PENSION BENEFIT GUARANTY CORPORATION

Exemption From Bond Escrow and Sale-Contract Requirements Relating to Sale of Assets by an Employer; Philadelphia National League Club and the Phillies

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of exemption.

SUMMARY: The Pension Benefit Guaranty Corporation has granted the Philadelphia National League Club and The Phillies an exemption from the bond/escrow and sale-contract requirements of section 4204(a)(1)(B) and (C) of the Employee Retirement Income Security Act of 1974, as amended. A notice of the request for exemption from these requirements was published on February 26, 1982 (47 FR 8440). The effect of this notice is to advise the public of the decision on the exemption request.

ADDRESS: The request for an exemption and the PBGC response to the request are available for public inspection at the PBGC Public Affairs Office, Suite 7100, 2020 K Street, NW., Washington, D.C. 20006, between the hours of 9:00 a.m. and 4:00 p.m. A copy of these documents may be obtained by mail from the PBGC Disclosure Officer (160) at the above address.

FOR FURTHER INFORMATION CONTACT: James M. Graham, Office of the Executive Director, Policy and Planning (140), 2020 K Street, NW., Washington, D.C. 20006; (202) 254–4862.

SUPPLEMENTARY INFORMATION:

Background

Section 4204(a)(1) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), 29 U.S.C. 1384, provides that the sale of assets of an employer that contributes to a multiemployer pension plan will not constitute a complete or partial withdrawal from the plan if certain conditions are met. One of these conditions is that the purchaser post a bond or deposit money in escrow for five plan years after the sale. Another condition is that the sales agreement provide that the seller will be secondarily liable for its withdrawal liability if the purchaser withdraw as within the first five plan years after the sale and fails to pay withdrawal liability.

Section 4204(c) of ERISA authorizes the Pension Benefit Guaranty Corporation ("PBGC") to grant individual or class variances or exemptions from the purchaser's bond/escrow and sale-contract requirements of section 4204(a)(1)(B) and (C). Under § 2643.3(a) of the PBGC's regulation on procedures for variances for sales of assets (46 FR 46127, September 17, 1981), the PBGC shall approve a request for a variance or exemption if it determines that approval of the request is warranted, in that it—

(1) Would more effectively or equitably carry out the purposes of Title IV of the Act; and

(2) Would not significantly increase the risk of financial loss to the plan.

The legislative history of section 4204 indicates a Congressional intent that the sales rules be administered in a manner that assures protection of the plan with the least practicable intrusion into normal business transactions.

Section 4204(c) and § 2643.3(b) of the regulation require the PBGC to publish a notice of the pendency of a request for a variance or an exemption in the **Federal Register**, and to provide interested parties with an opportunity to comment on the proposed variance or exemption.

Decision

On February 26, 1982 (47 FR 8440), the PBGC published a notice of the pendency of a joint request from the seller, the Philadelphia National League Club (the "Club") and the purchaser, The Phillies ("Phillies"), a limited partnership, (collectively referred to as the "Parties") for an exemption from the requirements of section 4204(a)(1)(B) and (C) of ERISA. No comments were received in response to the notice.

The Club was a participating employer in the Major League Baseball Players Benefit Plan (the "Plan"), which is established and maintained pursuant to a collective bargaining agreement between the 26 professional major league baseball teams and the Major League Baseball Players Association.

The major league clubs have established the Major League's Central Fund (the "Central Fund") pursuant to the "Major League Agreement in re Major League's Central Fund." Under this Agreement, the revenues to fund the Plan for all participating employers are received by the Office of the Commissioner of Baseball and are then remitted on behalf of the clubs in satisfaction of their pension liability arising under the Plan's funding agreement. In addition, other expenditures on behalf of all 26 clubs are made from the Central Fund. The monies in the Fund are derived directly from gate receipts from All-Star games and radio and television rights to certain other events.

The major league clubs are currently obligated to contribute the sum of $15,500,000 per year to cover both pension and welfare benefits; approximately $13 million of which is remitted to the pension plan for the current plan year. Each major league club is responsible for 1/26 of that amount. In 1980, the Central Fund paid $500,000 as pension contributions to the Plan on behalf of the Club.

Payment of employer contributions is made directly to the Plan from the Central Fund and the revenue of the Fund comes directly from certain gate receipts and radio and television rights. A change in team ownership has no direct effect on the Plan's funding and does not create any risk to the plan that there will be difficulty in collecting Plan contributions.

Based on the facts of this case and the representations and statements made in connection with the request for exemption, PBGC has determined that an exemption under section 4204(c) would more effectively or equitably carry out the purposes of Title IV of ERISA and would not significantly increase the risk of financial loss to the plan. Therefore, PBGC has granted the Parties' request for an exemption from the bond/escrow and sale-contract requirements. The granting of an exemption or variance from the requirements of section 4204(a)(1) (B) and (C) does not constitute a finding by PBGC that the transaction satisfies the other requirements of section 4204(a)(1). The determination of whether the transaction satisfies such other requirements is a determination to be made by the plan sponsor.

Issued at Washington, D.C. on this 1st day of July 1982.

Edwin M. Jones,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 82-19267 Filed 7-15-82; 8:45 am]

BILLING CODE 7708-01-M

SMALL BUSINESS ADMINISTRATION

[License No. 03/02-0273]

Inverness Capital Corp.; Filing of Application for Transfer of Control and Ownership of Licensed Small Business Investment Company

Notice is hereby given that an application has been filed with the Small Business Administration pursuant to § 107.701 of the Regulations governing small business investment companies (13 CFR 107.701 (1982)) for the transfer of control and ownership of Inverness

Capital Corporation, 424 N. Washington Street, Alexandria, Virginia 22314.

Inverness was licensed on October 1, 1969. Its present combined paid-in capital and paid-in surplus (private capital) is $1,364,778. The proposed transfer of control and ownership is subject to and contingent upon approval by SBA.

Old Port Company, which is located at the same address as Inverness, owns about 80 percent of the licensee and is the only ten or more percent shareholder. The name of the licensee will remain the same. Inverness will be moved to Tennessee and be located at Suite 1205, 210 25th Avenue, North, Nashville, Tennessee 37203.

The proposed officers, directors and stockholders are:

Floyd W. Kephart, Jr., 640 Timber Lane, Nashville, Tenn. 37215—President, Director

Ronald H. Bice, Jr., 4004 Lake Parkway, Hermitage, Tenn. 37076—Treasurer, Secretary.

Joaquin de Navasques, 210 25th Avenue, North, Nashville, Tenn. 37203—Director

Ms. Kirsten P. Murchison, 3857 So. Versailles, Dallas, Texas 75209—Director

Capital Communications and Management Corporation, 210 25th Avenue, North, Nashville, Tenn. 37203—100 percent

Capital Communications and Management Corporation is a holding company formed to purchase the stock of Inverness from Old Port and the other less than ten percent shareholders. Mr. Navasques owns all of the stock of Capital Communications and Management Corporation.

Matters involved in SBA's consideration of the application include the general business reputation and character of the new owner and the probability of successful operation of Inverness under the new control and ownership arrangement (including adequate profitability and financial soundness) in accordance with the Act and Regulations.

Notice is hereby given that any interested persons may, not later than August 2, 1982, submit to SBA, in writing, any relevant comments on the transfer of control and ownership. Any such comments should be addressed to the Associate Administrator for Finance & Investment, 1441 L Street, N.W., Washington, D.C. 20416.

A copy of this Notice shall be published by the transferee in newspapers of general circulation in Nashville, Tennessee and Alexandria, Virginia.

(Catalog of Federal Domestic Assistance Program No. 59.011 Small Business Investment Companies)

Dated: July 12, 1982.

Edwin T. Holloway,

Associate Administrator for Finance and Investment.

[FR Doc. 82-19316 Filed 7-15-82; 8:45 am]

BILLING CODE 8025-01-M

[License No. 03/03-0146]

James River Capital Associates; Filing of an Application for Approval of a Conflict of Interest Transaction

Notice is hereby given that James River Capital Associates (Licensee) 9 South 12th Street, Richmond, Virginia 23219, a Federal Licensee under the Small Business Investment Act of 1958, as amended (the Act), has filed an application pursuant to Section 107.1004 of the Regulations governing small business investment companies (13 CFR 107.1004 (1982)) for an exemption from the provisions of the conflict of interest regulation.

This exemption, if granted will permit the Licensee to provide financing of $170,000 to La Vogue Holdings, Inc. (La Vogue), 451 East Belt Boulevard, Richmond, Virginia 23224.

Mr. James B. Farinbolt, Jr., President of the Licensee, is also a director and 43.5 percent shareholder of La Vogue.

Pursuant to Paragraph (f) of the definition of "Associate of a Licensee" in § 107.3 of the SBA Regulations, La Vogue is considered to be an associate of the Licensee. As such, the transaction will require an exemption from the provisions of § 107.1004(b)(1) of the Regulations.

Notice is hereby given that any person may, no later than August 2, 1982, sumbit to the Small Business Administration, in writing, relevant comments on the proposed transaction. Any such communications should be addressed to the Acting Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street, N.W., Washington, D.C. 20416.

A copy of this Notice shall be published in a newspaper of general circulation in Richmond, Virginia.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: July 12, 1982.

Robert G. Lineberry,

Acting Deputy Associate Administrator for Investment.

[FR Doc. 82-19315 Filed 7-15-82; 8:45 am]

BILLING CODE 8025-01-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 137
Friday, July 16, 1982

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).

CONTENTS

1

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., July 20, 1982.

PLACE: 2033 K Street, NW., Washington, D.C., fifth floor hearing room.

STATUS: Partially open and closed.

MATTERS TO BE CONSIDERED: Budget Categories, Plans, Programs and Priorities.

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254-6314.

[S-1050-82 Filed 7-14-82; 3:40 pm]

BILLING CODE 6351-01-M

2

FEDERAL HOME LOAN BANK BOARD

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 47 FR 30351, Tuesday, July 13, 1982.

DATE: Thursday, July 15, 1982.

PLACE: Board room, fifth floor, 1700 G Street NW., Washington, D.C.

TIME: 10:00 a.m.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Marshall (202-377-6679).

CHANGES IN THE MEETING: The following item has been withdrawn from the open portion of the Bank Board meeting scheduled Thursday, July 15, 1982:

Liquidity Amendments

[No. 50, July 14, 1982]

[S-1044-82 Filed 7-14-82; 11:44 am]

BILLING CODE 6720-01-M

3

FEDERAL MARITIME COMMISSION

TIME AND DATE: 9 a.m., July 21, 1982.

PLACE: Hearing Room One, 1100 L Street, NW., Washington, D.C. 20573.

STATUS: Parts of the meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Portions open to the public:

1. Report on Notation Items disposed of during June 1982.
2. Report of the Secretary on times shortened for submitting comments on section 15 agreements pursuant to delegated authority during June 1982.
3. Report of the Secretary on Applications for Admission to Practice approved during June 1982, pursuant to delegated authority.
4. Agreement No. 5600-34: Modification of the Marseilles North Atlantic U.S.A. Freight Conference to revise voting requirements on intermodal rate matters.
5. Special Docket No. 919: Application of Pacific Westbound Conference on Behalf of Korea Marine Transport Co., Ltd. for the Benefit of Mitsui and Company (USA) Inc.—Consideration of the record.

Portions closed to the public:

1. Docket No. 79-2: Agreement No. 10293 and Docket No. 79-3: Agreement No. 10295—Appeal of denial of petition to intervene of the Government of Colombia.
2. Docket No. 81-57: Tractors & Farm Equipment Ltd. v. Waterman Steamship Corp. and Cosmos Shipping Company, Ltd.—Consideration of the record.
3. Docket No. 81-10: Sea-Land Service, Inc., Trailer Marine Transport Corporation; Gulf-Caribbean Marine Lines, Inc., Puerto Rico Maritime Shipping Authority—Proposed General Rate Increases in the Puerto Rico and Virgin Islands Trades—Consideration of petition of PRMSA for relief; motion of PRMSA to file reply; request of PRMSA for oral argument; and petition of Department of Transportation to intervene.

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

[S-1041-82 Filed 7-13-82; 4:45 pm]

BILLING CODE 6730-01-M

4

INTERNATIONAL TRADE COMMISSION

[USITC SE-82-27]

TIME AND DATE: 2:30 p.m., Tuesday, July 27, 1982.

PLACE: Room 117, 701 E Street, NW., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and complaints, if necessary:
   a. Textile spinning frames (Docket No. 849).
   b. Panel inserts (Inv. 377-TA-99)—possible institution of a second investigation.
5. Investigations 701-TA-179/181 (Certain Steel Products from Brazil)—briefing and vote.
6. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary, (202) 523-0161.

[S-1040-82 Filed 7-13-82; 4:14 pm]

BILLING CODE 7020-02-M

5

POSTAL RATE COMMISSION

TIME AND DATE: 2 p.m., Tuesday, July 20, 1982.

PLACE: Conference Room, Room 500, 2000 L Street, NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED: [Closed pursuant to 5 U.S.C. 552b(c)(10)]:

Warshawsky and Company v. Postal Rate Commission and Board of Governors, USPS (Suit filed 3-26-82 in United States District Court for the Northern District of Illinous—Docket No. 82C1895.)

CONTACT PERSON FOR MORE INFORMATION: Dennis Watson, Information Officer, Postal Rate Commission, Room 500, 2000 L Street, NW., Washington, D.C. 20268, Telephone (202) 254-5614.

[S-1049-82 Filed 7-14-82; 3:16 pm]

BILLING CODE 7715-01-M

6

POSTAL SERVICE

.(Board of Governors)

Vote to Close Meeting

On July 6, 1982, the Board of Governors of the United States Postal Service unanimously voted to close to public observation a portion of the meeting of the Board to be held on September 9. The meeting is expected to be attended by the following persons: Governors Hardesty, Babcock, Camp, Hughes, Jenkins, McKean, and Sullivan; Postmaster General Bolger; Deputy Postmaster General Benson; Secretary of the Board Cox; Counsel to the Governors Califano; Assistant Postmaster General Cummings; and

Executive Assistant to the Postmaster General Coughlin.

The portion of the Board meeting to be closed will consist of a discussion of Postal Service strategic planning.

The Board is of the opinion that public access to this discussion would be likely to disclose information in connection with future collective bargaining and information that will become involved in future rate litigation.

Accordingly, the Board of Governors has determined that, pursuant to section 552b(c)(3) of title 5, United States Code, and § 7.3(c) of Title 39, Code of Federal Regulations, this portion of the meeting is exempt from the opening meeting requirement of the Government in the Sunshine Act (5 U.S.C. 552(b)), because it is likely to disclose information in connection with proceedings under chapter 36 of Title 39 (having to do with postal ratemaking, mail classification, and changes in postal services), which is specifically exempted from disclosure by section 410(c)(4) of title 39, United States Code. The Board determined further that, pursuant to section 552b(c)(10) of title 5 and § 7.3(j) of Title 39, Code of Federal Regulations, the discussion is exempt because it is likely to specifically concern the participation of the Postal Service in a civil action or proceeding or the litigation of a particular case involving a determination on the record after opportunity for a hearing. It also determined, pursuant to section 552b(c)(9)(B) and § 7.3(i) of Title 39, Code of Federal Regulations, that the discussion is exempt because premature disclosure of information to be discussed would be likely significantly to frustrate implementation of future action in regard to future collective bargaining. The Board further determined that the public interest does not require that the Board's discussion of this matter be open to the public.

In accordance with section 552b(f)(1) of title 5, United States Code, and § 7.6(a) of Title 39, Code of Federal Regulations, the General Counsel of the United States Postal Service has certified that in his opinion the portion of the meeting to be closed may properly be closed to public observation, pursuant to sections 552b(c)(3), (9)(B) and (10) of title 5 and sections 410(c)(3) and (4) of Title 39, United States Code, and § 7.3(c), (i), and (j) of Title 39, Code of Federal Regulations.

Louis A. Cox,

Secretary.

[S-1043-82 Filed 7-14-82; 10:12 am]

BILLING CODE 7710-12-M

federal register

Friday
July 16, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

Anesthesiology Devices; General Provisions and Classification of 134 Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 78N-1648]

Anesthesiology Devices; General Provisions and Classification of 134 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule regarding general provisions applicable to the classification of anesthesiology devices. The final rule also includes the classification of 134 of these devices. The preamble to this rule responds to comments received on the proposals regarding classification of anesthesiology devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: August 16, 1982.

FOR FURTHER INFORMATION CONTACT: David S. Shindell, Bureau of Medical Devices (HFK-430), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 2, 1979 (44 FR 63292-63426), FDA published proposed regulations containing general provisions applicable to the classification of anesthesiology devices and individual proposed regulations to classify 149 anesthesiology devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval). Of the 149 anesthesiology devices subject to proposals, FDA is classifying 134; 21 devices into class I, 105 devices into class II, 7 devices into class III, and 1 device into either class II or class III, depending upon the intended use of the device. For the reasons described below, final regulations for 15 anesthesiology devices will not be published at this time.

Classification of medical devices in commercial distribution is required by the Medical Devices Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Comestic Act (the act) (21 U.S.C. 301-392). The effect of classifying a device into class I is to require that the device continue to meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. For a class III device not considered a new drug before the amendments and that either was in commercial distribution before May 28, 1976, or in substantially equivalent on or before February 28, 1985, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. For a class III device previously considered a new drug, the requirement of having premarket approval is already in effect. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to the general provisions regulation described the development of the general provisions and the proposed regulations classifying anesthesiology devices and the activities of the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel (formerly the Anesthesiology Device Classification Panel), and FDA advisory committee that makes recommendations to FDA concerning the classification of anesthesiology devices. FDA provided a period of 60 days for interested persons to submit written comments on these proposals. The comments received and FDA's responses to comments are discussed below.

Change in Format of Final Rules for Classification of Devices

To reduce printing costs, FDA is publishing as one final regulation the general provisions and classification of 134 anesthesiology devices. Formerly, a separate final classification regulation was published in the **Federal Register** for each generic type of device. The docket number used to identify each of the proposed classification regulations continues to be used in this final regulation to identify each generic type of device.

Exemptions for Class I Devices

FDA proposed to exempt 11 anesthesiology devices from certain requirements of the good manufacturing practice (GMP) regulation in Part 820 (21 CFR Part 820). The 11 devices are the manual algesimeter (Docket No. 78N-1649), the uncalibrated breathing system collection bottle (Docket No. 78N-1665), the stethoscope head (Docket No. 78N-1690), the switching valve (Ploss) (Docket No. 78N-1691), the blow bottle (Docket No. 78N-1726), the posture chair for cardiac and pulmonary treatment (Docket No. 78N-1738), the ether hook (Docket No. 78N-1743), the rebreathing device (Docket No. 78N-1767), the cuff spreader (Docket No. 78N-1775), the cardiopulmonary emergency cart (Docket No. 78N-1798), and the nose clip (Docket No. 78N-1799). The agency is publishing in this final rule the classification of 10 of these 11 devices; the final rule for 1 device (Docket No. 78N-1665) was published with the final rule classifying general hospital and personal use devices (Docket No. 78N-1357). The final rule for each of these devices exempts the device from all of the GMP requirements with the exception of §§ 820.180 and 820.198 relating to records and complaint files. The agency has determined that exemption of devices from §§ 820.180 and 820.198 of the GMP regulation would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensure that device manufacturers have adequate systems for complaint investigation and followup. The general requirements concerning records in § 820.180 ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the GMP regulation, if one has been granted, is still appropriate.

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** of Friday, January 18, 1980 (45 FR 3671).

Devices That Have Both Medical and Nonmedical Uses

FDA has clarified several regulations classifying products that have both medical and nonmedical uses. FDA will regulate a multipurpose product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." (Section 201(h) of the act (21 U.S.C. 321(h)).) FDA will determine the intended use of a product based upon the expressions of the person legally

responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them.

Relationship Between the Device Names in the Device Registration and Listing Codes and the Device Names in Classification Regulations

Some manufacturers have become accustomed to identifying a device by its registration and listing name and three-letter code used for purposes of device listing under section 510 of the act (21 U.S.C. 360). However, FDA is still making changes in the names and identifications of generic types of devices in the classification regulations for all devices for which final regulations have not been published. Because FDA has not used the present device registration and listing names in the proposed and final classification regulations, FDA has prepared an index of names of generic types of medical devices used in classification regulations to aid a manufacturer in matching its device with the proper classification regulation. The index shows the device registration and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which the device classification will be published in the **Federal Register**. The agency announced the availability of this index in the **Federal Register** of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be reannounced in the **Federal Register**. FDA believes that, because this index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and reissue the device registration and listing product code, so the device names to be used for registration and listing correspond to the device names in the final device classification regulations.

Final Regulations Not Published at This Time

The Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel made recommendations for, and FDA proposed classification of, 149 anesthesiology devices. After publishing the proposals, the agency determined not to publish at this time final regulations on 15 devices, for the reasons described below. A separate notice withdrawing these proposed regulations will be, or has been, published in the **Federal Register**.

1. FDA proposed that the nonindwelling blood carbon monoxide analyzer (44 FR 63303) be classified into class II. After publishing the proposal to classify the device as part of the anesthesiology device classification proceeding, the agency determined that the device is the same generic type of device as the carbon monoxide test system that the Clinical Toxicology Device Section of the Clinical Chemistry and Hematology Devices Panel recommends be classified into class II. The agency has determined that the generic type of device will be the carbon monoxide test system and its classification regulation will be published in the **Federal Register** with clinical chemistry and clinical toxicology devices.

Any comments submitted by the public and other parts of the administrative record for the anesthesiology proposal will be included in the administrative record for the carbon monoxide test system (Docket No. 78N–2503).

2. FDA proposed that the following three devices be classified into class II: the nonindwelling blood carbon dioxide (PCO_2) analyzer (44 FR 63307), the nonindwelling blood hydrogen ion (pH) concentration analyzer (44 FR 63309), and the nonindwelling oxygen partial pressure (PO_2) analyzer (44 FR 63311). After publishing the proposals to classify the three devices as part of the anesthesiology device classification proceeding, the agency determined that the three devices are the same generic type of device as the blood gases (PCO_2, PO_2) and blood pH test system that the Clinical Chemistry Device Section of the Clinical Chemistry and Hematology Devices Panel recommends be classified into class II. The agency has determined that the generic type of device will be the blood gases (PCO_2, PO_2) and blood pH test system, and its classification regulation will be published in the **Federal Register** with clinical chemistry and clinical toxicology devices. Any comments submitted by the public and other parts of the administrative record for the three anesthesiology proposals will be included in the administrative record for the blood gases (PCO_2, PO_2) and blood pH test system (Docket No. 78N–2305).

3. FDA proposed that the nonindwelling blood nitrogen partial pressure (PN_2) analyzer be classified into class II (44 FR 63309). After publishing the proposal as part of the anesthesiology device classification proceeding (Docket No. 78N–1661), the agency determined that the device was not in commercial distribution before May 28, 1976, the enactment date of the amendments. Because the device was not in commercial distribution, it is classified into class III by statute as provided in section 513(f) of the act (21 U.S.C. 360c), without agency publication of a classification regulation for the device.

4. FDA proposed that both the gas cylinder (44 FR 63421) and the gas cylinder holder (44 FR 63422) be classified into class II. After publishing the two proposals as part of the anesthesiology device classification proceeding, the agency determined that the two products are not medical devices. Thus, it is inappropriate to classify them. When a gas cylinder contains a gas, such as oxygen, that is intended for inhalation, the product is a drug.

5. FDA proposed that the calibrated breathing system collection bottle be classified into class II (44 FR 63312), the uncalibrated breathing system collection bottle be classified into class I (44 FR 63313) and the water-seal thoracic drainage system be classified into class II (44 FR 63371). After publishing the proposals to classify the three devices as part of the anesthesiology device classification proceeding, the agency determined that the three devices are included in another generic type of device, the vacuum-powered body fluid suction apparatus. A final regulation classifying into class II the vacuum-powered body fluid suction apparatus was published in the **Federal Register** of October 21, 1980 (45 FR 69729) with general hospital and personal use devices. Any comments submitted by the public and other parts of the administrative record for the three anesthesiology proposals will be included in the administrative record for the vacuum-powered body fluid suction apparatus (Docket No. 78N–1357).

