a bar soap and classified them in Category III as a health-care personnel handwash when formulated as a bar soap (39 FR 33103 at 33124 and 33126). No safety and effectiveness data for the use of clofucarban in the other health-care antiseptic drug product classes were submitted to the OTC drug review; no data were reviewed by the Panel; and no data were received by the agency.

Cloflucarban is therefore considered to be outside this monograph except as a health-care personnel handwash (formulated as a bar soap). Accordingly, cloflucarban remains Category II as a health-care antiseptic for use as a patient preoperative skin preparation and surgical scrub and Category III as an antiseptic handwash or health-care personnel handwash.

Additional safety data and information were submitted to the agency on triclocarban formulated as a soap. As discussed in the segment of this rulemaking covering first aid antiseptics (56 FR 33644 at 33664), the agency has reviewed a chronic toxicity study and other information and determined that triclocarban can be recognized as safe for OTC daily topical use in a concentration of 1.5 percent. However, no effectiveness data were submitted for any health-care antiseptic uses of this ingredient and the agency is classifying triclocarban in Category III as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub. In the previous tentative final monograph, the agency placed the combination of cloflucarban and triclocarban in Category III (43 FR 1210 at 1230) to be "used in antimicrobial soap * * *". No additional data were submitted on this combination. Therefore, the combination of cloflucarban and triclocarban remains in Category III for antiseptic handwash or health-care personnel handwash uses.

Based upon the Panel's recommendations on phenol, in the previous tentative final monograph, the agency classified phenol less than 1.5 percent as Category III and phenol greater than 1.5 percent as Category II for use as a health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub (43 FR 1227 and 1229). Hexylresorcinol was also classified in Category III for these uses in the previous tentative final monograph (43 FR 1229). No additional data were submitted on health-care antiseptic uses of phenol and hexylresorcinol and their classifications are unchanged in this amended tentative final monograph. In the previous tentative final monograph, the agency classified triple dye (a combination of gentian violet, brilliant green, and proflavine hemisulfate) in Category II as a health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub based on a lack of safety data (43 FR 1239). No additional data have been submitted and the ingredient remains in Category II for health-care antiseptic uses.

In comment 85 of the previous tentative final monograph (43 FR 1223), the agency deferred classification of several ingredients to the Miscellaneous External Panel. All of the ingredients have been classified with the exception of methyl alcohol and gentian violet 1 and 2 percent solutions. The Miscellaneous External Panel at its 38th meeting placed methyl alcohol in Category II as an OTC topical antimicrobial ingredient for both safety and effectiveness (Ref. 1). However, this classification was not included in the advance notice of proposed rulemaking for OTC alcohol drug products. The agency agrees with this classification. Further, the agency is not aware of any use of methyl alcohol in OTC drug products, except as a denaturant. Gentian violet was reviewed by the Advisory Review Panel on OTC Oral Cavity Drug Products and placed in Category III based on the lack of effectiveness data for use as a topical antimicrobial on the mucous membranes of the mouth. The agency is not aware of any data on the use of gentian violet as a health-care antiseptic and places this ingredient in Category III for this use.

Reference

(1) Transcript of the Proceedings of the 39th Meeting of the Advisory Review Panel on OTC Miscellaneous External Drug Products, April 20, 1980, pp. 121–123.

Fluorosalan was not classified as an OTC topical antimicrobial ingredient in the previous tentative final monograph because the agency stated that final regulatory action had been taken against "* * * the halogenated salicylanilides, particularly * * * fluorosalan (21 CFR 310.508) * * *" (43 FR 1210 at 1227). Although no comments were received, the agency notes that fluorosalan was not addressed in the final rule for halogenated salicylanilides (21 CFR 310.508), published in the **Federal Register** of October 30, 1975 (40 FR 5027). In reviewing the Antimicrobial I Panel's recommendations, the agency has determined that the Panel did not intend to include fluorosalan in the group of halogenated salicylanilides which it recommended be handled more expeditiously by the agency in a separate **Federal Register** notice. (See the notice of proposed rulemaking for certain halogenated salicylanilides as active or inactive ingredients in drug and cosmetic products (September 13, 1974, 39 FR 33102) and the advance notice of proposed rulemaking for OTC topical antimicrobial drug products (September 13, 1974, 39 FR 33103 at 33120).) The agency affirms the recommendation of the Antimicrobial I Panel (39 FR 33121) that fluorosalan be classified as Category II for use in antiseptic handwash, health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub drug products.

The following charts are included as a summary of the categorization of health-care antiseptic active ingredients proposed by the agency.

TOPICAL ANTIMICROBIAL INGREDIENTS[1] SUMMARY OF HEALTH-CARE ANTISEPTIC ACTIVE INGREDIENTS

Active ingredient	Patient preoperative skin preparation	Antiseptic handwash or health-care personnel handwash	Surgical hand scrub
Alcohol 60 to 95 percent[2]	I	I	I
Benzalkonium chloride	IIIE	IIISE[4]	IIISE
Benzethonium chloride	IIIE	IIISE	IIISE
Chlorhexidine gluconate[2]	(5)	(5)	(5)
Chloroxylenol	IIIE	IIISE	IIISE
Cloflucarban	II	IIISE	II
Fluorosalan	II	II	II
Hexachlorophene	II	II	II
Hexylresorcinol	IIIE	IIIE	IIIE
Iodine Active Ingredients:			
Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)[2]	NA	IIIE	IIIE
Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)	IIIE	IIIE	IIIE
Iodine tincture U.S.P	I	NA	NA

TOPICAL ANTIMICROBIAL INGREDIENTS[1] SUMMARY OF HEALTH-CARE ANTISEPTIC ACTIVE INGREDIENTS—Continued

Active ingredient	Patient preoperative skin preparation	Antiseptic handwash or health-care personnel handwash	Surgical hand scrub
Iodine topical solution U.S.P	I	NA	NA
Nonylphenoxypoly (ethyleneoxy) ethanoliodine	IIIE	IIIE	IIIE
Poloxamer-iodine complex	IIIE	IIIE	IIIE
Povidone-iodine 5 to 10 percent	I	I	I
Undecoylium chloride iodine complex	IIIE	IIIE	IIIE
Isopropyl alcohol 70–91.3 percent[2]	I	IIIE	IIIE
Mercufenol chloride[2]	IIIE	NA	NA
Methylbenzethonium chloride	IIIE	IIISE	IIISE
Phenol (less than 1.5 percent)	IIIE	IIISE	IIISE
Phenol (greater than 1.5 percent)	II	II	II
Secondary amyltricresols[2]	IIISE	IIIE	IIIE
Sodium oxychlorosene[2]	IIISE	IIISE	IIISE
Tribromsalan[3]	II	II	II
Triclocarban	IIIE	IIIE	IIIE
Triclosan	IIIE	IIISE	IIISE
Combinations			
Calomel, oxyquinoline benzoate, triethanolamine, and phenol derivative[2].	II	NA	NA
Mercufenol chloride and secondary amyltricresols in 50 percent alcohol[2].	IIISE	NA	NA
Triple Dye	II	NA	NA

[1]—All ingredients (unless otherwise noted) in Antimicrobial I Drug Products Advance Notice of Proposed Rulemaking (39 FR 33103) and Tentative Final Monograph (47 FR 1210).
[2]—Not categorized in previous tentative final monograph, but categorized in this amended tentative final monograph.
NA=Not Applicable because not evaluated for this use.
[3]—Categorized in Antimicrobial I Drug Products Advance Notice of Proposed Rulemaking (39 FR 33103) and in Certain Halogenated Salicylanilides as Active or Inactive Ingredients in Drug and Cosmetic Products (40 FR 50527).
[4]—S=safety; E=effectiveness
[5]—Determined by the agency to be a "new drug".

SUMMARY OF TOPICAL ANTIMICROBIAL ACTIVE INGREDIENTS NOT ADDRESSED IN THIS RULEMAKING

Ingredients not classified as health-care antiseptic ingredients but generally recognized as safe and effective for OTC first aid use within the established concentration(s) (see 56 FR 33644).

Single ingredients

Alcohol 48 to 59 percent
Hydrogen peroxide topical solution U.S.P.
Isopropyl alcohol 50 to 69 percent

Combinations

Eucalyptol 0.091 percent, menthol 0.042 percent, methyl salicylate 0.055 percent, and thymol 0.063 percent in 26.9 percent alcohol.

Complexes

Camphorated metacresol (3 to 10.8 percent camphor and 1 to 3.6 percent metacresol) in a ratio of 3:1
Camphorated phenol (10.8 percent camphor and 4.7 percent phenol) in light mineral oil, U.S.P. vehicle

Ingredients not classified as Category I as a health-care antiseptic because the agency is not aware of any health-care antiseptic uses for these ingredients.

Single ingredients

Ammoniated mercury
Benzyl alcohol
Calomel (Mercurous chloride)
Chlorobutanol
Gentian violet
Merbromin
Mercuric chloride (Mercury chloride)
Mercuric oxide, yellow
Mercuric salicylate
Mercuric sulfide, red
Mercury
Mercury oleate
Mercury sulfide
Methyl alcohol
Nitromersol

SUMMARY OF TOPICAL ANTIMICROBIAL ACTIVE INGREDIENTS NOT ADDRESSED IN THIS RULEMAKING—Continued

Para-chloromercuriphenol
Phenylmercuric nitrate
Thimerosal
Vitromersol
Zyloxin
Combinations and/or Complexes
None

2. Testing of Category II and Category III Conditions

Required testing procedures for evaluating the effectiveness of the complete formulation of a health-care antiseptic drug product are included in proposed § 333.470. These effectiveness testing procedures can also be used to demonstrate the effectiveness of active ingredients not in a final formulation. Suggested safety testing is described in the previous tentative final monograph. (See 43 FR 1210 at 1240 to 1242.)

Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any health-care antiseptic ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Conclusions Including Changes in the Panel's Recommendations and in the Agency's Previous Recommendations

FDA has considered the comments and other relevant information and is amending the previous tentative final monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency in this amended tentative final monograph follows.

1. All of the section numbers for health-care antiseptics in the previous tentative final monograph have been redesignated in this amendment. As a convenience to the reader, the following chart is included to show these redesignations.

REDESIGNATED SECTION NUMBERS OF THE TENTATIVE FINAL MONOGRAPH FOR ANTIMICROBIAL DRUG PRODUCTS

Old section No.	Section name	New section No.
General Provisions:		
333.1	Scope	333.401
333.3	Definitions Active Ingredients	333.403
333.20	Antimicrobial Soap	Deleted
333.30	Patient Preoperative Skin Preparation	333.410
333.50	Surgical Hand Scrub Labeling	333.410
333.80	Antimicrobial Soap	Deleted
333.85	Health-Care Personnel Handwash	333.455
333.87	Patient Preoperative Skin Preparation	333.460
333.97	Surgical Hand Scrub	333.465
333.99	Professional Labeling	Deleted

In addition, a number of format changes have been made that are consistent with the format used in recently published tentative final and final monographs.