6. FDA proposed that the automatic catheter flushing device be classified into class II (44 FR 63380). After publishing the proposal to classify the device as part of the anesthesiology device classification proceeding, the agency determined that the device is the same generic type of device as the cardiovascular continuous flush

catheter. On February 5, 1980, the agency published in the **Federal Register** (45 FR 7910), a final regulation classifying the cardiovascular continuous flush catheter into class II (Docket No. 78N–1414). Therefore, the agency has determined that the anesthesiology automatic catheter flushing device has already been classified into class II, following opportunity for public comment.

7. FDA proposed that the blood transfusion microfilter be classified into class II (44 FR 63406). After publishing the proposal to classify the device as part of the anesthesiology device classification proceeding, the agency determined that the device is included in another generic type of device, the intravascular administration set. FDA published in the **Federal Register** of August 24, 1979 (44 FR 49888), a proposal to classify the intravascular administration set into class II. A final regulation classifying the intravascular administration set was published in the **Federal Register** (45 FR 69702) with general hospital and personal use devices. Any comments submitted by the public and other parts of the administrative record for the anesthesiology proposal will be included in the administrative record for the intravasuclar administration set (Docket No. 78N–1309).

8. FDA proposed that both the hyperthermia device (44 FR 63378) and the hypothermia device (44 FR 63379) be classified into class II. After publishing the proposals to classify the two devices as part of the anesthesiology device classification proceeding, the agency determined that the two devices are included in another generic type of device, the cardiovascular thermal regulating system. On February 5, 1980, the agency published in the **Federal Register** (45 FR 7971) a final regulation classifying the thermal regulating system into class II (Docket No. 78N–1547).

9. FDA proposed that the nonindwelling blood oxyhemoglobin concentration analyzer be classified into class II (44 FR 63305). No comments were received on the proposal. After publishing the proposal to classify the device as part of the anesthesiology device classification proceeding, the agency determined that the device is part of another generic type of device, the whole blood hemoglobin assays. FDA published in the **Federal Register** of September 11, 1979 (44 FR 53019), a proposal to classify the whole blood hemoglobin assays into class II. A final regulation classifying the whole blood hemoglobin assays into class II was published in the **Federal Register** (45 FR 60622) with hematology and pathology devices (Docket No. 78N–1896). The administrative record for the anesthesiology proposal will be included in the administrative record for the whole blood hemoglobin assays. Therefore, the agency has determined that the anesthesiology nonindwelling blood oxyhemoglobin concentration anylyzer device has already been classified into class II, following opportunity for public comment.

Cigarette Filters

In the preamble to the proposed regulation setting forth general provisions for the proposed classification of anesthesiology devices, published in the **Federal Register** of November 2, 1979 (44 FR 63292–63299), FDA stated that the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel had recommended that attached and detached cigarette filters be classified into class III (premarket approval), that a citizen petition had been filed by Action on Smoking and Health (ASH) concerning cigarette filters, and that FDA was not at that time issuing a proposed classification regulation for cigarette filters. ASH's citizen petition (Docket No. 78P–0338/CP) had requested that FDA recognize jurisdiction over cigarette filters as medical "devices" as defined in section 201(h) of the act (21 U.S.C. 321(h)). On November 25, 1980, FDA issued a letter responding to the petition. FDA concluded that attached cigarette filters, as customarily marketed, are not devices and that some, but not all, detached cigarette filters are devices. FDA is preparing a proposed classification regulation for detached cigarette filters that are medical devices and intends to publish it in a separate notice.

Order Issued in Response to a Reclassification Petition on an Anesthesiology Device

In addition to classifying commercially marketed preamendment devices, FDA also announces its decisions on reclassification petitions for devices first marketed after the enactment date of the amendments. Postamendments devices that are not substantially equivalent to devices marketed before the amendments are classified by statute into class III by action of section 513(f)(1) of the act without FDA rulemaking. In response to a petition received by FDA under section 513(f)(2) of the act and 21 CFR Part 860 of the regulations, FDA may reclassify a new device into class I or class II. The agency has received one such petition concerning an anesthesiology device. FDA is announcing the agency's decision on the petition. FDA also is issuing a final regulation that describes the agency's reclassification of the device that was the subject of the petition.

Petition 77P–0398; § 868.5895, Docket No. 78N–1787; Continuous Ventilator

On October 24, 1977, FDA received petition 77P–0398 under section 513(f) of the act requesting that the agency reclassify the petitioner's "O.H.C. ventilator" from class III to class II. In the **Federal Register** (43 FR 12379) of March 24, 1978, FDA published the recommendation of the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel that the device be reclassified from class III to class II. The agency provided a period of 30 days for interested persons to submit written comments on the recommendation. No comments were received. FDA agreed with the panel's recommendation that the device be reclassified. In accordance with section 523(f)(c)(i) of the act and 21 CFR 860.134(b)(6) of the regulations, FDA approved the petition and, by order in the form of a letter dated April 25, 1978 and sent to the petitioner, reclassified the device from class III to class II.

FDA advises that the O.H.C. ventilator reclassified into class II in response to the petition is included in the generic type of device in this final rule identified § 868.5895 Continuous ventilator (Docket No. 78N–1787). Accordingly, FDA announces the agency's decision on reclassification petition 77P–0398 as provided in 21 CFR 860.134(b)(7).

Changes in Classification in Final Regulations

Based on the comments received or upon consideration of additional information, FDA has changed the classifications of several devices in the final regulations from those classifications originally proposed. Changes in classification were made in each of the following regulations with respect to all or some devices subject to the regulation: Cutaneous oxygen monitor (Docket No. 78N–1700), oxygen mask (Docket No. 78N–1757), breathing mouthpiece (Docket No. 78N–1761), and autotransfusion apparatus (Docket No. 78N–1782). FDA does not believe that it is necessary to issue a new proposal concerning these changes. The purpose of publishing a proposal and soliciting comments is to enable the agency to determine whether its proposed classification of a device is correct.

After reviewing the comments submitted on a proposal, the agency may be persuaded that its proposed classification is incorrect. Persons interested in the classification process should therefore anticipate that in a final regulation a device may be placed in a class different from the one originally proposed. This possibility was specifically identified in the proposed general provisions for anesthesiology devices (see 44 FR 63292; November 2, 1979). Persons who disagree with a final classification for a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860). Occasionally, FDA has made minor changes in the names or identifications of devices to clarify the final regulation. Additionally, the agency is adding an explanation in § 868.1 that references in Part 868 to other regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Changes in Device Advisory Committee Names

On April 28, 1978, the agency terminated all of the device classification panels, then reestablished them under new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The Anesthesiology Device Classification Panel was terminated, and its functions are now conducted by the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel.

Classification Regulations Published To Date

The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel and section name	Publication date in FEDERAL REGISTER
Circulatory Systems Devices Panel.	Mar. 9, 1979, 44 FR 13284–13434 (proposals); Feb. 5, 1980, 45 FR 7904–7971 (final regulations).
Clinical Chemistry and Hematology Devices Panel:	
Clinical chemistry device section.	Feb. 2, 1982; 47 FR 4802–4929 (proposals).
Clinical toxicology device section.	Feb. 2, 1982; 47 FR 4802–4929 (proposals).
Hematology and pathology device section.	Sept. 11, 1979, 44 FR 52950–53063 (proposals); Sept. 12, 1980, 45 FR 60576–60651 (final regulations).
General Medical Devices Panel:	
General hospital and personal use device section.	Aug. 24, 1979, 44 FR 49844–49954 (proposals); Oct. 21, 1980, 45 FR 69678–69737 (final regulations).
Gastroenterology-urology device section.	Jan. 23, 1981, 46 FR 7562–7641 (proposals).
Immunology and Microbiology Devices Panel:	
Immunology device section.	Apr. 22, 1980, 45 FR 27204–27359 (proposals).
Microbiology device section.	Apr. 22, 1980, 45 FR 27204–27359 (proposals).
Obstetrics-Gynecology and Radiologic Devices Panel:	
Obstetrics-gynecology device section.	Apr. 3, 1979, 44 FR 19894–19971 (proposals); Feb. 26, 1980, 45 FR 12682–12720 (final regulations).
Radiology device section.	Jan. 29, 1982, 47 FR 4408–4451 (proposals).
Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel:	
Ophthalmic device section.	Jan. 26, 1982, 47 FR 3694–3749 (proposals).
Ear, nose, and throat device section.	Jan. 22, 1982, 47 FR 3280–3325 (proposals).
Dental device section.	Dec. 30, 1980, 45 FR 85962–86168 (proposals).
Respiratory and Nervous System Devices Panel:	
Anesthesiology device section.	Nov. 2, 1979, 44 FR 63292–63426 (proposals); July 16, 1982 (final regulations).
Neurological device section.	Nov. 23, 1978, 43 FR 54640–55732 (proposals); Sept. 4, 1979, 44 FR 51726–51778 (final regulations).
Surgical and Rehabilitation Devices Panel:	
Physical medicine device section.	Aug. 28, 1979, 44 FR 50458–50537 (proposals).
Orthopedic device section.	
General and plastic surgery device section.	Jan. 19, 1982, 47 FR 2810–2853 (proposals).

List of Anesthesiology Devices and an Identification of Those Proposed Classification Regulations That Received Public Comment

The following is a list of anesthesiology devices being classified in this final regulation. The list shows the section of the Code of Federal Regulations under which the device classification is being codified, the docket number of the classification regulation, the classification of each device, and an identification (yes or no) of whether public comments were received on the proposed classification regulation. If no comments were received, the classification of the device is being adopted as proposed.

Section	Device	Docket No.	Class	Comments
	Subpart B—Diagnostic Devices			
868.1030	Manual algesimeter	78N-1649	I	No.
868.1040	Powered algesimeter	78N-1650	II	No.
868.1075	Argon gas analyzer	78N-1651	II	Yes.
868.1100	Arterial blood sampling kit	78N-1652	II	No.
868.1120	Indwelling blood oxyhemoglobin concentration analyzer	78N-1654	III	No.
868.1150	Indwelling blood carbon dioxide partial pressure (PCO_2) analyzer	78N-1657	III	No.
868.1170	Indwelling blood hydrogen ion concentration (pH) analyzer	78N-1659	III	No.
868.1200	Indwelling blood oxygen partial pressure (PO_2) analyzer	78N-1662	III	No.
868.1400	Carbon dioxide gas analyzer	78N-1666	II	Yes.
868.1430	Carbon monoxide gas analyzer	78N-1667	II	Yes.
868.1500	Enflurane gas analyzer	78N-1668	II	Yes.
868.1575	Gas collection vessel	78N-1669	II	No.
868.1620	Halothane gas analyzer	78N-1670	II	Yes.
868.1640	Helium gas analyzer	78N-1671	II	Yes.
868.1670	Neon gas analyzer	78N-1672	II	Yes.
868.1690	Nitrogen gas analyzer	78N-1673	II	Yes.
868.1700	Nitrous oxide gas analyzer	78N-1674	II	Yes.
868.1720	Oxygen gas analyzer	78N-1675	II	No.
868.1730	Oxygen uptake computer	78N-1676	II	No.
868.1750	Pressure plethysmograph	78N-1677	II	No.
868.1760	Volume plethysmograph	78N-1678	II	No.
868.1780	Inspiratory airway pressure meter	78N-1679	II	No.
868.1800	Rhinoanemometer	78N-1680	II	No.
868.1840	Diagnostic spirometer	78N-1681	II	Yes.
868.1850	Monitoring spirometer	78N-1682	II	No.
868.1860	Peak-flow meter for spirometry	78N-1683	II	No.
868.1870	Gas volume calibrator	78N-1684	II	Yes.
868.1880	Pulmonary-function data calculator	78N-1685	II	No.
868.1890	Predictive pulmonary-function value calculator	78N-1686	II	No.
868.1900	Diagnostic pulmonary-function interpretation calculator	78N-1687	II	No.
868.1910	Esophageal stethoscope	78N-1688	I	No.

Section	Device	Docket No.	Class	Comments
868.1920	Esophageal stethoscope with electrical conductors	78N-1689	II	No.
868.1930	Stethoscope head	78N-1690	I	No.
868.1965	Switching valve (ploss)	78N-1691	I	No.
868.1975	Water vapor analyzer	78N-1692	II	Yes.
	Subpart C—Monitoring Devices			
868.2025	Ultrasonic air embolism monitor	78N-1693	II	No.
868.2300	Bourdon gauge flowmeter	78N-1694	II	No.
868.2320	Uncompensated thorpe tube flowmeter	78N-1695	II	No.
868.2340	Compensated thorpe tube flowmeter	78N-1696	II	No.
868.2350	Gas calibration flowmeter	78N-1697	II	Yes.
868.2375	Breathing frequency monitor	78N-1698	II	No.
868.2450	Lung water monitor	78N-1699	III	No.
868.2500	Cutaneous oxygen monitor	78N-1700	II, III	Yes.
868.2550	Pneumotachometer	78N-1702	II	No.
868.2600	Airway pressure monitor	78N-1703	II	No.
868.2610	Gas pressure gauge	78N-1704	II	Yes.
868.2620	Gas pressure calibrator	78N-1705	II	Yes.
868.2700	Pressure regulator	78N-1706	II	Yes.
868.2775	Electrical peripheral nerve stimulator	78N-1707	II	No.
868.2875	Differential pressure transducer	78N-1708	II	Yes.
868.2885	Gas flow transducer	78N-1709	II	Yes.
868.2900	Gas pressure transducer	78N-1710	II	Yes.
	Subparts D–E [Reserved]			
	Subpart F—Therapeutic Devices			
868.5090	Emergency airway needle	78N-1714	II	No.
868.5100	Nasopharyngeal airway	78N-1715	II	Yes.
868.5110	Oropharyngeal airway	78N-1716	II	No.
868.5120	Anesthesia conduction catheter	78N-1717	II	No.
868.5130	Anesthesia conduction filter	78N-1718	II	No.
868.5140	Anesthesia conduction kit	78N-1719	II	No.
868.5150	Anesthesia conduction needle	78N-1720	II	No.
868.5160	Gas machines for anesthesia or analgesia	78N-1721	II	Yes.
868.5170	Laryngotracheal topical anesthesia applicator	78N-1722	II	No.
868.5180	Rocking bed	78N-1723	II	No.
868.5220	Blow bottle	78N-1726	I	No.
868.5240	Anesthesia breathing circuit	78N-1727	II	No.
868.5250	Breathing circuit circulator	78N-1728	II	No.
868.5260	Breathing circuit bacterial filter	78N-1729	II	No.
868.5270	Breathing system heater	78N-1730	II	No.
868.5280	Breathing tube support	78N-1731	I	Yes.
868.5300	Carbon dioxide absorbent	78N-1732	II	Yes.
868.5310	Carbon dioxide absorber	78N-1733	II	No.
868.5320	Reservoir bag	78N-1734	II	No.
868.5330	Breathing gas mixer	78N-1735	II	No.
868.5340	Nasal oxygen cannula	78N-1736	I	Yes.
868.5350	Nasal oxygen catheter	78N-1737	I	Yes.
868.5365	Posture chair for cardiac or pulmonary treatment	78N-1738	I	No.
868.5375	Heat and moisture condenser (artificial nose)	78N-1739	II	No.
868.5400	Electroanesthesia apparatus	78N-1741	III	No.
868.5420	Ether hook	78N-1743	I	No.
868.5430	Gas-scavenging apparatus	78N-1744	II	Yes.
868.5440	Portable oxygen generator	78N-1745	II	No.
868.5450	Respiratory gas humidifier	78N-1746	II	No.
868.5460	Therapeutic humidifier for home use	78N-1747	II	Yes.
868.5470	Hyperbaric chamber	78N-1748	II	No.
868.5530	Flexible laryngoscope	78N-1752	II	No.
868.5540	Rigid laryngoscope	78N-1753	II	No.
868.5550	Anesthetic gas mask	78N-1754	II	No.
868.5560	Gas mask head strap	78N-1755	I	Yes.
868.5570	Nonrebreathing mask	78N-1756	II	No.
868.5580	Oxygen mask	78N-1757	II	Yes.
868.5590	Scavenging mask	78N-1758	II	No.
868.5600	Venturi mask	78N-1759	II	No.
868.5610	Membrane lung for long-term pulmonary support	78N-1760	III	No.
868.5620	Breathing mouthpiece	78N-1761	I	Yes.
868.5630	Nebulizer	78N-1762	II	No.
868.5640	Medicinal nonventilatory nebulizer (atomizer)	78N-1763	I	No.
868.5650	Esophageal obturator	78N-1764	II	No.
868.5655	Portable liquid oxygen unit	78N-1765	II	No.
868.5665	Powered percussor	78N-1766	II	No.
868.5675	Rebreathing device	78N-1767	I	No.
868.5690	Incentive spirometer	78N-1768	II	Yes.
868.5700	Nonpowered oxygen tent	78N-1769	I	No.
868.5710	Electrically powered oxygen tent	78N-1770	II	Yes.
868.5720	Bronchial tube	78N-1771	II	No.
868.5730	Tracheal tube	78N-1772	II	Yes.
868.5740	Tracheal/bronchial differential ventilation tube	78N-1773	II	Yes.
868.5750	Inflatable tracheal tube cuff	78N-1774	II	No.
868.5760	Cuff spreader	78N-1775	I	Yes.
868.5770	Tracheal tube fixation device	78N-1776	II	No.
868.5780	Tube introduction forceps	78N-1777	II	No.
868.5790	Tracheal tube stylet	78N-1778	II	No.
868.5810	Airway connector	78N-1780	II	No.
868.5820	Dental protector	78N-1781	II	No.
868.5830	Autotransfusion apparatus	78N-1782	II	Yes.
868.5860	Pressure tubing and accessories	78N-1784	II	No.
868.5870	Nonrebreathing valve	78N-1785	II	Yes.
868.5880	Anesthetic vaporizer	78N-1786	II	Yes.
868.5895	Continuous ventilator	78N-1787	II	No.
868.5905	Noncontinuous ventilator (IPPB)	78N-1788	II	No.

Section	Device	Docket No.	Class	Comments
868.5915	Manual emergency ventilator	78N-1789	II	No.
868.5925	Powered emergency ventilator	78N-1790	II	No.
868.5935	External negative pressure ventilator	78N-1791	II	No.
868.5955	Intermittent mandatory ventilation attachment	78N-1793	II	No.
868.5965	Positive end expiratory pressure breathing attachment	78N-1794	II	No.
868.5975	Ventilator tubing	78N-1795	II	No.
868.5995	Tee drain (water trap)	78N-1796	II	No.
	Subpart G—Miscellaneous			
868.6100	Anesthetic cabinet, table, or tray	78N-1797	I	No.
868.6175	Cardiopulmonary emergency cart	78N-1798	I	No.
868.6225	Nose clip	78N-1799	I	No.
868.6250	Portable air compressor	78N-1800	II	No.
868.6400	Calibration gas	78N-1805	II	Yes.
868.6700	Anesthesia stool	78N-1806	I	No.
868.6810	Tracheobronchial suction catheter	78N-1810	I	No.
868.6820	Patient position support	78N-1807	II	No.
868.6885	Medical gas yoke assembly	78N-1808	II	Yes.

Summaries of Comments and FDA's Responses to Comments

FDA is responding to specific comments received on 42 of the proposed regulations for anesthesiology devices and to several general comments as follows:

1. FDA received two general comments regarding the classification process and the classification proposals for anesthesiology devices.

a. A comment objected to the publication of final rules for anesthesiology devices at this time. The comment recommended that the publication of these rules await completion of rulemaking that specifies the requirements for good manufacturing practices (GMP).

FDA rejects the comment. FDA published in the Federal Register of July 21, 1978, a final regulation establishing good manufacturing practice for the manufacture, packing, storage, and installation of medical devices. See Part 820 of the regulations (21 CFR Part 820).

b. A comment also expressed concern that the risks to health listed in each proposed classification regulation might lead to a standard requirement for all devices reflecting the risks to health described by the Panel.

FDA rejects the comment. The anesthesiology regulations only classify devices into class I, class II, or class III. Classification regulations do not require that devices by labeled to warn of, or marketed in a way that eliminates, the risks to health stated in the proposals.

Therefore, FDA is proceeding with the publication of the final regulation classifying anesthesiology devices.

2. Section 868.1075; Docket No. 78N-1651; Argon gas analyzer.

FDA published in the Federal Register (44 FR 63302) a proposed regulation to classify argon gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only argon gas analyzers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying the argon gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

3. Section 868.1400; Docket No. 78N-1666; Carbon dioxide gas analyzer.

FDA published in the Federal Register (44 FR 63314) a proposed regulation to classify carbon dioxide gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only carbon dioxide gas analyzers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying carbon dioxide gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

4. Section 868.1430; Docket No. 78N-1667; Carbon monoxide gas analyzer.

FDA published in the Federal Register (44 FR 63315) a proposed regulation to classify carbon monoxide gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only carbon monoxide gas analyzers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying carbon monoxide gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

5. Section 868.1500; Docket No. 78N-1668; Enflurane gas analyzer.

FDA published in the Federal Register (44 FR 63316) a proposed regulation to classify enflurane gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no

direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only enflurane gas analyzers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying enflurane gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

6. Section 868.1620; Docket No. 78N-1670; Halothane gas analyzer.

FDA published in the **Federal Register** (44 FR 63317) a proposed regulation to classify halothane gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only halothane gas analyzers intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying halothane gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

7. Section 868.1640; Docket No. 78N-1671; Helium gas analyzer.

FDA published in the **Federal Register** (44 FR 63318) a proposed regulation to classify helium gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only helium gas analyzers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying helium gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

8. Section 868.1670; Docket No. 78N-1672; Neon gas analyzer.

FDA published in the **Federal Register** (44 FR 63319) a proposed regulation to classify neon gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only neon gas analyzers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying neon gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

9. Section 868.1690; Docket No. 78N-1673; Nitrogen gas analyzer.

FDA published in the **Federal Register** (44 FR 63319) a proposed regulation to classify nitrogen gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classified only nitrogen gas analyzers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying nitrogen gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only minor changes.

10. Section 868.1700; Docket No. 78N-1674; Nitrous oxide gas analyzer.

FDA published in the **Federal Register** (44 FR 63320) a proposed regulation to classify nitrous oxide gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only nitrous oxide gas analyzers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying nitrous oxide gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

11. Section 868.1720; Docket No. 78N-1675; Oxygen gas analyzer.

FDA published in the **Federal Register** (44 FR 63321) a proposed regulation to classify oxygen gas analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only oxygen gas analyzers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying oxygen gas analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

12. Section 868.1840; Docket No. 78N-1681; Diagnostic spirometer.

FDA published in the **Federal Register** (44 FR 63326) a proposed regulation to

classify diagnostic spirometers into class II.

One comment was received on the proposal. The comment suggested that diagnostic spirometers intended to be used in routine clinical practice do not require the same level of performance accuracy as those devices that are intended to be used in epidemiologic and research studies. The comment suggested specific performance requirements for office spirometers.

FDA agrees that devices intended to be used in different circumstances may require different levels of accuracy. FDA believes that performance standards for diagnostic spirometers should include only those performance requirements that are necessary to assure the safety and effectiveness of the device. No comments were received that disagreed with classifying diagnostic spirometers into class II. Accordingly, the proposed regulation is being adopted with minor editorial changes only.

13. Section 868.1870; Docket No. 78N-1684; Gas volume calibrator.

FDA published in the **Federal Register** (44 FR 63328) a proposed regulation to classify gas volume calibrators into class II.

Two comments were received on the proposal. The comments stated that many types of gas volume calibrators are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use calibrators are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only gas volume calibrators that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying gas volume calibrators that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a clarifying change.

14. Section 868.1975; Docket No. 78N-1692; Water vapor analyzer.

FDA published in the **Federal Register** (44 FR 63335) a proposed regulation to classify water vapor analyzers into class II.

Two comments were received on the proposal. The comments stated that many types of nonindwelling analyzers are manufactured and sold for commercial, laboratory, or calibration applications including use in a hospital laboratory. The comments suggested that general use analyzers are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to the devices.

FDA disagrees with the comments. The regulation classifies only water vapor analyzers intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. No comments have been received that disagreed with classifying water vapor analyzers that are medical devices into class II. Accordingly, the proposed regulation is being adopted with only a minor change.

15. Section 868.2350; Docket No. 78N-1697; Gas calibration flowmeter.

FDA published in the **Federal Register** (44 FR 63339) a proposed regulation to classify gas calibration flowmeters into class II.

Three comments were received on the proposal. The comments stated that gas calibration flowmeters are not medical devices because the devices are used in industrial applications as well as in hospital laboratories. The comments pointed out that the devices never come into direct contact with patients and suggested that FDA not classify these devices.

FDA disagrees with the comments. The regulation classifies only gas calibration flowmeters that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. Medical purposes include claibration of other medical devices, or measurement of medical gas flow, when performed in health care facilities. Accordingly, the proposed regulation is being adopted with only a clarifying change.

16. Section 868.2500; Docket No. 78N-1700; Cutaneous oxygen monitor.

FDA published in the **Federal Register** (44 FR 63341) a proposed regulation to classify cutaneous oxygen monitors into class II.

Three comments were received on the proposal. All three comments agreed with the proposal to classify cutaneous oxygen monitors into class II. One comment noted that the primary application of the device has been for monitoring newborn infants. Another comment stated that the device is also useful for monitoring patients in the operating room and in surgical intensive care.

On January 21, 1980, FDA held a public meeting of the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel for discussion of the comments received on the proposal to classify this device. The discussion focused on the questions whether the device should be classified into class II for all indications as proposed, or whether the device should be classified into class II for some indications and class III for others. Also present at the meeting were representatives of companies that manufacture the device who supported the proposal to classify the device into class II and who stated that sufficient information exists to develop a performance standard for the device. During the meeting, the Panel members reconsidered their recommendation respecting the classification of the device. Recent reports have indicated that cutaneous oxygen monitors may vary widely in performance depending on the conditions of use. Some of the devices may produce inaccurate readings when used in the presence of certain anesthetics in the operating room. Virtually all of the data on this device have been on monitoring of newborn infants, and very little data are available for other uses, such as monitoring patients during surgery.

FDA has carefully considered the comments, available information, and the Panel's recommendation that the device be classified into class II, as proposed, when it is intended for use in monitoring infant patients who are not under gas anesthesia and into class III for other uses. The Panel's recommendation was based on its belief that the device has been shown to be safe and effective for use in monitoring infant patients who are not under gas anesthesia, but has not been shown to be safe and effective for other uses.

Based on the findings above, FDA is classifying the device into class II when it is intended for use in monitoring infant patients who are not under gas anesthesia and into class III when the device is intended for other uses. The device is purported or represented for a use (monitoring oxygen tension) that is of substantial importance in preventing impairment of human health. The use of the device for noninfant patients or for any patient while under gas anesthesia, presents a potential unreasonable risk of illness or injury to the patient, because of the variability of the data obtained. There is insufficient information, including clinical data, available to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device or to establish a standard that assures the safety and effectiveness of the device when it is intended for these purposes. This conclusion, which differs from the

tentative judgment contained in the proposed regulation, is prompted by FDA's belief that the device is still undergoing development which will show whether it may be safely and effectively used for these applications. FDA is issuing a final regulation to classify the cutaneous oxygen monitor into class II when it is intended for use in monitoring infants who are not under gas anesthesia. FDA has decided that there is sufficient data to show that the device is both safe and effective when used for this purpose. Therefore, premarket approval is not necessary for cutaneous oxygen monitors when intended for this purpose and a performance standard will provide reasonable assurance of the safety and effectiveness of the device when intended for this purpose.

Accordingly, FDA is adopting the proposed regulation for cutaneous oxygen monitors with a change in the classification, in that the device is in class II for use in monitoring infants who are not under gas anesthesia and in class III for all other uses. For the reasons discussed above in "Changes in Classification in Final Regulations," FDA has decided that it is unnecessary to issue a new proposal concerning this decision. Persons who disagree with this decision may petition for reclassification of this device under Subpart C of Part 860.

17. Section 868.2610; Docket No. 78N–1704; Gas pressure gauge.

FDA published in the **Federal Register** (44 FR 63344) a proposed regulation to classify gas pressure gauges into class II.

Four comments were received on the proposal.

a. One comment disagreed with classifying gas pressure gauges into class II and recommended that the devices be classified into class I instead. The comment stated that general controls are sufficient to control the risks to health presented by the device.

FDA disagrees with the comment. FDA has determined that gas pressure gauges should be classified into class II so that a performance standard may be issued that assures that the device accurately measures the pressure of respiratory gases. General controls will not provide reasonable assurance of the safety and effectiveness of the device.

b. Three comments stated that gas pressure gauges are not medical devices and should not be classified. One comment stated that the identification of the device should be changed to more clearly define the intended use of the device.

FDA partially agrees with the comments. FDA agrees that the identification of the device should be stated more clearly and is making minor changes to the regulation to make it clear that the classification applies to those devices intended for medical purposes, i.e., use in a medical gas delivery system. Accordingly, the proposed regulation is being adopted with these changes.

18. Section 868.2620; Docket No. 78N–1705; Gas pressure calibrator.

FDA published in the **Federal Register** (44 FR 63345) a proposed regulation to classify gas pressure calibrators into class II.

Two comments were received on the proposal. The comments stated that many types of gas pressure calibrators are manufactured and sold for commercial, industrial, or laboratory applications, including use in a hospital laboratory. The comments suggested that the devices are not medical devices because there is no direct contact with the patient and recommended that the proposed classification not apply to such devices.

FDA disagrees with the comments. The regulation classifies only gas pressure calibrators that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. Accordingly, the proposed regulation is being adopted with only a minor clarifying change.

19. Section 868.2700; Docket No. 78N–1706; Pressure regulator.

FDA published in the **Federal Register** (44 FR 63346) a proposed regulation to classify pressure regulators into class II.

Two comments were received on the proposal. The comments suggested that the device name and identification in the proposed regulation for pressure regulators be changed to make it clear that the regulation does not apply to those regulators intended or promoted for commercial, industrial, and aviation applications.

FDA agrees with the comments and is making minor changes in the identification of the device to make it clear that the rule applies only to those devices intended to be used for medical purposes. Accordingly, the proposed regulation is being adopted with these changes.

20. Section 868.2875; Docket No. 78N–1708; Differential pressure transducer.

FDA published in the **Federal Register** (44 FR 63348) a proposed regulation to classify differential pressure transducers into class II.

Two comments were received on the proposal. The comments stated that many types of differential pressure transducers are manufactured and sold for commercial, industrial, or laboratory applications, including use in a hospital laboratory. The comments suggested that general use transducers are not medical devices when there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only differential pressure transducers intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. Accordingly, the proposed regulation is being adopted without change.

21. Section 868.2885; Docket No. 78N–1709; Gas flow transducer.

FDA published in the **Federal Register** (44 FR 63349) a proposed regulation to classify gas flow transducers into class II.

Two comments were received on the proposal. The comments stated that many types of gas flow transducers are munufactured and sold for commerical, industrial, or laboratory applications, including use in a hospital laboratory. The comments suggested that these general use transducers are not medical devices when there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only gas flow transducers that are intended for medical purposes and that, therefore, are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. Accordingly, the proposed regulation is being adopted with only a minor clarifying change.

22. Section 868.2900; Docket No. 78N–1710; Gas pressure transducer.

FDA published in the **Federal Register** (44 FR 63349) a proposed regulation to classify gas pressure transducers into class II.

Two comments were received on the proposal. The comments stated that many gas pressure transducers are manufactured and sold for commercial, industrial, or laboratory applications, including use in a hospital laboratory. The comments suggested that these general use transducers are not medical devices when there is no direct contact with the patient and recommended that the proposed classification not apply to these devices.

FDA disagrees with the comments. The regulation classifies only gas pressure transducers that are intended for medical purposes and that, therefore,

are medical devices. Direct patient contact is not a legal prerequisite to the regulation of a product as a medical device. Accordingly, the proposed regulation is being adopted with only a minor clarifying change.

23. Section 868.5100; Docket No. 78N-1715; Nasopharyngeal airway.

FDA published in the Federal Register (44 FR 63351) a proposed regulation to classify nasopharyngeal airways into class II.

Two comments were received on the proposal. The comments objected to the Panel's identification, in its recommendation, of infection as a risk to health presented by the device because of concern that FDA may adopt a standard requirement that all nasopharyngeal airways be labeled and marketed as sterile.

FDA disagrees with the comments. The proposed regulation only classifies the device into class II. It does not contain a requirement that all nasopharyngeal airways be labeled and marketed as sterile. The need for such a requirement will be considered in any proceeding to establish a standard for the device. Accordingly, the proposed regulation is being adopted with only a minor change.

24. Section 868.5160; Docket No. 78N-1721; Gas machine for anesthesia or analgesia.

FDA published in the Federal Register (44 FR 63356) a proposed regulation to classify anesthesia gas machines into class II.

Six comments were received on the proposal. The comments disagreed with the inclusion of analgesia machines used in dentistry with the generic category of anesthesia gas machines. The comments asked that FDA establish a separate generic category for conscious sedation dental equipment and that these devices be reviewed by the Dental Device Classification Panel. The comments also asked that these devices be classified into class I.

On January 21, 1980, FDA held a public meeting of the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel for discussion of the comments received on the proposal. The Panel recommended that FDA create a separate generic category for gas machines for analgesia, that gas machines for analgesia remain in class II, and that the final regulation for the device be published with the anesthesiology devices. FDA agrees with the Panel recommendation and is publishing a separate final regulation within § 868.5160 that classifies gas machines for analgesia into class II. The proposed regulation for gas machines for anesthesia is being adopted with minor modifications reflecting the separation of the gas machines for analgesia. The agency advises that a premixed nitrous oxide-oxygen product is regarded as a new drug requiring an approved new drug application (21 CFR Part 314—New Drug Applications) prior to marketing.

25. Section 868.5280; Docket No. 78N-1731; Breathing tube support.

FDA published in the Federal Register (44 FR 63363) a proposed regulation to classify breathing tube supports into class I.

One comment was received on the proposal. The comment disagreed with the proposal to classify breathing tube supports into class I. The comment noted that FDA proposed that breathing tubes be classified into class II and suggested that breathing tube supports also be classified into class II because the two devices are connected together.

FDA disagrees with the comment. There is no requirement that two devices be classified into the same regulatory category simply because they are used together. For the reasons given in the proposal, FDA is classifying breathing tube supports into class I. Accordingly, the regulation is being adopted with only a minor clarifying change.

26. Section 868.5300; Docket No. 78N-1732; Carbon dioxide absorbent.

FDA published in the Federal Register (44 FR 63364) a proposed regulation to classify carbon dioxide absorbents into class II.

Two comments were received on the proposal. The comments disagreed with the Panel's recommendation that cross infection of carbon dioxide absorbents is a risk to health and asserted that the device is not designed to be sterilized or disinfected.

FDA believes that the risks of cross infection result from improper maintenance of the equipment. However, the regulation does not require that the absorbent be sterilized or disinfected. Accordingly, the proposed regulation is being adopted with only a minor clarifying change.

27. Section 868.5340; Docket No. 78N-1736; Nasal oxygen cannula.

FDA published in the Federal Register (44 FR 63367) a proposed regulation to classify nasal oxygen cannulae into class I.

Three comments were received on the proposal.

a. One comment disagreed with the proposal to classify nasal oxygen cannulae into class I and recommended that the device be classified into class II. The comment stated that performance standards for nasal oxygen cannulae are needed to provide the user with information necessary for specifying accuracy requirements for the metering equipment on some regulators and oxygen concentrators.

FDA disagrees with the comment. FDA believes that the safety and effectiveness of these devices can be adequately controlled by general controls. It is the responsibility of medical personnel to choose compatible equipment when constructing a system for patient therapy. Moreover, FDA has authority under sections 502 and 701(a) of the act (21 U.S.C. 352 and 371(a)) to require special labeling for any device, including a class I device. Thus, classification into class I does not preclude the establishment of special labeling requirements for nasal oxygen cannulae, should FDA decide that these requirements are needed.

b. Two comments objected to the Panel's identification, in its recommendation, of infection as a risk to health presented by the device, because of concern that FDA may adopt a standard requirement that all nasal oxygen cannulae be labeled and marketed as sterile.

FDA disagrees with the comments. The proposed regulation only classifies these devices into class I. It does not contain a requirement that all nasal oxygen cannulae be labeled and marketed as sterile. Accordingly, the proposed regulation is being adopted with only a minor editorial change.

28. Section 868.5350; Docket No. 78N-1737; Nasal oxygen catheter.

FDA published in the Federal Register (44 FR 63368) a proposed regulation to classify nasal oxygen catheters into class I.

One comment was received on the proposal. The comment disagreed with the proposal to classify nasal oxygen catheters into class I and recommended that the device be classified into class II. The comment stated that performance standards for nasal oxygen catheters are needed to provide the user with information necessary for specifying accuracy requirements for the metering equipment on some regulators and oxygen concentrators.

FDA disagrees with the comment. FDA believes that the safety and effectiveness of this device can be adequately controlled by general controls. It is the responsibility of medical personnel to choose compatible equipment when constructing a system for patient therapy. Moreover, FDA has authority under sections 502 and 701(a) of the act (21 U.S.C. 352 and 371(a)) to require special labeling for any device, including a class I device. Thus, classification into class I does not preclude the establishment of special

labeling requirements for nasal oxygen catheters, should FDA decide that these requirements are needed. Accordingly, the proposed regulation is being adopted with only minor editorial changes.

29. Section 868.5430; Docket No. 78N-1744; Gas-scavenging apparatus.

FDA published in the **Federal Register** (44 FR 63374) a proposed regulation to classify gas-scavenging apparatus into class II.

One comment was received on the proposal. The comment stated that the gas scavenging apparatus is used only to scavenge nitrous oxide that is used by dentists. The comment suggested that FDA refer the issue of the classification of the device to the Dental Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, to obtain its recommendation.

FDA disagrees with the comment. Gas scavenging devices are used to collect many types of anesthetic or analgesic gases used by various medical specialties and are not limited to dental use. It was appropriate for FDA to have obtained a recommendation from the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel, and it is unnecessary to obtain another recommendation from the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel. Accordingly, the proposed regulation is being adopted with only minor editorial changes.

30. Section 868.5460; Docket No. 78N-1747; Therapeutic humidifier for home use.

FDA published in the **Federal Register** (44 FR 63376) a proposed regulation to classify therapeutic humidifiers for home use into class II.

Four comments were received on the proposal. The comments expressed concern that the proposed rule might be interpreted to apply to all home humidifiers, including those that are part of home central air conditioning and heating systems. The comments suggested that FDA clearly state in the final rule for therapeutic humidifiers for home use that the classification applies only to those devices for which manufacturers make health or medical claims.

FDA believes that in the proposed regulation the identification of therapeutic humidifiers for home use clearly states that the proposed classification applies solely to those humidifiers that are intended to be used for medical purposes, such as respiratory therapy. FDA does not believe that humidifiers that are designed to be used with central air conditioning or heating systems in a home are medical devices unless they are intended for medical purposes, as discussed earlier in this preamble. FDA is clarifying the name and identification of the device to show the regulation applies only to those devices intended for medical purposes.

31. Section 868.5560; Docket No. 78N-1755; Gas mask head strap.

FDA published in the **Federal Register** (44 FR 63383) a proposed regulation to classify gas mask head straps into class I.

One comment was received on the proposal. The comment disagreed with the proposal to classify gas mask head straps into class I. The comment noted that FDA proposed that anesthesia gas masks be classified into class II and suggested that gas mask head straps also be classified into class II because the two devices are connected together.

FDA disagrees with the comment. There is no requirement that two devices be classified into the same regulatory category simply because they are used together. For the reasons given in the proposal, FDA is classifying gas mask head straps into class I. Accordingly, the regulation is being adopted with only a minor editorial change.

32. Section 868.5580; Docket No. 78N-1757; Oxygen mask.

FDA published in the **Federal Register** (44 FR 63384) a proposed regulation to classify oxygen masks into class I.

Three comments were received on the proposal.

a. Two comments objected to the Panel's identification, in its recommendation, of infection as a risk to health presented by the device because of concern that FDA may require all oxygen masks to be labeled and marketed as sterile.

FDA disagrees with the comments. The proposed regulation only classifies the device into class I. It does not contain a requirement that oxygen masks be labeled and marketed as sterile.

b. One comment disagreed with the proposal to classify the device into class I and recommended that it be classified in class II. The comment noted that manufacturers do not always use the same designations for oxygen mask sizes (e.g., small, medium, and large). Thus, a patient may receive a poorly fitting oxygen mask in an emergency situation if the user mistakenly assumes that oxygen mask sizes are uniform from manufacturer to manufacturer. The comment stated that a performance standard that assures uniformity of oxygen mask sizes is necessary to avoid this risk to the patient.

On January 21, 1980, FDA held a public meeting of the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel to discuss the comment. The Panel recommended that FDA classify oxygen masks into class II because it agreed that lack of uniformity of mask sizes is a hazard that cannot be controlled by general controls. The Panel recommended that the development of a performance standard for oxygen masks be a low priority. FDA has considered the comment and the Panel's revised recommendation, and is classifying oxygen masks into class II rather than class I as proposed. For the reasons discussed above in "Changes in Classification in Final Regulations," FDA does not believe that it is necessary to issue a new proposal concerning this decision. Persons who disagree with classifying oxygen masks in class II may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

For clarification purposes, FDA has amended the identification of oxygen masks to indicate that the device may also be placed over a patient's tracheostomy, and that it can be used to administer aerosols. Accordingly, the proposed regulation is being adopted with the changes noted.

33. Section 868.5620; Docket No. 78N-1761; Breathing mouthpiece.

FDA published in the **Federal Register** (44 FR 63388) a proposed regulation to classify breathing mouthpieces into class II.

One comment was received on the proposal. The comment disagreed with the proposal to classify breathing mouthpieces into class II and suggested that the device be classified into class I. The comment stated that general controls will provide sufficient control over the risks to health presented by this device.

On January 21, 1980, FDA held a public meeting of the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel to discuss the comment. The Panel recommended that FDA classify breathing mouthpieces into class I because the hazards to health presented by this device can be adequately controlled by general controls. The Panel also recommended that there be no exemptions for manufacturers of this device. FDA has considered the comment and the Panel's revised recommendation, and is classifying breathing mouthpieces into class I with no exemptions, rather than class II as proposed. For the reasons discussed above in "Changes in Classification of Final Regulations," FDA does not believe that it is necessary to issue a new proposal concerning this decision.

Persons who disagree with classifying breathing mouthpieces in class I may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860). Accordingly, the proposed regulation is being adopted with this change in classification and minor editorial changes.

34. Section 868.5690; Docket No. 78N-1768; Incentive spirometer.

FDA published in the **Federal Register** (44 FR 63394) a proposed regulation to classify incentive spirometers into class II.

Two comments were received on the proposal. The comments disagreed with the proposal to classify the device into class II and recommended that it be classified into class I. The comments noted that an incentive spirometer is intended to be used as a breathing exerciser to aid a patient in improving ventilation by indicating the patient's breathing volume or flow. The comments stated that volume and flow readings that are indicated on an incentive spirometer are not intended to be accurate enough for diagnostic or monitoring purposes.

FDA disagrees with the comments. The flow and volume indications obtained from an incentive spirometer may be used to measure a patient's progress in improving ventilation and should be reasonably accurate and reproducible. FDA agrees that an incentive spirometer need not be as accurate as a diagnostic spirometer. However, FDA believes that general controls are not sufficient to control the accuracy of the device and that a performance standard is necessary to provide assurance of the safety and effectiveness of the device. Accordingly, the proposed regulation is being adopted with only minor changes.

35. Section 868.5710; Docket No. 78N-1770; Electrically powered oxygen tent.

FDA published in the **Federal Register** (44 FR 63395) a proposed regulation to classify electrically powered oxygen tents into class II.

One comment was received on the proposal. The comment agreed with the proposal to classify electrically powered oxygen tents into class II but stated that the reasons the Panel gave for recommending the device be classified into class II do not apply to all devices that are being marketed.

FDA agrees with the comment. FDA believes that the reasons given by the Panel for the recommendation to classify the device in class II are valid for electrically powered oxygen tents as a generic group but these reasons may not always apply to every device that is marketed. Accordingly, the proposed regulation is being adopted with only minor editorial changes.

36. Section 868.5730; Docket No. 78N-1772; Tracheal tube.

FDA published in the **Federal Register** (44 FR 63397) a proposed regulation to classify tracheal tubes into class II.

Two comments were received on the proposal. The comments objected to the Panel's identification, in its recommendation, of infection as a risk to health presented by tracheal tubes because of concern that FDA may adopt a standard requirement that all tracheal tubes be labeled and marketed as sterile.

FDA disagrees with the comments. The proposed regulation only classifies the devices into class II. It does not contain a requirement that all tracheal tubes be labeled and marketed as sterile. The need for such a requirement will be considered in any proceeding to establish a standard for the device. Accordingly, the proposed regulation is being adopted without change.

37. Section 868.5740; Docket No. 78N-1773; Tracheal/bronchial differential ventilation tube.

FDA published in the **Federal Register** (44 FR 63398) a proposed regulation to classify tracheal/bronchial differential ventilation tubes into class II.

Two comments were received on the proposal. The comments objected to the Panel's identification, in its recommendation, of infection as a risk to health presented by tracheal/bronchial differential ventilation tubes because of concern that FDA may adopt a standard requirement that all tracheal/bronchial differential ventilation tubes be labeled and marketed as sterile.

FDA disagrees with the comments. The proposed regulation only classifies these devices into class II. It does not contain a requirement that all tracheal/bronchial differential ventilation tubes be labeled and marketed as sterile. The need for such a requirement will be considered in any proceeding to establish a standard for the device. Accordingly, the proposed regulation is being adopted with only a minor change.

38. Section 868.5760; Docket No. 78N-1775; Cuff spreader.

FDA published in the **Federal Register** (44 FR 63400) a proposed regulation to classify cuff spreader into class I.

Two comments were received on the proposal. The comments stated that a cuff spreader is not a medical device because it is used only to facilitate the assembly of a tracheal tube cuff on a tracheal or tracheostomy tube.

FDA disagrees with the comments. Cuff spreaders are clearly medical devices because they are intended for a medical purpose, i.e., to install tracheal tube cuffs on tracheal tubes or tracheostomy tubes for use on a patient. Accordingly, the proposed regulation is being adopted without change.

39. Section 868.5830; Docket No. 78N-1782; Autotransfusion apparatus.

FDA published in the **Federal Register** (44 FR 63405) a proposed regulation to classify Autotransfusion apparatus into class III.

Nine comments were received on the proposal. The comments disagreed with the proposal to classify the autotransfusion apparatus into class III. The comments recommended that the device be classified into class II because the devices in use have been shown to be safe and effective. The comments stated that a draft standard for autotransfusion devices has been written. The comments also pointed out that the proposed identification of autotransfusion apparatus describes only one type of device despite the fact that there are several devices on the market.