2. The agency is proposing the term "antiseptic" as the general statement of identity for the product categories of patient preoperative skin preparation, surgical hand scrub, and health-care personnel handwash drug products. The agency is also providing manufacturers the option to provide alternative statements of identity describing only the specific intended use of the product, e.g., surgical hand scrub. When the term "antiseptic" is used as the only statement of identity on a single-use or a multiple-use product, the intended use(s) is to be included as part of the indications. For multiple use products the agency proposes that a statement of the intended use(s) should also precede the specific directions for each use. (See section I.B., comment 3.)

3. The agency is proposing that the statement of identity "antiseptic handwash" may also be used for a health-care personnel handwash. The agency is proposing to expand the indications proposed for health-care personnel handwash drug products in the previous tentative final monograph to read, "Handwash to help reduce bacteria that potentially can cause disease" or "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.") The agency is also proposing "recommended for repeated use" as another allowable indication for this product class. (See section I.B., comment 5.)

4. The agency has replaced the previously proposed definition of an antimicrobial (active) ingredient with a definition of an "antiseptic" drug that is consistent with the definition of an antiseptic in section 201(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(o)). The agency is also including a definition for a health-care

antiseptic as follows: "An antiseptic containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination." The agency has also proposed revised definitions for patient preoperative skin preparations and surgical hand scrubs that reflect the agency's proposed effectiveness criteria for these products. (See section I.N., comment 28.) In addition, the agency has made minor revisions in the definitions of a health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub to reflect the revised terminology being used in this amended tentative final monograph.

5. The agency is adding to this amended tentative final monograph a definition of broad spectrum activity as follows: A properly formulated drug product, containing an ingredient included in the monograph, that possesses in vitro activity against the micro-organisms listed in § 333.470(a)(1)(ii), as demonstrated by in vitro minimum inhibitory concentration determinations conducted according to methodology established in § 333.470(a)(1)(ii). The agency is proposing to include "broad spectrum" in the definitions of the three product classes included in this tentative final monograph. (See section I.C, comment 6.)

6. The agency has reviewed the *Other Allowable Statements* proposed in the previous tentative final monograph in § 333.85 for health-care personnel handwash, in § 333.87 for patient preoperative skin preparation, and in § 333.97 for surgical hand scrub and determined that statements such as "contains antibacterial ingredient(s)," "contains antimicrobial ingredient(s)," and "non-irritating," are not related in a significant way to the safe and effective use of these products and are not necessary on products intended primarily for health-care professionals. Therefore, the agency is not including these statements in this amended tentative final monograph. The statement "recommended for repeated use," proposed for a health-care personnel handwash, has been included as an "other allowable indication" in proposed § 333.455. The terms "broad spectrum" and "fast acting" are included in the definitions of all three product classes and the agency does not see the need to include this information in the required labeling. (See section I.D., comment 7.)

7. The agency is proposing revised indications for patient preoperative skin preparations in order to more precisely describe the intended uses of these products. The previous indications "kills micro-organisms," "antibacterial," and "antimicrobial" are not being included. Likewise, the indications "kills micro-organisms," "bacteriostatic," and "bactericidal" previously proposed for surgical hand scrubs are not being included in this amended tentative final monograph. The agency believes that these terms are product attributes and not indications for use and should not be included as indications in the labeling of these products.

8. Based on the recommendations of the Miscellaneous External Panel in the advance notice of proposed rulemaking for OTC alcohol drug products (47 FR 22324 at 22332), the agency is proposing "for preparation of the skin prior to an injection" as an indication for OTC alcohol and isopropyl alcohol drug products.

9. The agency is proposing in § 333.450(c) of this amended tentative final monograph the following general warning statements for all health-care antiseptic drug products:

(1) "For external use only."

(2) "Do not use in the eyes."

(3) "Discontinue use if irritation and redness develops. If condition persists for more than 72 hours consult a doctor." The agency is further proposing that the second sentence of the proposed warning in (3) above may be deleted for products labeled "For Hospital and Professional Use Only." (See section I.D., comment 8.) In addition to the general warnings proposed for OTC health-care antiseptic drug products, the agency is proposing the following warning for patient preoperative skin preparations containing isopropyl alcohol identified in § 333.412(d): "Do not use this product with electrocautery procedures." The proposed warning is based on reports of burns associated with the use of isopropyl alcohol containing patient preoperative skin preparations with electrocautery procedures. (See section II.A., paragraph 1—Summary of Ingredient Categories.)

10. Based on its review of the published literature (Refs. 1, 2, and 3), the agency has determined that the way in which health-care antiseptic drug products are used, *e.g.*, method of application, duration of scrub or wash, or use in conjunction with a device (such as a scrub brush), contributes to the effectiveness of these drug products. Therefore, instead of proposing directions for use of these products that include fixed scrub or wash durations or methods of application, the agency is proposing in §§ 333.455(c), 333.460(d), and 333.465(c) directions for use that reflect the conditions used when the antiseptic product was tested according to § 333.470(b). In addition, based on data indicating that the largest bioburden of the hands lies in the subungual region (Ref. 4), the agency is proposing that the directions for use of surgical hand scrub drug products include the following instructions for the trimming and cleansing of the nails: "Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge."

References

(1) Ayliffe, G.A.J., "Surgical Scrub and Skin Disinfection," Infection Control, 5:23–27, 1984.

(2) Maki, D.G., "The Use of Antiseptics for Handwashing by Medical Personnel," *Journal of Chemotherapy*, 1:3–11, 1989.

(3) Ojajarvi, J., "Effectiveness of Hand Washing and Disinfection Methods in Removing Transient Bacteria After Patient Nursing," *Cambridge University Journal of Hygiene*, 85:193–203, 1980.

(4) Leyden, J. *et al.*, "Subungual Bacteria of the Hand: Contribution to the Glove Juice Test; Efficacy of Antimicrobial Detergents," *Infection Control Hospital Epidemiology*, 10:451–454, 1989.

11. The agency is aware that some manufacturers provide technical information relating to the antimicrobial activity of their health-care antiseptic drug products in the form of technical information bulletins. The agency considers such bulletins to be labeling under the provisions of the act. Section 201(m) of the act (21 U.S.C. 321(m)) defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of the containers or wrappers, or (2) accompanying such article." As labeling, technical information bulletins are subject to the OTC drug review.

The agency has no objection to the inclusion of technical information relating to the antimicrobial activity of these OTC drug products in the labeling of products intended for health-care professionals only. Therefore, in this amended tentative final monograph the agency is proposing that manufacturers have the option of including data derived from the in vitro and clinical effectiveness tests included in § 333.470 of the proposed monograph as additional labeling for products labeled and marketed "For Hospital and Professional Use Only." In order that such additional information provide a standardized comparison of the effectiveness of these OTC drug products, the agency is further proposing that only data on the antimicrobial activity of these OTC drug products derived from the effectiveness tests included in § 333.470 of this

proposed monograph be included in the labeling of these OTC drug products. At the present time, claims of product effectiveness against organisms other than those included in § 333.470(a)(1)(ii) will require an NDA containing information supporting the deviation from the monograph in accord with § 330.11.

12. Based on the wound healing data from studies of test wounds in laboratory animals that were discussed in the first aid antiseptic segment of this amended tentative final monograph (comment 37, 56 FR 33644 at 33662), the agency has reevaluated the labeling for iodine tincture as a patient preoperative skin preparation and is not including the warning "Do not apply this product with a tight bandage, as a burn may result."

13. The agency has determined that data and reports have not provided specific evidence that repeated use of health-care antiseptics has brought about overgrowth of gram-negative bacteria, particularly *Pseudomonas*. Therefore, the previously proposed caution in § 333.99(a) concerning this overgrowth is not being included in this amended tentative final monograph. (See section I.D, comment 9.) The warnings proposed in § 333.99 (b) and (c) of the previous tentative final monograph are not being included in this amendment because these warnings apply to quaternary ammonium compounds which currently are not Category I for health-care antiseptic uses. (See section I.J., comment 20.)

14. The agency is not including the warning proposed by the Miscellaneous External Panel in § 333.98(c)(2) for products containing isopropyl alcohol, "Use only in a well-ventilated area; fumes may be toxic." As discussed in section II.B., paragraph 32 of the segment of this rulemaking covering first aid antiseptics (56 FR 33644 at 33556), the agency invites comment on the need for such a warning, including any reports of adverse reactions due to inhalation that have not yet been brought to the agency's attention.

15. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments to these proposals, the agency has determined that final monographs and any applicable OTC drug regulations will give manufacturers the option of using the word "physician" or the word "doctor." This amended tentative final monograph proposes that option in § 333.450(e).

16. Based on the withdrawal of the majority of the comments on chlorhexidine gluconate as a health-care antiseptic, sufficient data upon which to make a safety and effectiveness determination are no longer present in the rulemaking. (See section I.F., comment 11.)

17. The agency has reviewed the data submitted on chloroxylenol and is classifying chloroxylenol 0.24 percent to 3.75 percent as Category I for safety and Category III for effectiveness for short-term use (patient preoperative skin preparation) and Category III for both safety and effectiveness for long-term uses (antiseptic handwash or health-care personnel handwash and surgical hand scrub). (See section I.G., comment 12.)

18. In § 333.30(a) of the previous tentative final monograph, the agency included United States Pharmacopeia (U.S.P.) specifications for iodine tincture and topical solution. In this amended tentative final monograph, the agency is identifying these Category I patient preoperative products as iodine tincture U.S.P. and iodine topical solution U.S.P.

19. The agency has reviewed the submitted data on hexachlorophene and concludes that the data do not address the safety concerns expressed by the Antimicrobial I Panel on this ingredient. Therefore, the agency is proposing that hexachlorophene remain available by prescription only. (See section I.H., comment 13.)

20. The agency has evaluated a "mixed iodophor" consisting of iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate and found it to be safe for use as a surgical hand scrub and health-care personnel handwash, but there are insufficient data available to determine its effectiveness for these uses. Therefore, it is being classified in Category III. (See section I.I., comment 15.) The other iodine-surfactant complexes classified by the Antimicrobial I Panel remain in Category III for health-care uses due to a lack of data.

21. The agency is including povidone-iodine 5 to 10 percent as a Category I health-care antiseptic ingredient for use as a surgical hand scrub, patient preoperative skin preparation, and antiseptic handwash or health-care personnel handwash. (See section I.I., comment 17.) As discussed in section I.I., comment 16, the agency is not including the warning about the interaction of iodophors and starch-containing compounds proposed in comment 66 of the previous tentative final monograph (43 FR 1221). The agency is also not including professional labeling to limit the molecular weight of povidone-iodine or special warnings related to the molecular weight of povidone-iodine. (See section I.I., comment 18.)

22. The agency has evaluated the data submitted on benzalkonium chloride and determined that the data are not sufficient to establish the efficacy of this ingredient as a patient preoperative skin preparation. (See section I.J., comment 20.) No data were received on other health-care uses of this ingredient or health-care uses of the two other quaternary ammonium compounds (benzethonium chloride and methylbenzethonium chloride) classified by the Antimicrobial I Panel. Accordingly, quaternary ammonium compounds remain in Category III as health-care antiseptics.

23. The agency has reviewed data submitted on sodium oxychlorosene, an ingredient not previously classified for OTC topical antiseptic use, and is placing this ingredient in Category III for both safety and effectiveness. (See section I.K., comment 22.)

24. The agency has reclassified triclosan up to 1 percent from Category II to Category III as a health-care antiseptic for use as a patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub. While submitted data indicate that triclosan—when properly formulated—may be effective, data that meet the criteria described in section I.N., comment 28 are needed to establish effectiveness. In addition, based upon submitted safety data and other information, the agency has reclassified the ingredient from Category III to Category I for safety for short-term use as a patient preoperative skin preparation. Triclosan remains classified in Category III for long-term use (antiseptic handwash or health-care personnel handwash and surgical hand scrub). (See section I.L., comment 23.)

25. The agency is proposing a number of Category I health-care antiseptic ingredients in this document. All of the ingredients included in this proposal as Category I health-care antiseptic ingredients are standardized and characterized for quality and purity and are included as articles in the current United States Pharmacopeia or National Formulary (U.S.P./N.F.) (Ref. 1). However, a number of other ingredients being considered in this rulemaking, *e.g.*, triclosan and triclocarban are not listed in the U.S.P./N.F. For an active ingredient to be included in an OTC

drug final monograph, in addition to information demonstrating safety and effectiveness, it is necessary to have publicly available sufficient chemical information that can be used by all manufacturers to determine that the ingredient is appropriate for use in their products.

The agency believes that it would be appropriate for parties interested in upgrading nonmonograph ingredients to monograph status to develop with the United States Pharmacopeial Convention appropriate standards for the quality and purity of health-care antiseptic ingredients that are not already included in official compendia. However, should interested parties fail to provide necessary information so that appropriate standards may be established, ingredients otherwise eligible for monograph status will not be included in the final monograph.

Reference

(1) "United States Pharmacopeia XXII—National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, 1989, pp. 34, 703, 731, and 1119.

26. The agency is proposing testing requirements for patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub drug products in § 333.470 of this tentative final monograph. As part of the effectiveness criteria for a patient preoperative skin preparation, the agency is proposing new testing requirements for products labeled with the proposed indication "for the preparation of the skin prior to an injection." (See section I.N., comment 28.)

27. The agency acknowledges that deodorancy is considered a cosmetic claim. However, some deodorant soap products also bear antimicrobial claims. The agency stated in comment 10 of the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33648) that deodorant soap products making antimicrobial claims are considered to be drugs and that the testing guidelines for antimicrobial claims would be addressed in this rulemaking. Any deodorant soap product containing a monograph ingredient may be labeled with antimicrobial claims provided the product meets the testing requirements for health-care antiseptic drug products or surgical hand scrubs as described under proposed § 333.470.

The agency stated in the previous tentative final monograph for topical antimicrobial drug products (43 FR 1210 at 1244) that actual claims of deodorancy should correlate the microbial reduction achieved in a modified Cade handwashing test to an "adequately designed and executed deodorancy test, such as controlled sniff test." Several comments to that proposal objected to such a correlation of deodorancy and microbial reduction. However, none of the comments provided satisfactory data to enable the agency to include any test in a monograph as a standard for deodorancy due to antimicrobial activity. Specific testing for antimicrobial claims for deodorancy has not yet been developed. The agency intends to review any comments or methods submitted for such a purpose in response to this publication and invites comments and data on this topic.

28. The Panel's evaluation of OTC topical antimicrobial drug products did not include an evaluation of the use of these products by the food industry as hand sanitizers or dips. Historically, hand sanitizers and dips have been marketed as hand cleansers for use by food handlers in federally inspected meat and poultry processing plants and in food handling establishments. Regulation of these products has been under the jurisdiction of the U. S. Department of Agriculture. However, it has come to the agency's attention that many of these products include label claims that the agency considers drug claims, *i.e.*, "antibacterial handwash," "kills germs and bacteria on contact," or "effectively reduces bacterial flora of the skin". (See comment 10 of the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33648).) Examination of the labeling of these products (Ref. 1) has led the agency to conclude that the intended use of these products, *i.e.*, the reduction of micro-organisms on human skin for the purpose of the prevention of disease caused by contaminated food, makes them drugs under the provisions of the act. Section 201(g)(1) of the act (21 U.S.C. 321(g)(1)) defines a "drug" as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man * * *."

The safety and effectiveness of active ingredients in these products for drug use needs to be demonstrated. Therefore, the agency is including evaluation of the safety and effectiveness of topical antimicrobial active ingredients indicated for use as hand sanitizers or dips in the rulemaking for OTC topical antimicrobial drug products. Accordingly, the agency invites the submission of data, published or unpublished, and any other information pertinent to the use of topical antimicrobial ingredients in hand sanitizers or dips. The agency also invites comment on applicable effectiveness standards for these products. These data and information will facilitate the agency's review and aid in its determination as to whether these OTC drug products for human use are safe, effective, and not misbranded under their recommended conditions of use. This evaluation will provide all interested parties an opportunity to present for consideration the best data and information available to support the stated claims for these products. The agency suggests that all submissions be in the format described in 21 CFR 330.10(a)(2).

In order to be eligible for review under the OTC drug review procedures, the ingredient must have been marketed in a hand sanitizer or dip to a material extent and for a material time (21 U.S.C. 321(p)(2)). The submission of data should include information that demonstrates that the ingredient(s) has been marketed as a hand sanitizer or dip to a material extent and for a material time. Products with ingredients under consideration in the OTC drug review may be marketed (at the same dosage strength and in the same dosage form) under the manufacturer's good faith belief that the product is generally recognized as safe and effective and not misbranded and in accord with FDA's enforcement policies related to the OTC drug review. (See FDA's Compliance Policy Guides 7132b.15 and 7132b.16.) Such products are marketed at the risk that the agency may adopt a position requiring relabeling, recall, or other regulatory action.

The agency notes that antimicrobial hand sanitizers/dips marketed for use in food handling/processing are typically labeled for a variety of other antimicrobial uses that may include various animal "drug" uses and the disinfection of inanimate objects. These other uses of hand sanitizer or dips will not be included in the agency's evaluation as part of this rulemaking.

Reference

(1) Labeling for hand sanitizer products, in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

29. The agency is proposing to remove a portion of § 369.21 applicable to OTC health-care antiseptic drug products when the final monograph eventually becomes effective because a portion of the regulations will be superseded by the final monograph. The item proposed for removal is the entry for "ALCOHOL RUBBING COMPOUND" in § 369.21.

III. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order

12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule increases the number of ingredients tentatively classified as generally recognized as safe and effective for use in OTC health-care antiseptic drug products from the previous proposal and, if finalized as proposed, would reduce the need for further safety and effectiveness testing for a number of health-care antiseptic drug products. The detailed testing procedures included in the proposed rule should assist manufacturers of products containing ingredients not included in the proposed monograph, due to a lack of demonstrated effectiveness, in performing the tests that would demonstrate effectiveness so the ingredients can be included in the final rule. The testing procedures will also provide manufacturers guidance on testing requirements for regulatory compliance. Products that contain ingredients for which safety and effectiveness are not established will require reformulation. The proposed monograph includes ingredients that may be used if reformulation becomes necessary. All products will need some relabeling. One year will be provided from the date of publication of the final rule for any necessary relabeling or reformulation. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC health-care antiseptic drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulation. Comments regarding the impact of this rulemaking on OTC health-care antiseptic drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on health-care antiseptic drug products, a period of 180 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before December 14, 1994, submit to the Dockets Management Branch, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before December 14, 1994. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before June 19, 1995, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before August 17, 1995. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch. Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on August 17, 1995. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

Therefore, the agency is proposing to amend 21 CFR part 333 by adding new subpart E, consisting of §§ 333.401 through 333.470, and to amend 21 CFR part 369 by amending § 369.21 in order to establish conditions under which OTC health-care antiseptic drug products are generally recognized as safe and effective and not misbranded.

List of Subjects

21 CFR Part 333

Labeling, Over-the-counter drugs, Incorporation by reference.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 333 and 369 be amended as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 333 is revised to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. New subpart E, consisting of §§ 333.401 through 333.470, is added to read as follows:

Subpart E—Health-Care Antiseptic Drug Products

Sec.

Subpart E—Health-Care Antiseptic Drug Products

§ 333.401 Scope.

(a) An over-the-counter health-care antiseptic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each of the general conditions established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.403 Definitions.

As used in this subpart:

(a) *Antiseptic drug.* In accordance with section 201(o) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(o)), "The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

(b) *Broad spectrum activity.* A properly formulated drug product, containing an ingredient included in the monograph, that possesses in vitro activity against the micro-organisms listed in § 333.470(a)(1)(ii), as demonstrated by in vitro minimum inhibitory concentration determinations conducted according to methodology established in § 333.470(a)(1)(ii).

(c) *Health-care antiseptic.* An antiseptic containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination.

(1) *Antiseptic handwash or health-care personnel handwash drug product.* An antiseptic containing preparation designed for frequent use; it reduces the number of transient micro-organisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is broad spectrum, fast acting and, if possible, persistent.

(2) *Patient preoperative skin preparation drug product.* A fast acting, broad spectrum, and persistent antiseptic containing preparation that significantly reduces the number of micro-organisms on intact skin.

(3) *Surgical hand scrub drug product.* An antiseptic containing preparation that significantly reduces the number of micro-organisms on intact skin; it is broad spectrum, fast acting, and persistent.

§ 333.410 Antiseptic handwash or health-care personnel handwash active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient properly formulated to meet the test requirements in § 333.470, and the product is labeled according to §§ 333.450 and 333.455:

(a) Alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR part 20; or

(b) Povidone-iodine 5 to 10 percent.

§ 333.412 Patient preoperative skin preparation active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient properly formulated to meet the test requirements in § 333.470, and the product is labeled according to §§ 333.450 and 333.460:

(a) Alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR part 20;

(b) Iodine tincture U.S.P.;

(c) Iodine topical solution U.S.P.;

(d) Isopropyl alcohol 70 to 91.3 percent by volume in an aqueous solution; and

(e) Povidone-iodine 5 to 10 percent.

§ 333.414 Surgical hand scrub active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient properly formulated to meet the test requirements in § 333.470, and the product is labeled according to §§ 333.450 and 333.465:

(a) Alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR part 20; or

(b) Povidone-iodine 5 to 10 percent.

§ 333.420 Permitted combinations of active ingredients.

[Reserved]

§ 333.450 Labeling of health-care antiseptic drug products.