On January 21, 1980, FDA held a public meeting of the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel to consider the comments on the proposal. At the meeting, several users of autotransfusion apparatus described their experiences with some of the autotransfusion devices that are being marketed. All of these users stated that the devices are safe and effective and asked that the Panel recommend that the device be classified into class II rather than class III. It was reported that virtually all problems that have been reported have been associated with one particular type of the device that is not now marketed. Participants in the meeting also discussed the standard for these devices being developed by a committee of The Association for the Advancement of Medical Instrumentation (AAMI). The chairperson of this committee stated that a standard for these devices was nearly completed and that it was expected to be balloted later that year. The Panel recommended that autotransfusion apparatus be classified into class II rather than class III as proposed. The Panel believes that there is now sufficient information available to develop a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The critical issue is whether a standard can provide reasonable assurance of the safety and effectiveness of autotransfusion devices. FDA has carefully considered the comments, available information, and the Panel's

recommendation and is classifying autotransfusion apparatus into class II, rather than class III as proposed. FDA also is changing the identification of the device in the final rule to clarify that the regulation applies to all autotransfusion devices. The agency encourages the AAMI committee to complete the development of the standard for this device as quickly as possible. FDA will closely monitor the progress of the standard. If the agency believes that the standard being developed does not provide reasonable assurance of the safety and effectiveness of the device, it may at a later date reconsider the classification of the device into class II.

Accordingly, the final regulation is being changed as described above. For the reasons discussed above in "Changes in Classification of Final Regulations," FDA does not believe that it is necessary to issue a new proposal concerning this decision. Persons who disagree with classifying autotransfusion apparatus in class II may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

40. Section 868.5870; Docket No. 78N-1785; Nonrebreathing valve.

FDA published in the **Federal Register** (44 FR 63407) a proposed regulation to classify nonrebreathing valves into class II.

One comment was received on the proposal. The comment objected to the proposal to classify nonrebreathing valves into class II and recommended that the device be classified into class I. The comment stated that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, when the device is not used in a life support situation. The comment also agreed that the proposed classification regulation made no distinction between the risks to health presented by a nonrebreathing valve when it is used in a life supporting system and those present when it is used in a system that is not a life supporting system.

FDA disagrees with the comment. FDA believes that a performance standard is necessary to assure that nonrebreathing valves are safe and effective. FDA agrees that the consequences of a valve failure may be more severe when the valve is used in a life supporting system. However, the types of valve failure cited in the proposed classification regulation are applicable regardless of the type of system in which the valve is used. Accordingly, the proposed regulation is being adopted with only a minor change.

41. Section 868.5880; Docket No. 78N-1786; Anesthetic vaporizer.

FDA published in the **Federal Register** (44 FR 63408) a proposed regulation to classify anesthetic vaporizers into class II.

Three comments were received on the proposal. The comments expressed concern that the proposed rule might lead FDA to adopt a standard requirement that all anesthetic vaporizers be labeled and marketed as sterile or sterilizable. The comments suggested that FDA remove any references to sterilization from the final rule.

FDA disagrees with the comments. The proposed regulation only classifies the devices into class II. The regulation does not contain a requirement that all anesthetic vaporizers be labeled or marketed as sterile. The need for such a requirement will be considered in any proceeding to establish a standard for the device. Accordingly, the proposed regulation is being adopted without change.

42. Section 868.6400; Docket No. 78N-1805; Calibration gas.

FDA published in the **Federal Register** (44 FR 63423) a proposed regulation to classify calibration gases into class II.

Three comments were received on the proposal.

a. A comment disagreed with the proposal to classify calibration gases into class II and stated that the risks to health presented by the device can be controlled by classifying it into class I.

FDA disagrees with the comment. The device is used to calibrate other medical devices and must provide a gas concentration that is precise. FDA believes that general controls will not provide reasonable assurance that the gas concentration provided by the device is accurate and believes that a performance standard is necessary to provide this assurance.

b. One comment agreed with the proposal to classify the device into class II. Another comment did not disagree with the proposal, but suggested that FDA more clearly identify the function of calibration gases so that it is clear that nonmedical products are excluded.

FDA agrees with the comments. The agency is making minor changes in the identification of the device so that it is clear that the regulation applies only to those calibration gases intended to be used for medical purposes. Accordingly, the proposed regulation is being adopted with these changes.

43. Section 868.6885; Docket No. 78N-1808; Medical gas yoke assembly.

FDA published in the **Federal Register** (44 FR 63426) a proposed regulation to classify medical gas yoke assemblies into class II.

Three comments were received on the proposal. The comments noted that the filter used with a medical gas yoke assembly is an optional piece of equipment intended ony to protect the apparatus from particle contamination and is not intended to prevent contamination of the breathing system or patient infection.

The agency agrees with the comments and is making minor changes in the language used in the identification of medical gas yoke assemblies to clarify that the filter is a particulate filter. Accordingly, the proposed regulation is being adopted with these changes.

List of Subjects in 21 CFR Part 868

Anesthesiology devices; Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 868, to read as follows:

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

Sec.
868.1 Scope.

Subpart B—Diagnostic Devices

868.1030 Manual algesimeter.
868.1040 Powered algesimeter.
868.1075 Argon gas analyzer.
868.1100 Arterial blood sampling kit.
868.1120 Indwelling blood oxyhemoglobin concentration analyzer.
868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO2}) analyzer.
868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.
868.1200 Indwelling blood oxygen partial pressure (P_{O2}) analyzer.
868.1400 Carbon dioxide gas analyzer.
868.1430 Carbon monoxide gas analyzer.
868.1500 Enflurane gas analyzer.
868.1575 Gas collection vessel.
868.1620 Halothane gas analyzer.
868.1640 Helium gas analyzer.
868.1670 Neon gas analyzer.
868.1690 Nitrogen gas analyzer.
868.1700 Nitrous oxide gas analyzer.
868.1720 Oxygen gas analyzer.
868.1730 Oxygen uptake computer.
868.1750 Pressure plethysmograph.
868.1760 Volume plethysmograph.
868.1780 Inspiratory airway pressure meter.
868.1800 Rhinoanemometer.
868.1840 Diagnostic spirometer.
868.1850 Monitoring spirometer.
868.1860 Peak-flow meter for spirometry.
868.1870 Gas volume calibrator.
868.1880 Pulmonary-function data calculator.

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).

Subpart A—General Provisions

§ 868.1 Scope.

(a) This part sets forth the classification of anesthesiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an anesthesiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in a subpart representing one use of the device, rather than in two or more subparts.

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

Subpart B—Diagnostic Devices

§ 868.1030 Manual algesimeter.

(a) *Identification.* A manual algesimeter is a mechanical device intended to determine a patient's sensitivity to pain after administration of an anesthetic agent, e.g., by pricking with a sharp point.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 868.1040 Powered algesimeter.

(a) *Identification.* A powered algesimeter is a device using electrical stimulation intended to determine a patient's sensitivity to pain after administration of an anesthetic agent.

(b) *Classification.* Class II (performance standards).

§ 868.1075 Argon gas analyzer.

(a) *Identification.* An argon gas analyzer is a device intended to measure the concentration of argon in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as mass spectrometry or thermal conductivity.

(b) *Classification.* Class II (performance standards).

§ 868.1100 Arterial blood sampling kit.

(a) *Identification.* An arterial blood sampling kit is a device, in kit form, used to obtain arterial blood samples from a patient for blood gas determinations. The kit may include a syringe, needle, cork, and heparin.

(b) *Classification.* Class II (performance standards).

§ 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.

(a) *Identification.* An indwelling blood oxyhemoglobin concentration analyzer is a photoelectric device used to measure, in vivo, the oxygen-carrying capacity of hemoglobin in blood to aid

in determining the patient's physiological status.

(b) *Classification.* Class III (premarket approval).

§ 868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO2}) analyzer.

(a) *Identification.* An indwelling blood carbon dioxide partial pressure P_{CO2} analyzer is a device that consists of a catheter-tip P_{CO2} transducer (e.g., P_{CO2} electrode) and that is used to measure, in vivo, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class III (premarket approval).

§ 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.

(a) *Identification.* An indwelling blood hydrogen ion concentration (pH) analyzer is a device that consists of a catheter-tip pH electrode and that is used to measure, in vivo, the hydrogen ion concentration (pH) in blood to aid in determining the patient's acid-base balance.

(b) *Classification.* Class III (premarket approval).

§ 868.1200 Indwelling blood oxygen partial pressure P_{O2} analyzer.

(a) *Identification.* An indwelling blood oxygen partial pressure (P_{O2}) analyzer is a device that consists of a catheter-tip P_{O2} transducer (e.g., P_{O2} electrode) and that is used to measure, in vivo, the partial pressure of oxygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class III (premarket approval).

§ 868.1400 Carbon dioxide gas analyzer.

(a) *Identification.* A carbon dioxide gas analyzer is a device intended to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory, circulatory, and metabolic status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, or mass spectrometry.

(b) *Classification.* Class II (performance standards).

§ 868.1430 Carbon monoxide gas analyzer.

(a) *Identification.* A carbon monoxide gas analyzer is a device intended to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as infrared absorption or gas chromatography.

(b) *Classification.* Class II (performance standards).

§ 868.1500 Enflurane gas analyzer.

(a) *Identification.* An enflurane gas analyzer is a device intended to measure the concentration of enflurane anesthetic in a gas mixture.

(b) *Classification.* Class II (performance standards).

§ 868.1575 Gas collection vessel.

(a) *Identification.* A gas collection vessel is a container-like device intended to collect a patient's exhaled gases for subsequent analysis. It does not include a sampling pump.

(b) *Classification.* Class II (performance standards).

§ 868.1620 Halothane gas analyzer.

(a) *Identification.* A halothane gas analyzer is a device intended to measure the concentration of halothane anesthetic in a gas mixture. The device may use techniques such as mass spectrometry or absorption of infrared or ultraviolet radiation.

(b) *Classification.* Class II (performance standards).

§ 868.1640 Helium gas analyzer.

(a) *Identification.* A helium gas analyzer is a device intended to measure the concentration of helium in a gas mixture during pulmonary function testing. The device may use techniques such as thermal conductivity, gas chromatography, or mass spectrometry.

(b) *Classification.* Class II (performance standards).

§ 868.1670 Neon gas analyzer.

(a) *Identification.* A neon gas analyzer is a device intended to measure the concentration of neon in a gas mixture exhaled by a patient. The device may use techniques such as mass spectrometry or thermal conductivity.

(b) *Classification.* Class II (performance standards).

§ 868.1690 Nitrogen gas analyzer.

(a) *Identification.* A nitrogen gas analyzer is a device intended to measure the concentration of nitrogen in respiratory gases to aid in determining a patient's ventilatory status. The device may use techniques such as gas chromatography or mass spectrometry.

(b) *Classification.* Class II (performance standards).

§ 868.1700 Nitrous oxide gas analyzer.

(a) *Identification.* A nitrous oxide gas analyzer is a device intended to measure the concentration of nitrous oxide anesthetic in a gas mixture. The device may use techniques such as infrared absorption or mass spectrometry.

(b) *Classification.* Class II (performance standards).

§ 868.1720 Oxygen gas analyzer.

(a) *Identification.* An oxygen gas analyzer is a device intended to measure the concentration of oxygen in respiratory gases by techniques such as mass spectrometry, polarography, thermal conductivity, or gas chromatography. This generic type of device also includes paramagnetic analyzers.

(b) *Classification.* Class II (performance standards).

§ 868.1730 Oxygen uptake computer.

(a) *Identification.* An oxygen uptake computer is a device intended to compute the amount of oxygen consumed by a patient and may include components for determining expired gas volume and composition.

(b) *Classification.* Class II (performance standards).

§ 868.1750 Pressure plethysmograph.

(a) *Identification.* A pressure plethysmograph is a device used to determine a patient's airway resistance and lung volumes by measuring pressure changes while the patient is in an airtight box.

(b) *Classification.* Class II (performance standards).

§ 868.1760 Volume plethysmograph.

(a) *Identification.* A volume plethysmograph is an airtight box, in which a patient sits, that is used to determine the patient's lung volume changes.

(b) *Classification.* Class II (performance standards).

§ 868.1780 Inspiratory airway pressure meter.

(a) *Identification.* An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient's airway during maximal inspiration.

(b) *Classification.* Class II (performance standards).

§ 868.1800 Rhinoanemometer.

(a) *Identification.* A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient's nasal passages.

(b) *Classification.* Class II (performance standards).

§ 868.1840 Diagnostic spirometer.

(a) *Identification.* A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs.

(b) *Classification.* Class II (performance standards).

§ 868.1850 Monitoring spirometer.

(a) *Identification.* A monitoring spirometer is a device used to measure continuously a patient's tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient's ventilatory status.

(b) *Classification.* Class II (performance standards).

§ 868.1860 Peak-flow meter for spirometry.

(a) *Identification.* A peak-flow meter for spirometry is a device used to measure a patient's maximum ventilatory flow rate.

(b) *Classification.* Class II (performance standards).

§ 868.1870 Gas volume calibrator.

(a) *Identification.* A gas volume calibrator is a device that is intended for medical purposes and that is used to calibrate the output of gas volume measurement instruments by delivering a known gas volume.

(b) *Classification.* Class II (performance standards).

§ 868.1880 Pulmonary-function data calculator.

(a) *Identification.* A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

(b) *Classification.* Class II (performance standards).

§ 868.1890 Predictive pulmonary-function value calculator.

(a) *Identification.* A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.

(b) *Classification.* Class II (performance standards).

§ 868.1900 Diagnostic pulmonary-function interpretation calculator.

(a) *Identification.* A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine clinical significance of pulmonary-function values.

(b) *Classification.* Class II (performance standards).

§ 868.1910 Esophageal stethoscope.

(a) *Identification.* An esophageal stethoscope is a nonpowered device that is inserted into a patient's esophagus to enable the user to listen to heart and breath sounds.

(b) *Classification.* Class I (general controls).

§ 868.1920 Esophageal stethoscope with electrical conductors.

(a) *Identification.* An esophageal stethoscope with electrical conductors is a device that is inserted into the esophagus to listen to a patient's heart and breath sounds and to monitor electrophysiological signals. The device may also incorporate a thermistor for temperature measurement.

(b) *Classification.* Class II (performance standards).

§ 868.1930 Stethoscope head.

(a) *Identification.* A stethoscope head is a weighted chest piece used during anesthesia to listen to a patient's heart, breath, and other physiological sounds.

(b) *Classification.* Class I (general controls).

§ 868.1965 Switching valve (ploss).

(a) *Identification.* A switching valve (ploss) is a three-way valve located between a stethoscope placed over the heart, a blood pressure cuff, and an earpiece. The valve allows the user to eliminate one sound channel and listen only to a patient's heart or korotkoff (blood pressure) sounds through the other channel.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 868.1975 Water vapor analyzer.

(a) *Identification.* A water vapor analyzer is a device intended to measure the concentration of water vapor in a patient's expired gases by using techniques such as mass spectrometry.

(b) *Classification.* Class II (performance standards).

Subpart C—Monitoring Devices

§ 868.2025 Ultrasonic air embolism monitor.

(a) *Identification.* An ultrasonic air embolism monitor is a device used to detect air bubbles in a patient's blood stream. It may use Doppler or other ultrasonic principles.

(b) *Classification.* Class II (performance standards).

§ 868.2300 Bourdon gauge flowmeter.

(a) *Identification.* A bourdon gauge flowmeter is a device intended for medical purposes that is used in conjunction with respiratory equipment to sense gas pressure. The device is calibrated to indicate gas flow rate when the outflow is open to the atmosphere.

(b) *Classification.* Class II (performance standards).

§ 868.2320 Uncompensated thorpe tube flowmeter.

(a) *Identification.* An uncompensated thorpe tube flowmeter is a device intended for medical purposes that is used to indicate and control gas flow rate accurately. The device includes a vertically mounted tube and is calibrated when the outlet of the flowmeter is open to the atmosphere.

(b) *Classification.* Class II (performance standards).

§ 868.2340 Compensated thorpe tube flowmeter.

(a) *Identification.* A compensated thorpe tube flowmeter is a device intended for medical purposes that is used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

(b) *Classification.* Class II (performance standards).

§ 868.2350 Gas calibration flowmeter.

(a) *Identification.* A gas calibration flowmeter is a device intended for medical purposes that is used to calibrate flowmeters and accurately measure gas flow.

(b) *Classification.* Class II (performance standards).

§ 868.2375 Breathing frequency monitor.

(a) *Identification.* A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate is outside predetermined limits.

(b) *Classification.* Class II (performance standards).

§ 868.2450 Lung water monitor.

(a) *Identification.* A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance

(resistance to alternating current) by means of electrodes placed on the patient's chest.

(b) *Classification.* Class III (premarket approval).

§ 868.2500 Cutaneous oxygen monitor.

(a) *Cutaneous oxygen monitor for an infant patient who is not under gas anesthesia*—(1) *Identification.* A cutaneous oxygen monitor for an infant patient who is not under gas anesthesia is a device that uses a noninvasive sensor (e.g., a Clark-type polarographic electrode) placed on the patient's skin and that is intended to monitor relative changes in the cutaneous oxygen tension in an infant patient who is not under gas anesthesia.

(2) *Classification.* Class II (performance standards).

(b) *Cutaneous oxygen monitor for all other uses*—(1) *Identification.* A cutaneous oxygen monitor for all other uses is a device that uses a noninvasive sensor (e.g., a Clark-type polarographic electrode) placed on the patient's skin and that is intended to monitor relative changes in the cutaneous oxygen tension in a noninfant patient or in any patient, including an infant, who is under gas anesthesia.

(2) *Classification.* Class III (premarket approval).

§ 868.2550 Pneumotachometer.

(a) *Identification.* A pneumotachometer is a device intended for medical purposes that is used to determine gas flow by measuring the pressure differential across a known resistance. The device may use a set of capillaries or a metal screen for the resistive element.

(b) *Classification.* Class II (performance standards).

§ 868.2600 Airway pressure monitor.

(a) *Identification.* An airway pressure monitor is a device used to measure the pressure in a patient's upper airway. The device may include a pressure gauge and an alarm.

(b) *Classification.* Class II (performance standards).

§ 868.2610 Gas pressure gauge.

(a) *Identification.* A gas pressure gauge (e.g., bourdon tube pressure gauge) is a device intended for medical purposes that is used to measure gas pressure in a medical gas delivery system.

(b) *Classification.* Class II (performance standards).

§ 868.2620 Gas pressure calibrator.

(a) *Identification.* A gas pressure calibrator is a device intended for medical purposes that is used to calibrate pressure-measuring instruments by generating a known gas pressure.

(b) *Classification.* Class II (performance standards).

§ 868.2700 Pressure regulator.

(a) *Identification.* A pressure regulator is a device, often called a pressure-reducing valve, that is intended for medical purposes and that is used to convert a medical gas pressure from a high variable pressure to a lower, more constant working pressure. This device includes mechanical oxygen regulators.

(b) *Classification.* Class II (performance standards).

§ 868.2775 Electrical peripheral nerve stimulator.

(a) *Identification.* An electrical peripheral nerve stimulator (neuromuscular blockade monitor) is a device used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.

(b) *Classification.* Class II (performance standards).

§ 868.2875 Differential pressure transducer.

(a) *Identification.* A differential pressure transducer is a two-chambered device intended for medical purposes that is often used during pulmonary function testing. It generates an electrical signal for subsequent display or processing that is proportional to the difference in gas pressures in the two chambers.

(b) *Classification.* Class II (performance standards).

§ 868.2885 Gas flow transducer.

(a) *Identification.* A gas flow transducer is a device intended for medical purposes that is used to convert gas flow rate into an electrical signal for subsequent display or processing.

(b) *Classification.* Class II (performance standards).

§ 868.2900 Gas pressure transducer.

(a) *Identification.* A gas pressure transducer is a device intended for medical purposes that is used to convert gas pressure into an electrical signal for subsequent display or processing.

(b) *Classification.* Class II (performance standards).

Subparts D–E—[Reserved]

Subpart F—Therapeutic Devices

§ 868.5090 Emergency airway needle.

(a) *Identification.* An emergency airway needle is a device intended to puncture a patient's cricothyroid membrane to provide an emergency airway during upper airway obstruction.

(b) *Classification.* Class II (performance standards).

§ 868.5100 Nasopharyngeal airway.

(a) *Identification.* A nasopharyngeal airway is a device used to aid breathing by means of a tube inserted into a patient's pharynx through the nose to provide a patent airway.

(b) *Classification.* Class II (performance standards).

§ 868.5110 Oropharyngeal airway.

(a) *Identification.* An oropharyngeal airway is a device inserted into a patient's pharynx through the mouth to provide a patent airway.

(b) *Classification.* Class II (performance standards).

§ 868.5120 Anesthesia conduction catheter.

(a) *Identification.* An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia.

(b) *Classification.* Class II (performance standards).

§ 868.5130 Anesthesia conduction filter.

(a) *Identification.* An anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

(b) *Classification.* Class II (performance standards).

§ 868.5140 Anesthesia conduction kit.

(a) *Identification.* An anesthesia conduction kit is a device used to administer to a patient conduction, regional, or local anesthesia. The device may contain syringes, needles, and drugs.

(b) *Classification.* Class II (performance standards).

§ 868.5150 Anesthesia conduction needle.

(a) *Identification.* An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.

(b) *Classification.* Class II (performance standards).

§ 868.5160 Gas machine for anesthesia or analgesia.

(a) *Gas machine for anesthesia*—(1) *Identification.* A gas machine for anesthesia is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation. The device may include a

gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency air supply.

(2) *Classification.* Class II (performance standards).

(b) *Gas machine for analgesia*—(1) *Identification.* A gas machine for analgesia is a device used to administer to a patient an analgesic agent, such as a nitrous oxide-oxygen mixture (maximum concentration of 70 percent nitrous oxide).

(2) *Classification.* Class II (performance standards).

§ 868.5170 Laryngotracheal topical anesthesia applicator.

(a) *Identification.* A laryngotracheal topical anesthesia applicator is a device used to apply topical anesthetics to a patient's laryngotracheal area.

(b) *Classification.* Class II (performance standards).

§ 868.5180 Rocking bed.

(a) *Identification.* A rocking bed is a device intended for temporary use to help patient ventilation (breathing) by repeatedly tilting the patient, thereby using the weight of the abdominal contents to move the diaphragm.

(b) *Classification.* Class II (performance standards).

§ 868.5220 Blow bottle.

(a) *Identification.* A blow bottle is a device that is intended for medical purposes to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 868.5240 Anesthesia breathing circuit.

(a) *Identification.* An anesthesia breathing circuit is a device that is intended to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.

(b) *Classification.* Class II (performance standards).

§ 868.5250 Breathing circuit circulator.

(a) *Identification.* A breathing circuit circulator is a turbine device that is attached to a closed breathing circuit and that is intended to circulate anesthetic gases continuously by maintaining the unidirectional valves in an open position and reducing mechanical dead space and resistance in the breathing circuit.

(b) *Classification.* Class II (performance standards).

§ 868.5260 Breathing circuit bacterial filter.

(a) *Identification.* A breathing circuit bacterial filter is a device that is intended to remove microbiological and particulate matter from the gases in the breathing circuit.

(b) *Classification.* Class II (performance standards).

§ 868.5270 Breathing system heater.

(a) *Identification.* A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's airway. The device may include a temperature controller.

(b) *Classification.* Class II (performance standards).

§ 868.5280 Breathing tube support.

(a) *Identification.* A breathing tube support is a device that is intended to support and anchor a patient's breathing tube(s).

(b) *Classification.* Class I (general controls).

§ 868.5300 Carbon dioxide absorbent.

(a) *Identification.* A carbon dioxide absorbent is a device intended for medical purposes that consists of an absorbent material (e.g., soda lime) that is intended to remove carbon dioxide from the gases in the breathing circuit.

(b) *Classification.* Class II (performance standards).

§ 868.5310 Carbon dioxide absorber.

(a) *Identification.* A carbon dioxide absorber is a device that is intended for medical purposes and that is used in a breathing circuit as a container for carbon dioxide absorbent. It may include a canister and water drain.

(b) *Classification.* Class II (performance standards).

§ 868.5320 Reservoir bag.

(a) *Identification.* A reservoir bag is a device, usually made of conductive rubber, intended for use in a breathing circuit as a reservoir for breathing gas and to assist, control, or monitor a patient's ventilation.

(b) *Classification.* Class II (performance standards).

§ 868.5330 Breathing gas mixer.

(a) *Identification.* A breathing gas mixer is a device intended for use in conjunction with a respiratory support apparatus to control the mixing of gases that are to be breathed by a patient.

(b) *Classification.* Class II (performance standards).

§ 868.5340 Nasal oxygen cannula.

(a) *Identification.* A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils.

(b) *Classification.* Class I (general controls).

§ 868.5350 Nasal oxygen catheter.

(a) *Identification.* A nasal oxygen catheter is a device intended to be inserted through a patient's nostril to administer oxygen.

(b) *Classification.* Class I (general controls).

§ 868.5365 Posture chair for cardiac or pulmonary treatment.

(a) *Identification.* A posture chair for cardiac or pulmonary treatment is a device intended to assist in the rehabilitation and mobilization of patients with chronic heart or lung disease.

(b) *Classification.* Class I (general controls).

§ 868.5375 Heat and moisture condenser (artificial nose).

(a) *Identification.* A heat and moisture condenser (artificial nose) is a device intended to be positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient.

(b) *Classification.* Class II (performance standards).

§ 868.5400 Electroanesthesia apparatus.

(a) *Identification.* An electroanesthesia apparatus is a device used for the induction and maintenance of anesthesia during surgical procedures by means of an alternating or pulsed electric current that is passed through electrodes fixed to a patient's head.

(b) *Classification.* Class III (premarket approval).

§ 868.5420 Ether hook.

(a) *Identification.* An ether hook is a device that fits inside a patient's mouth and that is intended to deliver vaporized ether.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 868.5430 Gas-scavenging apparatus.

(a) *Identification.* A gas-scavenging apparatus is a device intended to collect

excess anesthetic, analgesic, or trace gases or vapors from a patient's breathing system, ventilator, or extracorporeal pump-oxygenator, and to conduct these gases out of the area by means of an exhaust system.

(b) *Classification.* Class II (performance standards).

§ 868.5440 Portable oxygen generator.

(a) *Identification.* A portable oxygen generator is a device that is intended to release oxygen for respiratory therapy by means of either a chemical reaction or physical means (e.g., a molecular sieve).

(b) *Classification.* Class II (performance standards).

§ 868.5450 Respiratory gas humidifier.

(a) *Identification.* A respiratory gas humidifier is a device that is intended to add moisture to, and sometimes to warm, the breathing gases for administration to a patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

§ 868.5460 Therapeutic humidifier for home use.

(a) *Identification.* A therapeutic humidifier for home use is a device that adds water vapor to breathing gases and that is intended for respiratory therapy or other medical purposes. The vapor produced by the device pervades the area surrounding the patient, who breaths the vapor during normal respiration.

(b) *Classification.* Class II (performance standards).

§ 868.5470 Hyperbaric chamber.

(a) *Identification.* A hyperbaric chamber is a device that is intended to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to a patient's tissue by means of pressurization that is greater than atmospheric pressure. This device does not include topical oxygen chambers for extremities (§ 878.5650).

(b) *Classification.* Class II (performance standards).

§ 868.5570 Nonrebreathing mask.

(a) *Identification.* A nonrebreathing mask is a device fitting over a patient's face to administer oxygen. It utilizes one-way valves to prevent the patient from rebreathing previously exhaled gases.

(b) *Classification.* Class II (performance standards).

§ 868.5580 Oxygen mask.

(a) *Identification.* An oxygen mask is a device placed over a patient's nose, mouth, or tracheostomy to administer oxygen or aerosols.

(b) *Classification.* Class II (performance standards).

§ 868.5590 Scavenging mask.

(a) *Identification.* A scavenging mask is a device positioned over a patient's nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.

(b) *Classification.* Class II (performance standards).

§ 868.5600 Venturi mask.

(a) *Identification.* A venturi mask is a device containing an air-oxygen mixing mechanism that dilutes 100 percent oxygen to a predetermined concentration and delivers the mixed gases to a patient.

(b) *Classification.* Class II (performance standards).

§ 868.5610 Membrane lung for long-term pulmonary support.

(a) *Identification.* A membrane lung for long-term pulmonary support is a device used to provide to a patient extracorporeal blood oxygenation for longer than 24 hours.

(b) *Classification.* Class III (premarket approval).

§ 868.5620 Breathing mouthpiece.

(a) *Identification.* A breathing mouthpiece is a rigid device that is inserted into a patient's mouth and that connects with diagnostic or therapeutic respiratory devices.

(b) *Classification.* Class I (general controls).

§ 868.5630 Nebulizer.

(a) *Identification.* A nebulizer is a device intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing. Heated, ultrasonic, gas, venturi, and refillable nebulizers are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

§ 868.5640 Medicinal nonventilatory nebulizer (atomizer).

(a) *Identification.* A medicinal nonventilatory nebulizer (atomizer) is a device that is intended to spray liquid medication in aerosol form into the air that a patient will breathe.

(b) *Classification.* Class I (general controls).

§ 868.5650 Esophageal obturator.

(a) *Identification.* An esophageal obturator is a device inserted through a patient's mouth to aid ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure ventilation through the trachea. The device consists of a closed-end semirigid esophageal tube that is attached to a face mask.

(b) *Classification.* Class II (performance standards).

§ 868.5655 Portable liquid oxygen unit.

(a) *Identification.* A portable liquid oxygen unit is a portable, thermally insulated container of liquid oxygen that is intended to supplement gases to be inhaled by a patient, is sometimes accompanied by tubing and an oxygen mask. An empty portable liquid oxygen unit is a device, while the oxygen contained therein is a drug.

(b) *Classification.* Class II (performance standards).

§ 868.5665 Powered percussor.

(a) *Identification.* A powered percussor is a device that is intended to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.

(b) *Classification.* Class II (performance standards).

§ 868.5675 Rebreathing device.

(a) *Identification.* A rebreathing device is a device that enables a patient to rebreathe exhaled gases. It may be used in conjunction with pulmonary function testing or for increasing minute ventilation.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 868.5690 Incentive spirometer.

(a) *Identification.* An incentive spirometer is a device that indicates a patient's breathing volume or flow and that provides an incentive to the patient to improve his or her ventilation.

(b) *Classification.* Class II (performance standards).

§ 868.5700 Nonpowered oxygen tent.

(a) *Identification.* A nonpowered oxygen tent is a device that encloses a patient's head and upper body to

contain oxygen delivered to the patient for breathing. This generic type of device includes infant oxygen hoods.

(b) *Classification.* Class I (general controls).

§ 868.5710 Electrically powered oxygen tent.

(a) *Identification.* An electrically powered oxygen tent is a device that encloses a patient's head and, by means of an electrically powered unit, administers breathing oxygen and controls the temperature and humidity of the breathing gases. This generic type device includes the pediatric aerosol tent.

(b) *Classification.* Class II (performance standards).

§ 868.5720 Bronchial tube.

(a) *Identification.* A bronchial tube is a device used to differentially intubate a patient's bronchus (one of the two main branches of the trachea leading directly to the lung) in order to isolate a portion of lung distal to the tube.

(b) *Classification.* Class II (performance standards).

§ 868.5730 Tracheal tube.

(a) *Identification.* A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.

(b) *Classification.* Class II (performance standards).

§ 868.5740 Tracheal/bronchial differential ventilation tube.

(a) *Identification.* A tracheal/bronchial differential ventilation tube is a device used to isolate the left or the right lung of a patient for anesthesia or pulmonary function testing.

(b) *Classification.* Class II (performance standards).

§ 868.5750 Inflatable tracheal tube cuff.

(a) *Identification.* An inflatable tracheal tube cuff is a device used to provide an airtight seal between a tracheal tube and a patient's trachea.

(b) *Classification.* Class II (performance standards).

§ 868.5760 Cuff spreader.

(a) *Identification.* A cuff spreader is a device used to install tracheal tube cuffs on tracheal or tracheostomy tubes.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 868.5770 Tracheal tube fixation device.

(a) *Identification.* A tracheal tube fixation device is a device used to hold a tracheal tube in place, usually by means of straps or pinch rings.

(b) *Classification.* Class II (performance standards).

§ 868.5780 Tube introduction forceps.

(a) *Identification.* Tube introduction forceps (e.g., Magill forceps) are a right-angled device used to grasp a tracheal tube and place it in a patient's trachea.

(b) *Classification.* Class II (performance standards).

§ 868.5790 Tracheal tube stylet.

(a) *Identification.* A tracheal tube stylet is a device used temporarily to make rigid a flexible tracheal tube to aid its insertion into a patient.

(b) *Classification.* Class II (performance standards).

§ 868.5810 Airway connector.

(a) *Identification.* An airway connector is a device intended to connect a breathing gas source to a tracheal tube, tracheostomy tube, or mask.

(b) *Classification.* Class II (performance standards).

§ 868.5820 Dental protector.

(a) *Identification.* A dental protector is a device intended to protect a patient's teeth during manipulative procedures within a patient's oral cavity.

(b) *Classification.* Class II (performance standards).

§ 868.5830 Autotransfusion apparatus.

(a) *Identification.* An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.

(b) *Classification.* Class II (performance standards).

§ 868.5860 Pressure tubing and accessories.

(a) *Identification.* Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.

(b) *Classification.* Class II (performance standards).

§ 868.5870 Nonrebreathing valve.

(a) *Identification.* A nonrebreathing valve is a one-way valve that directs breathing gas flow to the patient and vents exhaled gases into the atmosphere.

(b) *Classification.* Class II (performance standards).

§ 868.5880 Anesthetic vaporizer.

(a) *Identification.* An anesthetic vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.

(b) *Classification.* Class II (performance standards).

§ 868.5895 Continuous ventilator.

(a) *Identification.* A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

§ 868.5905 Noncontinuous ventilator (IPPB).

(a) *Identification.* A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing.

(b) *Classification.* Class II (performance standards).

§ 868.5915 Manual emergency ventilator.

(a) *Identification.* A manual emergency ventilator is a device, usually incorporating a bag and valve, intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

(b) *Classification.* Class II (performance standards).

§ 868.5925 Powered emergency ventilator.

(a) *Identification.* A powered emergency ventilator is a demand valve or inhalator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

(b) *Classification.* Class II (performance standards).

§ 868.5935 External negative pressure ventilator.

(a) *Identification.* An external negative pressure ventilator (e.g., iron lung, cuirass) is a device chamber that is intended to support a patient's ventilation by alternately applying and releasing external negative pressure over the diaphragm and upper trunk of the patient.

(b) *Classification.* Class II (performance standards).

§ 868.5955 Intermittent mandatory ventilation attachment.

(a) *Identification.* An intermittent mandatory ventilation (IMV) attachment

is a device attached to a mechanical ventilator that allows spontaneous breathing by a patient while providing mechanical ventilation at a preset rate.

(b) *Classification.* Class II (performance standards).

§ 868.5965 Positive end expiratory pressure breathing attachment.

(a) *Identification.* A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.

(b) *Classification.* Class II (performance standards).

§ 868.5975 Ventilator tubing.

(a) *Identification.* Ventilator tubing is a device intended for use as a conduit for gases between a ventilator and a patient during ventilation of the patient.

(b) *Classification.* Class II (performance standards).

§ 868.5995 Tee drain (water trap).

(a) *Identification.* A tee drain (water trap) is a device intended to trap and drain water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.

(b) *Classification.* Class II (perfomance standards).

Subpart G—Miscellaneous

§ 868.6100 Anesthetic cabinet, table, or tray.

(a) *Identification.* An anesthetic cabinet, table, or tray is a device intended to store anesthetic equipment and drugs. The device is usually constructed to eliminate build-up of static electrical charges.

(b) *Classification.* Class I (general controls).

§ 868.6175 Cardiopulmonary emergency cart.

(a) *Identification.* A cardiopulmonary emergency cart is a device intended to store and transport resuscitation supplies for emergency treatment. The device does not include any equipment used in cardiopulmonary resuscitation.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 868.6225 Nose clip.

(a) *Identification.* A nose clip is a device intended to close a patient's external nares (nostrils) during diagnostic or therapeutic procedures.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 868.6250 Portable air compressor.

(a) *Identification.* A portable air compressor is a device intended to provide compressed air for medical purposes, e.g., to drive ventilators and other respiratory devices.

(b) *Classification.* Class II (performance standards).

§ 868.6400 Calibration gas.

(a) *Identification.* A calibration gas is a device consisting of a container of gas of known concentration intended to calibrate medical gas concentration measurement devices.

(b) *Classification.* Class II (performance standards).

§ 868.6700 Anesthesia stool.

(a) *Identification.* An anesthesia stool is a device intended for use as a stool for the anesthesiologist in the operating room.

(b) *Classification.* Class I (general controls).

§ 868.6810 Tracheobronchial suction catheter.

(a) *Identification.* A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.

(b) *Classification.* Class I (general controls).

§ 868.6820 Patient position support.

(a) *Identification.* A patient position support is a device intended to maintain the position of an anesthetized patient during surgery.

(b) *Classification.* Class II (performance standards).

§ 868.6885 Medical gas yoke assembly.

(a) *Identification.* A medical gas yoke assembly is a device intended to connect medical gas cylinders to regulators or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a particulate filter.

(b) *Classification.* Class II (performance standards).

The Food and Drug Administration has carefully analyzed the economic effects of this final rule in accordance with section 3(g)(1) of Executive Order 12291, and it has been determined that the final rule does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules classifying devices into class I generally maintain the status quo: These devices are now subject to only the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules are not major rules. The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rules on which it is based were issued prior to January 1, 1981, and are therefore exempt.

Effective date. This regulation is effective August 16, 1982.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)))

Dated: June 24, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

FR Doc. 82-18941 Filed 7-15-82; 8:45 am]

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federal register

Friday
July 16, 1982

Part III

Department of Labor

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 12–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and Supersedeas Decisions to General Wage Determination Decisions

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's orders 13–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Office of Government Contract Wage Standards, Division of Government Contract Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

Modifications to General Wage Determination Decisions

The numbers of the decisions being modified and their dates of publication in the **Federal Register** are listed with each State.

District of Columbia: DC81–3030	June 5, 1981.
Illinois: Il82–2033	May 14, 1982.
Kentucky:	
KY81–1281KY81–1282	Aug. 28, 1981.
KY81–1283	Sept. 4, 1981.
New York:	
NY81–3003	Jan. 23, 1981.
NY80–3054	Sept. 5, 1980.
Pennsylvania: PA82–3007	Feb. 26, 1981.
Ohio:	
OH82–2035	May 7, 1982.
OH82–2037	May 21, 1982.
Tennessee: TN81–1202	May 1, 1981.

Supersedeas Decision to General Wage Determination Decision

The number of the decision being superseded and its date of publication in the **Federal Register** is listed with the State. Supersedeas decision number is in parentheses following the number of the decision being superseded.

California: CA81–5132 (CA82–5112)	July 10, 1981.

Signed at Washington, D.C., this 9th day of July 1982.

Dorothy P. Come,

Assistant Administrator, Wage and Hour Division.

BILLING CODE 4510–27–M

DECISION NO. DC81-3040 - MOD. #13
(46 FR 30290 - June 5, 1981)
DISTRICT OF COLUMBIA; MARYLAND-MONTGOMERY AND PRINCE GEORGES; D.C. TRAINING SCHOOL; VIRGINIA - INDEPENDENT CITY OF ALEXANDRIA, ARLINGTON AND FAIRFAX

CHANGE:

	Basic Hourly Rates	Fringe Benefits
IRONWORKERS		
Structural, ornamental and chain link fence	15.11	2.835
TRUCK DRIVERS		
Boom Trucks	11.31	1.59
Small dump, water sprinkler, grease and oil	11.02	1.59
Flat, pick-up hauling materials, small euclids, dump over 8 wheels	11.14	1.59
Trailers, low boys, tractor pulls	11.38	1.59
Helpers	10.84	1.59
Carryalls, large Euclids, euclid water sprinklers, tunnel work underground and pay haulers	11.50	1.59
Mechanics	11.20	1.59
Greasers, tiremen, runners	11.02	1.59

DECISION NO. IL82-2033 - MOD. #1
(47 FR 20984 - May 14, 1982)
DuPage, Grundy, Kane, Kendall, Lake, McHenry, & Will Counties, Illinois

Change:

	Basic Hourly Rates	Fringe Benefits
Electricians:		
DuPage Co.	$17.65	$4.06

DECISION #KY81-1281 - Mod. #1
(46 FR 43616 - August 28, 1981)
Various Counties (Locality #2), Kentucky

CHANGE:

	Basic Hourly Rates	Fringe Benefits
POWER EQUIPMENT OPERATORS:		
HIGHWAY CONSTRUCTION -		
CLASS A	$12.87	$ 2.13
CLASS B	10.45	2.13
CLASS C	10.83	2.13
CLASS D	10.19	2.13

DECISION #KY81-1282 - Mod. #1
(46 FR 43618 - August 28, 1981)
Various Counties (Locality #3), Kentucky

CHANGE:

	Basic Hourly Rates	Fringe Benefits
POWER EQUIPMENT OPERATORS:		
HIGHWAY CONSTRUCTION -		
CLASS A	$12.87	$ 2.13
CLASS B	10.45	2.13
CLASS C	10.83	2.13
CLASS D	10.19	2.13

DECISION #KY81-1283 - Mod. #1
(46 FR 44628 - September 4, 1981)
Various Counties (Locality #1), Kentucky

CHANGE:

	Basic Hourly Rates	Fringe Benefits
POWER EQUIPMENT OPERATORS:		
HIGHWAY CONSTRUCTION -		
CLASS A	$12.87	$ 2.13
CLASS B	10.45	2.13
CLASS C	10.83	2.13
CLASS D	10.19	2.13

DECISION NO. NY81-3003 - MOD. #4
(46 FR 7737 - January 23, 1981)
ORANGE COUNTY, NEW YORK

CHANGE:

	Basic Hourly Rates	Fringe Benefits
LABORERS, BUILDING		
(TOTAL PROJECT PRICE $200,000 AND OVER)		
Common Laborers, Mason Tenders, Mortar Mixers, Hod Carriers, Scaffold Builders, Concrete Men, Vibrator men, poured gypsun, Roof work, wrecking, walking power buggy men, Landscaper, Chipping Hammer (air or electric 1" and under)	11.80	2.90
Asphalt men, Pipelayers, Air or Electric Jackhammer, Powdermen, Gunnite, Sandblasting, Air Trac, Barmen, Chain Saw, Riding Power Buggy, Vibro, Barco, Joy Tamper or similar, Joy or Jib Drills, Walk Behind Roller, Wagon Drill, All Fork Lifts Grade, Pipe, Concrete Clearing, Black Top, Drill, Paving etc., Blaster, Form Setter, Burner (acetylene torch), Ingersoll-Rand, Heavy Duty Crawler Type HCMZ, Drill Machines or Equivalent, All wrecking work fifty feet or more above	12.05	2.90
(TOTAL PROJECT PRICE UNDER $200,000)		
Common Laborers, Mason Tenders, Mortar Mixers, Hod Carriers, Scaffold Builders, Concrete men, Vibrator men, poured gypsun, Roof work, wrecking, walking power buggy men, Landscaper, Chipping Hammer (air or electric 1" and under)	10.62	2.90
Asphalt men, Pipelayers, Air or Electric Jackhammer, Powdermen, Gunnite, Sandblasting, Air Trac, Barmen, Chain Saw, Riding Power Buggy, Vibro, Barco, Joy Tamper or similar, Joy or Jib Drills, Walk Behind Roller, Wagon Drill, All Fork Lifts Grade, Pipe, Concrete Clearing, Black Top, Drill, Paving etc., Blaster, Form Setter, Burner (acetylene torch), Ingersoll-Rand, Heavy Duty Crawler Type HCMZ, Drill Machines or Equivalent, All wrecking work fifty feet or more above	10.85	2.90
	11.21	2.90
HEAVY & HIGHWAY CONSTRUCTION		
LABORERS:		
GROUP I	12.35	2.90
GROUP II	12.60	2.90
GROUP III	13.00	2.90

DECISION NO. NY80-3054 - MOD. #3
(45 FR 59104 - Sept. 5, 1980)
JEFFERSON COUNTY, NY

CHANGE:

	Basic Hourly Rates	Fringe Benefits
BUILDING CONSTRUCTION		
BRICKLAYERS, CEMENT MASONS, PLASTERERS & TILE SETTERS	15.54	1.81

DECISION NO. PA82-3007 - MOD. #4 (47 FR 8529 - February 26, 1982) BUCKS, CHESTER, DELAWARE, MONTGOMERY & PHILADELPHIA COUNTIES, PENNSYLVANIA	Basic Hourly Rates	Fringe Benefits
CHANGE:		
BRICKLAYERS:		
New Residential Under 4 Stories	13.47	2.57
Zone 3	14.11	2.11
ELECTRICIANS		
Zone 1		
Residential up to and including 4 stories	16.00	.67+ 11%
Zone 6		
Commercial	16.00	2.69+ 3%
Zone 7		
Commercial	14.55	1.84+3%
GLAZIERS		
Zone 2	12.79	1.465
IRONWORKERS		
Zone 3		
Structural & Ornamental	16.75	4.30
Reinforcing	15.64	4.75
IRONWORKERS:		
Rigger, Machinery Mover	16.36	3.20
LABORERS:		
Class 1	12.05	2.25
Class 2	12.15	2.25
Class 3	12.20	2.25
Class 4	12.35	2.25
Class 5	12.45	2.25
Class 6	11.99	2.25
MARBLE SETTERS	13.20	2.97
PAINTERS		
ZONE 3		
Brush	12.15	2.25
Steel & Spray	13.20	2.25
Roller	12.15	2.25
PILEDRIVERMEN	13.67	5.31+f
ROOFERS:		
Residential structure of not more than 4 stories re-roofing Zone 1	12.50	1.90
SHEET METAL WORKERS		
Zone 1 (Commercial)	17.81	4.04
SOFT FLOOR LAYERS	12.63	4.71
STEAMFITTERS		
Zone 2	17.86	3.00
STONEMASONS		
Zone 1	13.20	2.97
TERRAZZO WORKERS	12.86	3.10

DECISION NO. OH82-2035 - MOD. #2 (47 FR 19893 - May 7, 1982) Statewide, Ohio	Basic Hourly Rates	Fringe Benefits
Change:		
Ironworkers:		
Ashtabula (NE ¼) Co.	$15.50	$3.62

DECISION NO. OH82-2037 - MOD. #1 (47 FR 22307 - May 21, 1982) Ashtabula, Cuyahoga, Lake, Lorain, Portage, Stark, & Summit Counties, Ohio	Basic Hourly Rates	Fringe Benefits
Change:		
Ironworkers:		
Ashtabula (NE ¼) Co.	15.50	3.62

DECISION NO. TN81-1202 - MOD. #7 (46 FR 24886 - May 1, 1981) SHELBY COUNTY, TENNESSEE	Basic Hourly Rates	Fringe Benefits
CHANGE:		
BRICKLAYERS	14.90	1.68
CARPENTERS, PILEDRIVERMEN, AND SOFT FLOOR LAYERS	13.63	2.20
ELECTRICIANS	17.48	1.45+ 3.55%
IRONWORKERS	14.40	1.73
LABORERS:		
GROUP 1	9.535	1.00
GROUP 2	9.635	1.00
GROUP 3	9.685	1.00
GROUP 4	9.885	1.00
GROUP 5	10.085	1.00
MARBLE TILE & TERRAZZO FINISHERS	6.40	
PAINTERS:		
Brush	13.075	1.55
Spray	13.325	1.55
SPRINKLER FITTERS	14.57	2.83

STATE: California

COUNTIES: Alameda, Alpine, Amador, Butte, Calaveras, Colusa, Contra Costa, Del Norte, El Dorado, Fresno, Glenn, Humboldt, Kings, Lake, Lassen, Madera, Marin, Mariposa, Mendocino, Merced, Modoc, Monterey, Napa, Nevada, Placer, Plumas, Sacramento, San Benito, San Francisco, San Joaquin, San Mateo, Santa Clara, Santa Cruz, Shasta, Sierra, Siskiyou, Solnao, Sonoma, Stanislaus, Sutter, Tehama, Trinity, Tulare, Tuolumne, Yolo, and Yuba