(a) *Statement of identity.* The labeling of a single-use product contains the established name of the drug, if any, and identifies the product as an "antiseptic" and/or with the appropriate statement of identity described in §§ 333.455(a), 333.460(a), or 333.465(a). The labeling of a multiple-use product contains the established name of the drug, if any, and may use the single statement of identity "antiseptic" and/or the appropriate statements of identity described in §§ 333.455(a), 333.460(a), and 333.465(a). When "antiseptic" is used as the only statement of identity on a single-use or a multiple-use product, the intended use(s), such as patient preoperative skin preparation, is to be included under the indications. For multiple-use products, a statement of the intended use should also precede the specific directions for each use.

(b) *Indications.* The labeling of a single use antiseptic drug product contains the labeling identified in §§ 333.455, 333.460, or 333.465, as appropriate. Multiple-use products contain the labeling from any two or all three of §§ 333.455, 333.460, and 333.465. Indications, warnings, and directions applicable to each intended use of the product may be combined to eliminate duplicative words or phrases so that the resulting indications, warnings, and directions are clear and understandable.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only."

(2) "Do not use in the eyes."

(3) "Discontinue use if irritation and redness develop. If condition persists for more than 72 hours consult a doctor."

(4) *For products containing any ingredient identified in §§ 333.410(a), 333.412(a) and (d), and 333.414(a).* The following statement shall immediately follow the heading "Warnings": "Flammable, keep away from fire or flame." [sentence in boldface type]

(d) The second sentence of the warning in paragraph (c)(3) of this section may be omitted from the labeling of products labeled "For Hospital and Professional Use Only."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in §§ 333.455, 333.460, and 333.465.

(f) *Optional labeling information.* Technical information relating to the antimicrobial activity of products that is limited to data derived from the in vitro and clinical effectiveness tests included in § 333.470 may be included as

additional labeling for products labeled for "Hospital and Professional Use Only."

§ 333.455 Labeling of antiseptic handwash or health-care personnel handwash drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiseptic," as stated above under § 333.450(a), and/or "antiseptic handwash," or "health-care personnel handwash."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph that are applicable to the product. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products labeled as a health-care personnel handwash.* "Handwash to help reduce bacteria that potentially can cause disease" or "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.")

(2) *For products labeled as an antiseptic handwash.* "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.")

(3) *Other allowable indications for products labeled as either antiseptic or health-care handwash.* The labeling of the product may also contain the following phrase: "Recommended for repeated use."

(c) *Directions.* The labeling of the product contains the following statements, under the heading "Directions," that reflect the conditions used when the product was tested according to § 333.470(b)(2):

(1) *For products to be used with water.* "Wet hands and forearms. Apply 5 milliliters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for" (insert wash duration used when tested according to § 333.470(b)(2)). (Insert any applicable statements about also using a device, such as a scrub brush.) "Rinse and repeat."

(2) *For products to be used without water.* "Place a 'palmful' (5 grams) of product in one hand. Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes). Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds)" or "Wet hands thoroughly with product and allow to dry without wiping."

§ 333.460 Labeling of patient preoperative skin preparation drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiseptic," as stated under § 333.450(a), and/or "patient preoperative skin preparation."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in paragraph (b) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing ingredients identified in § 333.412 (a), (b), (c), and (e).* (i) "For preparation of the skin prior to surgery."

(ii) "Helps reduce bacteria that potentially can cause skin infection."

(2) *For products containing alcohol identified in § 333.412(a).* In addition to the indications listed in § 333.460(1), the labeling may also include the statement "For preparation of the skin prior to an injection."

(3) *For products containing isopropyl alcohol identified in § 333.412(d).* "For preparation of the skin prior to an injection."

(c) *Warnings.* For products containing 70 percent or more isopropyl alcohol the following warning shall immediately follow the warning statement in § 333.450(c)(4): "Do not use with electrocautery procedures."

(d) *Directions.* The labeling of the product contains the following statements, under the heading "Directions," that reflect the conditions used when the product was tested according to § 333.470(b)(3):

(1) *For products containing any ingredient identified in § 333.412(a), (d), and (e) that are intended to remain on the skin after application.* "Clean the area. Apply product to the operative site prior to surgery" (insert method of application, including any device used, when tested according to § 333.470 (b)(3).) If appropriate, insert "Dry and repeat procedure."

(2) *For products containing any ingredient identified in § 333.412(b) or (c) that are intended to be removed from the skin after application.* "Apply product to the operative site prior to surgery" (insert method of application, including any device used, when tested according to § 333.470(b)(3).) "When product dries, remove immediately with 70 percent alcohol, or use as directed by a physician."

§ 333.465 Labeling of surgical hand scrub drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiseptic," as stated above under § 333.450(a), and/or "surgical hand scrub."

(b) *Indication.* The labeling of the product states, under the heading "Indication," the following: "Significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Directions.* The labeling of the product contains the following statements, under the heading "Directions," that reflect the conditions used when the product was tested according to § 333.470(b)(1):

(1) *For products to be used with water.* "Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge. Wet hands and forearms. Apply 5 milliliters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for (insert scrub duration used when tested according to § 333.470(b)(1)) "with a sterile" (insert applicable device), "paying particular attention to the nails, cuticles, and interdigital spaces. Rinse and repeat scrub" (if applicable, insert instructions for second scrub used when

tested according to § 333.470(b)(1), if different from the first).

(2) *For products to be used without water.* "Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge. Place a 'palmful' (5 grams) of product in one hand. Spread on both hands, paying particular attention to the nails, cuticles, and interdigital spaces, and rub into the skin until dry (approximately 1 to 2 minutes). Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds)."

§ 333.470 Testing of health-care antiseptic drug products.

(a) *General testing criteria.* The procedures in this section are designed to characterize the effectiveness of antiseptic drug products formulated for use as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub. Requests for any modifications of the testing procedures in this section or alternative assay methods are to be submitted in accordance with paragraph (d) of this section.

(1) *In vitro testing.* The following tests must be performed using the antiseptic ingredient, the vehicle, and the finished product for all drug product classes:

(i) Determine the in vitro antimicrobial spectrum of the active ingredient, the vehicle, and the final formulation using both standard cultures and recently isolated strains of each species. A series of recently isolated mesophilic strains, including members of the normal flora and cutaneous pathogens (50 isolates of each species, half of which must be fresh clinical isolates), are to be selected.

(ii) Determine the minimal inhibitory concentrations (MIC) using methodology established by the National Committee for Clinical Laboratory Standards and entitled "Methods for Dilution Antimicrobial Susceptibility Test for Bacteria that Grow Aerobically," Document M7–A2, 2d ed., 10:8, 1990, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Committee for Clinical Laboratory Standards, 771 East Lancaster Ave., Villanova, PA 19085, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Twenty-five fresh clinical isolates and 25 laboratory strains of the organisms listed in this section are to be included. All in vitro tests must include the American Type Culture Collection (ATCC) reference strains (available from American Type Culture Collection, 12301 Parklawn Dr., Rockville, MD 20852) specified in paragraphs (a)(1)(ii)(A) and (a)(1)(ii)(B) of this section. The agency requires that these organisms be used in testing unless data can be presented to the agency that other organisms are equally representative of organisms associated with nosocomial infection. There must be no claims, either direct or by implication, that a product has any activity against an organism or that it reduces the number of organisms for which it has not been tested. The following organisms are to be included (note: special media and environmental conditions may be required):

(A) *Gram negative organisms: Acinetobacter* species; *Bacteroides fragilis*; *Haemophilus influenza*; *Enterobacter* species; *Escherichia coli* (ATCC Nos. 11229 and 25922); *Klebsiella* species, including *Klebsiella pneumonia*; *Pseudomonas aeruginosa* (ATCC Nos. 15442 and 27853); *Proteus mirabilis*; and *Serratia marcescens* (ATCC No. 14756).

(B) *Gram positive organisms*: Staphylococci: *Staphylococcus aureus* (ATCC Nos. 6538 and 29213); Coagulase-negative Staphylococci: *Staphylococcus epidermidis* (ATCC No. 12228), *Staphylococcus hominis*, *Staphylococcus haemolyticus*, and *Staphylococcus saprophyticus*; *Micrococcus luteus* (ATCC No. 7468); and Streptococci: *Streptococcus pyogenes*, *Enterococcus faecalis* (ATCC No. 29212), *Enterococcus faecium*, and *Streptococcus pneumoniae*.

(C) *Yeast: Candida* species and *Candida albicans*.

(iii) Determine the possible development of resistance to the chemical. Two approaches to determining the emergence of resistance to a particular antimicrobial are to be used. The first approach involves a determination of the evolution of a point mutation by the sequential passage of an organism through increasing concentrations of the antimicrobial included in the culture medium. The second approach is a thorough survey of the published literature to determine whether resistance has been reported for the antimicrobial ingredient. The survey is to include information on the microbial contamination of marketed products containing the antimicrobial ingredient in question irrespective of drug concentration. The survey is to cover all countries in which products containing the active ingredient are marketed. Any information submitted in a foreign language should include a translation. Alternate approaches to determining the development of resistance can be submitted as a petition in accord with § 10.30 of this chapter. The petition is to contain sufficient data to show that the alternate approach provides a reliable indication of the development of resistance to a particular antimicrobial ingredient.

(iv) *Time-kill studies.* (A) The assessment of the in vitro spectrum of the antimicrobial provides information on the types of genera and species that may be considered susceptible under the conditions of the test procedure described in paragraph (a)(1)(ii) of this section. However, information is also required that allows an assessment of how rapidly the antimicrobial product produces its effect. Such information may be derived from in vitro time-kill curve studies using a selected battery of organisms and a specified drug concentration.

(B) The satisfactory performance of the test product as assessed by the results of the MIC studies, the time-kill studies, and the simulated in vivo clinical trials of organisms representing the resident microbial flora can then be used to assess the effectiveness of the test product for the transient microbial flora most commonly encountered in the clinical setting. This procedure is required because methods, other than the health-care personnel hand test, do not exist for assessing the in vivo effectiveness of test products versus the transient microbial flora.

(C) It is recognized that a generally accepted or standardized method that may be used in conducting in vitro time-kill studies is not available, but the agency encourages the submission of proposed methods that may be considered applicable to this test. Many variables that should be considered in the development of a method have been addressed for antibiotics and are also applicable to these products. Such variables are described by Schoenknecht, F. D., L. D. Sabath, and C. Thornsberry, "Susceptibility Tests: Special Tests," in the "Manual of Clinical Microbiology," 4th ed., edited by E. H. Lennette et al., American Society for Microbiology, Washington, pp. 1,000–1,008, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Society for Microbiology, Washington, DC, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North

Capitol St. NW., suite 700, Washington, DC.

(D) The procedure to be used is to incorporate the recommendations described on page 1,004 of the chapter in the "Manual of Clinical Microbiology" cited in paragraph (a)(1)(iv)(C) of this section with the following modifications. Because the time frames of greatest interest for antiseptic drug products intended for health-care personnel handwash, surgical hand scrub, and patient preoperative skin preparation use are 1 to 30 minutes, the time-kill studies are to focus on these time frames and are to include enumerations at times 0, 3, 6, 9, 12, 15, 20, and 30 minutes. Enumerate the bacteria in the sampling solution by a standard plate count procedure such as that described in "Standard Methods for the Evaluation of Dairy Products" (available from American Public Health Association, Inc., 1015 15th St. NW., Washington, DC 20005), but using soybean-casein digest agar and a suitable inactivator for the antimicrobial where necessary. The suitability of the inactivator is to be demonstrated using a procedure such as described in E 1054, "Test Methods for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research (HFD–810), 5600 Fishers Lane, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. The battery of organisms selected is to represent the resident microbial flora most commonly encountered under actual use conditions of the test product and the transient microbial flora most likely to be encountered by health-care professionals in clinical settings. Therefore, the micro-organisms to be used in these time-kill studies are to be the standard ATCC strains identified in paragraph (a)(1)(ii) of this section. The drug concentration to be tested should be a tenfold dilution of the finished product.

(2) *In vivo testing.* The following tests, approximating use conditions for the clinical evaluation of each label claim of the finished product, are to be carried out using the finished product for the product classes specified.

(i) Test method for the evaluation of surgical hand scrub drug products. The procedure to be used (paragraph (b)(1)(iii) of this section) is a modification of the standard testing procedure for the evaluation of surgical hand scrub drug products published by the American Society for Testing and Materials, "Standard Method for Evaluation of Surgical Hand Scrub Formulation, Designation E 1115," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 201–204, 1986, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(ii) Test method for the evaluation of health-care antiseptic handwash or health-care personnel handwash drug products. The procedure to be used (paragraph (b)(2)(iii) of this section) is a modification of the standard testing procedure for the evaluation of health-care antiseptic handwash drug products published by the American Society for Testing and Materials, "Standard Method for the Evaluation of Health Care Handwash Formulation, Designation E1174," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 209–212, 1987, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(iii) Test method for the evaluation of patient preoperative skin preparation drug products. The procedure to be used (paragraph (b)(3)(iii) of this section) is a modification of the standard testing procedure for the evaluation of patient preoperative skin preparations published by the American Society for Testing and Materials, "Standard Test Method for the Evaluation of a Patient Preoperative Skin Preparation, Designation 1173," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 205–208, 1987, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b) *Specific testing criteria*—(1) *Effectiveness testing of a surgical hand scrub.* A surgical hand scrub drug product in finished form suitable for topical application will be recognized as effective provided that the formulated drug product at its recommended use concentration:

(i) Contains an ingredient in § 333.414 (a) or (b).

(ii) Demonstrates in vitro activity against organisms as described in paragraph (a)(1)(ii) of this section.

(iii) When tested, in vivo, by the test procedure for the evaluation of surgical hand scrub drug products in paragraph (b)(1)(iii) of this section, reduces the number of bacteria 1-$\log_{10}$ on each hand within 1 minute and the bacterial cell count on each hand does not subsequently exceed baseline within 6 hours on the first day, and produces a 2-$\log_{10}$ reduction of the microbial flora on each hand within 1 minute of product use by the end of the second day of enumeration, and a 3-$\log_{10}$ reduction of the microbial flora on each hand within 1 minute of product use by the end of the fifth day when compared to the established baseline.

(A) *Apparatus*—(*1*) *Colony Counter.* Any of several types may be used.

(*2*) *Incubator.* Any incubator capable of maintaining a temperature of 30±2 °C may be used.

(*3*) *Sterilizer.* Any suitable steam sterilizer capable of producing conditions of sterility is acceptable.

(*4*) *Timer (stop clock).* A timer that can be read in minutes and seconds.

(*5*) *Hand washing sink.* A sink of sufficient size to permit panelists to wash without touching hands to sink surface or other panelists.

(*6*) *Water faucet(s).* Water faucets should be located above the sink at a height that permits the hands to be held higher than the elbows during the washing procedure. (It is desirable for the height of the faucets to be adjustable.)

(*7*) *Tap water temperature regulator and temperature monitor.* Device(s) to monitor and regulate water temperature to 40±2 °C.

(B) *Materials and reagents*—(*1*) *Petri dishes.* Petri dishes for performing standard plate count should be 100 by 15 millimeters.

(2) *Bacteriological pipets.* Pipets of 10.0 and 2.2 or 1.1 milliliter capacity are recommended.

(3) *Water-dilution bottles.* Any sterilizable glass container having a 150 to 200 milliliter capacity and tight closures may be used.

(4) *Baseline control soap.* A liquid castile soap or other liquid soap containing no antimicrobial.

(5) *Gloves.* Sterile loose fitting gloves of latex, unlined, not possessing antimicrobial properties.

(6) *Test formulation.* Directions used to demonstrate the effectiveness of the test formulation are to be the same as those proposed for the use of the product including the use of a nail cleaner and/or brush, if indicated. If no directions are available, use directions provided in paragraph (b)(1)(iii)(J)(3) of this section.

(7) *Positive control formulation.* Any surgical hand scrub formulation approved by the Food and Drug Administration is acceptable.

(8) *Sampling solution.* (*i*) Dissolve 0.4 gram potassium phosphate, monobasic, 10.1 gram sodium phosphate, dibasic, and 1 gram Triton X–100 in 1 liter distilled water. Adjust to pH 7.8 with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide. Dispense 50 to 100 milliliter volumes into water dilution bottles, or other suitable containers, and sterilize for 20 minutes at 121 °C. Include in the sampling solution used to collect bacterial samples from the hand following the final wash with the test formulation an antimicrobial inactivator specific for the test formulation being evaluated.

(*ii*) A definitive recommendation regarding the inclusion of an inactivator prior to the final wash cannot be made. The questions of whether residual neutralizer on the skin will reduce the effectiveness of the test formulation in subsequent washes and result in higher than expected bacterial counts and whether or not samples can be processed rapidly enough to avoid a decreased bacterial count due to the continued action of the test formulation should be considered when the decision concerning the use of a neutralizer in sampling solutions used for bacterial collection prior to the final wash is made. Whatever the decision, to facilitate the comparison of results across studies, the investigator is to indicate whether or not a neutralizer has been included.

(9) *Dilution fluid.* Butterfield's phosphate buffered water adjusted to pH 7.2 and containing an antimicrobial inactivator specific for the test formulation. Adjust pH with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide.

(10) *Soybean-casein digest agar.* Supplemental polysorbate 80 (0.5 to 10 grams/liter) is to be added to the agar to stimulate the growth of lipophilic organisms. A suitable antimicrobial inactivator is also to be added.

(11) *Fingernail cleaning sticks.*

(12) *Sterile hand brushes (required only if specified for use with test formulation).* Products that specify the use of a device in conjunction with the antimicrobial are to include this information in the product labeling. The device is an integral part of the study. If gauze is to be used, then the product labeling is to reflect this condition of use.

(C) *Test panelists.* Panelists shall consist of healthy adult male and female volunteers who have no evidence of dermatosis, have not received antibiotics or taken oral contraceptives 2 weeks prior to the test, and who agree to abstain from these materials as described in paragraph (b)(1)(iii)(D)(2) of this section until the conclusion of the test.

(D) *Preparation of volunteers.* (1) At least 2 weeks prior to start of the test, enroll sufficient subjects per product being tested to satisfy the statistical criteria of the clinical trial design.

(2) Instruct the volunteers to avoid contact with antimicrobials (other than the test formulation) for the duration of the test. This restriction includes antimicrobial containing antiperspirants, deodorants, shampoos, lotions, soaps, and materials such as acids, bases, and solvents. Bathing in chlorinated pools and hot tubs is to be avoided. Volunteers are to be provided with a kit of nonantimicrobial personal care products for exclusive use during the test and rubber gloves to be worn when contact with antimicrobials cannot be avoided.

(E) *Selection of evaluable subjects.* After panelists have refrained from using antimicrobials for at least 2 weeks, perform wash with baseline control soap. Subjects are not to have washed their hands 2 hours prior to the baseline count determination. After washing, determine the first estimate of the baseline population by sampling both hands and enumerating the bacteria in the sampling solution. This is day 1 of the "baseline period." Repeat this baseline determination on days 3 and 7, days 3 and 5, or days 5 and 7 of the "baseline period" to obtain three estimates of the baseline population. Any subjects exhibiting counts greater than or equal to $1.5X10^5$ after the first and second estimates of the baseline populations are obtained can be assigned to products in accordance with the randomization plan described below. Sufficient evaluable subjects must be enrolled per arm to satisfy the statistical conditions of adequacy with at least 80 percent power and a test level of 5 percent.

(F) *Number of subjects.* The number of subjects required per arm of the study can be estimated from the following equation: $n \geq 2S^2(Z_{\alpha/2}+Z_b)^2/D^2$, where:

S^2 is your estimate of variance;

$Z_{\alpha/2}$ corresponds to the level of the test; for a 5 percent test level = 1.96;

Z_b corresponds to the power of the test; for 80 percent power = .842; and

D is the clinical difference of significance to be ruled out; say 20 percent of the active control's mean reduction from baseline at a specific time. For example, data from a number of glove juice studies submitted over the past few years to the agency as part of applications under part 314 of this chapter were reviewed to obtain information relative to the variance of the difference from baseline for count reduction data. For 128 standard deviations extracted, it was noted that 50 percent of the values are between .90 and 1.12; 25 percent are less than .90; and 25 percent are greater than 1.12. The range is from .49 to 1.73, the 25th percentile standard deviation is 0.86, the median standard deviation is 1.01, and the 75th percentile standard deviation is 1.20. The larger the standard deviation, the larger the sample size required to rule out a difference of clinical importance. Assuming that the active control surgical hand scrub produces a mean log reduction of 2.5 at hour 3 and the test hand scrub is to be within 20 percent of this, *i.e.*, D=0.5, and if S^2= 1.02, then n=64 subjects per arm of the study. Because blocks of six are recommended, the sample size per arm is 66. The S_2=1.44 corresponds to the 75th percentile in the data set. This gives a sample size of 90 subjects per arm. The total number of evaluable subjects required for a successful trial will depend upon the estimate of variance available and the number of products that need testing.