DECISION NUMBER: CA82-5112 DATE: Date of Publication

Supersedes Decision No. CA81-5132 dated July 10, 1981, in 46 FR 35860

DESCRIPTION OF WORK: Building Projects (does not include single family homes and apartments up to and including 4 stories), Heavy and Highway Projects and Dredging

	Basic Hourly Rates	Fringe Benefits
ASBESTOS WORKERS	$22.36	$2.81
BOILERMAKERS	20.01	3.59
BRICKLAYERS; Stonemasons:		
Area 1	17.79	4.51
Area 2	19.05	2.95
Area 3	17.35	3.05
Area 4	16.28	4.29
Area 5	15.18	3.27
Area 6	16.35	3.50
Area 7	17.47	3.80
Area 8	15.74	3.46
BRICK TENDERS:		
Area 1	14.73	3.05
Area 2	13.12	4.95
Area 3	14.73	3.05
Area 4	14.73	3.05
Area 5	12.39	5.40
Area 6	14.26	3.10
CARPENTERS:		
Area 1:		
Carpenters; Millwrights	16.95	6.225
Hardwood Floorlayers; Shinglers; Power Saw Operator; Steel Scaffold Erector and Steel Shoring; Saw Filers	17.10	6.225
Area 2:		
Carpenters	16.05	6.225
Hardwood Floorlayers; Shinglers; Power Saw Operators; Steel Scaffold Erector and Steel Shoring; Saw Filers	16.20	6.225
CEMENT MASONS:		
Cement Masons	15.60	5.48
Mastic; Magensite; All Composition Masons	15.85	5.48
Men working from Swinging or slip form scaffold	15.85	5.48
COMMUNICATION TECHNICIAN	$12.85	$3.07
DIVERS:		
Divers	33.89	6.225
Stand-by-divers	18.05	6.225
DRYWALL INSTALLERS	17.18	6.195
ELECTRICIANS:		
Area 1:		
Electricians	22.56	5.98
Cable Splicers	21.89	4.94
Area 2:		
Electricians	14.15	4.94
Cable Splicers	15.57	4.99
Area 3:		
Electricians	21.13	3.95
Cable Splicers	23.24	4.02
Area 4:		
Electricians	19.10	4.68
Cable Splicers	17.91	3.60
Area 5:		
Electricians; Technicians	19.81	4.88
Cable Splicers	22.29	4.97
Area 6:		
Electricians	23.01	5.29
Cable Splicers	25.01	5.35
Area 7:		
Electricians	17.08	5.41
Cable Splicers	18.45	5.45
Area 8:		
Electricians	17.90	3.95
Cable Splicers	19.69	4.00
Area 9:		
Electricians	21.85	4.46
Cable Splicers	22.94	4.49
Area 10:		
Electricians	17.57	3.72
Cable Splicers	19.33	3.78
Area 11:		
Electricians	19.66	6.86
Cable Splicers	22.12	6.93

	Basic Hourly Rates	Fringe Benefits
ELECTRICIANS: (Cont'd)		
Area 12:		
Electricians	$19.57	$4.68
Cable Splicers	22.02	4.75
Area 13:		
Electricians	21.20	6.19
Cable Splicers	23.85	6.27
Area 14:		
Electricians	22.93	4.94
Cable Splicers	25.80	5.02
Area 15:		
Electricians	21.00	6.05
Cable Splicers	23.63	6.13
ELEVATOR CONSTRUCTORS	24.22	2.47+a
ELEVATOR CONSTRUCTORS' HELPERS	16.95	2.47+a
ELEVATOR CONSTRUCTORS' HELPERS (PROB.)	12.11	
GLAZIERS:		
Area 1	19.56	4.40
Area 2	15.88	6.32
Area 3	14.50	3.90
Area 4	12.54	1.95
IRONWORKERS:		
Fence Erectors	14.86	6.83
Reinforcing, Ornamental, and Structural	15.75	6.83
LATHERS:		
Area 1	17.43	3.63
Area 2	12.35	2.17
Area 3	13.70	1.49
Area 4	16.71	3.08
Area 5	15.43	2.95
Area 6	15.93	4.90
Area 7	16.12	4.15
Area 8	16.46	1.86
Area 9	11.85	.01
Area 10	11.92	4.84
LINE CONSTRUCTION:		
Area 1:		
Groundman	16.51	4.50
Line Equipment Operators	19.81	4.59
Linemen	22.01	4.66
Cable Splicers	24.01	4.72
Area 2:		
Groundman	10.32	2.01
Headgroundman (Chipper); Powdermen; Jackhammermen	10.99	2.03
Line Equipment Man	12.57	2.09
Linemen Polesprayer; Heavy Line Equipment Men	14.59	2.66
Tree Trimmer	13.17	2.72
Cable Splicers	16.15	2.81

	Basic Hourly Rates	Fringe Benefits
LINE CONSTRUCTION: (Cont'd):		
Area 3:		
Groundmen	$17.08	$3.92
Linemen; Line Equipment Operators	17.90	3.95
Area 4:		
Groundmen	14.86	4.69
Line Equipment Operators	17.83	4.77
Linemen	19.81	4.83
Area 5:		
Linemen	15.47	3.25
Cable Splicers	17.02	3.30
Area 6:		
Groundmen	14.87	5.32
Linemen; Technicians	19.82	6.70
Cable Splicers	22.27	6.78
Area 7:		
Groundman and Truck Driver	14.68	4.53
Linemen	19.57	4.68
Cable Splicers	22.02	4.75
Area 8:		
Groundmen	13.02	3.45
Linemen; Equipment Operators	16.28	3.55
Cable Splicers	17.91	3.60
Area 9:		
Groundmen	13.19	2.63
Linemen	22.56	5.98
Line Equipment Operators	14.84	2.68
Area 10:		
Grounmen	14.88	5.27
Equipment Operators	16.74	5.33
Linemen	18.60	5.40
Cable Splicers	20.46	5.46
Area 11:		
Groundmen	13.21	3.43
Line Equipment Operators	13.99	3.45
Linemen	15.54	3.50
Cable Splicers	17.48	3.55
Area 12:		
Groundmen	13.66	5.31
Linemen	17.08	5.41
Cable Splicers	18.45	5.45
Area 13:		
Groundmen	19.49	4.84
Linemen; Technicians	22.93	4.94
Cable Splicers	25.80	5.02

	Basic Hourly Rates	Fringe Benefits
LINE CONSTRUCTION: (Cont'd)		
Area 14:		
Groundmen	$18.02	$6.09
Linemen; Line Equipment Operators	21.20	6.19
Cable Splicers	23.85	6.27
MARBLE SETTERS	15.62	6.32
PAINTERS:		
Area 1:		
Brush	13.39	4.60
Spray	14.14	4.60
Sheetrock; Taper; Swing; Stage; Scaffold; Sandblaster Structural Steel	13.79	4.60
Area 2:		
Brush; Roller	15.22	1.59
Area 3:		
Brush	13.65	4.22
Hazardous coating	14.65	4.22
Spray; Sandblasting; Taping	14.15	4.22
Area 4:		
Brush	20.06	3.83
Tapers	20.86	3.83
Area 5:		
Brush	15.93	1.47
Spray; Paperhanger; Tapers	16.43	1.47
Area 6:		
Brush	18.51	5.03
Spray; Sandblasting; Steam Cleaning	19.01	5.03
Drywall Finisher	9.31	5.03
Brush (exterior stage) 5, 6, and 7 story buildings; Erected steel over 50 feet	19.66	5.03
Area 7:		
Brush; Pot Tenders; Rollers	9.80	1.35
Spray; Sandblaster; Structural Steel; Swing Stage; Tapers	10.30	1.35
Area 8:		
Brush	18.62	5.03
Spray	19.12	5.03
Spray (coating) and Paperhangers	19.37	5.03
Tapers (paint)	19.42	5.03

	Basic Hourly Rates	Fringe Benefits
PAINTERS: (Cont'd)		
Area 9:		
Brush	$10.83	$1.67
Spray; Sandblasters; Structural Steel: Swing Stage; Tapers; Paperhangers	11.08	1.67
Parking Lot Striping Work and/or Highway Markers:		
Area 10:		
Traffic Delineating Device Applicator	12.42	1.55+b
Wheel Stop Installer; Traffic Surface Sandblaster; Striper	11.96	1.55+b
Slurry Seal Operation:		
Mixer Operator	11.96	1.55+b
Squeegee Man	10.60	1.55+b
Applicator Operator	10.60	1.55+b
Shuttleman	10.60	1.55+b
Top Man	8.91	1.55+b
Area 11:		
Traffic Delineating Device Applicator; Wheel stop Installer; Traffic Surface Sandblaster	12.37	1.55+b
Striper	13.57	1.55+b
Slurry Seal Operation:		
Mixer Operator	12.37	1.55+b
Squeegee Man	10.60	1.55+b
Applicator Operator	10.60	1.55+b
Top Man	8.91	1.55+b
PLASTERERS:		
Area 1	15.77	4.43
Area 2	18.14	5.80
Area 3	14.21	5.09
Area 4	15.93	4.39
Area 5	14.97	3.57
Area 6	13.85	5.40
Area 7	15.06	2.61
Area 8	13.95	6.65
PLASTERERS' TENDERS:		
Area 1	13.62	5.05
Area 2	15.16	4.45
Area 3	13.84	5.45
Area 4	13.71	4.45
Area 5	13.27	4.45
Area 6	13.82	4.45
Area 7	17.50	4.05
Area 8	16.15	3.10
Area 9	13.75	4.45
Area 10	14.95	2.70

	Basic Hourly Rates	Fringe Benefits
PLUMBERS:		
Area 1	$22.67	$5.18
Area 2	22.33	5.84
PLUMBERS; Steamfitters:		
Area 1	19.62	4.61
Area 2	20.34	2.43
Area 3	22.34	9.37
Area 4	17.90	5.09
Area 5	22.42	5.51
Area 6	14.32	8.30
Area 7	21.17	6.80
Area 8	21.39	5.72
ROOFERS:		
Area 1:		
Roofers	15.25	5.87
Mastic Workers; Kettlemen (2 kettles w/o pumps)	15.50	5.87
Bitumastic; Enamelers; Pipewrappers; Coal Tar Built up	17.25	5.87
Area 2:		
Roofers (slate, tile composition and built up)	16.85	2.59
Area 3:		
Roofers	14.51	2.42
Area 4:		
Roofers	13.05	2.40
Area 5:		
Roofers	15.00	6.14
Mastic Workers; Kettlemen (2 kettles w/o pumps)	15.25	6.14
Bitumastic; Enamelers; Pipewrappers; Coal Tar Pitch	17.00	6.14
Area 6:		
Roofers	10.32	1.15
Area 7:		
Roofers	16.85	2.90
Area 8:		
Roofers	15.50	5.79
Mastic Workers; Kettlemen (2 kettles w/o pumps)	15.75	5.79
Bitumastic; Enamelers; Pipewrappers; Coal Tar	17.50	5.79
Area 9:		
Roofers (slate, tile and composition)	14.30	5.99
Enameler and Pitch	16.30	5.99
Area 10:		
Roofers; Kettlemen (1 kettle)	16.36	3.99

	Basic Hourly Rates	Fringe Benefits
SHEET METAL WORKERS:		
Area 1	$22.90	$4.12
Area 2	17.93	4.25
Area 3	16.51	5.94
Area 4	18.05	4.02
Area 5	19.26	4.47
Area 6	17.80	3.56
Area 7	19.52	3.90
Area 8	13.74	2.78
Area 9	22.06	4.92
Area 10	22.16	4.70
Area 11	19.36	4.06
Area 12	21.73	4.67
SOFT FLOOR LAYERS:		
Area 1	17.31	2.85
Area 2	13.74	.90
Area 3	19.19	3.64
Area 4	11.96	2.27
Area 5	16.16	4.49
SPRINKLER FITTERS:		
Area 1	22.77	4.99
Area 2	20.03	2.43
STEAMFITTERS:		
Area 1	23.60	4.13
TERRAZZO WORKERS:		
Area 1	15.62	2.90
Area 2	16.28	4.29
Area 3	14.45	2.95
TILE SETTERS:		
Area 1	16.75	5.99
Area 2	18.02	3.05
Area 3	14.60	2.55
Area 4	16.73	3.43
MARBLE & TILE FINISHERS:		
Area 1	14.25	3.88
Area 2	11.90	1.90
LABORERS:		
Group 1	14.53	4.95
Group 1(a)	14.755	4.95
Group 1(b)	15.03	4.95
Group 1(c)	14.58	4.95
Group 1(d)	14.78	4.95
Group 1(e)	15.08	4.95
Group 1(f)	15.115	4.95
Group 1(g)	14.73	4.95
Group 2	14.38	4.95
Group 3	14.28	4.95

	Basic Hourly Rates	Fringe Benefits
LABORERS: (Cont'd)		
Gunnite:		
Group 1	$14.99	$4.95
Group 2	14.38	4.95
Group 3	14.28	4.95
Tunnel and Shaft Work:		
Group 1	16.24	4.95
Group 2	15.84	4.95
Group 3	15.60	4.95
Group 4	15.45	4.95
Wrecking Work:		
Group 1	14.53	4.95
Group 2	14.38	4.95
Group 3	14.28	4.95
Housemoving:		
Group 1	14.53	4.95
POWER EQUIPMENT OPERATORS:		
DREDGING - SCHEDULE I		
CLAMSHELL & DIPPER DREDGING (new Construction)		
Group 1:		
Area 1	14.05	8.56
Area 2	15.22	8.56
Area 3	15.57	8.56
Area 4	15.91	8.56
Group 2:		
Area 1	16.17	8.56
Area 2	17.44	8.56
Area 3	17.79	8.56
Area 4	18.16	8.56
Group 3:		
Area 1	16.75	8.56
Area 2	18.01	8.56
Area 3	18.37	8.56
Area 4	18.73	8.56
Group 4:		
Area 1	17.73	8.56
Area 2	19.00	8.56
Area 3	19.35	8.56
Area 4	19.71	8.56
Group 4-A:		
Area 1	19.23	8.56
Area 2	20.52	8.56
Area 3	20.92	8.56
Area 4	21.28	8.56

	Basic Hourly Rates	Fringe Benefits
POWER EQUIPMENT OPERATORS: (Cont'd): - SCHEDLUE II:		
HYDRAULIC SUCTION DREDGING AND ALL OTHER CLAMSHELL AND DIPPER DREDGING:		
Group A-1:		
Area 1	$14.03	$8.56
Area 2	15.20	8.56
Area 3	15.54	8.56
Area 4	15.89	8.56
Group A-2:		
Area 1	15.30	8.56
Area 2	16.52	8.56
Area 3	16.89	8.56
Area 4	17.24	8.56
Group A-3:		
Area 1	16.14	8.56
Area 2	17.41	8.56
Area 3	17.78	8.56
Area 4	18.14	8.56
Group A-4:		
Area 1	17.30	8.56
Area 2	18.58	8.56
Area 3	18.93	8.56
Area 4	19.29	8.56
TOW BOATS - (Dredging): Work on self-propelled vessels (except skiffs powered by outboard motors) engaged in towing vessels and water borne craft or in the transportation by water or personnel, materials, equipment and supplies:		
Deckhand/Mechanics	10.86	3.37
Operator Mechanic/ Watch Engineer	12.17	3.86
TOW BOATS: Work on self-propelled vessels):		
Boat Operators	12.17	3.86
POWER EQUIPMENT OPERATORS: PILEDRIVING:		
Group 1	14.04	8.75
Group 1A	14.50	8.75
Group 1B	14.77	8.75
Group 2A	14.77	8.75
Group 2B	15.50	8.75
Group 2C	15.78	8.75
Group 2D	15.98	8.75
Group 3	16.18	8.75
Group 3A	16.76	8.75
Group 4	17.49	8.75
Group 5	17.73	8.75
Group 6	19.15	8.75

	Basic Hourly Rates	Fringe Benefits
POWER EQUIPMENT OPERATORS: (Cont'd)-STEEL ERECTION:		
Group 1	$14.67	$8.75
Group 2	15.17	8.75
Group 3	16.55	8.75
Group 4	16.73	8.75
Group 4A	17.15	8.75
Group 5	17.82	8.75
Group 6	18.39	8.75
Group 7	18.80	8.75
Group 8	19.19	8.75
Group 9	20.59	8.75
POWER EQUIPMENT OPERATORS:		
Group 1:		
Area 1	13.98	8.75
Area 2	15.98	8.75
Group 2:		
Area 1	14.44	8.75
Area 2	16.44	8.75
Group 3:		
Area 1	14.72	8.75
Area 2	16.72	8.75
Group 4:		
Area 1	15.44	8.75
Area 2	17.44	8.75
Group 5:		
Area 1	15.72	8.75
Area 2	17.72	8.75
Group 6:		
Area 1	15.92	8.75
Area 2	17.92	8.75
Group 7:		
Area 1	16.12	8.75
Area 2	18.12	8.75
Group 8:		
Area 1	16.70	8.75
Area 2	18.70	8.75
Group 9:		
Area 1	16.99	8.75
Area 2	18.99	8.75
Group 10:		
Area 1	17.28	8.75
Area 2	19.28	8.75
Group 10-A:		
Area 1	17.44	8.75
Area 2	19.44	8.75
Group 11:		
Area 1	17.67	8.75
Area 2	19.67	8.75
Group 11-A:		
Area 1	19.19	8.75
Area 2	21.19	8.75
POWER EQUIPMENT OPERATORS: (Cont'd)		
Group 11-B:		
Area 1	$19.56	$8.75
Area 2	21.56	8.75
Group 11-C:		
Area 1	19.98	8.75
Area 2	21.98	8.75
TRUCK DRIVERS:		
Group 1	14.20	5.39
Group 2	14.37	5.39
Group 3	14.30	5.39
Group 4	14.31	5.39
Group 5	14.32	5.39
Group 6	14.33	5.39
Group 7	14.35	5.39
Group 8	14.37	5.39
Group 9	14.38	5.39
Group 10	14.40	5.39
Group 11	14.41	5.39
Group 12	14.45	5.39
Group 13	14.46	5.39
Group 14	14.47	5.39
Group 15	14.50	5.39
Group 16	14.51	5.39
Group 17	14.52	5.39
Group 18	14.54	5.39
Group 19	14.55	5.39
Group 20	14.56	5.39
Group 21	14.56	5.39
Group 22	14.64	5.39
Group 23	14.56	5.39
Group 24	14.74	5.39
Group 25	14.75	5.39
Group 26	14.75	5.39
Group 27	14.78	5.39
Group 28	14.80	5.39
Group 29	14.84	5.39
Group 30	14.85	5.39
Group 31	14.88	5.39
Group 32	14.94	5.39
Group 33	14.87	5.39
Group 34	15.09	5.39
Group 35	15.19	5.39
Group 36	15.24	5.39
Group 37	15.39	5.39
Group 38	15.54	5.39

AREA DESCRIPTIONS

BRICKLAYERS; Stonemasons:
Area 1: Del Norte, Humboldt, Lake, Marin, Mendocino, Napa, San Francisco, San Mateo, Siskiyou, Solano, Sonoma, and Trinity Counties
Area 2: Alameda and Contra Costa Counties
Area 3: Fresno, Kings, Madera, Mariposa, and Merced Counties
Area 4: Butte, Colusa, El Dorado, Glenn, Lassen, Modoc, Nevada, Placer, Plumas, Sacramento, Shasta, Sierra, Sutter, Tehama, Yolo, and Yuba Counties
Area 5: Monterey and Santa Cruz Counties
Area 6: San Benito and Santa Clara Counties
Area 7: Alpine, Amador, Calaveras, San Joaquin, Stanislaus, and Tuolumne Counties
Area 8: Tulare County

BRICK TENDERS:
Area 1: Amador, El Dorado, Nevada, Placer, Sacramento, and Yolo Counties
Area 2: San Francisco and San Mateo Counties
Area 3: Fresno, Kings, Madera, and Tulare Counties
Area 4: Remaining Counties
Area 5: Alamida and Contra Costa Counties
Area 6: San Benito, Santa Clara, and Santa Cruz Counties

CARPENTERS:
Area 1: Alameda, Contra Costa, Marin, Monterey, Napa, San Benito, San Francisco, San Mateo, Santa Clara, Santa Cruz, Solona, and Sonoma
Area 2: Alpine, Amador, Butte, Calaveras, Colusa, Del Norte, El Dorado, Fresno, Glenn, Humboldt, Kings, Lake, Lassen, Madera, Mariposa, Mendocino, Merced, Modoc, Nevada, Placer, Plumas, Sacramento, San Joaquin, Shasta, Sierra, Siskiyou, Stanislaus, Sutter, Tehama, Trinity, Tulare, Tuolumne, Yolo, and Yuba

ELECTRICIANS:
Area 1: Alameda County
Area 2: Amador, Colusa, Sacramento, Sutter, Yolo, and Yuba Counties; Alpine, El Dorado, Nevada, Placer, and Sierra Counties (those portions west of the Sierra Mountain Watershed)
Area 3: Lassen and Plumas Counties; those portions of Alpine, El Dorado, Nevada, Placer and Sierra Counties lying east of the Main Watershed divide
Area 4: Butte, Glenn, Modoc, Shasta, Siskiyou, Tehama, and Trinity Counties
Area 5: Calaveras and San Joaquin Counties
Area 6: Contra Costa County
Area 7: Del Norte and Humboldt Counties
Area 8: Fresno, Kings, Madera, and Tulare Counties
Area 9: Lake, Marin, Mendocino, and Sonoma Counties
Area 10: Mariposa, Merced, Stanislaus, and Tuolumne Counties
Area 11: Monterey County, San Benito and Santa Cruz Counties
Area 12: Napa and Solano Counties
Area 13: Santa Clara County
Area 14: San Francisco County
Area 15: San Mateo County

AREA DESCRIPTIONS (Cont'd)

GLAZIERS:
Area 1: Alameda and Contra Costa Counties; Mendocino County (southern half from north of Ft. Bragg); Monterey, Napa, San Benito, San Francisco, San Mateo, Santa Clara, and Santa Cruz Counties; Solano County (S.W. from east of Fairfield); and Sonoma County
Area 2: Alpine, Amador, Butte, Calaveras, El Dorado, and Mariposa Counties; Merced County (north of the City of Livingston); Modoc, Nevada, Placer, Sacramento, San Joaquin, Shasta, Sierra, Siskiyou, Stanislaus, Sutter, Tehama, Tuolumne, Yolo, and Yuba Counties
Area 3: Fresno, Madera, Merced, Kings, and Tulare Counties
Area 4: Del Norte and Humboldt Counties

LATHERS:
Area 1: Alameda and Contra Costa Counties
Area 2: Butte, Colusa, Glenn, and Humboldt Counties; Lake County (that portion from Lakeport up to the Lake County Line); Nevada, Placer, Plumas, Shasta, Sierra, Tehama, and Trinity Counties
Area 3: Calaveras and San Joaquin Counties
Area 4: Lake County (from City of Lakeport down to the Lake County Line); Marin, Mendocino, and Sonoma Counties
Area 5: Monterey, and Santa Cruz Counties
Area 6: San Francisco and San Mateo Counties
Area 7: Santa Clara County
Area 8: Fresno, Kings, Madera, and Tulare Counties
Area 9: Mariposa, Merced, Stanislaus, and Tuolumne Counties
Area 10: Amador, El Dorado, Sacramento, and Yolo Counties

LINE CONSTRUCTION:
Area 1: Contra Costa County
Area 2: Del Norte, Modoc, and Siskiyou Counties
Area 3: Fresno, Kings, Madera, and Tulare Counties
Area 4: Calaveras and San Joaquin Counties
Area 5: Mariposa, Merced, Stanislaus, and Tuolumne Counties
Area 6: Monterey, San Benito, and Santa Cruz Counties
Area 7: Napa and Solano Counties
Area 8: Butte, Glenn, Lassen, Plumas, Shasta, Tehama, and Trinity Counties
Area 9: Alameda County
Area 10: Amador, Colusa, Sacramento, Sutter, Yolo, and Yuba Counties; Alpine, El Dorado, Nevada, Placer, and Sierra Counties (those portions west of the Main Sierra Mountain Watershed)
Area 11: San Mateo County
Area 12: Humboldt County
Area 13: San Francisco county
Area 14: San Clara County