(G) *Study design.* A randomized, blinded, parallel arm design is to be used to test the products. Due to the nature of their constituents, some test surgical hand scrubs will require not only the use of an active control arm but also use of a vehicle control arm and perhaps a placebo control arm to demonstrate efficacy. The schematic layout of sampling times is given in Table 1 as follows:

TABLE 1.—SAMPLING TIMES FOR SURGICAL HAND SCRUB EFFECTIVENESS TEST

Days	Hours			
	Baseline period	1/60	3	6
Day 0	X			
Day 1		X	X	X
Day 3 or 5		X	X	X
Day 5 or 7		X	X	X

The schematic layout of randomization of subjects in blocks of 6 is given in Table 2; in Table 2, R refers to right hand and L refers to left hand as follows:

TABLE 2.—RANDOMIZATION OF SUBJECTS FOR SURGICAL HAND SCRUB EFFECTIVENESS TEST

Subjects	Hours		
	1/60	3	6
A	R	L	
B	L		R
C		L	R
D	L	R	
E	R		L
F		R	L
Total Observations.	4	4	4

Assume N evaluable subjects are enrolled (the issue of determining N, the sample size, is discussed in paragraph (b)(1)(iii)(F) of this section). First, randomly divide the N subjects into as many treatment groups as there are products to be tested (n_t). Secondly, randomize the n_t subjects within each treatment group in blocks of six subjects in accordance with the subject allocation scheme in Table 2 of paragraph (b)(iii)(G) of this section until all n_t patients are randomized to 6 hours. Repeat this process for each of the other treatment groups.

(H) *Count determinations.* No sooner than 12 hours, nor longer than 4 days after completion of their baseline determination, subjects perform the initial scrub with the test formulations. Determine the bacterial population on the randomly designated hand of all subjects assigned to hour 1/60 in Table 2 of paragraph (b)(iii)(G) of this section immediately (within 1 minute) after scrub with the appropriate scrub formulation. Determine the bacterial counts on the designated hands at 3 and 6 hours after scrub. Determine bacterial population by sampling hands and enumerating the bacteria in the sampling solution as specified in paragraphs (b)(1)(iii)(K) and (b)(1)(iii)(L) of this section. Repeat this scrubbing and sampling procedure the next day (day 2). On day 5, repeat the sampling procedure after scrubbing with the formulations two additional times on day 2 and three times per day on day 3 and day 4, with at least a 1-hour interval between scrubs. Perform one scrub on day 5, prior to sampling. In summary, the subjects scrub a total of 11 times with each formulation, once on days 1 and 5 and 3 times per day on days 2, 3, and 4. Collect bacterial samples following the single scrubs of days 1 and 5 and following the first scrub on day 2. This procedure mimics typical usage and permits determination of both immediate and longer-term reductions.

(I) *Washing technique for baseline determinations.* (*1*) Volunteers clean under fingernails with nail stick and clip fingernails to less than or equal to 2 millimeter free edge. Remove all jewelry from hands and arms.

(*2*) Rinse hands including two thirds of forearm under running tap water 38 to 42 °C for 30 seconds. Maintain hands higher than elbows during this procedure and steps outlined in paragraphs (b)(1)(iii)(I)(*3*), (b)(1)(iii)(I)(*4*), and (b)(1)(iii)(I)(*5*) of this section.

(*3*) Wash hands and forearms with baseline control soap for 30 seconds using water as required to develop lather.

(*4*) Rinse hands and forearms for 30 seconds under tap water to thoroughly remove all lather.

(*5*) Don rubber gloves used in sampling hands and secure gloves at wrist.

(J) *Surgical scrub technique to be used prior to bacterial sampling.* (*1*) Repeat procedure outlined in paragraphs (b)(1)(iii)(I)(*1*) and (b)(1)(iii)(I)(*2*) of this section.

(*2*) Perform surgical scrub with test formulation in accordance with directions furnished with the test formulation. If no instructions are provided with the test formulation, use the 10-minute scrub procedure described in paragraph (b)(1)(iii)(J)(*3*) of this section.

(*3*) Perform 10-minute scrub procedure as follows:

(*i*) Dispense formulation into hands.

(*ii*) Set and start timer for 5 minutes (time required for the steps described in paragraphs (b)(1)(iii)(J)(*3*)(*iii*) through (b)(1)(iii)(J)(*3*)(*vii*) of this section.

(*iii*) With hands, distribute formulation over hands and lower two-thirds of forearms.

(*iv*) If scrub brush is to be used, pick up with finger tips and pass under tap to wet without rinsing formulation from hands.

(*v*) Alternatively, scrub right hand and lower two-thirds of forearm and left hand and lower two-thirds of forearm.

(*vi*) Rinse both hands, the lower two-thirds of forearms, and the brush for 30 seconds.

(*vii*) Place brush in sterile dish within easy reach.

(*viii*) Repeat the timed 5 minute scrub in paragraphs (b)(1)(iii)(J)(*3*)(*iii*) through (b)(1)(iii)(J)(*3*)(*vii*) of this section so that each hand and forearm is washed twice. The second wash and rinse should be limited to the lower one-third of the forearms and the hands.

(*ix*) Perform final rinse. Rinse each hand and forearm separately for 1 minute per hand.

(*x*) Don rubber gloves used in sampling hands and secure at wrist.

(K) *Sampling techniques.* (*1*) At specified sampling times, aseptically add 50 to 100 milliliters of sampling solution to glove and hand to be sampled, and fasten glove securely above wrist.

(*2*) After adding sampling solution, uniformly massage all surfaces of hand for 1 minute, paying particular attention to the area under the nails.

(*3*) After massaging, aseptically sample the fluid of the glove. Transfer immediately a measured volume of the sample to a serial dilution tube containing a suitable antimicrobial inactivator.

(L) *Enumeration of bacteria in sampling solution.* Enumerate the bacteria in the sampling solution by a standard plate count procedure such as that described in "Standard Methods for the Evaluation of Dairy Products" (available from American Public Health

Association, Inc., 1015 15th St. NW., Washington, DC 20005) but using soybean-casein digest agar and a suitable inactivator for the antimicrobial where necessary. The suitability of the inactivator is to be demonstrated using a procedure such as described in E 1054, "Test Methods for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Prepare sample dilutions in dilution fluid. Plate in duplicate. Incubate plated sample at 30 ± 2 °C for 48 hours before reading.

(M) *Determination of reduction obtained.* (*1*) At each sampling interval, determine changes from baseline counts obtained with test material.

(*2*) For a more realistic appraisal of the activity of products, all raw data should be converted to common (base 10) logarithms. Reductions should be calculated from average of the logarithms. This will also facilitate statistical analysis of data.

(N) *Comparison of test materials with a positive control material.* (*1*) In order to validate the testing procedure, equipment, and facilities, it is required that the test formulation be compared with an active control formulation. This will require an equivalent number of panelists to be assigned to the control formulation on a random basis. All test parameters will be equivalent for both formulations, except that the scrub procedure for the established formulation may be different from that of the test formulation. Both test and control formulations are to be run concurrently. Identity of the formulations used by panelists are to be blinded from those individuals counting plates and analyzing data.

(*2*) To validate the assay, compare changes from baseline counts obtained with control material at each sampling interval.

(O) *Statistical analyses.* Either of the statistical approaches to the evaluation of the data detailed in paragraph (b)(1)(iii)(O) of this section is acceptable.

(*1*) Treat data as a binomial response. That is, if a subject achieves the target reduction, it is judged a success; if not it is a failure. A potential problem to this approach is that information may be lost. For example, if at the 1 minute time frame, a large number of subjects using one skin scrub achieve a 2-log reduction and those on the other scrub attain only a 1-log reduction, the binomial procedure will indicate both scrubs achieve the same degree of reduction. If it is believed that the binomial approach causes loss of information by not including numerical response data, then the alternate statistical analysis described in paragraph (b)(1)(iii)(0)(*2*) of this section is applicable. If the success rate is in the 90 percent range, then the variance is relatively small, sample size requirements are relatively small, and confidence intervals are reasonable. However, if the success rates drop to the 70 percent range, then relatively large sample sizes are required to obtain the same power as one gets for 90 percent success rates.

(*2*) Another option is to treat the log counts as numerical data and evaluate using the Student's t-test or similar procedure. The large variance that usually occurs with this type of data may cause problems with tests of significance and construction of confidence intervals. However, Monte Carlo techniques indicate that if entry is limited to subjects that exhibit 1.5×10^5 to 10^6 counts, then the reductions are rather homogeneous and the large variance problem is alleviated. If the variances are large, the sample size must be increased considerably to retain the same level of the test, same power, and same difference to be ruled out.

(2) *Effectiveness testing of an antiseptic handwash or health-care personnel handwash.* An antiseptic handwash or health-care personnel handwash drug product in finished form suitable for topical application will be recognized as effective provided that the formulated drug product at its recommended use concentration:

(i) Contains an ingredient in § 333.410 (a) or (b).

(ii) Demonstrates in vitro activity against organisms as described in paragraph (a)(1)(ii) of this section.

(iii) When tested, in vivo, by the test method for the evaluation of antiseptic or health-care personnel handwash drug products described in paragraph (b)(2)(iii) of this section, reduces the number of the indicator organism on each hand 2 $\log_{10}$ within 5 minutes after the first wash and demonstrates a 3-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the tenth wash.

(A) *Apparatus.*—(*1*) *Colony Counter.* Any of several types may be used.

(*2*) *Incubator.* Any incubator capable of maintaining a temperature of 25±2 °C may be used. This temperature is required to assure pigment production by the *Serratia marcescens.*

(*3*) *Sterilizer.* Any suitable steam sterilizer capable of producing conditions of sterility is acceptable.

(*4*) *Timer (stop clock).* A timer that can be read in minutes and seconds.

(*5*) *Hand washing sink.* A sink of sufficient size to permit panelists to wash without touching hands to sink surface or other panelists.

(*6*) *Water faucet(s).* Water faucet(s) should be located above the sink at a height that permits the hands to be held higher than the elbows during the washing procedure. (It is desirable for the height of the faucet(s) to be adjustable.)

(*7*) *Tap water temperature regulator and temperature monitor.* Device(s) to monitor and regulate water temperature to 40±2 °C.

(B) *Materials and reagents.*—(*1*) *Bacteriological pipets.* Pipets of 10.0 and 2.2 or 1.1 milliliter capacity are recommended.

(*2*) *Water-dilution bottles.* Any sterilizable glass container having a 150 to 200 milliliter capacity and tight closures may be used.

(*3*) *Erlenmeyer flask.* A 2-liter capacity for culturing test organism is recommended.

(*4*) *Baseline control soap.* A liquid castile soap or other liquid soap containing no antimicrobial.

(*5*) *Test formulation.* Directions used to demonstrate the effectiveness of the test formulation are to be the same as those proposed for the use of the product. If no directions are available, use directions provided in paragraph (b)(2)(iii)(H)(*5*) of this section.

(*6*) *Positive control formulation.* Any health-care personnel handwash formulation approved by the Food and Drug Administration is acceptable.

(*7*) *Gloves/bags.* Sterile loose fitting gloves of latex, unlined, possessing non-antimicrobial properties or sterile polyethylene bags are to be used.

(*8*) *Sampling solution.* Dissolve 0.4 gram potassium phosphate, monobasic, 10.1 gram sodium phosphate, dibasic, and 1 gram Triton X–100 in 1 liter distilled water. Adjust to ph 7.8 with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide. Dispense 50 to 100 milliliter volumes into water dilution bottles, or other suitable containers, and sterilize for 20 minutes at 121 °C.