AREA DESCRIPTIONS (Cont'd)

PAINTERS:
Area 1: Alpine, Amador, Calaveras, and San Joaquin Counties
Area 2: Fresno, Kings, Madera, and Tulare Counties
Area 3: Mariposa, Merced, Stanislaus, and Tuolumne Counties
Area 4: Monterey, San Benito, San Mateo, Santa Clara, and Santa Cruz Counties (excluding portions of Counties in the Lake Tahoe Area)
Area 5: Lassen County (that portion that lies eastward of Highway #395, northward to and including Honey Lake); Lake Tahoe Area
Area 6: Lake, Marin, Mendocino, San Francisco, and Sonoma Counties
Area 7: Butte, Colusa, and Glenn Counties; Lassen County (excluding the extreme SE corner); Modoc, Plumas, Shasta, Siskiyou, Sutter, Tehama, Trinity, and Yuba Counties
Area 8: Alameda, Contra Costa, El Dorado, Napa, Nevada, Solano, Sacramento, Sierra, Placer, and Yolo Counties (excluding portions of Counties in the Lake Tahoe Area)
Area 9: Del Norte and Humboldt Counties
Area 10: Fresno, Kings, and Tulare Counties
Area 12: Remaining Counties

PLASTERERS:
Area 1: Alameda and Contra Costa Counties
Area 2: San Francisco and San Mateo Counties
Area 3: Alpine, Amador, Butte, Calaveras, Colusa, El Dorado, Glenn, Lassen, Modoc, Nevada, Placer, Plumas, Sacramento, San Joaquin, Shasta, Sierra, Siskiyou, Sutter, Tehama, Trinity, Yolo, and Yuba Counties
Area 4: Del Norte, Humboldt, Lake, Marin, Mendocino, Napa, Solano, and Sonoma Counties
Area 5: San Benito, Santa Clara, and Santa Cruz Counties
Area 6: Fresno, Kings, Madera, and Tulare Counties
Area 7: Monterey County
Area 8: Mariposa, Merced, Stanislaus, and Tuolumne Counties

PLASTERERS' TENDERS:
Area 1: Alameda and Contra Costa Counties
Area 2: Fresno, Kings, Madera, and Tulare Counties
Area 3: San Francisco and San Mateo Counties
Area 4: Alpine, Amador, El Dorado, Nevada, Placer, Sacramento, Sierra and Yolo Counties
Area 5: Calaveras and San Joaquin Counties
Area 6: Marin County
Area 7: Monterey County
Area 8: San Benito, Santa Clara and Santa Cruz Counties
Area 9: Solano County
Area 10: Napa County

PLUMBERS:
Area 1: Alameda County
Area 2: Contra Costa County

AREA DESCRIPTIONS (Cont'd)

PLUMBERS; Steamfitters:
Area 1: Amador County (northern half); Sacramento, Yolo, El Dorado, Nevada, Placer, and Sierra counties (excluding Lake Tahoe Area)
Area 2: Lake Tahoe Area
Area 3: Marin, Mendocino, San Francisco, and Sonoma Counties
Area 4: Alpine County; Amador County (southern portion); Butte, Calaveras, Colusa, Fresno, Glenn, Kings, Lassen, Madera, Mariposa, Merced, Modoc, Monterey, Plumas, San Joaquin, Santa Cruz, Shasta, Sierra, Siskiyou, Stanislaus, Sutter, Tehama, Trinity, Tulare, Tuolumne, and Yuba Counties
Area 5: Lake, Napa, and Solano Counties
Area 6: Del Norte and Humboldt Counties
Area 7: San Benito and Santa Clara Counties
Area 8: San Mateo County

ROOFERS:
Area 1: Alameda and Contra Costa Counties
Area 2: Alpine, Calaveras, Mariposa, Merced, San Joaquin, Stanislaus, and Tuolumne Counties
Area 3: Butte, Colusa, El Dorado, Glenn, Lassen, Modoc, Placer, Plumas, Shasta, Sierra, Siskiyou, Sutter, Tehama, Trinity, and Yuba Counties
Area 4: Fresno, Kings, Madera, and Tulare Counties
Area 5: Lake, Marin, Mendocino, Napa, Solano, and Sonoma Counties
Area 6: Del Norte and Humboldt Counties
Area 7: Monterey and Santa Cruz Counties
Area 8: San Francisco and San Mateo Counties
Area 9: Amador, Sacramento, and Yolo Counties
Area 10: San Benito and Santa Clara Counties

SHEET METAL WORKERS:
Area 1: Alameda, Contra Costa, Napa, and Solano Counties
Area 2: Alpine, Calaveras, and San Joaquin Counties
Area 3: Amador, Butte, Colusa, El Dorado, Glenn, Modoc, Plumas, Sacramento, Shasta, Sierra, Siskiyou, Sutter, Tehama, Yolo, and Yuba Counties
Area 4: Mariposa, Merced, Stanislaus, and Tuolumne Counties
Area 5: Monterey and San Benito Counties
Area 6: Del Norte, Humboldt, and Trinity Counties
Area 7: San Mateo County
Area 8: Fresno, Kings, Madera, and Tulare Counties
Area 9: San Francisco County
Area 10: Marin, Mendocino, Sonoma, and Lake Counties
Area 11: Santa Cruz County
Area 12: Santa Clara County

SOFT FLOOR LAYERS:
Area 1: Alpine, Amador, Butte, Calaveras, Colusa, El Dorado, Glenn, and Lassen Counties (excluding Honey Lake Area); Merced County (east of San Joaquin River); Plumas, San Joaquin, Shasta, Sacramento, Stanislaus, Sutter, Tehama, Trinity, Tuolumne, Yolo, and Yuba Counties; El Dorado, Nevada, Placer, and Sierra Counties (those portions excluding Lake Tahoe Area)

AREA DESCRIPTIONS (Cont'd)

SOFT FLOOR LAYERS: (Cont'd)
Area 2: Honey Lake Area and Lake Tahoe Area
Area 3: Lake, Marin, Mendocino, Merced, Monterey, San Francisco, San Benito, San Mateo, Santa Clara, Santa Cruz, and Sonoma Counties
Area 4: Del Norte and Humboldt Counties
Area 5: Alameda, Contra Costa, Napa, and Solano Counties

SPRINKLER FITTERS:
Area 1: Alameda, Contra Costa, Marin, Napa, San Francisco, San Mateo, Santa Clara, Solano, and Sonoma Counties
Area 2: Remaining Counties

STEAMFITTERS:
Area 1: Alameda and Contra Costa Counties

TERRAZZO WORKERS:
Area 1: Alameda, Contra Costa, Del Norte, Humboldt, Lake, Marin, Mendocino, Napa, San Francisco, San Mateo, Siskiyou, Solano, Sonoma, and Trinity Counties
Area 2: Butte, Colusa, El Dorado, Glenn, Lassen, Modoc, Nevada, Placer, Plumas, Sacramento, Shasta, Sierra, Sutter, Tehama, Yolo, and Yuba Counties
Area 3: San Benito and Santa Clara Counties

TILE SETTERS:
Area 1: Alameda, Butte, Colusa, Contra Costa, Del Norte, El Dorado, Glenn, Humboldt, Lake, Lassen, Marin, Mendocino, Modoc, Napa, Nevada, Placer, Plumas, Sacramento, San Benito, San Francisco, San Mateo, Santa Clara, Shasta, Sierra, Siskiyou, Solano, Sonoma, Sutter, Tehama, Trinity, Yolo, and Yuba Counties
Area 2: Alpine, Amador, Calaveras, San Joaquin, Stanislaus, and Tuolumne Counties
Area 3: Fresno, Kings, Madera, Mariposa, Merced, and Tulare Counties
Area 4: Monterey and Santa Cruz Counties

MARBLE and TILE FINISHERS:
Area 1: Alameda, Contra Costa, Del Norte, Humboldt, Lake, Marin, Mendocino, Monterey, Napa, San Benito, San Francisco, San Mateo, Santa Clara, Santa Cruz, Siskiyou, Sonoma, Solano, and Trinity Counties
Area 2: Alpine, Amador, Butte, Calaveras, Colusa, El Dorado, Glenn, Lassen, Modoc, Nevada, Placer, Plumas, Sacramento, San Joaquin, Shasta, Sierra, Stanislaus, Sutter, Tehama, Yolo, and Yuba Counties

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

FOOTNOTES:
a. Employer contributes 8% of basic hourly rate for over 5 years' service, and 6% of basic hourly rate for 6 months' to 5 years' service as Vacation Pay Credit. Six Paid Holidays: A through F
b. Employer contributes $.32 per hour to Holiday Fund plus $.22 per hour to Vacation Fund for the first year of employment; 1 year but less than 5 years $.42 per hour to Vacation Fund; 5 years but less than 10 years $.60 per hour to Vacation Fund; over 10 years $.80 per hour to Vacation Fund

LABORERS

Group 1: Asphalt Ironers and Rakers; Asphalt Spreader Boxes (all types); Barko, Wacker and similar type Tampers; Buggy-mobile; Chainsaw, Faller, Logloader and Bucker; Compactors or all types; Concrete and Magnesite Mixer, 1/2 yd. and under; Concrete Pan Work; Concrete Saw; Concrete Sander; Cribber and/or Shoring; Cut Granite Curb Setter; Form Raisers; Slip Forms; Green Cutters, Headerboardmen, Hubsetters, Aligners; Jackhammer Operators; Jacking of pipe over 12 inches; Jackson and similar type Compactors; Kettlemen, Potmen and Men applying asphalt, lay-kold, creosote, lime, caustic and similar type materials; Lagging, Sheeting, Whaling, Bracing, Trenchjacking, hand-guided Lagging Hammer; Magnesite, Epoxyresin, Fiberglass, Mastic Workers (wet or dry); Perma Curbs; Precast-manhole Setters; Cast-in-place Manhole Form Setters; Pressure Pipe Tester; Pavement Breakers and Spaders, including Tool Grinder; Pipelayers, Caulkers, Banders, Pipewrappers, Conduit Layers, Plastic Pipelayers; Post Hole Diggers, air, gas, and electric; Power Broom Sweepers; Power Tampers of all types (except as shown in Group 2); Ram Set Gun and Stud Gun; Riprap-stonepaver and Rock-slinger, including placing of sacked concrete and/or sand (wet or dry); Rotary Scarifier, multiple Head Concrete Chipper; Davis Trencher, 300 or similar type (and all small Trenchers); Roto and Ditch Witch; Roto-tiller; Sandblasters, Potman, Gunman, Nozzleman; Signalling and Rigging; Tank Cleaners; Tree Climbers; Vibra-screed, Bull Float in connection with Laborers' work; Vibrators; Dri-pak-it Machine; High Pressure Blow Pipe (1½" or over, 100 lbs. pressure and over); Hydro Seeder and similar type; Laser Beam in connection with Laborers' work

Group 1(a): Joy Drill Model TWM-2A; Gardener-Denver Model DH143 and similar type drills; Track Drillers; Jack Leg Drillers; Diamond Drillers; Wagon Drillers; Mechanical Drillers, all types regardless of type or method of power; Multiple Unit Drills; Blasters and Powdermen; all work of loading, placing and blasting of all power and explosives of whatever type regardless of method used for such loading and placing; High Scalers (including drilling of same); Tree Topper; Bit Grinder

LABORERS (Cont'd)

Group 1(b); Sewer Cleaners receive an additional $4.00 per day, $5.00 per day on recently active large diameter sewers or sewer manholes

Group 1(c): Burning and Welding in connection with Laborers' work

Group 1(d): Repair Trackmen and Road Beds (cut and cover work of subway after the temporary cover has been placed)

Group 1(e): Laborers on general construction work on or in Bell Hole Footings and Shaft

Group 1(f): Wire Winding Machine in Connection with Guniting or Shotcrete - Aligner

Group 1(g); Contra Costa County Only: Pipelayers, Caulkers, Banders, Pipewrappers, Conduit Layers and Plastic Pipelayers; Pressure Pipe Tester, no joint pipe and stripping of same, including repair of Voids, Precast Manhole Setters, Cast-in-place Manhole Form Setters

Group 2: Asphalt Shovelers; Cement Dumpers and handling dry cement or gypsum; Choke-setter and Digger (clearing work); Concrete Bucket Dumper and Chuteman; Concrete Chipping and Grinding; Concrete Laborers (wet or dry); Chuck Tender; High Pressure Nozzleman, Adductors; Groutcrew; Hydraulic Monitor (over 100 lbs. pressure); Loading and unloading, carrying and hauling of all rods and materials for use in reinforcing concrete construction; Pittsburgh Chipper and similar type Brush Shredders; Sloper; Singlefoot, hand held, Pneumatic Tamper; All pneumatic, air, gas and electric tools not listed in Groups 1 through 1(f); Jacking of Pipe under 12 inches

Group 3: All Cleanup work of debris, grounds and buildings including but not limited to street cleaners; Cleaning and washing windows; Construction Laborers including bridge and general Laborers; Dumpman; Load Spotter; Fire Watcher; Street Cleaners; Gardeners, Horticultural and Landscape Laborers; Jetting; Limbers; Brush Loaders; Pilers, Maintenance Landscape Laborers on new construction; Maintenance, Repair Trackmen and Road beds; Streetcar and Railroad Construction Track Laborers; Temporary air and water lines, Victaulic or similar; Tool Room Attendent; Fence Erectors; Guardrail Erectors; Pavement Markers (button setters)

LABORERS (Cont'd)
GUNNITE

Group 1: Nozzleman (including Gunman, Potman); Rodmen; Groundman

Group 2: Reboundman

Group 3: General Laborers

(TUNNEL and SHAFT WORK)

Group 1: Diamond Driller; Groundman; Gunite and Shotcrete Nozzlemen; Rodmen; Shaft Work and raise (below actual or excavated ground level)

Group 2: Bit Grinder; Blaster; Drillers, Powderman-heading; Cherry Pickermen - where car is lifted; Concrete Finisher in Tunnel; Concrete Screed Man; Grout Pumpman and Potman; Gunite and Shotcrete Gunmen and Potmen; Headermen; High Pressure Nozzleman; Miners - Tunnel, including Top and Bottom Man on Shaft and Raise work; Nipper Nozzleman on slick line; Sandblaster-potman (work assignment interchangeable) Steel Form Raisers and Setters; Timberman, Retimberman - wood or steel or substitute materials therefore; Tugger

Group 3: Cabletender; Chucktender; Powderman - Primer House; Vibratormen, Pavement Breakers

Group 4: Bull Gang - Muckers, Trackmen; Concrete Crew - includes rodding and spreading; Dumpmen (any method); Grout Grew Reboundmen; Swamper

(WRECKING WORK)

Group 1: Skilled Wrecker (removing and salvaging of sash, windows, doors, plumbing and electric fixtures)

Group 2: Semi-skilled Wrecker (salvaging or other building materials)

Group 3: General Laborer (includes all cleanup work, loading, lumber, loading and burning of debris)

(HOUSEMOVING)

Group 1: Skilled Housemover

POWER EQUIPMENT OPERATORS
DREDGING

AREA DEFINITIONS FOR SCHEDULES I and II

Four centers designated: City Halls of Oakland, San Francisco, Sacramento and Stockton, California
Area 1: Up to 20 road miles from said Centers
Area 2: More than 20 road miles to and inclduing 30 road miles from said Centers
Area 3: Outside of 30 road miles from said Centers
Area 4: An area extending 25 road miles from shoreline of Lake Tahoe

SCHEDULE I
CLAMSHELL and DIPPER DERDGING (New Construction)

Group 1: Bargeman; Deckhand; Fireman; Oiler

Group 2: Deck Engineers; Deck Mate

Group 3: Welder; Mechanic Welder; Watch Engineer

Group 4: Clamshell Operator (up to and including 7 cu. yds. M.R.C.)(Long Boom Pay)

Group 4-A: Clamshell Operator (over 7 cu. yds. M.R.C.)(Long Boom Pay)

SCHEDULE II
HYDRAULIC SUCTION DREDGING and all Other CLAMSHELL and DIPPER DREDGING

Group A-1: Bargeman; Deckhand; Leveehand; Fireman; Oiler

Group A-2: Winchman (stern winch on Dredge); Deck Engineer

Group A-3: Watch Engineer; Welder; Welder Mechanic; Deckmate; Booster Pump Operator (Mud Cat)

Group A-4: Leverman; Clamshell Operator

PILEDRIVING

Group 1: Assistant to Engineer (Fireman, Oiler, Deckhand)

Group 1A: Compressor Operator

Group 1B: Assistant to Engineer (Truck Crane Oiler)

Group 2A: Tugger Hoist Operator (hoisting material only)

Group 2B: Forklift Operator

POWER EQUIPMENT OPERATORS (Cont'd)
PILEDRIVING (Cont'd)

Group 2C: Compressor Operator (over 2); Generators; Pumps (over 4); Welding Machines (pwwered by other than electricity)

Group 2D: A-Frames

Group 3: Deck Engineer (Deck Engineer Operator required when deck engine is used); Self-propelled Boom-type lifting device (center mount) (10 ton capacity or less M.R.C.)

Group 3A: Heavy Duty Repairman and/or Welder

Group 4: Operating Engineer in lieu of Assistant to Engineer tending boiler or compressor attached to Crane Piledriver; Operator of Piledriving Rigs, Skid or Floating and Derrick Barges (Assistant to Engineer required); Operator of diesel or gasoline power Crane Piledriver (without boiler) up to and including 1 cu. yd. rating (Assistant to Engineer required); Self-propelled Boom-type lifting device (center mount) (over 10 tons up to and including 25 tons); Truck Crane Operator (up to and including 25 tons) (hoisting material only) (Assistant to Engineer required)

Group 5: Operator of diesel or gasoline powered Crane Piledriver (without boiler) over 1 cu. yd. rating (Assistant to Engineer required); Operator of Crane (with steam, flash boiler, pump or compressor attached) (Group (4) Engineer required); Operator of steam powered Crawler or Universal type Driver (Raymond or similar) (Assistant to Engineer required) Truck Crane Operator (over 25 tons) (hoisting material or performing Piledriving work) (Assistant to Engineer required); Self-propelled Boom-type lifting device (center mount) (over 25 tons) (Assistant to Engineer required)

Group 6: Cranes (over 125 tons) (Assistant to Engineer required)

STEEL ERECTION

Group 1: Assistant to Engineer (Oiler)

Group 2: Compressor Operator, Generator, gasoline or diesel driven (100 K.W. or over) (structural steel or tank construction only)

Group 3: Compressors, Generators and/or Welding Machines or combination (2 to 6) (over 6 additional Engineers required) (structural steel or tank erection only)

Group 4: Heavy Duty Repairman, Tractor Operator

Group 4A: Combination Heavy Duty Repairman and/or Welder

POWER EQUIPMENT OPERATORS (Cont'd)
STEEL ERECTION (Cont'd)

Group 5: Boom Truck or Dual Purpose A-Frame Truck; Boom Cat; Chicago Boom; Crawler Cranes and Truck Cranes (15 tons M.R.C. or less) (Assistant to Engineer required); Self-propelled Boom type lifting device (center mount) (10 ton capacity or less M.R.C.); Single drum Hoist; Tugger Hoist

Group 6: Cary Lift, Campbell or similar; Crawler Cranes and Truck Cranes (over 15 tons M.R.C.) (Assistant to Engineer required); Derricks (2 operators when swing engine remote from hoist); Gantry Rider (or similar equipment); Highline Cableway (Signalman required); Self-propelled Boom-type lifting device (center mount) (over 10 tons up to and including 25 tons); Tower Cranes Mobile including rail mounted (Assistant to Engineer required); Tower Cranes, Universal Liebher and similar types (in the erection, dismantling and moving of equipment there shall be an additional Operating Engineer)

Group 7: Self-propelled Boom-type lifting device (center mount) (over 25 tons) (Assistant to Engineer required)

Group 8: Cranes (over 125 tons) (Assistant to Engineer required)

Group 9: Helicopter Operator

AREAS I and II

Group 1: Assistants to Engineers (Brakeman; Fireman; Heavy Duty Repairman Tender; Oiler; Deckhand; Signalman; Switchman; Tar Pot Fireman); Partsman (heavy duty repair shop parts room)

Group 2: Compressor Operator; Concrete Mixer (up to and including 1 yard); Conveyor Belt Operator (tunnel); Fireman Hot Plant; Hydraulic; Monitor; Mechanical Conveyor (handling building materials); Mixer Box Operator (concrete plant); Pump Operator; Spreader Boxman (with screeds); Tar Pot Fireman (power agitated)

Group 3: Box Operator (bunker); Helicopter Radioman (Signalman); Motorman; Locomotive (30 tons or under); Oiler; Ross Carrier (construction job site); Rotomist Operator; Screedman (except asphaltic concrete paving); Self-propelled, automatically applied concrete curing machine (on streets, highways, airports and canals); Trenching Machine (maximum digging capacity 5 ft. depth); Tugger Hoist, single drum; Truck Crane Oiler; Boiler Tender

Group 4: Ballast Jack Tamper; Ballast Regulation; Ballast Tamper Multi-purpose; Boxman (asphalt plant); Elevator Operator (inside); Fork Lift or Lumber Stacker (construction job site); Line Master; Material Hoist (1 drum); Shuttlecar; Tie Spacer; Towermobile

POWER EQUIPMENT OPERATORS (Cont'd)
AREAS I and II (Cont'd)

Group 5: Compressor Operator (over 2); Concrete Mixers (over 1 yard); Concrete Pumps of Pumpcrete Guns; Generators; Grouting Machine; Pressweld (air operated); Pumps (over 1); Welding Machines (powered other than by electricity)

Group 6: BLH Lima Road Pactor or similar; Boom Truck or Dual Purpose A-Frame Truck; Concrete Batch Plants (wet or dry); Concrete Saws (self-propelled unit) on streets, highways, airports and canals; Drilling and Boring Machinery, vertical and horizontal (not to apply to Waterliners, Wagon Drills or Jackhammers); Gradesetter, Grade Checker (mechanical or other-wise); Highline Cableway Signalman; Locomotives (steam of over 30 tons); Maginnis Internal Full Slab Vibrator (on airports, highways, canals and warehouses); Mechanical Finishers (concrete) (Clary, Johnson, Bidwell Bridge Deck or similar types); Mechanical Burm, Curb and/or Curb and Gutter Machine, concrete or asphalt; Portable Crusher; Post Driver (M-1500 and similar); Power Jumbo Operator (setting slip forms, etc. in tunnels); Roller (except Asphalt); Screedman (Barber-Greene and similar)(asphaltic concrete paving); Self-propelled Compactor (single engine); Self-propelled Pipeline Wrapping Machine, Perault, CRC, or similar types); Slip Forms Pumps (lifting device for concrete forms); Small Rubber Tired Tractor; Surface Heater; Self-propelled Power Sweeper; Self-propelled Tape Machine; Auger-type drilling equipment, up to and including 30 ft. depth digging capacity M.R.C.

Group 7: Concrete Conveyor or Concrete Pump, Truck or equipment mounted (boom length to apply); Concrete Conveyor, building site; Deck Engineers; Dual Drum Mixer; Fuller Kenyon Pump and similar types; Gantry Rider (or similar); Hydra-hammer (or similar); Material Hoist (2 or more drums); Mechanical Finishers or Spreader Machine (asphalt, Barber-Greene and similar); Mine or Shaft Hoist; Mixermobile; Pavement Breaker with or without Compressor Combination; Pipe Bending Machine (pipelines only); Pipe Cleaning Machine (tractor propelled and supported); Pipe Wrapping Machine (tractor propelled and supported); Refrigeration Plant; Roller Operator (finish asphalt); Self-propelled boom type lifting device (center mount) (10 tons or less M.R.C.); Self-propelled Elevating Grader Plane; Slusher Operator; Small Tractor (with boom) Soil Tester; Truck type Loader; Welding Machines (Gasoline or diesel)

Group 8: Armor-Coater (or similar); Asphalt Plant Engineer; Cast-in-place Pipe Laying Machine; Combination Slusher and Motor Operator; Concrete Batch Plant (multiple units); Dozer; Heading Shield Operator; Heavy Duty Repairman and/or Welder; Ken Seal Machine (or similar); Kolman Loader; Loader (up to 2 yards); Mechanical Trench Shield; Portable Crushing and Screening Plants; Puch Cat; Rubber Tired Earth-moving Equipment (up to and including 45 cu. yards "struck" M.R.C.) Euclids, T-Pulls, DW-10, 20, 21, and similar; Rubber Tired Dozer; Self-propelled Compactor with Dozer; Sheepfoot; Timber Skidder (rubber tired or similar equipment); Tractor drawn Scraper; Tractor (Trenching Machine; Tri-batch Paver; Tunnel Mole Boring Machine; Welder; Woods-mixer (and other similar Pugmill equipment)

POWER EQUIPMENT OPERATORS (Cont'd)
AREAS I and II (Cont'd)

Group 9: Canal Finger Drain Digger; Chicago Boom; Combination Mixer and Compressor (Gunite); Combination Slurry Mixer and/or Cleaner; Highline Cableway (5 tons and under); Lull Hi-lift or similar (20 ft. or over); Mucking Machine (rubber tired, rail or track type); Tracror (with boom) (D-6 or larger and similar)

Group 10: Boom-type Backfilling Machine; Bridge Crane; Cary-lift (or similar); Chemical Grouting Machine, truck mounted); Combination Backhoe and Loader (up to and including 1/2 cu. yd. M.R.C.); Derrick (2 operators required when swing engine remote from Hoist); Derrick Barges (except excavation work); Do-mor Loader; Adams Ele-grader; Elevating Grader; Heavy Duty Rotary Drill Rig (including Caisson Foundation work and Euclid Loader and similar type; Robbins type drills); Koehring Skooper (or similar); Lift Slab Machine; (Vagtborg and similar types); Loader (2 yds. up to and including 4 yds.); Locomotive, 100 tons (single or multiple units); Multiple Engine Earthmoving Machine (Euclids, Dozers, etc.)(no tandem scraper); Pre-stress Wire Wrapping Machine; Reservoir-debris Tug (self-propelled floating); Rubber-tired Scraper, self-loading (paddle wheels, etc.); Shuttle Cat (reclaim station); Single engine Scraper over 45 yds.; Soil Stabilizer (P & H or equal); Sub-grader (Gurrier or other automatic type); Tractor, Compressor Drill Combination; Track Laying type Earth Moving Machine (single engine with tandem scrapers); Train loading station; Trenching Machine, multi-engine with sliping attachment, Jeffco or similar; Vacuum Cooling Plant; Whirley Crane (up to and including 25 tons)

Group 10-A: Backhoe (hydraulic)(up to and including 1 cu. yd. M.R.C.); Backhoe (cable)(up to and including 1 cu. yd. M.R.C.); Combination Backhoe and Loader (over 3/4 cu. yd. M.R.C.); Continuous Flight Tie Back Auger (crane attached/separate controls); Cranes not over 25 tons, Hammerhead and Gantry; Gradalls (up to and including 1 cu. yd.); Power Blade Operator (single engine); Power Shovels, Clamshells, Draglines (up to and including 1 cu. yd. M.R.C)(Long Boom pay); Rubber-tired Scraper, self-loading (Paddle Wheel, twin engine); Self-propelled Boom-type lifting device (center mount) (over 10 tons up to and including 25 tons); CMI Dual Lane Auto Grader SP-30 or similar

POWER EQUIPMENT OPERATORS (Cont'd)
AREAS I and II (Cont'd)

Group 11: Automatic Concrete Slip-form Paver (Gradesetter, Screedman); Automatic Railroad Car Dumper; Canal Trimmer with ditching attachments; Cary Lift, Campbell or similar, Continuous Flight Tie Back Auger (Crane attached, single controls); Cranes (over 25 tons up to and including 125 tons); Drott Travelift 650-A-1 or similar (45 ton or over); Euclid Loader when controlled from the Pullcat; Highline Cableway (over 5 tons); Loader (over 4 cu. yds., up to and including 12 cu. yds.); Miller Formless M-900 Slope Paver or similar (grade Setter required); Multiple Engine Scraper (when used as Push Pull); Power Blade Operator (multi-engine); Power Shovels, Clamshells, Draglines, Backhoes, Gradalls (over 1 cu. yd. and up to and including 7 cu. yds. M.R.C., Long Boom Pay); Rubber-tired Earth-moving Machines (multiple propulsion power units and two or more Scrapers) (up to and including 75 cu. yds. struck M.R.C.); Self-propelled Compactor (with multiple propulsion power unit); Blob or similar; Self-propelled Boom-type lifting device (center mount) (over 25 tons M.R.C.); Single engine Rubber-tired Earthmoving Machines (with Tandem Scrapers); Slip-form Paver (concrete or asphalt) (Screedman required); Tandem Cats; Tower Cranes Mobile (including rail mounted); Trencher (pulling attached shield); Tower Cranes, Universal Liebher and similar types (in the erection, dismantling and moving of equipment); Wheel Excavator (up to and including 750 cu. yds. per hour); Whirley Crane (over 25 tons); Multi-earthmoving Equipment (up to and including seventy-five (75) cu. yds. "struck" M.R.C.); Truck mounted Hydraulic Crane when remote control equipped (over 10 tons up to and including 25 tons)

Group 11A: Band Wagons (in conjunction with wheel excavator); Cranes (over 125 tons); Loader (over 12 cu. yds., up to and including 18 cu. yds.); Power Shovels, Clamshells, Backhoes, Gradalls, and Draglines (over 7 cu. yds. M.R.C.); Rubber-tired Multi-purpose Earth Moving Machines (2 units over 75 cu. yds. "struck" M.R.C.); Wheel Excavator (over 750 cu. yds. per hour)

Group 11B: Loader (over 18 yds.)

Group 11C: Operator of Helicopter (when used in erection work); Remote controlled earthmoving equipment

TRUCK DRIVERS

Group 1: Bulk Cement Spreader (w/wo Auger, under 4 yards water level); Bus or Manhaul Driver; Concrete Pump Machine; Concrete Pump Truck (when Flat Rack Truck is used appropriate Flat Rack rate shall apply); Dump (under 4 yds. water level); Dumpcrete Truck (under 4 yds. water level); Dumpster (under 4 yds. water level); Escort or Pilot Car Driver; Nipper Truck (when Flat Rack Truck is used appropriate Flat Rack rate shall apply); Pickups; Skids (Debris Box, under 4 yds. water level); Team Drivers; Trucks (Dry Pre-batch Concrete Mix, under 4 yds. water level); Warehousemen

Group 2: Teamster Oiler and/or Greaser and/or Service Man

TRUCK DRIVERS (Cont'd)

Group 3: Bulk Cement Spreader (w/wo auger, 4 yd. and under 6 yds. water level); Dump (4 yds. and under 6 yds. water level); Dumpcrete (4 yds. and under 6 yds. water level); Dumpster (4 yds. and under 6 yds. water level); Skids (Debris Box, 4 yds. and under 6 yds. water level); Single Unit Flat Rack (2 axle unit); Industrial Lift Truck (mechanical Tailgate); Trucks (Dry Pre-batch Concrete Mix, 4 yds. and under 6 yds. water level)

Group 4: Jetting Truck and Water Truck (under 2,500 gallons)

Group 5: Road Oil Trucks or Boot Man

Group 6: Lift Jitneys, Fork Lift

Group 7: Transit Mix, Agitator (under 6 yards)

Group 8: Fuel and/or Grease Truck Driver or Fuelman

Group 9: Vacuum Truck, under 3,500 gallons

Group 10: Scissor Truck; single unit Flat Rack (2 axle unit); Industrial Lift Truck (mechanical tailgate); Small rubber tired tractor (when used within Teamsters' jurisdiction)

Group 11: Jetting Truck and Water Trucks, 2,500 gallons, under 4,000 gallons

Group 12: Combination Winch Truck with Hoist; Transit Mix Agitator (6 yards and under 8 yards)

Group 13: Vacuum Truck, 3,500 gallons and under 5,500 gallons

Group 14: Rubber-tired Muck Car (not self-loaded)

Group 15: Bulk Cement Spreader (w/wo auger, 6 yds. and under 8 yds. water level); Dump (6 yds. and under 8 yds. water level); Dumpcrete (6 yds. and under 8 yds. water level); Dumpster (6 yds. and under 8 yds. water level); Skids (Debris Box, 6 yds. and under 8 yds. water level); Trucks (Dry Pre-batch Concrete Mix, 6 yds. and under 8 yds. water level)

Group 16: A-Frame, Winch Truck; Buggymobile; Jetting and Water Truck (4,000 gallons and under 5,000 gallons); Rubber tired Jumbo

Group 17: Heavy Duty Rransport (high bed)

Group 18: Ross Hyster and similar straddle Carrier

Group 19: Transit Mix Agitator (8 yds. through 10 yds.)

Group 20: Vacuum Truck (5,500 gallons and 7,500 gallons)

Group 21: Jetting Truck and Water Truck (5,000 gallons and under 7,000 gallons)

Group 22: Combination Bootman and Road Oiler

TRUCK DRIVERS (Cont'd)

Group 23: Transit Mix Agitator (over 10 yds. through 12 yds.)

Group 24: Bulk Cement Spreader (w/wo auger, 8 yds. and including 12 yds. water level); Dump (8 yds. and including 12 yds. water level); Dumpcrete (8 yds. and including 12 yds. water level); Self-propelled Street Sweeper with self-contained refuse bin; Skids (Debris Box, 8 yds. and including 12 yds. water level); Snow Go and/or Snow Plow; Truck (Dry Pre-batch Concrete Mix, 8 yds. and including 12 yds. water level and including 12 yds. water level)

Group 25: Heavy Duty Transport (Gooseneck Lowbed)

Group 26: Transit Mix Agitator (over 12 yds. through 17 yds.)

Group 27: Ammonia Nitrate Distributor Driver and Mixer; Bulk Cement Spreader (w/wo auger, over 12 yds. and including 18 yds. water level); Dump (over 12 yds. and including 18 yds. water level); Dumpcrete (over 12 yds. and including 18 yds. water level); Dumpster (over 12 yds. and including 18 yds. water level); Truck (Dry Pre-batch Concrete Mix, over 12 yds. and including 18 yds. water level)

Group 28: Double Gooseneck (7 or more axles); Heavy Duty Transport Tiller Man

Group 29: P. B. or similar type self-loading truck

Group 30: Transit Mix Agitator (over 14 yds. through 16 yds.)

Group 31: Bulk Cement Spreader (w/wo auger, over 18 yds. and including 24 yds. water level); Combination Dump and Dump Trailer; Dump (over 18 yds. and including 24 yds. water level); Dumpcrete (over 18 yds. and including 24 yds. water level); Dumpster (over 18 yds. and including 24 yds. water level); Skid (Debris Box, over 18 yds. and including 24 yds. water level); Transit Mix Agitator over 12 yds. through 16 yds.); Trucks (Dry Pre-batch Concrete Mix, over 17 yds. and including 24 yds. water level)

Group 32: Bulk Cement Spreader (w/wo auger, over 24 yds. and including 35 yds. water level); Dump (over 24 yds. and including 35 yds. water level); Dumpcrete (over 24 yds. and including 35 yds. water level); Dumpster (over 24 yds. and including 35 yds. water level); DW 10's, 20's, 21's and other similar Cat type, Terra Cobra, LeTournapulls, Tournarocker, Euclid and similar type equipment when pulling Fuel and/or Grease Tank Trailers or other misc. trailers; Skids (Debris Box, over 24 yds. and including 35 yds. water level); Trucks (Dry Pre-batch Concrete Mix, over 24 yds. and including 35 yds. water level)

Group 33: Truck Repairman

TRUCK DRIVERS (Cont'd)

Group 34: Bulk Cement Spreader (w/wo auger, over 35 yds. and including 50 yds. water level); Dump (over 35 yds. and including 40 yds. water level); Dumpcrete (over 35 yds. and including 50 yds. water level); Dumpster (over 35 yds. and including 50 yds. water level); Skids (Debris Box, over 35 yds. and including 50 yds. water level); Trucks (Dry Pre-batch Concrete Mix, over 35 yds. and including 50 yds. water level)

Group 35: DW 10's. 20's, 21's and other similar Cat type, Terra Cobra, LeTournapulls, Tournarocker, Euclid and similar type equipment while pulling Aqua/Pak or water tank trailers

Group 36: Bulk Cement Spreader (w/wo auger, over 50 yds. and under 65 yds. water level); Dump (over 50 yds. and under 65 yds. water level); Dumpcrete (over 50 yds. and under 65 yds. water level); Dumpster (over 50 yds. and under 65 yds. water level); Helicopter Pilot (when transporting men or materials); Skids (Debris Box, over 50 yds. and under 65 yds. water level); Trucks (Dry Pre-batch Concrete Mix, over 50 yds. and under 65 yds. water level)

Group 37: Bulk Cement Spreader (w/wo auger, over 65 yds. and including 80 yds. water level); Dump (65 yds. and including 80 yds. water level); Dumpcrete (over 65 yds. and including 80 yds. water level); Dumpster (over 65 yds. and including 80 yds. water level); Skids (Debris Box, 65 yds. and including 80 yds. water level); Trucks (Dry Pre-batch Concrete Mix, 65 yds. and including 80 yds. water level)

Group 38: Bulk Cement Spreader (w/wo auger, over 80 yds. and including 95 yds. water level); Dump (over 80 yds. and including 95 yds. water level); Dumpcrete (over 80 yds. and including 95 yds. water level); Dumpster (over 80 yds. and including 95 yds. water level); Skids (Debris Box, over 80 yds. and including 95 yds. water level); Trucks (Dry Pre-batch Concrete Mix, over 80 yds. and including 95 yds. water level)

AREA DESCRIPTIONS
FOR
POWER EQUIPMENT OPERATORS
AREAS I and II

**AREA I: All areas included in the description defined below which is based upon Township and Range Lines of Areas I and II.

Commencing in the Pacific Ocean on the extension of the Southerly line of Township 19S.
Thence Easterly along the Southerly line of Township 19S, crossing the Mt. Diablo Meridian to the S.W. corner of township 19S, range 6E, Mt. Diablo Base Line and Meridian,
Thence Southerly to the S.W. corner of township 20S, range 6E,
Thence Easterly to the S.W. corner of township 20S, range 13E,
Thence Southerly to the S.W. corner of township 21S, range 13E,
Thence Easterly to the S.W. corner of township 21S, range 17E,
Thence Southerly to the S.W. corner of township 22S, range 17E,
Thence Easterly to the S.E. corner of township 22S, range 17E,
Thence Southerly to the S.W. corner of township 23S, range 18E,
Thence Easterly to the S.E. corner of township 23S, range 18E,
Thence Southerly to the S.W. corner of township 24S, range 19E, falling on the Southerly Line of Kings County, thence Easterly along the Southerly Boundary of Kings County and the Southerly Boundary of Tulare County, to the S.E. corner of township 24S, range 29E,
Thence Northerly to the N.E. corner of township 21S, range 29E,
Thence Westerly to the N.W. corner of township 21S, range 29E,
Thence Northerly to the N.E. corner of township 13S, range 28E,
Thence Westerly to the N.W. corner of township 13S, range 28E,
Thence Northerly to the N.E. corner of township 11S, range 27E,
Thence Westerly to the N.W. corner of township 11S, range 27E,
Thence Northerly to the N.E. corner of township 10S, range 26E,
Thence Westerly to the N.W. corner of township 10S, range 26E,
Thence Northerly to the N.E. corner of township 9S, range 25E,
Thence Westerly to the N.W. corner of township 9S, range 25E,
Thence Northerly to the N.E. corner of township 8S, range 24E,
Thence Westerly to the N.W. corner of township 8S, range 24E,
Thence Northerly to the N.E. corner of township 6S, range 23E,
Thence Westerly to the S.E. corner of township 5S, range 19E,
Thence Northerly to the S.E. corner of township 5S, range 19E,
Thence Westerly to the N.W. corner of township 5S, range 19E,
Thence Northerly to the N.E. corner of township 3S, range 18E,
Thence Westerly to the N.W. corner of township 3S, range 18E,
Thence Northerly to the N.E. corner of township 2S, range 17E,
Thence Westerly to the N.W. corner of township 2S, range 17E,

AREA DESCRIPTIONS (Cont'd)
For
POWER EQUIPMENT OPERATORS
AREAS I and II

AREA I: (Cont'd)

Thence Northerly crossing the Mt. Diablo Baseline to the N.E. corner of township 2N, range 16E,
Thence Westerly to the N.W. corner of township 2N, range 16E,
Thence Northerly to the N.E. corner of township 3N, range 15E,
Thence Westerly to the N.E. corner of township 3N, range 15E,
Thence Northerly to the N.E. corner of township 4N, range 14E,
Thence Westerly to the N.W. corner of township 4N, range 14E,
Thence Northerly to the N.E. corner of township 5N, range 13E,
Thence Westerly to the N.E. corner of township 5N, range 13E,
Thence Northerly to the N.E. corner of township 10N, range 12E,
Thence Easterly to the S.E. corner of township 11N, range 14E,
Thence Northerly to the N.E. corner of township 11N, range 14E,
Thence Westerly to the N.E. corner of township 11N, range 10E,
Thence Northerly to the N.E. corner of township 15N, range 10E,
Thence Easterly to the S.E. corner of township 16N, range 11E,
Thence Northerly to the N.E. corner of township 16N, range 11E,
Thence Easterly to the S.E. corner of township 17N, range 14E,
Thence Southerly to the S.W. corner of township 14N, range 14E,
Thence Easterly to the S.E. corner of township 14N, range 15E,
Thence Southerly to the S.W. corner of township 13N, range 16E,
Thence Easterly to the S.E. corner of township 13N, range 16E,
Thence Southerly to the S.W. corner of township 12N, range 17E,
Thence Easterly along the Southern Line to township 12N to the Eastern Boundary of the State of California, to the State of California to the N.E. corner of township 17N, range 18E,
Thence Westerly to the N.W. corner of township 17N, range 11E,
Thence Northerly to the N.E. corner of township 20N, range 10E,
Thence Westerly to the N.W. corner of township 20N, range 20E,
Thence Northerly to the N.E. corner of township 21N, range 9E,
Thence Westerly to the N.W. corner of township 21N, range 9E,
Thence Northerly to the N.E. corner of township 22N, range 8E,
Thence Westerly to the N.W. corner of township 27N, range 8E,
Thence Northerly to the S.W. corner of township 27N, range 8E,
Thence Easterly to the S.E. corner of township 27N, range 8E,
Thence Northerly to the N.E. corner of township 28N, range 8E,
Thence Westerly to the N.W. corner of township 28N, range 7E,
Thence Northerly to the N.E. corner of township 30N, range 6E,
Thence Westerly to the N.W. corner of township 30N, range 1E,
Thence Northerly along the Mt. Diablo Meridian to the N.E. corner of township 34N, range 1W,
Thence Westerly to the N.W. corner of township 34N, range 6W,
Thence Southerly to the N.E. corner of township 32N, range 7W,
Thenece Westerly to the N.W. corner of township 32N, range 7W,
Thence Southerly to the S.W. corner of township 30N, range 7W,
Thence Easterly to the S.E. corner of township 30N, range 7W,

AREA DESCRIPTIONS (Cont'd)
For
POWER EQUIPMENT OPERATORS
AREAS I and II

AREA 1: (Cont'd)

Thence Southerly to the S.W. corner of township 16N, range 6W,
Thence Easterly to the S.E. corner of township 16N, range 6W,
Thence Southerly to the S.W. corner of township 14N, range 5W,
Thence Westerly to the S.E. corner of township 14N, range 7W,
Thence Northerly to the N.E. corner of township 14N, range 7W,
Thence Westerly to the N.W. corner of township 14N, range 7W,
Thence Northerly to the N.E. corner of township 15N, range 8W,
Thence Westerly to the S.E. corner of township 16N, range 12W,
Thence Northerly to the N.E. corner of township 16N, range 12W,
Thence Westerly to the N.W. corner of township 16N, range 12W,
Thence Northerly to the N.E. corner of township 18N, range 12W,
Thence Westerly to the N.W. corner of township 18N, range 14W,
Thence Southerly to the S.W. corner of township 18N, range 14W,
Thence Easterly to the S.E. corner of township 18N, range 14W,
Thence Southerly to the S.W. corner of township 16N, range 13W,
Thence Westerly to the N.W. corner of township 15N, range 14W,
Thence Southerly to the S.W. corner of township 14N, range 14W,
Thence Easterly to the S.E. corner of township 14N, range 14W,
Thence Southerly to the S.W. corner of township 13N, range 13W,
Thence Easterly to the S.E. corner of township 13N, range 13W,
Thence Southerly to the S.W. corner of township 11N, range 12W,
Thence Easterly to the S.E. corner of township 11N, range 12W,
Thence Southerly along the Eastern line to range 12W, to the Pacific Ocean excluding that portion of Northern California within Santa Clara County included within the folloiwng line:
Commencing at the N.W. corner of township 6S, range 3E, Mt. Diablo Baseline and Meridian:
Thence in a Southerly direction to the S.W. corner of township 7S, range 3E,
Thence in a Easterly direction to the S.E. corner of township 7S, range 4E,
Thence in a Northerly direction to the N.E. corner of township 6S, range 4E,
Thence in a Westerly direction to the N.W. corner of township 6S, range 3E, to the point of beginning which portion is a part of Area 2.

AREA 1: also includes that portion of Northern California within the following lines:
Commencing in the Pacific Ocean on an extension of the Southerly line to township 2N; Humboldt Baseline and Meridian:
Thence Easterly along the Southerly line of township 2N, to the S.W. corner of township 2N, range 1W,
Thence Southerly to the S.W. corner of township 1N, range 1W,

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AREA DESCRIPTIONS
For
POWER EQUIPMENT OPERATORS
AREAS I and II

AREA 1: (Cont'd)

Thence Easterly along the Humboldt Baseline to the S.W. corner of township 1N, range 2E,
Thence Southerly to the S.W. corner of township 2S, range 2E,
Thence Easterly to the S.E. corner of township 2S, range 2E,
Thence Southerly to the S.W. corner of township 4S, range 3E,
Thence Easterly to the S.E. corner of township 4S, range 3E,
Thence Northerly to the N.E. corner of township 2S, range 3E,
Tehnce Westerly to the N.W. corner of township 2S, range 3E,
Thence Northerly crossing the Humboldt Baseline to the S.W. corner of township 1N, range 3E,
Thence Easterly along the Humboldt Baseline to the S.E. corner of township 1N, range 3E,
Thence Northerly to the N.E. corner of township 9N, range 3E,
Thence Westerly to the N.W. corner of township 9N, range 2E,
Thence Northerly to the N.E. corner of township 10N, range 1E,
Thence Westerly along the Northerly line to township 10N, into the Pacific Ocean.

AREA I; Also includes that portion of Northern California included within the following lines:
Commencing at the Northerly boundary of the State of California at the N.W. corner of township 48N, range 7W, Mt. Diablo Baseline and Meridian:
Thence Southerly to the S.W. corner of township 44N, range 7W,
Thence Easterly to the S.E. corner of township 44N, range 7W,
Thence Southerly to the S.W. corner of township 43N, range 6W,
Thence Easterly to the S.E. corner of township 43N, range 5W,
Thence Northerly to the N.E. corner of township 48N, range 5W, on the Northerly boundary of the State of California,
Thence Westerly along the Northerly boundary of the State of California to the point of beginning.

AREA II: All areas not included within AREA I as defined.

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).