(*9*) *Dilution fluid.* Butterfield's phosphate buffered water adjusted to pH 7.2 and containing an antimicrobial inactivator specific for the test formulation. Adjust pH with 0.1 Normal

hydrochloric acid or 0.1 Normal sodium hydroxide.

(*10*) *Plating medium.* Soybean-casein digest agar plus a suitable inactivator.

(*11*) *Broth.* Soybean-casein digest: 1,000 milliliters per 2-liter flask is recommended.

(C) *Test Organism.* (*1*) *Serratia marcescens* ATCC No. 14756 (available from American Type Culture Collection, 12301 Parklawn Dr., Rockville, MD 20852) is to be used as a marker organism. This is a strain having stable pigmentation.

(*2*) The application of microorganisms to the skin may involve a health risk. Prior to applying the *Serratia marcescens* strain to the skin, the antimicrobial sensitivity profile of the strain should be determined. If the strain is not sensitive to Gentamicin, do not use it. If an infection occurs, the antibiotic sensitivity profile should be made available to the attending clinician.

(*3*) Following the last contamination and wash with the test formulation, the panelists' hands are to be sanitized by scrubbing with a 70 percent ethanol solution. The purpose of this alcohol scrub is to destroy any residual *Serratia marcescens.*

(*4*) *Preparation of marker culture suspension.* From stock culture inoculate *Serratia marcescens* ATCC No. 14756 in a 2-liter flask containing 1,000 milliliters of Soybean-casein digest broth. Incubate for 24 ± 4 hours at 25 °C. Stir or shake the suspension before each aliquot withdrawal. Assay the suspension for number of organisms by membrane filtration technique or surface inoculation at the beginning and end of the use period. Do not use a suspension for more than 8 hours.

(D) *Test panelists.* Recruit a sufficient number of healthy adult male and female human volunteers who have no clinical evidence of dermatosis, open wounds, hangnail, or other skin disorders that may affect the integrity of the test, and enroll sufficient subjects per product being tested to satisfy the statistical criteria of the clinical trial design.

(E) *Preparation of volunteers.* Instruct the volunteers to avoid contact with antimicrobials (other than the test formulation) for the duration of the test. This restriction includes antimicrobial containing antiperspirants, deodorants, shampoos, lotions, soaps, and materials such as acids, bases, and solvents. Bathing in chlorinated pools and hot tubs is to be avoided. Volunteers are to be provided with a kit of nonantimicrobial personal care products for exclusive use during the test and rubber gloves to be worn when contact with antimicrobials cannot be avoided.

(F) *Number of subjects required.* The standard deviations for antiseptic handwash or health-care personnel handwash obtained when an inoculant such as *Serratia marcescens* is used are more homogeneous than those for surgical hand scrub products discussed in paragraph (b)(1)(iii)(F) of this section. The standard deviations extracted from data submitted to the agency as part of applications under part 314 of this chapter for these drug products range from 0.31 to 0.92; the median standard deviation is 0.71. The sample size estimation equation in paragraph (b)(1)(iii)(F) of this section may be used to estimate sample sizes required. For example, assume the active control hand scrub produces an immediate mean log reduction of 2.0 and the test hand scrub is to be within 20 percent of this, i.e., D=0.4. If S^2=0.71, then n=50 subjects per arm of the study. Because blocks of 6 are recommended, the sample size per treatment arm is 54 subjects.

(G) *Study design.* Randomization of subjects to time periods and treatment to hands will be accomplished in accordance with the plan presented previously.

(H) *Procedure.* (*1*) *Initial wash.* After panelists have refrained from using antimicrobials for at least 7 days, perform a 30-second practice wash in the same manner as is described for the test and control formulations, except that a solution of nonantimicrobial bland soap is used. This procedure removes oil and dirt and familiarizes the panelists with the washing technique.

(2) *Contaminant suspension and hand contamination.* The contaminant is a liquid suspension of *Serratia marcescens* containing at least 10^8 organisms per milliliter. Five milliliters of the contaminant culture are dispensed onto the hands then rubbed over the surfaces of the hands, not reaching above the wrist. Application and spreading should involve about 45 seconds. The hands are then held still away from the body and allowed to air dry for 2 minutes.

(3) *Contamination schedule.* The panelists' hands are contaminated with the marker organism according to the following schedule:

(*i*) Prior to the baseline bacterial sample collection.

(*ii*) Prior to all 10 washes with the test material.

(*4*) *Baseline recovery.* Baseline sample is taken after contamination of the hands to determine the number of marker organisms surviving on the hands after washing with a baseline control soap as described in paragraph (b)(2)(iii)(H)(*1*) of this section. Bacterial sampling will follow the procedures outlined in paragraph (b)(2)(iii)(H)(*6*) of this section.

(*5*) *Wash and rinse procedure.* The wash and rinse procedure described as follows is for all washes with the test formulation. A specified volume of the test formulation is dispensed onto the hands and rubbed over all surfaces, taking caution not to lose or dilute the substance. After the material is spread, a small amount of water is added from the tap and the hands are completely lathered for a specified time period. The lower third of the forearm is also washed. After completion of the wash, hands and forearms are rinsed under tap water at 40 ±2 °C for 30 seconds. A total of 10 washes with the test formulation is involved. Bacterial samples are taken following the 1st, 3rd, 7th, and 10th washes.

(*6*) *Bacterial sampling.* After the 1st, 3rd, 7th, and 10th washes, place rubber gloves or polyethylene bags used for sampling on the right and left hand. Sampling should occur within 5 minutes after each of these washes. Add 50 to 100 milliliters of sampling solution to each glove and secure gloves above the wrist. After adding sampling solution, uniformly massage all surfaces of the hand for 1 minute, paying particular attention to the area under the nails. After massaging aseptically, sample the fluid of the glove. Transfer immediately a measured volume of the sampling fluid to a test tube containing a suitable antimicrobial inactivator.

(*i*) Because contamination, product use, and enumeration are conducted sequentially within a time period of less than a day, an inactivator included in the sampling solution prior to the final wash may affect the test results. Therefore, no inactivator for the antimicrobial in the handwash formulation is to be included in the sampling solution prior to the final wash. The 50 to 100 milliliters of sampling fluid may be sufficient to dilute out the activity of the antimicrobial; however, this should be demonstrated using a procedure such as the one described in E 1054, "Test Methods for Evaluation Inactivators of Antimicrobial Agents Used in Disinfectants, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from The American Society of Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and

Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(*ii*) If neutralization is not accomplished by dilution, include in the sampling solution used to collect the bacterial samples from the hand following the final wash with the test formulation an antimicrobial inactivator specific for the test formulation being evaluated.

(I) *Enumeration of bacteria in sampling solution.* (*1*) Enumerate the *Serratia marcescens* in the sampling solution using standard microbiological techniques, such as membrane filter technique or surface inoculation technique. Prepare sample dilutions in dilution fluid. Use Soybean-casein digest agar with suitable inactivator as recovery medium. The suitability of the inactivator for the antimicrobial should be demonstrated using a procedure such as described in E 1054, "Test Methods for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society of Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Incubate prepared plates 48 hours at 25±2 °C. Standard plate counting procedures are used to count only the red pigmented *Serratia marcescens*.

(*2*) [Reserved]

(J) *Determination of reduction.* Determine at each sampling interval changes from baseline counts obtained with test material.

(K) *Comparison with a positive control material.* (*1*) In order to validate the testing procedure, equipment, and facilities, it is required that the test formulation be compared with an active control formulation. This will require an equivalent number of panelists to be assigned to the control formulation on a random basis. All test parameters will be equivalent for both formulations, although the handwash procedure for the established formulation may be different from that of the test formulation. Both test and control formulations are to be run concurrently. The identity of the formulations used by panelists is to be blinded from those individuals counting plates and analyzing data.

(*2*) To validate the assay, compare, at each sampling interval, changes from baseline counts obtained with test material to changes obtained with control material.

(L) *Statistical analysis.* Because the hands are inoculated prior to sampling it is possible to generate counts of 1.5×10^5 to 10^6 organisms. Therefore, reductions are less variable and evaluation of the log counts using the Student's t- test or similar procedure is recommended.

(3) *Effectiveness testing of a patient preoperative skin preparation.* A patient preoperative skin preparation drug product in finished form suitable for topical applications will be recognized as effective provided that the formulated drug product at its recommended use concentration:

(i) Contains an ingredient in § 333.412 (a), (b), (c), (d), or (e).

(ii) Demonstrates in vitro activity against organisms as described in paragraph (a)(1)(ii) of this section.

(iii) When tested, in vivo, by the standard testing procedure for the evaluation of patient preoperative skin preparation drug products described in paragraph (b)(3)(iii) of this section and labeled according to § 333.460(b)(1) of this section, reduces the number of bacteria 2 $\log_{10}$ per square centimeter on an abdomen test site and 3 $\log_{10}$ per square centimeter on a groin test site within 10 minutes after product use and the bacterial cell count for each test site does not subsequently exceed baseline 6 hours after product use. When labeled according to § 333.460(b)(2) and tested, in vivo, by the standard testing procedure described in paragraph (b)(3)(iii) of this section, reduces the number of bacteria 1 $\log_{10}$ per centimeter squared on a dry skin test site within 30 seconds of product use.

(A) *Apparatus.*—(*1*) *Colony Counter.* Any of several types may be used.

(*2*) *Incubator.* Any incubator capable of maintaining a temperature of 30±2 °C may be used.

(*3*) *Sterilizer.* Any suitable steam sterilizer capable of producing conditions of sterility is acceptable.

(*4*) *Timer (stop clock).* A timer that can be read in hours and minutes.

(*5*) *Examining table.* Any elevated surface such as a 3-by- 6-foot table with mattress or similar padding to allow subject to recline.

(B) *Materials and reagents.*—(*1*) *Bacteriological pipets.* Pipets of 10.0 and 2.2 or 1.1 milliliter capacity are recommended.

(*2*) *Water-dilution bottles.* Any sterilizable glass container having a 150 to 200 milliliter capacity and tight closures may be used.

(*3*) *Scrubbing cups.* Sterile glass cylinders, height approximately 2.5 centimeter, inside diameter of convenient size to place on anatomical area to be sampled. Useful sizes range from approximately 2.5 to 4.0 centimeters. Sampling should be conducted as described in paragraph (b)(3)(iii)(J) of this section.

(*4*) *Rubber policeman.* These can be fashioned in the laboratory or purchased from most laboratory supply houses.

(*5*) *Test formulation.* Directions used to demonstrate the effectiveness of the test formulation are to be the same as those proposed for the use of the product.

(*6*) *Positive control formulation.* Any patient preoperative skin preparation formulation approved by the Food and Drug Administration is acceptable.

(*7*) *Sterile Drape or dressing.* A sterile drape or dressing should be used to cover treated skin sites.

(*8*) *Sampling solution.* Dissolve 0.4 gram potassium phosphate, monobasic, 0.1 gram sodium phosphate, dibasic and 1 gram Triton X–100 in 1 liter distilled water. Include in this formulation an inactivator specific for the antimicrobial in the test formulation. Adjust to pH 7.8 with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide. Dispense 50 to 100-milliliter volumes into water dilution bottles, or other suitable containers, and sterilize for 20 minutes at 121 °C.

(*9*) *Dilution fluid.* Butterfield's phosphate buffered water adjusted to pH 7.2 and containing an antimicrobial inactivator specific for the test formulation. Adjust pH with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide.

(*10*) *Plating medium.* Soybean-casein digest agar plus a suitable inactivator.

(C) *Test and control skin sites.* (*1*) The skin sites selected for use in evaluating the effectiveness of the pre-operative skin preparation are to represent body areas that are common surgical sites and are to include both dry and moist skin areas. The sites are to possess bacterial populations large enough to allow demonstrations of bacterial reduction of up to 2 $\log_{10}$ per square centimeter on dry skin sites and up to 3 $\log_{10}$ per square centimeter on moist sites. A suitable dry skin area is the abdomen and a suitable moist area is the groin. For the effectiveness testing of patient preoperative skin preparation antiseptic drug products labeled according to § 333.460(b)(2), a dry skin site such as the arm, from the shoulder to the elbow, or the posterior surface of the hand below the wrist is to be selected. The sites to be tested are to have a bacterial

population of 3 $\log_{10}$ organisms per square centimeter of skin.

(2) Treatment and control sites are to be located contralateral to each other. Each site is to be 5 by 5 centimeters.

(D) *Test panelists.* Recruit healthy adult male and female human volunteers who have no clinical evidence of dermatosis, open wounds, or other skin disorders that may affect the integrity of the study, and in sufficient numbers per formulation being tested to satisfy the statistical criteria of the clinical trial design.

(E) *Preparation of volunteers.* (1) Instruct the volunteers to avoid contact with antimicrobials (other than the test formulation) for the duration of the test. This restriction includes antimicrobial containing antiperspirants, deodorants, shampoos, lotions, soaps, and materials such as acids, bases, solvents. Bathing in chlorinated pools and hot tubs should be avoided.

(2) Volunteers are to be provided with a kit of nonantimicrobial personal care products for exclusive use during the test. Volunteers are not to shower or tub bathe in the 24-hour period prior to the application of test material or microbial sampling. Sponge baths may be taken but the skin sites to be used in the study are to be excluded.

(3) If the skin sites to be used include areas that would require shaving prior to surgery, for example, the groin site, these sites should be shaved no later than 48 hours prior to the application of test formulation or microbial sampling.

(4) After volunteers have refrained from using antimicrobials for at least 2 weeks, obtain an estimate of baseline bacterial population from one groin and one abdominal site at least 72 hours prior to entering subjects into the study. Sampling and enumeration techniques described in paragraphs (b)(3)(iii)(J) and (b)(3)(iii)(K) of this section are to be used.

(5) Based on the initial estimate of baseline bacterial population, select sufficient numbers of subjects with high bacterial counts per formulation being tested to satisfy the statistical criteria of the clinical trial design.

(F) *Study design and randomization.* Subjects admitted to the study are to be identified as to whether they meet the groin portion or abdomen portion of the study, or both. Once a subject is admitted to the study, treatments are to be randomly assigned to one contralateral groin site, for subjects identified as belonging to this study group and similar treatments are to be randomly assigned to left or right side of the abdominal area, for subjects identified as belonging to the abdominal study group. This method of choosing subjects and sampling sites fits the paired comparison statistical design. Randomization of subjects to time periods and treatment to left or right side is to be accomplished in accordance with the plan similar to that presented for surgical hand scrub products.

(G) *Number of subjects required and statistical analysis of data.* (1) Two ways to statistically evaluate effectiveness of a preoperative scrub product are presented. The first depends upon calculating the average $\log_{10}$ reduction from baseline. This is accomplished by obtaining the difference in log counts for each paired sample for each subject in the appropriate sampling time frame. This will facilitate subsequent statistical evaluation of resulting data. It is usually fairly easy to enroll subjects with counts 1×10^5 or greater when working with the groin areas. It is anticipated this method will primarily be used to evaluate data collected from the groin areas. The sample size estimation equation given earlier may be used to estimate sample sizes required for this case. Standard deviations for preoperative scrub products are relatively homogeneous when inclusion criterion require counts of 1×10^5 or greater. The standard deviations extracted from files range from 0.82 to 1.72; the median standard deviation was 0.98. When counts in the range of 1×10^5 to 1×10^6 were used, the standard deviation ranged from 0.78 to 1.22, with a median value of 0.99. Using the sample size estimation equation given in paragraph (b)(1)(iii)(F) of this section and assuming the active control preoperative scrub produces an immediate mean log reduction of 2.0 and test scrub is to be within 20 percent of this, i.e., D=0.4, and S^2=0.98, gives n=97 subjects per arm of the study. Because blocks of 6 are recommended, the sample size per treatment arm is 96 subjects.

(2) The second method for evaluating the data depends upon establishing an entry target bacterial population of greater than 250 colony forming units per square centimeter and a target reduction criterion that a successful scrub reduces bacterial counts to below 25 colony forming units per square centimeter. A successful scrub product is to provide this degree of reduction in at least 90 percent of the subjects tested. Using the normal binomial confidence interval approach, it can be shown that if the standard preoperative scrub product achieves a 90 percent success rate and it is desired to rule out success rates less than 85 percent for the new product with power of 80 percent then 340 subjects per arm are required. If it is desired to rule out success rates less than 80 percent, then the sample size is only 100 per arm. Again, since blocks of 6 or some multiple thereof, are recommended, the sample size is 102 subjects per study arm.

(3) In both cases described in paragraphs (b)(3)(iii)(G)(1) and (b)(3)(iii)(G)(2) of this section, effectiveness is judged based on calculation of 95 percent confidence intervals on the difference of the "success rate for standard scrub product minus success rate for test scrub product."

(H) *Treatment application procedure.* Apply treatment according to label directions or as stated in the proposed directions for test formulation. The control product is to be used according to the labeling directions.

(I) *Sampling schedule.* (1) For patient preoperative skin preparation antiseptic drug products labeled according to § 333.460(b)(1), the treatment is randomly assigned to one contralateral groin site and one contralateral abdominal site on each of the subjects. The assignment is to be balanced such that an equal number of right and left sites in each anatomical area receive treatment. The untreated contralateral sites serve as control sites to establish baseline populations. Collect a baseline bacterial sample from one untreated groin site and from one abdominal site on each subject using the scrub cup technique just prior to application of the preoperative skin treatment to the corresponding contralateral site. Ten minutes after treatment, sample one treated groin site and one treated abdominal site on one-third of the subjects using the same sampling technique. Thirty minutes posttreatment, sample another one-third of the subjects as before, and 6 hours posttreatment, sample the remaining one-third of the subjects.

(2) Between the time of treatment allocation and the 6-hour sampling interval, the subjects movements should be restricted. Subjects treated in the groin area should avoid activities or positions that would cause untreated skin sites to contact treated sites or clothing. Positions that might be appropriate are lying on the back or sitting with the legs extended without flexing from the trunk. To allow subjects some degree of mobility between the time of treatment and the 4-hour posttreatment sampling, the treated skin areas should be loosely draped with a sterile nonocclusive dressing. This material is to be applied in such a manner as to protect the treated skin sites from contact with untreated skin.

(3) For patient preoperative skin preparation antiseptic drug products labeled according to § 333.460(b)(2), the treatment is randomly assigned to contralateral dry skin sites on each of the subjects. The assignment is to be balanced such that an equal number of right and left sites in each anatomical area receive treatment. The untreated contralateral site serves as a control site to establish baseline populations. Collect a baseline bacterial sample from an untreated site on each subject using the scrub cup technique just prior to application of the preoperative skin preparation to the corresponding contralateral site. Thirty seconds after application, sample the treated site using the same sampling technique.

(J) *Microbiological methods.* Samples for bacterial enumeration are obtained by the detergent scrub cup technique. Hold a sterile scrubbing cup firmly to the skin. Aseptically pipet 2.5 milliliters of sterile sampling solution into the scrubbing cup and rub the skin with a sterile rubber policeman for 1 minute using moderate pressure. Aspirate the wash fluid and place in a sterile test tube. Place a second 2.5-milliliter aliquot of sampling solution in the scrub cup and rub the skin again for 1 minute with the rubber policeman. Pool the two washes and enumerate the bacteria.

(K) *Enumeration of bacteria in sampling solution.* (1) Enumerate the bacteria in the sampling solution by a standard plate count procedure such as that described in "Standard Methods for the Evaluation of Dairy Products" (available from American Public Health Association, Inc., 1015 15th St. NW., Washington, DC 20005) but using soybean-casein digest agar and a suitable inactivator for the antimicrobial where necessary. The suitability of the inactivator is to be demonstrated using a procedure such as described in E 1054, "Test Methods for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Prepare sample dilutions in dilution fluid. Plate in duplicate. Incubate plated sample at 30 ± 2 °C for 48 hours before reading.

(2) Determine changes from baseline counts obtained with the test material at each sampling interval for each anatomical site. For a more realistic appraisal of the activity of products, all raw data should be converted to common (base 10) logarithms. Reduction should be calculated from the average of the logarithms. This will also facilitate statistical analysis of data.

(L) *Comparison of test material with control material.* (1) In order to validate the testing procedure, equipment, and facilities, it is required that the test material be compared with an active control material. The number of test subjects will depend upon the number of control posttreatment sampling intervals chosen and the level of statistical significance desired for the test results. The identity of the formulations used by panelists should be blinded from those individuals counting plates and analyzing data.

(2) To validate the assay, compare, at each sampling interval, changes from baseline counts obtained with the test material to changes obtained with the control materials.

(c) *Effects on microbial flora.* The agency notes that, if there is some reasonable scientific indication that the activity of an ingredient will affect the microbial flora, and thereby cause a shift in the composition of this flora, e.g., an increase in the fungus or virus level that might result in greater harm, then further safety and effectiveness testing will be required.

(d) *Test modifications.* The formulation or mode of administration of certain products may require modifications of the testing procedures in this section. In addition, alternative assay methods (including automated procedures) employing the same basic chemistry and microbiology as the methods included in this section may be used. Any proposed modification or alternative assay method shall be submitted as a petition under the rules established in § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative assay method provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in part 20 of this chapter.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

3. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371).

§ 369.21 [Amended]

4. Section § 369.21 *Drugs; warning and caution statements required by regulations* is amended by removing the entry for "Alcohol Rubbing Compound."

Dated: May 24, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–14503 Filed 6–16–94; 8:45 am]

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